

**DEVELOPMENT AND EVALUATION OF A NOVEL COMPLEX PHYSIOTHERAPY
BEHAVIOUR CHANGE INTERVENTION PROMOTING PHYSICAL ACTIVITY
ADOPTION AND MAINTENANCE IN PATIENTS WITH LOWER LIMB
OSTEOARTHRITIS**

By

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ABSTRACT

Lower-limb (hip and knee) Osteoarthritis (OA) is a prevalent condition that causes substantial pain and disability in adults over 45 years of age. Optimising physical activity (PA) can help patients with lower-limb OA self-manage their symptoms and reduce the likelihood of developing secondary non-communicable diseases. However, patients with lower-limb OA tend to be less active than people without musculoskeletal pain.

Individuals undergo several 'phases' of change when incorporating new behaviours (such as PA) into their lifestyle, with the most important phases to target in interventions being *adoption/initiation* and *maintenance*. Physiotherapists are specialists in the assessment and management of musculoskeletal conditions and the primary healthcare provider of PA interventions within the United Kingdom's National Health Service (NHS). Regarding the promotion of PA by physiotherapists, patients would be *adopting* PA behaviours while receiving treatment and *maintenance* would be manifested post-discharge.

Although physiotherapists believe that they have the necessary skills to promote PA, evidence suggests that they do not possess the requisite knowledge of behavioural theories or techniques to apply them effectively in their clinical practice. This PhD thesis details the iterative development and feasibility testing of a novel physiotherapy behaviour change intervention that aimed to promote PA adoption and maintenance in patients with lower-limb OA. The thesis structure includes several interconnecting studies including:

- A systematic review that identified the most effective behaviour change techniques (BCTs) used in physiotherapy interventions to promote short, medium, and long-term PA adherence in patients with lower-limb OA. Most BCTs demonstrated modest effects at optimising PA adherence. Findings also identified specific techniques to be most effective over the short-term while others were more effective over the longer-term.
- Semi-structured interviews that examined the views of patients with lower-limb OA regarding the barriers and facilitators to adherence to physiotherapist prescribed PA during treatment (adoption) and post-discharge (maintenance). The results revealed that the promotion of a PA routine within a positive patient-centred physiotherapy environment was deemed integral to behavioural adoption. Ensuring the PA environment is supportive was perceived to be critical to facilitate maintenance. Building on these findings, a theoretically informed physiotherapy intervention which incorporated 26 BCTs was proposed. The included BCTs were defined as either 'phase specific', targeting the theoretical determinants of PA adoption, routine formation, or maintenance or 'recurring' if they were relevant throughout the behaviour change process.
- Presentation of the proposed intervention to focus groups of physiotherapists to assess their perspectives on its acceptability and feasibility for implementation in an NHS physiotherapy department. Although the physiotherapists found the intervention highly acceptable and did not suggest any alteration of intervention BCTs, they believed that they required further training in behaviour change theory, especially in strategies for creating a more supportive motivational treatment climate and how to optimally deliver the BCTs.

- A review of the descriptions and conceptual models of theories of behaviour change to identify an appropriate candidate theory to underpin physiotherapy training in how to create a more supportive and motivational treatment climate. Self-determination Theory (SDT) was chosen as the primary theory to underpin physiotherapist training due to its' theoretical model interlinking a person's feelings of competence with their social interactions and motivation quality, which were consistent with patient perspectives identified in the interviews. A further mapping exercise linked the proposed interventions' BCTs against SDTs theoretical constructs, to refine intervention content in preparation for feasibility testing. The resulting intervention had the overarching aim of creating a more motivationally empowering treatment climate and to implement specific BCTs to support patients with lower-limb OA to adopt and maintain PA.
- A single-arm, mixed methods, feasibility trial which evaluated the feasibility and acceptability of delivering the behaviour change intervention in people with lower-limb OA. N=36 patients with lower-limb OA were recruited and followed up for 6 months post-baseline. The recruitment strategy, multi-component intervention, and training programme were acceptable and feasible to deliver with minor modifications. Further adaptations to data collection processes were required to optimise the amount of data secured.

Overall, the multi-component, sequentially developed, theory-based behaviour change intervention was feasible and acceptable to patients with lower-limb OA and practicing physiotherapists. However, refinement and further piloting of the data collection processes are required prior to undertaking a full-scale parallel group (1:1) randomised controlled trial to evaluate the intervention's effectiveness within post-COVID physiotherapy services.

DEDICATION

Dedicated to my beautiful wife, Luisa, and my amazing son Daniel; you are my life, my love, my everything.

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TABLE OF CONTENTS	
	Page
CHAPTER 1: BACKGROUND	
1.1 Introduction	2
1.1.1 <i>Burden of osteoarthritis</i>	2
1.1.2 <i>Diagnosis of Osteoarthritis</i>	3
1.2 Impact of Lower-limb Osteoarthritis on the individual	5
1.2.1 <i>Biological factors</i>	5
1.2.2 <i>Psychological factors</i>	7
1.2.3 <i>Social factors</i>	8
1.3 Management of Osteoarthritis	8
1.3.1 <i>Exercise and physical activity in patients with lower-limb osteoarthritis</i>	9
1.3.2 <i>Exercise versus Physical Activity</i>	11
1.4 Physical activity in patients with lower-limb osteoarthritis	12
1.5 The use of behaviour change theory and techniques to promote physical activity in patients with lower-limb osteoarthritis	14
1.5.1 <i>Conceptual definitions of physical activity adherence and Maintenance</i>	15
1.5.2 <i>Physiotherapists' use of behavioural change techniques to promote physical activity in patients with lower-limb osteoarthritis</i>	16
1.5.3 <i>Overview of systematic reviews examining use of behaviour change techniques on physical activity</i>	19
1.6 Summary of thesis rationale	24
1.6.1 <i>Thesis aims</i>	24
1.6.2 <i>Thesis objectives</i>	25
1.6.3 <i>Thesis objectives</i>	26
1.7 Public Involvement	27
CHAPTER 2: EFFECTIVENESS OF BEHAVIOUR CHANGE TECHNIQUES IN PHYSIOTHERAPY INTERVENTIONS TO PROMOTE PHYSICAL ACTIVITY ADHERANCE IN PATIENTS WITH LOWER LIMB OSTEOARTHRITIS: A SYSTEMATIC REVIEW	
2.1 Introduction	30
2.2 Methods	33
2.2.1 <i>Eligibility Criteria</i>	34
2.2.2 <i>Information sources and searches</i>	34
2.2.3 <i>Study selection</i>	36
2.2.4 <i>Data Collection Process and Items</i>	37
2.2.5 <i>Risk of bias (RoB) Assessment</i>	38
2.2.6 <i>Fidelity Assessment</i>	39
2.2.7 <i>BCT coding</i>	39
2.2.8 <i>Measurement of analysis and Summary Measure</i>	41
2.2.9 <i>BCT effectiveness</i>	42
2.3 Results	43
2.3.1 <i>RCT Selection</i>	43
2.3.2 <i>RCT Characteristics</i>	44
2.3.3 <i>PA adherence outcomes</i>	45
2.3.4 <i>Risk of bias within and across studies</i>	47

2.3.5 Fidelity	49
2.3.6 BCTs identified in interventions	49
2.3.7 BCT effectiveness	50
2.4 Discussion	55
2.5 Strengths and limitations	60
2.6 Conclusions	60
2.7 Dissemination of results	61

CHAPTER 3: UTILISING THE PERSPECTIVES OF PATIENTS WITH LOWER-LIMB OSTEOARTHRITIS OF PRESCRIBED PHYSICAL ACTIVITY TO DEVELOP A THEORETICALLY INFORMED PHYSIOTHERAPY INTERVENTION

3.1 Background	64
3.2 Methods	67
3.2.1 Theoretical Framework	67
3.2.2 Research team and reflexivity	67
3.2.3 Participant Selection	68
3.2.4 Data Collection	70
3.2.5 Data analysis and development of intervention	71
3.2.6 Ethics approval and consent to participate	75
3.3 Results	75
3.3.1 Participants	75
3.3.2 Step 1: Identification of barriers and facilitators and thematic analysis and Step 2: Mapping to the Theoretical Domains Framework	76
3.3.3 Personal factors grouping	77
3.3.4 Treatment phase factors grouping	81
3.3.5 Post-discharge factors grouping	82
3.3.6 Interrelationship of themes across groupings	83
3.3.7 Step 3: Behaviour change technique identification and Intervention development	85
3.4 Discussion	87
3.4.1 Personal Factors	87
3.4.2 Treatment factors	88
3.4.3 Post-discharge factors	90
3.4.4 Reflections on TDF mapping and BCT coding	90
3.5 Strengths and Limitations	91
3.6 Conclusions	93
3.7 Funding	93
3.8 Dissemination of findings	94

CHAPTER 4: PHYSIOTHERAPISTS PERCEPTIONS OF A THEORETICALLY INFORMED INTERVENTION DESIGNED TO PROMOTE ADOPTION AND MAINTENANCE OF PHYSICAL ACTIVITY IN PATIENTS WITH LOWER-LIMB OSTEOARTHRITIS: A QUALITATIVE STUDY

4.1 Background	96
4.2 Methods	99
4.2.1 <i>Ethics approval and study reporting</i>	99
4.2.2 <i>Research team and reflexivity</i>	99
4.2.3 <i>Study Design</i>	100
4.2.4 <i>Analysis and Findings</i>	102
4.3 Results	103
4.3.1 <i>Participants</i>	103
4.3.2 <i>Themes</i>	104
4.4 Discussion	109
4.4.1 <i>Themes reflecting intervention feasibility</i>	109
4.3.2 <i>Themes relating to patient-physiotherapist relationship</i>	111
4.5 Strengths and Limitations	115
4.6 Conclusions	116
4.6 Funding	116
CHAPTER 5: IDENTIFICATION OF BEHAVIOUR CHANGE THEORY AND FINALISATION OF INTERVENTION CONCEPTUAL MODEL	
5.1 Background	118
5.2 Methods	124
5.2.1 <i>Specification of eligibility criteria for choice of theory</i>	124
5.2.2 <i>Objectives 1-2: Identification of theory of behaviour change and training programme</i>	125
5.2.3: <i>Objective 3: Mapping of intervention behaviour change techniques to theoretical constructs</i>	128
5.2.4 <i>Objective 4: Integration of proposed intervention within chosen theory's theoretical framework</i>	128
5.3 Results	129
5.3.1 <i>Objective 1: Choice of behaviour change theory</i>	129
5.3.2 <i>Objective 2: Choice of training programme</i>	135
5.3.3 <i>Objective 3: Mapping BCTs to theoretical constructs and prioritising techniques</i>	136
5.3.4 <i>Objective 4: Proposed interventions theoretical Model</i>	137
5.4 Discussion	139
5.5 Conclusion	145
CHAPTER 6: FEASIBILITY AND ACCEPTABILITY OF A THEORETICALLY GROUNDED, MULTICOMPONENT, PHYSIOTHERAPY INTERVENTION AIMING TO PROMOTE AUTONOMOUS MOTIVATION TO ADOPT AND MAINTAIN PHYSICAL ACTIVITY IN PATIENTS WITH LOWER-LIMB OSTEOARTHRITIS	

6.1 Background	148
6.2 Methods	152
6.2.1 <i>Ethics</i>	152
6.2.2 <i>Trial Design</i>	152
6.2.3 <i>Trial setting and participant eligibility criteria</i>	153
6.2.4 <i>Participant identification and consent</i>	154
6.2.5 <i>Multi-component behaviour change intervention</i>	156
6.2.6 <i>Intervention materials and associated behaviour change Techniques</i>	158
6.2.7 <i>Intervention Delivery</i>	159
6.2.8 <i>Physiotherapist training</i>	161
6.2.9 <i>Trial Outcomes and Success Criteria</i>	163
6.2.10 <i>Methods of data collection</i>	164
6.2.11 <i>Patient and public involvement</i>	171
6.2.12 <i>Trial design and sample size</i>	171
6.2.13 <i>Data Analysis</i>	173
6.3 Results	178
6.3.1 <i>Participant recruitment and demographic information</i>	178
6.3.2 <i>Participant flow, drop out and data collection</i>	178
6.3.3 <i>Qualitative results</i>	185
6.3.4 <i>Integration</i>	200
6.4 Discussion	204
6.4.1 <i>Participant recruitment and eligibility</i>	204
6.4.2 <i>Intervention delivery and training programme</i>	205
6.4.3 <i>Outcome measures and data collection procedures</i>	206
6.4.4 <i>Summary of Progression Criteria</i>	210
6.5 Strengths and limitations	210
6.6 Conclusions	211
6.7 Funding	212
6.8 Dissemination of results	213
Chapter 7: Fidelity of intervention delivery of a complex theoretically grounded physiotherapy intervention aiming to promote physical activity adoption and maintenance in patients with lower-limb osteoarthritis	
7.1 Introduction	215
7.2 Methods	218
7.2.1 <i>Study reporting and ethical clearance</i>	218
7.2.2 <i>Setting and participants</i>	219
7.2.3 <i>Sampling and treatment sessions</i>	219
7.2.4 <i>Behaviour change intervention</i>	219
7.2.5 <i>Physiotherapy training programme</i>	221
7.2.6 <i>Outcome measure and assessment of fidelity</i>	224
7.2.7 <i>Data analysis and interpretation</i>	226
7.2.8 <i>Inter-researcher reliability</i>	228
7.3 Results	228
7.3.1 <i>Inter-rater agreement</i>	228
7.3.2 <i>Recorded Sessions</i>	228
7.3.3 <i>Physiotherapists</i>	229
7.3.4 <i>Protocol and non-protocol Behaviour Change Techniques delivered</i>	230

7.3.5 Fidelity delivery of protocol behaviour change techniques	232
7.3.6 Competence to create a motivational empowering treatment climate	234
7.4 Discussion	236
7.5 Strengths and limitations	240
7.6 Conclusions	242
7.7 Funding	243

CHAPTER 8: EFFECTIVENESS OF BEHAVIOUR CHANGE TECHNIQUES IN PHYSIOTHERAPY INTERVENTIONS TO PROMOTE PHYSICAL ACTIVITY ADHERENCE IN PATIENTS WITH LOWER LIMB OSTEOARTHRITIS: A SYSTEMATIC REVIEW UPDATE

8.1 Background	245
8.2 Methods	247
8.2.1 Eligibility criteria	247
8.2.2 Information sources	247
8.2.3 Risk of bias assessment tool	248
8.3 Results	248
8.3.1 Selection of updated trials	248
8.3.2 Characteristics of updated trials	250
8.3.3 PA adherence outcomes used in updated trials	250
8.3.4 Risk of Bias within and across updated trials	251
8.3.5 Fidelity assessment of updated trials	252
8.3.6 Behaviour change techniques in updated trials	253
8.3.7 BCT effectiveness ratios synthesising data from the original and updated systematic reviews	258
8.4 Discussion	260
8.4.1 Recent developments in physiotherapy Randomised controlled Trials	260
8.4.2 BCT use in the updated systematic review and their overall effectiveness on PA adherence	264
8.5 Strengths and weaknesses	268
8.6 Conclusions	270

CHAPTER 9: GENERAL DISCUSSION

9.1 Introduction	273
9.2 Discussion of results across thesis objectives and studies	275
9.2.1 Objective 1: To identify the BCTs used in physiotherapy interventions to promote PA adherence in lower limb OA patients and evaluate their effectiveness at different time points post-baseline.	275
9.2.2: Objective 2: 2a) To explore patients with lower-limb OA in-depth experiences of barriers and facilitators to physiotherapist prescribed PA while receiving treatment and post-discharge. 2b) To utilise barriers and facilitators to identify BCTs to propose a theoretically informed intervention that aimed to promote PA during treatment and post-treatment.	278

9.2.3: <i>Objective 3: To determine physiotherapists' perspectives of the feasibility and acceptability of delivering a proposed theoretically informed behaviour change intervention in a real-world clinical setting.</i>	282
9.2.4: <i>Objective 4: To identify an appropriate theory of behaviour change to integrate with the proposed intervention to support physiotherapist training and intervention delivery</i>	285
9.2.5: <i>Objective 5: To investigate the feasibility and acceptability of delivering a complex, multicomponent theoretical behaviour change physiotherapy intervention in the view of patients with lower-limb OA, treating physiotherapists, and research related staff.</i>	288
9.3 Thesis strengths and limitations	292
9.4 Conclusions	294

LIST OF TABLES

	Page
Table 1.1: International guidelines diagnostic criteria for lower-limb Osteoarthritis based on signs and symptoms	4
Table 1.2: Metabolic equivalent of task intensity of different physical activity intensity Levels	12
Table 1.3: Definitions of Physical Activity Adherence and Maintenance used within the thesis	16
Table 1.4: Overview of systematic reviews examining behaviour change technique use in musculoskeletal pain populations	21
Table 1.5: Thesis Structure	27
Table 2.1: Eligibility Criteria	34
Table 2.2: Summary of risk of bias assessment	48
Table 2.3: BCTs identified from protocols and trial reports of included physiotherapy randomised controlled trials	51
Table 2.4: BCT effectiveness ratios	54
Table 3.1: Participant demographic features	76
Table 3.2: Key Theoretical Domains Frameworks Domains that influenced Themes	77
Table 3.3: Theory-informed physiotherapy intervention outlining phases targeted by behavioural change techniques	83
Table 4.1: Physiotherapist demographic feature	104
Table 4.2: Themes and subthemes of physiotherapists perceptions of the intervention	107
Table 4.3: Optimisation of intervention based on integration of patient and physiotherapists views'	112
Table 5.1: Primary and secondary eligibility criteria used to determine compatibility of theory of behaviour change with proposed intervention	125
Table 5.2: Theory identification Matrix	131
Table 5.3: Final behaviour change intervention outlining phases of intervention and associated behaviour change techniques	137
Table 6.1: Trial eligibility criteria	154
Table 6.2: Intervention materials delivered across sessions and outline of content with associated theoretical constructs and behaviour change techniques	160
Table 6.3: Schedule of physiotherapist training in intervention delivery	163
Table 6.4: Trial outcomes and success criteria	167
Table 6.5: Planned participant secondary outcome measures for definitive trial	170
Table 6.6: Methods utilised to enhance trustworthiness	177
Table 6.7: Trial participant demographic characteristics	181
Table 6.8: Intervention physiotherapists demographic features and number of patients managed during the trial	183
Table 6.9: Participant outcome measures.	184
Table 6.10: Participants characteristics	186
Table 6.11 Verbatim quotes to demonstrate themes and subthemes from participant interviews	191
Table 6.12: Verbatim quotes to demonstrate themes and subthemes from physiotherapist interviews	195

Table 6.13: Research staff demographic features	196
Table 6.14: Verbatim quotes to demonstrate themes and subthemes from research staff interviews	199
Table 6.15: Evidence demonstrating the extent to which success criteria were met	201
Table 7.1: Fidelity of BCT delivery and treatment climate by individual physiotherapists	229
Table 7.2: Total number and frequency of behaviour change techniques delivered across phases	231
Table 7.3: Intervention fidelity delivery of protocol behaviour change techniques	233
Table 7.4: Treatment climate provided by the physiotherapists across the intervention phases as measured by the Interpersonal Support in Physical Activity Consultations Observational Tool	235
Table 8.1: Trial risk of bias in updated trials	252
Table 8.2: Fidelity domain assessment of updated trials	253
Table 8.3: BCTs identified from protocols and trial reports of physiotherapy randomised controlled trials included in the updated systematic review	255
Table 8.4: Overall BCT effectiveness ratios from synthesising data from the original and updated systematic reviews	260
Table 8.5: Direct measures of physical activity in the updated systematic review	264
Table 9.1: Thesis chapters and associated Medical Research Council actions	275

LIST OF FIGURES

	Page Number
Figure 2.1: Example search strategy: Medline (Ovid) Search Strategy	35
Figure 2.2: RCT selection flow diagram	45
Figure 3.1: Overview of intervention development process	65
Figure 3.2: Conceptual mindmap of Personal and Treatment Themes influencing adherence to physical activity	81
Figure 3.3: Conceptual mindmap of Personal and Post-Discharge Themes influencing adherence to physical Activity	81
Figure 5.1: Generic model of behaviour change	119
Figure 5.2: Overview of study methods	129
Figure 5.3: Results of Theory Identification (Objective 1)	134
Figure 5.4: Proposed theoretical model of behaviour change undergirding the intervention	138
Figure 6.1: Trial CONSORT flow diagram	182
Figure 7.1 Proposed model of empowering and disempowering psychological climates	223
Figure 7.2 Overview of behaviour change intervention and the physiotherapy training programme and their and assessment	224
Figure 8.1: Selection flow diagram of updated systematic review searches	249

LIST OF APPENDICES

	Page Number
Appendix 1.1: Article, BMJOpen, Effectiveness of behavioural change techniques in physiotherapy interventions to promote physical activity adherence in patients with hip and knee osteoarthritis: a systematic review protocol	297-301
Appendix 1.2: Article, PLOS One, Effectiveness of behaviour change techniques in physiotherapy interventions to promote physical activity adherence in lower-limb osteoarthritis patients: A systematic review	302-313
Appendix 1.3: Article, BMJ Open, Barriers and facilitators to recommended physical activity in lower-limb osteoarthritis: protocol for a qualitative study exploring patients and physiotherapist perspectives using the theoretical domains framework and behaviour change taxonomy	314-318
Appendix 1.4: Article, BMC Musculoskeletal Disorders, Utilising the perspectives of patients with lower-limb osteoarthritis on prescribed physical activity to develop a theoretically informed physiotherapy intervention	319-325
Appendix 1.5: Article, Pilot and Feasibility Studies, Feasibility of a theoretically grounded, multicomponent, physiotherapy intervention aiming to promote autonomous motivation to adopt and maintain physical activity in patients with lower-limb osteoarthritis: protocol for a single-arm trial	326-334
Appendix 2.1: Fidelity domains and components assessed in trials	335-341
Appendix 2.2: Characteristics of included RCTs table	342-346
Appendix 2.3: Physical activity and adherence outcomes in included trials	347-350
Appendix 2.4: Fidelity domain assessment of included RCTs	351
Appendix 2.5: Checklist PRISMA 2009 checklist, Systematic Review	352-353
Appendix 3.1: Semi-structured interview schedule	354-360
Appendix 3.2: Behaviour change technique and domains matrix	361-366
Appendix 3.3: Themes and subthemes with examples quote and corresponding Theoretical Domain Framework (TDF) Domain	367-394
Appendix 3.4: COREQ checklist, patient semi-structured interviews	394-396
Appendix 4.1: COREQ checklist, physiotherapy focus groups	397-399
Appendix 4.2: Physiotherapy focus group topic guide	400-404
Appendix 5.1: Reason for exclusion of behaviour change theories	405-406
Appendix 5.2: Mapping of intervention behaviour change techniques to Self Determination Theory constructs	407-410
Appendix 6.1: Schedule of enrolment, interventions, and assessments	411-412
Appendix 6.2: Overview of intervention development	413-414
Appendix 6.3: Overview of physiotherapist training	415-416
Appendix 6.4: Trial physical activity adoption workbook	417-424
Appendix 6.5: Physical Activity Maintenance workbook	425-434

Appendix 6.6 Physiotherapy treatment manual	435-456
Appendix 6.7: Treatment fidelity coding manual	457-475
Appendix 6.8: Additional trial Information	476-478
Appendix 6.9: Reasons for patient ineligibility identified during screening	479
Appendix 6.10: Reasons for ineligibility and declined participation in potential participants who were sent a participant information sheet	480
Appendix 6.11: CONSORT extension for pilot and feasibility trials checklist, feasibility Trial	481-484
Appendix 6.12: COREQ checklist, feasibility Trial	485-487
Appendix 6.13: TIDieR checklist-Word, feasibility Trial	488-489
Appendix 6.14: SPIRIT checklist, feasibility Trial	490-498
Appendix 6.15: Trial Participant Information Sheet and Consent Forms	499-507
Appendix 8.1: Characteristics of included trials in updated review	508-511
Appendix 8.2: Physical activity and adherence outcomes in updated review	512-515
Appendix 8.3: Updated systematic review PRISMA 2020 checklist	516-518
Appendix 9.1- AMSTAR 2 checklist for systematic review (Chapter 2, Chapter 8)	519
Appendix 9.2 - Self assessed risk of bias of qualitative study - patient semi structured interviews	520
Appendix 9.3 - Self assessed risk of bias of qualitative study - physiotherapist semi focus groups	521

LIST OF ABBREVIATIONS

ACR	American College of Rheumatology
APP	Advanced Physiotherapy Practitioner
AGT	Achievement Goal Theory
BCT	Behaviour change technique
BCW	Behaviour Change Wheel
BMI	Body mass index
CENTRAL	Cochrane Register of Controlled Trials
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COM-B	Capability-Opportunity-Motivation-Behaviour
CONSORT	<i>Consolidated Standards of Reporting Trials</i>
COREQ	COnsolidated criteria for REporting Qualitative research
CRD	Centre of Reviews and Dissemination
DTSM	Dillman Total Design Survey Methods
DHA	Danish Health Authority
EC	Empowerment coaching
EULAR	European League Against Rheumatism
GCP	Good Clinical Practice
GP	General Practitioner
HBIM	Health Behaviour Internalisation Model
HRA	Health Research Authority
IM	Intervention Mapping
ISPACOT	Interpersonal Support in Physical Activity Consultations Observational Tool
ISRCTN	International Standard Randomised Controlled Trial Number
LPA	Light physical Activity
MACP	Musculoskeletal Association of Chartered Physiotherapists
MET	Metabolic Equivalent of Task'
MPA	Moderate physical activity
MRC	Medical Research Council
MRI	Magnetic Resonance Imaging
MVPA	Moderate-to-vigorous physical activity
NHS	National Health Service
NICE	National institute for Clinical Excellence
NIHBCC	National Institutes of Health Behaviour Change Consortium
NSAIDs	Non-steroidal anti-inflammatory drugs
OA	Osteoarthritis
OARSI	The Osteoarthritis Research Society International
OR	Odds Ratio
PA	Physical Activity
PEDro	Physiotherapy Evidence Database
PIS	Participant Information Sheet
PPI	Patient and public involvement
PR	Probability ratio
PRISMA	<i>Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement</i>
PROM	Patient-reported outcome measure

QoI	Quality of life
RA	Rheumatoid arthritis
RCT	Randomised controlled trial
REVMAN	Review Manager
RoB	Risk of Bias
ROH	Royal Orthopaedic Hospital
SCT	Social-Cognitive Theory
SDT	Self-determination theory
SF HOOS	Short-form Hip Injury and Osteoarthritis Outcome Scores
SF KOOS	Short-form Knee Injury and Osteoarthritis Outcome Scores
SMD	Standardised mean difference
SPIRIT	Standard Protocol Items Recommendations for Interventional Trials
SSC	Study Steering Committee
TCM	Trans-Contextual Model of Motivation
TDF	Theoretical Domains Framework
THR	Total Hip Replacements
TKR	Total Knee Replacement
TOBC	Theory of behaviour change
TSG	Trial Steering Group
TsOBC	Theories of behaviour change
TTM	Transtheoretical model
UK	United Kingdom
V1	Version 1
VPA	Vigorous physical activity
WHO	World Health Organisation
X ray	X-radiation

CHAPTER 1: BACKGROUND

Chapter overview

This introductory chapter outlines the prevalence and concerns surrounding lower-limb OA in terms of symptoms and magnitude of disability and healthcare costs. The importance of physical activity, and the role physiotherapists play in helping patients with lower-limb OA to self-manage their symptoms is highlighted. Key influences of physical activity behaviours are detailed, and the rationale for the development of a physiotherapy intervention that targets adoption and maintenance of PA explained, by summarising the current evidence base. Finally, the thesis aims and objectives and a brief synopsis of the overarching structure are presented.

Sections of this chapter are taken verbatim from the background/Introductory and discussion sections of following publications of which I am primary author.

- Willett M, Duda J, Gautrey C, Fenton S, Greig C, Rushton A. Effectiveness of behavioural change techniques in physiotherapy interventions to promote physical activity adherence in patients with hip and knee osteoarthritis: a systematic review protocol. *BMJ Open*. 2017;7(6):e015833 (Appendix 1.1)
- Willett M, Duda J, Fenton S, Gautrey C, Greig C, Rushton A. Effectiveness of behaviour change techniques in physiotherapy interventions to promote physical activity adherence in lower limb osteoarthritis patients: A systematic review. *PLoS One*. 2019;14(7):e0219482. (Appendix 1.2)
- Willett MJ, Greig C, Rogers D, Fenton S, Duda J, Rushton A. Barriers and facilitators to recommended physical activity in lower-limb osteoarthritis: protocol for a qualitative study exploring patients and physiotherapist perspectives using the theoretical domains framework and behaviour change taxonomy. *BMJ Open*. 2019;9(10):e029199. (Appendix 1.3)
- Willett M, Greig C, Fenton S, Rogers D, Duda J, Rushton A. Utilising the perspectives of patients with lower-limb osteoarthritis on prescribed physical activity to develop a theoretically informed physiotherapy intervention. *BMC Musculoskelet Disord*. 2021;22(1):155. (Appendix 1.4)

1.1 Introduction

1.1.1 Burden of osteoarthritis

Osteoarthritis (OA) is a degenerative disease that causes people significant pain and reductions in function, social engagement, and quality of life (1, 2). OA is the most common form of arthritis and research estimates that between 240 (3) and 300 (4) million people suffer with OA globally, which represents an increase of over nine percent from prevalence figures reported in 1990 (4). In the United Kingdom (UK), OA is the leading cause of individual level disability and the most common cause of pain in older adults, with one-third of patients over 45 years old, meaning almost 9 million individuals have sought treatment for OA related symptoms (5).

The hip and knee (i.e. lower-limb) are the primary synovial joints effected by OA (6), with an overall point prevalence of 11% and 24% respectively (7). In the UK, Lower-limb OA accounts for approximately 70% of the total reported OA symptoms, with 4.1 and 2.5 million individuals experiencing knee and hip OA related symptoms respectively (8). The 2021 Global Burden Disease study (9) identified a rapid growth of the incidence of OA diagnoses, with 130% increase from 1990-2020. Furthermore, OA was ranked 7th in people ≥70 years of age for years lived with disability (YLD) and, by 2050 knee and hip OA are expected to further increase by 75% and 79% respectively (9).

Due to its high prevalence and associated disability, OA contributes substantially to health care costs and resource utilisation (10). In the UK annually, OA symptoms are estimated to be responsible for approximately two million general practitioner visits, with an expenditure totalling 1% of the country's gross national product (5). In

combination with rheumatoid arthritis (RA), associated healthcare costs in 2018 were over £10 billion with the 10-year cumulative costs projected to reach almost £120 billion by 2027 (11). As there is currently no cure for OA (5), and with increased life expectancy (7), the healthcare costs of OA are anticipated to continue to increase over the coming decades (12) and engulf healthcare systems within ten years (13).

1.1.2 Diagnosis of Osteoarthritis

OA is a heterogenous joint disease that is characterised by degenerative changes to the articular and peri-articular tissues, alongside reports of pain, functional impairment and morning stiffness by those who suffer symptoms (5). Despite the high prevalence and extensive research into the epidemiology and aetiology of OA, international guidelines lack consensus over diagnostic criteria (14). Commonly utilised guidelines to diagnose lower-limb OA include those proposed by the American College of Rheumatology (ACR) for knee (15) and hip OA (16), the European League Against Rheumatism (EULAR) knee guidelines (17), The Danish Health Authority hip guidelines (18) (DHA) and the National Institute for Clinical Excellence (NICE) (10). These guidelines, including their recommended signs and symptoms for diagnosis of lower-limb OA, are summarised in Table 1.1

Two recent cohort studies have evaluated the diagnostic accuracy of these guidelines to identify patients with knee (19) and Hip (20) OA in primary care. The ACR and EULAR guidelines identified only half of those (n= 13,459 patients) who presented with knee OA (19). Overall, the criteria for identifying hip OA (n = 4699) were more accurate, with the ACR and DHA guidelines identifying 64% and 80% of positive cases respectively (20). However, in both studies, the NICE guidelines most

accurately identified patients with knee (89%) (19) and Hip (94%) (20) OA.

Interestingly, NICE are the only guidelines which are not joint specific and do not include imaging within their eligibility criteria. The NICE guidelines propose that a person can be diagnosed with OA if they are 45 years or older and have joint related pain that is exacerbated by activity and exists for up to 30 minutes after waking and are the most widely used in the UK (10) and have been used as the eligibility criteria in contemporary RCTs using patients with lower-limb OA (21, 22, 23).

Table 1.1: International guidelines diagnostic criteria for lower-limb osteoarthritis based on signs and symptoms

Knee Classification systems	
European League Against Rheumatism (Zhang et al 2010)	Age > 40 • Symptoms • persistent knee pain • limited morning stiffness • reduced function Signs • Crepitus • restricted movement • bony enlargement
American College of Rheumatology (Altman et al., 1986)	Knee pain plus ≥ 3 of • Age > 50 years old • AM stiffness <30 minutes • Crepitus • Joint line tenderness • Bony enlargement • No heat of palpation
Hip Classification	
American College of Rheumatology (Altman et al., 1991)	• Hip pain • and internal rotation less than 15 degrees • and flexion less than or equal to 115 degrees or • Hip pain • and internal rotation ≥ 15 degrees • and painful internal rotation • and morning stiffness ≤ 60 mins • Age > 50 years
Danish Health Authority (DHA, 2016)	Activity-related hip pain AND reduced hip mobility
Global Classification	
National Institute for Health and Care Excellence (NICE, 2022)	• Age > 45 years old • AND Activity related joint pain • AND AM stiffness <30 minutes (or no stiffness)

1.2 Impact of Lower-limb Osteoarthritis on the individual

In the United Kingdom, OA is the primary cause of individual disability (5). Patients with lower-limb OA primarily complain of joint pain (8), which may be characterised as dull and intermittent initially, but will likely develop into cumulative bouts of increasing pain severity as the disease progresses (24). Critically, as pain severity increases, patients with lower-limb OA experience decreased physical function and psychological well-being and increased levels of disability (25). In 2016, a white paper population summary by the Osteoarthritis Research Society International (OARSI) reported that approximately 1 in 4 patients with lower-limb OA experienced significant limitations to their daily activities which impacted on their mental wellbeing and psychological health (26).

There is poor correlation between the physiological changes found in imaging and laboratory tests and the degree of pain and disability experienced by patients with lower-limb OA (27). The overarching symptoms experienced by patients with lower-limb OA cannot be explained by biological processes alone, and contemporary OA healthcare management aims to address psychological and social factors in addition to pathophysiological ones (28) (i.e. a biopsychosocial approach). The following sections briefly summarise key factors that may influence the lived experience of patients with lower-limb OA from a biopsychosocial perspective.

1.2.1 Biological factors (pathophysiology)

Despite the increased prevalence and burden of OA, the underlying pathophysiological processes involved are not well understood (5). Historically, OA was considered a progressive degenerative disease associated with a loss of local

articular cartilage, a local inflammatory response, and contiguous bone remodelling (5). However, as cartilage is poorly vascularised and lacks innervation by pain fibres, more recent research has identified other physiological processes associated with OA pain and symptoms. Among these, the role of the inflammatory (5) and immune systems (29, 30) are of particular interest.

Inflammatory mediators found in the synovium, such as cytokines and prostaglandins, produce a chemical cascade resulting in cartilage degeneration (31, 32). However, uncertainty remains over whether the inflammatory response is the initiation of the disease or the result of other underlying pathophysiological processes (29). As inflammation increases and cartilage degeneration proceeds, the immune system produces white blood cells, such as macrophages and growth factors, to target the areas of inflammation (30). Although the macrophages and growth factors are acting in a protective capacity, ongoing stimulation can lead to further degeneration in the articular and periarticular tissues (31).

A section of patients with hip (33) and knee (34) OA have demonstrated signs of central sensitisation, including reduced pain pressure thresholds and wide spread pain distribution (35). Central sensitisation is a physiological phenomenon characterised by reduced activation thresholds of central nervous system nociceptors (those proximal to the dorsal horn of the spinal column) (36). When sensitized, the nociceptors become responsive to non-noxious stimuli which results in increased afferent impulse generation and a clinical presentation of increased pain severity and irritability (37).

1.2.2 Psychological factors

The symptoms experienced by patients with lower-limb OA can influence their psychological well-being and cognitive functioning (28). Although the exact mechanism has not been established, it is hypothesised that physiological responses to psychological distress interact to reduce the quality of life in patients with lower-limb OA (8, 24).

Two well recognised psychological factors associated with lower-limb OA are fear avoidance and pain catastrophising (38). The pain caused by lower limb OA can impact the confidence/self-efficacy of people with lower-limb OA to carry out functional tasks (38, 39). If unresolved, this may lead to patients with lower-limb OA developing, avoidant behaviours when engaging with specific movements (i.e. kinesiophobia) which, over time, may reduce function (28). Catastrophising (an exaggerated cognitive/emotive response to actual or anticipated pain) (40) has consistently predicted increased pain and disability in patients with lower-limb OA (39, 41). Furthermore, pain catastrophising demonstrated significant correlation with symptoms of central sensitisation ($r^2 = 0.413$) in patients with hip OA (33) and may therefore be linked to higher levels of pain severity and irritability.

Evidence of an association between lower-limb OA and depression and/or low mood is growing. While a systematic review conducted in 2012 found no correlation between lower-limb OA and depression or low mood (42), a more recent systematic review estimated about 20% of patients with lower-limb OA experience feelings of anxiety and/or depression (43). These findings are supported by recent cohort studies totalling over 5000 participants (44, 45) which found that patients with lower-limb OA were significantly more likely to develop depression than control subjects.

Furthermore, patients with OA appear significantly more likely to develop suicidal thoughts (46). Therefore, taken together evidence demonstrates that an association between OA and psychological wellbeing in patients with lower-limb OA exists.

1.2.3 Social factors

The level of social support received by patients with lower-limb OA can greatly influence their lived experience (47). Patients with lower-limb OA who received spousal support demonstrated increased ability to self-manage their OA symptoms (48). Conversely those with lower levels of social support experience higher levels of pain (49) ($r = -0.18$, $P < 0.01$) and depression/low mood (50, 51) ($r = -0.44$, $P < 0.01$)

Lower-limb OA has been linked to lower-educational achievement (52, 53, 54, 55), decreased earning potential (56), and reduced socioeconomic status (57).

Occupations that require greater levels of physicality are associated with hip and knee OA symptoms (58, 59). Occupations that requires prolonged periods weightbearing on hard surfaces, excessive use a lot of stairs (60), kneeling or squatting down are associated with knee OA (61), whereas roles that necessitate long bouts of standing or heavy lifting are associated with Hip OA (61, 62).

1.3 Management of Osteoarthritis

Three primary management options for OA are outlined in international guidelines: Pharmacological, Non-pharmacological, and Surgical management (1, 7, 63).

Pharmacological management of lower-limb OA symptoms initially includes non-steroidal anti-inflammatory drugs (NSAIDs) and paracetamol, with opioids prescribed

if pain is not controlled (3, 64). If oral medication does not provide effective symptom management, corticosteroid joint injections may be offered (64). However, a recent systematic review showed intra-articular corticosteroid injections only provide effective short-term (≤ 6 weeks post baseline) management of pain and function compared to other interventions in patients with lower-limb OA (65).

If pharmacological treatment is insufficient to control OA symptoms, joint replacement surgery (i.e. arthroplasty) may be considered. Over 100,000 hip and knee replacements are conducted in the NHS each year and >90% of these are due to OA (66). In 2017, Total Hip Replacements (THR) and Total Knee Replacement (TKR) operations were estimated to cost the NHS almost £2 billion (67). As pain and loss of function often persist post-surgery (68), this option is only considered once all other options have been explored and if the patients symptoms and degree of disability correlate with imaging findings (3, 64). Patients with lower-limb OA have high prevalence of secondary health issues, such as cardiac disease (69) which may increase risks of with surgery or present complications with certain medications (70). Therefore, pharmacological, and surgical interventions require consideration prior to enactment.

1.3.1 Exercise and physical activity in patients with lower-limb osteoarthritis

Non-pharmacological healthcare interventions incorporate education and exercise prescription and are recommended for the initial management of OA by international guidelines (1, 3, 10, 64). Exercise and education interventions have less side effects and associated costs than pharmacological therapy and surgeries (19) and, in the

absence of a known cure, can provide patients with necessary knowledge and skills to aid self-management of symptoms.

A plethora of systematic reviews have examined the effectiveness of exercise interventions on lower-limb OA with each concluding that exercise interventions are more effective than no/minimal treatment at controlling OA symptoms (25, 71, 72, 73, 74, 75, 76). Furthermore, an overview of systematic reviews found exercise interventions provide similar pain relief to medication in people with lower-limb OA (77).

Although exercise interventions improve short-term clinical outcomes, such as reduced pain and increased function in patients with lower limb OA, these positive effects are generally not maintained at medium (6 months) to long-term (≥ 12 months) follow up assessments (25, 69, 74, 78). This could be due to several factors including limited long-term effectiveness of the prescribed intervention, progression of OA disease severity or a gradual reduction in patient adherence to health professional recommendations and an inability to maintain changes in their exercise behaviours (79, 80).

As OA is a life-long condition (81), and with point prevalence and incidence increasing with age (7), long-term adherence to exercise recommendations is critical to maintain the short-term improvements seen in a patient's pain (82) function (83) and disability (84). However, estimates exist that 60% (85) - to 90% (86) of patients do not adhere with healthcare exercise recommendations. Additionally, patients with lower-limb OA perceive that exercise is unsafe and that they require greater support to maintain their physical health, which likely further impacts on their exercise adherence (87).

1.3.2 Exercise versus Physical Activity

Exercise is a planned and structured physical activity (PA) aimed at improving or maintaining physical fitness (88). PA encompasses structured exercise as well as broader concepts such as leisure or occupational related activities (88, 89) and maybe important in improving lifestyle factors beyond clinical outcomes, such as patient well-being (90). Maintaining prescribed exercise levels requires greater patient effort and behaviour change than optimising more general PA behaviours (91). Therefore, it maybe important for healthcare interventions to target adherence to PA broadly, in addition to utilising specific exercises for targeting physical parameters solely (92). Interestingly, the broader aspects of PA have been acknowledged in the updated ACR and OARSI OA management guidelines (3, 64, 78) which advocate for mind body activities or tai chi to aid self-management of symptoms.

PA is typically measured by its 'Metabolic Equivalent of Task' (MET) and classified by its intensity as one of: sleeping, sedentary, light, moderate, or vigorous (93). The corresponding MET for each intensity is outlined in Table 1.2. PA is measured as either 'total' (summation of each minute for a specified period) or 'bouted' (quantity of time in intervals of 10 minutes or more of a defined PA intensity) (94). General recommendations advocate that individuals should aim for a minimum total of 150 minutes per week in moderate-vigorous levels of physical activity (MVPA) (95). Although contemporary guidelines primarily focus on total PA volume (95), currently, it is not clear which type of PA is most important to measure for health purposes (96).

Table 1.2: Metabolic equivalent of task intensity of different physical activity intensity Levels

PA intensity	Sedentary	Low	Moderate	Vigorous
MET	≤ 1.5	1.6-2.9	3.0-5.9	≥6

Legend: MET: Metabolic Equivalent of Task, PA: Physical Activity (WHO, 2019).

1.4 Physical activity levels in patients with lower-limb osteoarthritis

Wallis and colleagues' (2013) systematic review (97) identified the proportion of patients with lower-limb OA who met directly measured PA recommendations. Their sample included 3266 people with knee OA and 325 with hip OA respectively.

Overall, the findings demonstrated that patients with lower-limb OA are approximately 25% less active than non-symptomatic populations (97). Furthermore, patients with lower-limb OA spend approximately two-thirds their time sitting or in other sedentary activities (98) which is noteworthy as PA levels appear to remain fairly constant in the years prior to diagnosis (99). Importantly, prolonged physical inactivity has been associated with several reductions in the general health of patients with lower limb OA including the development of comorbidities such as obesity, diabetes, and heart disease (100), declining function and elevated pain levels, and an acceleration of the underlying OA disease process (101). However, a large survey found that between 54-79% of patients with lower-limb OA had never engaged with PA to help self-manage their OA related symptoms (102).

Longitudinal cohort studies, which taken together include almost 7500 patients with lower limb OA (24, 103, 104), have examined the influence of PA on clinical outcomes. Firstly, patients with lower-limb OA that meet activity recommendations

have better function than those who do not (103). Secondly, PA levels at baseline predicts physical function after two (105) and six (99) years respectively. However, for those who are inactive or have low levels of PA at baseline, relatively small overall increases in time spent in MVPA may be of benefit. For example, an increase of eight minutes per week (106) and a minimum total recommendation of 45 minutes per week spent in MVPA (107) have demonstrated functional improvement two years post baseline.

The most effective form of PA to aid symptom self-management in lower-limb OA has not been established (75, 76). A recent systematic review found that all types of PA benefitted pain and function but found no significant difference between aerobic, strengthening, proprioception and stretching training (108). Similarly, no significant differences in high versus low intensity exercise on OA symptoms have been found (109).

Walking is the most common form of general PA that patients with lower-limb OA engage with (110). Although the optimal number of daily steps likely varies from person to person, Wallis et al., (2013) demonstrated that approximately 50% of those with knee OA and 60% with hip OA undertaking PA interventions walk 7000 steps per day and most would optimally engage with about 6000 steps per day (97). Further evidence showed that patients with lower-limb OA who complete ≤ 2500 steps per day may have lower function levels than those who complete more (111). Conversely, those who complete > 10000 steps per day may be at greater risk of meniscal (RR: 1.52, (1.05, 2.20)) or articular bone (RR: 1.97 (1.19,3.27)) morphological changes after 2-3 years (112). Taken together, there are likely specific advantages and disadvantages with each type, form, and amount of PA and a personalised rehabilitation plan is recommended (113).

1.5 The use of behaviour change theory and techniques to promote physical activity in patients with lower-limb osteoarthritis

The Medical Research Council (MRC) advocates that interventions that alter participant behaviours should be underpinned by behaviour change theory (114). The use of theory enables specific behaviours (e.g. PA), and determinants of that behaviour (e.g. self-efficacy), to be conceptually targeted with behaviour change techniques (BCTs) (115). Based on the interventions effects on the outcomes of interest, the theoretical determinants and techniques can be adjusted, and therefore the theory can be refined and improved over time (116).

Systematic reviews have demonstrated that theoretical interventions are more effective than non-theoretical interventions at promoting PA in several patient populations (117, 118, 119), including lower-limb OA (120). However, data is lacking on patients with musculoskeletal pain (121). Williamson et al., (2015) systematically reviewed the effectiveness of behaviour change interventions at promoting long-term (>6 months post baseline) PA in patients with lower-limb OA. They identified 11 studies (n= 2741) and found a small effect in favour of behavioural interventions compared with comparators at 6 months post baseline on self-report PA. However, the authors found it problematic to establish which intervention techniques influenced PA (120). Identifying effective techniques within interventions for patients with chronic conditions is a research priority for NICE (122). Furthermore, behaviour change interventions are usually complex (114) and commonly reported inconsistently in trials (123, 124) making them difficult to replicate in clinical practice (125). BCTs are the smallest active components in behaviour change interventions (123). Michie et al., (p. 82) define BCTs as ‘an observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that

regulate behaviour' and include techniques such as 'reinforcement', 'self-monitoring' and 'feedback'. The Behaviour Change Taxonomy V1 (123) was developed by researchers with expertise in behaviour change to enable for consistent reporting and increased clarity when identifying BCTs within behaviour change interventions. The taxonomy contains 93 distinct BCTs grouped into 16 hierarchies (123) and has been used extensively in the behaviour change literature to transparently code BCTs within interventions (123).

1.5.1 Conceptual definitions of physical activity adherence and maintenance

There is considerable heterogeneity regarding the conceptual definitions of PA *adherence* and *maintenance* in the behaviour change literature. Regarding PA adherence, a recent systematic review by Bailey and Colleagues (126) summarised the definitions that trials that included patients with musculoskeletal pain used to conceptualise adherence to exercise. 60% of the included trials did not explicitly define exercise adherence (126). However, the most commonly cited definitions were those proposed by Sackett and Haynes (1976) (127) and the World Health Organization (WHO) (2003) (128) where exercise adherence was defined as how frequently a person's behaviour was in accordance with their healthcare provider's prescription (128). Bailey et al., (2020) (126) further detailed that Sackett and Haynes' definition had gradually evolved into that proposed by the WHO, where the specified behaviours needed to be agreed with their healthcare professional rather than simply prescribed.

Regarding behavioural maintenance, several definitions have been suggested by authors including: when a behaviour comes 'automatic' for a person (129, 130);

when an individual achieves behavioural competence (131); or after a specific time of behavioural practice (132). The most widely used definition of maintenance is that proposed by Prochaska and DiClemente's Transtheoretical model which posits that an individual is maintaining a behaviour after six months of behavioural practice (i.e. six months post baseline in clinical trials) (132). Although this definition was based on participants aiming to cease smoking, it has been consistently applied in PA related trials and systematic reviews (133, 134, 135, 136). Therefore, due to their widespread use within the PA behaviour change literature, the conceptual definitions of PA adherence and maintenance, as outlined by the WHO (2003) and in the TTM respectively, were utilised within this thesis (Table 1.3).

Table 1.3 Definitions of Physical Activity Adherence and Maintenance used within the thesis

Concept	Definition used within this thesis
PA adherence	The extent to which a person's behaviour (PA), corresponds with agreed recommendations from a healthcare provider' (128)
PA maintenance	PA evaluated on or after 6 months post baseline (132)

1.5.2 Physiotherapists' use of behavioural change techniques to promote physical activity in patients with lower-limb osteoarthritis

As the largest healthcare provider of PA prescription to patients with musculoskeletal pain in the NHS (92) physiotherapists are well placed to deliver interventions that incorporate BCTs (84). However, physiotherapists need to increase their understanding of patients' PA behaviours and motivations to enhance adherence to their recommendations (137). Although physiotherapists are encouraged (138, 139),

and attempt (140), to use behaviour change interventions in their clinical practice, evidence showed that they lack the knowledge base to do so effectively (140). A systematic review demonstrated that while incorporating behaviour change into physiotherapy programmes can enhance patient PA adherence, the most effective BCTs have not been determined (141).

Furthermore, physiotherapists and patients with lower-limb OA do not necessarily agree on the most effective BCTs to promote PA adherence (69). A survey by Nicolson et al., (2018) (142) examined the perceived effectiveness of physiotherapist delivered BCTs. Patients with lower-limb OA and treating physiotherapists ranked 36 BCTs based on their effectiveness on optimising adherence to physiotherapist prescribed exercise (142). BCTs relating to patient specific goal setting, reviewing and adjusting exercises (feedback on behaviour), and exercise practice were highly ranked by both groups (142). However, there were significant disagreements between groups, especially regarding BCTs which required physiotherapists to provide extra support to patients. For example, a three month follow up treatment session was ranked 5th by patients with lower-limb OA but 19th by physiotherapists. This supports a systematic review conducted by the same group of authors which identified moderate level evidence that 'booster' sessions facilitated adherence to physiotherapist prescribed exercise (143). Conversely, referral to an exercise class was considered the most effective strategy to promote exercise adherence by physiotherapists but ranked 25th in patients with lower-limb OA (142).

Differing treatment perspectives between patients and physiotherapists has been highlighted in previous research: patients with lower-limb OA believe they require more support (69, 87) and physiotherapists believe that PA adherence is the responsibility of the patient (144). These issues are further compounded by the state

of healthcare systems. Due to healthcare costs and time constraints, physiotherapy appointments are often limited in number and focus on short-term outcomes only (84). As there is usually a gradual decrease in clinical contact time between patient and therapist, long-term PA will most likely continue without supervision in the home/community (145).

In the UK, PA interventions are usually provided to patients with lower-limb OA in person by physiotherapists working within the NHS (92). Although physiotherapy PA interventions have demonstrated significant improvements to short-term pain and function, these effects are not usually sustained (146). The lack of long-term effect is thought relate to decreased adherence to PA prescription post discharge, when patients with lower-limb OA have less access to support and information (79).

Several strategies, including community based classes (147), phone call support (148), PA/lifestyle apps (149), or signposting to information/advice on an evidence based website (150) have been proposed to support patients with lower-limb OA maintain their PA post-discharge. However, no consensus exists as to which strategy is most beneficial to help patients with lower-limb OA maintain PA and, as OA is highly heterogenous, a tailored approach is likely required. As the positive effects of PA reduce if discontinued, and patient adherence diminishes when physiotherapist supervision ceases, long-term adherence to recommendations is important and requires patients to change and sustain this change in PA behaviours (102).

The behaviour change literature outlines that learning and consolidating new behaviours, such as PA, requires individuals to go through several phases of behaviour change including *initiation* (133, 151, 152) or *adoption* (130, 153) and *maintenance* (130, 154, 155). It is likely that most physiotherapy treatment periods

occur during the adoption/initiation phase when the individual would be learning new habits and techniques to optimise their PA levels. The post-treatment period would coincide with the 'maintenance' phase, where the individual consolidates their PA behaviours. The skills required to maintain a behaviour are distinct from those that enables an individual to adopt it (130, 155) and this may in part explain the drop off in effectiveness in clinical outcomes during the post-treatment phase. It is unlikely that any single BCT is universally effective in all situations (142) and a physiotherapy intervention aimed at optimising adherence to PA likely requires unique techniques that match the changing needs of its target patients during adoption and maintenance (25, 156). Therefore, identification of the most effective BCTs that physiotherapists can utilise to promote adherence to prescribed PA over short and longer time periods in patients with lower-limb OA is required.

1.5.3 Overview of systematic reviews examining use of behaviour change techniques on physical activity

Systematic reviews have examined BCT use in interventions to promote PA in musculoskeletal pain populations (Table 1.4). Overall, these reviews (157, 158, 159, 160, 161, 162, 163, 164, 165, 166) provided moderate-high confidence in their results (based on AMSTAR 2 criteria as judged by one author) and demonstrated between 18 (159) - 45% (158) of available BCTs are utilised to target PA behaviours. To date, five systematic reviews have identified the most effective BCTs to optimise PA adherence (157, 160, 161, 163, 165) in patients with musculoskeletal pain with 'Goal setting (behaviour or outcome)', 'Social Support (unspecified)' and 'Instruction on how to perform the behaviour' deemed effective across reviews. However, each

review had broad participant populations: four included all patients with musculoskeletal pain (157, 160, 161, 165) and one contained all upper limb disorders (163). Lower-limb OA is a highly heterogeneous condition and several factors influence the individual PA behaviour change process (91, 167, 168). Therefore, while several of BCTs will likely influence PA adherence in several populations, others will be unique to patients with lower-limb OA. Moreover, these reviews did not measure whether BCT effectiveness changed at different time points (i.e. during and post treatment) so cannot recommend when best to utilise specific techniques in an intervention. Furthermore, of those systematic review that measured BCT effectiveness, none evaluated intervention fidelity. Intervention fidelity is the degree to which an intervention's active ingredients are delivered as intended (169). Intervention fidelity assessment is especially important in behavioural change interventions as it can help determine whether the treatment effect is due to the interacting BCTs or from a variation in the delivery of the intervention protocol (170, 171). Greater intervention fidelity has also been correlated with optimised outcomes and reducing participant drop out (172).

Table 1.4: Overview of systematic reviews examining behaviour change technique use in musculoskeletal pain

Primary Author, year	Number of studies/ participants	Behaviour/ population targeted	Number of BCTs identified (n)	Most frequently identified BCTs	Potentially effective BCTs	Overall confidence rating (AMSTAR 2)
Bishop 2015 (166)	42 studies (n= 8243 participants)	Adherence to PA in adults with MSK pain	NR	- body changes - instruction on how to perform the behaviour - generalisation of target behaviour - graded tasks - behavioural practice/rehearsal.	NR	Low
Booth 2022 (157)	23 studies (n= 4012 participants)	PA and sedentary behaviours with persistent MSK pain	31	- Self-monitoring of behaviour - Instruction on how to perform a behaviour - Credible source	- Adding objects to the environment - Goal setting (outcome) - Action planning - Monitoring outcome(s) of behaviour by others without feedback - Feedback on outcome(s) of behaviour'	High
Eisele 2019 (158)	19 studies (n= 3715 participants)	Adherence to prescribed PA in chronic MSK pain	43	- Graded tasks - Goal setting (behaviour) - Self-monitoring of behaviour - Problem solving - Feedback on behaviour	None identified from 'narrative analysis'	Moderate
Hall 2021 (173)	17 studies (n= 1953 participants)	Exercise adherence in rotator cuff related	17	- Instruction on how to perform the behaviour - Demonstration of the behaviour Behavioural practice and rehearsal - Goal setting (behaviour)	Not tested	High

shoulder
pain.

Marley 2017 (160)	20 studies (n= 3441 participants)	Increasing PA patients with persistent MSK pain	31	• Goal setting behaviour • Information on health consequences • Instruction on how to perform the behaviour • Behavioural practice/rehearsal	• Goal setting behaviour • Instruction on how to perform the behaviour • Self-monitoring behaviour • Social support (unspecified) • Framing/reframing	High
Meade 2018 (161)	8 studies (n=1,018 participants)	Exercise adherence in MSK pain	30	• Instruction on how to perform behaviour • Demonstration of behaviour • Behaviour practice/rehearsal	• Social support (unspecified) • Goal setting (behaviour) • Instruction of behaviour • Demonstration of behaviour • Behaviour practice/ rehearsal	Moderate
O'Dwyer 2019 (162)	8 studies (n=1416 participants)	PA fibro	32	• Instruction on how to perform the behaviour • Demonstration of the behaviour Behavioural practice/rehearsal • Credible source	Not tested	Moderate
Thacker 2020 (163)	6 studies (n= 570 participants)	Adherence to exercise in upper limb disorders	20	• Generalisation of the target behaviour • Instruction on how to perform a behaviour • Social Support (Unspecified)	• Social Support (unspecified)'	Moderate
Physiotherapy specific reviews						
Chester 2023 (165)	28 studies (n= 5279 participants)	Home exercise adherence for people attending physio with	42	• Problem solving • Instruction on how to perform a behaviour	• Problem Solving • information about health consequences • Social support	Moderate

MSK conditions						
Keogh 2015 (164)	22 studies (n=3766 participants)	Group based lower-limb OA and LBP	33	• Instruction on how to perform the behaviour. • Demonstration of the behaviour • Behavioural practice/rehearsal • Credible source • Graded tasks • Body changes	Not tested	High

Legend: NR: Not reported; NT: Not tested; PA: Physical Activity; Y: Yes ; N: No; OA: Osteoarthritis; LBP: Low back pain; AMSTAR: A Measurement Tool to Assess systematic Reviews; AMSTAR 2 ratings of confidence in results based on guidance from Shea, et al. (2017). AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ.;358:j4008. (174); MSK: Musculoskeletal; Physio: Physiotherapy; Fibro: Fibromyalgia.

1.6 Summary of thesis rationale

Patients with OA display the highest level of disability in the UK (5) and point prevalence and treatment waiting lists are increasing. As such, lower-limb OA is becoming more expensive and problematic to manage (10) and evidence-based, cost-effective interventions are required to help patients with lower-limb OA self-manage their symptoms. PA interventions are advocated as the primary treatment option for patients with lower-limb OA (1, 3, 10, 64). Although PA interventions are effective at aiding short-term OA symptoms, they lack long-term effectiveness (69, 175). Long-term adherence to PA recommendations through adoption and maintenance of prescribed PA is critical to preserve the short-term improvements seen in a patient's pain (82), function, and disability (83).

Physiotherapists are the primary healthcare professionals who deliver PA interventions and well placed to help patients with lower-limb OA. However, physiotherapists have underdeveloped knowledge of behaviour change theory and BCTs to promote PA adoption and maintenance (140). No study has developed and tested the feasibility of a theoretically grounded behaviour change physiotherapy intervention incorporating BCTs that target adoption and maintenance of PA in patients with lower-limb OA.

1.6.1 Thesis Aims

This thesis aims to following MRC guidelines to develop and determine the feasibility and acceptability of a novel theoretically grounded physiotherapy behaviour change

intervention that promotes adoption and maintenance of PA in patients with lower-limb OA.

1.6.2 Objectives

- 1) To identify the BCTs used in physiotherapy interventions to promote PA adherence in lower limb OA patients and evaluate their effectiveness at different time points post baseline (Chapter 2)
- 2) A) To explore patients' in-depth experiences of barriers and facilitators to physiotherapist prescribed PA within sessions that effect adherence while receiving treatment and post-discharge (Chapter 3).

B) To utilise the barriers and facilitators to patient's adherence to prescribed PA during treatment and post-discharge to identify appropriate BCTs and propose a theoretically informed intervention aimed at optimising PA (Chapter 3).
- 3) To determine physiotherapists' perspectives on the feasibility and acceptability of delivering the proposed theoretically informed behaviour change intervention in a real-world physiotherapy setting (Chapter 4).
- 4) To identify appropriate theory/theories of behaviour change to underpin physiotherapist training and intervention delivery (Chapter 5)
- 5) To investigate the feasibility and acceptability of delivering a complex, multicomponent theoretical behaviour change physiotherapy intervention in the view of patients with lower-limb OA, treating physiotherapists and research related staff (Chapters 6-7).

1.6.3 Thesis structure

The updated MRC framework (176, 177) for developing and evaluating complex interventions outlines four overlapping phases: development, feasibility, evaluation, and implementation. This theses' focuses on the initial two phases. Development phase steps include reviewing the existing evidence, incorporating stakeholders who will deliver and receive the intervention, and identifying/developing theory (178). The development steps will be covered in Chapters 2-5. Feasibility testing of trial design (e.g. recruitment and data collection) and intervention acceptability (e.g. BCT content) is recommended as part of the MRCs second stage (176). Therefore, once developed, the acceptability and feasibility of intervention implementation in clinical practice is required to determine if a definitive trial is recommended. This will require determining the perspectives of key stakeholder patients with lower-limb OA, research staff, and delivering physiotherapists) and evaluating treatment fidelity as is detailed in Chapters 6-7. Chapter 8 updates the body of evidence to highlight changes that occurred during PhD conduct. Chapter 9 evaluates how well each Objective was achieved and provides future research suggestions. Chapters are outlined in Table 1.5. Each chapter iteratively informs the thesis' narrative by utilising previous chapters findings to develop subsequent aims and objectives.

Table 1.5: Thesis Structure

Chapter number	Outline
1	Provides a general introduction and overview
2	Details a comprehensive systematic review which identified which BCTs are utilised in physiotherapy interventions, and which were most effective at promoting PA adherence at key post-baseline time-points
3	Presents the rational, methods and results of a qualitative study which identified key barriers and facilitators that patients with lower-limb OA perceive influenced their adherence to physiotherapist prescribed PA during and post treatment. The theoretical domains framework (TDF) is utilised to identify BCTs to propose a theoretically informed behaviour change intervention to PA during and post treatment in patients with lower-limb OA.
4	Investigates the views of musculoskeletal physiotherapists of the theoretically informed prototype behaviour change intervention. The real-world perspectives of the physiotherapists identify additional requirements in preparation for delivery in a real-world physiotherapy NHS clinical setting.
5	Explores the building blocks (constructs) of theories of behaviour change to identify an appropriate theory that can be integrated with the proposed intervention. BCTs from the proposed intervention are mapped against the theoretical constructs of the chosen theory to prioritise intervention content.
6	Presents the feasibility trial including methods and analysis and evaluates whether the specific objectives have met based the a priori criteria to inform whether a definitive RCT is indicated.
7	Explores the fidelity of physiotherapist intervention delivery (BCTs delivered and treatment climate developed) in the feasibility trial.
8	Updates the systematic review from chapter 2 to inform the key changes to the body of evidence that have occurred during conduct of PhD
9	Provides an in-depth discussion of the PhD's aims and objectives and identifies key areas for development of appropriate physiotherapy training and treatments to promote PA behaviours in lower-limb OA. The thesis's conclusions are outlined

1.7 Public involvement

A person with lower-limb OA represented public involvement (PI) throughout the interconnected studies that make up this thesis and their input followed guidance from the UK Standards as outlined by the National Institute for Health Research

(NIHR) (179). The PI representative was integrated within each primary studies' research team including the Study Management and Steering Groups respectively. As part of their role, the PI representative helped develop and gave critical feedback on: study protocols and funding applications; interview topic guides; study consent forms and participant information sheets; patient reported and performance based outcomes; and intervention materials. They made substantial contributions to the examination and developed understanding of study findings and drafting of summaries of results for lay audiences.

CHAPTER 2: EFFECTIVENESS OF BEHAVIOUR CHANGE TECHNIQUES IN PHYSIOTHERAPY INTERVENTIONS TO PROMOTE PHYSICAL ACTIVITY ADHERENCE IN LOWER LIMB OSTEOARTHRITIS PATIENTS: A SYSTEMATIC REVIEW

Chapter overview:

This chapter presents a comprehensive systematic review of randomised controlled trials (RCTs) that include behaviour change techniques (BCTs) targeting PA adherence in patients with lower-limb OA (Thesis objective 1). Twenty-four RCTs (n=2366 participants) of variable risk of bias (RoB) (5 low; 7 moderate; 12 high) and poor intervention reporting from 10 countries are included. BCT effectiveness ratios were calculated and RCT risk of bias and intervention fidelity were summarised narratively. The key results are integrated and discussed in context with the wider evidence base and recommendations for BCT use in physiotherapy clinical practice are made.

Most of this chapter is taken verbatim from publications for which I am the primary author. The primary source is taken from the systematic review publication (PLOSone 2019) with additional methodological detail (risk of bias, fidelity analysis and BCT coding) replicated from the protocol paper and linking text to the subsequent chapter reproduced from the follow up qualitative study protocol.

- Willett M, Duda J, Gautrey C, Fenton S, Greig C, Rushton A. Effectiveness of behavioural change techniques in physiotherapy interventions to promote physical activity adherence in patients with hip and knee osteoarthritis: a systematic review protocol. *BMJ Open*. 2017;7(6):e015833 (Appendix 1.1)
- Willett M, Duda J, Fenton S, Gautrey C, Greig C, Rushton A. Effectiveness of behaviour change techniques in physiotherapy interventions to promote physical activity adherence in lower limb osteoarthritis patients: A systematic review. *PLoS One*. 2019;14(7):e0219482. (Appendix 1.2)
- Willett MJ, Greig C, Rogers D, Fenton S, Duda J, Rushton A. Barriers and facilitators to recommended physical activity in lower-limb osteoarthritis: protocol for a qualitative study exploring patients and physiotherapist perspectives using the theoretical domains framework and behaviour change taxonomy. *BMJ Open*. 2019;9(10):e029199.(Appendix 1.3)

Initials used in the text correspond to the following names: Matthew Willett (MW), Joan Duda (JD), Sally Fenton (SF), Carolyn Greig (CG), Charlotte Gautrey (CNG), Alison Rushton (AR).

2.1 Introduction:

Osteoarthritis (OA) is a progressive degenerative disease associated with a loss of local articular cartilage, a local inflammatory response, and contiguous bone remodelling (180). In the United Kingdom, OA is the primary cause of individual level disability and it contributes substantially to global health care costs (180). The hip and knee are the primary synovial joints effected by OA, with a point prevalence of 11% and 24% respectively (7). Patients with lower limb (hip and knee) OA may experience severe pain and disability, and a loss of function and psychological well-being (181, 182). As no known cure for OA exists (180), and the population ages, the global point prevalence of lower limb OA is likely to increase further (7).

Interventions that incorporate exercise are recommended first forms of non-pharmacological treatment to aid patients with lower limb OA to manage their symptoms (180). Physiotherapists are the primary health professionals responsible for providing exercise interventions to patients with lower limb OA in several countries (183). Although exercise interventions improve short-term clinical outcomes, such as reduced pain and increased function, in patients with lower limb OA, these positive effects are generally not maintained at medium (6 months) to long-term (≥ 12 months) follow up assessments (181, 182). This could be due to several factors including limited long-term effectiveness of the prescribed intervention, progression of OA disease severity, or a gradual reduction in patient adherence to health professional recommendations and an inability to maintain changes in their exercise behaviours (175).

To experience exercise related health benefits, patients need to maintain their activity level for a sustained period of time (184). However, patients with OA are less

active than non-symptomatic populations (185), and perceive that exercise is unsafe and that they require greater support to maintain their physical health, which likely impacts on their exercise adherence (186).

Prolonged physical inactivity has been associated with several reductions in the general health in patients with lower limb OA including the development of comorbidities such as obesity, diabetes, and heart disease (187), declining function and elevated pain levels, and an acceleration of the underlying OA disease process (101). Exercise is a planned and structured physical activity (PA) aimed at improving or maintaining physical fitness (188). PA encompasses structured exercise as well as broader concepts such as leisure activity which could be important at improving lifestyle factors beyond clinical outcomes, such as patient well-being (188).

Furthermore, maintaining prescribed exercise levels requires greater patient effort and behaviour change than optimising more general PA behaviours (189).

Therefore, it is important for physiotherapist interventions to incorporate behavioural techniques which target adherence to PA broadly, in addition to specific exercises.

However, knowledge of the most effective techniques to optimise patient adherence to PA behaviours is currently lacking (140).

Behaviour change techniques (BCTs) are the smallest active components of interventions which are designed to optimise patient health behaviours (123).

However, identifying BCTs within research has proved problematic due to inconsistent reporting of behaviour change interventions (123). The Behaviour Change Taxonomy V1 (123) was developed by researchers with expertise in behaviour change to enable for consistent reporting and increased clarity when identifying BCTs within RCT interventions. The taxonomy contains 93 distinct BCTs

grouped into 16 hierarchies (123) and has been used extensively in the behaviour change literature.

Systematic reviews have examined the effectiveness of BCTs on PA in people with diabetes (190), cardiac conditions (191), older adults (192, 193), rheumatoid arthritis (194), obesity (195, 196), and broader patient populations (160, 197, 198, 199). In these reviews goal setting, problem solving, action planning, feedback on behaviour, self-monitoring of behaviour, instruction in how to perform the behaviour, demonstration of the behaviour, and behavioural practice/rehearsal have been commonly identified BCTs that increase patient PA.

To date, two systematic reviews (164, 200) have reported on BCT use in physiotherapy interventions on musculoskeletal pain populations. However, these reviews did not measure individual BCT effectiveness and therefore could not make evidence-based recommendations of their use in clinical practice. Furthermore, these reviews focused on broader patient groups and their results may not be specific to lower limb OA patients, and they did not search the grey literature, meaning that up to 10% of relevant literature could have been missed (201).

Keogh et al., (2015) identified 33 BCTs within physiotherapy led group-classes. Patients with lower limb OA are most commonly treated individually (1 to 1) in clinical practice (202) as tailoring the intervention to a patients specific presentation is fundamental to optimising PA adherence (203) and attendance levels are generally higher at individual consultations than group classes (204). Kunstler et al., (2017) identified 30 BCTs across physiotherapy RCT interventions that aimed to optimise PA. However, only one researcher was involved in BCT coding and the authors did not outline any training that was undertaken to enable accurate identification of intervention BCTs. Training is recommended prior to using the V1 taxonomy (205),

and reduced inter-rater reliability has been measured in systematic reviews where coders have not undergone the prescribed training (Kappa = 0.55) (205), compared with those that have (Kappa range 0.68–0.92) (194, 196, 198, 206, 207). Therefore, the accuracy of BCT identification within this review cannot be verified. To date no systematic review has identified the most effective BCTs utilised in physiotherapy interventions to promote PA adherence in patients with lower-limb OA. The identification of the most effective BCTs to promote PA is required to inform the development of a physiotherapy behaviour change intervention aiming to promote adoption and maintenance of PA in patients with lower-limb OA.

Therefore, the primary objective of this systematic review was to identify the BCTs used in individual (1 to 1) physiotherapy interventions to promote PA adherence beyond the clinic (home and community) in lower limb OA patients. The secondary objective was to evaluate the effectiveness of individual BCTs at optimising PA adherence to make evidence-based recommendations to aid effective management of patients with lower limb OA.

2.2 Methods

A systematic review was conducted according to a registered (CRD42016039932) and published protocol (208) using methodological guidelines from the Cochrane Collaboration's Musculoskeletal group (209) and Centre of Reviews and Dissemination (CRD) (210); and is reported in line with the *Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (PRISMA)* (211).

2.2.1 Eligibility Criteria

The eligibility criteria are detailed in Table 2.1.

Table 2.1: Eligibility Criteria

Population	Adult participants (≥ 18 years) with lower limb OA (hip and/or knee), diagnosis through self-report of symptoms or imaging (7). RCTs including participants with other joint related pathologies (e.g. rheumatoid arthritis, hemochromatosis) that contributed to $\geq 25\%$ of the population, or participants who were awaiting, or had undergone joint surgery for treatment of OA symptoms were excluded.
Interventions	Land based outpatient intervention where a physiotherapist delivered the intervention individually (1 to 1) to the patient. Although others (e.g. healthcare professionals/ spouses) could be involved in the intervention's delivery, the physiotherapist had to be the primary healthcare provider and their role needed to be clearly established. The intervention had to include at least one BCT specifically enhancing PA adherence away from the clinic e.g. activity diary/pedometer or follow up care (phone calls) that made it unique from its comparator group (as defined by the V1 taxonomy) to enable measurement of its effectiveness.
Comparisons	Other 'active' or 'placebo' interventions, 'no treatment' or 'usual care'
Outcomes	Primary Outcomes: Physical Activity or Adherence measures Secondary Outcomes: Pain, Function, Quality of Life, Self-Efficacy, Any adverse events
Trial design	Randomised controlled trials (RCTs)
Language	Written in, or translated into English

2.2.2. Information sources and searches:

Two independent researchers (MW, ChG) conducted a highly sensitive search strategy, developed in collaboration with a subject specific librarian, on the following sources from inception up to January 2nd 2018:

- Databases: Medline (OVID), EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Cochrane Register of Controlled Trials (CENTRAL), PsycInfo (OVID) and the Physiotherapy Evidence Data base (PEDro).
- Grey Literature: 'ZETOC' and 'Conference Proceedings Citation Index'.
- Trial registries: The 'clinicaltrial.gov' and World Health Organisation's (WHO) trial portal

The search strategy was developed by incorporating terms from previous systematic reviews on participants with lower limb OA, who were treated with behavioural, and physiotherapy interventions (25, 74, 212). Additional keywords were added from RCTs identified in the scoping search undertaken prior to the review (80, 213), and filters recommended by the Cochrane Collaboration. The strategy was adapted for each database, and the Medline (OVID) search strategy is included below in Figure 2.1.

Figure 2.1 Example search strategy: Medline (Ovid) Search Strategy. Ran 2nd January 2018

```

1) exp osteoarthritis/
2) osteoarthr$.tw.
3) (degenerative adj2 arthritis).tw.
4) arthrosis.tw.
5) Or/ 1-4
6) knee/
7) exp knee Joint/
8) knee$.tw.
9) hip/
10) exp hip joint/
11) hip$.tw.
12) Or/ 6-11
13) exp Self Care/
14) ((self or symptom$) adj (care or help or manag$ or directed or monitor$ or efficacy or
admin$)).tw.
15) Patient Education as Topic/
16) ((health or patient$) adj2 (educat$ or information)).tw.
17) exp Consumer Participation/
18) ((patient$ or consumer$) adj part$).tw.
19) "Power (Psychology)"/
20) empower$.tw.
21) Holistic Health/
22) (holistic or wholistic).tw.
23) "activities of daily living"/
24) (activit$ adj2 daily adj living).tw
25) social support/
26) (social adj (support or network$)).tw.
27) (support adj system$).tw.
28) exp Adaptation, Psychological/
29) (psychologic$ adj (adjust$ or adapt$)).tw.
30) (cope or copes or coping).tw.
31) exp Behavior Therapy/ or exp cognitive therapy/ or self manage$.ti.
32) (adapt$ adj behav$).tw.
33) (behav$ adj (therap$ or intervention$)).tw.
34) health education/ or self efficacy/ or Exercise/ or health behavior/

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35) compliance/ or patient compliance/
 36) conditioning, operant/
 37) exp "Reinforcement (Psychology)"/
 38) operant conditoning.mp.
 39) respondent treatment.mp.
 40) relaxation.mp. or exp Relaxation/
 41) graded activity.mp.
 42) health promotion/
 43) (psycholog* technique or behavio?r technique).mp.
 44) behavio?r Change.mp.
 45) self efficacy.mp.
 46) Motivation/ or motivation*.mp.
 47) primary prevention/
 48) Psychology.mp. or Psychology/
 49) Adherence.mp.
 50) Or/ 13-49
 51) exp Physical Therapy Modalities/
 52) physiotherap\$.tw.
 53) (physiotherap\$ or physical therap\$ or pt).mp.
 54) physiotherap\$.mp.
 55) kinesiotherap\$.tw.
 56) exp Rehabilitation/
 57) rehab\$.tw
 58) Physical Activity.mp.
 59) Or/ 51- 58
 60) randomi?ed controlled trial.pt.
 61) controlled clinical trial.pt.
 62) randomi?ed.ab.
 63) placebo.ab.
 64) drug therapy.fs.
 65) randomly.ab.
 66) trial.ab.
 67) groups.ab.
 68) Or/ 60-67
 69) exp animals/ not humans.sh.
 70) 68 not 69
 71) 5 and 12 and 50 and 59 and 70

2.2.3 Study selection

Two independent researchers (MW, ChG) reviewed the titles and abstracts generated by the initial searches and then obtained full text copies of those RCTs which appeared appropriate for inclusion, or where doubt remained. The same two researchers then conducted a citation search using the 'Web of Science' database (included RCTs) and reviewed the reference lists (included RCTs and relevant reviews) to identify further RCTs. At each stage, if the two researchers could not agree on the eligibility of an RCT, a third researcher was asked to mediate the final

decision (AR, subject and methodological expertise). Initial search results were uploaded to Refworks prior to the review of titles and abstracts. Included trials were managed through EndNote.

2.2.4 Data Collection Process and Items

A data extraction sheet (based on the Cochrane Back and Neck group template) was piloted, adjusted, and subsequently used by two independent researchers (MW, SF) to record information on RCT participants, interventions, and characteristics of those delivering the BCTs including any training they undertook. Data obtained for PA, adherence, pain, function, quality of life, self-efficacy, and adverse effects outcome measures were also extracted. An analysis of contemporary related systematic reviews showed large variation in definitions of short, medium, and long-term follow up periods. Therefore, outcome timings of included RCTs were reviewed by two independent researchers (MW, SF) and short, medium, and long-term time points were determined after data extraction, to more accurately reflect the body of literature. Any disagreement in reporting was handled through researcher discussion. If agreement could not be reached, a third researcher with expertise in systematic review methodology (AR) was asked to mediate. Authors were emailed if data were missing or unclear, and intervention manuals were sought if they were not included in either RCT publications or as supplementary materials to aid further coding of BCTs. Two independent researchers (MW, SF) piloted RCT RoB and intervention fidelity assessments to clarify understanding and increase consistency. They subsequently assessed RoB and intervention fidelity of all included RCTs.

2.2.5 Risk of bias (RoB) Assessment

Two independent researchers (MJW, SF) used the Cochrane Risk of Bias tool to assess the internal validity of included trials (214). The tool was developed by a research working group and was recommended for use in systematic reviews. It uses domain-based evaluation rather than a check list or scoring system to assess internal validity (214) and allows review authors space to justify their conclusions (215). The tool addresses six domains: 'sequence generation', 'allocation concealment', 'blinding', 'incomplete outcome data', 'selective outcome reporting' and 'other' sources of bias. A judgement of 'high', 'unclear' or 'low' risk of bias was made for each domain. A judgement of 'Unclear' was allocated to a domain where insufficient information is provided. Trials were screened for selective outcome reporting by comparing outcomes used in the finalised articles with registered protocols. If no trial protocol existed, outcomes from the trials published methods and results sections were compared and a judgement of 'unclear' was allocated (216). When assessing trials risk of bias, researchers paid special attention to the 'blinding' domain. Blinding of the treating physiotherapists and trial participants is often problematic; however, assessor blinding is achievable and important (214). Therefore, trials were judged to have overall 'low risk' for the blinding domain if the assessor was adequately blinded (214). Any disagreement between researchers was be resolved through discussion. If agreement could not be reached, a third reviewer (AR) mediated. The risk of bias assessment across trials was displayed graphically using REVMAN 5.3.

2.2.6 Fidelity Assessment

Although several checklists exist to assess intervention fidelity (217, 218), The National Institutes of Health Behaviour Change Consortium's (NIHBCC) checklist is unique in its focus on behavioural change trials and has demonstrated validity and reliability (170). The NIHBCC checklist has 40 components and was developed in 2011 (172) from the initial version which had 25 components (170). The NIHBCC's checklist comprises five domains: 'Treatment design', 'Training Providers', 'Delivery of Treatment', 'Receipt of Treatment' and 'Enactment of Treatment skills'. Although Toomey et al., (2015) (171) did not find any association between trial date and fidelity, the consideration and assessment of fidelity is a relatively contemporary concept and the scoping search revealed several trials conducted prior, or at a similar time, to the NIHBCC checklists creation. While it is not the primary research question in this systematic review, trials treatment fidelity needs to be acknowledged when determining intervention effectiveness. Therefore, in order not to overtly penalise trials but to aid interpretation, each domain on the NIHBCC checklist was judged as 'present' or 'absent' by two independent researchers (MW, SF), depending on the number of individual components which were clearly reported (which were in turn judged as 'present', 'absent' or 'unclear'), but no score was be given to individual items. Details on the NIHBCC checklist, as outlined by Borelli (2011) (172), including the conceptual domains, individual components, and examples of when each would be coded as present can be seen in Appendix 2.1.

2.2.7 BCT coding

RCT interventions were coded for BCTs using Michie and colleagues' V1 behaviour change taxonomy (123) by two independent researchers (MW, SF) following training in the taxonomy's use (219). Both the behavioural physiotherapy (i.e. the physiotherapy intervention that contained a BCT specifically targeting PA adherence) and any active comparator group, including other forms of physiotherapy, were coded for BCTs. The taxonomy was piloted on several RCTs a priori and the researchers met regularly to maintain understanding and minimise any post-learning effect during coding (220). Any disagreement between reviewers was resolved through discussion. If agreement could not be reached, a third reviewer (JD, expertise in subject area of behavioural change) was asked to mediate. BCT coding agreement between researchers was calculated using Cohen's Kappa Statistic (221). Only BCTs that are directed at PA adherence behaviour were coded (222). Trials that had available protocols and fidelity papers were also coded.

Pilot BCT coding highlighted several problems with the V1 taxonomy's use which led to the following alterations.

- 1) The BCTs 1.1 goal setting (behaviour) and 1.3 goal setting (outcome) were subdivided into 1.1a (patient-led) and 1.1b (therapist-led). Goal setting has a very broad definition in the taxonomy ('set or agree on a goal defined in terms of the behaviour/outcome to be achieved') (123). Evidence suggests that goals that are decided by the patient (patient-led) lead to greater engagement and achievement than goals which are set by the therapist (therapist-led) (223).

2) The BCTs 2.1 monitoring of others without feedback, 2.3 self-monitoring of behaviour, 2.5 monitoring of outcomes of behaviour without feedback, and 3.1 social support (unspecified) were subdivided into 'a' (reported as a technique within the intervention), and 'b' (reported as an outcome measure). The taxonomy does not code BCTs which are data collection only processes (222). However, due to the behaviour of interest, several RCTs included a monitoring device (e.g. exercise diary/follow up telephone call), which were not necessarily an explicit intervention component but would likely increase PA adherence.

2.2.8 Measurement of analysis and Summary Measures:

BCT use within and across RCTs and their associated taxonomy hierarchies were tabulated (Objective 1). The initial scoping search, which was conducted prior to the systematic review, suggested there would be considerable heterogeneity of intervention BCTs, comparator groups, and PA adherence measures and therefore, meta-analysis and meta-bias assessment would not be appropriate. Therefore, effect sizes were used to determine intervention effectiveness and enable comparison between RCTs to inform the narrative synthesis. Effect sizes of PA and/or adherence outcomes were calculated using the standardised mean difference (SMD) and probability ratio (PR) for continuous and dichotomous data respectively (224). The term 'probability' was used in favour of 'risk' as in this review optimisation of PA adherence was desirable (224). For dichotomous data, an event was considered to have occurred when a participant achieved their PA or adherence goals to the levels stated in the associated RCT. It was calculated by dividing the number of times the

PA or adherence level was achieved by the number of participants in a group (224). Effect sizes where confidence intervals did not pass 0 for continuous outcomes (negative values favouring behavioural physiotherapy intervention) or 1 for dichotomous (> 1 favouring the behavioural physiotherapy intervention) were considered statistically significant. To enable inclusion of data from RCTs that contained more than one intervention or comparator group, data were combined into a single pairwise comparison using methods suggested by the Cochrane collaboration when groups were considered sufficiently homogenous (225). 95% confidence intervals were calculated, and significance was set at $p < 0.05$. Due to outcome heterogeneity, RCT outcomes were grouped into self-report measures of adherence and PA and direct measures of PA domains respectively. Although all PA and adherence data were extracted where available, if more than one outcome was reported within a domain, the effect size was calculated using summary measures of PA (160). Due to the focus of the systematic review, PA or adherence to physiotherapist recommendations was used to calculate effect sizes if total PA or adherence data were not available.

2.2.9 BCT effectiveness

As meta-analysis was not anticipated, meta-regression could not be incorporated into the analysis to determine the effectiveness of BCTs. Therefore, the 'effectiveness ratio' was used to determine the effect of each BCT on optimising PA adherence (226). The effectiveness ratio offers a simple, user-friendly technique for interpreting the effectiveness of individual BCTs by comparing effective interventions with ineffective interventions (226), and has been used in several contemporary

systematic reviews published in peer review journals. It was calculated by dividing the number of times the BCT was identified in behavioural physiotherapy interventions that demonstrated a favourable significant effect (as measured by SMD and PR effect sizes) by the number of times it was coded across all interventions (226) (Objective 2). BCT effectiveness ratios were calculated at short, medium, and long-term time points to evaluate whether they changed over time. To ensure that BCT effectiveness ratios reflected the active ingredients within interventions that optimized PA adherence, only those techniques unique to the behavioural physiotherapy intervention (when compared to active comparator and control interventions) were used when calculating BCT effectiveness ratios (166).

2.3 Results

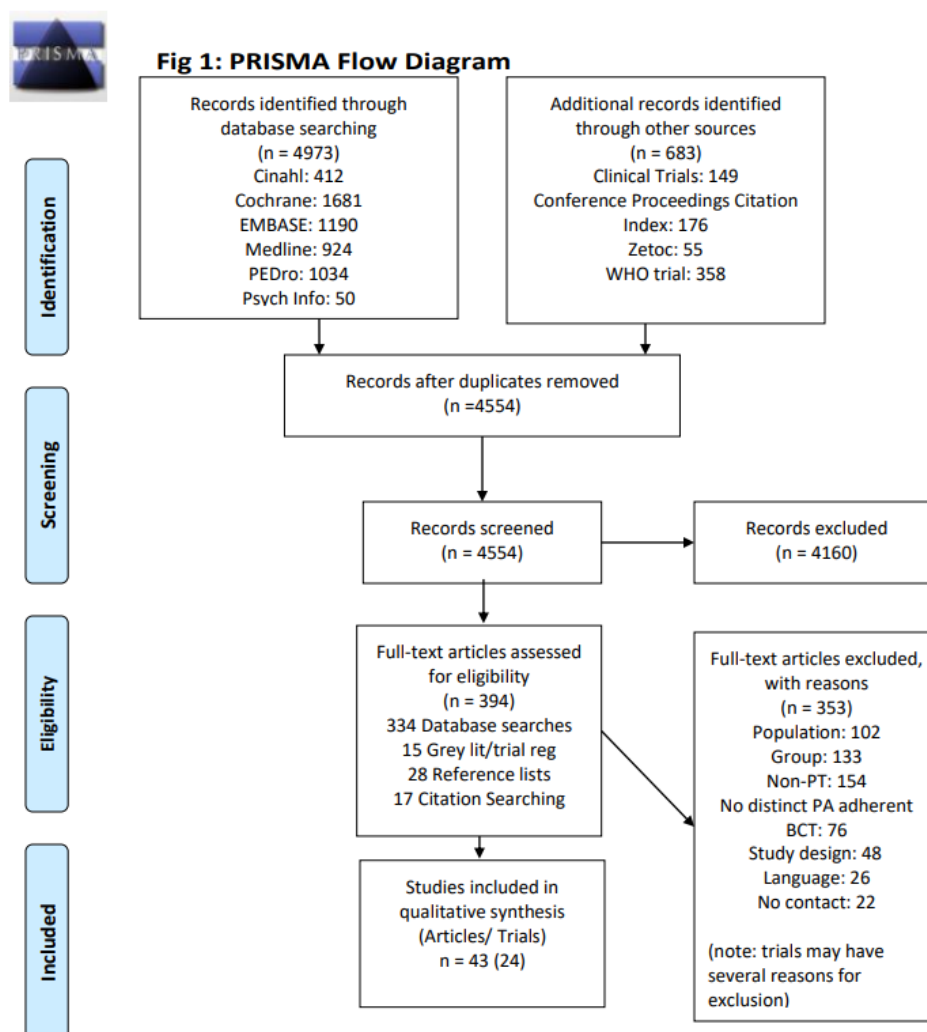
2.3.1 RCT Selection

Initial searches retrieved 5656 references with 4554 titles and abstracts once duplicates were removed. 394 full text articles were reviewed and 24 RCTs from 43 articles were included. At the full text stage, articles were excluded because RCT interventions were group based (n=133), not conducted by a physiotherapist (n=154) or did not contain an appropriate or unique BCT (n=76). Additional reasons for RCT exclusion were; alternative populations (n=102), non-RCT study design (n=48), not written or translated into English (n=26), or having no response from authors where eligibility required clarification (n=22). The RCT selection process is outlined in Figure 2.2.

2.3.2 RCT Characteristics

The characteristics of included RCTs are summarised in Appendix 2.2. The 24 RCTs incorporated a total of n=2366 participant from 10 countries. 18 RCTs recruited participants with knee OA (227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244), 3 RCTs recruited participants hip OA (245, 246, 247), and 3 RCTs (213, 248, 249) recruited participants with both knee and hip OA. In 21 RCTs all BCTs were delivered solely by physiotherapists. In 3 RCTs, the BCTs were delivered by both a physiotherapist (PA component) and either a nurse (241), health advisor (231), or researcher (242) delivering the telephone counselling. Training of BCT providers was not well reported, with 11 RCTs (233, 234, 236, 237, 238, 239, 240, 241, 242, 243, 244) not mentioning any training of the intervention provider and four RCTs (227, 228, 246, 248) not reporting detail of the training duration. Training ranged from 3 hours (79) for instruction in an exercise intervention, to 4 days for pain coping skills training (230) and telephone behavioural counselling (231) respectively.

Figure 2.2 RCT selection flow diagram



2.3.3 PA adherence outcomes

Detail on PA and adherence outcomes used and the effect sizes at different time points within each domain is detailed in Appendix 2.3. Analysis of outcome measure timings enabled short-term to be defined as up to 3 months (post-randomisation), medium-term approximately 6 months, and long-term 12 months or longer. The data closest to the temporal boundary of each time point was used to measure the effect sizes. 9 RCTs (228, 234, 235, 236, 238, 239, 240, 243, 244) did not measure

outcomes beyond short term, with 7 RCTs evaluating outcomes up to medium-term (227, 229, 232, 237, 245, 247, 248) and 8 to long-term (213, 230, 231, 241, 242, 246, 249) respectively. Eight RCTs authors were contacted to provide additional data or clarify points, of which 5 (228, 245, 246, 247, 248) responded with additional data, 1 (238) clarified that PA was measured only at baseline, and 2 (213, 242) could not be contacted to clarify information. Thirteen RCTs (213, 228, 229, 230, 231, 235, 241, 243, 244, 245, 246, 247, 248) measured PA adherence and contributed to BCT effectiveness ratio calculations. Therefore, despite using a BCT that promoted PA adherence as part of the behavioural physiotherapy intervention, 11 RCTs that did not measure PA adherence between groups post baseline and therefore the effectiveness ratios could not be calculated. The BCTs identified in these RCT interventions were therefore used to demonstrate the breadth of BCT use and assist the narrative synthesis. PA adherence outcomes showed considerable heterogeneity between RCTs with 13 PA and 6 adherence measures identified. The quantity of PA adherence measures used in RCTs demonstrated further variability, with a range of 1 (228, 235, 244) to 6 (231, 243).

RCTs most commonly used a diary to measure adherence (148, 227, 232, 234, 235, 236, 237, 239, 250, 251, 252, 253, 254, 255, 256, 257). Further adherence measures included self-rated adherence (229, 246, 258, 259), numerical rating scales (NRS), (148, 229, 252) and monitoring phone calls by study personnel (260). For self-report PA, four RCTs used the Physical Activity Scale for the Elderly (PASE), (148, 242, 250, 251, 252), two the International Physical Activity Questionnaire (IPAQ) (254, 260), one using minutes per day (246) and one the Zutphen Physical Activity Questionnaire respectively (259). Three RCTs used a

pedometer (244, 251, 252) and two an accelerometer (148, 261) to directly measure PA behaviour.

When RCTs completed between group measurements were, behavioural physiotherapy interventions were statistically significantly more effective at promoting PA than comparator groups in 58% (7 of 12 comparisons) of adherence comparisons (2/5 short term; 2/3 Medium term; 3/4 long term), 40% (6/15) of self-report PA comparisons (3/5 short term; 2/5 medium term; 1/5 long term) and 40% (2/5) of direct PA comparisons (2/3 short term; 0/2 medium term) respectively.

2.3.4 Risk of Bias within and across RCTs

Six RCTs were assessed as low RoB (228, 230, 231, 235, 236, 247) with five conducted by the same group of authors, suggesting some publication bias (Table 2.2). Seven and 12 RCTs were assessed as moderate (227, 232, 239, 243, 245, 248, 249) and high (213, 229, 233, 234, 237, 238, 240, 241, 242, 244, 246) RoB respectively. As meta-analysis was not indicated (see below), funnel plot use for meta-bias assessment was not appropriate (262). Overall, there was high risk of performance bias with participant blinding assessed as either unclear or high RoB in 20 RCTs. Further internal validity issues included high risk of reporting and attrition bias with 10 (42%) and 8 (33%) RCTs at unclear or high RoB respectively.

Table 2.2 Summary of risk of bias assessment

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bennell 2005	+	+	+	+	+	?	+
Bennell 2010	+	+	-	+	+	+	+
Bennell 2014	+	+	-	-	+	+	+
Bennell 2014b	+	+	+	+	+	+	+
Bennell 2016	+	+	-	+	+	+	+
Bennell 2017	+	+	-	+	+	+	+
Crossley 2015	+	+	+	+	+	?	+
Deyle 2000	+	?	?	+	?	?	-
Dincer 2016	+	?	-	+	+	?	-
EMPART 2013	+	+	-	+	?	+	+
Hiyama 2012	+	+	-	+	+	?	-
Hunt 2013	+	+	+	+	+	+	+
Jones 2012	+	+	-	+	+	+	+
Kawasaki 2009	+	-	-	+	?	?	?
Kuru-Colak 2017	+	+	-	-	-	-	-
Lim 2008	+	+	-	+	+	?	+
MOA 2013	+	+	-	+	+	+	?
Odole 2013	+	-	-	-	?	?	-
Schlenk 2011	+	-	-	-	+	?	+
Segal 2015	+	+	-	-	?	+	-
Teirlinck 2016	+	+	-	-	?	+	+
Van Baar 1998	+	+	-	+	+	+	?
Veenhof 2006	+	-	-	+	+	+	?
Wallis 2017	+	+	-	+	?	+	?

2.3.5 Fidelity

Overall, the quality of reporting of fidelity components within domains was low (Appendix 2.4). The mean component score per RCT was 38.9% (range 19% (240) to 68% (247)). No RCT was assessed as achieving 'high fidelity', which has been defined as having reported at least 80% of individual fidelity components clearly (172). Furthermore, only 5 RCTs reported >50% of individual fidelity components clearly. (230, 231, 235, 247, 249). In particular, the theoretical aspects of intervention design and delivery, and practitioner training were poorly reported. However, 3 of the 5 domains were generally well met with all RCTs assessed to have reported enactment of skills, 23 RCTs receipt of treatment, and 20 RCTs treatment design satisfactorily. Overall, the provider training and delivery of treatment domains were poorly reported with only 5 and 3 RCTs reporting them satisfactorily respectively.

2.3.6 BCTs identified in interventions

31 interventions (mean (SD): 11.1 (3.3)) were coded across the 24 RCTs (Table 2.3) with a total of 344 BCTs identified. Twenty-four interventions were classified as behavioural physiotherapy which interventions incorporated 269 BCTs (11.2 (2.9)), with a further 7 identified as active comparator groups which included 75 BCTs (10.71 (4.4)) respectively. The highest number of BCTs used in a single intervention was 20 (230) and the lowest 5 (213, 244). 31 distinct BCTs (including 'a' and 'b' subgroups) representing 32% of possible taxonomy definitions (n=98) were identified and 12 out of 16 hierarchies were used. The most frequently identified BCTs were 8.6 generalisation of target behaviour (100% of interventions), 9.1 credible source (100%), 12.6 body changes (100%), 1.4 action planning (94%), 4.1 instruction on

how to perform a behaviour (94%), and 8.1 behavioural practice/rehearsal (87%). The two independent researchers coded BCTs with 'excellent' inter-rater reliability ($\kappa = 0.83$). BCTs were identified from protocol and trial papers (Table 2.3). Generally, BCTs that were outlined in protocol papers were also coded in articles of RCT results. Three RCTs reported conducting fidelity assessment (148, 252, 255). However, the detail provided by each RCT was insufficient enable BCT coding.

2.3.7 BCT effectiveness

As anticipated from the pilot search, heterogeneity of intervention BCTs, comparator group treatment, PA adherence measures and timings precluded meta-analysis. BCT effectiveness ratios calculated for short, medium and long-term PA adherence outcomes across domains are presented in Table 2.4. Overall, the BCTs with effectiveness ratios of 100% across all measured time frames were 1.8 behavioural contract, 2.7 Feedback on outcomes of behaviour, and 10.3 non-specific reward. Eight BCTs had a short-term effectiveness ratio of $\geq 50\%$ in at least 2 outcome domains. Of these, 3 BCTs were from the goals and planning and 2 from the feedback and monitoring hierarchies respectively. Similarly, 8 BCTs had long-term effectiveness ratios of $\geq 50\%$ with 4 BCTs coming from the goals and planning hierarchy. Medium-term effectiveness ratios were generally lower than short, or long-term measures. Adherence outcomes had higher proportions of effectiveness ratios of $\geq 50\%$ than PA self-report or direct measures respectively. There was minimal long-term PA direct measure data available for analysis.

Table 2.3 BCTs identified from protocols and trial reports of included physiotherapy randomised controlled trials

BCT LABEL		BEHAVIOURAL PHYSIOTHERAPY INTERVENTIONS																				ACTIVE COMPARATORS											N (%)	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31		
1.1A	Goal Setting (behaviour)					P, T	P, T																P, T			T		P, T						5 (16)
1.1B	goal setting (behaviour)	T	P, T	P, T	P, T	P, T		P, T	T	T	P, T	T			T	T	T	P, T	T	T	T	P, T	P		T	P, T		P, T					22 (71)	
1.2	Problem Solving			P, T		P, T	P, T						T											P, T			P, T		P, T				7 (23)	
1.3B	Goal setting (outcome)																				T		P, T								P, T		3 (10)	
1.4	Action planning	T	P, T	P, T	P, T	P, T	P, T	P, T	T	T	P, T	T	T		T	T	T	P, T	T	T	T	P, T	P, T	P, T	T	P, T	P, T	P, T	P, T	T	T		29 (94)	
1.5	Review behaviour goal (s)						P, T												T														2 (6)	
1.8	Behavioural contract																							P, T									1 (3)	
2.1 A	Monitoring of behaviour by others without feedback				P, T	P, T				T									T			P, T			T		P, T	P, T					8 (26)	
2.1 B	Monitoring of behaviour by others without feedback												T		T		T						P, T								T		5 (16)	
2.2	Feedback on behaviour		P, T	P, T		P, T							T			T						P, T		P, T		P, T	P, T	P, T			T		12 (39)	
2.3A	Self-Monitoring of behaviour	T		P, T		P, T	P, T	P, T	T		P, T	T						P, T	T	T				P, T	T	P, T	P, T	P, T	P, T	T			18 (58)	
2.3B	Self-Monitoring of behaviour		P, T		P, T								T	T	T		T															T	7 (23)	
2.6	Biofeedback																				T												1 (3)	
2.7	Feedback on outcomes of behaviour																			T	T												2 (6)	
3.1A	Social Support (Unspecified)					P, T	P, T	P, T			P, T					T			T	T	T			P, T	T		P, T	P, T	P, T				13 (42)	
3.1B	Social Support (Unspecified)				P, T					T													P, T										3 (10)	

4.1	Instruction in how to perform the behaviour	T	P, T	P, T	P, T	P, T	P, T	P, T	T	T	P, T		T	T	T	T	T	P, T	T	T	T	P, T	P, T	P, T	T	P, T	P, T	P, T	P, T	T	P, T	29 (94)	
4.2	Information on Antecedents				P, T																			P, T								2 (6)	
5.1	Information about health consequences				P, T		P, T				T															P, T						4 (13)	
5.3	Information about social and environmental consequences					P, T										T										P, T						3 (10)	
6.1	Demonstration of the behaviour				P, T	P, T	P, T	P, T	T							P	T	T		P		P, T				P, T	P, T					12 (39)	
8.1	Behavioural Practice/rehearsal	T	P, T	P, T	P, T	P, T	P, T	T	T	T	P, T		T	T	T	T	T	P, T	T	T	T	P, T	P, T	P, T	T		P, T	P, T	P, T	T		27 (87)	
8.6	Generalisation of the target behaviour	T	P, T	P, T	P, T	P, T	P, T	P, T	T	T	P, T	T	T	T	T	T	T	P, T	T	T	T	P, T	P, T	P, T	T	P, T	P, T	P, T	P, T	T	T	P, T	31 (100)
8.7	Graded tasks		P, T		P, T	P, T	P, T	P, T	T		P, T		T			T	P		T				P, T			P, T	P, T	P, T	T			16 (52)	
9.1	Credible Source	T	P, T	P, T	P, T	P, T	P, T	P, T	T	T	P, T	T	T	T	T	T	T	P, T	T	T	T	P, T	P, T	P, T	T	P, T	P, T	P, T	P, T	T	T	P, T	31 (100)
10.3	Non-specific Reward																															1 (3)	
11.2	Reduce Negative Emotions					P, T							T													P, T							3 (10)
12.4	Distraction					P, T							T													P, T							3 (10)
12.5	Adding objects to the environment	T	P, T	P, T	P, T	P, T	P, T							T		T									P, T			P, T	P, T				11 (35)
12.6	Body Changes	T	P, T	P, T	P, T	P, T	P, T	P, T	T	T	P, T	T	T	T	T	T	T	P, T	T	T	T	P, T	P, T	P, T	T	P, T	P, T	P, T	P, T	T	T	P, T	31 (100)
15.4	Self-talk					P, T																					P, T						2 (6)
TOT		9	11	11	14	20	16	11	1	9	10	7	13	7	9	9	11	10	11	15	11	10	10	15	10	9	17	14	15	5	10	5	344
																																	0

Key: **TOT:** Total number of BCTs found in RCT interventions; **N:** Number of times BCT identified across interventions; **%:** Percentage of times BCT appears across interventions; **Intervention** number 1-24 represent behavioural physiotherapy interventions; numbers 25-31 represent active comparator groups; **P:** BCT identified from a protocol paper; **T:** BCT identified from trial/results write up (including supplementary results).

Behavioural Physiotherapy Interventions:

Intervention numbers:

1) Bennell 2005	2) Bennell 2010	3) Bennell 2014 (PT + Booster)	4) Bennell 2014b	5) Bennell 2016 (PT + PCST)	6) Bennell 2017 (PT+ TP coaching)	7) Crossley 2015
8) Deyle 2009	9) Dincer 2016	10) EMPART 2013 (Both Ex + MT interventions)	11) Hiyama 2012(PT +PA goal)	12) Hunt 2013 (PT + PCST)	13) Jones 2012	
14) Kawasaki 2009	15) Kuru-Colak 2017	16) Lim 2008	17) MOA 2013	18) Odole 2013	19) Schlenk 2011	20) Segal 2015
21) Teirlinck 2016	22) Van Baar 1998	23) Veenhof 2006 (PT + BGA)	24) Wallis 2016			

Active Comparators:

25) Bennell 2014 (PT Control)	26) Bennell 2016 (PCST)	27) Bennell 2016 (PT control)	28) Bennell 2017 (PT control)	29)
Hiyama(PT control)	30) Hunt 2013 (PT control)	31) Veenhof 2006 (PT control)		

Table 2.4 BCT effectiveness ratios

OUTCOME DOMAIN/ TIMEFRAME									
BCT	PA- Self Report			PA- direct measure			Adherence		
	Short	Medium	Long	Short	Medium	Long	Short	Medium	Long
1.1A	1/2 (50)	0/1 (0)	1/2 (50)				1/2 (50)		1/2 (50)
1.1B	2/5 (40)	1/4 (25)	0/2 (0)	2/3 (67)	0/1 (0)		1/1 (100)	1/1 (100)	1/1 (100)
1.2	1/2 (50)	0/1 (0)	1/2 (50)				1/4 (25)	0/1 (0)	1/2 (50)
1.3B	0/1 (0)	0/1 (0)							
1.4	3/6 (50)	1/4 (25)	1/3 (33)	1/1 (100)	0/1 (0)	0/1 (0)	2/2 (100)	1/1 (100)	2/2 (100)
1.5		2/2 (100)	1/2 (50)		0/1 (0)			1/1 (100)	1/1 (100)
1.8	1/1 (100)		1/1 (100)				1/1 (100)		1/1 (100)
2.1A	0/2 (0)	0/2 (0)	0/1 (0)	1/2 (50)	0/1 (0)		1/1 (100)	1/1 (100)	1/1 (100)
2.1B	0/1 (0)	0/1 (0)							
2.2	1/2 (50)	1/2 (50)	0/2 (0)				1/1 (100)	1/1 (100)	1/1 (100)
2.3A	2/2 (100)	1/1 (100)	1/2 (50)	1/1 (100)			1/1 (100)		1/1 (100)
2.3B	1/2 (50)	0/1 (0)		0/1 (0)	0/1 (0)				
2.7		1/1 (100)	1/1 (100)						
3.1A	2/2 (100)	1/1 (100)	1/2 (50)				1/1 (100)		1/1 (100)
3.1B	0/2 (0)	0/2 (0)		0/1 (0)	0/1 (0)				
4.1	1/4 (25)	1/4 (25)	0/2 (0)	1/2 (50)	0/1 (0)		1/1 (100)	1/1 (100)	1/1 (100)
4.2	0/1 (0)	0/1 (0)	0/1 (0)				0/1 (0)		0/1 (0)
5.1	0/1 (0)	0/1 (0)		1/2 (50)	0/1 (0)				
5.3		1/1 (100)	0/1 (0)						
6.1	1/3 (33)	1/3 (33)	1/3 (33)	0/1 (0)	0/1 (0)		2/2 (100)	2/2 (100)	2/2 (100)
8.1	3/6 (50)	1/4 (25)	1/3 (33)	1/2 (50)	0/1 (0)		2/3 (67)	1/2 (50)	2/2 (100)
8.6	2/5 (40)	1/4 (25)	0/2 (0)	1/2 (50)	0/1 (0)		1/1 (100)	1/1 (100)	1/1 (100)
8.7	3/4 (75)	1/2 (50)	1/2 (50)	0/1 (0)	0/1 (0)		1/1 (100)		1/1 (100)
9.1	2/5 (40)	1/4 (25)	0/2 (0)	1/2 (50)	0/1 (0)		1/1 (100)		1/1 (100)
10.3	1/1 (100)		1/1 (100)				1/1 (100)		1/1 (100)
11.2	0/2 (0)	0/1 (0)	0/1 (0)				0/1 (0)		0/1 (0)

12.4	0/2 (0)	0/1 (0)	0/1 (0)			0/1 (0)	0/1 (0)
12.5	1/2 (50)	0/1 (0)		0/1 (0)	0/1 (0)		
12.6	2/5 (40)	1/4 (25)	0/2 (0)	1/2 (50)	0/1 (0)	1/1 (100)	1/1 (100)
15.4	0/1 (0)	0/1 (0)	0/1 (0)			0/1 (0)	0/1 (0)
TOTALS	12/15	7/21	9/15	10/5	0/15	0/1	16/5 10/ 1 18/4

Key: BCT part of statistically effective intervention/BCT part of all interventions (effectiveness ratio %); Blank areas indicate where no PA adherence data was available for this domain/ timeframe

2.4 Discussion

This is the first systematic review to measure the effectiveness of BCTs used within physiotherapy interventions to promote PA adherence in lower limb OA patients. The body of literature is defined by RCTs of medium to high RoB with poor intervention reporting. Further heterogeneity of BCTs and PA adherence outcome measures meant meta-analysis was not appropriate and limited the evidence-based recommendations that could be made.

The BCT taxonomy was found to have excellent inter-rater agreement (Kappa= 0.83) (221), which showed similar reliability to other systematic reviews where the coders undertook training, (164, 190, 191, 192, 193, 194, 196, 197, 198, 199, 226, 263) (range 0.68-0.92) and the 31 BCTs identified across interventions (mean (SD): 11.2(2.9)) were consistent with the most closely related systematic reviews (164, 166, 264). Most BCTs had effectiveness ratios of <50% across time frames and outcome domains, meaning that they were components of interventions that were statistically no more effective than comparator groups at optimizing PA adherence. This overall lack of effect could be due to several reasons. Firstly, to be included, RCT interventions had to incorporate a BCT which would promote PA adherence when away from the clinic and possess at least

one BCT which was distinct from its comparator group (when coded on the V1 taxonomy) to enable for its effectiveness ratio to be calculated. Despite this, of the 24 RCTs, only 13 reported PA adherence data between groups post baseline to enable effectiveness ratios to be calculated. This was reflected in the RCTs primary treatment aims objectives and outcome measures which generally focused on pain and function. The assessment of pain and function might not reflect changes in patient PA adherence as physical activity interventions generally aim to teach patients coping and self-management skills rather than trying to ameliorate their clinical symptoms (171).

Secondly, to determine individual BCT effectiveness on PA adherence, it was essential to code both the behavioural physiotherapy intervention and any active comparator groups. As several RCTs used physiotherapy comparison groups, the number of unique BCTs in the behavioural physiotherapy interventions that were used to calculate effectiveness ratios was reduced. Previous research has shown that greater numbers of unique BCTs are associated with increased effect sizes and therefore this may have contributed to the modest results (166).

Overall, five BCTs demonstrated effectiveness ratios of $\geq 50\%$ in more than one outcome domain in both the short and long-time periods. These were 1.1A Patient led goal setting, 1.8 behavioural contract, 2.3A self-monitoring of behaviour, 3.1 A social support unspecified, and 10.3 non-specific reward. The most effective BCTs across time points were behavioural contract and non-specific reward (e.g. a reward was given to the patient if PA goals were met), both of which have been highlighted as effective in previous systematic reviews on PA (194, 263). However, these BCTs were only present in a single intervention in 1 high RoB RCT (213), therefore these results should be

interpreted cautiously. The 3 further BCTs identified were the 'a' variations used specifically in this systematic review. Therefore, items which promote self-monitoring (e.g. activity diaries) and the provision of social support, which are explicitly intervention components may be more effective at promoting changes in PA adherence than if they are used for monitoring purposes only. This review showed that of the 26 interventions that incorporated the BCT goal setting (behaviour), only five reported it in a patient-led manner. Patients are more likely to adhere to health behaviours if their goals are related to activities they enjoy and fit with their values (155), therefore promoting intrinsically motivated autonomy and subsequently PA adherence (184).

Further BCTs that demonstrated high short-term effectiveness ratios were 1.4 action planning, 2.2 feedback on behaviour, 8.1 behavioural practice/rehearsal which have been shown effective on PA in other systematic reviews (190). Overall, the BCTs that had the highest short-term effectiveness ratios were characterised as patient reminders to do their prescribed PA, either from the therapist directly (e.g. phone calls for monitoring purposes) or as physical items that were taken home (e.g. logbooks/diaries or handouts including detailed information about exercises). In the behaviour change literature, the initial period where patients learn new habits and health behaviours is termed the 'adoption' phase (184). During adoption, new behaviours are enhanced by extrinsic factors, so the addition of BCTs that help form new habits likely optimised short-term PA adherence.

The period of longer-term behaviour change is commonly referred to as the 'maintenance' phase (155). There are varying opinions in the literature about when a patient achieves maintenance, with authors using time scales or when the behaviour

becomes the patients 'dominant' response (155) as key indicators. Interestingly the 6-month medium-term time period when BCT effectiveness ratios were reduced corresponds to the Transtheoretical model of changes' (265) definition of maintenance, which is the most widely used in the behaviour change literature (155), and may explain the drop off in effectiveness at this point. Maintenance is theorised to require different skills and habits from adoption to prevent patients from relapsing to their previous behaviours (184). However, most BCTs that had the highest effectiveness ratios at short-term follow up were the same techniques with the highest ratios at long-term time points. Further BCTs which demonstrated effectiveness ratios of $\geq 50\%$ in at least two domains at long-term follow up were 1.2 problem solving, 1.5 review behaviour goals, and 8.7 graded tasks. Taken together, These BCTs are thought to be important at promoting self-regulation and habits (problem-solving, behavioural contract, self-monitoring of behaviour, graded tasks) or sustaining motivation (patient led goal setting, reviewing behaviour goals, non-specific reward, social support (unspecified)) which have been identified as critical factors that help maintain behavioural changes (155). Therefore, the increase in BCT effectiveness ratios from medium to long-term follow up may be due to patients with lower limb OA overcoming their relapses using the identified BCTs. Although these techniques show promise, these results should be interpreted cautiously as the effectiveness ratios of these BCTs were generally modest and there was insufficient data to draw firm conclusions. However, they were the only techniques for which the ratios demonstrated effectiveness at both short and long-term follow ups and warrant further investigation in physiotherapy practice, especially their use and effect around the 6-month post baseline time period.

RCT intervention fidelity demonstrated poor reporting. Although the domains receipt of treatment and enactment of skills were judged present in all RCTs, the only other systematic review that has used the NIHBCB checklist (171) judged these to be much lower. The high percentage reported in this review is likely due to its focus on targeting PA adherence in the community and home as several components within these domains focused on the performance of the target behaviour and skills outside from the clinic. The delivery of treatment and provider training domains were identified as poorly reported in both reviews. 12 RCTs reported that some form of training or monitoring took place but only 8 reported any timing with the majority lacking detail to enable replication (Appendix 2.2). Therefore, limited conclusions can be drawn on BCT effectiveness and replicating them in clinical practice is problematic (170). Similarly to Toomey et al., (2015) (171), fidelity assessment demonstrated a lack of use of theoretical models of behaviour change used to underpin their interventions. Although several RCTs mentioned behavioural models (213, 230, 231, 235), only one (Schlenk et al., 2011) (241) explicitly used theory to inform their intervention. Theoretically derived interventions are thought to be more effective than non-theoretical interventions at increasing patient adherence (266) as they address specific determinants of health behaviour to enable treatment effects to be attributed to intervention techniques and therefore further refinement over time (164). However, Schlenk et al., (2011) (241) was assessed as high RoB and therefore, the results from this RCT must be viewed with caution. Interestingly, the BCTs that showed the most consistently high effectiveness i.e. patient-led goal setting (267), self-monitoring (268), and social support (269) are key constructs of several theories of health behaviour change. Therefore, as

physiotherapists have demonstrated a lack of knowledge of theoretical models of behavioural change and confidence in putting them into practice (140), this represents a gap in the professional knowledge base and literature.

2.5 Strengths and Limitations

The strengths of this thoroughly conducted systematic review include its rigorous methodology conducted according to a published protocol. The key limitation was the limited number of RCTs that were characterised by poor intervention reporting and moderate to high RoB combined with heterogeneity of BCTs and PA adherence outcomes. This meant meta-analysis was not indicated, therefore limiting the evidence-based recommendations that could be made. Furthermore, despite several BCT effectiveness ratios showing statistically significant increases in PA and adherence, it was not possible to determine whether the results were clinically significant. As PA (270) and adherence (271) outcomes are measured heterogeneously, no standardised process exists to covert the data into clinical meaningful parameters. This remains a gap in the literature and requires further investigation.

2.6 Conclusions

Overall, BCTs have limited effectiveness at promoting PA adherence as part of physiotherapy interventions with the medium term (6 months post baseline) the most difficult period to target. The BCTs patient-led goal setting, behavioural contract, self-monitoring of behaviour, social support (unspecified), and non-specific reward were the

most effective at optimising PA adherence across time points. Future research should include low RoB and transparently reported RCTs incorporating physiotherapy interventions with pre-specified BCTs aimed at optimising PA adherence in patients with lower limb OA. The inclusion of interventions underpinned by behaviour change theory is a research priority.

As the overall effectiveness of BCTs was modest and based on results from RCTs graded as medium-high risk of bias and with poor intervention reporting, further research was needed to verify and expand on these results. To develop a physiotherapy intervention aimed at optimising adherence to prescribed PA that is underpinned by behaviour change theory and incorporates the most appropriate BCTs, key barriers and facilitators that patients face need to be identified. Therefore, the following chapter aims to clarify barriers and facilitators to physiotherapist prescribed PA and to utilise these themes to develop a theoretically informed intervention.

2.7 Dissemination of results

The protocol for this systematic review has been published in BMJ OPEN:

- Willett M, Duda J, Gautrey C, Fenton S, Greig C, Rushton A. Effectiveness of behavioural change techniques in physiotherapy interventions to promote physical activity adherence in patients with hip and knee osteoarthritis: a systematic review protocol. *BMJ Open*. 2017;7(6):e015833.

The results of this systematic review were published in PLOS ONE:

- Willett M, Duda J, Fenton S, Gautrey C, Greig C, Rushton A. Effectiveness of behaviour change techniques in physiotherapy interventions to promote physical activity adherence in lower limb osteoarthritis patients: A systematic review. *PLoS One*. 2019;14(7):e0219482.

The results have also presented at peer reviewed conferences:

- Physiotherapy UK, November 10-11, 2017, Birmingham UK. 'Rapid 5' Presentation. 'Effectiveness of behaviour change techniques in physiotherapy interventions to promote physical activity adherence in patients with osteoarthritis: a systematic review.'
- WCPT May8-11, 2019, Geneva Switzerland. 'Rapid 5' Presentation. 'Effectiveness of behaviour change techniques in physiotherapy interventions to promote physical activity adherence in patients with osteoarthritis: a systematic review.'

CHAPTER 3: UTILISING THE PERSPECTIVES OF PATIENTS WITH LOWER-LIMB OSTEOARTHRITIS OF PRESCRIBED PHYSICAL ACTIVITY TO DEVELOP A THEORETICALLY INFORMED PHYSIOTHERAPY INTERVENTION

Chapter overview:

This chapter details the development and proposal of a theoretically informed physiotherapy intervention that aims to promote physical activity (PA) adoption and maintenance in patients with lower-limb osteoarthritis (OA). A purposive sample of 13 patients with lower-limb OA participated in semi-structured interviews following physiotherapy treatment. Inductive analysis identified themes/subthemes reflecting barriers and facilitators to physiotherapist prescribed PA, which were organised deductively according to personal factors, treatment, and post-discharge phases. Themes/subthemes were mapped onto the Theoretical domains framework (TDF) and Behaviour change techniques (BCTs) were coded from the key identified domains and a theoretically informed physiotherapy intervention addressing barriers and using facilitators, was developed.

Patient confidence, mind-set and motivation were primary personal factors that influenced PA adherence with the TDF domain '*Beliefs about capabilities*' most important to target. During treatment, the theme of routine formation was the major driver of personal factors; and primarily influenced by developing a positive physiotherapist-patient relationship. Post-discharge, physical factors, psychosocial factors, and ongoing access to resources were important themes influencing PA maintenance. '*Environmental context and resources*' and '*social influences*' emerged as the key TDF domains to target during treatment and post-discharge. The proposed theoretically informed intervention included twenty-six BCTs delivered across conceptual phases of adoption, routine formation, and maintenance.

The central features of the proposed intervention are outlined and related to the wider literature. The further steps required to prepare the proposed intervention for feasibility testing are outlined.

Most of this chapter is taken verbatim from a publication for which I am the primary author. Titles of some tables, figures and appendices have been altered to fulfil thesis submission requirements.

Willett, M. Greig, C. Fenton, S. Rogers, D. Duda, J. Rushton, A. Utilising the perspectives of patients with lower-limb osteoarthritis on prescribed physical activity to develop a theoretically informed physiotherapy intervention. *BMC Musculoskeletal Disord* 2021;22(1):155. doi: 10.1186/s12891-021-04036-8 (Appendix 1.4)

Initials used in the text correspond to the following names: MW: Matthew Willett; CG: Carolyn Greig; SF: Sally Fenton; DR: David Rogers; JD: Joan Duda; AR: Alison Rushton.

3.1 Background

Osteoarthritis is a leading cause of pain and reduced function and quality of life (1) . In the United Kingdom (UK), OA is a burden on health services and the greatest cause of individual level disability in people aged 45 years or older, with approximately two million general practitioner (GP) visits each year related to OA symptoms (5). The large synovial joints of the lower-limb (hip and knee) are the most common cause of OA related pain, accounting for approximately 70% of symptoms (272). As there is currently no cure for OA (273), and with increased life expectancy (7), it is likely that greater numbers of patients with lower-limb OA will be required to self-manage their symptoms to reduce the load on healthcare systems in the coming years.

Promoting physical activity is a key non-pharmacological strategy that healthcare guidelines recommend to aid patients with lower-limb OA to manage their symptoms (1, 113, 273, 274). However, the majority of patients with lower-limb OA are less active than asymptomatic populations (275), and healthcare PA interventions are generally only effective at reducing short-term ($\leq$ three months post baseline) (276) symptoms, with pain and loss of function returning after about six months (277). This is likely associated with a gradual reduction in patient adherence to prescribed PA after discharge, when approximately 90% of patients with lower-limb OA do not maintain their PA (86).

People undergo several 'phases' of behaviour change when integrating new behaviours into their lifestyle (278). The most important phases are '*adoption*' (153, 279), which occurs while people are receiving treatment from a health professional, and '*maintenance*' (155) which would be ongoing post-discharge and occurs after six

months of behavioural practice. While adoption and maintenance have several overlapping influences, they also possess unique determinants (267, 278, 280). Therefore, a healthcare intervention needs to incorporate specific behaviour change techniques (BCTs) to match these phases in the behaviour change process to optimise PA adherence.

Physiotherapists are the primary healthcare provider of non-pharmacological treatments for patients with lower-limb OA (281). As such, they are in an optimal position to promote PA adherence (282). However, physiotherapists and patients with lower-limb OA do not necessarily agree with the most effective BCTs to promote PA adherence (142). Furthermore, patients with lower-limb OA believe they require more support and can perceive prescribed PA (e.g. exercise) as unsafe (87). Physiotherapists also perceive they do not have sufficient understanding of BCTs to deliver them consistently in practice (140).

The Medical Research Council (MRC) advocates that interventions should be informed by behaviour change theory (114) to enable a greater understanding of the assumed intervention mediators (e.g. self-efficacy) effects on the target behaviour to enable refinement for future testing, and therefore, greater clinical effectiveness over time (151). The Theoretical Domains Framework (TDF) is a validated framework which synthesises constructs from 33 theories of behaviour change into 14 overarching domains (283, 284). By mapping barriers and facilitators to specific domains, the TDF can be used to identify key determinants of behaviour change (285) and important BCTs to develop theoretically informed interventions (124, 286).

Qualitative methods are utilised to provide an in-depth understanding of patients experiences and identify barriers and facilitators to treatment (287). Although previous qualitative studies (288, 289, 290, 291, 292, 293, 294, 295, 296) have determined barriers and facilitators to PA for patients with lower-limb OA, only one study has considered stages of behaviour change in their analysis (297). Hammer et al., (297) found that patient self-efficacy and severity of symptoms were highly influential on PA maintenance. However, due to their long-term focus, it was problematic to identify similarities or differences in determinants that occurred while under treatment (related to adoption) or post-discharge (related to maintenance) and their results were not utilised to develop a behaviour change intervention. Currently there are no theoretically informed interventions that incorporate BCTs that target the overlapping and unique features of PA adherence during the adoption *and* maintenance phases. Therefore, this study aimed to gain an in-depth understanding of the overlapping and unique barriers and facilitators to physiotherapist prescribed PA that patients with lower-limb OA experience during treatment and post-discharge to develop a theoretically informed physiotherapy intervention.

Objectives

- 1) To explore patients' in-depth experiences of barriers and facilitators to physiotherapist prescribed PA within sessions that effect adherence while receiving treatment and post-discharge.
- 2) To use the barriers and facilitators to identify themes/subthemes that influence patient's adherence to prescribed PA during treatment and post-discharge.

- 3) To map themes/subthemes to the TDF to identify key domains that effect adherence to PA during treatment and post-discharge.
- 4) To identify appropriate BCTs from the TDF domains to propose a theoretically informed intervention aimed at optimising PA adherence.

3.2 Methods

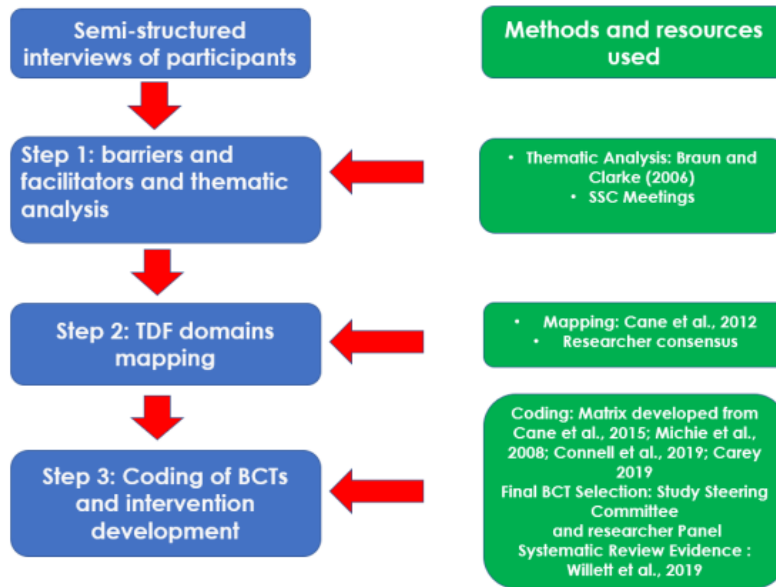
3.2.1 Theoretical Framework

The in-depth perspectives of patients with lower-limb OA and their individual experiences of attending physiotherapy for the management of their OA related symptoms were sought to propose a theoretically informed intervention (298). This study utilised a phenomenological framework (299), which followed a published protocol (300), and was reported using the COnsolidated criteria for REporting Qualitative research (COREQ) (301). A summary of the study processes is outlined in Figure 3.1.

3.2.2 Research team and reflexivity

One-to-one semi structured interviews were conducted by the lead researcher (MW); an experienced physiotherapist who has treated patients with lower-limb OA for > 15years. Participants were informed of MW's occupation, but his role as a researcher was emphasised. Participants had not met MW prior to the interview.

Figure. 3.1: Overview of intervention development process



Legend: TDF: Theoretical Domains Framework; BCT: Behaviour Change Technique

3.2.3 Participant Selection

Adult patients (≥ 18 years) with hip or knee OA (diagnosed through NICE guidelines (273) or imaging), who had attended physiotherapy at the Royal Orthopaedic Hospital (ROH), in Birmingham, England, were recruited. The target sample comprised those who had experienced the phenomenon of interest (i.e. patients with lower-limb OA who had received physiotherapy treatment and would likely have perceptions of the barriers and facilitators to prescribed PA) and therefore, purposive sampling was utilised (302).

Initially, stratified purposive sampling (303) aimed to recruit approximately 60% of participants with knee OA and 60% being female (304) (based on UK epidemiological data). Theoretical purposeful sampling (303) was then utilised in the final stages of recruitment to ensure secondary demographic factors (e.g. working status, age, educational background) that may influence patient perspectives could be included in the analysis (305). Sampling continued until data saturation (the point where no new themes emerge from the data analysis) had been achieved (306). Within phenomenology, a sample of up to 10 is generally accepted to reach data saturation (302). However, Francis et al., (306) advocated that a further three interviews should be conducted post saturation, to ensure no new themes emerge. Therefore, a sample of 10-15 participants was anticipated which was consistent with previous phenomenological studies on patients with lower-limb OA (288, 289, 297).

Potential participants were identified by their treating physiotherapist and the study was outlined at the final treatment session. Each interested patient was given a participant information sheet (PIS) and asked to sign a consent to contact form passed to the site lead investigator (DR) who sent the form to MW by encrypted email. MW telephoned potential participants to verify eligibility, outline the study, answer any queries, and negotiate a time and place for the interview to take place. Potential participants were given at least one week to enable them to make an informed decision regarding participation. Participants could have interviews at their home, the ROH or at the University of Birmingham.

3.2.4 Data Collection

The interview schedule (Appendix 3.1) was developed by integrating content from contemporary research examining the perspectives on PA in patients with lower-limb OA (288, 292, 293, 307) and refined by piloting with the study's patient and public representation (ED) who has lower-limb OA. The schedule included questions on patients' current levels of PA (adapted three day Physical Activity Recall interview (308, 309)) and key demographic data (gender, age, Body Mass Index (BMI)), ethnicity, length of time since OA diagnosis and their highest educational level. Several patient reported outcome measures were integrated into the interview schedule: bothersomeness (310) and average pain (311) of their symptoms over the previous week, and either the short form Hip (312) or Knee (313) Injury and Osteoarthritis Outcome Scores (HOOS/KOOS). Open questions (with prompting where required) were used to gain participants' in-depth opinions on: the received physiotherapy intervention and key barriers and facilitators or BCTs that influenced their prescribed PA during treatment and post-discharge. Participants were invited to offer any further perspectives that they felt were not addressed in the topic guides. Interviews were audio-recorded, transcribed verbatim, and mailed/emailed (dependent on preference) to participants for member checking so researcher interpretation of the data could be reviewed (314). No follow up interviews were planned.

3.2.5 Data analysis and development of intervention

Development of the theoretically informed physiotherapy intervention followed a modified version of the steps outlined by French et al., (2012) (315).

Step 1: Identification of barriers and facilitators and thematic analysis

Barriers and facilitators to physiotherapists prescribed PA were identified and synthesised to generate themes and subthemes following thematic analysis guidance as outlined by Braun and Clarke (2006) (316) (Objectives 1 and 2).

Familiarisation with the data and generating initial codes: MW took field notes to summarise key thoughts at salient points of the semi-structured interviews which enabled initial familiarisation with the data. Transcribed verbatim interviews were uploaded into NVivo software and read several times by two researchers (MW, SF) who attempted to put aside their pre-conceived thoughts to maintain the unique experiences of the participants in the analysis (302). MW and SF coded the first transcript in tandem and the second independently to establish consistency (317). The researchers included additional text so that each code maintained its own meaning (302), with as many examples as possible included to ensure contextual factors were recorded (316). Any explicit details outlining participants perspectives on specific BCTs and/or their mode of delivery or perspectives on sessions (i.e. number, frequency, or duration) that appeared in the transcript were noted by the coders to ensure that the proposed intervention matched participants suggestions. MW and SF worked collaboratively to arrange codes (with quotations) from the first transcript into preliminary themes/sub-themes with

several follow up meetings used to iteratively update the emerging results from the second transcript. The remaining transcripts were coded by MW.

Searching for themes: The interview topic guide included questions outlining barriers and facilitators during treatment and post discharge, and those which were intrinsic to the participants experience. Therefore, a deductive framework was utilised initially to cluster preliminary codes and quotations (including both barriers and facilitators) into three overlapping groupings of themes.

- 1) 'Personal factors' grouping encompasses themes which could influence PA adherence across both during treatment and post-discharge.
- 2) 'Treatment factors' grouping encompasses themes that primarily influenced PA adoption including effects that the physiotherapist and treatment sessions had on patients.
- 3) 'Post-discharge factors' grouping encompasses themes that primarily influenced PA maintenance beyond the clinic after the patient is discharged from care.

Reviewing, defining, and naming themes: Data on NVIVO were reviewed by MW who grouped barriers and facilitators to develop preliminary themes and subthemes. MW wrote all subthemes and supporting quotations on post-it notes and generated an initial inductive mind-map which enabled visual exploration of patterns of themes and subthemes including any overlap and delineation of individual perspectives and experiences (318). Common subthemes and deviant cases were sought to ensure individual perspectives were captured within the analysis (302). The mind-maps were videoed with theme associations outlined for later review. Emerging themes/subthemes and mind maps were audited and clarified through presentations to the chief

investigator (AR) and results, supported by quotations, were developed iteratively through presentations and feedback at Study Steering Committee (SSC) meetings. The SSC included researchers, clinicians, and patient and public involvement and the in-depth, collaborative feedback aided the analyses' value and the studies reflexivity (319).

Step 2: Mapping to the Theoretical Domains Framework

To provide a comprehensive overview of associated domains, all subthemes were mapped onto the TDF (Objective 3). TDF Mapping was piloted by two researchers (MW, SF) over a series of meetings and supported by a modified manual from a previous study (320). Mapping was completed by MW and audited by SF with any issues discussed. In the case of any mapping disagreements, an expert in behaviour change theory (JD) mediated. If agreement of mapping a subtheme to single domain could not be reached, it was mapped onto all domains identified by either coder (285). Each subtheme was evaluated across three criteria to clarify its relative importance (321): The number of participants who identified each subtheme; the presence of strong beliefs; the presence of conflicting beliefs. The domains outlined from the subtheme mapping were synthesised to identify the most important domains for each theme for the intervention to target.

Step 3: Behaviour change technique identification and intervention development

A coding matrix (Appendix 3.2), synthesising research linking BCTs to theoretical constructs (124, 286) and mechanisms of action (322, 323) was used to identify all

potential BCTs from the key TDF domains within each theme (objective 4). BCTs were categorised as ‘unique’ if they were coded exclusively/primarily to a one grouping, or ‘overlapping’ if they were identified consistently across groupings (Appendix 3.2). To reflect clinical practice and enable capture of the phases of behaviour change, the proposed intervention was split into early (adoption), middle, and late (maintenance) sessions. BCTs coded to the treatment or post-discharge grouping were incorporated into the early-middle sessions to target PA adoption, or middle-late sessions to target PA maintenance respectively. Those that were coded to the personal factors grouping, or across groupings, were generally considered reoccurring and repeated across sessions. Although the aforementioned studies (124, 286, 323) offer a useful way to identify BCTs, there is currently no guidance regarding prioritisation or mode of delivery (324). Therefore, if conflicts were identified during BCT identification, Cane et al., (2015) (286) was preferentially used as it is the only study that has demonstrated reliability and validity when linking BCTs to behavioural domains. The final selection of BCTs, including their mode of delivery and physiotherapy session detail (i.e. suggested number of sessions, duration, and frequency), was further informed by: repeated review of participants transcripts; collaborative discussions at SSC meetings; the lead investigators clinical experience; the BCTs most commonly used in clinical practice (286); the most effective BCTs from low risk of bias trials identified in by our systematic review (277).

3.2.6 Ethics approval and consent to participate

National Health Service ethical and Health Research Authority approval and site capacity and capability were obtained (IRAS 247904) prior to the study. All methods were performed in accordance with the relevant guidelines and regulations. Informed Consent to participate was gained from all participants verbally and in written form prior to their involvement in the study. All participants were over 18 years of age. Informed Consent included the permission for the interview data to be presented in publications in an anonymized format.

3.3 Results

3.3.1 Participants

All thirteen patients (n= 4 males) who were approached agreed to participate and interviews were conducted March-November 2019 and lasted 46-70 minutes (mean 56 minutes). All participants were of White British descent, nine with knee OA, three with unilateral hip OA, and one with severe hip and mild bilateral knee OA (considered as a hip participant in the analysis). Although two participants had family members in the house during their interview, no person other than the participant and interviewer were present in the interview room. Saturation of themes was reached after 10 participants, and a further three interviews ensured no further themes emerged (306). Participants' ages ranged between 44-76 years (mean 63; standard deviation 10.7) and BMI ranged between 24-42 (31.9; 5.3). Participants' average pain intensities ranged from 1-6 (3.9;1.9) and six participants rated their bothersomeness as 'moderately' over the past

week. The SF-KOOS and HOOS scores ranged from 24.9-66.6 (38.77;11.35) and 33.9-46.1 (40.9; 4.4) respectively. PA levels ranged from 1975-4250 kcal/day for the previous three days with a mean of 2920.8 (660.0) kcal/day. Twelve participants had their diagnosis confirmed with an X-ray and one with patient history and clinical examination data. Symptom duration varied from <one year to 48 years. Participant data are shown in Table 3.1. Transcripts were sent to six participants at their request, but none responded with comments.

3.3.2 Step 1: Identification of barriers and facilitators and thematic analysis and Step 2: Mapping to the Theoretical Domains Framework

Due to the integrative nature of the data analysis, and to avoid repetition, the results for Steps 1 and 2 are presented together. A summary of themes within each deductive grouping, and their associated primary TDF domains are presented in Table 3.2.

Overall, thirteen of fourteen TDF domains (all accept '*attention and decision-making processes*') were identified as important influences of PA adherence in at least one theme. Nine TDF domains were identified within the personal factors grouping with '*Beliefs about Capabilities*' influential to all themes. The treatment phase grouping identified ten TDF domains as important with '*Environmental Context and Resources*' and '*Social Influences*' associated across three themes. Seven TDF domains were identified in the post-discharge grouping with domain '*Environmental Context and Resources*' important across all themes. Additional detail on subthemes and TDF mapping, with example supporting quotations are included for the personal factors,

treatment and post- discharge groupings in Appendix 3.3, Tables 1-3 respectively and further detailed below.

3.3.3 Personal factors grouping

Five interrelated themes contributed to the personal factors grouping; participant's motivation, confidence, mindset, arthritic symptoms, and experiences of PA (Appendix 3.3, Table 1).

Motivation theme: Patients motivation to adhere to PA was influenced by a continuum of factors and included internal and external sources. Subthemes related to internal sources of motivation included: enjoyment (or not) of PA; seeing progress; having a purpose; wanting to maintain function or moderate arthritic symptoms; fear of functional decline or need of invasive surgery; and a sense of personal-responsibility or guilt at not doing prescribed PA. Subthemes related to external sources of motivation were; use of the physiotherapist or reminders (e.g., use one's theraband) as motivators. The most important TDF domains associated with motivation were '*Intentions*', '*Goals*', and '*Emotion*', and '*Beliefs about Capabilities*'.

Confidence theme: Participant confidence was highly influential in promoting PA adherence. Subthemes included: the effect of PA on symptoms and function; feelings of PA capability; and fear avoidance. The most important TDF domains associated with this theme were '*Knowledge*', '*Skills*', '*Beliefs about Capabilities*', and '*Beliefs about Consequences*'.

Mindset theme: Several participants outlined the importance of a positive mindset, or having the mental energy or headspace to engage with prescribed PA. This theme was very closely linked with participant confidence to undertake PA and included the subthemes: psychological effects of symptoms and PA; mental and emotional resources; and comfort zone. The most important TDF domains were '*Beliefs about Capabilities*', '*Optimism*', '*Environmental Context and Resources*', and '*Emotions*'.

Arthritic Symptoms: Pain and other arthritic symptoms (e.g. articular stiffness) were key influences of PA adherence. Subthemes included the effect of symptoms on: Undertaking PA; mood; enjoyment of PA; and the effect of pharmacology on pain. The key associated TDF domains were '*Beliefs about Capabilities*', '*Knowledge*', '*Optimism*', and '*Emotion*'.

Experiences of PA: Participants' previous PA experiences influenced their PA adherence. Sub-themes included: PA effects on participants wellbeing, mind-set, arthritic symptoms and function; and participants identifying oneself as physically active; their expectations of treatment; and frustration at loss of function. The most important associated TDF domains were '*Skills*', '*Beliefs about capabilities*', '*Beliefs about Consequences*', and '*Reinforcement*'.

Table 3.1: Participant demographic features

Participant no	Gender	Age	BMI	Joint	NPRS	BSM	SF KOOS	SF HOOS	PA	HEL	TSSB	TSD	EM
1	F	60	26	Right knee	1	Slightly	35.3	N/A	2155	O levels	2	0.5	N
2	F	75	35	Right knee	2	Moderately	46.1	N/A	2588	PG Diploma	25	25	N
3	M	75	33	Both knees	6	Very much	42	N/A	3800	High School	30	0.75	N
4	F	63	28	Right knee	3	Moderately	33.6	N/A	2692	UG degree	1.5	0.5	Y
5	M	76	25	Left knee	5	Slightly	35.3	N/A	2580	Left school at 14	48	3	N
6	F	53	42	Right knee	6	Very much	66.6	N/A	4250	Left School at 16	12	1	Y
7	F	75	35	Right hip; both knees	4	Moderately	37	41.7	2672	College	6	4	N
8	F	63	24	Left knee	6	Moderately	42	N/A	2376	UG degree	4	1	Y
9	F	67	37	Left hip	3	Slightly	N/A	33.9	3197	UG degree	0.5.	0.5	Y
10	F	53	27	Left knee	2	Slightly	24.9	N/A	1975	College	6	5	
11	F	67	N/G	Both knees	1	Slightly	24.9	N/A	N/G	High School	10	10	Y
12	M	44	30	Left hop	6	Moderately	N/A	41.7	3201	College	2.5	0.5	Y
13	M	48	29	Right hip	6	Moderately	N/A	46.1	3564	Master's Degree	6	3	Y

Legend: no: number; BMI: Body Mass Index; NPRS: Numerical Pain Rating Scale; BSM: Bothersomeness; SF KOOS: Short Form Knee Injury and Osteoarthritis Outcome Score; SF HOOS: Short Form Hip Injury and Osteoarthritis Outcome Score; PA: Physical Activity level (mean kcal/day for past three days); HEL: Highest Education Level Achieved at time of interview; TSSB: Time since symptoms began; TSD: Time Since diagnosis of OA; EM: Employed at time of interview.

Table 3.2: Key Theoretical Domains Frameworks Domains that influenced Themes

		TDF Domain													
		Kn	Sk	SPRI	BACap	Op	BACon	Rein	Intent	Goals	MAD	ECR	Socl	Em	BehR
Grouping	Theme														
Personal factors	Motivation				✓				✓	✓				✓	
	Confidence	✓	✓		✓		✓								
	Mindset				✓	✓						✓		✓	
	Pain	✓			✓	✓								✓	
	Previous Experience		✓		✓		✓	✓							
Treatment Phase	Routine	✓	✓					✓	✓	✓		✓			✓
	Access											✓			
	Value											✓	✓		
	Relationship					✓							✓		
	Personalised Rx	✓	✓		✓			✓	✓	✓			✓		✓
Post-Discharge Phase	Access							✓				✓	✓		
	Psychosocial factors			✓	✓	✓						✓	✓		
	Physical factors				✓		✓					✓			

Legend: TDF: Theoretical Domains Framework; Kn: Knowledge; Sk: Skills; SPRI: Social/Professional Role and Identity; BACap: Beliefs about Capabilities; Op: Optimism; BACon: Beliefs about Consequences; Rein: Reinforcement; Intent: Intention; MAD: Memory, Attention and Decision Processes; ECR: Environmental Context and Resources; Socl: Social Influences; Em: Emotion; BehR: Behavioural Regulation.

3.3.4 Treatment phase factors grouping

The treatment phase grouping included the themes: routine formation; person-centred treatment; the patient-physiotherapist relationship; access; and value of physiotherapy sessions (Appendix 3.3, Table 2).

Routine Formation: PA routine formation emerged as the primary mechanism to promote patient confidence, motivation, and a positive mindset. Subthemes were grouped into barriers and facilitators. Facilitators included: having a PA plan; integrating PA into daily life; promoting habits; and the effects of routine on motivation and well-being. Barriers to routine included: health concerns; memory; other commitments; and time. The primary associated TDF domains were '*Knowledge*', '*Skills*', '*Intentions*', '*Goals*', and '*Behavioural Regulation*' which contained both barriers and facilitators and '*Environmental Context and Resources*' which was exclusively identified as a barrier to this theme.

Person-centred Treatment: A collaborative, person-centred treatment approach was important to developing a PA routine. Subthemes included: a personalised treatment plan; a detailed PA routine; ongoing assessment and reassessment; and understanding of OA. The primary associated TDF domains were '*Knowledge*', '*Skills*', '*Reinforcement*', '*Intention*', '*Goals*', and '*Behavioural Regulation*'.

Relationship with the physiotherapist: Participants outlined the importance of their relationship with the physiotherapist in adhering to prescribed PA. Subthemes included: personal level knowledge; collaborative relationship; familiarity; encouragement (from physiotherapist); motivation (from physiotherapist); communication; and the

physiotherapist's attitude. The most important TDF domains were '*Optimism*' and '*Social Influences*'.

Access to physiotherapy sessions: Participant's access to their physiotherapist influenced the development of a PA routine. Subthemes included: other commitments; appointment flexibility; number and of sessions; and referral process. The primary associated TDF domain theme was '*Environmental Context and Resources*'.

Value of physiotherapy sessions: PA adherence was influenced by how valuable participants perceived their physiotherapy sessions to be. Subthemes include: motivation from sessions; empowerment from sessions; too much talking; and PA within sessions. The primary associated TDF domains were '*Environmental Context and Resources*' and '*Social Influences*'.

3.3.5 Post-discharge factors grouping

The post-discharge grouping included the themes: access to resources; psychosocial factors; and physical factors (Appendix 3.3, Table 3).

Access to resources: Access to a community facility or physical space influenced post-discharge PA maintenance. Subthemes included: Follow-up with the physiotherapist; Appropriate facilities, and; Ease of access. The primary associated TDF domains were '*Environmental Context and Resources*' and '*Social Influences*'.

Psychosocial factors: Ongoing psychosocial support influenced PA post-discharge. Subthemes included: Relatedness to others; Fear of judgement; and Psychosocial

support. The most important TDF domains were '*Environmental Contexts and Resources*', '*Social Influences*', '*Social Identity*', '*Beliefs about Capabilities*', and '*Optimism*'.

Physical Factors: Physical factors impacted participants adherence to PA post-discharge. Subthemes included: Perceived physical capability; intrinsic physical factors (e.g. age, weight); and extrinsic physical factors (e.g. hills, weather). The primary associated TDF domains were '*Beliefs about Capabilities*', '*Beliefs about Consequences*' and '*Environmental Context and Resources*'.

3.3.6 Interrelationship of themes across groupings

The relationships of the themes within the personal factors and treatment and post-discharge groupings can be visualised in Figures 3.2 and 3.3 respectively. The conceptual mind-maps demonstrate the importance of the participant's mindset and confidence to adhere with prescribed PA and their influence on motivation. The smaller curved arrow details the feedback and ongoing relationship between these personal factors. The figure also takes into account the interrelation of patients unique PA experiences and OA symptoms with the other personal factors. The main vertical arrows demonstrate PA routine as the key mechanism in the adoption (Figure 3.2) and maintenance (Figure 3.3) of the key personal factor themes. The bottom of each model outlines the interacting themes of each grouping and their influence on PA routine adoption and maintenance.

Figure 3.2: Conceptual mindmap of Personal and Treatment Themes influencing Adherence to Physical Activity

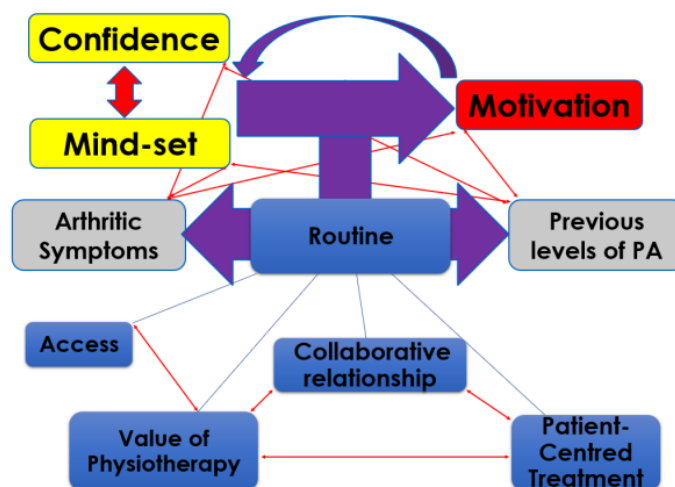
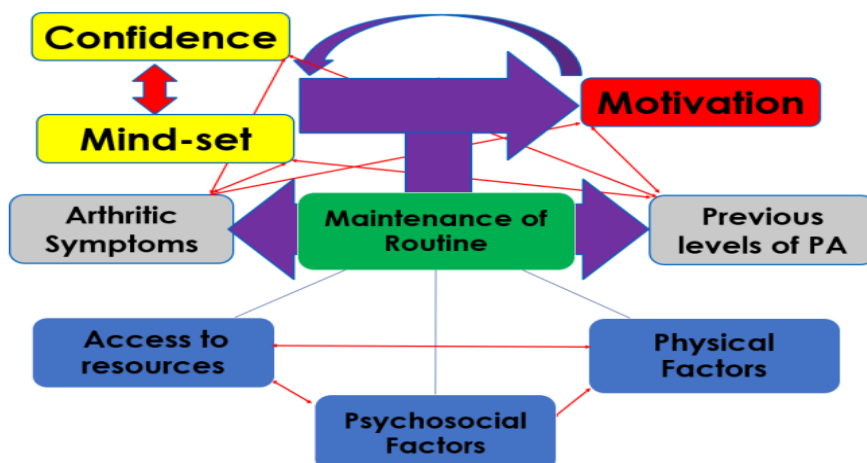


Figure 3.3: Conceptual mindmap of Personal and Post-Discharge Themes influencing Adherence to Physical Activity



3.3.7 Step 3: Behaviour change technique identification and intervention development

A proposal of the theoretically informed intervention is outlined in Table 3.3 and includes 26 BCTs with two additional BCTs (*body changes* and *credible source*) naturally occurring due to the sessions being delivered. The conceptual phases of adoption, routine formation, and maintenance were based on the inductive thematic analysis and behaviour change literature with the number of sessions informed by the interview transcripts. Of the included BCTs, eleven were recurrent, five were primarily coded to adoption, five to routine formation, and eight to the maintenance phases respectively. BCTs with a 'behaviour' and 'outcome' variant (e.g. goal setting) were listed as a single BCT and the final selection will be determined by patient's preference when the intervention is delivered. For example, if the patient's goal is to lose weight as a result of optimising PA, then the BCT would become goal-setting (outcome) as weight would be the outcome of consistently applying the behaviour.

Table 3.3: Theory-informed physiotherapy intervention outlining phases targeted by behavioural change techniques

Session Number	Targeted Phase	Specific BCTs	Reoccurring BCTs
1-2	Adoption	• Goal setting (behaviour and/or outcome) • Action planning (including implementation intentions) • Information on health consequences of performing the behaviour • Information on social and environmental consequences • Rewards (one of: Material, non-specific, social, self-reward, or outcome)	• Review behaviour goals (and/or outcome) • Feedback on behaviour (and/or outcomes) • Self-monitoring of behaviour (and/or outcomes of behaviour) • Social support (unspecified) • Social support (practical) • Instruction in how to perform the behaviour • Modelling/demonstration of behaviour • Behavioural rehearsal/practice • Graded Tasks • Pharmacological Support • Body changes^a • Credible source^a
3-4	Routine Formation	• Prompts/cues • Habit formation • Generalisation of a target behaviour • Adding objects to the environment (e.g. objects to facilitate behaviour)	
5-6	Maintenance	• Problem Solving • Behavioural Contract • Reduce negative emotions • Restructuring of social environment • Verbal persuasion about capability • Social comparison • Information about others' approval	

Legend: BCT: Behaviour Change Technique; ^a: denotes associated BCT occurrences naturally from delivering the intervention as planned

3.4 Discussion

This is the first qualitative study to gain in-depth perspectives of the barriers and facilitators to physiotherapist prescribed PA during the treatment and post-discharge phases in patients with lower-limb OA. Inductive thematic analysis synthesised barriers and facilitators and themes and subthemes were collated into an a priori deductive framework which included three over-arching groupings: personal factors; treatment factors and; post-discharge factors. Subthemes were mapped to the TDF and results synthesised to outline the key domains to target for each theme. Thirteen TDF domains were identified and 26 BCTs were included in the proposed intervention, which represents the first theoretically informed physiotherapy intervention to target adherence to prescribed PA during treatment and post-discharge.

3.4.1 Personal Factors

Personal factors that influenced participants perceptions of PA adherence were consistent with previous literature, specifically: motivation (288, 291, 325), confidence (288, 292, 293, 297, 326), mindset (288, 292, 293, 297, 326) and experiences of arthritic symptoms (291, 292, 297) and/or PA (288, 292, 297). Themes relating to personal factors were highly interactive and participants could be categorised into two broad profiles;

- Those with higher levels of arthritic symptoms and/or decreased physical capabilities, or who experienced symptoms as a result of PA reported less confidence, motivation and/or a negative mindset reported difficulty adopting

and/or maintaining PA behaviours and required ongoing practical and social support (288).

- Participants who had internalised PA behaviours (267) or had high levels of social support reported feeling greater confidence, motivation and/or a positive mindset to adopt and maintain their PA post-discharge without additional need of support (288).

The TDF domain '*Beliefs about Capabilities*' was influential for all personal factor themes. This domain includes constructs such as of 'self-confidence', 'empowerment', 'perceived competence', and 'perceived behavioural control'. These constructs relate closely with participant confidence, mindset, and the theoretical cognition of self-efficacy (327) which is a salient correlate of overall PA behaviours in patients with lower-limb OA (297). Participants discussed that positive PA experiences increased their confidence and generated a positive mindset, which facilitated motivation to engage with prescribed PA. Therefore, self-efficacy may act as an antecedent to motivation in the behaviour change process (280) and BCTs that targeted the '*beliefs about capabilities*' construct (e.g. *instruction in how to perform the behaviour* and *demonstration of the behaviour*) were introduced early in the proposed intervention with several reoccurring.

3.4.2 Treatment factors

Forming a PA routine was the key mechanism to promote PA behaviours during treatment. Participants felt that physiotherapists could optimise their routine by

instructing prescribed PA and enabling participants' to practice/rehearse within sessions (289, 290, 293, 294, 297, 326), slowly increasing PA in a graded manner, and providing feedback about PA or its associated outcomes (e.g. weight loss). Participants suggested that providing a demonstration of the behaviour (e.g. exercise sheet or video) and/or integrating self-monitoring of PA (e.g. pedometers or exercise diaries) into programmes would help regulate PA outside of the clinic during the treatment phase (328). Interestingly, participants linked these BCTs to promoting confidence and purposeful PA. However, they are underutilised in clinical practice (328, 329) suggesting that physiotherapists may not be effective at utilising strategies which encourage PA adherence (168). Therefore, these BCTs were introduced in sessions to and reinforced in sessions three-four to facilitate behavioural adoption and routine formation respectively.

The beneficial effects of a positive patient-physiotherapist relationship are in line with previous studies, as participants commented that encouragement (330), reassurance (294), and developing a strong personal connection enhanced adherence to PA (288, 331). The proposed intervention therefore utilises the reoccurring BCTs *social support (unspecified)* and *(practical)* respectively. Participants discussed how patient-centred treatment that involved collaboratively generated PA goals, led to feelings of empowerment and enhanced motivation to engage with PA (289, 332). The use of a collaborative approach is associated with advanced clinical reasoning and expert physiotherapist practice (333). Moreover, goal setting techniques with recurring review, were identified as important BCTs to promote PA adherence by patients with lower-limb OA (142), and were included in the adoption phase of the proposed intervention.

3.4.3 Post-discharge factors

Several participants believed their physiotherapist could provide additional support post-discharge, as they perceived negative reactions from family/friends or peer PA groups (288, 296) due to their reduced physical capacity. As intervention time is limited for physiotherapists, it would be beneficial if community resources for post-discharge PA provision were integrated with the physiotherapy provider (292). In line with previous studies, participants discussed that any post-discharge PA group needed to be exclusive to individuals of similar physical abilities (290, 292, 294, 296, 297, 326) and diagnosis to enhance relatedness (290, 294) and reduce feelings of anxiety or embarrassment (290, 297, 326). Therefore, the proposed intervention incorporated BCTs relating to *problem solving*, and an indepth discussion on *how to structure the social environment* during the maintenance phase (286, 322, 323). Community facilities primarily target those with decreased physical ability and lower income and need to be highly accessible (288, 289) and at minimal cost (19, 21). However, participants discussed that they found access to services highly problematic. Therefore, the proposed intervention included BCTs that alter the home environment, in order (to prompt routine formation and maintenance post discharge (e.g. using prompts and cues, or leaving Theraband in a prominent place to act as a reminder to their PA).

3.4.4 Reflections on TDF mapping and BCT coding

With the exception of the motivation theme, TDF mapping was intuitive and consistent with all discussion points clarified by the two researchers. Motivation has a multi-faceted

influence on PA adherence (288, 291, 325) that may change at different parts of the behaviour change process (267). This is perhaps reflected in the refined TDF (286) which separated the original 'goals and motivation' domain (124) into the distinct 'goals' (preferred outcome), and intentions (determination to act in a certain way). While it is acknowledged that motivation is a distinct mechanism or process of action in current research (322, 323) further clarification of its definition within the TDF domains would likely increase consistency during mapping. These difficulties may also be linked to the topic guide design which was not informed by the TDF domains.

The TDF domains 'environmental context and resources' and 'social influences' were highly influential across both treatment and post-discharge phases. While the separation of themes into the personal factors, and treatment and post-discharge phases enabled some clarity of sequencing of BCTs, there was considerable overlap of domains across groupings. This suggests that behavioural adoption and maintenance have both unique and similar determinants.

Although the constructed matrix provided a useful tool, several BCTs did not overlap between studies and further work to establish agreement of the coding of BCTS from behavioural domains and mechanisms of action is required.

3.5 Strengths and Limitations

Strengths include the transparent methodology (192) to identify barriers and facilitators of PA adherence, which incorporated a valid and reliable framework to map them to determinants of behaviour change (283), and an extensively utilised strategy of

identifying BCTs (286). These strengths may enhance the interventions effectiveness at optimising adherence to PA. The study design facilitated an in-depth understanding of participant views and incorporating patient and public involvement further aided participants perspectives to be integrated during the intervention's initial development. The COREQ checklist, detailing all aspects of study reporting is included in Appendix 3.4

A key limitation is that all participants were familiar with the person who recruited them, which may have influenced the findings. Furthermore, all participants were fluent English speakers of White British descent. While this reflected the hospital demographics, findings may not be generalisable beyond this population. In addition, participants recall PA levels were higher than those typically reported for patients with lower-limb OA (275). Although the sample may have included only active participants, inconsistent and over-reporting of PA levels with patient reported methods of data collection is widely outlined in the literature (334), and perhaps strengthens the need for validated measures of objective PA in patients with lower-limb OA.

Furthermore, all interviews were conducted within six weeks of participants completing their physiotherapy sessions. Therefore, the proposed intervention was largely based on participants' anticipated barriers and facilitators to PA rather than their lived experiences. Repeat interviews conducted several months post-discharge may have provided a more detailed picture of the barriers and facilitators to PA maintenance experienced by patients with lower-limb OA. The theoretically informed physiotherapy intervention represents the initial proposal only. Prior to implementation, further data is required on the intervention's feasibility to other stakeholders to clarify points on BCT

mode of delivery, session lengths and frequency, and training needs of physiotherapists. Therefore, the feasibility and acceptability of delivering the intervention will now be tested in focus groups of physiotherapists working clinically prior to a phase two feasibility study.

3.6 Conclusions

A proposed theoretically informed physiotherapy intervention to optimise PA adherence in patients with lower-limb OA during treatment and post-discharge was developed through a transparent and rigorous methodology. The intervention BCTs primarily target patients' perceived beliefs about their capabilities, by developing a PA routine during treatment and facilitating appropriate psychosocial support and access to resources for PA maintenance post-discharge. The perceptions of physiotherapists on the feasibility of delivery of the proposed intervention now requires evaluation.

3.8 Funding

This study was supported by the Musculoskeletal Association of Chartered Physiotherapists level 3 research award. The funding body had no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript

3.9 Dissemination of results

The protocol for this qualitative study has been published in BMJ OPEN:

Willett, M. Greig, C. Fenton, S. Rogers, D. Duda, J. Rushton, A. Utilising the perspectives of patients with lower-limb osteoarthritis on prescribed physical activity to develop a theoretically informed physiotherapy intervention. *BMC Musculoskeletal Disord* 2021;22(1):155. doi: 10.1186/s12891-021-04036-8.

The results of this qualitative study were published in BMC musculoskeletal disorders:

Willett M, Greig C, Fenton S, Rogers D, Duda J, Rushton A. Utilising the perspectives of patients with lower-limb osteoarthritis on prescribed physical activity to develop a theoretically informed physiotherapy intervention. *BMC musculoskeletal disorders*. 2021;22:155.

The results have been presented at peer reviewed conferences:

Physiotherapy UK, November 2020. Virtual Conference. 'Rapid 5' Presentation. 'Development of a theoretically informed physiotherapy intervention aimed at optimising physical activity adherence in patients with lower-limb osteoarthritis: A qualitative study using the theoretical domains framework and behaviour change taxonomy.

CHAPTER 4: PHYSIOTHERAPISTS PERCEPTIONS OF A THEORETICALLY INFORMED INTERVENTION DESIGNED TO PROMOTE ADOPTION AND MAINTENANCE OF PHYSICAL ACTIVITY IN PATIENTS WITH LOWER-LIMB OSTEOARTHRITIS: A QUALITATIVE STUDY

Chapter overview:

This chapter presents musculoskeletal physiotherapists' perceptions of a proposed theoretically informed intervention (thesis Objective 3) that incorporated 26 behaviour change techniques (BCTs) to address barriers and utilise facilitators to promote PA adoption and maintenance in patients with lower-limb OA. The proposed intervention, as developed in chapter 3 of this thesis was presented to physiotherapists. Two focus groups, comprising 12 physiotherapists (n=7 females), explored the feasibility and acceptability of delivering the intervention in clinical practice. Thematic analysis identified six themes that summarised physiotherapists perceptions of the intervention. Four themes related to the feasibility of intervention delivery including: acceptability, physiotherapist capacity, and the use of either group classes or remote delivery as treatment options. Two further interlinking themes summarised factors that influenced the patient-physiotherapist relationship and the physiotherapists training needs. Points of similarity and differences between the opinions of patients with lower-limb OA (identified from chapter 3) are discussed to further develop the intervention in preparation for feasibility testing.

Sections from the background and methods section of this chapter are taken verbatim from the following publications for which I am the primary author:

Willett, M.J. Greig, C. Rogers, D. Fenton, S. Duda, J. Rushton, A. Barriers and facilitators to recommended physical activity in lower-limb osteoarthritis: protocol for a qualitative study exploring patients and physiotherapist perspectives using the theoretical domains framework and behaviour change taxonomy. *BMJ Open* 2019;9:e029199. doi: 10.1136/bmjopen-2019-029199 doi: 10.1136 (Appendix 1.3)

Initials used in the text correspond to the following names: Matthew Willett (MW), Joan Duda (JD), Sally Fenton (SF), Carolyn Greig (CG), David Rogers (DR), Alison Rushton (AR)

4.1 Background

Lower-limb OA is a global health concern with associated assessment and management costs placing a high burden on national healthcare systems (335). Patients with lower-limb OA experience high levels of disability (181, 182) and the ongoing increase in global point prevalence due to aging populations makes the disease highly challenging to manage (336).

Physical Activity (PA) interventions, including structured exercise and lifestyle activities, are advocated as core management options for OA in international guidelines (1, 113, 273, 337). Optimising PA can help people with lower-limb OA self-manage their symptoms (97), reduce the likelihood of developing secondary non-communicable diseases (100), and have a positive effect on patient well-being (338). However, most patients with lower-limb OA do not meet PA guidelines (86) and are generally less active than non-symptomatic populations (185).

A core theoretical concept that influences patient behaviours, such as PA, is the 'phase' of behaviour change that they currently occupy (132). The phases of behaviour change are often heterogenous and generally conceptualised uniquely across theoretical models. However, the phases of 'adoption/initiation' and 'maintenance' (130, 132, 155) are consistent across theoretical models.

Physiotherapists are the primary healthcare professionals responsible for PA intervention delivery to people with lower-limb OA (92). Conceptually, PA adoption would occur during the period of physiotherapy treatment and maintenance would be most relevant post discharge (155). While there are common determinants that

influence both PA adoption and maintenance, others are unique. Therefore, a physiotherapy intervention that aims to optimise PA would likely require both unique and phase specific BCTs to target the most appropriate PA determinants during adoption and maintenance. Robust development of a behaviour change physiotherapy intervention targeting adoption and maintenance of PA in patients with lower-limb OA is therefore required.

To initially address this issue, a proposed theoretically informed physiotherapy intervention targeting adoption and maintenance of PA in patients with lower-limb OA following Medical Research Council (MRC) guidance (114, 176, 178) was developed.

Initially, a systematic review (Chapter 2) investigated the effectiveness of physiotherapy BCTs at promoting PA adherence in people with lower-limb OA (277, 339). Certain BCTs demonstrated statistically significant effects on PA and adherence outcomes at up to three months post baseline (e.g. Action planning), after six months post baseline (e.g. Problem solving) or across time points (e.g. Non-specific reward) (277). Although these BCTs were potentially useful as part of an intervention, their effectiveness on PA/adherence outcomes was generally uncertain and based on high risk of bias trials with poor fidelity reporting (277).

Secondly, a qualitative study (Chapter 3) (300, 340) examined the views of patients with lower-limb OA of barriers and facilitators to adherence to physiotherapist prescribed PA during treatment (adoption) and post-discharge (maintenance). The findings supported contemporary literature that feelings of competence/self-efficacy and motivation are key determinants of PA behaviours in patients with lower-limb OA (341, 342). The results progressed understanding by identifying '*routine formation*' as a potential linking phase

between PA adoption and maintenance (340). Based on the perceptions of patients with lower-limb OA, the proposed intervention incorporated 26 BCTs that targeted the determinants of PA behaviours across the conceptual phases of adoption, routine formation, and maintenance (343).

However, patients may not possess a full understanding of the practical requirements to deliver an intervention in an NHS physiotherapy outpatient department. Moreover, physiotherapists may have limited insights into behaviour change and the role it plays in terms of delivering effective treatments (140). For the proposed intervention to be optimally delivered, physiotherapists were required to understand the theoretical components of behaviour change (conceptual model, phases of behaviour change) and agree that the management plan was acceptable and feasible to deliver. Therefore, this study aimed to determine the perceptions of physiotherapists regarding the feasibility and acceptability of delivering the proposed intervention (Chapter 3) in a physiotherapy outpatient setting.

Objective:

To determine the perceptions of physiotherapists on the feasibility and acceptability of delivering the proposed behaviour change intervention in a musculoskeletal outpatient setting.

4.2 Methods

4.2.1 Ethics approval and study reporting

NHS ethical and Health Research Authority (HRA) approval and site capacity and capability were obtained (IRAS 247904) prior to the study. The study is reported in line with the Consolidated Criteria for Reporting Qualitative Research (COREQ) recommendations and the completed checklist can be found in Appendix 4.1 (301).

4.2.2 Research team and reflexivity

The focus groups were led by a co-I (AR), an experienced musculoskeletal physiotherapist with a PhD and extensive experience conducting qualitative research. MW acted as an observer who recorded who was speaking at each time point and participants' reactions. MW is an advanced physiotherapy practitioner (APP) who has treated patients with lower-limb OA for several years. MW completed the semi-structured interviews on patients with lower-limb OA (Chapter 3) but had not undertaken focus groups prior to the study. Although both interviewers were familiar to some physiotherapists, their roles as researchers were emphasised at the beginning of the focus groups. The focus group participants were told that the study formed part of a programme of research (MWs PhD) and that it would be used to develop a physiotherapy intervention based on behaviour change theory that sought to optimise adherence to PA prescription during the treatment and post-treatment periods in patients with lower-limb OA.

4.2.3 Study Design

Theoretical Framework: The study aimed to develop understanding of the in-depth perceptions of physiotherapists, who had lived experience managing patients with lower-limb OA in an NHS outpatients setting, to determine the feasibility and acceptability of delivering the proposed intervention. Therefore, the study was based on a phenomenological framework (299).

Participants selection and setting: The study followed a published protocol (300) and no protocol deviations occurred during conduct. Physiotherapists who regularly delivered PA interventions to patients with lower-limb OA within one NHS trust (hospital and associated community health services) site, the Royal Orthopaedic Hospital (ROH), Birmingham, were eligible to participate. The site lead researcher (DR, an APP within the ROH and familiar to all participants), used convenience sampling (303) to approach and recruit the physiotherapists in person. Focus groups were conducted in the ROH physiotherapy gym for pragmatic reasons, time commitments, and convenience of the clinicians. At the time of recruitment, there were approximately 16 physiotherapists who regularly treated patients with lower-limb OA. Therefore, it was anticipated that two focus groups would be conducted (based on the optimum number of 6–8 in each group). The total number of physiotherapists approached compared with those who attended the focus groups was recorded.

Data Collection: The focus group topic guide sought the physiotherapists' perceptions on the structure and content of the proposed intervention including its acceptability, feasibility, and practicality (capability, opportunity, challenges to delivery) (307) the

incorporated BCTs and any areas where training was required. The focus group topic guide can be viewed in Appendix 4.2.

The focus groups were used to maximise insight of physiotherapist perceptions through an interactive group process providing multiple perspectives (344). This enabled physiotherapists to propose and, through challenging and adding to others' points (345) to articulate logistical issues around implementation of the outlined physiotherapy intervention within their NHS trust, that would not be apparent to the researchers (346). Prior to the focus group, basic demographic data was recorded from the participating physiotherapists (gender, age, total time in clinical practice since graduation and amount specifically treating patients with lower-limb OA, their level of education, frequency treating patients with lower-limb OA, and how often they use strategies to target adherence to prescribed PA and their perceived effectiveness during the treatment and post-treatment time periods). MW outlined the proposed intervention and AR facilitated discussion to gain the physiotherapists' opinions on its feasibility, acceptability, and practicality (347) of delivery. MW noted salient points on a white board to encourage elaboration or to revisit at the end of the focus groups. These points were photographed to act as field notes at the conclusion of the focus groups.

Each focus group was anticipated to last approximately 90 minutes and the discussion continued until saturation was achieved (i.e. no further opinions were put forward by physiotherapists). Although focus groups were not repeated, they were audiotaped and transcribed verbatim, with the transcripts emailed to participating physiotherapists to enable further review and feedback.

4.2.4 Analysis and Findings

Data analysis: Data Analysis followed the thematic analysis processes as outlined by Braun and Clarke (316). This is an established method (344) having been utilised extensively in qualitative studies, and enables flexibility (316) to analyse the research topic while developing unexpected themes that emerge from the transcripts during coding (348).

Familiarisation and transcript coding: The first focus group was coded by two researchers independently (MW, SF, the latter with expertise in behaviour change theory and intervention development), who read the transcript several times and attempted to suspend any presuppositions before commencing coding (349). Coders deliberately coded for as many patterns as possible during the early stage. Any explicit opinions about BCTs were noted for further review. The preliminary coding framework was based on the topic guide (programme structure and content, acceptability, feasibility, capability, opportunities, challenges to delivery, and training needs) and adjusted iteratively following analysis of the first transcript.

Identifying potential themes: MW wrote all codes on post-it notes and both reviewers met regularly to deductively map codes to the preliminary framework and discuss emerging themes.

Reviewing and finalising themes: The second transcript was coded by MW and reviewed by SF, who met to further discuss additional themes and deviant perceptions (349). Agreed themes supported by physiotherapist quotations were presented to the Study Steering Group (SSG), which included patient and public involvement, practicing

physiotherapists and research academics, for elaboration and challenge to iteratively develop the thematic analysis.

To enable transparency within the audit trail, NVivo software was used to store information and coders kept a reflexive journal to identify their initial thoughts and perceptions.

4.3 Results

4.3.1 Participants

Sixteen physiotherapists were approached of whom four did not attend due to the focus groups being conducted on their scheduled non-workdays (n=2) or having patients in their clinical diaries (n=2). Two focus groups of physiotherapists (n=12, 7 female), aged 26-39 years (Mean 31.5; Standard deviation 4.4) who had treated patients with lower-limb OA from 1-10 years (Mean 5.4; Standard deviation 2.7) were conducted in January 2020 and lasted 53 and 60 minutes respectively. 10 physiotherapists were treating patients with lower-limb OA from once (defined as 'frequently'; n=6) to 5 times per week ('very frequently'; n=4), with two physiotherapists seeing only one patient per month (somewhat frequently) or every six months (very infrequently). 10 physiotherapists reported using BCTs to increase PA adherence in >50% of their treatment sessions with the most used involving advice or education about OA and/or PA (n=7) or referral to additional further services or exercise classes (n=4). Transcripts were sent to all 12 physiotherapists, of whom 3 responded with no additional comments. No physiotherapists who agreed to participate dropped out post focus group. During the

focus group, several physiotherapy assistants were working in an open office and patients were being escorted to treatment. The demographic detail of the physiotherapists is included in Table 4.1.

Table 4.1: Physiotherapist demographic features

Participant no	Sex	Age	years qual	Education	Freq treat OA (very infrequently-very frequently)	BCTs used (Never-Always)
1	M	38	5	MSc	Frequently	Occasionally
2	F	31	11	Studying MSc	Frequently	Usually
3	F	38	5	BSc	Frequently	Always
4	M	26	4	Studying MSc	Frequently	Usually
5	M	27	7	Msc	Frequently	Always
6	F	39	3.5	BSc	Very frequently	50% of time
7	M	29	5	MSc	Very infrequently	Always
8	F	30	10	BSc	Very frequently	Always
9	F	28	8	BSc	Frequently	Usually
10	F	31	10	BSc	Somewhat frequently	Usually
11	F	30	6	MSc	Very Frequently	Always
12	M	31	5	BSc	Very Frequently	Always

Legend: BCT: Behaviour Change Technique; M: Male; F: Female; NO: number; Years qual: number of years qualified; Education: highest education level achieved; Freq treat OA: How often participant treats patients with lower-limb OA on average; **options include:** Very infrequent: 1 in the last 6 months; Infrequently: between 2-5 in last 6 months; somewhat frequently: at least one per month; frequently; at least 1 per week; Very frequently; 5 or more per week; BCTs used: The frequency that participants use BCTs to promote adherence to physical activity in patients with lower-limb OA: **options include:** Never, Occasionally, 50% of the time, usually, always (100%).

4.3.2 Themes

Six themes emerged from the analysis. The first 4 themes related to the feasibility of intervention delivery and included: acceptability; physiotherapist capacity; group classes; and remote delivery. The final two interrelated themes included the patient-physiotherapist relationship; and physiotherapists' training-needs. The themes, subthemes, and supporting example quotations are outlined in Table 4.2.

Intervention feasibility

Acceptability: Physiotherapists perceived the intervention as highly acceptable and commented positively on its conceptual structure, flexibility, and patient-centredness. Subthemes included: Well-structured; Tailored to patient; and Clinically relevant.

Capacity: Physiotherapists disagreed about whether they could deliver all intervention BCTs within the current appointment times. To enhance feasibility, physiotherapists suggested reducing the overall number of BCTs and making intervention materials simple and easy to deliver. Subthemes included: Time; and Intervention components.

Group classes: Group classes were discussed as a resourceful treatment option. However, physiotherapists disagreed about what influence group classes had on patient PA engagement, when they should be sequenced, and cited previous poor uptake within the trust. Subthemes included: Effects on patient confidence and motivation; Sequencing of classes; Poor attendance; and Problems individualising treatment.

Remote Delivery: Physiotherapists felt remote delivery (phone, teams/zoom) was a convenient and resourceful treatment option. The primary barrier was the available departmental equipment (laptops and headphones) and internet speed.

Physiotherapists also disagreed about patients' ability to use information technology and how remote delivery would be perceived. Subthemes included: Remote delivery is feasible; Optimal sequencing; Patients' perceptions of remote delivery; Patient ability to use technology; and Resources.

Patient-physiotherapist relationship: Physiotherapists discussed several interacting patient and physiotherapist psychological factors that influenced the patient-

physiotherapist relationship and treatment environment. Subthemes included: Patient engagement (with treatment), patient expectations, patient belief; patient knowledge; and physiotherapist confidence and ability to deliver intervention.

Physiotherapist training needs: Physiotherapists suggested training they felt would positively influence the psychological factors from the patient-physiotherapist relationship theme. Primarily, training suggestions focused on how to empower patients and optimally deliver BCTs to aid patient confidence and motivation for PA. Physiotherapists also requested training to modify patients smoking and diet. Subthemes included: Empowering patients; Behaviour change Theory; Intervention structure and content; and Supplementary behaviours.

Table 4.2 Themes, subthemes, and example verbatim quotes illustrating physiotherapists' perceptions of the intervention

Theme	Subthemes: Participant ID: Illustrative quotes
Intervention Feasibility	
Acceptability	Well structured: FM 2: 'But I quite like how the sections are put into, yeah, Section 1 and 2 is... you're right, it is the adoption of the information that you've given them, and then it takes a couple of sessions to build up the habit. And then by 5 and 6 they might not be 100% better because of all the things that we know about arthritic changes.' Tailored to patient: FM 3: 'I like there's an emphasis on physical activity.... So I like the emphasis. It sounds like it's not just specific exercises because,...but it's just getting people doing something that they enjoy again...' Clinically relevant: M 1: 'They're all things that are relevant actually. Once you know what they mean and how they can do it, it comes out as stuff that we do routinely, I think. I can't see anything that we wouldn't necessarily do.'
Capacity	Time: M 12: 'My problem would probably be time, we probably would be able to do that but to draft up a contract that specific to someone in that time would be very, very difficult.' FM 8: 'Yeah, I think it's certainly doable from a physio point of view..... But I think what – we say everything we need to say in 20 minutes certainly.' Intervention components: FM 9: 'Just something dead easy (booklet), just to pull out of a folder and just put in.'
Group classes	Effects on patient confidence and motivation: FM 10: 'And actually they're all coming here they probably would go to the same gym so you could find a gym buddy from your, yeah. And that would help them go.' Problems individualising treatment: M 5: 'I think you can to a certain extent individualise it but when you've got a class of 10 and ultimately they will run it as like a circuit, so they may not get that specific individual...But generally, it might be that they don't get the specific like one to one of, "Can I just look at your technique with that?" because you're trying to keep an eye on 10 people and make sure ultimately that they're safe.' Poor attendance: FM 11: 'We did used to do that as part of it but I think again it's just because of the timing of it, you'd end up with two people a month which then isn't really very effective.' Sequencing of classes: M 1: 'What I think would be quite good is if Sessions 1 and 2 were one-to-one, 3 and 4 were like group, and then maybe 5 and 6 would be either a group or one-to-one.'
Remote delivery	Remote delivery is feasible: FM 7: 'If you've booked it as a diary slot, as if they were coming in and you put a note to phone them, then that would be doable' Optimal sequencing: M 1: 'I'm thinking adoption, they're speaking, they come in for two appointments. In my head that's what I'd do and then in the final four you could potentially follow that up through phone. Or half and half.' Patients' perceptions of remote delivery: M 6: 'But I think they always worry with that, because I think they presume that we don't care and that we're just trying to get them out of the hospital and we're trying to save money and things like that.'

Patient's ability to use technology: FM 2: 'I quite regularly ask patients if they have a camera phone that I can video them doing their exercises on rather than giving them a generic exercise sheet. And so many of the people who come in for OA don't yet have that access or don't really know how to use their phone in that way

Resources: FM 1: 'We just don't have the best systems that we use. We barely have working telephones, let alone anything to do Skype on. But, yeah. That is something that is an ongoing project

Patient-physiotherapist relationship

Patient engagement: M 1: 'I think also probably one of the more important sessions for me is the first initial session that you have with them, so sometimes I personally feel like a say all this, like you've got to kind of have your pitch and that buys in the patient or it doesn't.'

Patient expectations: FM 9: 'I think it's exploring their expectations from the start though, isn't it? ...Because if they think, "I want someone to massage my knee," well you might say, "Well, that's not the best treatment for this type of problem," but they need to know from the offset what you're expecting of them, but what also they're expecting of you as well.

Patient belief in physiotherapist: FM 11 'And that's really hard to move forward from. Even if you tell them, "Grade it, it's going to be sore." You give them all their... ultimately they've come to you for pain and maybe it flares up or feels a bit worse, and so they lose their confidence in you. It's getting past that. It's really hard.'

Patient knowledge: M 4: 'Yeah. Yeah, I think that's really important because a lot of people don't understand arthritis and they have no idea what it is. They've just been told by a doctor they've got, you know, "Your joints are crumbling," they're sort of over the road and they think, "Oh God, well I've obviously got to stop doing what I'm doing because it's probably going to make things worse."

Physiotherapist confidence to deliver intervention: M12: 'Because then I think from our point of view, we want to see, in the nicest possible way, success with patients, don't we? So, if we're setting them up on this pathway and suddenly they're going off and failing, then we lose confidence in it.'

Physiotherapist training needs

Empowering patients: FM 3: 'And I think probably an element of knowing how to get them to come up with the ideas themselves. So kind of a motivational interviewing and actually getting the skills to be able to formulate our language and our questions in a way that it encourages the patients to take control.'

Behaviour change theory: M1: 'I think we'd probably need some training in behavioural change theory definitely. It's just something that we don't touch on.'

Intervention structure and content: FM 8: 'Yeah, and I guess like self-talk isn't necessarily something we do directly as in like, "Oh, go away and say to yourself I can do this." Like I don't think I generally do that with patients.'

Supplementary behaviours: FM 11: 'The other thing from a training point of view, I don't know whether just things that are slightly out of our remit, so stuff like diet and nutrition and things that we wouldn't necessarily be... and smoking and the effect that these things can have.

4.4 Discussion

To the authors knowledge, this is the first study to evaluate physiotherapists' perceptions of a theoretically informed proposed behaviour change intervention which aimed to promote adoption and maintenance of PA in patients with lower-limb OA. Six interrelated themes emerged from the thematic analysis reflecting the acceptability of the intervention, physiotherapist capacity, group classes, remote delivery, the patient-physiotherapist relationship, and physiotherapists' training needs.

4.4.1 Themes reflecting intervention feasibility

The number of intervention sessions outlined (6) was based on the analysis of interviews with patients with lower-limb OA who had attended physiotherapy at the ROH. As the proposed intervention was considered acceptable and aligned with the trust parameters, no alterations were made to the intervention phases or number of sessions.

Although most physiotherapists suggested that trust appointment times were sufficient for feasible intervention delivery, some felt they required extra time, especially to deliver all 26 protocol BCTs. However, physiotherapists agreed that for the intervention to be adopted by the trust over the longer term, it needed to fit within their current time slots. Therefore, to aid practicality, physiotherapists requested that any patient facing intervention materials were user friendly and could be given to patients for review between sessions to be discussed collaboratively during the appointments. Previous research has found that patients with lower-limb request greater access to

physiotherapy services and cite ongoing support as integral for PA maintenance (87). While the focus group physiotherapists acknowledged that patients with higher OA symptoms or less mobility required greater provision, they appeared hesitant to offer it. Consistent with previous research, the physiotherapists felt their primary role was to provide education about OA and facilitate PA behaviours to enable patients to self-manage their own symptoms (168). Therefore, focus group discussion naturally progressed to resourceful intervention delivery options already employed by the trust, namely group classes and remote delivery options.

The physiotherapists agreed that the use of group classes and/or remote delivery would aid trust resources. However, physiotherapists disagreed when both approaches should be sequenced within the intervention, and some were concerned that patients would perceive the use of group classes and remote delivery as evidence of an attempt to reduce contact time with patients. Regarding group classes, physiotherapists' perceptions were supported by findings from the patient interviews and a recent survey which evaluated physiotherapists and patients with lower-limb OA perceptions on the effectiveness of 36 BCTs to aid PA adherence (142). Interestingly, physiotherapists identified referral to an exercise group as the most effective BCT while patients with lower-limb OA ranked it 25th (142). These features may have contributed to the very poor group class attendance reported within the trust and have been highlighted in trials using group-based interventions for patients with lower-limb OA (350). Difficulties personalising treatment, class organisation logistics, and variable effects of group dynamics on patients' confidence and motivation for PA were further cited barriers to using group classes. Therefore, overall group classes were not considered a feasible

intervention delivery option. While some physiotherapists believed that remote delivery would enhance patient choice and reduce missed appointments, others argued that most patients preferred face to face appointments and questioned patients' ability at utilising visual technology (e.g. zoom).

Overall, data from the patient interviews (Chapter 3) did not fit seamlessly with the physiotherapists' perceptions regarding remote intervention delivery. While several patients preferred face to face treatment, those that were active, had milder symptoms, were working, or had other commitments, often suggested a remotely delivered intervention was preferable. These patients felt travel and paying for parking at physiotherapy appointments were barriers to attendance, a point also raised by some the focus group physiotherapists. Remotely delivered interventions provide patients greater flexibility and access to rehabilitation service than in-person treatment and increased use of remote interventions is part of the wider NHS long term healthcare plan (351). Furthermore, remotely delivered physiotherapy interventions were considered acceptable by physiotherapists (352) and patients with lower-limb OA (353, 354) and have demonstrated comparable effectiveness on pain and function to in person treatments (354, 355, 356). Individual patient preferences should be considered when planning an intervention (94). Therefore, the use of remote delivery (telephone or a virtual platform) was considered an appropriate optional intervention adaptation with the specific number and timing of sessions to be negotiated between the patient and physiotherapist to individualise treatment.

The primary barriers to optional remote delivery were the digital facilities (e.g. connectivity, computers) and physical resources (e.g. departmental laptops and

headphones) available at the ROH. Therefore, the original feasibility trial development plan included securing funding for appropriate equipment. However, shortly after the focus groups were conducted, the COVID-19 pandemic emerged and modified physiotherapy service delivery in the UK. The ROH subsequently invested in additional digital resources, including departmental laptops and headsets, which the focus groups suggested were previously unavailable. Decisions regarding intervention delivery (e.g. session lengths and mode of delivery) based on an integration of patients and physiotherapists' perceptions are outlined in Table 4.3.

Table 4.3: Optimisation of intervention based on integration of patient and physiotherapists views'

Consideration	Decision	Rationale
Sessions and resources		
Number of sessions	Continue with 6 sessions as standard. More/fewer available if needed	• Patients and physiotherapists agreed with number. • Matches trust parameters.
Session Lengths	Continue with trust parameters: 40-minute initial, 20-minute follow up.	• Most patients and physiotherapists agreed that session lengths were of adequate duration. • Matches trust parameters
Time between sessions	Dependent on physiotherapists and patients symptoms/availability	• Personalises treatment. • Fits with clinical practice
Mode of Delivery		
Remote delivery option	Include remote delivery as option	• Patients and Physiotherapists suggest useful resourceful option. • Useful during COVID.
Group classes	Do not offer	• Physiotherapists suggested poor uptake and difficulty scheduling. • Limited interest from patients • Poor attendance in recent studies • COVID 19 adds further barrier.

4.3.2 Themes relating to patient-physiotherapist relationship and physiotherapy training needs

Details from patient interviews (Chapter 3) that were emphasised during the focus group presentations included the patient-physiotherapist relationship, the proposed model of behaviour change where patient confidence and motivation interacted to promote PA, and the intervention BCTs (343). Consistent with the literature, focus group physiotherapists acknowledged the importance of developing a positive relationship with patients (357). However, physiotherapists highlighted patient specific factors, including the patients' knowledge about OA, expectations of treatment, belief in the physiotherapist, and engagement with treatment that also influenced the relationship and their own confidence to deliver the intervention. Moreover, physiotherapists believed that patients needed to take ownership of their own PA as the intervention progressed for the intervention to be successful. However, physiotherapists felt they did not possess the requisite knowledge to competently deliver the BCTs to develop a positive patient-physiotherapist relationship and empower patients to take ownership of their own PA.

Developing a positive patient-physiotherapist relationship is a cornerstone of patient-centred treatment (358). Although systematic reviews have demonstrated the benefits that patient-centred treatment have on clinical outcomes and patient satisfaction (359, 360), physiotherapists have difficulty delivering patient-centred care in practice (168, 361). However, research has demonstrated that training can help physiotherapists develop these skills (362, 363, 364). Analysis of the physiotherapists' training needs highlighted further theoretical developments required by the proposed intervention

required prior to feasibility testing. The proposed interventions model of PA behaviour change conceptualised a bidirectional interaction between a patients' confidence, motivation, and interpersonal relationships (343).

The Theoretical Domains Framework (TDF) (286) was used during the initial development of the proposed intervention, rather than an explicit theory of behaviour change (365). Although the TDF identified theoretical determinants/constructs (patients feelings of capability for PA) for the interventions' BCTs to target (366), it did not consider the interactions between these constructs (365). Therefore, the TDF does not conceptualise the interrelationships between patient motivation, confidence, and the patient-physiotherapist relationship and cannot be used to develop the model of behaviour change, which may be required if taken to a definitive trial for theory refinement. Secondly, the TDF did not provide guidance on how to deliver the intervention BCTs to create a positive patient-physiotherapist relationship and treatment environment to optimise patients' confidence and motivation for PA which left the intervention package underdeveloped. These issues were discussed within the study team. As the interaction between patient confidence, motivation, and the development of a positive patient-physiotherapist relationship were fundamental to the proposed intervention, a further developmental stage prior to feasibility testing was agreed. This stage aimed to identify an appropriate theory (or theories) of behaviour change to underpin the physiotherapist training in intervention delivery. Theories were sought whose model matched (as closely as possible) that of the proposed intervention. As the focus group physiotherapists felt there were too many protocol BCTs to deliver

effectively within trust time scales, theories would be further prioritised if their constructs were linked to BCTs, so the overall number of techniques could be reduced.

Although physiotherapists requested training to modify patients smoking and diet, these are supplementary behaviours to PA that require unique approaches and BCTs to effectively target. Therefore, it was agreed to integrate additional information on appropriate referral into the physiotherapy training rather than detailing specific strategies to alter these behaviours.

4.5 Strengths and Limitations

The interactions between focus group physiotherapists appeared to permit open discussion of topics raised to develop and highlight key points (367). Using the perceptions of physiotherapists clarified which intervention components were feasible to deliver and where modifications were required and highlighted key physiotherapist training and intervention development needed prior to feasibility testing. Synthesising the treatment preferences of patients with lower-limb OA with the practicality of physiotherapists should enhance delivery at the ROH.

The primary limitations of this study related to its generalisability. The use of patients and physiotherapists at one clinical site likely biased the results and the intervention may require additional adaptation if a multi-centre trial is indicated post feasibility testing. A further potential study limitation is the sample size. Two focus groups were planned for a priori based on the number of musculoskeletal physiotherapists at the ROH. Although the focus groups included a relative gender (7 female and 5 male) and

years-experience (1-10 years treating OA patients) spread, some authors suggest a minimum of three focus groups per clinical setting to achieve data saturation (344). These issues are compounded due to the lack of available studies with which to compare our results.

4.6 Conclusion

Focus group physiotherapists perceived the proposed intervention as highly acceptable. No changes were suggested to intervention length or number of sessions. Trust specific considerations around mode of delivery were discussed and the optional use of remote delivery was integrated into the intervention to enhance its feasibility. Although the acceptability and overall feasibility of the intervention offered preliminary evidence to support its use in practice, physiotherapists require training to develop a positive patient-physiotherapist relationship and deliver BCTs to develop patients' feelings of confidence and motivation to adopt and maintain PA. Acknowledging the identified physiotherapist training needs, the following chapter identifies an appropriate theory of behaviour change to underpin physiotherapist training in preparation for a trial to assess the interventions feasibility in practice.

4.7 Funding: This study was supported by the Musculoskeletal Association of Chartered Physiotherapists (MACP) level 3 research award.

CHAPTER 5: IDENTIFICATION OF BEHAVIOUR CHANGE THEORY AND FINALISATION OF INTERVENTION CONCEPTUAL MODEL

Chapter overview:

This chapter builds upon chapters 2-4 by presenting the systematic identification of a theory of behaviour change (TOBC) to underpin intervention content and manner of delivery. A comprehensive review of the descriptions and models of theories of behaviour change (TsOBC) was undertaken by two researchers and compared to the proposed intervention to identify an appropriate candidate theory to undergird the multi-component intervention package. The proposed intervention behaviour change techniques (BCTs) (n=26) were mapped against the pertinent TOBC constructs to refine the interventions' content and the final conceptual model was clarified to enable feasibility testing. Self-Determination Theory (SDT; (368)) was identified as an appropriate TOBC to underpin the way in which the intervention was delivered to patients and needed to be addressed as part of physiotherapist training. The refined multi-component intervention included 21 core BCTs (12 phase specific and 9 recurring) which target patients' needs for competence, relatedness and autonomy respectively. The intervention development and associated limitations are discussed in the context with the wider behaviour change literature in preparation for feasibility testing.

Sections of this chapter are taken verbatim from publications for which I am the primary author. Note: Most of the verbatim sections are from the initial submission of the feasibility trial protocol to BMC musculoskeletal disorders that do not appear in the final publication. The only parts from the published article are those included in the appendix outlining the stages of intervention development. Further short sections of the introduction are taken from the qualitative studies protocol.

Willett, M. Rushton, A. Stephens, G. Fenton, S. Rich, S. Greig, C. Duda, J. Feasibility of a theoretically grounded, multicomponent, physiotherapy intervention aiming to promote autonomous motivation to adopt and maintain physical activity in patients with lower-limb osteoarthritis: protocol for a single-arm trial. *Pilot Feasibility Stud.* 2023;9(1):54 (Appendix 1.5).

Willett MJ, Greig C, Rogers D, Fenton S, Duda J, Rushton A. Barriers and facilitators to recommended physical activity in lower-limb osteoarthritis: protocol for a qualitative study exploring patients and physiotherapist perspectives using the theoretical domains framework and behaviour change taxonomy. *BMJ Open.* 2019;9:e029199. doi: 10.1136/bmjopen-2019-029199 (Appendix 1.3).

Initials used in the text correspond to the following names:

Matthew Willett (MW), Joan Duda (JD), Sally Fenton (SF), Eric Deason (ED).

5.1 Background

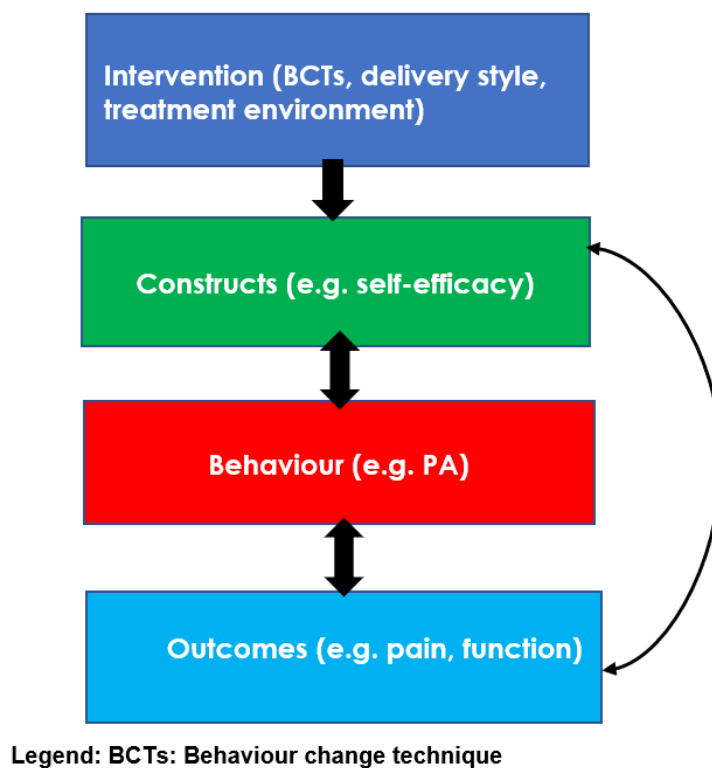
Hip and knee (lower-limb) osteoarthritis (OA) is a significant contributor to global disability with approximately 300 million people diagnosed with the condition (3), representing an increase of over 9% between 1990-2017 (4). With the population aging (4) the point prevalence is anticipated to continue to rise and place unsustainable load on global healthcare systems within the next decade (13).

Healthcare professional delivered PA interventions, including structured exercises and habitual activities, are recommended by international guidelines for initial management of lower-limb OA (3, 10, 64). Physiotherapists are the most common healthcare provider of PA interventions in the United Kingdom's NHS and therefore, well placed to deliver PA interventions (92). Physiotherapy PA interventions have consistently demonstrated statistically significant benefits on pain and function compared with non-PA comparator groups in patients with lower-limb OA (25, 74). However, these benefits tend to reduce over the longer term (369), especially after patients are discharged from care (370), and can result in re-referral to healthcare services.

The MRC encourages the use of theory when developing and testing complex interventions (114, 176) to help progress understanding of the intervention's conceptual model of behaviour change (365). An important constituent of behaviour change is the theoretical 'construct/constructs' that the intervention is attempting to influence. Michie and colleagues' (2014) (371) define a construct as '*a component of ... theory that is a representation of an object, event, state of affairs, feature of one of these, derived from observation and inference*' and includes concepts such as 'self-efficacy' or 'intentions'. Theoretical interventions utilise BCTs to target constructs (371) that are assumed to

influence target behaviours (365). By evaluating the intervention's effects on constructs such as assumed processes/mechanisms and, by proxy, the target behaviour (by measuring changes in outcomes), researchers can modify the intervention's underlying conceptual model and potentially increase clinical effectiveness over time (114). Therefore, clearly linking BCTs to their targeted constructs (371) is an integral step in developing a behaviour change intervention (372, 373). However, over 70% of theoretically grounded interventions do not link BCTs to their targeted construct/processes of change (116, 322). A generic conceptual model of behaviour change is outlined in Figure 5.1.

Figure 5.1 Generic Model of Behaviour change



A further important theoretical consideration relevant to intervention delivery, is the 'stage' or 'phase' of change (132) that an individual currently occupies on their behaviour change journey, with behavioural 'adoption' or 'initiation' and 'maintenance' commonly represented in conceptual models (130, 132, 155). When considering a physiotherapy intervention that promotes PA in patient with lower-limb OA, PA adoption would likely occur while the patient is under care with maintenance continuing post discharge. There are likely overlapping and unique techniques and strategies that influence PA adoption and maintenance (155). Therefore, overlapping and unique BCTs need to be incorporated into an intervention during these two phases. To address this issue, a theoretically informed physiotherapy intervention was proposed that aimed to utilise BCTs that targeted specific constructs influencing PA during adoption *and* maintenance in patients with lower-limb OA. The intervention was developed sequentially following MRC guidelines (114, 176, 178).

Initially, a comprehensive systematic review (Chapter 2) of randomised controlled trials (277, 374) was conducted to identify the most effective physiotherapist delivered BCTs to promote short (< 3 months post-baseline), medium (6 months post-baseline), and long-term (12 months post-baseline) PA in patients with lower-limb OA. Although some BCTs showed promise in promoting PA at specific timepoints (e.g. Action planning for short term) or across all time points (e.g. Social support (unspecified)), the results were inconclusive and based on poorly reported RCTs with high risk of bias (277). Therefore, semi-structured interviews (300, 340) that examined the views of patients with lower-limb OA regarding the barriers and facilitators to adherence to physiotherapist prescribed PA during treatment (adoption) and post-discharge (maintenance) were

conducted (Chapter 3). Based on the analyses of the data generated from the patient interviews, a conceptual model of behaviour change was created where patient confidence and a positive, patient-centred physiotherapy relationship drove patient motivation to adopt a PA routine. Ongoing access to a supportive PA environment and appropriate resources was deemed to facilitate confidence and motivation for PA maintenance post-discharge. Barriers and facilitators were mapped to the constructs on the Theoretical Domains Framework (TDF) (375) and BCTs identified following Michie's V1 taxonomy (123). Pulling from these findings, a theoretically informed physiotherapy intervention which incorporated 26 BCTs was proposed to target theoretical constructs which were assumed to influence PA adoption and maintenance in patients with lower-limb OA (343).

Finally, the proposed intervention was presented to physiotherapists to assess their perceptions on its acceptability and feasibility for implementation in clinical practice (Chapter 4). Although the physiotherapists found the intervention highly acceptable, they believed they required further training in how to create a positive patient-physiotherapist relationship and optimally deliver the proposed BCTs to empower patients to adopt and maintain PA. A reduction in the overall number of BCTs was also suggested to optimise feasible delivery. Analysis of the focus group data highlighted queries with certain theoretical components of the proposed intervention that required further consideration prior to feasibility testing. These are summarised below.

Prioritising BCTS and manner of delivery:

- The proposed intervention included 26 BCTs (343). However, previous research found training physiotherapists to deliver a theoretically grounded intervention incorporating 31 BCTs with high fidelity was problematic (376) and the systematic review (Chapter 2) identified a mean number of 11 BCTs were used within RCT interventions (277). Repeat review of the findings of the systematic review and qualitative study with patients with lower-limb OA (Chapter 3) did not further clarify which BCTs should be prioritised.
- The V1 BCT Taxonomy (123) was utilised to identify the proposed intervention's BCTs. Although the V1 taxonomy describes BCT content, it does not specify how to optimally deliver them in practice to favourably influence targeted processes and outcomes (322, 323).

Limitations associated with the TDF:

- Interviewed patients (Chapter 3) highlighted a variety of reasons (i.e. motivations) for engaging with PA. However, motivation is poorly defined within the TDF, and the themes did not map well to related factors. Therefore, coded BCTs did not target these theoretical factors effectively.
- The TDF is a 'model' rather than a theory of behaviour change and as such does not provide insights into the interplay between the variables of interest (365). Furthermore, each TDF domain encompasses several constructs but does not help identify the most appropriate outcome measures to evaluate them.

Therefore, it was problematic to prioritise BCTs and specify the optimal way for physiotherapists to deliver them to target the proposed intervention constructs (particularly motivational factors) to empower patients to adopt and maintain PA. In addition, there was no process to further develop the conceptual model of the intervention that would be required if taken forward to a definitive trial.

Discussion amongst the SSG agreed that further work was required to identify an appropriate TOBC that could clarify the conceptual model, prioritise intervention BCTs, and underpin physiotherapist training to deliver the intervention. Although the use of theory is encouraged by the MRC, there is no agreed process to identify a TOBC (377). TOBC choice should be based on a detailed understanding of the targeted behaviour, population, and theoretical constructs (312). However, the choice of TOBC can be inappropriate or not suitable and it's selection may be influenced by researcher preference (365) or limited knowledge of available TsOBC (378).

A scoping review by Davis and colleagues (2015) (365) identified 82 TsOBC utilised to develop individual level behaviour change interventions. Interestingly, eight TsOBC accounted for the development and implementation of 75% of interventions (365). These results have been replicated in systematic reviews of musculoskeletal pain populations, with Social Cognitive Theory (SCT) and the Transtheoretical model (TTM) most frequently utilised (157, 161, 365). However, frequently used TsOBC may be no more effective than less common theories at promoting PA (116, 379). Furthermore, it has been argued that choosing a TOBC can be challenging as several theories incorporate the same constructs (380). However, these same constructs may have different names across TsOBC, or different constructs may have the same name in

alternative theories (365, 371). Recent work by Hale et al., (2020) (380) and West et al., (2019) (381) have developed an ontology system to enable comparison of the conceptual models of TsOBC. A clear description of how theory is chosen is important to help enhance an intervention's practicality (322, 366).

The present study aimed to transparently review TsOBC to identify an appropriate candidate theory that matched (as closely as possible) the proposed intervention's conceptual model. The study sought a TOBC that would assist in prioritising BCTs and undergird physiotherapist training in regard to intervention delivery in preparation for feasibility testing.

Objectives

- 1) To identify an appropriate TOBC which corresponds with the proposed intervention's conceptual model.
- 2) To use the chosen TOBC from Objective 1 to identify an appropriate training programme to support physiotherapists in intervention delivery.
- 3) To map the proposed interventions BCTs to the theoretical constructs of the TOBC identified in Objective 1 to prioritise BCTs.
- 4) To integrate the chosen TOBC with the proposed intervention to refine the model of behaviour change based on Objectives 1 and 3.

5.2 Methods

5.2.1 Specification of eligibility criteria for choice of theory: Prior to commencing the formal identification process, The SMG met to establish the criteria that TsOBC

would be compared against so the final choice of theory was as compatible with the proposed intervention as possible. Due to the number of available TsOBC and complex decisions required, the criteria were divided into primary (highly important to the proposed intervention) and secondary (preferred but not essential). The primary criteria included concepts relevant to Objective 1 (i.e. the conceptual model) with secondary criteria comprising factors related to Objectives 2-3 (training programmes and BCTs). The primary and secondary criteria are outlined in Table 5.1.

Table 5.1 Primary and secondary eligibility criteria used to determine compatibility of theory of behaviour change with proposed intervention

Primary criteria: • The conceptual model included the constructs of patient confidence/self-efficacy and motivation • Confidence/self-efficacy acted as a precursor to motivation in the conceptual model. • The theoretical description included a detailed understanding of the different facets of motivation regulation that upon inspection appeared consistent with the qualitative work (343). • The conceptual model considered the phases of behaviour change (i.e. adoption and maintenance).
Secondary criteria: • The theory had associated existing training programmes that aimed to create a positive patient treatment relationship/environment that could be employed and/or adapted for physiotherapists • BCTs that linked to the theory and associated constructs. • The theory was previously utilised to underpin PA interventions (preferable focus on musculoskeletal populations)

5.2.2: Objectives 1-2: Identification of theory of behaviour change and training programme

Step 1: Screening of theories: The overviews of 82 TsOBC, as defined by Davis et al., (2015) (365) and expanded upon by Michie et al., (2014) (371), were screened for initial

compatibility with the conceptual model underlying the proposed intervention. At this early stage, TsOBC were only excluded if they were clearly incompatible with the model. For example, TsOBC could be excluded if they were developed to target a specific behaviour (e.g. sexual practices) with limited relevance to PA promotion in patients with lower-limb OA. All relevant theories to PA promotion that included a detailed focus on a key component of the proposed intervention's conceptual model (e.g. feelings of confidence/competence) were included at this stage. TsOBC were screened by one researcher (MW) and decisions audited by a second researcher (SF, PhD in behaviour change) with any disagreements resolved through discussion. If agreement could not be reached, a third researcher with expertise in behaviour change (JD) was available to mediate.

Step 2: Full text review of potential theories and conceptual models: The official (original or updated) full text descriptions of each potentially relevant TOBC identified in Step 1 were retrieved for in-depth review. The primary focus at this stage was a detailed comparison of the description and conceptual model of each TOBC (i.e. review against primary eligibility criteria) with the proposed intervention (343) to identify candidate TsOBC that could underpin intervention delivery. To ensure a comprehensive overview, all conceptual models were further compared with the those updated in West et al., (2019) (381) and Hale et al., (2020) (380) respectively, (available at: <https://theory-database.appspot.com/theory/>). Each TOBC was reviewed independently by two researchers (MW and SF) who met to iteratively narrow down the potential options. Further discussions were held between MW and JD (PhD in behavioural

psychology/expertise in motivation) who met to mediate any researcher disagreements and refine the choice of candidate TsOBC.

Step 3: Scoping searches of secondary criteria associated with candidate

theories: Scoping searches of each candidate TOBC identified in Step 2 were conducted by one researcher in Google Scholar and Medline (MW) in April 2021.

The scoping searches included:

- A citation search of the official full text of each candidate theory
- Individual searches combining each TOBC with terms related to the secondary criteria: 'physical activity', 'training programme', and 'behaviour change techniques'.
- Review of theory associated websites

Where the searches identified a high number of references to review, the first 200 were screened by one researcher (MW) and the full reports retrieved for further examination where necessary. MW and JD met to discuss the strengths and weaknesses of the secondary criteria associated with each candidate TOBC and to determine the best fit to integrate into the proposed intervention. Based on the chosen TOBC, further discussions finalised the focus of the training programme to be delivered to intervention physiotherapists (Objective 2).

5.2.3: Objective 3: Mapping of intervention behaviour change techniques to theoretical constructs

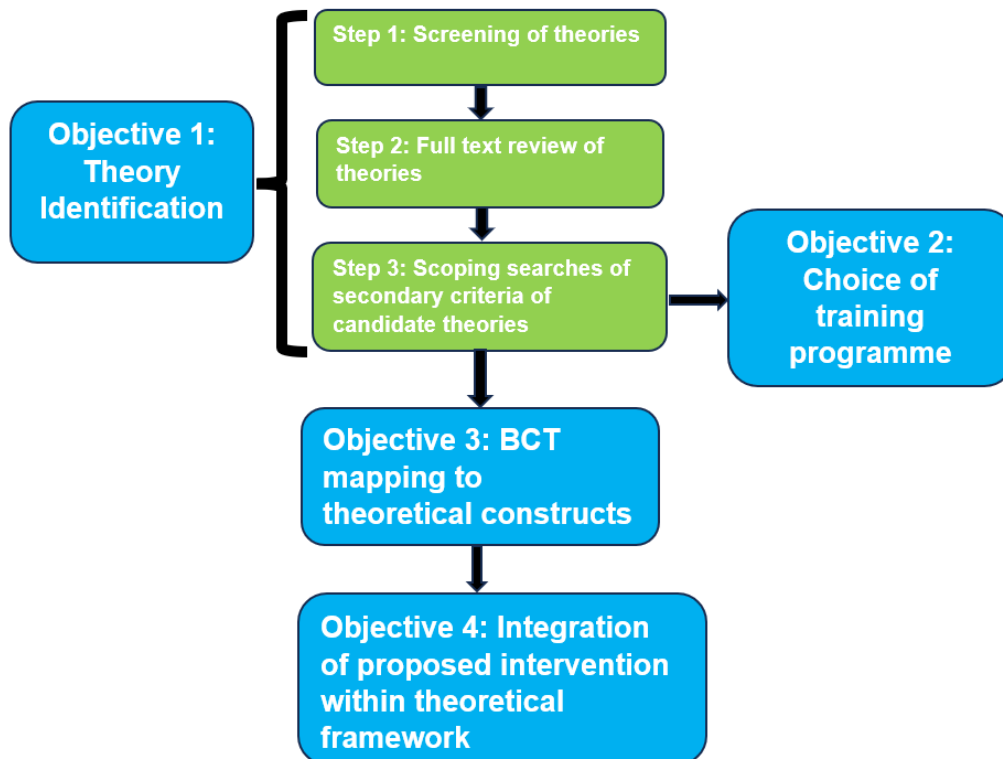
The proposed intervention's BCTs were mapped against any BCTs associated with the TOBC identified in Objective 1: Step 3. BCTs were classified as 'core', to be explicitly employed within the intervention, or 'optional', to be delivered if time and resources permit (376). One researcher (MW) completed BCT mapping, and a further researcher (JD) audited the results. Intervention BCTs were then reviewed in line with the previous findings (systematic review and qualitative studies) and discussed amongst the wider study team to finalise content. Priorities were given to BCTs that mapped to theoretical constructs and/or were regularly delivered within physiotherapy interventions (164, 277, 382).

5.2.4 Objective 4: Integration of proposed intervention within chosen theory's theoretical framework

Finally, the proposed intervention (including its' prioritised BCTs and constructs) was integrated with the chosen TOBCs framework to finalise a conceptual model of PA behaviour change in patients with lower-limb OA. This stage was conducted by one researcher (MW) with audit and feedback from another (JD). The study PPI representative (ED) trialled and offered critical feedback on potential measures of theoretical constructs, pain, function, and PA behaviours. After further discussion between MW and JD, the chosen outcomes were synthesised into the final proposed

intervention model. An overview of the methods used to meet Objectives 1-4 is outlined in Figure 5.2.

Figure 5.2: Overview of study methods



5.3 Results

5.3.1 Objective 1: Choice of behaviour change theory

Steps 1-2: Summary of screening and full-text review

An overview of the number of TsOBC identified from Steps 1-3 is outlined in Figure 5.3.

83 TsOBC were screened, of which 48 were excluded. TsOBC were primarily excluded due to their explicit focus on an alternative behaviour (e.g. smoking cessation) or

population (e.g. people with the Human Immunodeficiency Virus or young people with diabetes) and thus, were incompatible with the proposed intervention. Further detail is provided in Appendix 5.1. The full-text and conceptual models of 35 TsOBC were reviewed, and decisions summarised in Table 5.2.

The description and conceptual model of three TsOBC most consistently fit with the proposed intervention: the Health Behaviour Internalisation Model (383) (HBIM), Self-Determination Theory (384, 385, 386) (SDT), and the Trans-Contextual Model of Motivation (387) (TCM). Critically, the theoretical models of HBIM, SDT, and TCM included a clear overview of the self-regulatory processes to internalise behaviours (i.e. the motivation to engage in the behaviour). HBIM and TCM also incorporate stages of behaviour change but neither included 'identified regulation' (i.e. engaging with a behaviour because it, or the desired outcome, is valued by the individual) as part of their process of self-regulation. As several patients with lower-limb OA from the qualitative study (Chapter 3) reported engaging with PA to maintain their level of function or strengthen musculature around the hip/knee, identified regulation was important to capture within the chosen TOBC if possible.

Table 5.2: Theory identification Matrix (n=35 theories)

Theory	Step 2: criteria (n= 35 Theories)					Step 3: Secondary criteria (n=3 theories)			
	Com/SE	Mot	Con/SE»Mot	FOMot	Phases	PA Int	OMs	Train	BCTs linked
CEOS Theory (388)	?	?	X	X	Y	N/A	N/A	N/A	N/A
COM-B (115)	✓	✓	✓	?	X	N/A	N/A	N/A	N/A
Control Theory (389)	?	?	X	X	X	N/A	N/A	N/A	N/A
Feedback Intervention Theory (390)	✓	✓	✓	X	?	N/A	N/A	N/A	N/A
Focus Theory of Normative Conduct (391)	X	✓	X	X	X	N/A	N/A	N/A	N/A
Goal Directed Theory (392)	✓	?	?	X	X	N/A	N/A	N/A	N/A
Goal Framing Theory (393)	?	?	X	X	X	N/A	N/A	N/A	N/A
Goal setting Theory (394, 395)	✓	?	?	X	X	N/A	N/A	N/A	N/A
Health Action Process Approach (396)	✓	?	?	X	✓	N/A	N/A	N/A	N/A
Health Behaviour Goal Model (397)	✓	?	?	X	✓	N/A	N/A	N/A	N/A
Health Behaviour Internalisation Model (383)	✓	✓	X	✓	✓	✓	?	?	✓
Health Belief Model (398)	✓	?	?	X	X	N/A	N/A	N/A	N/A
Heath Promotion Model (399)	✓	?	?	X	X	N/A	N/A	N/A	N/A
Integrated change Model (400)	✓	✓	?	X	✓	N/A	N/A	N/A	N/A
Integrated Theory of Health Behaviour Change (401)	✓	?	X	X	?	N/A	N/A	N/A	N/A
Integrative Model of Behavioural Prediction (402)	✓	?	?	X	X	N/A	N/A	N/A	N/A
Precaution Adoption Process Model (403)	?	X	X	X	✓	N/A	N/A	N/A	N/A
Pressure Systems Model (Katz)(404)	✓	✓	?	X	✓	N/A	N/A	N/A	N/A
PRIME Theory (addiction) (405)	✓	✓	?	?	X	N/A	N/A	N/A	N/A
Protection Motivation Theory (Health threats) (406)	✓	✓	✓	X	X	N/A	N/A	N/A	N/A
Reflective Impulsive Model (407)	?	?	?	X	X	N/A	N/A	N/A	N/A
Regulatory Fit Theory (408, 409)	?	✓	?	X	X	N/A	N/A	N/A	N/A
Self-Determination Theory (384, 385, 386)	✓	✓	✓	✓	X	✓	✓	✓	✓
Self-Efficacy Theory (410)	✓	?	?	X	?	N/A	N/A	N/A	N/A
Self-Regulation Theory (411)	✓	✓	?	X	✓	N/A	N/A	N/A	N/A
Social Cognitive Theory (412)	✓	?	?	X	X	N/A	N/A	N/A	N/A

Social Ecological model of change (413)	✓	✓	?	X	✓		N/A	N/A	N/A	N/A
Social Ecological Model of walking (414)	✓	✓	X	X	X		N/A	N/A	N/A	N/A
Systems model of Health Behaviour Change (415)	?	?	X	X	✓		N/A	N/A	N/A	N/A
Temporal Self-Regulation Theory (416)	?	✓	?	X	?		N/A	N/A	N/A	N/A
Theory of Interpersonal behaviour (417)	✓	?	?	X	X		N/A	N/A	N/A	N/A
Theory of planned behaviour (418)	✓	?	✓	X	X		N/A	N/A	N/A	N/A
Theory of Triadic Influence (419)	✓	✓	?	X	?		N/A	N/A	N/A	N/A
Trans-contextual model of Motivation (387)	✓	✓	?	✓	?		✓	✓	✓	X
Transtheoretical model of behaviour change (420)	✓	?	?	X	✓		N/A	N/A	N/A	N/A

Com/SE: Conceptual model explicitly includes competence/self-efficacy; *Mot*: Conceptual model explicitly includes motivational processes; *Com/SE»Mot* : Conceptual model explicitly identifies competence or self -efficacy as a precursor to motivation; *FOMot*: Facets of motivation in conceptual model and theory description fit with qualitative work; *Phases*: Conceptual model includes phases of behaviour change process: *PA Int*: Scope Search identifies research that theory been previously utilised to underpin physical activity interventions; *OM*: Scoping search identifies whether theory has related valid and reliable outcomes that measure competence/self-efficacy and/or motivation; *Train*: Scoping searches identifies whether theory has associated training programme for intervention provider; ✓: Identified; ?: Unclear; X: Not present/Not identified; N./A: Not applicable

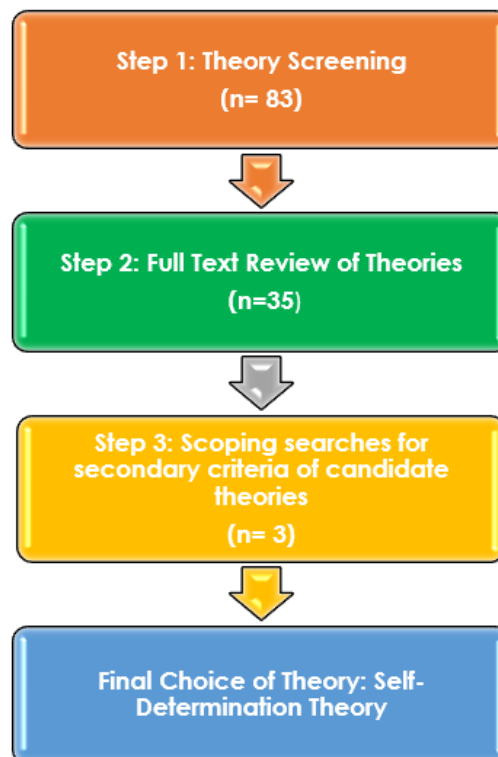
Step 3: Results of scoping searches

HBIM, SDT, and TCM were included in the scoping searches of secondary criteria. The searches demonstrated that the development of HBIM and TCM were highly influenced by SDT. Furthermore, SDT had undergirded a significantly greater number of PA interventions compared to TCM and HBIM. Although SDT has been identified as a prominent TOBC (365), few physiotherapy interventions were identified that were conducted on patients with musculoskeletal pain grounded in this framework. The most closely related feasibility trial to date was conducted in the Republic of Ireland and utilised a group-based intervention which aimed to aid people with spinal pain and lower-limb OA to develop self-management behaviours (350). While the intervention and training were highly acceptable to all stakeholders, the trial was deemed unfeasible due to severe recruitment delays related to patient preferences for individual treatment (350). Therefore, due to its conceptual and empirical support (421), but lack of clear feasibility testing within an individual physiotherapy intervention on people with lower-limb OA in the United Kingdom, SDT was chosen to underpin the intervention.

Briefly, SDT (280, 422) is a contemporary behaviour change theory which conceptualises motivation in regard to its quality (i.e. how self-determined are the reasons people undertake a specific behaviour) (384). The quality of a person's motivation can be broadly defined as autonomous (driven by personal importance or enjoyment) and controlled (driven by feelings of guilt or pressure outside of the individual) (385). SDT (368) emphasises the concept of 'psychological needs' which are assumed to be fundamental to more autonomous striving, personal growth, optimal functioning and wellbeing: namely, competence; autonomy; and relatedness.

Competence refers to patients' feelings of confidence, capacity, and capability to undertake a behaviour (280). Autonomy relates to patient's making informed decisions (i.e. having volition) and accepting responsibility for their new behaviours (422). Relatedness refers to patient's feeling connected to others in a helpful, caring, mutually respectful way (e.g. physiotherapist during treatment or others in a group exercise class post discharge) (423). If satisfaction of each of these psychological needs is realised, autonomous motivation is promoted for the patient to adopt and maintain the behaviour (385, 421). An overview of the theory identification process is outlined in Figure 5.3.

Figure 5.3: Results of Theory Identification (Objective 1)



5.3.2: Objective 2: Choice of training programme

A further feature of SDT, which holds relevance to the intervention, is its consideration of features of the social environment and the influence this exerts on people's need satisfaction and self-determined behaviour. The interviews with patients (Chapter 3) highlighted the central influence that the social environment has on their adoption and maintenance of PA. However, focus group physiotherapists (Chapter 4) felt underprepared to develop an optimally supportive social environment to empower patients to adopt and maintain PA. Therefore, the version of the *Empowering Coaching* programme tailored for physiotherapy/health care (424, 425), which is grounded in the overarching framework of SDT, was chosen to constitute a key part of the training of the trial physiotherapists. This training programme includes a more comprehensive look at the environment by integrating concepts embedded in a further theory of motivation which takes into account environmental supports for more or less resilient perceptions of competence i.e., Achievement Goal Theory (AGT) (426, 427). AGT proposes that individuals employ task and/or ego related criteria to define whether they feel competent or have been successful in performing a behaviour (426, 427). A more task-involving environment employs principles that encourage emphasis on an individual's effort, mastery and developing iterative improvement through practice. More ego involving environments promote judgements of competence based on comparisons of an individual's ability to perform a behaviour when contrasted with others (i.e., the focus is on demonstrating superiority) (426, 427).

5.3.3 Objective 3: Mapping BCTs to theoretical constructs and prioritising techniques

The literature searches of secondary parameters identified two recent sources, Gillison et al., (2019) (428) and Teixeira et al., (2020) (429), which mapped BCTs from the V1 Taxonomy (123) to SDT constructs. The cross-taxonomy mapping and refined multi-component intervention are presented in Table 5.3 and Appendix 5.2 respectively. The refined intervention includes 21 core BCTs (12 phase specific and 9 recurring) which are outlined in Table 5.3 (columns 2-3). BCTs that appear in *Italics* were not mapped to an SDT construct and considered optional BCTs.

The intervention phases are outlined in the first column of Table 5.3. The key constructs which are targeted at each phase are identified next to the associated BCTs in columns 2 (phase specific) and 3 (recurring) respectively. The BCTs within the adoption phase focused on developing patients' feelings of autonomy and competence and those in routine formation targetted furthering feelings of competence and autonomous motivation for PA when away from the clinic. The maintenance phase incorporated BCTs aiming to help patients develop problem solving skills around identification of their specific physical and psychosocial barriers to ongoing participation and brainstorming of and practical solutions (autonomy, competence and relatedness) for promoting ongoing PA. The primary focus of the recurring BCTs is to promote feelings of patient competence as this was identified as the primary overarching determinant of PA initial engagement and facilitator of motivation in the semi-structured interviews (Chapter 3).

Table 5.3: Final behaviour change intervention outlining phases of intervention and associated behaviour change techniques

Core BCTs and Associated SDT psychological need (in bold)		
Intervention phase	Phase Specific	Reoccurring
Adoption	• Goal setting (behaviour and/or outcome) (autonomy, competence)	• Review behaviour goals (or outcome) (competence)
	• Action planning (autonomy, competence)	• Feedback on behaviour (or outcomes) (competence)
	• Information on health consequences of performing the behaviour (autonomy)	• Self-monitoring of behaviour (or outcomes of behaviour) (competence)
	• Information on social and environmental consequences (autonomy)	• Social support (unspecified) (competence, relatedness)
	• <i>Rewards (one of: Material, non-specific, social, self-reward, or outcome)</i>	• Social support (practical) (relatedness)
Routine Formation	• Prompts/cues (competence)	• Instruction in how to perform the behaviour (competence)
	• Adding objects to the environment (competence)	• Modelling/demonstration of behaviour (competence)
	• Habit formation (competence)	• Behavioural rehearsal/practice (competence)
	• Generalisation of a target behaviour (competence)	• Graded Tasks (competence)
Maintenance	• Problem Solving (Competence)	• <i>*Pharmacological support</i>
	• Reducing negative emotions (competence)	• Body changes ^a
	• Restructuring of social environment (autonomy)	• Credible source ^a
	• Verbal persuasion about capability (relatedness)	
	• <i>Behavioural Contract</i>	
	• <i>Social comparison</i>	
	• <i>Information about others' approval</i>	

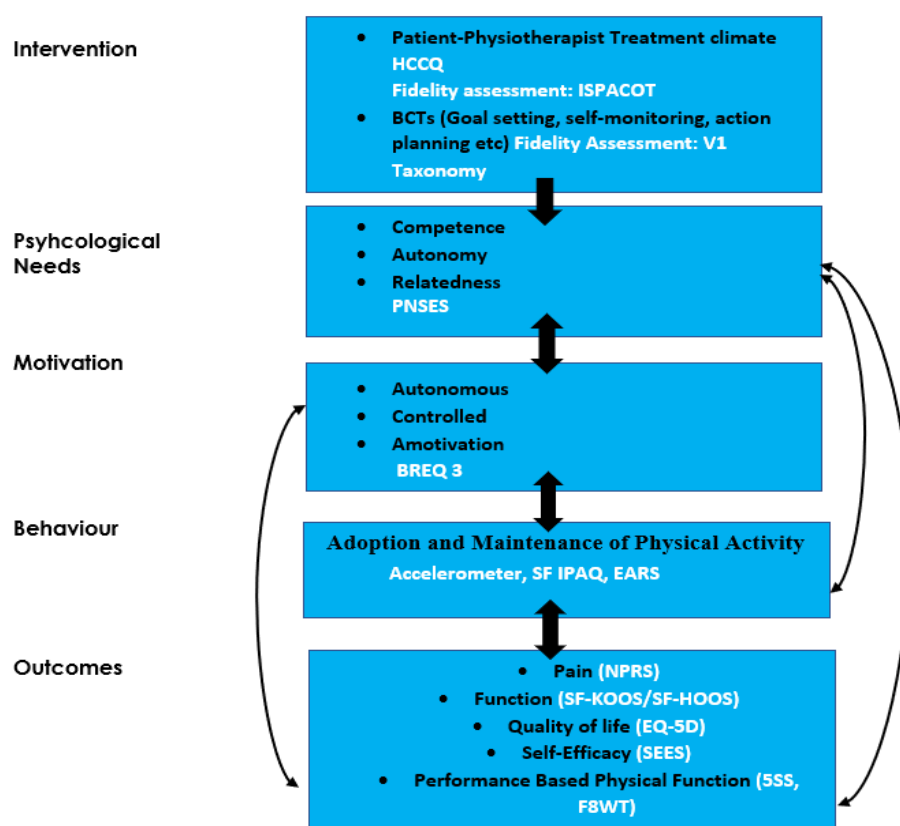
Legend: BCT: Behaviour Change Technique; SDT: Self-Determination Theory; BCTs in standard type are core BCTs mapped to SDT constructs; BCTs in italics not linked to any SDT construct (optional BCTs): *Pharmacological support not linked to any SDT construct but included as anticipated to be important to some participants (those of lower function and greater pain) based on semi-structured interviews. ^a: denotes associated BCT occurrences naturally from delivering the intervention as planned

5.3.4 Objective 4: Proposed interventions theoretical Model

Figure 5.4 outlines the intervention's proposed process model of behaviour change as underpinned by SDT. It is hypothesised that exchanges with patients and the delivery of the BCTs in a more empowering way will support the satisfaction of patients' psychological needs of autonomy, relatedness, and competence which will, in turn, positively impact upon their autonomous motivation for PA to facilitate the adoption and maintenance of PA. The adoption and maintenance of PA are hypothesised to reduce patients' pain levels and positively impact function, as well as psychosocial outcomes

including self-efficacy for PA. The model also accounts for the direct interplay between the psychological needs and PA behaviour and life-style outcomes, such as quality of life, and between the types of motivation and patient outcomes (Note: If the intervention is deemed feasible to deliver and progression to a definitive trial is indicated, the process model will be refined as needed, and the additional outcomes evaluated).

Figure 5.4: Proposed model of behaviour change undergirding the intervention



Legend: Outcome measure in white text; HCCQ: Health Care Climate Questionnaire 15-items; ISPACOT: The Interpersonal Support in Physical Activity Consultations Observational Tool; PNSES: Psychological Need Satisfaction in Exercise Scale; BREQ-2: Behavioural Regulation in Exercise Questionnaire-2; Short-Form (7-questions) International Physical Activity Questionnaire; The Exercise Adherence Rating Scale (6 Items) Questionnaire; NPRS: 11-point Numerical Pain Rating Scale; SF-HOOS: Short form Hip Disability and Osteoarthritis Outcome Score (SF-HOOS); SF-KOOS: Short-Form Knee Injury and Osteoarthritis Outcome Score; EQ-5D: EuroQol 5-domain instrument; SEES: Self-Efficacy for Exercise Scale; 5SS: five times sit-stand test; F8WT: Figure of 8 walking test

5.4 Discussion

Aligned with MRC guidelines (176, 177), this chapter outlines the latter stages of the initial development of a complex, multi-component theoretically-grounded behaviour change physiotherapy intervention targeting the adoption and maintenance of physical activity in patients with lower-limb osteoarthritis (114, 176, 177). It progresses the literature by providing an in-depth explanation of key decisions made including:

- The identification of a TOBC to underpin delivery and physiotherapist training.
- Prioritised intervention BCTs
- Clarification of the intervention's theoretical model

The feasibility of intervention delivery, including the acceptability of the training programme and fidelity review of delivery of BCTs and creation of the motivational treatment environment, will now be tested in an NHS physiotherapy outpatient department.

When developing complex interventions, TsOBC are commonly chosen based on preference or popularity (365, 378). Furthermore, most behaviour change interventions do not explicitly link BCTs to their targeted constructs (322), leaving empirical decisions of TOBC choice underdeveloped (430) and thus making it difficult to subsequently revise and refine. The foundation qualitative work with patients (Chapter 3) helped to conceptualise the theoretical model of behaviour change and propose this to physiotherapists working clinically. Therefore, the identification of TOBC was determined by conceptual fit and alignment with what was gleaned from interviews of

patients with lower-limb OA and developed with input from PPI, and not biased by initial thinking or preferences.

During the full text review of TsOBC, it became apparent that most theories conceptualisation of motivation did not match the proposed intervention's conceptual model (343). Of particular note were the constructs 'intentions' (396, 402, 406, 413, 417, 418) and 'commitment' (394), which functioned as a quantitative product from the interaction between other constructs or as a direct synonym for motivation (418) in several models. 'Intention' focuses on conscious action directing a person's will power (286). However, in agreement with other qualitative studies, the interviews with patients (Chapter 3) (343) suggested that motivation quality was at least as important as how much motivation they had at any point in time (quantity). Interviewed patients with lower-limb OA (Chapter 3) had diverse reasons for engaging (or not) with PA including:

- Enjoyment of doing physical activity (intrinsic motivation) (288, 290, 294)
- Personally identifying as 'physically active' (integrated regulation)
- Wanting to avoid losing function (292, 297, 326) and/or moderation of arthritic symptoms (identified regulation) (293, 297)
- Having a sense of personal responsibility or guilt at not doing the exercises (introjected regulation) (289, 294, 296, 326).
- The perceived approval of the physiotherapist (external regulation).
- Being too lazy or uninterested in PA (amotivation).

The theories that most clearly agreed conceptually with the proposed intervention's model included the HBIM (383), SDT (384, 385, 386), and TCM (387). As such, they were included in the scoping search of secondary factors.

Although the use of behaviour change theory is encouraged by the MRC (114, 176), there is little guidance on the most appropriate way to choose a theoretical framework to underpin intervention development and delivery (176). A recent systematic overview identified eight overlapping methodological approaches to complex intervention development (431): *Partnership, Theory and evidence based, Target population, Implementation based, Efficiency based, Stepped/phased, Intervention specific and Combination* (431). Although overlapping with several of these approaches, the development of the intervention would be most closely linked with the 'Theory and evidence-based' methods.

Further prominent examples of published intervention development frameworks which utilise the Theory and evidence-based approach (431) include the Behaviour Change Wheel (BCW) (372) and Intervention Mapping (IM) (373). However, no evidence exists to suggest whether a specific approach is superior for intervention development (178). Although the intervention development followed the flexible MRC guidance (114, 176, 177), the iterative studies significantly overlap with several steps of both the IM and BCW approaches. For example, the qualitative work highlighted patients' and physiotherapists' needs in relation to overcoming PA barriers and resources for intervention delivery which corresponds to stage 1 of IM (logic model of the problem) (373). Similarly, the intervention development utilised the TDF (286) to identify key determinants of PA behaviours to target within the intervention (Stage 4a of the BCW).

Interestingly, one prominent TOBC, the COM-B (Capability-Opportunity-Motivation-Behaviour) (432) is integrated with the BCW and has been widely utilised to develop recent physiotherapy PA interventions (433, 434). While the COM-B was discussed at length when finalising selection, the motivation construct within the model (reflective and automatic), and how assessed, focuses on facilitators of behaviours but not *why* one engages in the behaviour. Moreover, the COM-B conceptualisation still appeared primarily quantitative (i.e., considering how much motivation one might have). Therefore, it was not chosen for the intervention.

To the authors' knowledge, this is the first time that an explicit screening and full text review of the models of available TsOBC to identify a candidate theory has been conducted. Although this approach aimed to be exhaustive, the identification of the underpinning theory and core constructs involved several subjective decisions that were based on limited qualitative findings (semi structured interviews with 13 patients with lower-limb OA). This personal bias was somewhat mitigated by using two independent researchers to review the description and conceptual model of each theory, meeting to discuss the most appropriate fit with the proposed intervention, and disagreements being mediated by a third party.

After selecting SDT, several associated training programmes (e.g. the '5A's' (435)) previously utilised in physiotherapy trials (436) were reviewed. The final decision to implement the *Empowering Coaching* training programme (as tailored for physiotherapists/health care providers; i.e. *Empowering Physio™*) to train physiotherapists was primarily based on its' theoretical foundations (SDT and AGT). This programme was also selected as it focused on developing participants' more

comprehensive understanding of key aspects of interpersonal relationships and social environment (treatment climate). However, programme choice was also influenced by practicality as the developer (JD), is a core member of the study team and an internationally recognised expert in motivational processes. Therefore, some preference based on experience and access existed when finalising the choice of theory.

To address any bias in the multi-component training programme, the theoretical foundations of the interventions development and the *Empowering PhysioTM* programme, including their conceptual models, will be presented to physiotherapists for challenge and feedback. The training programme will be further assessed during the planned feasibility trial by determining its' acceptability to intervention physiotherapists in a qualitative study and evaluating the fidelity of intervention delivery (BCTs and treatment climate created).

In agreement with previous literature (428, 437), some inconsistencies were found when mapping BCTs across taxonomies. For example, all but one BCT from the proposed intervention's recurring (pharmacological support) and adoption phases (those related to rewards) were selected as 'core' techniques. This contrasts with the routine formation (two core and three optional) and maintenance (three core and five optional) phase BCTs. As such, these results of the mapping process may highlight the lack of clarity of the behaviour change processes that occur after adoption (155).

In the final intervention, fifteen core BCTs target competence, five are assumed to influence autonomy, and three are expected to impact relatedness (some BCTs theoretically influence more than one construct). These findings potentially reinforce the importance of feelings of competence/self-efficacy in people with lower-limb OA as they

move through the behaviour change process. However, the constructs targeted by the intervention BCTs do not fit seamlessly with the behaviour change process as outlined by SDT (267). For example, two relatedness BCTs are included in the recurring grouping and one in the maintenance phase, respectively. Relatedness is thought to be most essential during behavioural adoption (438). Therefore, physiotherapy training will encourage physiotherapists to utilise the recurring relatedness BCTs [(Social support (unspecified) and Social support (practical))] frequently during adoption. Alternatively, four of five autonomy BCTs were included in the adoption phase. However, autonomy potentially most useful during maintenance to help internalise behaviours (267, 438). These issues may further highlight underdeveloped insight into how to utilise BCTs to target SDT constructs.

A challenge with delivery of the complex, multi-component intervention will be to ensure that it continues to utilise the evolving evidence identifying BCTs and their target constructs. For example, the TDF (286, 375) which was used to build the proposed intervention, has largely been succeeded by the 'Theory and Techniques Tool' (322, 323), available at: <https://theoryandtechniquetool.humanbehaviourchange.org/tool> . One of the new mechanisms of action included in the tool is 'motivation' (defined as 'Processes relating to the impetus that gives purpose or direction to behaviour and operates at a conscious or unconscious level') which perhaps demonstrates the importance and evolution in understanding of this concept.

5.5 Conclusion

This chapter outlines the latter stages of development of a complex, multi-component theoretically informed behaviour change physiotherapy intervention targeting adoption and maintenance of physical activity in patients with lower-limb osteoarthritis. The intervention has followed MRC guidelines by synthesising systematic review findings with perspectives of key stakeholders to guide selection of a TOBC to underpin physiotherapist training and intervention delivery and prioritisation of BCTs. A feasibility trial will now evaluate the intervention's delivery in an NHS physiotherapists' outpatient department. Specific areas of evaluation within the trial related to this chapter will include:

- Evaluating the feasibility and acceptability of the multi-component behaviour change intervention to patients and physiotherapists.
- Evaluating the acceptability of the *Empowering Physio* training programme to physiotherapists
- Measuring fidelity of intervention delivery (the treatment climate developed and BCTs delivered) by treating physiotherapists.

CHAPTER 6: FEASIBILITY AND ACCEPTABILITY OF A THEORETICALLY GROUNDED, MULTICOMPONENT, PHYSIOTHERAPY INTERVENTION AIMING TO PROMOTE AUTONOMOUS MOTIVATION TO ADOPT AND MAINTAIN PHYSICAL ACTIVITY IN PATIENTS WITH LOWER-LIMB OSTEOARTHRITIS

Chapter overview

This chapter builds upon chapters 2-5 by detailing the objectives, method and results of a single-arm feasibility trial. The trial aimed to determine the feasibility and acceptability of a complex multi-component physiotherapy behaviour change intervention centred on the promotion of PA adoption and maintenance in patients with lower-limb OA (Thesis Objective 5). The trial findings are presented in-line with success criteria that were agreed a priori. 36 patients with lower-limb OA were recruited, meeting the progression criteria. The intervention and training programme were acceptable to patients with lower-limb OA and delivering physiotherapists. Loss of follow up outcome data at 6-m (33% captured) did not meet progression criteria. Patients with lower-limb OA felt that accelerometers should be wrist-worn, and performance-based tests should be conducted in person. In person outcome assessment was suggested by all research staff. The feasibility of conducting a two-arm parallel definitive randomised controlled trial is discussed.

Sections of this chapter are taken verbatim from publications for which I am the primary author. The first half of the chapter outlines the intervention protocol. This has been modified by use of the past tense, with methodological aspects expanded to reflect changes that occurred during trial conduct.

Willett, M. Rushton, A. Stephens, G. Fenton, S. Rich, S. Greig, C. Duda, J. Feasibility of a theoretically grounded, multicomponent, physiotherapy intervention aiming to promote autonomous motivation to adopt and maintain physical activity in patients with lower-limb osteoarthritis: protocol for a single-arm trial. *Pilot Feasibility Stud.* 2023;9(1):54 (Appendix 1.5).

Key trial roles and responsibilities

Name (initials)	Role in trial
Matthew Willett (MW)	Lead researcher; PhD student; Trial administration and coordination; Ethics application; Physiotherapy training; qualitative data collection; qualitative data analysis; quantitative data analysis; Data integration; Trial Steering Group; Trial Management Group
Joan Duda (JD)	Chief Investigator; Supervisory team, Trial Steering Group; Trial Management Group; Physiotherapy training; Ethics application; Critical feedback on workbooks, trial protocol and write up
Alison Rushton (AR)	Supervisory team; Trial Steering Group; Trial Management Group; Critical feedback on trial protocol and write up
Carolyn Greig (CG)	Supervisory team; Trial Management Group; Critical feedback on trial protocol and write up
Eric Deeson (ED)	Patient and Public Involvement; Trial Steering Group; Trial Management Group; Critical feedback on trial Outcomes, Ethics application, Intervention materials and data analysis.
Gareth Stephens (GS)	Lead researcher (Royal Orthopaedic Hospital); Trial Steering Group; Trial Management Group.
Sarah Rich (SR)	Data controller; Trial administration and coordination.
Sally Fenton (SF)	Trial Management Group; Data analysis accelerometers
Jet Veldhuijzen van Zanten (JV)	Chair: Trial Steering Group
Aiden Chantry (AC)	Fidelity analysis: Treatment climate
Manasi Pimple (MP)	Fidelity analysis: Behaviour change techniques
Aishwarya Jalgaonkar (AJ)	Qualitative Analysis
Purvi Ganguli (PG).	Qualitative analysis
Research nurses	Screening, approach and consent of participants (during trial and for qualitative study); Outcome assessment

6.1 Background

Osteoarthritis (OA) is the leading cause of disability for elderly adults (273) and a significant socioeconomic burden (335) which is anticipated to continue to increase (12) and engulf global healthcare systems within ten years (13). Lower-limb (hip and knee) OA is of primary concern, with over 300 million global cases reported, which represents an increase of over nine percent from figures detailed in 1990 (439). In the United Kingdom (UK), approximately one-in-three people over 45 years, equating to 6.6 million individuals, experience lower-limb OA symptoms (273).

Strategies to promote physical activity (PA), including planned exercises and lifestyle activities (188), are fundamental aspects of non-pharmacological interventions to help patients reduce pain and optimise function in several international OA guidelines (1, 3, 273, 337). Physiotherapists are specialists in the assessment and management of musculoskeletal conditions and the primary healthcare provider of PA interventions within the National Health Service (NHS) in the UK (282). However, physiotherapy PA interventions help patients with lower-limb OA to moderate their clinical symptoms only over short time periods ($\leq$ three months post baseline) with symptom recurrence about six months post-baseline (25, 277). Therefore, patients with lower-limb OA may seek further treatment, which places additional strain on the healthcare services. Clinical symptom regression and subsequent re-referral are likely associated with difficulties that patients with lower-limb OA experience when maintaining their prescribed PA behaviours post-discharge (175).

The Medical Research Council (MRC) (114) recommends that behaviour change theory should be utilised when developing complex interventions. Using theory enables

hypothesised specific behavioural determinants (e.g. self-efficacy for PA) to be targeted by the intervention treatment techniques [i.e. behaviour change techniques (BCTs)] (121). Therefore, the interventional active ingredients can be modified over time, leading to potential increased clinical effectiveness on the target behaviour (121). However, there is a lack of theoretically-grounded behaviour change interventions tested on patients with musculoskeletal pain (121).

Researchers postulate that individuals undergo several 'phases' of behaviour change when incorporating new behaviours into their lifestyle, with the most important phases for intervention delivery being *adoption/initiation* and *maintenance* (155). In regard to the promotion of PA by physiotherapists, it was assumed that patients would be *adopting* new or more extensive PA behaviours while receiving physiotherapy treatment and *maintenance* was manifested and hopefully ongoing post-discharge. While it is likely that several BCTs are consistently relevant to the behaviour change process overall, others are more pertinent to either the adoption or maintenance of PA phase (340).

Randomised controlled trials (RCTs) are considered the gold standard procedure to evaluate the clinical effectiveness of an intervention. However, due to the complex processes and costs that occur when delivering and evaluating behaviour change interventions, robust scoping work prior to a definitive RCT is essential (440). Feasibility trials are advocated to test implementation of the intervention procedures (441) and trial design (440), thus informing whether a full scale RCT is warranted (347).

To date, one theoretical physiotherapy behaviour change feasibility trial has been undertaken on patients with lower-limb OA. Hurley et al., (2020) (350) evaluated the

feasibility and acceptability of a complex group intervention that aimed to promote self-management behaviours in patients with musculoskeletal pain. Although the intervention was found to be highly acceptable, eligible participants preferred to be managed individually (i.e. one-to-one). Low recruitment rates and delays in commencing the group intervention led to a full-scale trial considered unfeasible to deliver (350). Patients and physiotherapists have highlighted that it is problematic to personalise group based treatment that are conducted within the current NHS appointment times (442). Furthermore, physiotherapists most commonly treat patients with lower-limb OA 1-to-1 in clinical practice (202) and this more individualised delivery maybe more effective than group classes at aiding patients' self-management of their levels of pain and function (182). To address the limitations associated with group based treatment, an individually delivered, complex, multi-component theoretical behaviour change physiotherapy intervention was developed. Briefly, the intervention and the principal component of the associated training programme (*Empowering Physio™*) were underpinned primarily by Self-Determination Theory (SDT) which focuses on the underlying reasons for individuals' behavioural engagement, their antecedents, and potential consequences (443). The overarching aim of the intervention was to create a more motivationally empowering treatment climate to enable physiotherapists to implement BCTs to promote PA adoption and maintenance in patients with lower-limb OA.

Aim

The trial had two primary aims:

- 1) To investigate the feasibility and acceptability of a complex, multi-component theoretical behaviour change physiotherapy intervention in the view of patients with lower limb OA and treating physiotherapists.
- 2) To evaluate the feasibility and acceptability of trial related procedures (e.g. recruitment, outcome assessment) to participants and research related staff.

Objectives

Intervention Feasibility and Acceptability

- 1.1: To determine the feasibility (1.1a) and acceptability (1.1b) of the complex and multi-component behaviour change intervention to participants and treating physiotherapists.
- 1.2: To determine the acceptability of the bespoke *Empowering Physio* training programme and instruction of intervention BCTs to treating physiotherapists
- 1.3: To evaluate fidelity of intervention delivery by treating physiotherapists (reported in Chapter 7)

Trial feasibility and acceptability

- 2.1: To measure the recruitment rates of participants
- 2.2: To measure the completeness of data collection of performance based and patient reported outcome measures at baseline, three and six-months post-baseline.

- 2.3: To determine the feasibility (2.3a) and acceptability (2.3b) of trial related procedures (recruitment, outcome assessment) to participants and research staff (data controller and research nurses)
- 2.4: To determine the feasibility (2.4a) and acceptability (2.4b) of utilising an accelerometer as the primary outcome in a definitive randomised controlled trial
- 2.5: To determine the acceptability of the patient reported and performance-based outcome measures to participants.

6.2 Methods

6.2.1 Ethics

The trial protocol received a favourable ethical approval from the Health Research Authority via the Integrated Research Application System (IRAS number: 303710). This ensured that the trial was conducted following best practice ethical guidelines. It followed guidance from the Research Governance Framework for Health and Social Care and complied with the Data Protection Act 2018. If a person withdrew, data collected up to the point of withdrawal was used in the analysis unless the participants specifically withdrew consent for this.

6.2.2 Trial Design

The trial utilised a single-centre mixed-methods feasibility design including a quantitative prospective, single-arm feasibility trial with a six-month follow up (440, 444)

and a qualitative component to provide an in-depth examination of the intervention's feasibility and acceptability (347) in the view of participants, physiotherapists and research staff. Six-months was the planned primary end point of the anticipated future definitive RCT. This is based on the generally accepted definition of behavioural maintenance in the literature (278), and large drop off in reported clinical effectiveness on PA behaviours (277) around this time point.

The trial was registered with the International Standard Randomised Controlled Trial Number (ISRCTN) database (Trial ID: ISRCTN12002764) and follows Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) guideline (445). The trial was reported in accordance with the CONSORT Statement for Pilot and Feasibility studies (446) and the COnsolidated criteria for REporting Qualitative research (COREQ) guidelines for quantitative and qualitative components, respectively (301). Appendix 6.1 outlines the schedule of enrolment, intervention, and assessments respectively.

6.2.3 Trial setting and participant eligibility criteria

Patients referred for physiotherapy treatment of their hip or knee OA symptoms at the Royal Orthopaedic Hospital (ROH), Birmingham, were invited to participate (please see Table 6.1 for eligibility criteria). All intervention procedures took place in the ROH physiotherapy clinics or virtually via phone (based on patient preference). Ongoing PA was undertaken by patients with lower-limb OA in their own home or the community.

Alteration to trial protocol: The original trial protocol specified that the 'Attend Anywhere', the secure NHS video call service would be available for virtual

appointments. However, the trust discontinued this service early in the trial to encourage in person appointments. Therefore, virtual appointments were conducted via phone.

Table 6.1 Trial Eligibility Criteria

Inclusion Criteria Diagnosis of unilateral or bilateral lower-limb OA based on the NICE guidelines:(273) Males or Females ≥ 45 years old and • Morning Joint related stiffness lasting ≤ 30 minutes or no morning joint related stiffness and • Activity related joint pain Exclusion Criteria • A further joint related pathology that could affect the biomechanics of the hip or knee e.g. rheumatoid arthritis or lumbar nerve root lesion • Previously had or awaiting knee or hip joint replacement • Wheelchair dependent • Unwilling/Unable to give informed consent for treatment • Unable to communicate fluently in English • Diagnosed with a psychiatric illness (e.g. schizophrenia) • Diagnosed with an upper motor neurone lesion e.g. Multiple Sclerosis • Unwilling/unable to attend physiotherapy sessions

6.2.4 Participant identification and consent

Feasibility Trial

Potential participants were identified from the physiotherapy waiting lists at the ROH by a research nurse or data controller (SR). If the patient appeared to meet the eligibility criteria, they were sent a Participant Information Sheet (PIS) and trial consent form via post. Each potential participant was phoned by a research nurse a minimum of one week later. Potential participants were asked if they had reviewed the PIS and if they were interested in trial participation. If they reported being interested, the research

nurse confirmed eligibility, outlined the trial, and answered any outstanding questions. Consent was taken by the research nurse during the phone call and witnessed by another ROH staff member. During the meeting, the research nurse reiterated that participants were free to withdraw from the trial at any time, and that this would not impact on their current or future healthcare (447).

Semi-structured interviews with participants, physiotherapists, and research staff

A purposive sample of participants who underwent the physiotherapy intervention (anticipated n=8-10) were invited to attend individual semi-structured interviews. Participation in the semi-structured interviews was discussed at the three-month post-baseline assessment with the research nurse and consent was gained in the same manner as for the main trial. If the participant consented to having an interview, the lead researcher (MW) contacted the participant approximately 1 week later. Interviews were offered either in person at the ROH, by telephone, or skype/zoom depending on the participant's preference and were scheduled as close to the end of their treatment sessions as convenient for the participant.

All physiotherapists who delivered intervention and trial research staff team were invited to attend semi-structured interviews. The participating physiotherapists and research staff were approached by the site lead researcher (GS), an Advanced Physiotherapy Practitioner within the ROH. MW did not know any participants prior to the study commencing.

Prior to the interviews, all interviewees were given the opportunity to ask any questions, and the PIS was reviewed in real time. MW conducted all semi-structured interviews and established informed consent prior. MW is experienced in clinical practice, establishing consent (has in-date GCP training), and conducting and analysing qualitative data obtained from semi-structured interviews. Interviews were not repeated.

Alteration to trial protocol: The original trial protocol outlined that intervention physiotherapists and research staff were to be invited to focus groups to discuss their perceptions of the trial processes/intervention. However, during the trial, there was a high turnover of staff. To maximise data available, the protocol was modified to enable physiotherapists and research staff to choose between semi-structured interviews and focus groups. All physiotherapists and research staff chose to undertake semi-structured interviews.

6.2.5 Multi-component behaviour change intervention

The complex, multi-component theoretical behaviour change intervention was developed iteratively through several interconnecting projects including:

- A systematic review that identified the most effective BCTs used in physiotherapy interventions to promote PA adherence in patients with lower-limb OA (277, 374).
- Semi-structured interviews with patients with lower-limb OA (343, 448).
- Focus groups with outpatient physiotherapists.

- A scoping review and mapping exercise to identify appropriate theories of behaviour change to underpin the intervention delivery and physiotherapy training.

The resulting intervention, which is primarily underpinned by Self-Determination Theory (SDT), has the overarching aim of promoting the creation of a more motivationally empowering treatment climate and to implement particular BCTs to support patients with lower-limb OA to adopt and maintain appropriate individual levels of PA. Briefly, SDT outlines three universal psychological needs (competence, relatedness, and autonomy) which influence the quality of an individual's motivation (i.e., how self-determined that motivation is) (422). An individual's competence relates to their ability to effectively do the behaviour; autonomy refers to whether the engagement is voluntary and the degree of agency that an individual has with regards to the behaviour; relatedness involves feelings of being associated and optimally supported by others in regard to the behaviour (443). SDT postulates that fulfilment of the three psychological needs leads to more autonomous forms of motivation and facilitates behaviour adoption and maintenance and well-being (368). A primarily SDT based training programme *Empowering Coaching* (424, 425), which was adapted for delivery to physiotherapists (i.e., the bespoke *Empowering Physio* training), was selected to guide the training of the trial physiotherapists in regard to the motivational aspects of the intervention delivery. A brief overview of the sequential development of the intervention and associated training programme is outlined in Appendix 6.2.

6.2.6 Intervention materials and associated behaviour change techniques

Support material was utilised to assist delivery of intervention BCTs. Participants were given two paper-based workbooks. The first workbook (please see Appendix 6.4) targeted facilitating PA adoption by encouraging the patient to reflect on their PA preferences to identify appropriate patient centred PA goals ('Goal setting'; 'Review behaviour goals') and included a weekly activity planner ('Action planner'). Each participant was given a Yamax pedometer (Tokyo, Japan) to keep, that acted as a self-monitoring device ('Self-monitoring of behaviour'; 'Feedback of behaviour') and as a thanks for participation.

Participants were given the second workbook in session 4 (Appendix 6.5). This workbook aided participants to identify necessary modifications to their physical and/or social environment ('Problem solving'; 'Restructuring of the social environment') to help develop a PA routine and then maintain these behaviours ('Habit formation'; 'Generalisation of the target behaviour'). A detailed list of local PA services and supports was also included ['Social support (practical)']. Each workbook was written using needs supportive language to aid participants' feelings of competence, autonomy, and relatedness towards establishing PA as a lifestyle behaviour.

The trial specific workbooks were supported by the *Versus Arthritis* information booklets on knee or hip OA which outline general information on OA epidemiology, pathophysiology, management strategies (exercise and medication) and appropriate support services ('Information on health consequences'; 'Information on social and environmental consequences'). An outline of the intervention materials, their intended sequencing and associated BCTs is outlined in Table 6.2. The adoption and

maintenance workbooks were drafted by MW. They were reviewed by JD (PhD in psychology and subject specific expertise) for use of autonomy supportive language and ED (PPI representative) for readability and relevance to patients with lower-limb OA. ED also reviewed and offered critical feedback on the pictures included in the workbooks and the Versus Arthritis booklet. The use of manual therapy techniques and supportive braces/walking devices was incorporated into the intervention at the discretion of the treating physiotherapist (273). Participants were asked to not seek any additional treatments for their OA symptoms for the duration of the trial and to maintain their standard medications. Any co-interventions or adverse events were recorded in the assessment appointments with the research nurses.

6.2.7 Intervention Delivery

Participants attended individual intervention sessions (approximately six based on patient preference reflected in previous work related to the intervention development (300) and the standard number of physiotherapy sessions offered by the ROH) with the trained physiotherapists. Appointment frequency depended on participant availability and related PA goals and the physiotherapist clinical schedule.

Alteration to trial protocol: At the beginning of the trial, initial physiotherapy sessions were 45-minutes and follow ups were 30-minutes. However, after four months of the trial, session lengths reverted to pre-pandemic timings of 40-minute initial sessions and 20-minute follow ups.

Table 6.2: Intervention materials delivered across sessions and outline of content with associated theoretical constructs and behaviour change techniques

Session numbers	Intervention Material	Intervention Content	SDT constructs Targeted	Associated Behaviour Change Techniques
1-2	Activity Adoption Workbook	Aims of physiotherapy Information on benefits of PA Exercises to identify patient centred PA goals Activity Diary	Autonomy, Competence	• Goal Setting (behaviour and outcome) • Problem solving • Review behaviour goals (and/or outcome) • Action planning • Self-monitoring of behaviour (and/or outcomes of behaviour)
	Pedometer	Pedometer to self-monitor number of steps	Autonomy, Competence	• Self-monitoring of behaviour (and/or outcomes of behaviour) • Feedback on behaviour (and/or outcomes)
	Versus Arthritis Book: Osteoarthritis of the Knee/Hip General Information	Epidemiology of OA Pathophysiology of OA General treatment strategies		• Information on health consequences of performing the behaviour • Information on social and environmental consequences • Modelling/demonstration of behaviour
3-4	Routine Formation and Maintenance Booklet	Problem solving exercises to identify barriers and solutions to physical and social environment as needed to maintain PA. Detail of local physical activity resources and support	Competence Autonomy Relatedness	• Problem Solving • Social Support (practical) • Habit formation • Generalisation of a target behaviour • Restructuring of the social environment
Any	Theraband	Resistance band to enhance or make prescribed exercises more difficult	Autonomy, Competence	• Prompts and Cues • Habit formation • Adding objects to the environment

Legend: SDT: Self -Determination Theory

6.2.8 Physiotherapist training

Trial physiotherapists (n=5) undertook 11 hours of training in intervention delivery which was via 3 x 3-hour sessions one week apart, and a further 2-hour 'top-up' session about four weeks later. The training programme comprised four components which are summarised in Table 6.3 and expanded upon in Appendix 6.3. Initially, the interventions rationale and development were outlined and physiotherapists received printed and electronic versions of the training handbook (Appendix 6.6) that included BCT definitions and clinical examples, and key research articles relevant the intervention (component 1; scheduled for 1 hour). The bespoke *Empowering Physio*TM training programme (component 2; scheduled for 5 hours) aimed to enhance physiotherapists' understanding of differences in the quality of patient motivation (and implications), and awareness of the treatment climate they create and how it can influence patients' psychological needs of competence, autonomy, relatedness and their subsequent autonomous motivation to adopt and maintain their PA goals. The training involved presentations and interactive exercises to convey why, when, and how physiotherapists interact with, and provide feedback to, patients may influence their levels of controlled and autonomous motivation to engage in PA. TProtocol BCTs (component 3; scheduled for 3 hours) across PA adoption, routine formation, and/or maintenance, including their theoretical background were presented and example videos detailing their delivery were shown for interactive discussion. Finally, the Top-up training (component 4; scheduled for 2 hours) focused on collaboratively discussion of any issues encountered by physiotherapists when delivering the initial intervention sessions and reviewing initial content that physiotherapists found unclear.

Training was delivered by two members of the research team; Professor Joan Duda (JD), the developer of the *Empowering Coaching/Empowering Physio* programme who possesses a PhD in social/sport and exercise psychology and is an internationally renowned expert in motivational processes and MW, whose PhD focused on the development of the intervention. JD led the delivery of the *Empowering Physio* training component and MW led components 1,3 and 4 respectively.

Alteration to trial protocol: the Empowering Physio™ training was scheduled for 5 hours. However, during training, physiotherapists naturally engaged with the Empowering Physio™ exercises, and the associated discussions that developed elongated this component to approximately 7 hours. Consequently, BCT delivery, especially discussion in how to deliver BCTs in a more motivationally empowering way, received less time than originally scheduled (2 hours as opposed to the intended 3 hours). No pre-training measures of physiotherapists knowledge or competence to deliver BCTs or to create an empowering treatment climate were recorded.

Table 6.3 Schedule of physiotherapist training in intervention delivery

Component	Duration	Core content
Intervention introduction	1 hour	• Review of NICE OA management guidelines (10) • Justification for, and overview of, intervention development • Detail of intervention phases and behaviour change techniques • Training manual (Appendix 6.6) and key articles given out to physiotherapists.
Empowering Physio™	5 hours	• Presentation of theoretical elements of creating an empowering or disempowering treatment climate based on the conceptual model proposed by Duda (2013) (425) • Interactive discussion, board games, and role-playing exercises to develop awareness of how communication style influences treatment climate.
BCT delivery	3 hours	• Description of protocol BCTs • Videos and discussions of BCT delivery and how to make them more empowering
Top up training	2 hours	• Problem solving discussion focused on early difficulties encountered in intervention delivery and revision of key or requested topics

NICE: National Institute of Health and Care Excellence Legend; OA: Osteoarthritis; BCT: Behaviour Change Technique

6.2.9 Trial Outcomes and Success Criteria

Once data analyses were completed, the overall trial success (i.e. trial related procedures and intervention feasibility and acceptability) was determined by evaluating the results against *a priori* established criteria for success (Table 6.4). The criteria were established by the Trial Management Group (TMG), which included experts in musculoskeletal physiotherapy, ROH physiotherapists and researchers with expertise in trial methodology and behaviour change supported by contemporary literature in

contemporary feasibility trial methodology (449). Each criterion was evaluated against guidance outlined by Thabane et al., 2010 (450) to determine if progression to a definitive trial is recommended. Possible overall outcomes include:

- Stop: A definitive trial is not feasible
- Continue with modification: Modification of the protocol is required to make definitive trial feasible.
- Continue without modification: Modification of the protocol is not required to make definitive trial feasible but requires close monitoring.
- Continue without modifications: A definitive trial appears feasible.

Once it was established if each criterion has been met, further consultation with patient and public involvement (PPI) at Trial Steering Group (TSG) meetings were utilised to determine if, and what, modifications the intervention required to progress to the full-scale RCT (e.g. adaptations to intervention to enable delivery in alternative NHS physiotherapy departments).

6.2.10 Methods of data collection

Patient reported and performance-based outcomes during trial

Participants completed outcome assessment at baseline, three months post-baseline, and six months post-baseline. Baseline outcome assessment appointments were scheduled in person with a research nurse immediately prior to the initial physiotherapy session. Post baseline outcome assessments were anticipated to be conducted remotely in the participants' own homes. However, if participants did not feel confident

about completing their performance-based outcomes at home, they were offered a choice of having their assessments done in person. Outcomes assessed included the use of an accelerometer to measure daily PA, Patient Reported Outcome Measures (PROMs), and performance-based outcomes. Accelerometers and PROMs were posted to participants' home addresses one week prior to outcome assessment appointments. A 150cm tape measure was included for standardisation of one of the performance-based tests (Figure of 8 walking test: Table 6.5) (451). Participants were asked to complete PROMs prior to assessment appointments so the session could be used to collect performance-based outcomes, and the research nurse could answer any questions. A stamped, addressed envelope was included for return of accelerometers (including simple fitting instructions and a belt to secure the accelerometer) and PROMs to the ROH. If accelerometers and PROMs were not returned within 2 weeks of their assessment appointment, participants were contacted via text/telephone by the data controller or research nurse and asked to send them back at their earliest convenience.

The accelerometer was fitted over the right anterior superior iliac spine (452, 453, 454) (research nurse at initial appointment, the participant was self-directed at follow up appointments). Following a standardised and widely used protocol (455), participants were asked to wear accelerometers for 7 consecutive days (456, 457, 458, 459) with removal for sleep or when in water (e.g. swimming or shower) (452, 453, 459, 460). The patient reported and performance-based outcomes assessed, including their rationale is detailed in Table 6.5.

Alteration to trial protocol: The original trial protocol specified that the 'Attend Anywhere', the secure NHS video call service would be available for virtual

assessments. However, the trust discontinued this service early in the trial to encourage in person appointment. Therefore, virtual assessments were conducted via phone.

Collection of qualitative data

MW completed all interviews. As the main aim of the qualitative component of the trial was to gain the in-depth perspectives on the feasibility and acceptability of the trial intervention and associated processes, the epistemological stance was based on phenomenology (299). Questions were initially asked in an open manner with clarification sought if key points were identified. Participants, physiotherapists and research staff were invited to introduce new topics and/or issues. as the discussions progressed. The respective topic guides were developed a priori with questions determined through collaboration of the Trial Steering Group (TSG) which included clinical physiotherapists, researchers with expertise in qualitative research methods and behaviour change, and PPI (461). Demographic detail was recorded to enable description of participants, intervention physiotherapists, and ROH research staff respectively.

Table 6.4 Trial outcomes and success criteria

Aim 1: Intervention Feasibility and Acceptability		
Objective	Method of assessment	Success criteria
Objective 1.1 Intervention Feasibility and Acceptability		
1.1a: Intervention feasibility: To determine the feasibility (1.1a) of the behaviour change intervention to participants and treating physiotherapists	Participants and physiotherapists semi-structured interviews	Continue: Thematic analysis identifies that trial participants and treating physiotherapists believed the intervention feasible to deliver. Stop: Thematic analysis identifies that trial participants and treating physiotherapists do not believe the intervention is feasible to deliver
1.1b: intervention acceptability: To determine the acceptability of the behaviour change intervention to participants and treating physiotherapists	Participants and physiotherapists semi-structured interviews	Continue: Thematic analysis identifies that trial participants and treating physiotherapists were happy with the intervention (i.e. it was feasible and acceptable) in semi-structured interviews. Stop: Thematic analysis suggests that trial participants and treating physiotherapists did not find the intervention acceptable.
1.2 Acceptability of training programme		
To determine the acceptability of the Empowering Coaching training programme (Empowering Physio) to treating physiotherapists	Physiotherapists semi-structured interviews	Continue: Thematic analysis identifies that intervention physiotherapists perceived the training programme developed their understanding and enactment of how to create an empowering treatment climate. Stop: Thematic analysis suggests that intervention physiotherapists perceived that the EC training programme was insufficient to develop their understanding or enactment of how to create an empowering treatment climate
1.3 Intervention fidelity		
To evaluate fidelity of intervention delivery by treating physiotherapists	Two members of the research team assessed transcripts of one intervention session from the adoption, routine formation, and maintenance phases from first and third participants for: 1) Intervention content by Coding of BCTs	Essential pre-specified BCTs were delivered with at least mean 'moderate' levels of fidelity ($\geq 50\%$)(172) Mean score of $\geq 4/7$ on Likert scale when using ISPACOT to evaluate treatment climate(463, 464)

2) Treatment Climate
using the ISPACOT
(462)

Aim 2: Trial feasibility and acceptability

Objective 2.1: Recruitment rates

To measure the recruitment rates of participants

Recording number (n) of participants who were sent a participant information sheet, number who agreed to participate, number recruited per month.

Continue

- Target of n= 35 participants recruited in 9 months (approx. 4 /month).
- Conversion rate of $\geq 30\%$ (number sent PIS/ number who agreed to participate).

Stop

- Target of n= 35 participants recruited takes > 12 months (less than 3/month).
 - Conversion rate of $\leq 15\%$ (number sent PIS/ number who agreed to participate).
-

Objective 2.2: Data collection

To measure the completeness of data collection of performance based and patient reported outcome measures at baseline, three and six-months post-baseline

Record number of PROMs returned to trial team and number of participants who completed performance-based outcomes during outcome assessments at each timepoint.

Continue

- $\leq 80\%$ PROM and performance-based data collected at three-month post baseline
- $\leq 70\%$ PROM and performance-based data collected at six-month post baseline

Stop

- $\leq 50\%$ PROM and performance-based data collected at three-month post baseline
 - $\leq 50\%$ PROM and performance-based data collected at six-month post baseline
-

Objective 2.3: feasibility and acceptability of trial related procedures

2.3a: To determine the feasibility and of trial related procedures (recruitment, outcome assessment) to

Participants and ROH research staff semi-structured interviews

Continue

Thematic analysis identifies that trial participants and ROH research staff were happy (i.e. feasible and acceptable) with trial

participants and ROH research staff

procedures (e.g. recruitment, outcome assessment) in semi-structured interviews and focus groups respectively.

Stop

Thematic analysis identifies that trial participants and ROH research staff do not perceive trial related procedures are feasible to undertake.

Continue

Thematic analysis identifies that trial participants and ROH research staff found trial procedures acceptable.

Stop

Thematic analysis identifies that trial participants and ROH research staff did not find trial procedures acceptable.

2.3b: To determine the acceptability and of trial related procedures (recruitment, outcome assessment) to participants and ROH research staff

Participants and ROH research staff semi-structured interviews

2.4 Feasibility and Acceptability of Accelerometer

2.4a: To determine the feasibility of utilising an accelerometer as the primary outcome in a definitive randomised controlled trial

- % Of accelerometers returned to research staff with valid data
- Participant Semi-structured interviews

- ≤ 70% of accelerometer data collected at six-month post baseline.
- Accelerometer data was considered valid if it has been recorded for ≥ 10 hours (456, 465) for ≥ 4/7 days, with at least one falling on a weekend.(452, 453, 466)
- Participants state that they believe that accelerometer is feasible to use for data collection.

Objective 2.4b: To determine the acceptability of utilising an accelerometer as the primary outcome in a definitive randomised controlled trial.

Participant Semi-structured interviews

Participants state that they believe that accelerometer is acceptable to use for data collection.

2.5 Acceptability of outcome measures

To determine the acceptability of patient reported and performance-based outcome measures to participants

- Participant semi-structured interviews

- Participants report that they found the patient reported and performance-based outcomes acceptable and the time taken to complete was satisfactory for use in a definitive randomised controlled trial.

Legend: ISPACOT: Interpersonal Support in Physical Activity Consultations Observational; (P): Primary feasibility outcome related to progression to definitive trial; (S): Secondary feasibility outcome

Table 6.5 Planned Participant Secondary outcome measures for definitive trial

Outcome Domain	Instrument	Administered at	Rationale
Physical Activity	Short-Form (7-questions) International Physical Activity Questionnaire (467)	Baseline, 3 months, 6 months	Primary aim of physiotherapy intervention. Has demonstrated reliability and validity (467)
Adherence to PA/Exercise recommendations	Section B of The Exercise Adherence Rating Scale (6 Items) (468)	Baseline, 3 months, 6 months post baseline	Primary aim of the physiotherapy intervention. Has demonstrated reliability (468) and validity (469)
Pain	11-point Numerical Pain Rating Scale (311)	Baseline, 3 months, 6 months	Suggested to include as a core outcome domain in international guidelines (311) Shown excellent reliability (470) and suggested as more reliable than a visual analogue scale in patients who are older or less literate patients, and more useful for demonstrating change (471)
Function: Self-report	Short form Hip Disability and Osteoarthritis Out-come Score (SF-HOOS)/ Short-From Knee Injury and Osteoarthritis Outcome Score (SF-KOOS) (311)	Baseline, 3 months, 6 months	Suggested to include as a core outcome domain in international guidelines (311) Have shown good levels of reliability (312, 313)
Function: Performance Based	5 times sit-stand test	Baseline, 3 months, 6 months post baseline	Direct, observable measure of physical function. Has demonstrated excellent validity and reliability when tested in home setting (472)
	Figure of 8 Walking test	Baseline, 3 months, 6 months	Direct, observable measure of physical function. Has demonstrated validity and reliability when tested at home (451)
Bothersomeness	Bothersomeness Index: 5-point Likert scale	Baseline, 3 months, 6 months	Outlined as important outcome domain by Public Involvement representative.
Quality of Life	EuroQol 5-domain instrument (EQ-5D)(311)	Baseline, 3 months, 6 months	A domain recommended by international Guidelines. Has shown good reliability and validity (473)
Self-Efficacy for physical activity/exercise	Self-Efficacy for Exercise Scale 9-items(474)	Baseline, 3 Months, 6 Months	Outlined as an important influence on behaviour change in preliminary work. Measures several aspects of self-efficacy including perceived barriers to exercise (475) Valid and reliable (474)

Motivation Regulations to participate in physical activity/exercise	Behavioural Regulation in Exercise Questionnaire-3 24-Items (476, 477).	Baseline, 3 Months, 6 Months	Motivation was outlined as important influence on behaviour change in preliminary work. Grounded in SDT. Important stage of intervention process model. Valid (476, 478) and reliability (479)
Psychological needs satisfaction	A modified version of the Psychological Need Satisfaction in Exercise Scale (480) (481)	Baseline, 3 Months, 6 Months	Grounded in SDT. Important stage of intervention process model. Valid and reliable (480, 481)
Social psychological environment/ perceptions of autonomy support	Health Care Climate Questionnaire 15-items (482)	3 Months post baseline	Assesses the participants perceptions of the motivational social climate provided in physiotherapy sessions. Grounded in SDT. Important stage of intervention process model. Identified as an important influence on behaviour change in preliminary work. Reliable (482)

6.2.11 Patient and public involvement

All patient facing documents were designed in collaboration with a lay person (ED) with extensive experience in public involvement and a lifetime's work in effective communication. ED was a central member of the of the Trial Management and Steering Groups. They reviewed and offered extensive feedback on all patient facing documents including the patient information sheets, consent forms, semi structured interview forms, intervention content, trial protocol, ethics application, and PROMs.

6.2.12 Trial design and sample size

An important consideration for the Study Steering Group (which included PPI, local physiotherapists, and academics) during trial set up was the choice between using a

single or double arm design. The focus of this body of work thus far had been to develop a complex, theoretically grounded behaviour change intervention with several interacting components. Therefore, the SSG decided the trial's primary focus should be to assess the feasibility and acceptability of the intervention components (e.g. training programme, intervention resources) and trial procedures (e.g. use of accelerometer, remote outcome assessment) (483) and to determine if any modifications were required prior to conducting a definitive RCT.

Several trials have been conducted on patients with lower-limb OA in NHS physiotherapy departments and considerations such as participant willingness to be randomised had largely been established. Furthermore, as the intervention offered a novel treatment which targeted the theoretical determinants of adoption and maintenance of PA, it may have been unethical to withhold treatment (484).

Therefore, a single-arm trial design incorporating a comprehensive mixed-methods assessment was considered an appropriate design to determine the feasibility and acceptability of the intervention and related trial components. Single arm trial design has gained popularity in recent years (484, 485) with several contemporary behavioural trials conducted on elderly patients (486) and those with lower-limb OA (487) using this approach.

To mitigate any disparity between single and double arm trial designs, the planned analyses included using accelerometry findings (anticipated primary outcome measure) from large scale, low risk of bias RCTs (23, 252, 488) to provide surrogate data for the control group in the sample size calculation for the planned definitive trial.

Furthermore, study research nurses were not informed of the overall trial design or primary aims and were therefore considered blinded assessors in the trial.

Although a formal calculation was not completed, total sample sizes of between $n = 24$ to 50 are recommended in feasibility trials and a sample of 30 (440) to 35 (489) is considered sufficient to ensure normal distribution of participants. An audit of the ROH physiotherapy waiting lists suggested that approximately 65 patients with musculoskeletal pain are referred to the ROH each week and that approximately 5% would be eligible to participate in the trial (i.e. three per week). Based on previous trials conducted at the ROH, approximately one in three of those approached consents to participate. Therefore, based on trial resources and timelines, recruitment of a target sample of up to 35 participants over a nine-month period was estimated.

6.2.13 Data Analysis

Quantitative

The primary quantitative data analysis was descriptive (441, 447). A CONSORT diagram (please see results section below) presented the number of participants who were identified, recruited, commenced and finished treatment and the recruitment rate (number/month and number approached/number recruited) was reported as a percentage (490). Where possible, reasons for refusal and dropout during the intervention were recorded and reported. A Shapiro-Wilkes test determined the normality of continuous data (e.g. PROM and accelerometer data) and the mean and 95% confidence intervals was reported for each. The number of non-completed/partially

completed PROMs, performance measures, and accelerometer data at each time-point was expressed as a percentage. Partially completed PROM and accelerometer data were not included in the data analysis but potential reasons, including practicality, were discussed in the interviews. MW conducted the quantitative analysis with assistance from a subject specific expert (SF) when completing the accelerometer data analysis. Findings were presented iteratively to the TSG for feedback and challenge.

Intervention Fidelity

Fidelity assessment of delivery of the intervention included evaluation of two aspects; what was delivered (i.e. the BCTs) and the overall exchange between the physiotherapist and patient (i.e. the motivational treatment climate). Physiotherapists were asked to audio record one session from each of the adoption, routine formation, and maintenance phases from their first and third participants. The specific sessions to be recorded in each intervention phase were randomised. The audio recordings were transcribed verbatim.

What was delivered: Evaluation of Behaviour Change Techniques

Two researchers (MW, MP) coded all transcripts to identify the BCTs delivered. A coding manual (Appendix 6.7) was provided to coders to optimise consistency. It included intervention BCTs definition as per the V1 taxonomy (123), and examples of how the technique may be delivered or described in the intervention. BCTs were coded only once per session and were written as either 1) fully delivered or 2) partially

delivered (491). BCTs that were present but not part of the specific protocol were also noted (376). Coders (re) completed online training for BCT identification using the V1 Taxonomy. One coder (MW) had experience coding BCTs from intervention manuscripts from the original systematic (Chapter 2) (277) and transcribed interviews (Chapter 3). The second coder's training (MP) included identifying BCTs from trials in the original (Chapter 2) and updated (Chapter 8) systematic reviews respectively. The median and interquartile range of each BCTs delivered per session in the adoption, routine formation and maintenance phases were reported respectively. The number of times each BCT was fully delivered compared to when it was outlined in the treatment manual was averaged across physiotherapists and calculated as a percentage. Overall fidelity was categorised as *high* if $\geq 80\%$ of essential BCTs were present, *moderate* if 50-79% were present, and *low* if 0-49% were present (172, 376).

How was it delivered: Evaluation of the Treatment Motivational Climate

Two researchers (MW, AC) used the Interpersonal Support in Physical Activity Consultations Observational Tool (ISPACOT) (462), a 21-item tool that is grounded in SDT, to evaluate the treatment climate of the physiotherapy sessions. The tool assesses four aspects of the motivational climate created: Autonomy Support, Involvement, Structure, and Interpersonal Control and has demonstrated moderate to high levels of inter-rater reliability when assessments were carried out by trained users (462). A 7-point Likert-scale, ranging from 1 'not at all true' to 7 'Very True', was used to determine the degree of need support. The mean Likert scores was calculated for all physiotherapists and reported for the adoption, routine formation, and maintenance

phases, respectively. In line with previous research, scores of $\geq 4/7$ were considered the minimum required to deliver a need supportive treatment climate (463, 464).

Qualitative data analysis

Several steps were taken to enhance data trustworthiness, as proposed by Lincoln and Guba (1985) (492), of the qualitative data analysis (Table 6.6). Although all physiotherapists and research staff were invited to interview, stratified purposive sampling targeted participants with lower-limb OA based on gender (approx. 60-70% female) and joint (60% knee) which were representative of the wider population (8). Participant interviews continued until data saturation was achieved (where no additional themes were identified) and negative cases were actively sought. The interviews were audio recorded and transcribed verbatim. Interviews were not repeated. Transcripts were returned to all interviewees for member checking and any supplementary comments which were highlighted were presented to the TSG, noted and integrated with the main analysis (314). MW took supplementary field notes and kept a reflexive diary during the interviews to enable triangulation during data analysis.

All transcripts were analysed following a six step deductive method as outlined in Braun and Clarke (2006) (316). The initial framework was largely based on the respective topic guides which were in turn informed by the trial objectives. Two researchers (MW plus either AJ or PG) coded the first transcript together to establish a preliminary framework and identify initial themes using NVivo 11 software (QSR International, Melbourne, Australia). A second transcript was coded independently by the same two researchers

(MW plus either AJ or PG) with in-depth meetings to test the initial framework. The remaining transcripts were coded by both researchers, with codes and emerging themes clarified through researcher meeting (approximately every two transcripts). To prioritise themes that influenced the feasibility and acceptability of trial objectives, coders noted perspectives that were frequent, opposing the general consensus, or intensely accentuated by interviewees (493). Barriers and potential solutions that interviewees suggested that could impact on progression to a definitive trial were noted for further discussion. Iterative results from interviews, supported by direct quotations to enable thick description, were presented to the research team and at TSG meetings for feedback and challenge.

Additional Information

Further trial information, including data storage, monitoring of adverse events, and intended dissemination of findings can be viewed in Appendix 6.8.

Table 6.6: Methods utilised to enhance trustworthiness

Trustworthiness Criteria	
Credibility	• Prolonged engagement • Researcher triangulation • Peer discussion • Negative case analysis*
Dependability	• Research audit: Raw data, Audio recordings, field notes, transcription, NVIVO and reflexive journal. • Transparent reporting (COREC)
Confirmability	• Reflexive journal • Reasons for theoretical, methodological, and analytic choices outlined. • Raw data included
Transferability	• Thick description

Lincoln and Guba, 1985

6.3 Results

6.3.1 Participant recruitment and demographic information

Trial recruitment opened on 25/4/2022 after an initial delay of four weeks due to COVID illness in research staff members. 537 people were screened and 191 identified as potentially eligible. The primary reasons for ineligibility included people having previous surgery (n=80), a non-OA articular diagnosis (n=71) or accessing an optional exercise/lifestyle App (n=61). Reasons for ineligibility during screening are summarised in Appendix 6.9. Of those potentially eligible, 152 were sent a PIS (39 potentially eligible did not reach the top of the waiting list prior to recruitment completion). Primary reasons for non-participation from those sent a PIS included: refusal (n=25), not being eligible (n=42), or unable to be contacted (n=44). Further detail on non-participation in those sent a PIS is outlined in Appendix 6.10.

Overall, 36 participants (n=28 females, 8 males) were recruited in 38 weeks. 26 participants had knee OA and 10 had hip OA. The mean age was 61.1 (Standard Deviation 10.97) and the BMI was 29.2 (5.7). Participant baseline demographic profiles can be seen in Table 6.7. The recruitment (number recruited/number of weeks recruitment open) was 0.95 participants per week (3.96 participants per month) and the conversion rate (number agreed to participate/number sent a PIS) was 23.7%.

6.3.2 Participant flow, drop out and data collection.

The identification and flow of participants, including reasons for withdrawal and returned data through the trial, can be viewed in the CONSORT flow diagram in Figure 6.1. 33

patients with lower-limb OA presented for baseline assessments and commenced physiotherapy treatment. At 3 months valid data from 20 accelerometers (56%), 23 PROMS (64%), and 9 physical tests (25%) were recorded. At 6 months valid data from 12 (33%) accelerometers, 14 PROMS (39%) and 10 (28%) physical tests were returned, representing 33% of the maximum total (36/108). Periods of postal strikes during follow-up led to reported widespread loss of mail which influenced the return of PROMs and accelerometers to the trust. The primary reason for invalid physical tests was due to protocol deviations (n=14 at 3 months; n= 10 at 6 months).

In total, 122 intervention sessions were delivered (mean of 3.4 session per participant), 120 face to face and 2 remotely via phone, by 5 physiotherapists (three female; two male). Participants were under physiotherapy treatment for between 1 (i.e. the participant attended only one physiotherapy session) to 37 weeks (participant attended 6 sessions) respectively. Individual physiotherapists treated between 2 (6% of sample) and 10 participants (28% of sample). The physiotherapist who treated two participants left the trust early in the intervention period with the remaining patients spread relatively evenly across the remaining physiotherapists, who each managed between 7-10 participants respectively. Please see Table 6.8 for the demographic features of intervention physiotherapists and the number of participants managed by each

Table 6.9 presents the patient-reported and performance-based outcomes, and accelerometer data at baseline, three-months, and six-months respectively. Normality was calculated for each variable. Mean pain scores demonstrated a gradual decrease from 6.0 at baseline and 4.7 at 6 months. Patients with knee OA demonstrated gradual

functional improvement (SF-KOOS) but those with hip OA demonstrated improvement at 3 months then decline at 6 months (SF-HOOS). Psychological variables remained consistent except for self-efficacy for exercise (decrease) and autonomous motivation (increase) between 3-6 months. IPAQ scores demonstrated considerably less sedentary and greater MVPA than accelerometer recorded data at all time points. Four minor adverse events were reported. However, these were secondary to changes in PA levels and seasons and resolved quickly.

Table 6.7: Trial participant demographic characteristics

Demographic Data (n=36)	
Gender	
Females	28
Males	8
Primary joint effected	
Knee	26
Hip	10
Baseline demographics of those who commenced treatment (n=33)	
Age (years)	61.1 (10.97) *
Height (m)	1.67 (0.09) *
Weight (kg)	82.5 (18.06) *
Body Mass Index	29.20 (5.70)
Marital status	
Married	22
Cohabiting	4
Single	3
Divorced	2
Widowed	1
Prefer not to say	1
Employment status	
Working full time	11
Retired	12
Unemployed	5
Part time	2
Redundant	2
Homemaker	1
Previous experience of physiotherapy	20
Country of Birth	
United Kingdom	30
Pakistan	1
India	2
Age when left education (years)	19.20 (5.68)*
Highest educational award	
Completed Highschool (or equivalent)	11
Undergraduate Degree	8
Diploma	4
GCSE (or equivalent)	3
Apprenticeship/NVQ	3
Prefer not to say/no detail	4

*: reported as mean (Standard Deviation)

Figure 6.1: Trial CONSORT flow diagram

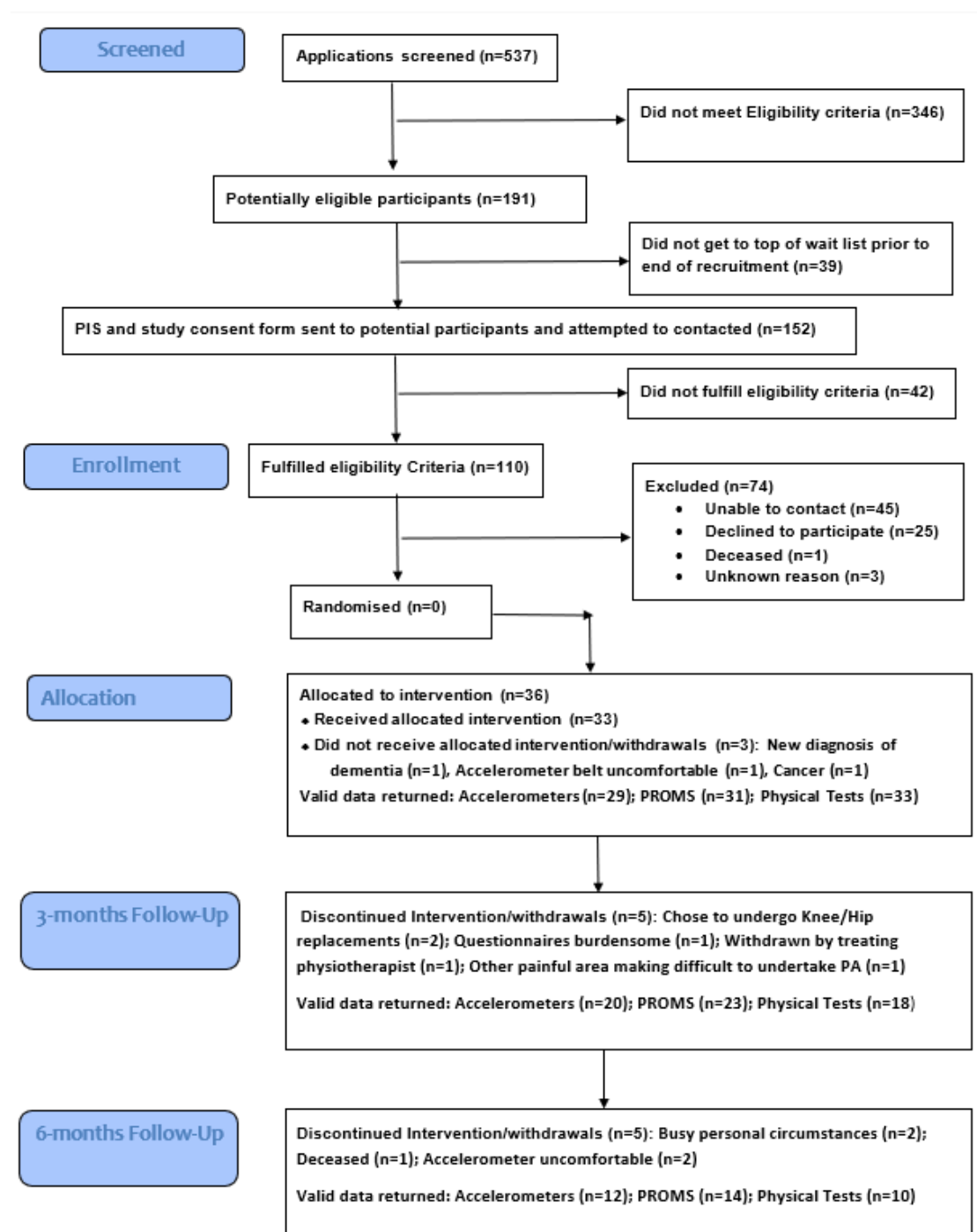


Table 6.8: Intervention physiotherapists demographic features and number of patients managed during the trial

Physiotherapist number	Gender	Age (years)	Years treating OA	Highest Qualification	Number of patients managed (n=36)
1	Male	27	3	MSc	2
2	Male	29	7	Post Graduate Modules	8
3	Female	33	12	Studying for MSc	9
4	Female	42	2	Studying for MSc	10
5	Female	41	7	Post Graduate Modules	7

Legend: OA: Osteoarthritis; Msc: Master of Science; BSc Bachelor of Science;

Table 6.9: Participant Outcome Measures

	Baseline (n=33) Mean (SD)	3 months (n=23) Mean (SD)	6 months (n=14) Mean (SD)
Pain and bothersomeness			
Numerical Pain Rating Scale (0-10)	6.0 (2.3)	5.5 (2.7)	4.7 (2.4)
Bothersomeness (n reported at each level (% of total))			
Not at all	2 (6.5%)	2 (8.7%)	2 (13.3%)
Slightly	5 (16.7%)	8 (34.8%)	4 (30.8%)
Moderately	16 (61.5%)	8 (34.8%)	6 (46.2%)
Very much	6 (29.4%)	3 (13.0%)	1 (7.1%)
Extremely	2 (6.5%)	2 (8.7%)	1 (7.1%)
Function			
5 x Sit-Stand (seconds to complete)	18.2 (6.3)	18.6 (6.1)	16.0 (5.5)
Figure of 8 (seconds to complete)	13.6 (3.5)	14.1 (4.7)	15.2 (6.0)
Short Form Knee Injury and Osteoarthritis Outcome Score (n=22) (0-100)	44.6 (14.3)	37.6 (12.3)	29.5 (23.2)
Short Form Hip Disability and Osteoarthritis outcome score (n=9) (0-100)	52.5 (28.3)	30.8 (12.7)	57.4 (22.2)
Wellbeing characteristics			
EuroQol-5 Dimension Health State (-0.285-1.000)	0.662 (0.209)	0.650 (0.231)	0.777 (0.210)
EuroQol-5 Dimension Visual Analogue Scale (0-100)	67.9 (20.7)	68.0 (24.0)	57.1 (25.8)
Psychological variables			
Self-Efficacy for Exercise Scale (0-90)	58.7 (19.8)	55.0 (20.2)	46.6 (19.3)
Behavioural Regulation in Exercise Questionnaire Autonomous Motivation (0-4)	2.4 (1.3)	2.4 (1.1)	2.9 (0.8)
Behavioural Regulation in Exercise Questionnaire Controlled Motivation (0-4)	1.6 (1.0)	1.6 (0.8)	1.5 (1.1)
Psychological Need Satisfaction in Physical Activity Scale Baseline Mean score (0-36)	20.2 (8.8)	20.2 (6.4)	23.2 (5.9)
Healthcare Climate Questionnaire (1-7)		5.5 (1.0)	
Physical Activity Behaviour			
International Physical Activity Questionnaire			
Sitting (mins/day)	353.9 (175.6)	316.7 (184.9)	233.2 (210.1)
Walking (mins/day)	80.5 (73.4)	103.2 (83.4)	81.7 (43.4)
Moderate-Vigorous (mins/day)	217.7 (197.4)	125.4 (117.3)	93.0 (89.3)
Accelerometer			
Valid days of data (0-7)	N=33 5.8 (1.1)	N=20 6.2 (0.9)	N=12 5.6 (1.5)
Sedentary time (mins/day)	446.3 (91.1)	553.5 (89.4)	465.3 (122.4)
Light Activity time (mins/day)	749.1 (98.2)	789.9 (78.1)	747.9 (129.1)
Moderate-Vigorous (mins/day)	35.5 (23.7)	27.8 (16.3)	32.3 (24.0)
Steps/day	6374.6 (3292.3)	4645.1 (1542.2)	5547.0 (2799.5)

Legend: All calculations at one decimal place with exception of EuroQol-5 Dimension Health State; Healthcare Climate Questionnaire recorded at 3-months post-baseline only; SD: Standard Deviation.

6.3.3 Qualitative results

Participant interviews

The demographic features of the 10 participants who consented to semi-structured interviews are presented in Table 6.10. Stratified purposive sampling enabled for a spread of gender (7 female, 3 male), age (mean 60.6, SD 9.3, range 47-76) and OA joints (6 knees, 2 hips, 2 both) that was representative of the wider population. Data saturation was reached after the 8th participant, with two further participants interviewed and analysed to ensure no further themes emerged. Participants' perspectives on the feasibility and acceptability of the intervention and trial procedures were thematically analysed and grouped into the two overarching groupings, Intervention Acceptability and Trial operations, which encompassed themes and subthemes. Example quotes illustrating each theme/subtheme are included in Table 6.11.

Grouping 1: Intervention Acceptability

- Theme 1: Physiotherapists' manner
- Theme 2: Treatment elements
- Theme 3: Intervention Effects
- Theme 4: Resources
 - Pedometer
 - Booklets
- Theme 5: Appointments

Grouping 2: Trial operations

Theme 1: Recruitment and eligibility criteria

Theme 2: Outcome measures and data collection

- Accelerometer
- Physical Tests
- Patient Reported Outcomes

Intervention Acceptability

All participants found the intervention highly acceptable, commenting that it was novel and helpful. The Intervention acceptability grouping include five overlapping themes that influenced participant perceptions of the interventions appropriateness and satisfaction (347), including the themes *physiotherapists' manner*, *important treatment elements*, *intervention effects*, *resources* (subthemes: *pedometer* and *booklets*), and *appointments*.

Theme 1: Physiotherapists' manner: Some participants reported that previous physiotherapists who they had seen for treatment had been unsympathetic or strict. In contrast, all participants spoke positively about the physiotherapists' manner complementing their attitude, patience, empathy, and the support given. Patients felt physiotherapists' openness and honesty built trust and gave them confidence and belief they could improve their symptoms and function.

Table 6.10: Participants characteristics

Participant	Gender	Joint affected	Age	BMI
1	Female	Hip	56	33.8
2	Male	Hip	76	22.5
3	Female	Knee	64	N/S
4	Male	Knee	69	23.7
5	Male	Knee/hip	47	28.4
6	Female	Knee	58	38.5
7	Female	Knee	56	34.6
8	Female	Knee	64	27.4
9	Female	Knee	70	33.6
10	Female	Knee/hip	46	32.0
Totals	Females (n=7); Males (n=3)	Knee (n=6); Hip (n=2) Both (n=2)	Mean 60.6 (9.3)	Mean 30.5 (5.0)

Legend: BMI: Body Mass Index; Summary measures of Age and BMI expressed as mean (standard deviation)

Theme 2: Treatment elements: Participants highlighted treatment elements that promoted or thwarted PA, several of which relate to intervention BCTs. Generally, participants who practiced their exercises (behavioural practice) and received feedback (feedback on behaviour/instruction on how to perform behaviour) felt the sessions were valuable. Conversely, some participants reported that they expected to practice their PA or have more hands-on contact with the physiotherapist. These participants felt that they only saw the physiotherapist for a 'discussion'. Experimentation to optimise PA type and dose was considered positive and associated with individualised treatment. Participants valued having a PA schedule (action plan) and strategies prepared if symptoms increased (problem solving).

Theme 3: Intervention Effects: Some participants commented that they had lost confidence to undertake PA due to a fall or pain prior to attending physiotherapy. However, participants spoke about a 'eureka' moment when they realised that they could gain some control over their symptoms. Several participants felt that PA improved their symptoms and function, which provided belief or hope (e.g. they no longer needed a total hip replacement) and motivation for further engagement in PA. However, two participants commented that they only experienced pain and no benefits after their prescribed exercises.

Theme 4: Resources

Booklets: Participants commented positively about the booklets' structure, usefulness to identify PA goals and plan activity, and as an informational source. However, several participants lost or forgot about their booklets. Furthermore, some participants commented that they were too long, repetitive in regard to previous content, and one participant felt that they were 'preachy'.

Pedometers: Participants outlined pedometers were helpful when setting goals and increasing awareness of daily steps. However, some participants felt guilty if they did not achieve their PA goals. Furthermore, some participants lost their pedometers as they did not have a strap and suggested using their phone or using a wrist worn pedometer. Two participants felt that the pedometer did not pick up their type of physical activity (e.g. table tennis) so questioned if another measure would be more useful.

Theme 5: Appointments: Most participants commented that physiotherapy appointments were the right length and appropriately spaced. However, some patients felt their sessions were too short and requested additional time with one hour or two x two-hour sessions each week suggested as appropriate. One patient suggested a follow up call a month and six months after the initial consultation would be useful to act as an ongoing PA motivator. Eight participants preferred in-person to remote appointments for feedback and promoting their motivation during PA activities. Work, parking, and rescheduling appointments were highlighted as barriers to attendance to physiotherapy appointments.

Trial operations

The analysis of participants' responses in regard to trial operations resulted in two themes and associated subthemes: *Recruitment and eligibility* and *Outcome measures and data collection* (subthemes: *Accelerometers*, *Performance-Based Tests*, *Patient Reported Outcome Measures*).

Theme 1: Recruitment and eligibility: Participants reported they were happy with how they were approached, recruited, and consented. Patients felt that they were given appropriate information and choice by the research staff. Participants felt the PIS had a lot of information but was appropriate and easy to understand. Most participants reported that they felt that they possessed suitable characteristics to undertake the intervention (e.g. correct age and symptoms to be eligible).

Theme 2: Outcome measures and data collection

Accelerometer: Although most participants commented that the accelerometers were acceptable, several commented they were uncomfortable to wear around the waste or they forget to wear the accelerometer in the morning. Participants suggested other parts of the body as wear points, including the wrist (n=9), and/or the chest (n=2), and/or foot and ankle (n=2). While most participants agreed that wearing the accelerometer for seven days was feasible, some felt three-four days wear time would be more acceptable. Some participants were worried that the blank screen meant they had broken the device, or it was not working and suggested further explanation should be included in the PIS.

Performance-based tests: Most participants felt that the performance-based tests were appropriate and acceptable, but there was disagreement whether physical testing should be done remotely or in person. Although most participants did not feel further physical tests were required, one participant suggested kneeling, crossing legs, stair climbing, and walking over uneven ground could be considered.

Patient Reported Outcomes: All participants felt the PROMs were acceptable, reportedly taking 5-30 minutes to complete them. However, some participants commented that the PROMs were poorly written, repetitive, and that scale changes across measures reduced overall clarity. However, participants felt that the research team provided ample support when required and no additional assessment domains were recommended.

Table 6.11 Verbatim quotes to demonstrate themes and subthemes from participant interviews

Theme	Example quote
Themes relating to Intervention Acceptability	
Physiotherapists' manner	• 'They've understood, at my level, where I'm coming from, sort of thing, so I haven't felt belittled, or in the wrong or anything. That has really helped.' Participant 3.
Treatment elements	• Routine: 'We did it every night when we got in, before we did anything else. I thought, "I'm going to do this when I go home," it's just about embedding some good routines, really.' Participant 3. • Action plan: 'If I'm going for a walk, I like to know how far we're going before we go. So that gives me an idea.' Participant 6 • Gradual progression: 'he was great. We started off so low with whatever we needed to do and just gradually built it off so that you could cope with what you're doing.' Participant 4.
Intervention effects	• Psychological 'Before I started the programme, I'd had two falls at work, because I sort of had this weakness in my hips and into my legs... And I had a real horrible feeling about falling in the shower. And I had lost a lot of my confidence because of it, because of these falls. So now, I don't even think about it, I just get into the shower.' Participant 7 • Clinical Symptoms and physical ability: 'The pain's come down by quite a bit, actually. I've had one real flare up, that's all, whereas I used to have regular flare ups and it'd swell up, so it's been much better.' Participant 10.
Intervention Resources	
Sub theme 1: Booklets	• 'I have to see things in front of me, like sometimes I draw a diagram if I'm not sure of instructions, so that I understand what I'm doing, sort of thing. So, it is nice to have them, to have that facility...' Participant 3. • '...a lot of people take the books like I've forgotten all about this. How many leaflets comes in the house? How many read it?' Participant 6.
Subtheme 2: Pedometer	• 'It's useful but 've got a step counter on my phone. I think I do find it useful. I don't know how many I've done today, not that many.' Participant 2.
Appointments	• Face to face: 'Because sometimes there's stuff that can be missed. If you take the analogy of a GP, you go in with a certain problem. There's a skin cancer on somebody's forehead that gets missed because it's a phone consultation.' Participant 5.
TRIAL OPERATIONS	

Recruitment and eligibility criteria	• Contact method: 'Somebody rang me up. that was fine, yeah. There was no problem with that.' Participant 5. • Informed Consent: 'I was given the option whether I wanted to do it or not.' Participant 7. • Appropriate participant: 'I think I was the right age. I had the relevant problems with the arthritis. ' Participant 1.
Outcomes measures and data collection	
Subtheme 1: Accelerometer	• Body position: 'Something around your wrist would be a lot more comfortable.' Participant 5 • Comfort: 'As I say, maybe around your wrist, it might be a bit more comfortable, yeah, sort of around your middle, it's a bit uncomfortable.' Participant 6. • Forgot: 'I think the key part is trying to remember to put it on first thing in the morning, because there were occasions when I'd go out, do my exercises and then realise I hadn't put it on. And it was like, oh, crap.' Participant 7.
Subtheme 2: Physical Tests	• Mode of assessment (in person vs remote): ' So, it just felt that you'd got somebody there that was explaining it. You knew exactly what you'd got to do. They were watching that you did it.' Participant 4.
Subtheme 3: Patient Reported Outcomes	• Length: 'It took me about 15 minutes to complete the questionnaires. This was absolutely fine. They were not confusing at all' Participant 2. • Clarity: 'I found the questionnaire easy to understand and quite straightforward. What the questions were about was fine. It's the actual wording, the phraseology of the questions plus the way they were set up. So for example, if you looked at the last one that I filled in, I carried it on, you know where you've got the numbers one, two, three, four, five, etc., the grading.' Participant 5.

Physiotherapists

All intervention physiotherapists (n=5; 3 female, 2 male), whose demographic features were outlined in Table 6.8 above, chose to participate in semi-structured interviews rather than focus groups. The perspectives of physiotherapists that are pertinent to the trials' objectives were collated into two overarching themes and related themes.

Physiotherapists quotes relating to each theme are included in Table 6.12.

- Theme 1: Training Programme

- Theme 2: Intervention delivery
 - Resources
 - Capacity
 - Eligibility criteria

Theme 1: Training programme

All physiotherapists spoke positively about the *Empowering Physio* training programme, finding it enjoyable, energizing, empowering for themselves, and aligned with their treatment philosophies. All physiotherapists felt the training exercises/activities embedded in the *Empowering Physio* promoted a collaborative learning environment and increased their levels of critical reflection. Physiotherapists agreed that the training improved their theoretical understanding of motivation and how to create an empowering treatment climate and deliver intervention BCTs. Some physiotherapists suggested incorporating additional training to provide feedback on recordings of interactions with their patients during the sessions or including role play exercises with an actor or real-world patient.

In regard to the BCTs comprising the interventions, three physiotherapists felt there were too many BCTs to remember to successfully deliver the intervention clinically. They also suggested developing a video database of exemplar BCT delivery which could be reviewed as required.

Theme 2: Intervention delivery

The intervention delivery theme included the subthemes *Resources*, *Capacity* and *Eligibility criteria*.

Resources: The physiotherapists considered the intervention booklets comprehensive and a valuable source of information, bringing structure to sessions. However, some physiotherapists felt they were less relevant to patients who were already physically active and that participants did not bring the booklets back to subsequent sessions. Therefore, physiotherapists suggested simplifying the content into one booklet or integrating into it an App.

Capacity: Although all physiotherapists commented that it was feasible to deliver the intervention, they recommended simplifying and reducing some of the content (i.e. the booklets and number of BCTs). The physiotherapists reported that, due to COVID, the waiting lists had increased to unprecedented levels (41 weeks) and they felt under pressure to see patients in person and discharge as early as possible. Furthermore, during the trial, physiotherapy appointment times reduced. The option of using a group class for different phases of the intervention was discussed and then dismissed by two physiotherapists due to practical difficulties. Additional discussions with department managers were suggested to clarify how the intervention could be integrated into the post COVID physiotherapy service.

Eligibility Criteria: Although physiotherapists generally felt participants were appropriate for the trial, one queried the accuracy of the OA diagnoses. Therefore, this physiotherapist suggested X-rays should be included in the eligibility criteria. Two physiotherapists felt that some participants were already physically active and/or had mild OA symptoms at baseline and therefore required less treatment, which contributed to non-attendance/drop out.

Table 6.12: Verbatim quotes to demonstrate themes and subthemes from physiotherapist interviews

Theme	Example quotes
Training programme	• 'I just thought it was great. I just loved, I loved the exploration of our thoughts around behaviour change and motivation. And I loved the group work, I thought (trainer) was fantastic. We were all, especially that first session, we were all fully buzzing when we came out of there.' Physiotherapist 4 • 'And it felt like... I am fairly sure I can speak for me and (another physio), probably as well. But that's how we want to deliver physio.' Physiotherapist 2 • 'I thought it was really good to look at the kind of styles of external and internal motivation and be like, "Well, you think you're being really helpful by really praising the patient but actually, in order to have that carry over, recognising that they need to be able to recognise themselves when they're doing well." Physiotherapist 3
Themes relating to intervention delivery	
Resources	• 'The content of the books... I think it was easy to understand in general, the way was laid out, it was straightforward, use of text, use of images, use of tables, I thought that was all good, I thought it made sense to read through it. It was simple in terms of how you would fill it out.' Physiotherapist 1 • 'The problem for me is that people will come back and go, I've forgotten to bring my exercise diary or... there's lots of still needing people to be very engaged despite these extra things that we might not be able to give in physiotherapy normally.' Physiotherapist 3 • 'I think for the pedometer, most patients have it on their phones now. So, I think you could probably save yourself a bit of money on the trial with those. And also, they're not always reliable, are they?' Physiotherapist 5.
Capacity	• 'in terms of getting them physically active. I definitely think the six sessions should be long enough over that timeframe.' Physiotherapist 1. • 'I never have enough time in sessions because I think the power of talking and exploring somebody's thought processes, emotions, trauma, diet, all of that is just so important, A for building rapport with the patient and also finding out what makes them tick to enable you to set something appropriate with them to get where they want to go. So no, I never have enough time. But I think 45 minutes for a new should be fine, and then the follow-ups at that point were half an hour. Again, that is okay. They are now 20 minutes, madness, actual madness.' Physiotherapist 4.
Eligibility criteria	• '.....it (the intervention) was worthwhile for all the patients that I saw.' Physiotherapist 3 • 'Yes, I mean, I had some who I think had been diagnosed elsewhere, maybe from a GP or something like that and sort of when treating them in my mind, it was a bit like, "It's not really an arthritic issue that you've got." Maybe it was a sort of patellofemoral kind of, or a kind of tendinopathy type pain just because they were tendinopathic in their presentation.' Physiotherapist 2

Research Staff

Five research members of staff (n= 5 females), including four research nurses and one data controller, agreed to semi-structured interviews over focus groups. One further research nurse declined to participate owing to lack of time. Demographic detail of trials research staff is outlined in Table 6.13.

Table 6.13: Research staff demographic features

Participant number	Role	Gender	Age	Time working in research (years)
1	Research Nurse	F	40	2
2	Research Nurse	F	31	2
3	Research Nurse	F	47	5
4	Data Manager	F	30	6
5	Research nurse	F	44	3

The research teams perspectives that relate to the trials' objectives were integrated into two themes and associated subthemes. Quotations from the research team that relate to each theme can be found in Table 6.14.

- Theme 1: Recruitment
- Theme 2: Retention
 - Communication
 - Data collection and outcome measures

Theme 1: Recruitment: All research staff felt that the recruitment processes were acceptable, and a large pool of eligible patients were available. Research staff reported that the consent procedures were acceptable and resourceful. Screening of the physiotherapy waitlists was described as straightforward but time consuming. Research

nurses reported that the eligibility criteria was generally acceptable to establish eligibility of potential participants. However, two research nurses reported some difficulty utilising the NICE guidelines, and felt further guidance was required when determining eligibility of potential participants based on co-existing musculoskeletal conditions, cointerventions, and mental health conditions.

Theme 2: Retention

This theme includes the subthemes *Communication* and *Data collection and Outcome Measures* which incorporate perceived barriers and potential solutions to participant retention.

Communication: All research staff reported that trial communication was acceptable. Messaging within the team was generally efficient apart from periods of staff sickness or research staff transition. However, participants could be hard to contact and research staff spent considerable time arranging assessment appointments or prompting participants to return outcome measures. Communication issues were exacerbated by reduced research staff availability (3-4 days maximum per week) during the trial. Therefore, additional research support was suggested in a full-scale trial. Research staff suggested further strategies to increase retention, including: clarifying participant communication preferences (e.g. phone, email, post, text), prompting participants with additional reminders and thank you messages, including a three and/or six-month booster session to coincide with in-person outcome assessments, and increasing details of assessment requirements in the PIS.

Data collection and outcome measures: All research nurses commented that it was feasible to blind them as outcome assessors and the overall data collection processes were acceptable, although changes were suggested to improve feasibility. During the trial, two key factors greatly impacted on the data collection. Firstly, several nationwide postal strikes disrupted the flow of data collection. Research staff reported that, when contacted, participants frequently stated they had not received the accelerometers and PROMs or had posted the items back weeks earlier. However, the posted items did not arrive at the ROH. Secondly, to encourage patients to attend appointments in-person as the pandemic receded, the trust discontinued the 'Attend Anywhere' app early in the trial. Therefore, phone was the only remote option available for data collection. All research nurses agreed that it was difficult to accurately assess the performance-based outcomes over the phone, especially the figure of 8, as they could not see the participant. Therefore, all research nurses suggested that data collection should be conducted in-person and felt that doing so would also build rapport. Research staff suggested these appointments could also be used to fit the accelerometer. If participants preferred to have their outcomes completed remotely, research staff proposed utilising tracked/recorded posting or that the PROMs could be recorded online.

Table 6.14: Verbatim quotes to demonstrate themes and subthemes from research staff interviews

Theme	Example Quotes
Recruitment	• 'I think in general recruitment in terms of patient cohort, there was a massive pool of patients to pick from so recruitment went pretty smoothly.' Research staff 2 • 'When I think back, I remember the research nurses having quite a few questions about whether other treatments were okay to be involved, so if a patient was having steroid injections, could they still be included?' Research staff 1 • 'The telephone recruitment is definitely a bonus, I think that works really well and having a witnessed verbal consent.' Research staff 1
Retention	
Subtheme 1: Communication	• 'There's another lady I need to phone, actually, today who should have gone... it was two weeks, I think, post, and she still hadn't had it (accelerometer). I resent the PROMs again, and I haven't managed to get in touch with her again and nothing has come back to us.' Research staff 3. • 'If I emailed you (primary investigator) you would answer me straight away. And if I have issues as well, and (data manager) is very supportive and stuff so yeah, I didn't have any issues with that one.' Research staff 2 • 'Reminding them about their six-month follow-up and to make note of any flare-ups. Extra contact is important' Research staff 2
Subtheme 2: Data collection and Outcome Measures	• 'I think face to face is important; it's all very well doing everything virtual and with Covid and everything, everything else has gone that way, but I do think sometimes you need to... they do forget that they've signed up for stuff.' Research staff 1 • 'Standing up from a chair seemed quite easy, they understood that, but the figure of eight, I didn't manage – I don't think – to do any of those.' Research staff 2 • '...if you were to do the PROMS and the accelerometer in person it would provide extra clarity for the patients and they might be more at ease with the study. Because they are seeing somebody, they've been able to ask any questions at that time point.' Research staff 5. • '...a lot (accelerometers) have gone walkies unfortunately, so a secure courier system would work better just to make sure.' Research staff 5.

6.3.4 Integration:

Overall, 82% of trial objectives met the a priori progression criteria (including modifications). However, some outcome assessment feasibility criteria were not met.

Table 6.15 outlines progression decisions, the integrated evidence and potential adaptations. Considerations for progression to a definitive trial are also outlined.

Table 6.15: Evidence demonstrating the extent to which success criteria were met

Objective	Met progression criteria	Key Evidence and Considerations
1: INTERVENTION		
1.1 Intervention delivery		
A: To determine the feasibility of delivery of the behaviour change intervention to participants and treating physiotherapists	Yes	- All patients with lower-limb OA and physiotherapists reported that the intervention was feasible. - Modifications to the intervention resources and quantity of BCTs should be considered if progressing to definitive trial
B: To determine the acceptability of the behaviour change intervention to participants and treating physiotherapists	Yes	All patients with lower-limb OA and physiotherapists reported that the intervention was acceptable.
1.2 Training programme		
To determine the acceptability of the bespoke Empowering Coaching training programme to treating physiotherapists	Yes	- All Physiotherapists reported that the Empowering Physio training programme was acceptable and developed their theoretical knowledge. - Modification to utilise real patients, feedback on sessions and a video database of BCTs may be considered.
1.3 Intervention Fidelity		
To evaluate fidelity of intervention delivery by treating physiotherapists (detailed in chapter 7)	Yes	Protocol BCTs fidelity median score: 66.7% interquartile range: 50.0- 86.1. Overall ISPACOT Median score: 5/7 interquartile range 4.5-6 - Data from only 6 intervention sessions from routine formation and 3 from maintenance available for analysis
TRIAL CONDUCT		
2.1 Recruitment Rates		

To measure the recruitment rates of participants	Yes	Recruitment rate: 0.95 participants per week (3.96 participants per month) Conversion rate: 23.7%. Context: Staff sickness and turnover Further research staff training to identify eligible participants may be considered

2.2 Trial Procedures

A: To determine the feasibility of trial related procedures (recruitment, outcome assessment) and ROH research staff	Yes	• Context: Postal strikes, Trust discontinuation of Attend Anywhere App, high staff sickness and turnover • In-person assessment as primary method of data collection will be considered for definitive trial • An increase in research staff support may be considered to enable more flexible assessment timings for participants.
B: To determine the acceptability of trial related procedures (recruitment, outcome assessment) to participants and ROH research staff	Yes	• All participants and research staff report recruitment acceptable. • In-person assessment as primary method of data collection will be considered for definitive trial

2.3 Data Collection

To measure the completeness of data collection of performance based and patient reported outcome measures at baseline, three and six-months post-baseline	No	<table border="1"> <thead> <tr> <th></th><th>PROM (n (%))</th><th>PBO (n (%))</th></tr> </thead> <tbody> <tr> <td>3M</td><td>23 (64%)</td><td>9 (25%)</td></tr> <tr> <td>6M</td><td>14 (39%)</td><td>10 (28%)</td></tr> </tbody> </table> • Context: Postal strikes, Trust discontinuation of Attend Anywhere App, high staff sickness and turnover.		PROM (n (%))	PBO (n (%))	3M	23 (64%)	9 (25%)	6M	14 (39%)	10 (28%)
	PROM (n (%))	PBO (n (%))									
3M	23 (64%)	9 (25%)									
6M	14 (39%)	10 (28%)									

2.4: Accelerometer

A: To determine the feasibility of utilising an accelerometer as the primary outcome in a definitive randomised controlled trial	No	• 33% of valid Accelerometers returned at 6 months. • Context: Postal strikes, high staff turnover. • Wrist worn accelerometers will be considered for definitive trial. • Recorded delivery may be considered to collect accelerometers for definitive trial

B: To determine the acceptability of utilising an accelerometer as the primary outcome in a definitive randomised controlled trial	Yes	• Most participants felt the accelerometers were acceptable. • Wrist worn accelerometers will be considered for definitive trial.

2.5 Outcome measures

To determine the acceptability of the patient reported and performance-based outcome measures to participants	Yes	• Participants reported that patient reported and performance-based outcome measures acceptable. • In-person assessment as primary method of data collection will be considered for definitive trial • Minor changes to PROMs and removal of figure of 8 test maybe considered in definitive trial

Legend: ISPACOT: Interpersonal Support in Physical Activity Consultations Observational Tool;

6.4 Discussion

This trial assessed the feasibility and acceptability of a complex, multi-component theoretical behaviour change physiotherapy intervention that aimed to promote PA adoption and maintenance in patients with lower limb OA. This was done to determine whether a full-scale parallel group (1:1) effectiveness randomised controlled trial was indicated. Although the sample included a higher proportion of females than the wider population, (78% versus approximately 60%), participant mean age and BMI were consistent with demographic and large-scale trial profiles (23, 494). Overall, 82% of trial objectives met the a priori progression criteria. The intervention, training programme, and recruitment processes were highly acceptable and feasible to deliver. However, data collection processes did not meet a priori progression criteria.

6.4.1 Participant recruitment and eligibility

Thirty-six participants (n=28 females) with lower-limb OA were recruited over a 38-week period (recruitment rate: 0.95 participants/week; conversation rate: 24%). Therefore, a sufficient target population appears available to support a definitive trial. The recruitment methods were positively viewed by participants and research staff. However, limited research staff availability during the trial (generally 1 person working 3 days per week) reduced opportunities when potential participants were contacted for consent. Therefore, further funding for additional research staff support to increase available time dedicated to contacting potential participants may be sought in a definitive trial.

Participants, physiotherapists, and research staff generally agreed that the eligibility criteria were acceptable and appropriate. However, research staff reported some difficulty determining eligibility if a potential participant had not completed an X-ray to confirm OA diagnosis. The trial eligibility criteria were based on NICE guidelines (10), which do not include an X-ray for standard OA diagnoses. The NICE guidelines have demonstrated greater accuracy than all other international guidelines at identifying knee (19) and Hip (20) OA. Therefore, current eligibility criteria will be carried forward to a definitive trial, but further training may be provided to research staff regarding eligibility.

Some physiotherapists felt that participants were more physically active than most patients with lower-limb OA that presented clinically at the ROH. However, participant baseline daily accelerometer recorded MVPA minutes (mean 35.5; median 28.2) and steps (mean 6374.6; median 5347) were consistent with, albeit at the lower end of PA ranges found in systematic reviews (97) and contemporary physiotherapy RCTs conducted on patients with lower-limb OA (MVPA: 31-70 (495, 496, 497, 498); steps 6294-10898 (495, 499)). Therefore, no alteration to the eligibility criteria is warranted based on baseline PA data.

6.4.2 Intervention delivery and training programme

Intervention and training programme feasibility and acceptability criteria were met. The training programme aimed to develop physiotherapists' understanding of the why and how to create a more empowering, patient centred treatment climate to promote autonomous motivation for PA. The positive response to the *Empowering Physio* training highlighted the need for this component of the intervention package in physiotherapy practice. Feasible adaptations to the *Empowering Physio* training

programme suggested by physiotherapists included further time practicing a more empowering delivery with real patients or actors and individual feedback on pilot treatment sessions. In regard to the training on the BCTs to be delivered, development of a video database of all BCTs was suggested. These videos would then be available for review by physiotherapists as required.

Although all patients and physiotherapists agreed that the intervention was acceptable, they felt the booklets required simplification and reduction in length. It was also suggested that the pedometers could be replaced by phone step counters. Some physiotherapists reported it was problematic to deliver all protocol BCTs within the time available to work/exchange with the participants. They felt under pressure to discharge patients due to long waiting lists in a post-covid NHS service. Fidelity analysis (Chapter 7) found that physiotherapists created an overall empowering treatment climate and delivered the protocol BCTs competently. However, BCT delivery fidelity competency notably reduced through the routine formation and maintenance phases.

Therefore, the feasibility of the intervention can be enhanced by simplifying the booklets and reducing the number of BCTs, especially the phase specific techniques. Consultation with physiotherapy managers to clarify appropriate intervention parameters (e.g. number of sessions) in a post COVID NHS service was suggested by physiotherapists and may be undertaken prior to a definitive trial.

6.4.3 Outcome measures and data collection procedures

The trial aimed to determine whether an accelerometer was feasible and acceptable to use as the primary outcome measure in a definitive trial. Accelerometer data

collection followed a standardised protocol where the device was secured over the participants right anterior superior iliac spine using a belt and pouch (452, 453, 454). Although participants felt the accelerometer was acceptable, the belt was reportedly uncomfortable and led to at least three withdrawals (8% of those enrolled). Nine of ten interviewees suggested the wrist would be an appropriate alternative wear point.

Choice of wear point is an important consideration in PA data collection via accelerometry, and a balance between participant acceptability and data accuracy is required. Although wrist worn accelerometers demonstrate greater participant compliance than waist worn accelerometers (500, 501, 502), they consistently overestimate steps count and MVPA minutes in patients with lower-limb OA (503, 504, 505). The discrepancy likely relates to arm movements that occur independently of the axial skeleton and the wrist devices providing visual PA prompts (506, 507, 508). Recently, wrist worn accelerometry has gained popularity in research to capture PA data and the wear-point has been validated in patients with lower-limb OA (503, 504). However, although wrist accelerometry PA intensity cut points have been proposed for older adults (509, 510), currently no lower-limb OA specific cut-points exist. Therefore, feasible adaptations for a definitive trial include altering the accelerometer wear point to the wrist with potential further pilot work to clarify wrist specific PA cut points in patients with lower-limb OA.

Participants considered the PROM burden acceptable. Regarding PA, IPAQ scores reported considerably less sedentary and greater MVPA time than the accelerometer recorded data which echoes the evidence when self-report is compared to direct measures of PA (157, 511, 512). Due to its inaccuracy, the IPAQ will be removed from PROMs recorded.

The data collection procedures were the primary barriers to progressing to a definitive trial. Only 48% and 33% of valid outcome data were recorded at 3 and 6-months post baseline which did not meet the a priori progression criteria and are below the range of recorded six-month post-baseline data in contemporary physiotherapy RCTs of 51-85% (23, 496, 498, 499). However, research staff felt that COVID related contextual factors greatly contributed to the limited data collection in this feasibility trial. Firstly, the trust discontinued the Attend Anywhere App option for physiotherapy appointments and data collection early in the trial. Although acceptable to participants, research staff felt that the performance-based tests (notably the figure of eight) were problematic to conduct via phone as participants could not be guided appropriately. Secondly, several postal strikes coincided with the highest concentration of intended data collections and PROMs and accelerometers were lost during transit to or from participant addresses. Further instances of lost data via post were recorded outside of the postal strikes.

To address these barriers, research staff suggested several evidence-based strategies to aid retention. Research staff unanimously agreed that in-person assessments (513) should be offered as the primary option. If participants chose remote assessment, PROMS and accelerometers could be sent by recorded delivery (514), but problems collecting performance-based outcomes would remain.

Interestingly, several recent physiotherapy trials did not include performance-based outcomes (350, 433, 488). Consequently, the inclusion of performance-based tests was further discussed with the trial PPI representative (ED), who felt that physical tests were important to perform. Therefore, in-person data collection and tracked post are feasible adaptations that should be implemented when progressing to a full-scale trial. Monetary incentives may also be considered for participants (to cover

travel and parking costs) to attend in person assessments (513, 514). Modification of the performance-based tests by replacing the figure of 8 with simpler assessments that can be completed remotely may also be considered.

While it may be preferable to conduct in-person assessment during the anticipated definitive trial, it is likely that several participants will chose to have data collected remotely. Specific techniques to optimise remote data collection rates (e.g. phone and/or post) have been suggested in the literature. A frequently utilised method is Dillman's 'Total Design Survey Method' (TDSM) (515, 516). TDSM is underpinned by Social Change Theory and details steps that have achieved response rates of approximately 80% for remotely collected data (517). Suggested steps in the TDSM include: Incorporating a comprehensive cover letter, emphasising the importance of the research, and following up prompts to those who are slow to respond (517). These strategies were not employed in the feasibility trial and may have further contributed to the lower-than-expected data collection rates seen in the feasibility trial. Interestingly, trial research staff suggested strategies consistent with, and in addition to, those outlined in the TDSM to assist in remote data collection during their interviews. Further strategies suggested by research staff included: clarifying participants preferred communication methods at baseline, sending frequent reminders (514) and trial updates (518, 519), and scheduling outcome assessments at the preceding appointments to aid structure. These strategies for remote data collection rates are feasible adaptations, commonly used in healthcare trials (520), and may be integrated into a definitive trial protocol.

Although the data collection procedures did not meet success criteria and require modification, they were heavily influenced by COVID-related contextual factors. As such, these challenges related to data collection are likely addressable due to the

adaptations proposed. Moreover, there is substantial supporting evidence via trials conducted on patients with lower-limb OA within NHS physiotherapy services (23, 521, 522), to facilitate the achievement of recommended levels of data collection of 80% at 6 months post- baseline (518, 519) with appropriate resourcing.

6.4.4 Summary of progression criteria

As 82% of the trial *a priori* success criteria were met including the feasibility and acceptability of the recruitment processes, physiotherapist training, and behaviour change intervention, the feasibility trial warrants progression to a definitive trial. The overall progression criteria would currently sit in the ‘continue with modification (modifications to protocol)’ stage suggested by Thabane (523) (equivalent to the ‘Amber-light’ phase proposed by Avery (524)). Therefore, an initial internal pilot study phase (525, 526) will be included as part of a definitive trial to determine whether the following adaptations to data collection procedures are satisfactory.

- Alteration of the accelerometer wear point to the wrist
- Use of in person assessment as the primary option to collect PROMS and performance-based outcomes. Where this is not possible, recorded/tracked delivery to be utilised.
- Removing the figure of eight from the protocol as a performance-based test

6.5 Strengths and limitations

This trial utilised evidence based mixed-methods to evaluate the feasibility and acceptability of a novel, complex, behaviour change intervention that was

sequentially developed following MRC guidelines to promote PA adoption and maintenance in patients with lower-limb OA. Analysis and synthesis of findings were strengthened by input from PPI representatives, academics, psychologists, and clinicians and transparently reported in line with CONSORT (527), TIDIER (528), COREC (529), and SPIRIT (530) guidelines (please see Appendices 6.11-14 inclusive for the appropriate checklists). The trial sample reflected a normal distribution of participants which were representative of the wider population of patients with lower-limb OA. Although the overall sample participating in the qualitative methods was small (n=20), participant, physiotherapists and research staff interviews enabled a range of opinions to be synthesised and gave a rounded in-depth insight into trial feasibility and acceptability. The additional perspectives of physiotherapy managers will be sought to provide helpful insights into a post-COVID outpatient department's capacity to support intervention delivery.

The primary limitation was the reduced data collection at 3 and 6-months post baseline which did not meet a priori progression criteria. The single armed trial design meant participants were not blinded to an intervention group and no comments can be made about data collection rates or processes among usual care in physiotherapy. The use of single site further limited the generalisability of results to other physiotherapy departments.

6.6 Conclusion

A definitive trial is feasible with modifications to the protocol. The complex, multi-component intervention (and embedded physiotherapy training) was highly acceptable to participants, physiotherapists, and research staff. The intervention's

feasibility can be enhanced by simplifying and reducing the length of the booklets and reducing the number of phase-specific protocol BCTs.

Required modifications to physiotherapist training include further time spent practicing intervention delivery, individual feedback on their delivery of participant sessions (how empowering and disempowering), and development of a video database of all BCTs for review as required by the physiotherapists.

Data collection processes did not meet a priori progression criteria. Required modifications to data collection include further research staff resource, offering in-person assessment, and using wrist worn accelerometry. Consultation with physiotherapy managers to identify realistic intervention parameters (e.g. session numbers and lengths) in a post COVID outpatients department and clarifications of population specific PA cut points for wrist worn accelerometers in patients with lower limb OA may be undertaken prior to progression. Strategies to aid data collection will be assessed in an internal pilot across multiple sites as the initial phase of a definitive RCT.

6.7 Funding

This trial is primarily funded by the Private Physiotherapy Educational Foundation (A1 scheme) and the Musculoskeletal Association of Chartered Physiotherapists level 1 research awards. The funding bodies had no role in the design and writing of the trial protocol and does not have a role in data collection, management, analysis and interpretation of data, writing of the report and the decision to submit the report for publication.

6.7 Dissemination of results

The protocol for the feasibility trial has been published in Pilot and Feasibility Studies an international peer review journal:

Willett, M. Rushton, A. Stephens, G. Fenton, S. Rich, S. Greig, C. Duda, J. Feasibility of a theoretically grounded, multicomponent, physiotherapy intervention aiming to promote autonomous motivation to adopt and maintain physical activity in patients with lower-limb osteoarthritis: protocol for a single-arm trial. Pilot Feasibility Stud. 2023;9(1):54.

Findings have also been dissemination at a peer reviewed international conference:

Willett, M. Rushton, A. S. Greig, C. Duda, J. Physical Activity Adoption and Maintenance in People with Lower-limb Osteoarthritis: Feasibility and Acceptability of a Single Arm Complex Theory-Based Physiotherapy Behaviour Change Intervention. Poster, International Federation of Orthopaedic Manipulative Physical Therapists. July 2024; Basel, Switzerland.

CHAPTER 7: FIDELITY OF INTERVENTION DELIVERY OF A COMPLEX THEORETICALLY GROUNDED PHYSIOTHERAPY INTERVENTION AIMING TO PROMOTE PHYSICAL ACTIVITY ADOPTION AND MAINTENANCE IN PATIENTS WITH LOWER LIMB OSTEOARTHRITIS

Chapter overview

This chapter details the assessment of fidelity of intervention delivery (physiotherapist delivery of protocol BCTs and competence to develop a motivationally empowering treatment climate) of the behaviour change intervention developed in chapters 2-5 and feasibility tested in chapter 6.

Intervention physiotherapists (n=5) undertook 11 hours of a bespoke training programme which aimed to develop physiotherapists understanding of how to create a motivationally empowering treatment climate to deliver intervention BCTs to promote PA adoption and maintenance in patients with lower-limb OA. The physiotherapists were asked to record one intervention session from each of the adoption, routine formation, and maintenance intervention sessions with their 1st and 3rd patient. Fidelity of intervention delivery was evaluated by two independent researchers. Intervention session transcripts were coded for BCTs following V1 taxonomy guidance. The Interpersonal Support in Physical Activity Consultations Observational Tool (ISPACOT) evaluated how motivationally empowering the treatment climate was via session audio recordings. BCT delivery fidelity was defined as high: ≥80% of BCTs present; moderate: 50-79% present; low < 50% present. Competence in developing an empowering treatment climate items was defined as a score of ≥4 on a seven-point Likert scale.

19 sessions (10 adoption; 6 routine formation; 3 maintenance) were rated with *strong* agreement (BCT $\kappa = 0.81$; ISPACOT $\kappa = 0.87$). Due to low numbers of routine formation and maintenance session recordings, conclusions regarding the influence of behaviour change phases on intervention fidelity were limited. A median of 14.25 BCTs were delivered per session (Interquartile range=12.5-16.5) with 'moderate' fidelity (median 63.2%; Interquartile range 22.3-80). A motivationally empowering treatment climate was generally competently developed (median score 5/7) although physiotherapists demonstrated an increased use of controlling communication during maintenance sessions. The results are discussed in context of the wider evidence base and potential developments to the physiotherapy training programme and behaviour change intervention recommended.

Initials used in the text correspond to the following names: MW- Matthew Willett; SF- Sally Fenton; AC: Aiden Chautry; MP: Manasi Pimple JD: Joan Duda: JD

7.1 Introduction

Lower-limb OA causes high levels of disability and presents a significant financial burden to global healthcare services (4). PA interventions incorporating coordinated exercises and lifestyle education are supported by healthcare guidelines to aid patients with lower-limb OA self-manage their symptoms (3, 10, 94). In the UKs' NHS, physiotherapists are the primary healthcare professionals who provide PA interventions to patients with musculoskeletal pain (92). However, physiotherapist delivered PA interventions are not necessarily significantly more effective compared to other treatments for moderating clinical symptoms (175). This may be explained by several factors including ineffective PA prescription, OA disease progression, and/or physiotherapists not delivering the intervention as intended (42).

Treatment Fidelity is the evaluation and, as needed, iterative modification of an intervention to optimise its delivery and effectiveness (172, 531). If treatment fidelity is not assessed, researchers cannot conclude whether the observed results are due to the intervention's effect(s) or a supplementary feature of variability in intervention delivery. Therefore, assessment of treatment fidelity reduces the chance of false significant (type 1 error) or non-significant (type 2 error) treatment effects being missed/misinterpreted (172, 532).

Despite widespread acknowledgement of its importance in trial evaluation (532), intervention fidelity remains largely under-explored and/or under-reported in comparison to trial effectiveness and cost analyses (533). The National Institute of Health Behavioural Change Consortium (NIHBCC) outlined five domains that encompass Treatment fidelity: Trial design, Provider training, Intervention delivery, Intervention receipt, and Participant enactment (172). Of these, fidelity of

Intervention delivery is the most commonly evaluated domain (172). Fidelity of intervention delivery assesses whether the intervention has been delivered as per protocol (217) and is encompassed in the MRC's guidance on process evaluations (532).

Behaviour change Techniques (BCTs), such *Action planning* or *Problem solving* are the active intervention components that influence target behaviours and represent the 'content' of an intervention (i.e. what is delivered) (123). Physiotherapists utilise BCTs to promote PA in patients seen within clinical practice (200). Evaluating fidelity of BCT delivery may highlight protocol techniques (i.e. those that are explicitly part of the intervention) that are easy or problematic to deliver (534), or those that are commonly delivered but not previously considered (i.e. non protocol BCTs). However, BCT fidelity assessment in isolation does not determine how well each technique is delivered.

The quality of BCT delivery is influenced by the psychological or motivational *climate* that they are delivered within. The psychological climate is a product of the social interactions and environment created between the subject (i.e. patient) and their 'significant other' (i.e. physiotherapist) (425, 535). Regarding physiotherapist treatment sessions, their actions, communication style, and behaviours can create a more or less motivationally *empowering* and *disempowering* climate that could promote or thwart patient PA engagement. Physiotherapists can develop an empowering treatment climate by including patients in PA goals and encouraging them to defining their competence based on the effort they expend while undertaking PA (424, 425). Conversely, physiotherapists would create a more motivationally disempowering treatment climate if they used a controlling/paternalistic communication style or demonstrated interest in their patient based on their ability to

achieve their PA goals relative to their peers (424, 425). BCTs that are competently delivered within a more empowering treatment climate may facilitate behavioural maintenance and self-management of clinical symptoms (536, 537), while those delivered within a disempowering climate likely thwart patients' feelings of well-being and PA engagement. As the treatment climate influences the quality of BCT delivery, intervention delivery fidelity should evaluate both components (538).

Previous studies have evaluated physiotherapists' fidelity of BCT delivery (363, 376, 539) and/or competence to utilise patient-centred communication/develop features of empowering treatment climates (364, 436, 540, 541, 542). Overall results suggest that physiotherapists can competently deliver patient-centred communication and promote an empowering treatment climate (363, 364, 436, 540, 541). However, physiotherapist BCT delivery has demonstrated inconsistent fidelity (539).

The research in this thesis developed and feasibility tested a complex multicomponent theoretically based behaviour change intervention that aimed to have physiotherapists create a more empowering treatment climate to deliver BCTs that targeted PA adoption and maintenance in patients with lower-limb OA (543). To achieve this, physiotherapists were trained to develop understanding of how an empowering or disempowering treatment climate could be created and how to deliver the intervention BCTs (the details of the intervention and training program are expanded in the methods section).

With the aforementioned studies conducted in the Republic of Ireland (364, 376, 436, 540, 541), Australia (363), and Germany (539), this was the first intervention of its type designed for delivery in the UK's NHS. Therefore, in physiotherapists who were trained to deliver a theoretically grounded behaviour change intervention that aimed

to promote PA adoption and maintenance in patients with lower-limb OA, the aims of this study were to assess the fidelity of intervention delivery of a) protocol BCTs and (b) development of a motivationally empowering treatment climate.

Objectives

- 1) To identify BCTs (protocol and non-protocol) delivered within intervention sessions.
- 2) To evaluate the fidelity of physiotherapists' delivery of protocol BCTs
- 3) To evaluate physiotherapists' competence to promote a motivationally empowering treatment climate.
- 4) To determine whether fidelity of delivery of protocol BCTs and competence to develop a motivationally empowering treatment climate varied based on the phase of the intervention.

7.2 Methods

7.2.1 Study reporting and ethical clearance

This fidelity study follows an observational design and was integrated into the Staying Active with Physiotherapy in patients with Lower-limb Osteoarthritis (STAPLO) single-arm feasibility trial (ISRCTN 12002764; Chapter 6) that received Health Research Authority ethical approval (Integrated Research Application number: 303710) (543). Although fidelity reporting guidelines are being developed (544), currently none exist. However, items from the Template for Intervention Description and Replication (TIDieR) guidelines (528) are most relevant in this case

(533). Therefore, TIDieR (528) and NIHBCC recommended components (172) pertinent to ascertaining fidelity of intervention delivery are reported.

7.2.2 Setting and participants

Physiotherapists from one NHS trust (the Royal Orthopaedic Hospital, Birmingham, England) who were delivering the intervention as part of a single arm feasibility trial (Chapter 6) were invited to participate in the study. Trial patients were also consented prior to recording each intervention session.

7.2.3 Sampling of treatment sessions

To enable direct (audio) observation of intervention sessions, participating physiotherapists were provided with a digital audio recorder. To determine whether the intervention phases influenced BCT delivery and the treatment climate developed, physiotherapists were asked to record one session from each of the adoption, routine formation, and maintenance sessions of their initial and third patient, with the specific session in each phase randomised. Therefore, 30 audio recordings/transcripts were anticipated for analysis in total. The audio recordings were sent to MW by encrypted email and transcribed verbatim.

7.2.4 Behaviour change intervention

A complex multicomponent theoretically based behaviour change intervention which was developed through several interconnecting studies including: a systematic review (Chapter 2), qualitative interviews with patients (Chapter 3), focus groups with

physiotherapists (Chapter 4), and a theory identification and intervention mapping exercise (Chapter 5). The intervention utilised SDT, a contemporary meta-theory which posits that motivational quality is of equivalent importance to quantity in regard to a person's behaviour and further consequences (368, 384). As outlined in SDT, an individual's motivation regulation can be autonomous (driven from within) or controlled (actioned in response to external sources or internalised contingencies) and is influenced by three psychological needs (constructs); an individual's sense of autonomy, competence, and relatedness (368). The intervention also considered the 'phase' of behaviour change that influenced patients' PA. For patients attending physiotherapy, PA 'adoption' (130) was assumed to occur while under care, while 'maintenance' (130, 420) would continue after discharge. The qualitative work (343) also identified a connecting phase between behavioural adoption and maintenance where patients with lower-limb OA develop PA habits (termed 'routine formation').

The intervention was based around a model of approximately six sessions of physiotherapy treatment (initial session 40 mins; follow up sessions 20 mins). The conceptual phases of PA adoption, routine formation, and maintenance were integrated into the intervention protocol (adoption sessions 1-2, routine formation 3-4, maintenance 5-6). The intervention included 21 protocol (12 phase specific and 9 recurring) and 8 *optional* BCTs (543). Linked to the *Empowering Physio™* training programme (please see following section), if intervention BCTs were delivered within an empowering treatment climate, it was assumed that patients would (through the satisfaction of their psychological needs) develop autonomous motivation for PA and exhibit more positive treatment outcomes (please see Chapter 5 for further details on the interventions proposed model). Therefore, the intervention aimed to deliver BCTs within an empowering treatment climate that targeted patients' feelings of

competence, autonomy, and relatedness and promoted autonomous motivation for PA adoption, routine formation, and maintenance in patients with lower-limb OA. Further details can be found in the intervention protocol paper (543).

7.2.5 Physiotherapy training programme

Prior to intervention delivery, the physiotherapists completed 11 hours of training including 3 x 3-hour weekly sessions and a 2-hour top-up session one month later. Training consisted of four overlapping components:

Overview of intervention (1 hour): A summary of the intervention, including the protocol BCTs and phases of behaviour change were presented to physiotherapists. The NICE guidelines (10) for assessment and management of OA were also reviewed.

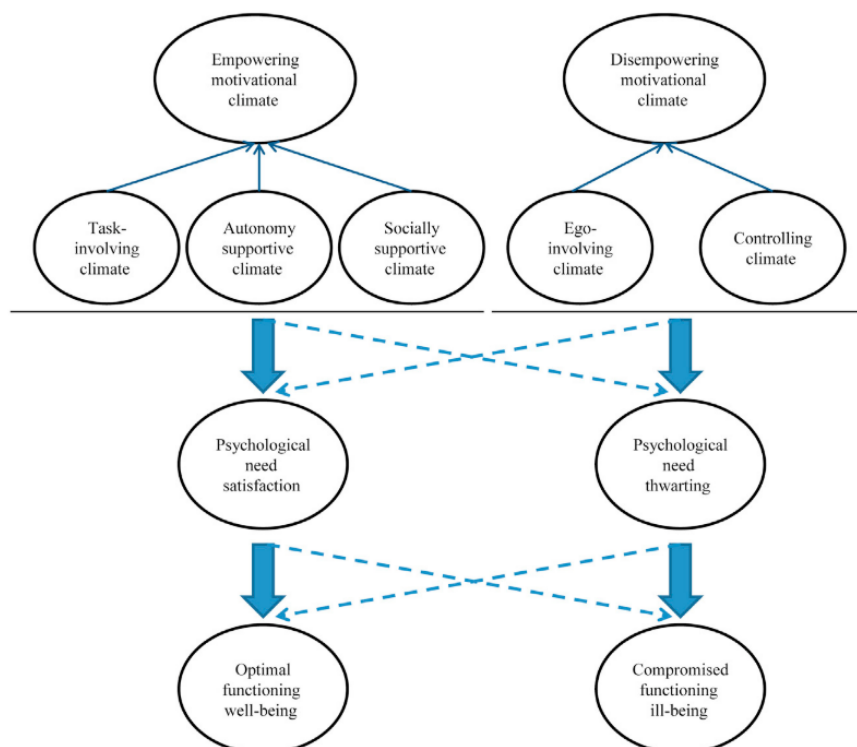
Empowering Physio™ (5 hours): Formative work by Duda (2013) (424, 425) integrated findings from prominent theories of motivation [Self Determination Theory (SDT) (384) and Achievement Goal Theory (AGT) (545)] to develop a theoretical empowering and disempowering model of the motivational climate (Figure 7.1). Based on this work, *The Empowering Coaching™* training programme (425, 535) was created to help coaches create an empowering motivational climate to optimise athletes function and well-being. Although the conceptualisation was based on research conducted in sporting environments, the core tenets have been applied to healthcare settings. A tailored, and adapted version of the *Empowering Coaching™* training programme (i.e. *Empowering Physio™*) was delivered as part of this feasibility trial. Based on the proposed model in Figure 7.1 (425, 535), physiotherapists can create a motivationally empowering climate by encouraging

patients to define their PA competence based on the effort they expend (task involved conception of their competence), by providing choice over PA activities (one example of an autonomy supportive strategy), and by demonstrating care and respect for their patients (social support). Conversely, physiotherapists would create a more motivationally disempowering treatment climate if their interactions were coercive (controlling) or based on the patients' ability to achieve their PA goals in comparison to their peers (more ego-involved). Training aimed to develop understanding and awareness of how physiotherapist-patient communication and interaction could lead to an empowering (task focused, autonomy and socially supportive) as well as disempowering (ego driven and controlling) treatment climate. The training emphasised how varying motivational treatment climates could be created through the promotion or compromising of SDT based constructs of competence, relatedness, and autonomy, impacting the quality of motivation to adopt and maintain PA behaviours and their anticipated influence on patient outcomes.

BCT delivery (3 hours): Videos demonstrating protocol BCT delivery (with links to the intervention materials including booklets and a pedometer) were presented to physiotherapists. Interactive discussion highlighted areas of strength and weaknesses of the demonstrations and how to optimally deliver the BCTs in a more empowering way.

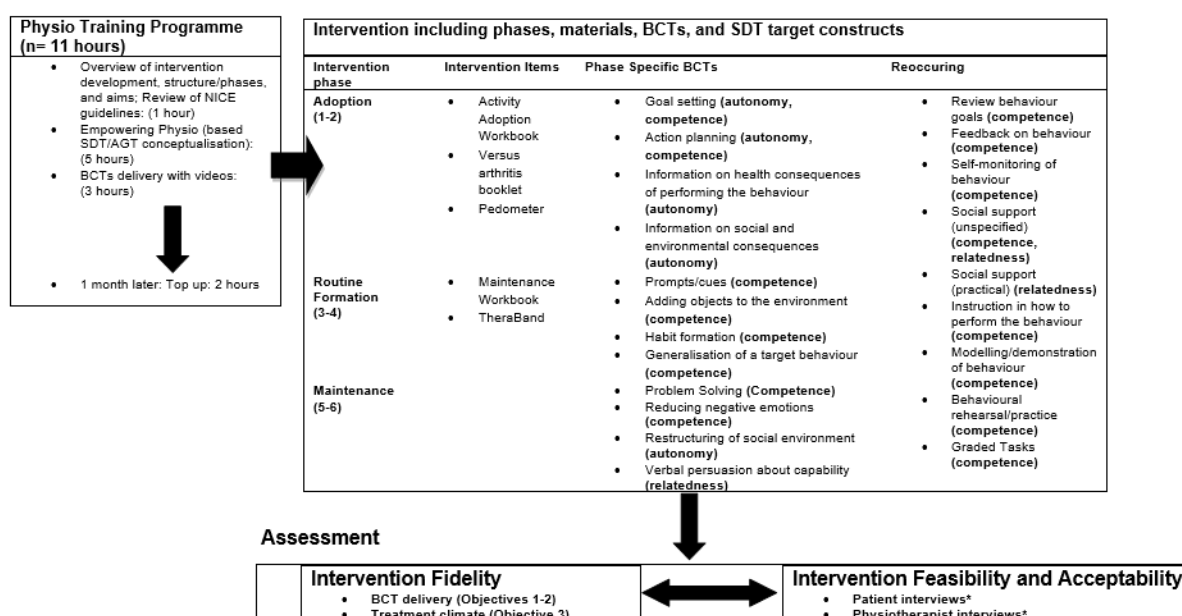
Top up session (2 hours, one month after initial training): Addressed physiotherapists' implementation of, and reflection on, the BCTs and consulting in a more empowering way. This session also focused on troubleshooting of any problems encountered during the early phase of intervention delivery.

Physiotherapists were given an intervention manual which included an outline of the feasibility trial, definitions of V1 BCTs and examples of supportive language in how to operationalise them, and pertinent research articles. The *Empowering Physio*™ training was delivered by JD (the programme's creator), and MW who introduced the BCTs and developed the intervention as the primary focus of their PhD. No formal pre-training physiotherapy competence or knowledge measurements to deliver BCTs or create an empowering treatment climate were taken. An overview of the behaviour change intervention and training program and the associated assessment can be viewed in Figure 7.2.



Alterations from intended delivery: During the training, discussions naturally developed among the physiotherapists during the Empowering Physio™ sessions which prolonged this component to approximately 7 hours. Therefore, less time was devoted to the BCT training (approximately 2 hours) than originally intended and did not cover in depth how to deliver techniques in a more empowering way.

Figure 7.2 Overview of behaviour change intervention and physiotherapy training programme and their assessment



Legend: NICE: National Institute for Health and Care Excellence; SDT: Self-Determination Theory; AGT: Achievement Goal Theory; BCT: Behaviour change technique; * Interviews evaluated perceptions of intervention phases, BCTs, and items (reported in Chapter 6)

7.2.6 Outcome measure and assessment of Fidelity:

Intervention behaviour change techniques (Objective 1-2): Two independent researchers (MW, MP) utilised Michie and colleagues 'V1 Taxonomy' to code intervention transcripts (123). Previous fidelity studies where trained researchers

utilised the V1 taxonomy (376, 546) have demonstrated high levels of inter-rater reliability. Initially, researchers undertook online V1 BCT training (547) and coded BCTs (222) from several published randomised controlled trials conducted on patients with lower-limb OA. To further aid familiarisation, the researchers coded the first two transcripts together and the following three in parallel, meeting after each transcript to discuss BCT coding interpretation. The remaining transcripts were coded independently, and the researchers met after coding every 2-3 transcripts to compare results and resolve any coding disagreements. A further researcher (SF), who had experience coding BCTs, was available to mediate if consensus could not be reached. Both protocol (those that were prescribed as part of the intervention) and non-protocol BCTs were coded as either fully or partially delivered (376) and BCTs were identified as present only once in each transcript (123).

Treatment climate (Objective 3): Two researchers (MW, AC) utilised the Interpersonal Support in Physical Activity Consultations Observational Tool (ISPACOT) (462) to evaluate physiotherapist competence to develop a motivationally empowering treatment climate by reviewing the audio recordings of intervention sessions. The ISPACOT is an SDT grounded tool and includes 21 items which evaluates the degree to which the motivational climate is empowering or disempowering through provision of autonomy support, interpersonal control, structure, and involvement (social support) (462). To maintain consistency across dimensions, scores for the Interpersonal control domain were reversed so higher scores reflected a less controlling consultation style.

The ISPACOT utilises a 7-point Likert scale ('not at all true' to 7 'very true') to evaluate the degree of environmental support for each of item. The ISPACOT has demonstrated moderate-high levels of inter-rater reliability in assessing the degree of

environmental need support in PA promotion in appropriately experienced and trained users (462). To aid ISPACOT familiarisation, the researchers reviewed the first two audio recordings together and discussed each item and how to interpret scoring. The items and scoring were then further clarified with another researcher (JD), who supported the initial development of the tool (462). The next three audio recordings were reviewed separately, with the researchers meeting after each session to clarify interpretation of scoring. The remaining audio recordings were evaluated independently with the researchers meeting after every 2-3 recordings to review findings and resolve disagreements. JD was available for mediation in case any disagreements persisted.

Each researcher was provided with a coding manual, which included definitions of all protocol and optional BCTs and examples of how these may be delivered and the ISPACOT tool (and background reading) prior to commencing the rating process.

7.2.7 Data analysis and interpretation

Data were uploaded to Excel and Statistical Package for the Social Sciences (SPSS) Version 29 for analysis.

Behaviour change techniques: The number of times each protocol and non-protocol (i.e. BCTs delivered which were not officially part of the intervention) BCT was identified and the median number of BCTs present within each phase and across all phases was calculated (Objective 1). The fidelity of protocol delivered BCTs was calculated by dividing the number of times the BCT was fully delivered by the number of times it should have been delivered (as per the protocol) and expressed as a percentage (376) (Objective 2). BCT fidelity interpretation was

classified as high ($\geq 80\%$ of expected BCTs present), moderate (50–79% of expected BCTs present) or low ($<50\%$ of expected BCTs present) (172). BCT ‘families’ (as outlined in the V1 taxonomy) and those protocol and non-protocol techniques that were commonly partially delivered were also noted to inform the discussion.

Treatment climate: The median and interquartile range scores for each ISPACOT item was calculated (Objective 3). In line with previous studies (464, 540), a score of ≥ 4 on the 7 point Likert scale was deemed evidence of physiotherapist competence to deliver each strategy/behaviour during interactions with patients.

To determine whether the behaviour change phase influenced BCT delivery and the treatment climate, the median values for the adoption, routine formation, and maintenance sessions were calculated in addition to the overall totals (Objective 4). The overall median BCT fidelity percentage and ISPACOT scores for each physiotherapist were also calculated.

Integration of results with feasibility trial: The feasibility trial (Chapter 6) included an a priori progression criterion relating to intervention fidelity:

- Protocol BCTs needed to be delivered with overall moderate fidelity (median score $\geq 50\%$)
- ISPACOT items needed to be developed competently (median item score $\geq 4/7$ score)

Once fidelity analysis was complete, the results were integrated with the wider feasibility trial findings (e.g. physiotherapists perspectives of multi-component training programme) to inform overall progression to definitive trial (Chapter 6).

7.2.8 Inter-researcher reliability: Inter-rater reliability for BCT coded and treatment climate scores was calculated using the Cohen's Kappa Statistics, with interpretations taken from recommendations from McHugh (2012) (548) where κ = 0.0-0.2 = no agreement; 0.21-0.39 = minimal agreement; 0.40-0.59 = weak agreement; 0.60-0.79 = moderate agreement; 0.80-0.90 = Strong agreement and >0.90 = almost perfect agreement.

7.3 Results

7.3.1 Inter-rater agreement

BCTs were coded and ISPACOT values identified with κ values of 0.81 and 0.87 respectively representing 'strong' agreement across both components.

7.3.2 Recorded Sessions

19 of the planned 30 (63%) physiotherapy sessions, equating to 15.6% of the total intervention sessions delivered in the feasibility trial (Chapter 6), were recorded. Session lengths ranged from 15-50 minutes (median = 32 minutes; interquartile range (IQR): 18.5-41 mins). 10 adoption, six routine formation, and three maintenance sessions were recorded respectively. The median duration of adoption sessions was 37.5 mins (IQR= 32.5-45.5), routine formation 20.5 minutes (IQR=17.5-31.5), and maintenance sessions 18.0 minutes (IQR= 16.5-18.5) respectively. Of those sessions that were not completed ($n=11$), four were due to the physiotherapist leaving the Trust, three to a recorder not being available, and four to

patients being discharged prior to what would constitute the maintenance sessions (i.e., prior to intervention session 5).

7.3.3 Physiotherapists

Demographic detail and fidelity results of each physiotherapist is summarised in Table 7.1. 5 physiotherapists (n=3 females) undertook training of the delivery of the intervention. Physiotherapists had a median of seven years' experience treating patients with lower limb OA. Individual physiotherapists treated between 2-10 participants in the trial. Those physiotherapists who treated the most patients (physiotherapists 3-4) had the highest number of recorded sessions (n= 5-6) and were the only ones who had maintenance sessions recorded. All physiotherapists demonstrated 'moderate' fidelity in BCT delivery and competently developed an empowering treatment climate.

Table 7.1: Fidelity of BCT delivery and treatment climate by individual physiotherapists

Physio number	Gender	Years treating lower limb OA	Highest Educational Qualification	Number of patients managed (n=36)	Number of sessions recorded	Session phases	Per session BCT fidelity median (IQR)	Per session ISPACOT score median (IQR)
1	Male	7	MSc module	2	3	2 Adoption 1 Routine formation	71.4 (64.25-85.7)	5 (4.5-5)
2	Male	3	MSc	8	2	2 Adoption	72.9 (67.1-78.8)	4 (3.5-4.5)
3	Female	12	MSc modules	9	5	2 Adoption 2 Routine formation 1 Maintenance	53.8 (38.5-69.2)	6 (5-6)
4	Female	7	MSc modules	10	6	2 Adoption 2 Routine formation 2 Maintenance	57.7 (34.6-69.2)	6 (5-6)
5	Female	1.5	BSc	7	3	2 Adoption 1 Routine formation	61.5 (38.5-65.4)	5 (5-5)

Legend: OA: Osteoarthritis; Msc: Master of Science; BSc Bachelor of Science; IQR: Inter quartile range; BCT: Behaviour Change Technique; Interpersonal Support in Physical Activity Consultations Observational Tool; IQR: Interquartile range; ISPACOT items evaluated by Likert scale [1-7]; IQR: interquartile range.

7.3.4 Protocol and non-protocol Behaviour Change Techniques delivered (Objective 1)

Across the 19 sessions, 272 BCTs were fully delivered and a median of 14.25 BCTs delivered per session (IQR= 12.5-16.5; range= 7-22). 166 BCTs were delivered during adoption (median 15.5 (IQR 14.25-17), 81 during routine formation (median 14 (IQR 11-6), and 25 during maintenance sessions respectively (Median 8, IQR- 7.5-9). 15 BCTs were partially delivered across sessions (0.8 per session). Of these, 9 (60%) were from the family *goals and planning* group with 1.2 *Problem solving* partially delivered four times. 33 BCTs, including 10 non-protocol techniques, were identified across sessions with 15 being coded frequently (identified in > 50% of sessions). Of those frequently coded, four were from the *goals and planning* group and three were from *Repetition and substitution* family. The most common BCTs identified included the protocol BCTs: *Social Support (unspecified)* (identified in 100% of recorded sessions), *Information about health consequences* (89%), *Social support (emotional)* (89%), and *Instruction on how to perform the behaviour* (84%) and the non-protocol BCT: *Social reward* (100%). A summary of BCTs coded within sessions and across the phases can be seen in Table 7.2.

Table 7.2: Total number and frequency of behaviour change techniques delivered across phases

	Total (n=19)		Adopt (n=10)		Routine (n=6)		Main (n=3)	
BCT grouping/BCT	F	P	F	P	F	P	F	P
Recurring								
1.5/1.7 Review behaviour goals or outcome	11	1	6	0	4	1	1	0
2.2/2.7 Feedback on behaviour or outcomes of behaviour	12	0	7	0	3	0	2	0
2.3/2.4 Self-monitoring of behaviour or outcomes of behaviour	13	0	9	0	2	0	2	0
3.1 Social support (unspecified) or encouragement	19	0	10	0	6	0	3	0
3.2 Social support (practical)	3	2	2	1	1	1	0	0
4.1 Instruction in how to perform the behaviour	16	0	9	0	5	0	2	0
6.1 Modelling/demonstration of behaviour	9	0	7	0	2	0	0	0
8.1 Behavioural rehearsal/practice	13	0	8	0	4	0	1	0
8.7 Graded Tasks	12	0	8	0	4	0	0	0
11.1 Pharmacological Support	2	1	1	1	1	0	0	0
Adoption								
1.1/1.3 Goal setting (behaviour and/or outcome)	14	2	8	1	5	1	1	0
1.4 Action planning (including implementation intentions)	14	2	8	1	5	1	1	0
5.1 Information on health consequences of performing the behaviour	17	0	10	0	5	0	2	0
5.3 Information on social and environmental consequences	7	0	5	0	2	0	0	0
<i>Rewards one of: Material 10.2, Non-Specific 10.3, Social 10.4, Self 10.9, Outcome, 10.10*</i>	19	0	10	0	6	0	3	0
Routine Formation								
7.1 Prompts/cues	3	1	2	1	0	0	1	0
8.3 Habit formation	3	0	1	0	2	0	0	0
8.6 Generalisation of a target behaviour	14	0	7	0	5	0	2	0
12.5 Adding objects to the environment	12	0	8	0	4	0	0	0
Maintenance								
1.2 Problem Solving	11	4	7	3	3	1	1	0
11.2 Reduce negative emotions	1	1	1	1	0	0	0	0
12.2 Restructuring of social environment	9	0	4	0	4	0	1	0
15.1 Verbal persuasion about capability	4	1	3	0	1	0	0	1
Non protocol BCTS								
1.8 Behavioural contract	1	0	1	0	0	0	0	0
3.3 Social Support (Emotional)	17	0	10	0	5	0	2	0
4.4 behavioural experiment	2	0	2	0	0	0	0	0
5.4 Monitoring of emotional consequences	1	0	1	0	0	0	0	0
5.6 Information about emotional consequences	2	0	2	0	0	0	0	0
9.2 Pros and Cons	1	0	1	0	0	0	0	0
12.1 Restructuring the physical environment	7	0	5	0	2	0	0	0
13.2 Framing/reframing	1	0	1	0	0	0	0	0
15.2 Mental rehearsal of successful performance	1	0	1	0	0	0	0	0
16.3 Vicarious consequences	1	0	1	0	0	0	0	0
Totals	272	15	166	9	81	5	25	1

Legend: BCT: Behaviour Change Technique; Adopt: Adoption; Routine: Routine Formation; Main: Maintenance; F: BCT fully delivered; P: BCT partially delivered

7.3.5 Fidelity delivery of protocol behaviour change techniques (Objective 2)

Overall BCT intervention fidelity was moderate (median percentage 63.2; IQR = 33.3-80). 6 BCTs were delivered with high fidelity: 2 from the recurring group, 3 from the adoption group, 1 from routine formation. 7 BCTs were delivered with moderate fidelity (5 recurring; 1 adoption; 1 routine formation). 8 BCTs, including all maintenance phase specific techniques, were delivered with low fidelity (2 recurring; 2 routine formation; 4 maintenance BCTs). Overall, adoption phase specific BCTs were delivered with high fidelity (Median: 80; IQR 72.5-85), recurring BCTs (Median: 63.2 IQR= 57.9-68.4) and routine formation BCTs (Median 50; IQR= 25.0-70.1) were delivered with moderate fidelity, and maintenance BCTs (Median 16.65; IQR= 0.0-33.3) were delivered with low fidelity. Fidelity of delivery of protocol BCTs is summarised in Table 7.3.

Table 7.3: Intervention fidelity delivery of protocol behaviour change techniques

BCTs	Number of sessions BCT expected to be fully delivered in	Number of times BCT fully coded in expected sessions	BCT fidelity percentages	Fidelity level
Recurring				
1.5/1.7 Review behaviour goals or outcome	19	11	57.9	Moderate
2.2/2.7 Feedback on behaviour or outcomes of behaviour	19	12	63.2	Moderate
2.3/2.4 Self-monitoring of behaviour or outcomes of behaviour	19	13	68.4	Moderate
3.1 Social support (unspecified) or encouragement	19	19	100	High
3.2 Social support (practical)	19	3	15.8	Low
4.1 Instruction in how to perform the behaviour	19	16	84.2	High
6.1 Modelling/demonstration of behaviour	19	9	47.4	Low
8.1 Behavioural rehearsal/practice	19	13	68.4	Moderate
8.7 Graded Tasks	19	12	63.2	Moderate
Adoption (n= 5 physiotherapists)				
1.1/1.3 Goal setting (behaviour and/or outcome)	10	8	80.0	High
1.4 Action planning (including implementation intentions)	10	8	80.0	High
5.1 Information on health consequences of performing the behaviour	10	10	100.0	High
5.3 Information on social and environmental consequences	10	5	50.0	Moderate
Routine Formation (n= 5 physiotherapists)				
7.1 Prompts/cues	6	0	0	Low
8.3 Habit formation	6	2	33.3	Low
8.6 Generalisation of a target behaviour	6	5	83.3	High
12.5 Adding objects to the environment	6	4	66.7	Moderate
Maintenance (n= 2 physiotherapists)				
1.2 Problem Solving	3	1	33.3	Low
11.2 Reduce negative emotions	3	0	0.0	Low
12.2 Restructuring of social environment	3	1	33.3	Low
15.1 Verbal persuasion about capability	3	0	0.0	Low

Legend: BCT: Behaviour Change Technique; Fidelity levels: High: BCT identified in > 80% of expected sessions; Moderate: BCT identified in 50-79% of expected sessions; Low: BCT identified in <50% of expected sessions

7.3.6 Competence to develop a motivationally empowering treatment climate

(Objective 3)

Table 7.4 outlines the total and phase specific median scores across the ISPACOT dimensions. Overall, physiotherapists competently developed an empowering treatment climate (median ISPACOT score 5; IQR = 5-6). All components met the minimum satisfactory competency median score threshold of 4/7 except one, *Risk of inactivity* (median 2/7) from the *Structure* dimension. Both components in the *Involvement* dimension (*demonstrating affection* and *acceptance of behaviours and beliefs*) were graded as a median of 6 demonstrating high levels of relatedness support given to patients. One component of the *controlling* domain (highlighting external benefits) was judged as very-well delivered (median score of 7). Most components scored equally throughout the conceptual phases. However, three components in the 'controlling' dimension demonstrated a reduction of ≥ 1.5 on the likert scale during the maintenance sessions: two components (*Forcing change* and *Enforcing compliance*) reduced from 6 to 4 and one (*encouraging specific beliefs*) from 5.5 to 4, indicating physiotherapists became more controlling in the defined 'maintenance' phases.

Table 7.4: Treatment Climate provided by the physiotherapists across the intervention phases as measured by the Interpersonal Support in Physical Activity Consultations Observational Tool

ISPACOT domain/subject	Overall (n=19) Median [IQR]	Adoption (n=10) Median [IQR]	Routine Formation (n=6) Median [IQR]	Maintenance (n=3) Median [IQR]
Autonomy support				
Acknowledging feelings (negative affect)	4 [4-5]	4.5 [4-5]	4.5 [4-5]	4 (4-4.5)
Acknowledging feelings (positive affect)	5 [4-5]	5 [4-5]	4.5 [4-5]	5 (5-5.5)
Provide Rationale	4 [4-5]	4 [4-5]	4 [4-4]	5 (4.5-5)
Encouraging self-initiative	5 [4-5]	5 [3.75-5.25]	4.5 [4-5]	4 (4-5)
Effective non-verbal skills	5 [4-5]	5 [4-6]	4.5 [4-5]	4 (4-5)
Providing choice	5 [3-6]	5 [3-6]	5.5 [3.75-6]	4 (4-5)
Taking perspective	5 [4-6]	5 [4.75-5.25]	4.5 [4-6]	5 (4.5-5.5)
Enhancing self-worth	5 [5-6]	5 [4.75-5.25]	5.5 [5-6]	6 (5.5-6.5)
Involvement				
Demonstrating affection	6 [5-6]	6 [4.75-6]	6 [5.75-6]	6 (5.5-6.5)
Accepting all behaviours and beliefs	6 [5-6]	6 [4.75-6]	6 [5.5-6]	5 (5-6)
Structure				
Non-controlling reinforcement	5 [5-6]	5 [4-5]	5 [4.75-6.25]	6 (5.5-6.5)
Encouraging questions	4 [4-5]	4 [4-5]	4 [4-6.5]	5 (5-6)
Appropriate goal setting	4 [4-5]	4 [3.75-5.25]	4 [3-4.25]	4 (4-4.5)
Informative (risks of inactivity)	2 [1-3]	2 [1.75-3]	1 [1-3.5]	2 (1.5-3)
Informative (benefits of activity)	5 [3-6]	5 [3-6]	4 [2.5-5]	5 (4.5-5.5)
Controlling				
Over authoritative	5 [4-6]	4 [3.75-5.25]	5.5 [4.5-7]	5 (4.5-6)
Enforcing compliance	6 [4-7]	6 [4.75-7]	6 [4.75-7]	4 (3.5-5.5)
Forcing change	6 [4-7]	6 [5.75-7]	6 [3.75-6]	4 (3.5-5.5)
Controlling language	5 [4-5]	4.5 [3-5]	5 [4.75-6]	5 (4-6)
Using deadlines	6 [5-6]	6 [4.75-6]	5.5 [5-6]	6 (5-6.5)
Highlighting external benefits	7 [6-7]	7 [7-7]	7 [4.5-7]	7 (4-7)
Using conditional acceptance	5 [4-6]	5.5 [4.75-6]	5.5 [3.5-6.25]	5 (3.5-5.5)
Encouraging specific beliefs and behaviours	5 [4-6]	5.5 [3.75-6]	5.5 [4.75-7]	4 (4-5.5)

Legend: ISPACOT: Interpersonal Support in Physical Activity Consultations Observational Tool; IQR: Interquartile range; All items evaluated on likert scale [1-7].

7.4 Discussion

This study outlines the robust assessment of physiotherapists' fidelity of BCT delivery and competence to develop an empowering treatment climate as part of a feasibility trial. In this trial, a multi-component and theory-grounded behaviour change intervention was delivered which targeted PA adoption, routine formation, and maintenance in patients with lower-limb OA. Overall, physiotherapists delivered the protocol BCTs with moderate fidelity (median percentage 63.2) and competently developed an empowering treatment climate (median ISPACOT score 5/7) and met the feasibility trials' a priori progression criteria. However, limited data from the routine formation and maintenance sessions were available for analysis in regard to both aspects. Therefore, no firm conclusions can be drawn regarding the influence of intervention phases on fidelity of BCT delivery or competence to develop an empowering treatment climate.

The total number of BCTs identified (33) and median number delivered per session (14.25) agree with other studies (376, 549). Furthermore, the overall 'moderate' fidelity value (median value of 63.2%) sits within the range of other PA studies [56.8% (376)-63.6% (550)], and the number and fidelity percentage of BCTs that were delivered with high (n=6; 29%), moderate (n=7; 33%) and low (n=8; 38%) fidelity are consistent with the literature (376).

Of the non-protocol BCTs identified, Social support (emotional) was coded in 100% of intervention sessions. The V1 taxonomy defines 'Social support (emotional)' as *'Advise on, arrange, or provide emotional social support (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour'* (123) and was coded if the physiotherapist clearly demonstrated empathy or patient centred

communication. As the intervention aimed to promote a motivationally empowering treatment climate which entails increasing feelings of relatedness (via the creation of a more caring, respectful, trustworthy environment), it is perhaps unsurprising that this BCT was frequently coded. Moreover, the high frequency of the Social support (emotional) BCT agrees with previous fidelity studies of other SDT based interventions (376) and will be added to the intervention protocol.

Overall, the recurring (2 high fidelity; 5 moderate; 2 low) and adoption phase (3 high; 1 moderate) BCTs were delivered with greater fidelity than BCTs in later intervention phases. Although it is acknowledged that there are limited data, there was a noticeable drop in BCT fidelity percentage in the routine formation and maintenance phases, with 2 (50%) and 4 (100%) phase specific BCTs delivered with low fidelity respectively. Our preliminary work (Chapter 3) (343) suggested that the formation of a PA routine was integral to embed PA behaviours and consideration of wider environmental factors influential of maintenance. However, physiotherapists did not frequently utilise the BCTs *Prompts and cues* and *Habit formation* during routine formation or consider the social and physical environmental factors in depth during maintenance sessions. Therefore, the frequently identified BCTs may be relevant throughout the behaviour change process and less detail required to delineate phase specific from recurring BCTs. Alternatively, and in agreement with the interviewed physiotherapists (Chapter 6), there may have been too many BCTs within the intervention, which included 21 protocol BCTs (376). Moreover, the systematic review examining BCTs delivered within physiotherapy interventions (Chapter 2) (277) found approximately 11 techniques were delivered per intervention. Thus, the intervention could be refined to primarily utilise the recurring and frequently delivered phase specific BCTs with further consideration of those techniques that were

problematic (e.g. *Problem solving*) or infrequently (e.g. *Restructuring of the social environment*) delivered. This may reduce the total number of BCTs and enable them to be delivered with high(er) fidelity.

All ISPACOT items except one (*risks of an inactive lifestyle*) met the threshold for competence, with an overall median score of 5/7 across dimensions. These findings support previous individual (436) and group based (540, 541) SDT based training programmes that aimed to enhance physiotherapists' communication skills and patient centred care (which are promotive of a more empowering climate). The *involvement* domain, which examined physiotherapists commitment to developing the patient-physiotherapist relationship (551), was evaluated to be consistently high (median of 6). Although this domain included only two items (*demonstrating affection* and *acceptance of behaviours and beliefs*), these components overlap with the frequently delivered social support BCTs [i.e. Social support (unspecified), Social support (emotional) and Social reward]. Taken together, the results suggest that physiotherapists provided Overall, those physiotherapists who recorded the highest number of sessions (n= 5-6) also treated the most participants (n= 9-10) and achieved higher overall treatment climate ratings compared to physiotherapists who recorded less sessions or treated fewer participants. This may demonstrate that familiarity with the intervention and specific patients generated a more empowering treatment climate. Alternatively, those physiotherapists who were more experienced with the intervention (i.e. those who delivered higher numbers of sessions) may have been more willing to have them recorded.

Three items in the 'controlling' domain demonstrated decreased scores of 2 (*enforcing compliance* and *enforcing change*) and 1.5 (*encouraging specific beliefs and behaviours*) respectively during the maintenance sessions. An increase in

controlling communication can reduce the quality of the interpersonal relationship (552), promote controlled motivation (364), and lead to inflexible PA behaviours (553). While it is noted that competence was sustained and very limited maintenance data are available, these results demonstrate a clinically significant drop (554) and may require further consideration. Patient-centred communication is important for maintenance of PA (555). Therefore, top-up training or booster sessions could review how to reduce controlling communication through additional role-play or practice with real patients.

The intervention focussed on promoting PA rather than decreasing sedentary behaviour. Therefore, it is perhaps unsurprising that physiotherapists educated patients about the importance and benefits of PA behaviours (linked to the BCT *Information about health consequences*) but did not frequently instruct on the risks associated with inactivity. Sedentary [stationary postures utilising ≤ 1.5 metabolic equivalent of task (93)] and PA behaviours are recognised as distinct entities with unique determinants (556). Although sedentary lifestyles (e.g. from prolonged sitting) are a growing global health concern and associated with the development of non-communicable diseases (557), there has been little research conducted on this compared with PA in patients with lower-limb OA (558). Therefore, advice on educating patients about reducing sedentary time, and how to do this in a more empowering way, will be incorporated into the intervention.

Overall, the treatment climate items were more frequently competently developed compared to protocol BCTs being delivered with high fidelity. This may reflect the hours allocated to the delivery of the *Empowering Physio*TM (6 hours) and defining and practicing BCT delivery (3 hours) within the training programme. Therefore, physiotherapists may have prioritised developing an empowering treatment climate

or recalled it more clearly than BCT delivery during intervention delivery. Moreover, during training, physiotherapists highlighted the importance of the treatment climate which prolonged discussions and took additional time away from the BCT practice. There were also some problems with the audio quality of the videos presented as part of the training programme, which made some BCTs difficult to understand and see demonstrated. The 11 hours of the multi-component physiotherapist training reflected the existing funding and limited time physiotherapists were available for release from the NHS service towards the end of the COVID pandemic restrictions. However, it is important to note that the *Empowering Coaching™/Empowering Physio™* component alone is often delivered over 12 hours, which includes time dedicated to linking BCTs to their targeted constructs and practicing (and receiving feedback on) delivery in a more motivationally empowering way. Furthermore, the intervention physiotherapists suggested reducing the number of intervention BCTs (Chapter 6). Taken together, there may be too many intervention BCTs, and insufficient time allotted during training to appropriately define BCTs and develop physiotherapists understanding of how to deliver them in a more motivationally empowering way. Therefore, additional funding may be sought to cover further physiotherapist training time to address these issues when progressing to a definitive trial.

7.5 Strengths and limitations

This study has several strengths. Two coders independently measured fidelity of physiotherapists' BCT delivery and competence to develop an empowering treatment climate utilising reliable and valid measures with strong inter-rater

agreement. Audio recording sessions enabled direct measurement of intervention delivery and these methods have been identified as a gold standard (559) as they are more reliable (172) and accurate (560) than practitioner or patient self-report, but less invasive than an observer physically monitoring during (559, 561).

However, this study also had several limitations. Only 19 intervention sessions (63% of anticipated) were recorded and the limited data available from the routine formation and maintenance phases meant Objective 4 could not be sufficiently answered. One researcher (MW) was involved in intervention design, physiotherapy training, and fidelity assessment. While attempts were made to ensure decisions were transparent and robust (e.g. use of two trained researchers evaluating components independently), some bias may have influenced the results. Although physiotherapists delivered BCTs with moderate fidelity and competently developed an empowering treatment climate, their pre-training skills were not measured. Therefore, no determination of the effectiveness of the training programme in changes in the behaviours and strategies used by the physiotherapists can be made. It would be useful to explore this in future studies.

As of July 2024, there are no agreed published guidelines to inform detailed reporting of fidelity studies. Therefore, this study's reporting followed recommendations from related guidelines (e.g. TIDIER) and frameworks (e.g. NIHBC). However, there may have been some items which lacked clarity or detail to some readers and the publication of the ReFiND guidelines (544) will inform improved reporting in future fidelity studies.

Finally, the criteria to determine 'low/moderate/high' fidelity of BCT delivery (low < 50%, moderate-high $\geq$ 50%) (172) and 'competence' to develop an empowering

treatment climate ($\leq 4/7$ on the Likert scale) (464, 540) were based on expert opinion and previous studies and currently lack empirical support. Therefore, establishing valid and robust criteria for the fidelity and competency assessment across these measures is warranted.

7.6 Conclusions

This study assessed physiotherapists' fidelity of BCT delivery and competency to develop an empowering treatment climate while delivering a theoretically grounded behaviour change intervention aiming to promote PA in patients with lower-limb OA. 19 intervention sessions across the behaviour change phases of adoption, routine formation, and maintenance phases were audio recorded and two independent researchers evaluated the delivery of protocol BCTs and promotion of an empowering treatment climate.

Overall, BCTs were delivered with moderate fidelity and the treatment climate was developed competently, which met the feasibility trials progression criteria. However, there was insufficient data to conclude how physiotherapists' fidelity of intervention delivery was influenced by the intervention phases.

The number of intervention BCTs will be reviewed, and where possible reduced, and further training time allocated to help physiotherapists develop understanding of BCTs and practice their delivery. Future studies should evaluate pre-training BCT delivery and empowering treatment climate promotion so the effectiveness of the training on physiotherapist behaviours can be measured. Establishing valid and robust levels of fidelity for BCT delivery and competency of treatment climate development and proposing fidelity reporting guidelines are required.

7.7 Funding

This study was primarily funded by the Private Physiotherapy Educational Foundation (A1 scheme) and the Musculoskeletal Association of Chartered Physiotherapists level 1 research awards. The funding bodies had no role in the design and writing of the trial protocol and did not have a role in data collection, management, analysis and interpretation of data or writing of the report.

CHAPTER 8: EFFECTIVENESS OF BEHAVIOUR CHANGE TECHNIQUES IN PHYSIOTHERAPY INTERVENTIONS TO PROMOTE PHYSICAL ACTIVITY ADHERENCE IN PATIENTS WITH LOWER LIMB OSTEOARTHRITIS: A SYSTEMATIC REVIEW UPDATE

Chapter overview

This chapter details an update of the findings from the original systematic review (Chapter 2) which examined the effectiveness of physiotherapist delivered behaviour change techniques at promoting physical activity (PA) adherence in patients with lower-limb OA (Thesis Objective 1). The primary aim of the updated systematic review was to identify additional BCTs that had been utilised within physiotherapy interventions since the conduct of the original searches (January 2018) until the end of the PhD study period. The secondary aim was to synthesise data from the original and updated systematic reviews to evaluate BCT effectiveness ratios to promote PA adherence at short, medium, and long term timepoints post baseline. The tertiary aim was to highlight developments in the evidence base (e.g. intervention design and delivery and outcome assessment) since the original systematic review was published. Searches were conducted on March 1st, 2023. Twelve additional RCTs (n=2414 participants) were identified from 7 countries of variable risk of bias (2 low; 2 some concerns; 8 high) and overall moderate fidelity reporting. Overall, 39 distinct BCTs were identified from RCTs. The BCT effectiveness ratios from the original and updated systematic reviews were synthesised and placed in context with contemporary evidence to inform current recommendations for use in physiotherapy clinical practice. The updated RCTs demonstrated increased blended physiotherapy intervention delivery, a higher number of interventions underpinned by behaviour change theory, and increased use of directly measured PA.

8.0 Background

Lower-limb (Hip and knee) Osteoarthritis (OA) is a prominent cause of global disability (4). In the United Kingdom approximately 7 million people ≥ 45 years of age experience hip or knee OA related symptoms (8). Furthermore, OA is increasing in prevalence, including in people aged 35-45 years (562). With the increase in aging populations, the healthcare burden and the associated costs are estimated to escalate over the coming years and over run global healthcare systems.(13)

Physical Activity (PA) interventions, which include formal exercise routines and more general daily-life activities, are endorsed by healthcare guidelines as frontline treatment for patients with lower-limb OA. (3, 10, 64). Physiotherapists are the primary healthcare providers of PA interventions in several countries, and well place to utilise BCTs to promote PA behaviours in patients with lower-limb OA to help self-manage their symptoms (92).

The original published systematic review (Chapter 2) (277) examined the effectiveness of physiotherapist delivered BCTs to promote short (≤ 3 months post baseline), medium (3-6 months post baseline), and long-term (≥ 12 months post baseline) PA adherence in patients with lower-limb OA. The results demonstrated that certain BCTs were most effective over short (e.g. Action planning) or medium-long term (e.g. Problem solving) timeframes, while others (e.g. Self-monitoring of behaviour) were effective across all timepoints. However, these results were based on modest effectiveness ratios from medium-high risk of bias RCTs with poor fidelity reporting. Therefore, limited evidence-based recommendations on BCT usage in physiotherapy practice could be made (277).

The outbreak of the COVID-19 pandemic in 2020 caused prolonged disruption and alterations to NHS physiotherapy outpatient delivery. Therefore, the planned behavioural physiotherapy feasibility trial was delayed by approximately 2 years.

The original systematic review was published in 2019, with the searches completed in January 2018. A scoping search was conducted during the latter stages of the feasibility trial (early 2023) which identified that further physiotherapy RCTs had been completed during this time and therefore, the systematic review searches required updating. This chapter reports an update of the original systematic review (Chapter 2) to identify RCTs completed since January 2018.

A primary driver for the update was to identify developments within the evidence base that had occurred during the conduct of this part-time PhD that was further prolonged due to COVID 19. This updated systematic review will therefore inform whether changes are required in the planning of a definitive trial based on changes in recent trial conduct. Therefore, developments that are identified in the updated systematic review (e.g. intervention mode of delivery, additional BCTs used) are presented individually rather than being synthesised with the original systematic review. However, BCT effectiveness ratio data from the updated and original reviews have been synthesised so recommendations on the influence of each technique on PA adherence can be made based on the overall body of evidence. For transparency, the following definitions are applied to systematic review findings in this chapter:

Original: Any data from the systematic review reported in Chapter 2 (i.e. from RCTs published up to January 1st 2018)

Updated: Any data collected from the systematic review outlined in Chapter 8 (i.e. from RCTs published since January 1st, 2018)

Synthesised: Findings from combined data from the original and updated systematic reviews.

8.2 Methods

This is an update of the original systematic review (Chapter 2). Therefore, most methods utilised in this chapter mirror those used in the original systematic review and only items that are amendments to the original protocol are outlined below. The updated systematic review is reported in line with the most recent version of the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) recommendations (563).

8.2.1 Information sources

In the original systematic review, the Zetoc database was used to identify grey literature. However, Zetoc was discontinued in 2022. Therefore, in the updated systematic review, Google Scholar was utilised in addition to the Conference Proceedings Citation Index from the Web of Science to identify grey literature.

8.2.2 Selection process

The updated searches were conducted on 1st March 2023 (from 1st January 2018). All searches were uploaded to Endnote (Refworks used in the original systematic

review). An updated PRISMA flow diagram (563) was used to demonstrate the flow of identified studies subsequently included or discarded at each stage.

8.2.3 Risk of bias assessment tool

RCT risk of bias (RoB) was assessed using the Cochrane Risk of Bias 2 tool (564) which was not published at the time of the original systematic review. The updated tool utilises 5 domains (randomization, intervention deviations, missing outcome data, outcome measurement, reported results selection) to evaluate trial internal validity (565). Each domain includes questions which are interpreted on a flow chart algorithm to establish whether the domain is at: Low risk of bias, Some concerns, or High risk of bias (565). A trial was deemed 'Low' RoB if all domains were low risk. A trial was graded at 'some concerns' if one of more domains were at 'some concerns' but no domain was 'high' RoB (564). The trial was judged at 'high' RoB if any domain was high risk, or if there cumulative domains were at 'some concerns' that reduced the RCTs overall internal validity (564).

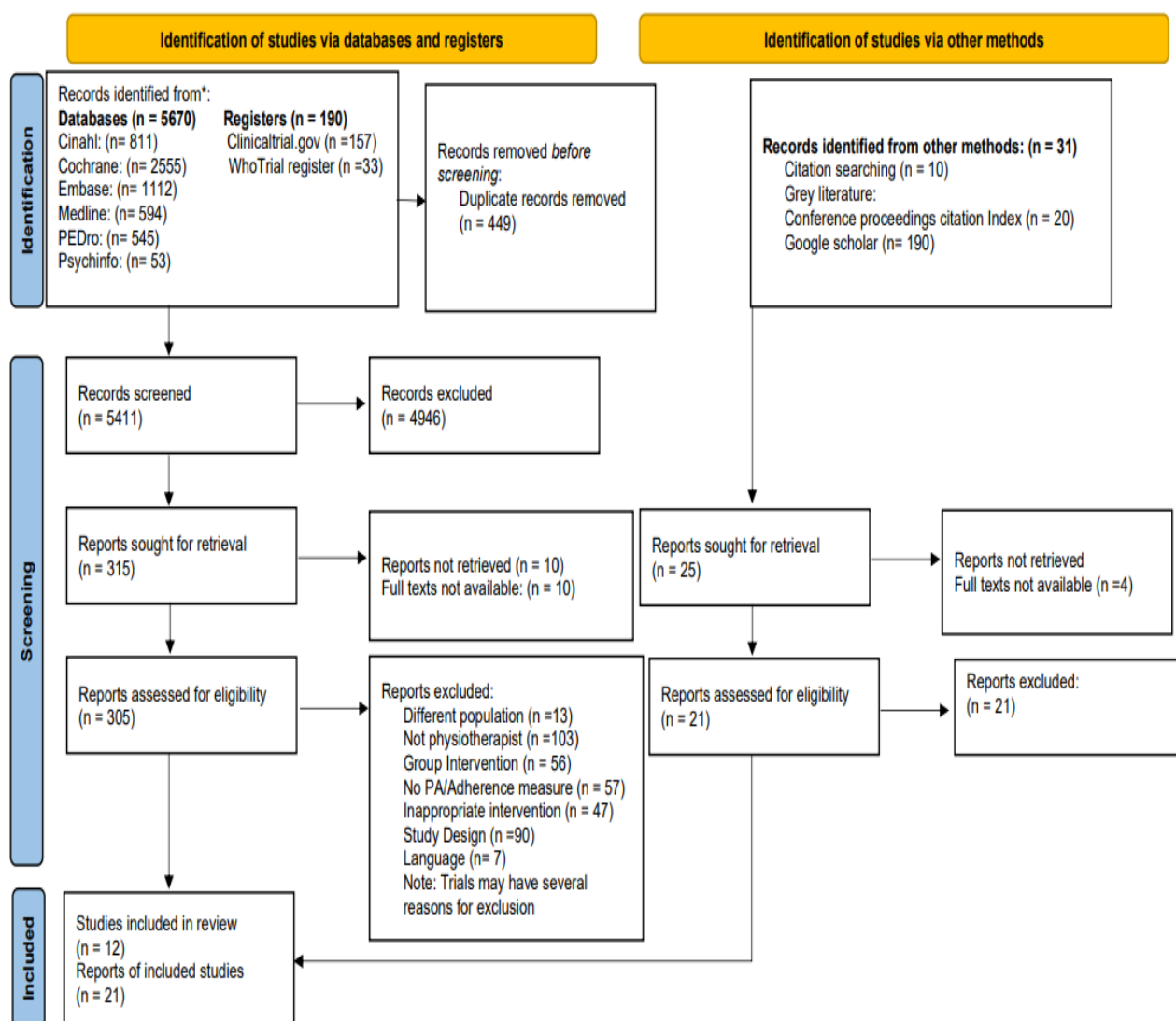
8.3 Results

8.3.1 Selection of updated trials

The updated searches identified 5891 publications with 5411 titles and abstracts screened (after duplicates removed). 340 full text reports were reviewed and 12 RCTs were included in the updated systematic review. Reports were excluded at the full text stage for focusing on a different participant population (n=13), the intervention being group-based (n=56) or not delivered by a physiotherapist (n=103), the trial not including a PA/adherence measure (n= 57), and non-use of an RCT

study design (n=90). The flow of RCT selection in the updated systematic review is detailed in Figure 8.1.

Figure 8.1: Selection flow diagram of updated systematic review searches



8.3.2 Characteristics of updated trials

The characteristics of the updated RCTs are summarised in Appendix 8.1. The 12 RCTs (355, 488, 495, 496, 497, 498, 499, 566, 567, 568, 569, 570) included a total of n=2414 participants from 7 countries. 9 RCTs (355, 495, 497, 499, 566, 567, 568, 569, 570) included patients with knee OA, two RCTs included patients with both hip and knee OA (496, 498), and one RCT (488) included patients with hip OA respectively.

In-person BCTs were delivered by physiotherapists in 10 RCTs, with nurses (497) and dieticians (569) offering additional BCT support in two trials. The internet was utilised to deliver supplementary BCTs in four behavioural physiotherapy interventions (488, 498, 566, 567) and one comparator intervention (355). Phone calls provided supplementary BCTs in five behavioural physiotherapy interventions (495, 497, 499, 567, 570) with two of these trials also using phone calls in the comparator intervention (497, 499).

Ten RCTs (355, 488, 495, 497, 498, 499, 567, 568, 569, 570) reported that intervention providers undertook training and three (355, 497, 567) did not report any details on training provisions. For those that provided detail, training duration ranged from 2 hours for a comparator group exercise intervention (569) to five days for a detailed behavioural physiotherapy intervention targeting exercise adherence (568).

8.3.3 PA adherence outcomes used in updated trials

Detail on PA and adherence outcomes used and the effect sizes at short, medium, and long-term time points for each domain is provided in Appendix 8.2. 3 RCTs (495, 566, 570) included only short-term (3 months post baseline) PA adherence data, two

RCTs measured (496, 499) medium-term data (6 months post baseline), and seven recorded long term data (≥ 12 months post baseline).

PA and adherence outcomes demonstrated considerable heterogeneity across trials. Self-report PA was evaluated in seven RCTs (355, 488, 496, 497, 498, 567, 568). The Physical Activity Scale for the Elderly (PASE) was the most common self-report PA tool utilised (four RCTs (355, 488, 567, 568)). Seven RCTs used accelerometers as a direct measure of PA (495, 496, 497, 498, 499, 568, 570). These were worn around the waist (497, 498, 568), triceps (495, 496, 570) and wrist (499) respectively. The accelerometers measured a number of aspects of PA behaviours including daily steps and bouts or total time spent in moderate-vigorous PA. RCTs gathered between three (495, 570) - five (496, 499) features of directly measured PA.

Four RCTs evaluated adherence (488, 566, 568, 569). Overall, adherence measurement was highly heterogeneous with one RCT measuring adherence in four separate ways (488). Adherence measures included: PA/exercise diaries, patient and therapist rated PA adherence measures, therapist rated adherence, and the number of PA sessions completed outside of the clinic.

Across RCTs that enabled SMD calculations to be completed, behavioural physiotherapy interventions were statistically significantly more effective at promoting PA adherence than comparator groups in 25% (1 out of 4 comparisons) of adherence outcomes (1/1 short-term; 0/1 medium term; 0/2 long term), 14% (3/21 comparisons) of self-report PA outcomes (0/7 short-term; 2/6 medium term; 1/8 long-term) and 14% (1/7) of directly measured PA outcomes (0/3 short-term; 1/2 medium-term; 0/2 long-term) respectively.

8.3.4 Risk of Bias within and across updated trials

Two RCTs were assessed as 'low' RoB (488, 568), two 'at risk' (499, 569) and eight as 'high' RoB. Overall, 11 of 12 trials were deemed low RoB for selecting outcome reporting. However, 8 RCTs (67%) were at risk or high RoB for deviating from the intended interventions (performance bias) and 9 (75%) were at risk or high RoB in measuring the outcome (measurement error) respectively. A summary of the updated RoB data for the RCTs is shown in Table 8.1.

Table 8.1: Trial risk of bias in updated trials

Domain	1	2	3	4	5	Overall ROB
Trial						
Alasfour 2022	L	H	H	H	S	H
Allen 2018	L	S	L	H	L	H
Allen 2021	L	S	L	H	L	H
Bendrik 2021	L	S	L	H	L	H
Bennell 2018	L	L	L	L	L	L
Hay 2018	L	L	L	L	L	L
Kloek 2018	H	H	L	H	L	H
Knoop 2022	L	L	L	S	L	S
Li 2018	L	H	H	H	L	H
Li 2020	L	S	H	S	L	H
Schlenk 2020	S	L	L	H	L	H
Stanton 2020	L	S	L	L	L	S

Legend: 1: Bias arising from the randomisation process; 2: Bias due to deviations from the intended intervention; 3: Bias due to missing outcome data; 4: Bias in measurement of the outcome; 5: Bias in selection of the reported result; ROB: Risk of Bias; Judgement: H: High, S: Some concerns: L: Low

8.3.5 Fidelity assessment of updated trials

Overall fidelity was 'moderate' ($\geq 50\% < 80\%$ of fidelity components present) with the mean component score 53.5% (range 35-72.5%) across RCTs. 8 RCTs (488, 495, 497, 498, 499, 567, 568, 569) were judged at 'moderate' fidelity and four (355, 496, 566, 570) were 'low' ($> 50\%$) fidelity. No RCTs achieved 'high fidelity' (80% of fidelity components present). Treatment design (75% of RCTs), receipt of treatment (100%), and enactment of skills (100%) were generally well met by RCTs. However, provider

training (25% of RCTs) and delivery of treatment (25%) were poorly reported. The updated RCTs' fidelity assessment is outlined in Table 8.2.

Table 8.2 Fidelity domain assessment of updated Trials

Trial	Domains					Components	
	Treatment Design	Training Provided	Treatment Delivery	Treatment Receipt	Skill Enactment	% of individual components present	Overall Fidelity rating
Alasfour 2022	A	A	A	P	P	35.0	L
Allen 2018	A	A	A	P	P	39.5	L
Allen 2021	A	P	A	P	P	50	M
Bendrik 2021	P	A	A	P	P	42.5	L
Bennell 2018	P	A	P	P	P	65.0	M
Hay 2018	P	P	P	P	P	72.5	M
Kloek 2018	P	A	A	P	P	50.0	M
Knoop 2022	P	A	A	P	P	57.5	M
Li 2018	P	A	A	P	P	47.5	L
Li 2020	P	A	A	P	P	57.5	M
Schlenk 2020	P	P	P	P	P	72.5	M
Stanton 2020	P	A	A	P	P	52.5	M
Total (N/12)	9	3	3	12	12	MCP: 53.5 SD: 11.6	M= 8 L=4

Key: MCP- Mean components present; SD: Standard Deviation: P- Present; A- Absent; M- Moderate; L- Low

8.3.6 Behaviour change techniques in updated trials

273 BCTs were identified over 23 interventions (mean (SD): 11.9 (5.0)) across the 12 updated RCTs. Thirteen interventions were identified as behavioural physiotherapy interventions with one RCT (568) utilising two behavioural physiotherapy interventions and an active comparator. The number of BCTs within a single intervention ranged from three in an arthritis control group (567) to 22 in a behavioural physiotherapy intervention which included physiotherapy and internet based pain coping skills training (488). 39 individual BCTs (plus 3 b 'variants'), encompassing 42% of BCTs on the V1 taxonomy (123), were identified in interventions with 14 of 16 hierarchies utilised. Commonly used BCTs included 12.6 Body Changes (coded in 83% of interventions), Social support (unspecified) (78%), Instruction on how to perform the behaviour (78%), Credible source (78%), Graded tasks (74%) and Action planning (70%). BCTs were coded with 'substantial' inter-rater reliability ($\kappa = 0.72$). All BCTs were identified from protocol papers or reports of RCTs results (including appendices/supplementary papers). Although seven RCT reported evaluating intervention fidelity (23, 355, 488, 495, 497, 567, 569), these did not no trial included sufficient detail to enable coding of BCTs. BCT use within and across RCTs can be seen in Table 8.3 below

Table 8.3: BCTs identified from protocols and trial reports of physiotherapy randomised controlled trials included in the updated systematic review

BCT LABEL		BEHAVIOURAL PHYSIOTHERAPY INTERVENTIONS													ACTIVE COMPARATORS										N (%)
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	
1.1 A	Goal Setting behaviour (behaviour): patient led	T			T	P, T	P, T	P, T			T	T							P, T						8 (35)
1.1 B	Goal setting (behaviour): Therapist led			P					P, T	P, T				T	T									T	6 (26)
1.2	Problem Solving		P, T	P, T		P, T		P, T			T	T	T	T				P, T						T	10 (43)
1.3 A	Goal setting (outcome)																	T							1 (4)
1.4	Action planning	T	P, T	P, T	T	P, T		P, T	P, T	P, T	T	T	T				P, T	T	P, T		P, T			T	16 (70)
1.5	Review behaviour goal (s)			P	T	P, T	P, T				T			T											6 (26)
1.8	Behavioural contract								P, T	P, T															2 (8)
1.9	Commitment								P, T																1 (4)
2.1 A	Monitoring of behaviour by others without feedback	T						P, T				T													3 (13)
2.1 B	Monitoring of behaviour by others without feedback				T	P, T			P, T		T			T				T	P, T		P, T		T		9 (39)
2.2	Feedback on behaviour	T				P, T		P, T	P, T		T	T						P, T							7 (30)
2.3 A	Self-Monitoring of behaviour			P, T	T	P, T	P, T	P, T			T	T	T												8 (35)

2.3 B	Self-Monitoring of behaviour	T							P, T								T	P, T		P, T	P, T		6 (26)	
2.5 B	Monitoring of outcomes of behaviour without feedback			P					P, T											P, T		T	5 (22)	
2.7 A	Feedback on outcomes of behaviour																P						1 (4)	
3.1 A	Social Support (unspecified)	T	P, T	P, T	T	P, T	P, T	P, T	P, T	P, T	T	T	T				P, T		P, T	P, T	P, T	T	T	18 (78)
3.2 A	Social Support (practical)							P, T	P, T			T	T				P, T		P, T					6 (26)
3.3 A	Social Support (emotional)													T										1 (4)
4.1	Instruction in how to perform the behaviour	T	P, T	P, T		P, T	P, T	P, T	P, T	P, T	T	T	T	T			T	P, T		P, T	P, T		T	18 (78)
4.4	Behavioural experiments																						T	2 (9)
5.1	Information about health consequences				T			P, T	P, T	P, T	P, T	T	T	T	T		P	T	T				T	13 (57)
5.3	Information about social and environmental consequences	T		P		P, T											T		P, T		P, T			6 (26)
5.4	Monitoring of emotional consequences					P, T								T										2 (9)
6.1	Demonstration of the behaviour	T		P, T	T	P, T	P, T		P, T								T	P, T		P, T	P, T			11 (48)
6.2	Social Comparison																T							1 (4)
7.1	Prompts and Cues					P, T		P, T	P, T															4 (17)
8.1	Behavioural Practice/ rehearsal	T		P, T		P, T	P, T	P, T		P, T	T		T				T		P, T		P, T		T	12 (52)
8.3	Habit Formation							P, T																1 (4)
8.6	Generalisation of the target behaviour		P, T	P, T		P, T	P, T	P, T	P, T	P, T									P, T	P, T	P, T		T	12 (52)

8.7	Graded tasks	T	P,	P,	T	P,	P,	P,	P,	P,	T	T		T	P,	T	P,	T	17 (74)
			T	T		T	T	T	T	T									
9.1	Credible Source	T	P,	P,	T	P,	P,	P,	P,	P,	T	T	T	T		P,	P,	P,	18 (78)
			T	T		T	T	T	T	T						T	T		
9.2	Pros and Cons				T										T				2 (8)
10.3B	Non-specific reward			P,											P,				2 (8)
				T											T				
11.1	Pharmacological support																T		2 (8)
11.2	Reduce Negative Emotions					P,													1 (4)
						T													
12.1	Restructuring the physical environment							P,			T								2 (8)
								T											
12.4	Distraction					P,													1 (4)
						T													
12.5	Adding objects to the environment	T	P	P,							T	T	T		T				8 (35)
				T															
12.6	Body Changes	T	P,	P,	T	P,	P,	P,	P,	P,	T	T	T	T	T		P,	P,	19 (83%)
			T	T		T	T	T	T	T							T	T	
13.2	Framing/Reframing					P,													2 (8)
						T													
15.1	Verbal persuasion about capabilities														T				1 (4)
15.4	Self-talk					P,									T				2 (8)
						T													
TOT		14	9	17	12	22	13	11	11	11	11	2	11	8	10	3	7	15	273

Key: TOT: Total number of BCTs found in RCT interventions; N: Number of times BCT identified across interventions; %: Percentage of times BCT appears across interventions: Intervention number 1-13 represent behavioural physiotherapy interventions; numbers 14-23 represent active comparator groups; P: Identified from trial protocol; T: Identified from Trial results paper (could include: supplementary files or secondary analysis)

Behavioural Physiotherapy Interventions:

Intervention numbers:

1) Alasfour (My Dear Knee App plus Exercise) 2) Allen 2018 (Physiotherapy) 3) Allen 2021 (Stepped Exercise Programme) 4) Bendrik 2021 (Physical Activity on Prescription) 5) Bennell 2018 (Internet based Education + Physiotherapy + Pain Coping Skills Training) 6) Hay 2018 (Individually Tailored Exercise) 7) Hay 2018 (Targeted Exercise Adherence) 8) Kloek 2018 (Physiotherapy + E-Exercise) 9) Knoop 2021 (Stratified Care Physiotherapy) 10) Li 2018 (Immediate physiotherapy group) 11) Li 2020 (Immediate physiotherapy group) 12) Schlenk (STAR intervention) 13) Stanton 2020 (Physiotherapy Pain Science Education)

Active Comparators:

14) Alasfour 2022 (Paper hand out plus exercise) 15) Allen 2018 (Internet Based Exercise Training) 16) Allen 2021 (Arthritis Education Control Group) 17) Bendrick 2021 (Advice group) 18) Bennell 2018 (Internet based education plus physiotherapy) 19) Hay 2018 (Usual Physiotherapy Care) 20) Kloek 2018 (Usual care physiotherapy control) 21) Knoop 2021 (Usual care physiotherapy) 22) Schlenk 2021 (Telephone attention control) 23) Stanton 2020 (Control physiotherapy)

8.3.7 BCT effectiveness ratios synthesising data from the original and updated systematic reviews

The synthesised BCT effectiveness ratios from the original and updated systematic reviews are presented in Table 8.4. The BCT 10.3 Non-specific reward was the only BCT that demonstrated an effectiveness ratio of 100% across all measured outcomes and timeframes. However, this BCT was present only in one behavioural physiotherapy intervention. Two BCTs, 2.3A Self-monitoring of behaviour and 3.1A Social support (unspecified) had effectiveness ratios of $\geq 50\%$ in more in than two interventions, across two outcome domains for both short and medium-term outcomes. 1.5 Review goal (behaviour) had effectiveness ratios of $\geq 50\%$ in more than one intervention across two outcome domains for medium and long-term outcomes. 1.1B Therapist led goal setting (behaviour) and 8.6 Generalisation of target behaviour demonstrated short-term effectiveness ratios of $\geq 50\%$ in two outcome domains. 6.1 Demonstration of the behaviour had medium-term effectiveness ratios of $\geq 50\%$ in 2 outcome domains. Although two of the most effective BCTs were from the goals and planning family, there was no distinct pattern to identify the most effective BCT hierarchy. Overall, the adherence outcome domain had greater quantity of BCT effectiveness ratios of $\geq 50\%$ (52%) across time frames than) than PA self-report (20%) or direct measures (approximately 14%).

Table 8.4: Overall BCT effectiveness ratios from synthesising data from the original and updated systematic reviews

OUTCOME DOMAIN/ TIMEFRAME									
BCT	PA- Self Report			PA- direct measure			Adherence		
	Short	Medium	Long	Short	Medium	Long	Short	Medium	Long
1.1A	1/4 (25)	1/4 (25)	1/4 (0)	0/2 (0)	1/1 (100)		2/3 (67)		1/2 (50)
1.1B	2/7 (29)	2/6 (33)	1/5 (20)	2/4 (50)	0/2 (0)	0/2 (0)	1/1 (100)	1/1 (100)	1/2 (50)
1.2	1/5 (20)	1/5 (20)	2/6 (33)	0/2 (0)	0/1 (0)	0/1 (0)	1/4 (25)	0/2 (0)	1/3 (33)
1.3B	0/1 (0)	0/1 (0)							
1.4	3/8 (37)	2/7 (29)	2/6 (33)	1/3 (0)	0/3 (0)	0/2 (0)	3/3 (100)	1/1 (100)	2/3 (67)
1.5	1/3 (33)	4/6 (67)	3/6 (50)	0/1 (0)	1/3 (33)	0/1 (0)		1/2 (50)	1/2 (50)
1.8	1/3 (33)	0/1 (0)	1/3 (33)	0/1 (0)		0/1 (0)	1/1 (100)		1/1 (100)
1.9	0/1 (0)		0/1 (0)	0/1 (0)		0/1 (0)			
2.1A	0/3 (0)	0/3 (0)	0/2 (0)	1/3 (0)	0/1 (0)		1/2 (0)	1/1 (100)	1/1 (100)
2.1B	0/1 (0)	0/1 (0)		0/1 (0)					
2.2	1/5 (20)	1/3 (33)	0/5 (0)	0/3 (0)		0/1 (0)	1/2 (50)	1/2 (50)	1/2 (50)
2.3A	3/6 (50)	4/7 (57)	3/7 (43)	1/3 (33)	1/2 (50)	0/1 (0)	1/1 (100)	0/1 (0)	1/2 (50)
2.3B	1/2 (50)	0/1 (0)		0/1 (0)	0/1 (0)				
2.5B	0/1 (0)	0/1 (0)	0/1 (0)						
2.7		1/1 (100)	1/1 (100)						
3.1A	2/3 (67)	2/3 (67)	1/3 (0)	0/2 (0)	1/1 (100)		2/2 (100)		1/2(50)
3.1B	0/2 (0)	0/2 (0)		0/1 (0)	0/1 (0)				
3.2A				0/2 (0)					
3.3A				0/1 (0)					
4.1	1/7 (14)	2/8 (25)	1/6 (17)	1/4 (25)	0/2 (0)	0/1 (0)	1/1 (100)	1/1 (100)	1/1 (100)
4.2	0/1 (0)	0/1 (0)	0/1 (0)				0/1 (0)		0/1 (0)
4.4		1/1 (100)	1/1 (100)		0/1 (0)	0/1 (0)			
5.1	0/4 (0)	1/4 (25)	1/4 (25)	1/5 (20)	0/2 (0)	0/2 (0)			0/1 (0)
5.3	0/1 (0)	0/1 (0)	0/1 (0)						
5.4	0/1 (0)	0/1 (0)	0/1 (0)	0/1 (0)				0/1 (0)	0/1 (0)
6.1	1/5 (20)	3/7 (43)	2/6 (33)	0/1 (0)	1/2 (50)		2/2 (100)	2/3 (67)	2/3 (67)
7.1	0/2 (0)	1/3 (33)	1/4 (25)	0/1 (0)	0/1 (0)	0/2 (0)		0/1 (0)	0/1 (0)
8.1	3/9 (33)	2/8 (25)	2/7 (29)	1/3 (33)	0/2 (0)	0/1 (0)	2/3 (67)	1/2 (50)	2/2 (100)
8.6	2/6 (33)	1/5 (20)	0/5 (0)	1/2 (50)	0/1 (0)		1/1 (100)	1/1 (100)	1/2 (50)
8.7	3/7 (43)	2/6 (33)	2/6 (33)	0/2 (0)	0/2 (0)	0/1 (0)	1/1 (100)		1/2 (50)
9.1	2/9 (22)	2/7 (29)	0/6 (0)	1/4 (25)	1/2 (100)		1/2 (50)		1/1 (100)
10.3	1/1 (100)		1/1 (100)				1/1 (100)		1/1 (100)
11.2	0/3 (0)	0/2 (0)	0/2 (0)				0/1 (0)	0/1 (0)	0/2 (0)
12.1	0/1 (0)	0/1 (0)	0/1 (0)	0/1 (0)					
12.4	0/3 (0)	0/2 (0)	0/2 (0)				0/1 (0)	0/1 (0)	0/2 (0)
12.5	1/5 (20)	1/3 (33)	1/4 (25)	0/2 (0)	0/2 (0)	0/1 (0)			
12.6	2/10 (20)	2/8 (25)	1/8 (13)	1/4 (25)	0/2 (0)	0/1 (0)	1/1 (100)	1/1(100)	1/1 (100)
13.2	0/1 (0)	0/1 (0)	0/1 (0)				0/1 (0)	0/1 (0)	0/1 (0)
15.1		1/1 (100)	1/1 (100)		0/1 (0)	0/1 (0)			
15.4	0/2 (0)	1/3 (33)	1/3 (33)		0/1 (0)	0/1 (0)	0/2 (0)	0/1 (0)	0/2 (0)
TOTALS	32/133	38/124	30/121	11/61	6/37	0/22	23/37	11/24	21/44

Key: BCT part of statistically effective intervention/BCT part of all interventions (effectiveness ratio %); Blank areas indicate where no PA adherence data was available for this domain/ timeframe

8.4 Discussion

This study details the update of an original systematic review which identified, and evaluated the effectiveness, of BCTs delivered within physiotherapy interventions to promote PA adherence in patients with lower-limb OA. The original systematic review was published in 2019 and included 24 RCTs, of which 13 (54%) included PA adherence data. The original searches were completed from database inception to January 2018. Although the updated systematic review inclusion criteria were adjusted to focus on only those RCTs which included PA adherence data, a further 12 RCTs were identified over the 5-year period from the initial searches (2018-23).

The relative increase in RCTs with PA adherence data demonstrate the contemporary relevance of this topic. Overall, the participant profile was similar in the original and updated systematic reviews with 75% of RCTs including patients with knee OA, and most studies of medium to high RoB.

The mean fidelity component score in the updated systematic review 53.5% was 'moderate' compared to 'low' 38.9% in the original review, with noted improvements in treatment delivery reporting, especially the dose of interventions. However, no RCT in the updated systematic review achieved 'high' fidelity and the overall range is similar to the original systematic review (35-72.5 vs 19-68), with provider training and treatment delivery domains remaining poorly reported.

8.4.1 Recent developments in physiotherapy Randomised controlled trials

Although there are similarities between the original and updated systematic reviews, some key differences were observed. Regarding outcome assessment, a higher proportion of RCTs in the updated systematic review (58%) collected long-term PA

adherence data (≥ 12 months post baseline) compared with the original systematic review (33%). 13 (50%) of the RCTs included in the original systematic review measured self-report PA and only five (21%) directly measured PA. However, an equal number of RCTs (7 RCTs; 58% of total) in the updated systematic review evaluated self-report and directly measured PA. Research has found that self-report may not be as accurate as direct measurement for evaluating PA behaviour (120, 160, 571) and the increased use of objective measures may demonstrate a shift PA measurement for research purposes.

The instrument to capture directly measured PA may also have evolved. All updated RCTs utilised an accelerometer while three of five from the original systematic review used a pedometer (229, 230, 244). Pedometers usually measure a single aspect of PA behaviour (e.g. step count) while accelerometers can evaluate several features. The updated RCTs measured time spent in MVPA, light and sedentary behaviour, and average step count, but were generally unclear about which PA outcome was their primary focus. Further heterogeneity was found in the PA units, bouts or total time (497, 498, 499, 568), and the cut points used to differentiate PA levels. Recommendations suggest adults should aim for a total minimum of 150 minutes per week in moderate-vigorous PA (MVPA) (95). Although contemporary guidelines focus on total PA volume (95), it is not clear which type of PA is most important to measure for health purposes or which cut points are most appropriate to be used for patients with lower-limb OA (96).

Further heterogeneity was found in accelerometer placement, with RCTs using the waist (497, 498, 568), triceps (495, 496, 570) and wrist (499) for PA data collection. Choice of positioning may influence the readings amount of data available (508). Therefore, further accelerometer validation studies are required to clarify the most appropriate model, optimal wear position, and population specific cut points and intensities in patients with lower-limb OA (96). The summary of direct measures across trials in the updated systematic review is summarised in Table 8.5.

In the updated systematic review, a lower proportion of BCTs had effectiveness ratios of $\geq 50\%$ across outcome domains and timepoints than the original. Previous systematic reviews have demonstrated that PA interventions are less effective at providing significant changes to directly measured PA than self-reported outcomes (160, 571). However, the increased use of direct measure PA did not reflect these findings: the proportion of behavioural physiotherapy interventions with statistically significant improvements over comparators was only marginally less for direct measured PA (14%) than self-reported PA (20%).

The overall reduction of statistically significant results in favour of behavioural physiotherapy interventions in PA adherence may be related to the choice of comparator interventions. In the updated systematic review, 10 of 12 RCTs included active comparators, which were either physiotherapy sessions and/or exercise prescription (355, 488, 496, 498, 499, 566, 568, 569). Systematic reviews have demonstrated PA interventions are significantly more effective than no/minimal interventions on pain, function, quality of life, and PA in patients with lower-limb OA (25, 71, 72, 73, 74, 75, 76) but no specific type of PA has demonstrated superiority over another (108). As several comparator interventions incorporated BCTs equivalent to the

Table 8.5: Direct measures of physical activity in the updated systematic review

Trial	Accelerometer Brand	Body position	Physical Activity behaviour measured	Cut points	Wear time/ valid data
Bendrick 2021	SenseWear mini	Arm	• Bouts $\geq$10 mins Moderate-vigorous time/day • Total mins light/day • Total sedentary time/day • Average number of steps/day • Total energy expenditure, kcal/day	Troiano	4 days
Hay 2018	Actigraph	Hip	• Total average mins moderate activity/day • Total time vigorous activity/day • Proportions of participants who met physical activity guideline levels	Freedson	5 days for 10 hours
Kloek 2018	Actigraph	Waist	• Total time in Moderate-vigorous activity/ day	Freedson	3 days for 8 hours
Li 2018	SenseWear Mini	Triceps	• Average bout moderate-vigorous activity time/day • Average steps/day • Average sedentary activity time/day	Not stated	4 days
Li 2020	SenseWear Mini	Triceps	• Average bout moderate activity time/day • Average steps/day • Average sedentary activity time/day	Not stated	4 days
Schlenk 2021	Actigraph	Waist	• Total time moderate activity mins/day • Total time in light activity mins/day • Total Sedentary activity mins/ day	Troiano	Not stated
Stanton 2020	Actigraph	Wrist	• Number of steps/day • Total average moderate activity mins /day • Total average light activity mins /day • Total sedentary activity mins/day	Troiano	4 days of 10 hours.

behavioural physiotherapy interventions, the overall difference in effectiveness on PA adherence between groups may have been reduced.

Additionally, the lack of effectiveness of behavioural physiotherapy interventions relative to comparators may relate to how the interventions were delivered (i.e. mode of delivery). The updated RCTs demonstrated increased use of blended delivery with face-to-face physiotherapy being supplemented with an App (566), the internet (488, 498, 567), or telephone (495, 497, 499, 567, 570) sessions. Decreased face-to-face contact has been associated with reduced patient adherence to recommendations and limiting the therapeutic relationship between physiotherapist and patient (572), which likely effects PA. However, one updated RCT (355) and further contemporary trials (573, 574) have demonstrated no difference in the effectiveness of in-person versus remotely delivered interventions on PA. Physiotherapy services are costly to deliver (575, 576) and access can be problematic for patients with lower-limb OA (577). Moreover, the COVID pandemic has evolved physiotherapy delivery and remote and blended delivery options will likely continue to increase (573). Entirely internet (433) and phone (578) delivered physiotherapy interventions, that were not eligible for inclusion in this systematic review, have recently been developed and tested. However, to date, these trials are providing small and inconsistent effects on PA adherence in patients with lower-limb OA. Therefore, it is currently not clear what mode (in person, remote, or blended) or type of remote intervention (e.g. internet versus phone) of physiotherapy delivery is optimal for promoting PA adherence patients with lower-limb OA. Based on the current issues and changes in physiotherapy service delivery, this is a research priority.

The updated systematic review demonstrated increased use of behaviour change theory in physiotherapy intervention design and delivery. The original systematic

review identified a solitary theoretical intervention (257) while the updated systematic review included six (50%) (488, 495, 497, 498, 568, 570). Increased use of behaviour change theory in RCTs is supported by comparing a systematic review conducted in 2015 (164) where 12% of RCTs incorporated a theoretical foundation to 55% of RCTs from a systematic review published in 2022 (157). Theoretical interventions are posited to be more effective than non-theoretical interventions as BCTs can target specific determinants/constructs that modify the target behaviour (116). However, the use of theory did not appear to significantly affect PA adherence outcomes in the updated systematic review. Although it is beyond the scope of this systematic review update to provide an in-depth analysis, the lack of effectiveness of theoretical interventions may relate to the ineffective use of behaviour change theory. Similar to other systematic reviews (116, 157), the updated RCTs limited theory use to intervention development with few trials explicitly testing or refining theory (121, 378), which are essential steps to develop an interventions effectiveness. As the use of theory in physiotherapy interventions remains underutilised (164), further PA interventions which test (measure pre-defined theoretical constructs) and refine (change in constructs analysed) (378) behaviour change theory in patients with lower-limb OA.

8.4.2 BCT use in the updated systematic review and their overall effectiveness on PA adherence

The mean number of BCTs per intervention identified in the original (mean (SD): 11.1 (3.3)) and updated systematic reviews (i.e. published since 2018) (11.9 (5.0)) were similar. 39 individual BCTs (plus 3 b 'variants'), representing 42% of the V1 taxonomy, and 14 hierarchies were identified in the updated systematic review which

is greater number than the original systematic review (31 BCTs, 12 hierarchies). However, the additional BCTs identified in the updated systematic review were coded infrequently: 1.9 Commitment, 6.2 Social comparison, 8.3 Habit formation, and 15.1 Verbal persuasion about capability coded to one intervention; 5.4 Monitoring of emotional consequences, 9.2 Pros and cons, 11.1 Pharmacological support, 12.1 Restructuring the physical environment, 13.2 Framing/reframing coded to two interventions respectively. The BCTs 12.6 Body changes, 1.4 Action planning, 4.1 Instruction on how to perform behaviour, and 9.1 Credible source were frequently coded in both the original and updated systematic reviews and have been previously highlighted as common in other interventions (162, 163, 164, 165, 166).

When the results of the original and updated systematic reviews were synthesised, the BCTs with the greatest evidence to promote PA adherence were 1.5 review behaviour goals, 2.3A self-monitoring of behaviour and 3.1A Social support (unspecified). These BCTs demonstrated effectiveness ratios of $\geq 50\%$ in a minimum of two interventions across two outcome domains. Furthermore, these were the only BCTs to demonstrate effectiveness over more than one time-period. The BCT 1.5A Review behaviour goals was effective at promoting medium and long-term PA. 1.1B Physiotherapy-led goal setting (behaviour) also demonstrated a short-term effectiveness ratio of $\geq 50\%$ across two outcome domains. These results support previous findings where patients with lower limb OA and physiotherapists agreed that setting and reviewing goals were among the most effective BCTs at promoting PA adherence (142). Interestingly, the BCT 1.1A Patient lead goal setting (behaviour) also demonstrated short-term PA adherence effectiveness in the original systematic review. Locke and Latham's prominent goal setting theory (394) recommends patient-led goal setting can bring focus and self-regulation skills.

Furthermore, patient-led goal setting is thought to enhance enjoyment and behavioural maintenance (161, 579). This is the first systematic review to delineate between patient and physiotherapy-led goal setting during BCT coding and therefore, comparisons with other sources are not possible. Previous systematic reviews have cited difficulty accurately coding goal setting in physiotherapy interventions using the V1 taxonomy (164). Therefore, there may have been insufficient detail in the included RCTs to differentiate between patient-led and physiotherapist-led goal setting. Although the results do not clearly support which type of goalsetting is most important to promote short term PA, they reinforce that goal setting techniques are useful in physiotherapy interventions, and they remain relevant throughout the behaviour change process.

The BCT 2.3 Self-monitoring of behaviour was effective at promoting short to medium-term PA adherence. Several aspects of PA are habitual, meaning cognitive processing is not required to undertake them (580) and forming habits is important when developing behavioural maintenance (155). Self-monitoring techniques can be utilised to develop PA habits by explicitly drawing attention to an otherwise unnoticed activity e.g. daily steps walked (580, 581). Apps, pedometers, and accelerometers are commonly used to assist patients to self-monitor their PA behaviours and previous systematic reviews have demonstrated increased PA with these devices (582). Moreover, additional BCTs, such as goal setting can be programmed into Apps, accelerometers, and pedometers (582). As remote physiotherapy delivery is increasing, investigation into the most appropriate way to promote self-monitoring is warranted.

The BCT 3.1 Social support (unspecified) was effective at promoting short-medium term PA. The use of social support is thought to influence the treatment climate (163)

and reinforce patients self-efficacy (583, 584) for PA adherence (585). However, social support is not commonly utilised in 1-to-1 physiotherapy consultations (159, 165) and patients with lower-limb OA and physiotherapists do not agree on the best way to employ social support. While booster sessions have been requested by patients (142) and demonstrated effectiveness at promoting longer term PA (143), they have been resisted by physiotherapists (142). Similarly, referral to group classes have been perceived as resourceful by physiotherapists but ineffective by patients with lower-limb OA (142). More recently, social support has been applied remotely through phone calls or texts to monitor progress and provide pastoral support. The social support required by each person is unique and likely influenced by a range of factors such as patient self-efficacy and fear of movement (38). Therefore, individual social support needs should be agreed collaboratively with patients.

8.5 Strengths and weaknesses

The key strengths of this updated systematic review include its thorough methodology. Key changes to physiotherapy practice were identified, including the use of behaviour change theory, mode of intervention delivery, use of direct measure of PA and clarify the most effective physiotherapy BCTs to promote PA adherence. However, despite 12 further RCTs, the evidence base remains characterised by heterogenous and poorly reported behavioural physiotherapy interventions with low internal validity which diminishes the impact of potential evidence-based recommendations. Although additional BCTs were identified compared with the original systematic review, the heterogeneity of intervention BCTs, comparator

groups, and PA adherence outcomes identified in RCTs meant meta-analysis was again inappropriate, and limited the strength of clinically relevant evidence-based recommendations. Although there has been an increased use of behaviour change theory in intervention design, further low RoB RCTs that utilise explicit BCTs to test and refine theory are required. Furthermore, lack of evidence exists for the most effective mode of physiotherapy intervention delivery or the most appropriate type, wear point and PA behaviour for direct measures to evaluate.

8.6 Conclusions

This study aimed to update the original published systematic review (Chapter 2) which identified and evaluated the effectiveness of physiotherapist delivered BCTs at promoting PA adherence in patients with lower-limb OA. This chapter highlighted key developments in physiotherapy RCTs conduct since the original review was published to inform whether changes were required in the planning of a definitive trial. The updated systematic review demonstrated that increased numbers of physiotherapy interventions have been developed based on theory and delivered through blended approaches. Physiotherapy RCTs are also collecting more directly reported PA data and for longer periods. Although a wider variety of BCTs were identified in updated systematic review compared to the original, overall, the effectiveness of BCTs to promote PA adherence remains unclear. The BCTs Self-monitoring of behaviour and Social support (unspecified) were effective at promoting short to medium term PA adherence and goal setting techniques may be useful throughout all time periods.

The behaviour change intervention that has been developed through this thesis is theoretically grounded and offered through blended delivery. The feasibility trial utilised an accelerometer to collect PA until six months post baseline. Furthermore, the BCTs that demonstrated the highest effectiveness ratios [1.5 review behaviour goals, 2.3A self-monitoring of behaviour and 3.1A Social support (unspecified)] are already part of the protocol. Therefore, taken together the key developments seen in the body of evidence agrees do not suggest that any key changes have occurred within the timeframe to support a change in the planned definitive trials protocol.

CHAPTER 9: GENERAL DISCUSSION

Chapter overview

This chapter reviews the aims and objectives of the thesis and summarises the key findings from each study (Chapters 2-8). Each objective is reviewed, whether it has been achieved, and its contribution to the evolving evidence base discussed. The body of research realised in this thesis is summarised including a change in focus that occurred from commencement of the thesis to completion. Directions for future research on physiotherapy behaviour change intervention development is suggested.

Sections of this chapter are taken verbatim following publications of which the I am primary author:

- Willett M, Duda J, Gautrey C, Fenton S, Greig C, Rushton A. Effectiveness of behavioural change techniques in physiotherapy interventions to promote physical activity adherence in patients with hip and knee osteoarthritis: a systematic review protocol. *BMJ Open*. 2017;7(6):e015833. (Appendix 1.1)
- Willett MJ, Greig C, Rogers D, Fenton S, Duda J, Rushton A. Barriers and facilitators to recommended physical activity in lower-limb osteoarthritis: protocol for a qualitative study exploring patients and physiotherapist perspectives using the theoretical domains framework and behaviour change taxonomy. *BMJ Open*. 2019;9(10):e029199. (Appendix 1.3)
- Willett, M. Rushton, A. Stephens, G. Fenton, S. Rich, S. Greig, C. Duda, J. Feasibility of a theoretically grounded, multicomponent, physiotherapy intervention aiming to promote autonomous motivation to adopt and maintain physical activity in patients with lower-limb osteoarthritis: protocol for a single-arm trial. *Pilot Feasibility Stud*. 2023;9(1):54. (Appendix 1.5)

9.1 Introduction

In the UK annually, OA symptoms are estimated to be responsible for healthcare costs totalling 1% of the country's gross national product (5). In combination with rheumatoid arthritis (RA), associated healthcare costs in 2018 were over £10 billion with the 10-year cumulative costs projected to reach almost £120 billion by 2027 (11). As there is currently no cure for OA (5), and with increased life expectancy (7), the healthcare costs of OA are anticipated to continue to increase over the coming decades (12).

International guidelines (1, 3, 10, 64) advocate that PA interventions should be offered for initial management of OA symptoms. Despite improving short-term (≤ 3 months post-baseline) pain and function in patients with OA, the benefits from PA interventions are generally not sustained beyond 6 months (25, 69, 74, 78), which likely relates to a limited ability to maintain changes in PA behaviours (79, 80).

Physiotherapists are the primary healthcare providers of PA interventions in the NHS, with over 5 million professional outpatient appointments conducted annually (586). Individuals undergo several 'phases' of change when incorporating new behaviours (such as PA) into their lifestyle (130, 420). Regarding the promotion of PA by physiotherapists, patients would likely be *adopting* PA behaviours while receiving treatment and *maintenance* would be manifested post-discharge. As a profession, physiotherapists have reported difficulties delivering behavioural techniques (140) and promoting PA (587, 588).

This thesis aimed to develop and test the feasibility of a novel theoretically grounded, multi-component physiotherapy behaviour change intervention that sought to promote adoption and maintenance of PA in patients with lower-limb OA. This

overarching aim was met through a series of interconnected studies which followed MRC guidelines (114, 176). Each chapter's relevance to intervention development and feasibility testing has been mapped against specific MRC actions, as outlined by O'Cathain et al., (2019) (178) (Table 9.1). As outlined in Table 9.1, a comprehensive review of the literature was undertaken initially to identify gaps in the existing knowledge base (Chapter 2, 8). A team of key stakeholders, including patient and public representatives, academics, psychologists, and clinicians were brought together to design, analyse, and discuss progress throughout the project (Chapters 3-7). Intervention development and testing drew on behaviour change theory (Chapters 2-5) and primary data collection methods (Chapters 3,4,6,7), which provided insights into challenges faced in the NHS (Chapters 6-7) and subsequent intervention refinement (Chapters 6-8) in preparation for a definitive trial. This Chapter reviews key results from Chapters 2-8 and puts them into contemporary perspectives that have evolved during the undertaking of the PhD. Limitations and suggestions for future research are also highlighted.

Table 9.1 Thesis Chapters and Associated Medical Research Council actions (O’Cathain et al., (2019)(178)

MRC Actions	Chapter number								
	1	2	3	4	5	6	7	8	9
Plan the development process	✓								
Involve stakeholders			✓	✓	✓	✓	✓		
Bring together a team			✓	✓	✓	✓	✓		
Review published research evidence		✓						✓	
Draw on existing theories		✓	✓	✓	✓				
Undertake primary data collection			✓	✓		✓	✓		
Understand context			✓	✓		✓	✓		
Pay attention to future implementation of the intervention in the real world						✓	✓	✓	✓
Design and refine the intervention				✓		✓	✓	✓	
End the development phase									✓

9.2 Discussion of results across thesis objectives and studies

9.2.1 Objective 1: To identify the BCTs used in physiotherapy interventions to promote PA adherence in lower limb OA patients and evaluate their effectiveness at different time points post-baseline.

The achieving of Objective 1 was detailed in Chapters 2 and 8, with the systematic review protocol and findings published in BMJOpen (374) and PLOSONe (277), respectively. The original systematic review identified 24 RCTs where physiotherapist interventions included BCTs that promoted PA adherence in patients with lower-limb OA. The systematic review was updated (Chapter 8) in March 2023. 12 further RCTs were identified highlighting the contemporary focus of the topic and summarised the developments in the evidence base.

The original and updated reviews progressed the evidence base by identifying the most effective techniques at promoting PA adherence at short (3 months), medium (6 months), and long term (≥ 12 months) time points post-baseline. When the data from the original and updated reviews were synthesised, the BCTs 'Self-monitoring of behaviour' and 'Social support (unspecified)' were most effective (as measured by likelihood ratios) at promoting short to medium term PA adherence and goal setting techniques were effective across all time-periods. However, there are several limitations with the body of literature across both reviews and overall, BCTs demonstrated limited effectiveness at promoting PA adherence. Heterogeneity of interventional BCTs and PA adherence outcomes meant that performing a meta-analysis was not appropriate. Even for those

techniques which demonstrated statistically significant increases in PA adherence, it was unclear if these results were clinically significant. Furthermore, the RCTs were generally of moderate-high risk of bias and interventions poorly reported, which further limited potential evidence-based recommendations.

The updated systematic review demonstrated that contemporary RCTs are more frequently utilising theoretical interventions and offering remote or blended delivery than was seen in the original review. The RCTs in the updated systematic review also included a higher proportion of active comparator groups and increased use of direct measures (i.e. accelerometers) to measure PA.

The proposed intervention that was delivered in the feasibility trial (Chapter 6) was theory based, offered via blended delivery, and utilised an accelerometer to collect PA data. Furthermore, the comparator arm of the intended definitive trial will be usual care physio (i.e. an active comparator). Therefore, based on the changes that have occurred in physiotherapy RCTs since the original systematic review was conducted in 2018, the planned definitive trial fits within contemporary research.

The AMSTAR 2 tool, (A Measurement Tool to Assess systematic Reviews, version 2), which evaluates systematic reviews quality across 16 items (174), was utilised by one researcher (MW) to self-assess the Risk of Bias (RoB) of the systematic review. Quality was further self-assessed by mapping systematic review components to the PRISMA checklist. As the systematic review achieved all relevant AMSTAR 2 criteria (Appendix 9.1), and the PRISMA checklist has been completed (Appendix 2.5), it is asserted that the systematic review was of low RoB and high overall quality.

9.2.2: Objective 2:

2a) To explore patients with lower-limb OA in-depth experiences of barriers and facilitators to physiotherapist prescribed PA while receiving treatment and post-discharge.

2b) To utilise barriers and facilitators to identify BCTs to propose a theoretically informed intervention that aimed to promote PA during treatment and post-treatment.

The addressing of Objective 2 was described in Chapter 3, with evidence provided via a published protocol (BMJ open) (448) and write up (BMC musculoskeletal disorders) (343), respectively. To establish barriers and facilitators to physiotherapist prescribed PA during and post-treatment, a purposive sample of 13 patients with lower-limb OA participated in semi-structured interviews following physiotherapy treatment. Inductive analysis identified themes/subthemes reflecting barriers and facilitators to physiotherapist prescribed PA, which were organised deductively into personal factors, treatment, and post-discharge phases groupings. Themes/subthemes were mapped onto the theoretical domains framework (TDF) and behaviour change techniques (BCTs) were coded to propose a theoretically informed physiotherapy intervention.

Themes of patient confidence, mindset, motivation, OA symptoms and PA experiences were primary personal factors that influenced PA; with the TDF domain 'Beliefs about capabilities' emerging as the most important to target. During treatment, the theme of routine formation was the major driver of personal factors; and primarily influenced by developing a positive physiotherapist-patient relationship. Post-discharge, physical

factors, psychosocial factors, and ongoing access to resources were themes related to perceived influences on PA maintenance. 'Environmental context and resources' and 'Social influences' emerged as the key TDF domains to target during treatment and post-discharge. The proposed theoretically informed intervention included 26 BCTs delivered across conceptual phases of adoption, routine formation, and maintenance.

Comprehensive analysis of the qualitative data was supported by critical feedback from clinicians, subject specific experts, and PPI representation. Results progressed knowledge by identifying unique and overlapping barriers and facilitators of physiotherapist prescribed PA during (adoption) and post-treatment (maintenance) and suggesting BCTs to address these factors. Thematic analysis enabled a conceptual model of behaviour change to be developed where patients' feelings of competence/self-efficacy preceded motivation for PA. The primary driver of PA during treatment was formation of a PA routine which functioned as a conceptual interlink between PA adoption and maintenance and enhanced patients' confidence and motivation.

The primary TDF domains identified are in agreement with previous reviews (575, 589) and reinforce the influence that interpersonal relationships and social environments play in patients PA throughout the behaviour change process (130, 155). Collectively, these findings suggest that physiotherapists can support patients' PA by developing a positive patient-physiotherapist relationship and treatment environment and agreeing a patient centred PA routine.

Although data saturation was achieved, the study was limited by the transferability of findings: participants were all of White British heritage and recruited from a single NHS site. Furthermore, the patients may have been more inclined to participate as they were recruited by their treating physiotherapist.

Semi-structured interviews were conducted in 2019 and therefore, analysed through a pre-covid lens. Patient perceptions of physiotherapy and PA may have changed during and since this time. Therefore, an updated study may be warranted to examine if barriers and facilitators to physiotherapy prescribed PA have evolved.

Mapping of themes to the TDF and BCT coding was intuitive except for those themes/subthemes related to motivation. The original TDF (375) utilised the domains 'Intentions' and 'Goals' as surrogates for motivation. However, patient motivation for PA is complex (91, 291) and variable across adoption and maintenance (155). As such, coders felt the original TDF did not capture the breadth of underlying reasons for engaging with PA identified in the participant interviews. Since the behaviour change intervention was proposed, a literature synthesis (322), expert opinion (323), and triangulation study (590) have identified 12 further TDF domains, one of which is motivation.

The motivation domain in the updated TDF has six linked BCTs including: Goal setting (outcome), Feedback on behaviour, Pros and cons, Incentives (outcome), Rewards (outcome) and Self-talk. However, Goal setting (outcome) and Feedback on behaviour were already included in the behaviour changed intervention. Furthermore, incentives and rewards were removed when the behaviour change intervention model was clarified and content refined (Chapter 5), as these BCTs can promote external regulation. Of the

remaining BCTs, only Self-talk is associated with another key domain (Beliefs about capabilities) and may have been included. Therefore, use of the updated TDF would only have minimally influence intervention content.

There are over 100 available quality appraisal tools to evaluate qualitative studies with no consensus on the most appropriate (591). The 10 item Critical Appraisal Skills Programme (CASP) Qualitative tool (592), and the additional criteria suggested by Lincoln and Guba to (1995) to gauge trustworthiness (492) as proposed in Kanavaki et al., (2016) (593), was used to self-evaluate the study. The study conducted as part of this thesis fulfils the associated criteria of critical appraisal (Appendix 9.2) and COREQ checklist (Appendix 3.4). It also has been included in a systematic review and judged to be of 'good' methodological quality (589). Therefore, it is suggested there that the qualitative study presented in Chapter 3 is considered to be of high quality.

The proposed physiotherapy intervention was the first to include BCTs explicitly targeting the behavioural determinants across the conceptual phases of adoption, routine formation, and maintenance in patients with lower-limb OA. It clearly established the importance of a positive patient-physiotherapy relationship and wider rehabilitation environment play in promoting patient confidence and motivation for PA. However, further consultation with clinicians was necessary to concept test the proposed intervention. Subsequently, the proposed intervention was presented to physiotherapists to determine its feasibility and acceptability of delivery in a clinical setting and the physiotherapists training needs for implementation (Chapter 4).

9.2.3: Objective 3: To determine physiotherapists' perspectives of the feasibility and acceptability of delivering a proposed theoretically informed behaviour change intervention in a real-world clinical setting.

Objective 3 was addressed in Chapter 4. The proposed intervention was presented to a convenience sample of physiotherapists. The presentation detailed the proposed intervention conceptual model, phases of behaviour change and associated BCTs, and patients' perspectives on the importance of developing a PA routine and positive patient-physiotherapist relationship and treatment environment. After the presentation, physiotherapists' perspectives on the feasibility and acceptability of delivering the proposed intervention in clinical practice were sought. Deductive thematic analysis synthesised physiotherapists perspectives of the evolving intervention and any articulated departmental barriers and facilitators to delivery. Further deductive analysis identified physiotherapy training needs. Emerging themes were presented in SSG meetings to clinicians, psychologists, academics with expertise in qualitative analysis, and a PPI representative who challenged the findings. The input of all these individuals strengthened the analysis.

Twelve physiotherapists (n=7 females) attended two focus groups. Findings were synthesised into themes related to intervention feasibility (Intervention is acceptable, resources, group classes, remote delivery), the treatment climate, and physiotherapists' training needs. Physiotherapists found the intervention highly acceptable, and spoke positively about the conceptual model, phases of behaviour change, and aims of the targeted BCTs. However, physiotherapists suggested the optional use of remote delivery and reducing the total number of available BCTs to enhance feasibility.

In support of previous literature, physiotherapists also felt they required further training to deliver the intervention. Two topic areas were suggested:

- How to develop a positive patient physiotherapist-relationship and treatment environment (360, 363).
- How to deliver the BCTs to develop psychological constructs (i.e. feelings of competence and motivation for PA) (140, 361, 594).

Although these topics were suggested separately, the treatment climate, which includes the patient-physiotherapist relationship and treatment environment (595), greatly influences the quality of BCTs delivery and receipt. Therefore, it was deemed prudent that any training should integrate both topics.

The proposed conceptual model of behaviour change interlinked the theoretical constructs of patient competence and motivation for PA. If the intervention was taken forward to a definitive trial, to test and refine the behaviour change model, mediation analysis would be intended to clarify the bidirectional effects of BCTs on the theoretical constructs (121).

As previously outlined, the TDF was used during initial intervention development.

Although the TDF aided clarification of important domains (i.e. psychological constructs) to target as part of the intervention, it is not a theory of behaviour change and, as such, does not conceptualise links between domains or basis for a theory grounded hypothesis. Therefore, the identification of an appropriate theory of behaviour change that mirrored (as closely as possible) the proposed model emanating from Chapter 3 was required. If identified, this theory (or theories) would underpin physiotherapist

training to deliver the intervention and, in response to other focus group suggestions, potentially refine the BCTs to aid feasibility of delivery.

Although there are no studies to offer direct comparison regarding the acceptability and overall feasibility of the intervention, physiotherapists positive perceptions offered preliminary evidence to support its implementation in clinical practice. Synthesising the treatment preferences of patients with lower-limb OA with the practicality of physiotherapists enabled clarification of which intervention components were feasible to deliver and which required modification. The interactions between focus group physiotherapists appeared to permit open discussion of topics raised and developed and highlighted key points (367).

The primary limitations of this study relate to the generalisability of the findings to other clinical sites and (as with the previous objectives) when the focus groups were conducted. Using patients and physiotherapists at one clinical site likely biased the results and the intervention may require additional adaptations in preparation for a multicentre definitive trial.

A further potential study limitation is the sample size. Based on the number of musculoskeletal physiotherapists available, two focus groups were planned a priori. However, authors have suggested a minimum of three focus groups per clinical setting is required to gain a comprehensive overview of barriers and facilitators to implementation (344). These issues were compounded due to the lack of available studies to which the present results could be compared to.

The focus groups were conducted in January 2020 (i.e. just prior to COVID pandemic in the UK) and physiotherapist delivery has evolved rapidly since then. Therefore, further qualitative studies with physiotherapists and other clinical stakeholders, such as managers and physiotherapy assistants, to clarify contemporary barriers and facilitators may be warranted.

Although the results of the focus groups have not been published to date, the studies quality has been self-assessed (Appendix 9.3) in the same manner as was the case when examining Objective 2. The completed COREQ checklist can be found in Appendix 4.1. The items across checklists are satisfied and, therefore the present qualitative study of physiotherapists' perspectives can be considered of high quality.

Building upon the physiotherapists' training requests and need for clarification of underpinning theory, Objective 4 (Chapter 5) details a scoping review which aimed to identify an appropriate theory of behaviour change to provide the conceptual underpin physiotherapy training and support intervention delivery.

9.2.4: Objective 4: To identify an appropriate theory of behaviour change to integrate with the proposed intervention to support physiotherapist training and intervention delivery

Objective 4 was addressed in Chapter 5 and builds upon the proposed intervention model of behaviour change and physiotherapy training needs identified in Objectives 2-3 respectively. Two independent researchers reviewed the official written descriptions of theories of behaviour change (365, 371) and compared their conceptual models with the

proposed intervention (343). Specifically, theories were sought whose models conceptualised: feelings of confidence as a precursor to motivation; interactions with others and/or the wider environment and implications for engagement; detailed understanding of motivation regulation that was consistent with the perspectives of patients with lower-limb OA (Chapter 3). Researchers discussed findings to identify a list of candidate theories, and a third researcher was available to mediate disagreements.

Three theories of behaviour change: the Health Behaviour Internalisation Model (383) (HBIM), Self-Determination Theory (384, 385, 386) (SDT), and the Trans-Contextual Model of Motivation (387) (TCM) were identified as candidate theories. To finalise theory choice, further searches were undertaken to identify whether each candidate theory's body of evidence included PA interventions, validated measures that allowed for the testing of theory-related hypotheses, and established, associated training programmes. After these additional factors were reviewed and discussed, SDT was chosen as the preferred theory to underpin physiotherapist training in intervention delivery.

The use of theory is advocated when developing complex interventions (114, 176). However, theory choice is often influenced by researcher preference (365) or limited by lack of knowledge (378). To support the present work, a scoping review was conducted to identify RCTs that involved the delivery (and testing) of theoretically-grounded PA interventions on patients with lower-limb OA. Interventions based on Social Cognitive Theory (147, 412, 488, 596, 597, 598, 599), Self-Efficacy Theory (257, 497, 600, 601), Goal Setting Theory (498), Self-regulation Theory (602), The Information-Motivation-

Behavioural Skills theoretical model (21), the Health Action Process Approach (603), the Transtheoretical model (604), or a combination of theories (568, 605) were identified. Physiotherapy specific theoretical PA interventions (including recently published protocols) were also identified which demonstrated a preference for the Capability-Opportunity-Motivation-Behaviour (COM-B) model (22, 433, 434, 606, 607). Currently musculoskeletal physiotherapy SDT interventions have either been group based (350) or aimed at patients with low-back pain (608). Therefore, drawing from the additional insight provided by the scoping review, the proposed intervention grounded in SDT appears novel and further supports progressing to feasibility testing.

Few of the above RCTs justified their choice of theory. Furthermore, the effectiveness of theoretical interventions, how well theory has been applied to intervention development, testing and refinement, and clarifying if a particular theory is most effective at promoting PA in patients with lower-limb OA, has not been investigated. Therefore, a systematic review is currently being undertaken to address these issues.

A strength of the present research was the comprehensive review of the available behaviour change theories. Furthermore, the use of two independent researchers to screen and then review of full texts with consensus meetings planned, were based on systematic review methodology (609), and enabled transparent reporting on decisions made. However, the validity of this highly novel method remains questionable, and some personal bias likely influenced decisions. Furthermore, there is no RoB tool or reporting guidelines for such methodology so self-assessment is not possible. Future research is needed to identify the most appropriate method of choosing a theory of behaviour change when developing a complex intervention. In that regard, the proposed

intervention appears novel. It progresses knowledge by aiming to identify a theory of behaviour change to undergird the present intervention based on conceptual fit rather than preference or knowledge. Objective 5 builds on Objectives 1-4 by evaluating the feasibility and acceptability of the proposed intervention.

9.2.5: Objective 5: To investigate the feasibility and acceptability of delivering a complex, multicomponent theoretical behaviour change physiotherapy intervention in the view of patients with lower-limb OA, treating physiotherapists, and research related staff.

Objective 5 was achieved by the details reported in Chapters 6 (main trial write up) and 7 (intervention fidelity analysis) and the trial protocol that was published in Pilot and Feasibility Studies (543). The trial utilised a mixed methods single-arm design to evaluate the feasibility and acceptability of a theoretically grounded physiotherapy behaviour change intervention that was sequentially developed (as described in Chapters 2-5 and in regarding to the meeting of Objectives 1-4). Patients with lower-limb OA were recruited from one NHS site. Intervention physiotherapists undertook bespoke training which included the tailored *Empowering Physio*[™] programme which aimed to develop awareness of how physiotherapist-patient communication and interaction affects the treatment climate, and education regarding the delivery of intervention BCTs to promote PA adoption and maintenance.

36 patients (n=26 females) with lower-limb OA participated. Descriptive statistics and a CONSORT flow diagram provided an overview of the trial population and flow. PROMs,

performance-based outcomes, and direct measures of PA (accelerometers) were completed at baseline, 3 months, and 6 months post baseline. 19 Intervention sessions were audio recorded and reviewed by two authors to evaluate the fidelity of intervention delivery (BCTs used and treatment climate). Participants (n=10), physiotherapists (n=5) and research staff (n=5) attended semi-structured interviews to give their perspectives on the trials' feasibility and acceptability. Physiotherapists also gave their perceptions on the feasibility and acceptability of the training programme. Thematic analysis summarised the qualitative data. Quantitative and qualitative data were integrated to evaluate whether each a priori success criteria had been achieved.

Overall, 82% of trial objectives met the success criteria. The intervention, multi-component training programme, and recruitment processes were highly acceptable and feasible to deliver with minor modifications. Fidelity analysis demonstrated that, overall, protocol BCTs and the treatment climate were delivered competently. However, the data collection processes did not meet the progression criteria with only 48% and 33% of valid outcome data recorded at 3 and 6-months respectively post baseline.

Simplifying the intervention materials (i.e., the booklets), reducing the number of phase specific BCTs, using the wrist as the accelerometer wear point, prioritising in person assessments, and securing increased funding for research staff involved in the delivery of the trial were accepted as feasible adaptations. Further pilot work to clarify wrist specific PA accelerometer cut points in patients with lower-limb OA and consultation with physiotherapy managers across sites to clarify intervention parameters will be conducted prior to undertaking a definitive trial. An internal pilot study phase (525, 526)

will test the proposed adaptations to data collection processes during the preliminary phase of the definitive trial to ensure they are satisfactory.

Key methodological considerations were discussed extensively within the studies Steering Group at the trial planning stage. Two of the most important decisions included the primary data collection endpoint and choice of a single-arm or randomised parallel two-arm trial design.

Regarding data collection endpoint, as the intervention targeted PA across the conceptual phases of behaviour change, the SSC agreed that it was important to capture data that represented behavioural 'maintenance'. Within the behaviour change literature, the definition of maintenance is subject to considerable heterogeneity (155). However, the most utilised definition in research is that proposed in the Transtheoretical Model, which suggests behavioural maintenance occurs after approximately six months of behaviour change practice (i.e. from when a behaviour change intervention commences) (132). Although this definition was originally based on addictive behaviours, it has been utilised in previous systematic reviews examining PA in healthy young and middle-aged (610) and inactive adult populations (135). Interestingly, the original systematic review included in this thesis (277) (Chapter 2) identified six months post-baseline as the timeframe where BCTs were statistically the least effective at promoting PA. Therefore, six months post-baseline was chosen as the primary endpoint for the feasibility study. However, the plan would be for intervention effectiveness to be measured at further time points post baseline (e.g. 9 and/or 12 months) in the anticipated definitive trial to ensure PA maintenance data is adequately captured.

Regarding the choice of a single versus parallel arm design, there have been an extensive number of RCTs conducted on patients with lower-limb OA and patients willingness to be randomised has already been established. As information on randomisation exists, and the feasibility trial did not aim to test the interventions' efficacy, adding a parallel arm was considered unresourceful and potentially unethical. As such, the trial utilised a single arm study with a sample size sufficient to provide a normal distribution of patients (611). Patient data enabled a primarily descriptive quantitative analysis. Purposive sampling was employed to gain a wide range of opinions on the feasibility and acceptability of the intervention from participants, intervention physiotherapists, and research staff. Furthermore, study research nurses were not informed of the overall trial design (single arm versus parallel arms) or primary aims. They were asked about the effectiveness of blinding within interviews and stated that blinding was successful.

The use of mixed-methods followed evidence based recommendations to integrate qualitative and quantitative findings which increased the quality of analyses (612). However, as outlined in Chapter 6, the COVID-19 pandemic greatly influenced the conduct of the feasibility trial. The ROH discontinued the Attend anywhere app to encourage in person appointments post-COVID, which likely reduced the number of remote intervention sessions delivered within the trial. However, the pre-covid NHS long term plan (586) intended to increase remote treatment offerings across specialties, and several physiotherapy services have maintained remote delivery as their primary outpatient option. As the planned definitive trial will be multicentre, an increased

understanding of the most appropriate BCTs to use in remotely delivered PA interventions to patients with lower-limb OA is warranted.

No critical appraisal tool for mixed methods single-arm feasibility trials exists. However, the CONSORT (613), COREQ (529), TIDIER (528), and SPIRIT (530) checklists were utilised in the design and conduct of the trial. These tools were used to self-assess the trial's reporting and can be found in Appendices 6.11-6.14 respectively. Overall, the findings demonstrated comprehensive reporting of items and suggesting high quality and low RoB.

9.3 Thesis strengths and limitations

In line with MRC guidelines, this thesis aimed to develop and determine the feasibility and acceptability of a novel, theoretically grounded, multi component physiotherapy behaviour change intervention that promoted adoption and maintenance of PA in patients with lower-limb OA (114, 176). This aim was met through a series of interconnected studies where each step of the intervention development and testing was informed by preceding studies with gaps in evidence informing subsequent objectives.

Most of the studies that constitute this thesis have been reviewed by wider audiences including funding bodies and professional peers through the submission process to open access journals and/or conference presentations. The studies constituting this thesis were, where appropriate, registered with regulatory bodies, conducted according to published protocols, and reported following established guidelines. Studies involved

key stake holders, including public representatives, clinicians, and academics to assist in the research conduct and interpretation of results. Therefore, clinicians and musculoskeletal academics can use the results to aid their decision making in clinical practice and research. With the increase in lower-limb OA and the growth of associated secondary health concerns leading to increased burden on global healthcare systems (12), consideration of the role of physiotherapists in the promotion of PA in patients with lower-limb OA is an important and relevant topic.

It is important to recognise that this part-time, self-funded PhD has been completed alongside full-time work commitments and was delayed by approximately two years by the COVID-19 pandemic. The extended time frame to PhD completion and evolution of physiotherapy practice since the commencement of the thesis has led to some limitations. During the pandemic-driven repeated lockdowns, UK physiotherapists were redeployed and in-person provision offered only to in-patients (e.g. those having surgery) (614). Remote delivery increases appointment flexibility and reduces costs for travel and parking (615, 616). Therefore, this practice has continued post COVID, with remote physiotherapy sessions being offered in several trusts and practices (614). However, the behaviour change intervention was mostly developed pre-pandemic and designed for in-person delivery primarily, with remote delivery optional (as was practiced at the local trust). The bias towards in person delivery can be seen in the eligibility criteria used in the systematic review (Chapter 2), patient interviews (Chapter 3), and physiotherapists focus groups (Chapter 4) where data were generated that informed most of the intervention development. Although there was no way for this doctoral student to predict the pandemic, the NHS long term plan of increased remote

delivery of healthcare was established in 2019 (351). Therefore, this type of delivery could have been more explicitly bought into the aims and objectives within the project to enhance its relevance in contemporary physiotherapy practice. Further COVID related limitations include obtaining optimal levels of trial funding and staff sickness which impacted on trial conduct, most notably compromising data collection.

Based on the lack of long-term PA data available for analysis and the recent developments in NHS physiotherapy provision, further consideration in how best to support post discharge PA maintenance in patients with lower-limb OA may be warranted. Although the intervention's maintenance booklet (Appendix 6.5) included detail on local PA groups/community classes, alternative strategies and modes of delivery, such as PA/lifestyle apps (149, 566), have been developed since the intervention's conception. Furthermore, the Royal Orthopaedic Hospital has developed a website that provides specific knee and hip exercises (617) and access to the 'getuBetter' app (618) to aid PA maintenance. Due to the heterogeneity of presentation of OA and individual PA needs, further discussion with local physiotherapists and PPI will be undertaken to ensure that additional options to support PA maintenance are integrated into the intervention.

9.4 Conclusions

Lower-limb OA represents a current and growing global health concern (7, 12). PA interventions (1, 3, 10, 64) that are underpinned by theory (114) are recommended to aid symptom self-management in patients with lower-limb OA. However, most

behaviour change interventions targeting this population are of low quality and choice of underpinning theory and BCTs poorly reported or underdeveloped (116, 371). The present body of work followed the MRC framework (114, 176) and utilised a combination of evidence based and novel methods to iteratively develop and feasibility test the first theoretically grounded physiotherapy intervention that explicitly targeted PA adoption and maintenance in patients with lower-limb OA. The findings of this thesis suggested that a parallel group definitive low RoB RCT, evaluating the clinical effectiveness of the behaviour change intervention versus usual care in patients with lower-limb OA is feasible with the following modifications:

- Simplification of the intervention materials (particularly, the informational booklets)
- Reducing the total number of intervention BCTs
- Utilising the wrist as the accelerometer wear point
- Prioritising in person assessments and using tracked delivery where this is not possible.
- Securing appropriate levels of funding for dedicated to physiotherapist training time and research staff support.

The proposed definitive trial remains contemporary and necessary despite 12 further RCTs being published since commencement of this part-time PhD. However, further research to determine population specific wrist PA intensity cut points and clarification of the most effective remotely delivered BCTs to promote PA in patients with lower-limb OA is required prior to undertaking the definitive trial. Consultation with physiotherapy

managers across NHS sites to determine realistic intervention parameters to match post-covid healthcare delivery in the UK is also warranted.

APPENDICES

1.1 Article, BMJOpen, Effectiveness of behavioural change techniques in physiotherapy interventions to promote physical activity adherence in patients with hip and knee osteoarthritis: a systematic review protocol

Open Access
Protocol

BMJ Open Effectiveness of behavioural change techniques in physiotherapy interventions to promote physical activity adherence in patients with hip and knee osteoarthritis: a systematic review protocol

Matthew Willett,^{1,2} Joan Duda,^{2,3} Charlotte Gautrey,⁴ Sally Fenton,² Carolyn Greig,^{2,3} Alison Rushton^{1,2}

ABSTRACT

Introduction Osteoarthritis (OA) is a common degenerative articular disease, the highest cause of individual level disability and a significant socioeconomic burden to healthcare services. Patient education and physical activity (PA) prescription are recommended components of interventions in several healthcare guidelines and are commonly provided by physiotherapists. However, these interventions lack long-term clinical effectiveness. Patient adherence to PA prescription requires patients to modify their PA behaviour and appears critical in maintaining symptomatic improvements. This systematic review aims to evaluate the effectiveness of behavioural change techniques (BCTs) used in physiotherapy interventions to improve PA adherence.

Methods and analysis Medline, Cochrane and PEDro registers of Controlled Trials, EMBASE, CINAHL and PsycInfo databases, and key grey literature sources will be rigorously searched for randomised controlled trials that compared a physiotherapy intervention incorporating BCTs with other therapies, placebo interventions, usual care or no-treatment. Two independent researchers will conduct literature searches, assess trial eligibility, extract data, conduct risk of bias assessment (using Cochrane risk of bias tool), classify BCTs and evaluate the quality of the body of literature following Grading of Recommendations, Assessment, Development and Evaluation (GRADE) guidelines. Narrative synthesis of key outcomes will be presented and meta-analysis will be performed if included trials are clinically homogenous, based on their intervention and comparator groups and outcome measures. This review will be reported in line with the Preferred Reporting Items for Systematic review and Meta-Analysis guidelines.

Ethics and dissemination Research ethics approval is not required. This review will help inform clinicians and researchers on the most effective behavioural change techniques used in physiotherapy interventions to enhance adherence to PA prescription for patients with lower limb OA. The findings will be disseminated through publication in a peer-reviewed journal and conference presentations.

Trial registration number PROSPERO CRD42016039932.

BACKGROUND Osteoarthritis (OA) is a common degenerative disease that causes patients significant pain and reductions in function, social engagement and quality of life.¹⁻³ OA results in considerable societal healthcare costs and resource utilisation. In UK, OA is the most common cause of individual disability, where it is estimated to affect approximately 8.5 million people.³ Annually, OA symptoms are estimated to be responsible for approximately 2 million general practitioner visits in the UK, with an expenditure totalling 1%

Strengths and limitations of this study

- This systematic review will be the first to rigorously search for, and evaluate the effectiveness of, behavioural change techniques (BCTs), using the behavioural change taxonomy V1, in physiotherapy randomised controlled trials (RCTs) to promote physical activity (PA) adherence in patients with lower limb osteoarthritis (OA).
- This research will offer physiotherapists and other clinician's evidence-based guidance in selecting BCTs to enhance adherence to PA prescription in patients with lower limb OA.
- Several heterogeneous interventions and comparison groups, variabilities in OA severity, and a limited number of trials are anticipated based on a scoping search. This may preclude meta-analysis, affecting the overall level of evidence for RCT groupings and therefore not enabling firm conclusions on BCT effectiveness to be established.

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6

effectiveness than 'passive' techniques²⁸ (provision of information and advice) at maintaining PA behaviours on patients with OA.⁷

Behavioural change techniques (BCTs) are the active components in behaviour change interventions.²⁹ Michie *et al* (p. 82) define BCTs as 'an observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour' and include techniques such as 'reinforcement', 'self-monitoring' and 'feedback'. The identification of BCTs has allowed for specific techniques to be transparently highlighted within interventions and subsequently demonstrated clinical effectiveness.³⁰

Intervention fidelity is the degree to which an intervention's active ingredients are delivered as intended.³¹ Intervention fidelity assessment is especially important in behavioural change interventions as it can help determine whether the treatment effect is due to the interacting BCTs or from a variation in the delivery of the intervention protocol.³²⁻³⁵ The Behaviour Change Taxonomy V1³⁶ has been developed to help authors identify BCTs and improve consistency of reporting,³⁷ allowing trials to comply with CONSORT³⁸ Medical Research Council³⁹ and Template for Intervention Description and Replication⁴⁰ guidelines for the transparent reporting of interventions and its use should therefore improve intervention fidelity assessment.

Existing PA systematic reviews examining BCTs have focused on broad patient populations:²⁹⁻³²⁻³⁵ diabetes,⁴¹ cardiovascular disease⁴² and rheumatoid arthritis (RA).⁴³ To date, only one systematic review⁴⁰ has examined BCT use in physiotherapy practice treating patients with lower limb OA and chronic low back pain with an associated paper assessing each trial's intervention fidelity.³⁷ This scoping review identified 33 BCTs used within physiotherapy self-management interventions with no trial (out of n=22) demonstrating 'high' treatment fidelity (>80% of components present).³⁵ Therefore, individual BCT effectiveness was difficult to measure and meta-analysis was not conducted. Furthermore, the grey literature was not searched, meaning up to 10% of eligible trials were not included,³⁷ the review did not target a specified health behaviour (PA adherence) and focused on group classes only. Physiotherapists most commonly treat patients with lower limb (hip and knee) OA individually (1:1),⁴⁴ and tailoring an intervention to the patients' particular situation is critical to enhance adherence to PA prescription.⁴⁵ Furthermore, recent systematic reviews suggested that 1:1 treatments may provide greater improvements on pain and function than group classes on patients with knee OA⁴⁶ and RA,⁴⁷ respectively.

Identifying effective BCTs within interventions for patients with chronic conditions is a research priority for the National Institute of Clinical Excellence with 'social support', 'feedback and monitoring' and 'goals and planning', suggested as integral components of programmes to support PA behavioural change.³⁸ Additionally, in systematic reviews of PA behaviours,³⁸⁻⁴²⁻⁴⁴ the BCTs

of the country's gross national product.⁴ OA primarily affects the hip and knee synovial joints, with an overall point prevalence of 11% and 24%, respectively.⁴

Healthcare interventions that incorporate education and physical activity (PA)/exercise prescription are recommended for the non-pharmacological management of OA in several international guidelines.¹⁻³⁻⁵⁻⁶ Physiotherapists are commonly the primary healthcare practitioner to whom patients with lower limb OA are referred and are well placed to deliver these interventions.⁷⁻⁸ Although education⁹ and PA interventions¹⁰ are effective at reducing short-term OA symptoms and clinical outcomes, they lack long-term effectiveness.¹¹ With estimates that 50%-70% of patients do not comply with physiotherapy PA recommendations,¹²⁻¹³ adherence has been identified as a critical reason for this lack of long-term effectiveness.⁷ As OA is a life-long condition,¹⁴ with point prevalence and incidence increasing with age,⁴ long-term adherence to PA recommendations is critical to maintain the short-term improvements seen in a patient's pain,¹⁵ function¹⁶ and disability.¹⁷

Due to healthcare costs and time constraints, physiotherapy appointments are often limited in number and focus on short-term outcomes only.¹⁸ As there is usually a gradual decrease in clinical contact time between patient and therapist, long-term PA will most likely continue without supervision in the home/community.¹⁹ As the positive effects of PA reduce if discontinued, and patient adherence diminishes when physiotherapist supervision ceases,²⁰ long-term adherence to recommendations is important and requires patients to change and sustain this change in PA behaviour.²⁰

Despite the importance of monitoring PA adherence, at present there is limited evidence to suggest the most appropriate outcomes to measure the maintenance of PA in patients with lower limb OA.²¹ A recent systematic review concluded that no recommendations could be made for any PA adherence outcomes in patients with chronic musculoskeletal pain²² due to methodological issues with diagnostic accuracy trial design. Furthermore, none of the seven outcomes identified in the review were validated on patients with OA. A further systematic review identified PA adherence measures used in self-management interventions for patients with musculoskeletal pain.²³ Six of the 47 trials in the review included participants with lower limb OA, with three of these incorporating exercise diaries and three a multi-item measure to measure PA adherence.²³

Behavioural change interventions incorporate synchronised techniques that target specific patient health behaviours.²⁴ Behavioural change interventions are usually complex²⁵ and commonly reported inconsistently in trials,²⁶⁻²⁷ making them difficult to replicate in clinical practice.²⁸

Incorporating 'active' behavioural techniques (eg, pacing and self-regulatory skills)²⁹ into interventions, which encourage patients to participate in their own symptom management has demonstrated greater

effectiveness than 'passive' techniques²⁸ (provision of information and advice) at maintaining PA behaviours on patients with OA.⁷

Behavioural change techniques (BCTs) are the active components in behaviour change interventions.²⁹ Michie *et al* (p. 82) define BCTs as 'an observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour' and include techniques such as 'reinforcement', 'self-monitoring' and 'feedback'. The identification of BCTs has allowed for specific techniques to be transparently highlighted within interventions and subsequently demonstrated clinical effectiveness.³⁰

Intervention fidelity is the degree to which an intervention's active ingredients are delivered as intended.³¹ Intervention fidelity assessment is especially important in behavioural change interventions as it can help determine whether the treatment effect is due to the interacting BCTs or from a variation in the delivery of the intervention protocol.³²⁻³⁵ The Behaviour Change Taxonomy V1³⁶ has been developed to help authors identify BCTs and improve consistency of reporting,³⁷ allowing trials to comply with CONSORT³⁸ Medical Research Council³⁹ and Template for Intervention Description and Replication⁴⁰ guidelines for the transparent reporting of interventions and its use should therefore improve intervention fidelity assessment.

Existing PA systematic reviews examining BCTs have focused on broad patient populations:²⁹⁻³²⁻³⁵ diabetes,⁴¹ cardiovascular disease⁴² and rheumatoid arthritis (RA).⁴³ To date, only one systematic review⁴⁰ has examined BCT use in physiotherapy practice treating patients with lower limb OA and chronic low back pain with an associated paper assessing each trial's intervention fidelity.³⁷ This scoping review identified 33 BCTs used within physiotherapy self-management interventions with no trial (out of n=22) demonstrating 'high' treatment fidelity (>80% of components present).³⁵ Therefore, individual BCT effectiveness was difficult to measure and meta-analysis was not conducted. Furthermore, the grey literature was not searched, meaning up to 10% of eligible trials were not included,³⁷ the review did not target a specified health behaviour (PA adherence) and focused on group classes only. Physiotherapists most commonly treat patients with lower limb (hip and knee) OA individually (1:1),⁴⁴ and tailoring an intervention to the patients' particular situation is critical to enhance adherence to PA prescription.⁴⁵ Furthermore, recent systematic reviews suggested that 1:1 treatments may provide greater improvements on pain and function than group classes on patients with knee OA⁴⁶ and RA,⁴⁷ respectively.

Identifying effective BCTs within interventions for patients with chronic conditions is a research priority for the National Institute of Clinical Excellence with 'social support', 'feedback and monitoring' and 'goals and planning', suggested as integral components of programmes to support PA behavioural change.³⁸ Additionally, in systematic reviews of PA behaviours,³⁸⁻⁴²⁻⁴⁴ the BCTs

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'instruction on how to perform the behaviour', 'demonstration of the behaviour', 'problem-solving' and 'use of follow-up prompts' have been identified as strategies within effective interventions.

As the largest healthcare provider of exercise prescription to patients with musculoskeletal pain in the National Health Service,³ physiotherapists are well placed to deliver interventions that incorporate BCTs. However, physiotherapists need to increase their understanding of patients' PA behaviours and motivations to enhance adherence to their recommendations.⁵¹ Although physiotherapists are encouraged,^{52, 53} and attempt⁵⁴ to use behavioural change interventions in their clinical practice, recent evidence suggests that they lack the knowledge base to do so effectively.⁵⁴ A recent systematic review suggested that while incorporating behavioural change into physiotherapy programmes can enhance patient PA adherence, the most effective BCTs have not been determined.⁵⁵ Furthermore, there is a lack of standardised definitions and understanding of BCTs used in physiotherapy interventions when treating patients with OA.

Therefore, the aim of this systematic review is to identify which BCTs used in individual physiotherapy interventions to improve adherence to PA recommendations are most effective in treating patients with lower limb (knee and hip) OA symptoms.

OBJECTIVES

- To identify BCTs used in individual outpatient physiotherapy interventions to increase or maintain PA adherence outside of the clinic in patients with hip and knee OA.
- To evaluate the clinical effectiveness (on outcomes of PA, adherence, pain, function, quality of life, self-efficacy and adverse effects) of BCTs used in individual outpatient physiotherapy interventions to increase or maintain PA adherence outside of the clinic in patients with hip and knee OA.

METHODS

This systematic review will be conducted according to a predefined protocol (CRD42016039932) which complies with recommendations from the Cochrane Collaboration Musculoskeletal group⁵⁶ and Centre of Reviews and Dissemination guidelines,⁵⁷ and will be reported following Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.⁵⁸

Eligibility criteria

1. Trial design: Randomised controlled trials (RCTs) including protocols, results and fidelity papers where available.
2. Participants: Adult participants (≥18 years) with hip and/or knee OA. Diagnosis can be based on acknowledged symptoms, self-reported joint pain or radiographic evidence due to the inconsistency of criteria used across guidelines for hip and knee OA.

diagnosis.⁴ RCTs whose participants have OA with other chronic coexisting articular pathologies⁵⁹ that contribute >25% of their population will be excluded⁶⁰ (eg, septic arthritis, inflammatory joint disease, gout, articular fracture, hemochromatosis). Trials whose participants have had,^{61, 62} or are awaiting,^{63, 64} surgery for OA treatment (eg, joint arthroplasty) will be excluded, as PA adherence behaviours in this patient population may be different.⁶⁵

3. Interventions: Any structured outpatient physiotherapy programme that incorporates a BCT that appears on the V1 Taxonomy⁶⁶ as defined by Michie et al that focuses on maintaining or increasing patient PA adherence when away from the physiotherapy clinic (eg, at home or in community). BCTs can include, but are not exclusively: 'prompt self-monitoring of behaviour', 'goal setting', 'social support'⁶⁷ and 'reinforcement'.⁶⁸ The intervention must be delivered individually by a physiotherapist (with the profession stated clearly) although follow-up or 'booster' sessions may take different forms (eg, telephone calls). Other members of a multidisciplinary team may be involved in any aspect of the patient's management provided that the physiotherapist is the primary healthcare professional involved and their role can be established by the researcher. Trials that incorporate carers or peer support will be included as long as the patient is the primary target of the physiotherapy intervention.
4. Comparators: Other therapies, placebo interventions, 'no treatment', 'usual care' will be included. RCTs that examined two physiotherapy interventions incorporating BCTs will be included provided that there are different BCTs in each intervention arm, therefore allowing their effectiveness to be determined. RCTs that include cointerventions will be included if the comparison group receives the same cointervention, thereby enabling the effectiveness of the BCTs to be evaluated.
5. Outcomes: It is preferable for trials to have measured PA adherence. Therefore, the main outcomes of interest include PA (eg, pedometers, self-report questionnaires)²¹ and adherence measures (eg, exercise diaries)²³ although other clinical outcomes of effectiveness (pain, function, quality of life, self-efficacy and adverse effects) will be considered provided they are collected with validated measures.⁶⁹ A note will be made during data extraction whether the trial measured PA adherence specifically and this will be interpreted in the discussion section. Only trials that measured PA adherence will be considered for meta-analysis.
6. Language: Trials that are not written in English will be excluded (at full text stage).

Search methods for trial identification

Medline (OVID) from 1946, the Cochrane Register of Controlled Trials (CENTRAL) from 1940, EMBASE from

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1946, the Physiotherapy Evidence Data base (PEDro) from 1999, Cumulative Index to Nursing and Allied Health Literature (CINAHL) from 1937 and PsycInfo (OVID) from 1806, will be searched.⁶⁶ The clinicaltrial.gov trial register and WHO's trial portal will be searched for relevant trials.⁶⁰ Grey literature will be searched on the 'ZETOC' and 'Conference Proceedings Citation

Index' websites. Reference lists of all included trials and relevant review articles and a citation search using 'web of science' will be conducted. The search strategy for Medline (table 1) has been developed in consultation with a subject-specific librarian and will be adapted for use in other databases. Search terms are informed from recent systematic reviews investigating OA,^{59, 63, 64} physiotherapy,

Table 1 Search strategy to be used for the MEDLINE electronic database

Database	Search terms
MEDLINE (OVID) 1946-present	1) exp osteoarthritis/ 2) osteoarthritis.tw. 3) (degenerative adj2 arthritis).tw. 4) arthritis.tw. 5) Or 1-4 6) knee/ 7) exp knee joint/ 8) knee\$.tw. 9) hip/ 10) exp hip joint/ 11) hip\$.tw. 12) Or 6-11 13) exp Self Care/ 14) (self or symptom\$) adj (care or help or manage\$ or directed or monitor\$ or efficacy or advice).tw. 15) Patient Education as Topic/ 16) (health or patient\$) adj2 (educat\$ or informati\$).tw. 17) exp Consumer Participation/ 18) (patient\$ or consumer\$) adj part\$.tw. 19) "Power (Psychology)"/ 20) empower\$.tw. 21) Holistic Health/ 22) (holistic or wholistic).tw. 23) "activities of daily living"/ 24) (activity\$ adj2 daily adj living).tw. 25) social support/ 26) (social adj (support or network\$)).tw. 27) (support adj system\$).tw. 28) exp Adaptation, Psychological/ 29) (psychologic\$ adj (adapt\$ or adapt\$)).tw. 30) (cope or coping or coping).tw. 31) exp Behavior Therapy/ or exp cognitive therapy/ or self manage\$.it. 32) (adapt\$ adj behavior).tw. 33) (behavior\$ adj (therap\$ or intervention\$)).tw. 34) health education/ or self efficacy/ or Exercise/ or health behavior/ 35) compliance/ or patient compliance/ 36) conditioning, operant/ 37) exp "Reinforcement (Psychology)"/ 38) operant conditioning.mp. 39) respondent treatment.mp. 40) relaxation.mp. or exp Relaxation/ 41) graded activity.mp. 42) health promotion/ 43) (psycholog\$ technique or behavior\$ technique).mp. 44) behavior\$ Change.mp. 45) self efficacy.mp. 46) Motivation/ or motivation'.mp. 47) primary prevention/ 48) Psychology.mp. or Psychology/ 49) Adherence.mp. 50) Or 13-49 51) exp Physical Therapy Modalities/ 52) physiotherap\$.tw. 53) (physiotherap\$ or physical therap\$ or pt).mp. 54) physiotherap\$.mp. 55) kinesiotherap\$.tw. 56) exp Rehabilitation/ 57) rehab\$.tw. 58) Physical Activity.mp. 59) Or 51- 58 60) randomised controlled trial.pt. 61) controlled clinical trial.pt. 62) randomised.ab. 63) placebo.ab. 64) drug therapy.fs. 65) randomis.ab. 66) trial.ab. 67) groups.ab. 68) Or 60-67 69) exp animals/ not humans.sh. 70) \$S not \$D 71) 5 and 12 and 50 and 59 and 70

behavioural and education interventions^{49 50 55 63–65} and the scoping search to identify keywords in relevant trials.^{7 66} RCT filters, as recommended by the Cochrane Collaboration, will be used to prioritise sensitivity over specificity.^{47 67–69}

Study selection and data management

Two independent researchers (MJW, ChG) will conduct the initial searches, review abstract and titles, read the full text of included trials or those where uncertainty remains, review relevant reference lists and conduct the citation search. In cases where the two researchers cannot agree on eligibility, a third researcher (AR, subject and methodological expertise) will mediate. Initial search results will be uploaded to Refworks prior to the review of titles and abstracts. Included trials will be managed through EndNote. A PRISMA flow chart will be used to provide transparency of the number of trials included or excluded at each stage.

Data collection process and analyses

Two independent researchers (MJW, SF) will use a standardised data extraction form developed from the Cochrane Back and Neck group template to record information on participants, trial setting, eligibility criteria, risk of bias assessment, methodology design, intervention, outcome measures (with special attention on PA adherence measures), assessment time points, PA adherence BCTs within the intervention, the deliverer of BCTs and any training they undertook and the main trial results.⁷⁰

Data extraction will include detail on trial treatment fidelity. Although several checklists exist to assess intervention fidelity,^{71 72} The National Institutes of Health Behaviour Change Consortium's (NIHBC) checklist is unique in its focus on behavioural change trials and has demonstrated validity and reliability.³² The NIHBC checklist has 40 components and was developed in 2011⁷³ from the initial version which had 25 components.³² The NIHBC's checklist comprises five domains: 'Treatment design', 'Training Providers', 'Delivery of Treatment', 'Receipt of Treatment' and 'Enactment of Treatment skills'. Although Toomey *et al.*⁶³ did not find any association between trial date and fidelity, the consideration and assessment of fidelity is a relatively contemporary concept and the scoping search revealed several trials conducted prior, or at a similar time, to the NIHBC checklists creation. While it is not the primary research question in this systematic review, trials treatment fidelity needs to be acknowledged when determining intervention effectiveness. Therefore, in order not to overly penalise trials but to aid interpretation, each domain on the NIHBC checklist will be judged as 'present' or 'absent' by two independent researchers (MJW, SF) but no score will be given to individual items. These details will be included as part of the narrative synthesis and interpreted in the discussion when drawing conclusions regarding BCT effectiveness.

The data extraction form will be piloted on the full texts of several included RCTs to ensure reliability and will be altered as necessary to optimise data collection. Any disagreement between researchers will be resolved through discussion. If agreement cannot be reached, a third reviewer (AR) will mediate. Where there are multiple reports of the same trial, data will be extracted using separate forms and collated on a single form subsequently.⁷⁰ Trial authors will be contacted by email if information is missing or unclear.

Two independent researchers (MJW, SF) will code interventions using the 'Behaviour Change Taxonomy'.⁷² BCTs and their associated hierarchy will be included as a component of the data extraction. As per training instructions, the associated text and page number will be recorded and the BCT will be given a 'score' of + (present in all probability) or ++ (present beyond all reasonable doubt)⁷⁴ to facilitate further discussion. Only BCTs that are directed at PA adherence behaviour will be coded.⁷⁵ Trials that have available protocols and fidelity papers will also be coded.⁴⁰ The researchers will undergo online training on the use of the taxonomy and the coding process will be piloted a priori. To ensure that a 'postlearning effect'⁷⁵ is minimised, a period of integration will be observed after the training, and coders will meet regularly to minimise discrepancies in taxonomy understanding and enhance agreement. Taxonomy use will be piloted a priori, and coder agreement will be calculated using Cohen's Kappa statistic. Any disagreement between the researchers will be resolved by researcher consensus. In the event that consensus cannot be reached, a third researcher (JD, expertise in subject area of behavioural change) will mediate the decision (objective 1).

Risk of bias assessment

Two independent researchers (MJW, SF) will use the Cochrane Risk of Bias tool to assess the internal validity of included trials.⁷⁶ The tool was developed by a research working group and is recommended for use in systematic reviews. It uses domain-based evaluation rather than a check list or scoring system to assess internal validity⁷⁶ and allows review authors space to justify their conclusions.⁷⁷ The tool addresses six domains: 'sequence generation', 'allocation concealment', 'blinding', 'incomplete outcome data', 'selective outcome reporting' and 'other' sources of bias. A judgement of 'high', 'unclear' or 'low' risk of bias will be made for each domain. A judgement of 'Unclear' will be allocated to a domain where insufficient information is provided. Trials will be screened for selective outcome reporting by comparing outcomes used in the finalised articles with registered protocols. If no trial protocol exists, outcomes from the trials published methods and results sections will be compared and a judgement of 'unclear' will be allocated.⁵⁸ When assessing trials risk of bias, researchers will pay special attention to the 'blinding' domain. Blinding of the treating physiotherapists and trial participants is often problematic; however, assessor blinding is achievable and important.⁷⁸

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Therefore, trials will be judged to have overall 'low risk' for the blinding domain if the assessor is adequately blinded.⁷⁸ The risk of bias assessment across trials will be displayed graphically using REVMAN 5.3.

Data presentation

A table will be presented that details the BCTs used in each trial. The total number of BCTs (individually and hierarchical groups) used across trials, their frequency per trial and how accurately they were reported will be detailed (objective 1).⁴⁰ A 'risk of bias' table showing internal validity decisions within and across trials will also be presented. A 'characteristics of included trials' table with PICOS data with explicit detail noting:

- Intervention: fidelity assessment, whether other intervention providers were involved in BCT delivery and any training in physiotherapist BCT delivery.
- Outcomes: Trials that used a PA adherence measure.

Data synthesis

Narrative synthesis will be reported following stages as recommended by Cochrane Qualitative Research Group.⁷⁹

Developing a preliminary synthesis

Trials (≥ 2) will be grouped together if they are clinically homogenous as determined by two researchers (MJW, SF), based on:

- Interventions: specific BCTs with or without cointerventions
- Comparator groups
- Outcome measure domains⁷⁹

The results of groupings will be presented in tables (objective 1).

Assessing the robustness of the synthesis

Each table and statement will include information detailing overall quality of evidence for each grouping. The quality of the body of evidence for each outcome will be evaluated using the GRADE approach (Grading of Recommendations, Assessment, Development and Evaluation).⁸⁰ GRADE determines overall quality of evidence based on risk of bias, inconsistency, indirectness, imprecision of results and publication bias.⁸⁰ The quality of evidence will be adjudicated as 'high', 'moderate', 'low' or 'very low' based on the guidance from the GRADE working group by two researchers (MJW, SF).⁸⁰ with a third researcher (AR) asked to mediate if consensus cannot be reached.

Exploring relationships within and between trials

Further textual descriptions will accompany the tables to highlight key points on trial population, BCTs identified and accuracy of reporting, intervention fidelity assessment, the BCT intervention provider and their training or outcome measures that could explain the differences in results as outlined in the tables.

BCT effectiveness

Individual BCT effectiveness will be determined narratively and supported quantitatively by the use of its 'percentage effectiveness ratio'.⁸¹ Trial interventions will be categorised as 'effective' or 'ineffective' with effective trials demonstrating a significantly greater effect on PA or adherence outcome measures when displayed in a forest plot. The ratio will be calculated by dividing the number of times that the BCT was part of an 'effective' intervention by the number of times the BCT was used in all trials (objective 2).⁸¹

Meta-analysis

Based on the scoping search, it is anticipated that eligible trials will demonstrate high intervention, comparator and outcome variability (clinical heterogeneity).⁷⁷ Therefore, when meta-analysis is indicated, a random effects model will be used to calculate effect sizes based on the groupings outlined in the narrative synthesis (objective 2). The risk ratio with 95% CIs and mean differences (MD) with 95% CIs will be used to measure the treatment effect of dichotomous and continuous outcomes, respectively. The standardised mean difference will be used to measure continuous outcomes where several measures are used within one outcome domain.⁷⁹ Where mean data are not available and trial authors do not respond to an email request for raw data (a maximum of three follow-up emails), the median will be used as an estimate of the mean.⁸²

Sensitivity analysis

A sensitivity analysis will be conducted to determine whether excluding high risk of bias RCTs has influenced the findings of the meta-analysis to enable further discussion (objective 2).

Meta-bias

Publication bias will be assessed by use of funnel plots where meta-analysis includes ≥ 10 trials.⁸³ Meta-analyses will be tested for 'small-study effects' by comparing fixed and random effects sizes where the random-effects model will show greater intervention effect sizes for trials with smaller sample sizes.⁸³

DISCUSSION

Patients with OA currently display the highest level of individual level disability in the UK. Interventions incorporating BCTs have the potential to increase long-term patient adherence to PA recommendations, increasing patient function and quality of life, and physiotherapists are well placed to deliver them. At present, there is a lack of understanding of specific BCTs used in physiotherapy interventions when treating patients with OA. This review will help identify BCTs currently being used in physiotherapy clinical practice and recommend those which are the most effective at reducing lower limb OA symptoms and encouraging long-term patient PA adherence. Clinicians will be able to apply the evidence from this

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systematic review on patients with OA by incorporating the most appropriate BCTs into their interventions to maximise their adherence to PA. This systematic review will also inform the planning and implementation of a trial to determine the feasibility of an active behavioural physiotherapy intervention on patients with lower limb OA.

LIMITATIONS

Several heterogeneous interventions, comparison groups, variability of OA severity and time periods and a limited number of trials (15–20) are anticipated based on the scoping search. This may preclude meta-analysis, affecting the overall level of evidence for RCT groupings. Furthermore, the fidelity assessment and BCTs within interventions may be poorly reported, making it difficult to determine the effectiveness of individual BCTs with consideration of the degree to which the intervention was delivered as intended.

ETHICS AND DISSEMINATION

No research ethics approval is required for this systematic review as no confidential patient data will be used. It is intended that the results of this systematic review will be disseminated through publication in a peer reviewed journal and conference presentations.

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Contributors All authors conceived the focus of the systematic review. MW is a PhD student and AR (lead supervisor), JD and CaG are supervisors. MW drafted the initial version of the protocol manuscript. AR, CaG and JD provided critical guidance on the direction, methodological decisions and proposed analyses. MW developed the search strategy and data extraction form that was piloted by MW and ChG/SF, respectively. All authors reviewed and commented on each draft of the systematic review protocol. MW is the guarantor of the review.

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Appendix 1.2: Article, PLOS One, Effectiveness of behaviour change techniques in physiotherapy interventions to promote physical activity adherence in lower limb osteoarthritis patients: A systematic review

RESEARCH ARTICLE

Effectiveness of behaviour change techniques in physiotherapy interventions to promote physical activity adherence in lower limb osteoarthritis patients: A systematic review

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Abstract

Background

Lower limb osteoarthritis (OA) causes high levels of individual pain and disability and is an increasing socio-economic burden to global healthcare systems. Physical Activity interventions are commonly provided by physiotherapists to help patients with lower limb OA manage their clinical symptoms.

Objective

To identify and evaluate the effectiveness of behavioural change techniques (BCTs) within physiotherapy interventions to increase physical activity (PA) adherence in patients with lower limb OA.

Design

A systematic review was conducted, following Cochrane guidelines according to a published and registered protocol (CRD42016039932). Two independent researchers conducted searches, determined eligibility, assessed risk of bias (Cochrane tool), intervention fidelity (NIHBC checklist), and coded randomised controlled trials (RCTs) for BCTs (V1 taxonomy). BCT effectiveness ratios were calculated and RCT risk of bias and intervention fidelity were summarised narratively.

Data sources

A highly sensitive search strategy was conducted on Medline, Embase, PsycINFO, CENTRAL, CINAHL and PEDro and grey literature databases from inception to January 2nd, 2018. Reference lists of included RCTs and relevant articles were reviewed, and a citation search was conducted using Web of Science.

Eligibility criteria for selecting studies

RCTs that evaluated the effectiveness of a physiotherapy intervention that incorporated ≥ 1 BCT that promoted home or community-based PA adherence in patients with lower limb osteoarthritis.

Results

Twenty-four RCTs ($n = 2366$ participants) of variable risk of bias (RoB) (5 low; 7 moderate; 12 high) and poor intervention reporting from 10 countries were included. Heterogeneity of intervention BCTs and PA adherence outcome measures precluded meta-analysis. Thirty-one distinct BCTs were identified in 31 interventions across RCTs. In general, BCTs demonstrated higher effectiveness ratios for short-term and long-term PA adherence compared with medium-term outcomes. The BCTs 'behavioural contract', 'non-specific reward', 'patient-led goal setting' (behaviour), 'self-monitoring of behaviour', and 'social support' (unspecified) demonstrated the highest effectiveness ratios across time points to promote PA adherence.

Conclusions

BCTs demonstrate higher short and long-term than medium-term effectiveness ratios. Further research involving low RoB RCTs incorporating transparently reported interventions with pre-specified BCTs aimed at optimising lower limb OA patient PA adherence is required.

Introduction

Osteoarthritis (OA) is a progressive degenerative disease associated with a loss of local articular cartilage, a local inflammatory response, and contiguous bone remodelling [1]. In the United Kingdom, OA is the primary cause of individual level disability and it contributes substantially to global health care costs [1]. The hip and knee are the primary synovial joints effected by OA, with a point prevalence of 11% and 24% respectively [2]. Patients with lower limb (hip and knee) OA may experience severe pain and disability, and a loss of function and psychological well-being [3,4]. As no known cure for OA exists [1], and the population ages, the global point prevalence of lower limb OA is likely to increase further [2].

Interventions that incorporate exercise are recommended first forms of non-pharmacological treatment to aid patients with lower limb OA to manage their symptoms [1]. Physiotherapists are the primary health professionals responsible for providing exercise interventions to patients with lower limb OA in several countries [5]. Although exercise interventions improve short-term clinical outcomes, such as reduced pain and increased function, in patients with lower limb OA, these positive effects are generally not maintained at medium (6 months) to long-term (≥ 12 months) follow up assessments [3,4]. This could be due to several factors including limited long-term effectiveness of the prescribed intervention, progression of OA disease severity, or a gradual reduction in patient adherence to health professional recommendations and an inability to maintain changes in their exercise behaviours [6].

To experience exercise related health benefits, patients need to maintain their activity level for a sustained period of time [7]. However, patients with OA are less active than non-symptomatic populations [8], and perceive that exercise is unsafe and that they require greater support to maintain their physical health, which likely impacts on their exercise adherence [9].

Prolonged physical inactivity has been associated with several reductions in the general health in patients with lower limb OA including the development of comorbidities such as obesity, diabetes, and heart disease [10], declining function and elevated pain levels, and an acceleration of the underlying OA disease process [11]. Exercise is a planned and structured physical activity (PA) aimed at improving or maintaining physical fitness [12]. PA encompasses structured exercise as well as broader concepts such as leisure activity which could be important at improving lifestyle factors beyond clinical outcomes, such as patient well-being [12]. Furthermore, maintaining prescribed exercise levels requires greater patient effort and behaviour change than optimising more general PA behaviours [13]. Therefore, it is important for physiotherapist interventions to incorporate behavioural techniques which target adherence to PA broadly, in addition to specific exercises. However, knowledge of the most effective techniques to optimise patient adherence to PA behaviours is currently lacking [14].

Behaviour change techniques (BCTs) are the smallest active components of interventions which are designed to optimise patient health behaviours [15]. However, identifying BCTs within research has proved problematic due to inconsistent reporting of behaviour change interventions [15]. The Behaviour Change Taxonomy V1 [15] was developed by researchers with expertise in behaviour change to enable for consistent reporting and increased clarity when identifying BCTs within RCT interventions. The taxonomy contains 93 distinct BCTs grouped into 16 hierarchies [15] and has been used extensively in the behaviour change literature.

Systematic reviews have examined the effectiveness of BCTs on PA in people with diabetes [16], cardiac conditions [17], older adults [18,19], rheumatoid arthritis [20], obesity [21,22], and broader patient populations [23–26]. In these reviews goal setting, problem solving, action planning, feedback on behaviour, self-monitoring of behaviour, instruction in how to perform the behaviour, demonstration of the behaviour, and behavioural practice/rehearsal have been commonly identified BCTs that increase patient PA.

To date, two systematic reviews [27,28] have reported on BCT use in physiotherapy interventions on musculoskeletal pain populations. However, these reviews did not measure individual BCT effectiveness and therefore could not make evidence-based recommendations of their use in clinical practice. Furthermore, these reviews focused on broader patient groups and their results may not be specific to lower limb OA patients, and they did not search the grey literature, meaning that up to 10% of relevant literature could have been missed [29]. Keogh et al., (2015) [27] identified 33 BCTs within physiotherapy led group-classes. Patients with lower limb OA are most commonly treated individually (1 to 1) in clinical practice [30] as tailoring the intervention to a patients specific presentation is fundamental to optimising PA adherence [31] and attendance levels are generally higher at individual consultations than group classes [32]. Kunstler et al., (2017) identified 30 BCTs across physiotherapy RCT interventions that aimed to optimise PA. However only one researcher was involved in BCT coding and the authors did not outline any training that was undertaken to enable accurate identification of intervention BCTs. Training is recommended prior to using the V1 taxonomy [15], and reduced inter-rater reliability has been measured in systematic reviews where coders have not undergone the prescribed training (Kappa = 0.55) [33], compared with those that have (Kappa range 0.68–0.92) [18,20,22–24,34]. Therefore, the accuracy of BCT identification within this review cannot be verified.

Therefore, the primary objective of this systematic review was to identify the BCTs used in individual (1 to 1) physiotherapy interventions to promote PA adherence beyond the clinic (home and community) in lower limb OA patients. The secondary objective was to evaluate the effectiveness of individual BCTs at optimising PA adherence to make evidence-based recommendations to aid effective management of patients with lower limb OA.

Methods

A systematic review was conducted according to a registered (CRD42016039932) and published protocol [35] using methodological guidelines from the Cochrane Collaboration's Musculoskeletal group [36] and Centre of Reviews and Dissemination (CRD) [37]; and is reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (PRISMA) [38].

Eligibility criteria

The eligibility criteria are detailed in Table 1.

Information sources and searches

Two independent researchers (MW, ChG) conducted a highly sensitive search strategy, developed in collaboration with a subject specific librarian, on the following sources from inception up to January 2nd 2018:

- Databases: Medline (OVID), EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), the Cochrane Register of Controlled Trials (CENTRAL), PsycInfo (OVID) and the Physiotherapy Evidence Data base (PEDro).
- Grey Literature: 'ZETOC' and 'Conference Proceedings Citation Index'.
- Trial registries: The 'clinicaltrial.gov' and World Health Organisation's (WHO) trial portal

The search strategy was developed by incorporating terms from previous systematic reviews on participants with lower limb OA, who were treated with behavioural, and physiotherapy interventions. Additional keywords were added from RCTs identified in the scoping search undertaken prior to the review [39,40], and filters recommended by the Cochrane Collaboration. The strategy was adapted for each database, and the Medline (OVID) search strategy is included below.

Example search strategy: Medline (Ovid) Search Strategy: 2nd January 2018.

Table 1. Eligibility criteria.

Population	Adult participants (≥ 18 years) with lower limb OA (hip and/or knee), diagnosis through self-report of symptoms or imaging [2]. RCTs including participants with other joint related pathologies (e.g. rheumatoid arthritis, hemochromatosis) that contributed to $\geq 25\%$ of the population, or participants who were awaiting, or had undergone joint surgery for treatment of OA symptoms were excluded.
Interventions	Land based outpatient intervention where a physiotherapist delivered the intervention individually (1 to 1) to the patient. Although others (e.g. healthcare professionals/ spouses) could be involved in the intervention's delivery, the physiotherapist had to be the primary healthcare provider and their role needed to be clearly established. The intervention had to include at least one BCT specifically enhancing PA adherence away from the clinic e.g. activity diary/pedometer or follow up care (phone calls) that made it unique from its comparator group (as defined by the V1 taxonomy) to enable measurement of its effectiveness.
Comparisons	Other 'active' or 'placebo' interventions, 'no treatment' or 'usual care'
Outcomes	Primary Outcomes: Physical Activity or Adherence measures Secondary Outcomes: Pain, Function, Quality of Life, Self-Efficacy, Any adverse events
Trial design	Randomised controlled trials (RCTs)
Language	Written in, or translated into English

<https://doi.org/10.1371/journal.pone.0219482.t001>

1. exp osteoarthritis/
2. osteoarthr\$.tw.
3. (degenerative adj2 arthritis).tw.
4. arthrosis.tw.
5. Or/ 1–4
6. knee/
7. exp knee Joint/
8. knee\$.tw.
9. hip/
10. exp hip joint/
11. hip\$.tw.
12. Or/ 6–11
13. exp Self Care/
14. ((self or symptom\$) adj (care or help or manag\$ or directed or monitor\$ or efficacy or admin\$)).tw.
15. Patient Education as Topic/
16. ((health or patient\$) adj2 (educat\$ or information)).tw.
17. exp Consumer Participation/
18. ((patient\$ or consumer\$) adj part\$).tw.
19. "Power (Psychology)"/
20. empower\$.tw.
21. Holistic Health/
22. (holistic or wholistic).tw.
23. "activities of daily living"/
24. (activit\$ adj2 daily adj living).tw
25. social support/
26. (social adj (support or network\$)).tw.
27. (support adj system\$).tw.
28. exp Adaptation, Psychological/
29. (psychologic\$ adj (adjust\$ or adapt\$)).tw.
30. (cope or copes or coping).tw.
31. exp Behavior Therapy/ or exp cognitive therapy/ or self manage\$.ti.
32. (adapt\$ adj behav\$).tw.
33. (behav\$ adj (therap\$ or intervention\$)).tw.

34. health education/ or self efficacy/ or Exercise/ or health behavior/
35. compliance/ or patient compliance/
36. conditioning. operant/
37. exp "Reinforcement (Psychology)"/
38. operant conditioning.mp.
39. respondent treatment.mp.
40. relaxation.mp. or exp Relaxation/
41. graded activity.mp.
42. health promotion/
43. (psycholog\$ technique or behavior?r technique).mp.
44. behavior?r Change.mp.
45. self efficacy.mp.
46. Motivation/ or motivation\$.mp.
47. primary prevention/
48. Psychology.mp. or Psychology/
49. Adherence.mp.
50. Or/ 13–49
51. exp Physical Therapy Modalities/
52. physiotherap\$.tw.
53. (physiotherap\$ or physical therap\$ or pt).mp.
54. physiotherap\$.mp.
55. kinesiotherap\$.tw.
56. exp Rehabilitation/
57. rehab\$.tw
58. Physical Activity.mp.
59. Or/ 51–58
60. randomi?ed controlled trial.pt.
61. controlled clinical trial.pt.
62. randomi?ed.ab.
63. placebo.ab.
64. drug therapy.fs.
65. randomly.ab.
66. trial.ab.

67. groups.ab.
68. Or/ 60–67
69. exp animals/ not humans.sh.
70. 68 not 69
71. 5 and 12 and 50 and 59 and 70

Study selection

Two independent researchers (MW, ChG) reviewed the titles and abstracts generated by the initial searches and then obtained full text copies of those RCTs which appeared appropriate for inclusion, or where doubt remained. The same two researchers then conducted a citation search using the 'Web of Science' database (included RCTs) and reviewed the reference lists (included RCTs and relevant reviews) to identify further RCTs. At each stage, if the two researchers could not agree on the eligibility of an RCT, a third researcher was asked to mediate the final decision (AR).

Data collection process and items

A data extraction sheet was piloted, adjusted, and subsequently used by two independent researchers (MW, SF) to record information on RCT participants, interventions, and characteristics of those delivering the BCTs including any training they undertook. Data obtained for PA, adherence, pain, function, quality of life, self-efficacy, and adverse effects outcome measures were also extracted. An analysis of contemporary related systematic reviews showed large variation in definitions of short, medium, and long-term follow up periods. Therefore, outcome timings of included RCTs were reviewed by two independent researchers (MW, SF) and short, medium, and long-term time points were determined after data extraction, to more accurately reflect the body of literature. Any disagreement in reporting was handled through researcher discussion. If agreement could not be reached, a third researcher with expertise in systematic review methodology (AR) or behaviour change (JD) was asked to mediate. Authors were emailed if data were missing or unclear, and intervention manuals were sought if they were not included in either RCT publications or as supplementary materials to aid further coding of BCTs.

Risk of bias (RoB) and fidelity assessment in individual RCTs

Two independent researchers (MW, SF) piloted RCT RoB and intervention fidelity assessments to clarify understanding and increase consistency. They subsequently assessed RoB and intervention fidelity of all included RCTs. RCT RoB was assessed using the Cochrane risk of bias tool across six domains, with each domain judged as either 'Low', 'High', or 'Unclear' [41]. The tool was developed from evidence from empirical studies [41] and has been used extensively in contemporary systematic reviews. RCT intervention fidelity was assessed using the National Institutes of Health Behavioural Change Consortium's (NIHCCC) checklist which has demonstrated validity and reliability and was developed specifically for assessing behavioural change interventions [42]. The checklist contains 40 components across 5 domains [43]. Each domain was graded as either 'present' or 'absent' depending on the number of individual components which were clearly reported, which were in turn judged as 'present', 'absent' or 'unclear'. Any disagreements over RCT RoB or fidelity were resolved by researcher consensus. If consensus could not be reached, a third researcher with expertise in

internal validity (AR) or fidelity (JD) respectively, was asked to mediate the decision. Full justification of RoB and fidelity assessment tools and their use can be found in the protocol for this systematic review [35].

BCT coding

RCT interventions were coded for BCTs using Michie and colleagues' V1 behaviour change taxonomy [15] by two independent researchers (MW, SF) following training in the taxonomy's use [44]. Both the behavioural physiotherapy (i.e. the physiotherapy intervention that contained a BCT specifically targeting PA adherence) and any active comparator group, including other forms of physiotherapy, were coded for BCTs. The taxonomy was piloted on several RCTs a priori and the researchers met regularly to maintain understanding and minimise any post-learning effect during coding [45]. Any disagreement between reviewers was resolved through discussion. If agreement could not be reached, a third reviewer (JD) was asked to mediate. BCT coding agreement between researchers was calculated using Cohen's Kappa Statistic [46].

Pilot BCT coding highlighted several problems with the V1 taxonomy's use which led to the following alterations.

1. The BCTs 1.1 goal setting (behaviour) and 1.3 goal setting (outcome) were subdivided into 1.1a (patient-led) and 1.1b (therapist-led). Goal setting has a very broad definition in the taxonomy ('set or agree on a goal defined in terms of the behaviour/outcome to be achieved') [15]. Evidence suggests that goals that are decided by the patient (patient-led) lead to greater engagement and achievement than goals which are set by the therapist (therapist-led) [47].
2. The BCTs 2.1 monitoring of others without feedback, 2.3 self-monitoring of behaviour, 2.5 monitoring of outcomes of behaviour without feedback, and 3.1 social support (unspecified) were subdivided into 'a' (reported as a technique within the intervention), and 'b' (reported as an outcome measure). The taxonomy does not code BCTs which are data collection only processes [48]. However, due to the behaviour of interest, several RCTs included a monitoring device (e.g. exercise diary/follow up telephone call), which were not necessarily an explicit intervention component but would likely increase PA adherence.

Measurement of analysis and summary measures

BCT use within and across RCTs and their associated taxonomy hierarchies were tabulated (Objective 1). The initial scoping search, which was conducted prior to the systematic review, suggested there would be considerable heterogeneity of intervention BCTs and PA adherence measures and therefore, meta-analysis and meta-bias assessment would not be appropriate. Therefore, effect sizes were used to determine intervention effectiveness and enable comparison between RCTs to inform the narrative synthesis. Effect sizes of PA and/or adherence outcomes were calculated using the standardised mean difference (SMD) and probability ratio (PR) for continuous and dichotomous data respectively [49]. The term 'probability' was used in favour of 'risk' as in this review optimisation of PA adherence was desirable [49]. For dichotomous data, an event was considered to have occurred when a participant achieved their PA or adherence goals to the levels stated in the associated RCT. It was calculated by dividing the number of times the PA or adherence level was achieved by the number of participants in a group [49]. Effect sizes where confidence intervals did not pass 0 for continuous outcomes (negative values favouring behavioural physiotherapy intervention) or 1 for dichotomous (> 1 favouring the behavioural physiotherapy intervention) were considered statistically significant. To enable inclusion of data from RCTs that contained more than one intervention

or comparator group, data were combined into a single pairwise comparison using methods suggested by the Cochrane collaboration when groups were considered sufficiently homogeneous [50]. 95% confidence intervals were calculated, and significance was set at $p < 0.05$. Due to outcome heterogeneity, RCT outcomes were grouped into self-report measures of adherence and PA and direct measures of PA domains respectively. Although all PA and adherence data were extracted where available, if more than one outcome was reported within a domain, the effect size was calculated using summary measures of PA [26]. Due to the focus of the systematic review, PA or adherence to physiotherapist recommendations was used to calculate effect sizes if total PA or adherence data were not available.

BCT effectiveness

As meta-analysis was not anticipated, meta-regression could not be incorporated into the analysis to determine the effectiveness of BCTs. Therefore, the 'effectiveness ratio' was used to determine the effect of each BCT on optimising PA adherence [51]. The effectiveness ratio offers a simple, user friendly technique for interpreting the effectiveness of individual BCTs by comparing effective interventions with ineffective interventions [51], and has been used in several contemporary systematic reviews published in peer review journals. It was calculated by dividing the number of times the BCT was identified in behavioural physiotherapy interventions that demonstrated a favourable significant effect (as measured by SMD and PR effect sizes) by the number of times it was coded across all interventions [51] (Objective 2). BCT effectiveness ratios were calculated at short, medium, and long-term time points to evaluate whether they changed over time. To ensure that BCT effectiveness ratios reflected the active ingredients within interventions that optimized PA adherence, only those techniques unique to the behavioural physiotherapy intervention (when compared to active comparator and control interventions) were used when calculating BCT effectiveness ratios [52].

Results

RCT Selection

Initial searches retrieved 5656 references with 4554 titles and abstracts once duplicates were removed. 394 full text articles were reviewed and 24 RCTs from 43 articles were included. At the full text stage, articles were excluded because RCT interventions were group based ($n = 133$), not conducted by a physiotherapist ($n = 154$) or did not contain an appropriate or unique BCT ($n = 76$). Additional reasons for RCT exclusion were; alternative populations ($n = 102$), non-RCT study design ($n = 48$), not written or translated into English ($n = 26$), or having no response from authors where eligibility required clarification ($n = 22$). The RCT selection process is outlined in Fig 1.

RCT characteristics

The characteristics of included RCTs are summarised in S1 Table. The 24 RCTs incorporated a total of $n = 2366$ participant from 10 countries. 18 RCTs recruited participants with knee OA [53–70], 3 RCTs recruited participants hip OA [71–73], and 3 RCTs [40,74,75] recruited participants with both knee and hip OA. In 21 RCTs all BCTs were delivered solely by physiotherapists. In 3 RCTs, the BCTs were delivered by both a physiotherapist (PA component) and either a nurse [67], health advisor [57], or researcher [68] delivering the telephone counselling. Training of BCT providers was not well reported, with 11 RCTs [59,60,62–70] not mentioning any training of the intervention provider and four RCTs [53,54,72,74] not reporting detail of the training duration. Training ranged from 3 hours [76] for instruction in an exercise

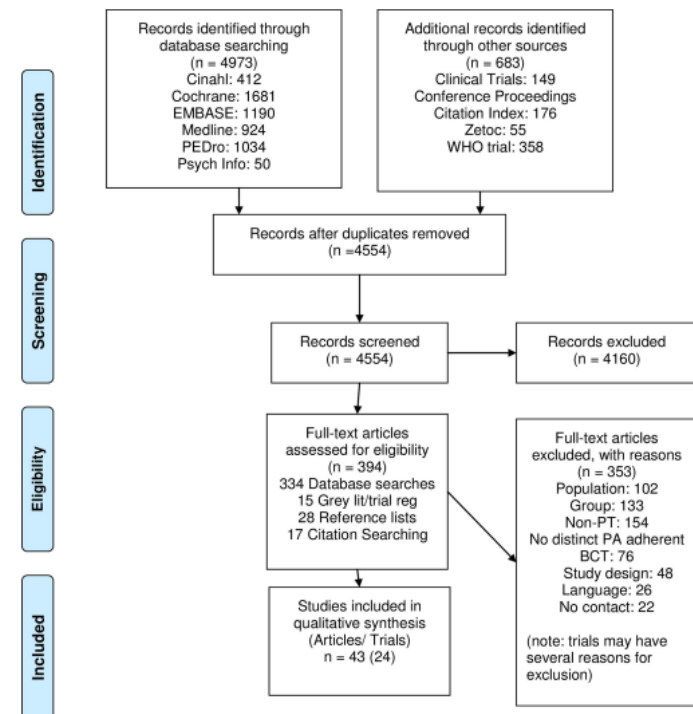


Fig 1. RCT selection flow diagram.

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intervention, to 4 days for pain coping skills training [56] and telephone behavioural counselling [57] respectively.

PA adherence outcomes

Detail on PA and adherence outcomes used and the effect sizes at different time points within each domain is detailed in S2 Table. Analysis of outcome measure timings enabled short-term

to be defined as up to 3 months (post-randomisation), medium-term approximately 6 months, and long-term 12 months or longer. The data closest to the temporal boundary of each time point was used to measure the effect sizes. 9 RCTs [54,60–62,64–66,69,70] did not measure outcomes beyond short term, with 7 RCTs evaluating outcomes up to medium-term [53,55,58,63,71,73,74] and 8 to long-term [40,56,57,67,68,72,73] respectively. Eight RCTs authors were contacted to provide additional data or clarify points, of which 5 [54,71–74] responded with additional data, 1 [64] clarified that PA was measured only at baseline, and 2 [40,68] could not be contacted to clarify information. Thirteen RCTs [40,54–57,61,67,69–74] measured PA adherence and contributed to BCT effectiveness ratio calculations. Therefore, despite using a BCT that promoted PA adherence as part of the behavioural physiotherapy intervention, 11 RCTs did not measure PA adherence between groups post baseline and therefore the effectiveness ratios could not be calculated. The BCTs identified in these RCT interventions were therefore used to demonstrate the breadth of BCT use and assist the narrative synthesis. PA adherence outcomes showed considerable heterogeneity between RCTs with 13 PA and 6 adherence measures identified. The quantity of PA adherence measures used in RCTs demonstrated further variability, with a range of 1 [54,61,70] to 6 [57,69]. Self-report PA measures included questionnaires, PA times and volumes, and direct PA measures included pedometers and accelerometers. Adherence measures included diaries/logbooks, self-rated PA adherence, and the number of PA sessions completed in the home/community.

Risk of bias within and across RCTs

Six RCTs were assessed as low RoB [54,56,57,61,62,73] with five conducted by the same group of authors, suggesting some publication bias (Table 2). Seven and 12 RCTs were assessed as moderate [53,58,65,69,71,74,75] and high [40,55,59,60,63,64,66–68,70,72] RoB respectively. As meta-analysis was not indicated (see below), funnel plot use for meta-bias assessment was not appropriate [77]. Overall, there was high risk of performance bias with participant blinding assessed as either unclear or high RoB in 20 RCTs. Further internal validity issues included high risk of reporting and attrition bias with 10 (42%) and 8 (33%) RCTs at unclear or high RoB respectively.

Fidelity

Overall the quality of reporting of fidelity components within domains was low (S3 Table). The mean component score per RCT was 38.9% (range 19% [66] to 68% [73]). No RCT was assessed as achieving 'high fidelity', which has been defined as having reported at least 80% of individual fidelity components clearly [43]. Furthermore, only 5 RCTs reported >50% of individual fidelity components clearly [56,57,61,73,75]. In particular, the theoretical aspects of intervention design and delivery, and practitioner training were poorly reported. However, 3 of the 5 domains were generally well met with all RCTs assessed to have reported enactment of skills, 23 RCTs receipt of treatment, and 20 RCTs treatment design satisfactorily. Overall the provider training and delivery of treatment domains were poorly reported with only 5 and 3 RCTs reporting them satisfactorily respectively.

BCTs identified in interventions. 31 interventions (mean (SD): 11.1 (3.3)) were coded across the 24 RCTs (Table 3) with a total of 344 BCTs identified. Twenty-four interventions were classified as behavioural physiotherapy which interventions incorporated 269 BCTs (11.2 (2.9)), with a further 7 identified as active comparator groups which included 75 BCTs (10.71 (4.4)) respectively. The highest number of BCTs used in a single intervention was 20 [56] and the lowest 5 [40,70]. 31 distinct BCTs (including 'a' and 'b' subgroups) representing 32% of possible taxonomy definitions (n = 98) were identified and 12 out of 16 hierarchies were used. The most frequently identified BCTs were 8.6 generalisation of target behaviour (100% of

Table 2. Summary of risk of bias assessment.

Trial	Risk of Bias components						
	1	2	3	4	5	6	7
Bennell 2005	L	L	L	L	L	U	L
Bennell 2010	L	L	H	L	L	L	L
Bennell 2014	L	L	H	H	L	L	L
Bennell 2014b	L	L	L	L	L	L	L
Bennell 2016	L	L	H	L	L	L	L
Bennell 2017	L	L	H	L	L	L	L
Crosley 2015	L	L	L	L	L	U	L
Deyle 2000	L	U	U	L	U	U	H
Dincer 2016	L	U	H	L	L	U	H
EMPART 2013	L	L	H	L	U	L	L
Hiyama 2012	L	L	H	L	L	U	H
Hunt 2010	L	L	L	L	L	L	L
Jones 2012	L	L	H	L	L	L	L
Kawasaki 2009	L	H	H	H	U	U	U
Kuru-Colak 2017	L	L	H	H	H	H	H
Lim 2008	L	L	H	L	L	U	L
MOA 2013	L	L	H	L	L	L	U
Odole 2013	L	H	H	H	U	U	H
Schlenk 2011	L	H	H	H	L	U	L
Segal 2015	L	L	H	H	U	L	H
Teirlinck 2016	L	L	H	H	U	L	L
Van Baar 1998	L	L	H	L	L	L	U
Veenhof 2006	L	H	H	L	L	L	U
Wallis 2017	L	L	H	L	U	L	U

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interventions), 9.1 credible source (100%), 12.6 body changes (100%), 1.4 action planning (94%), 4.1 instruction on how to perform a behaviour (94%), and 8.1 behavioural practice/rehearsal (87%). The two independent researchers coded BCTs with 'excellent' inter-rater reliability ($\kappa = 0.83$).

BCT effectiveness

BCT effectiveness ratios calculated for short, medium and long-term PA adherence outcomes across domains are presented in Table 4. Overall, the BCTs with effectiveness ratios of 100% across all measured time frames were 1.8 behavioural contract, 2.7 Feedback on outcomes of behaviour, and 10.3 non-specific reward. Eight BCTs had a short-term effectiveness ratio of $\geq 50\%$ in at least 2 outcome domains. Of these, 3 BCTs were from the goals and planning and 2 from the feedback and monitoring hierarchies respectively. Similarly, 8 BCTs had long-term effectiveness ratios of $\geq 50\%$ with 4 BCTs coming from the goals and planning hierarchy. Medium-term effectiveness ratios were generally lower than short, or long-term measures. Adherence outcomes had higher proportions of effectiveness ratios of $\geq 50\%$ than PA self-report or direct measures respectively. There was minimal long-term PA direct measure data available for analysis.

Discussion

This is the first systematic review to measure the effectiveness of BCTs used within physiotherapy interventions to promote PA adherence in lower limb OA patients. The body of literature

Table 3. BCTs used in physiotherapy interventions of included RCTs.

BCT LABEL	BEHAVIOURAL PHYSIOTHERAPY INTERVENTIONS																								N (%)
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	
1.1A Goal Setting behaviour (behaviour)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	5 (16)
1.1B Goal setting (behaviour)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	22 (71)
1.2 Problem Solving	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	7 (23)
1.3B Goal setting (outcome)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	3 (10)
1.4 Action planning	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	29 (94)
1.5 Review behaviour goal (s)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	2 (6)
1.6 Behavioural contract	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	1 (3)
2.1 Monitoring of behaviour by others without feedback	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	8 (26)
2.1 B Monitoring of behaviour by others without feedback	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	5 (16)
2.2 Feedback on behaviour	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	12 (39)
2.1A Self Monitoring of behaviour	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	18 (58)
2.1B Self Monitoring of behaviour	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	7 (23)
2.6 Biofeedback	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	1 (3)
2.7 Feedback on outcomes of behaviour	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	2 (6)
3.1A Social Support (Unspecified)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	13 (42)
3.1B Social Support (Unspecified)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	3 (10)
4.1 Instruction in how to perform the behaviour	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	29 (94)
4.2 Instruction in how to perform the behaviour	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	2 (6)
5.1 Information on Antecedents	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	2 (6)
5.2 Information about health consequences	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	4 (13)
5.3 Information about social and environmental consequences	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	3 (10)
6.1 Demonstration of the behaviour	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	12 (39)
8.1 Behavioural Practice/ rehearsal	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	27 (87)
8.6 Generalisation of the target behaviour	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	31 (100)
8.7 Graded tasks	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	16 (52)
9.1 Credible Source	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	31 (100)
10.3 Non-specific Reward	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	1 (3)
11.2 Reduce Negative Emotions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	3 (10)
12.4 Distraction	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	3 (10)
12.5 Adding objects to the environment	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	11 (35)
12.6 Body Changes	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	31 (100)
15.4 Self-talk	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	2 (6)

(Continued)

Table 3. (Continued)

BCT LABEL	BEHAVIOURAL PHYSIOTHERAPY INTERVENTIONS																								N (%)						
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24							
TOT	9	11	11	14	20	16	11	10	9	10	7	13	7	9	11	10	11	15	11	10	10	15	10	9	17	14	15	5	10	5	344
																									ACTIVE COMPARATORS						

Key: TOT: Total number of BCTs found in RCT interventions; N: Number of times BCT identified across interventions; %: Percentage of times BCT appears across interventions; Intervention number 1–24 represent behavioural physiotherapy interventions; numbers 25–31 represent active comparator groups.

Behavioural Physiotherapy Interventions

1) Bennell 2005(2) Bennell 2010 (3) Bennell 2014 (PT + Booster) 4) Bennell 2016 (PT + PCST) 5) Bennell 2016 (PT + TP coaching) 7) Crossley 2015 (8) Doyle 2009(9) Dwyer 2016

10) EMPART 2013 (Both Ex + MT interventions 11) Hiyama 2012(PT + PA goal) 12) Hunt 2013 (PT + PCST) 13) Jones 2012 14) Kawasaki 2009 15) Kerr-Cobb 2017 16) Lin 2008 17) MDA 2013

18) Oude 2013 19) Schenk 2011 20) Segal 2012 21) Teichgraber 2016 22) Van der 199(23) Yessierli 2006 (PT + RGA 24) Wallis 2016

Active Comparison

25) Bennell 2014 (PT Control) 26) Bennell 2016 (PCST) 27) Bennell 2016 (PT control) 28) Bennell 2017 (PT control) 29) Hiyama (PT control) 30) Hunt 2013 (PT control) 31) Yessierli 2006 (PT control)

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Table 4. BCT effectiveness ratios.

	OUTCOME DOMAIN/ TIMEFRAME								
	PA- Self Report			PA- direct measure			Adherence		
BCT	Short	Medium	Long	Short	Medium	Long	Short	Medium	Long
1.1A	1/2 (50)	0/1 (0)	1/2 (50)				1/2 (50)		1/2 (50)
1.1B	2/5 (40)	1/4 (25)	0/2 (0)	2/3 (67)	0/1 (0)		1/1 (100)	1/1 (100)	1/1 (100)
1.2	1/2 (50)	0/1 (0)	1/2 (50)				1/4 (25)	0/1 (0)	1/2 (50)
1.3B	0/1 (0)	0/1 (0)							
1.4	3/6 (50)	1/4 (25)	1/3 (33)	1/1 (100)	0/1 (0)	0/1 (0)	2/2 (100)	1/1 (100)	2/2 (100)
1.5		2/2 (100)	1/2 (50)		0/1 (0)			1/1 (100)	1/1 (100)
1.8	1/1 (100)		1/1 (100)				1/1 (100)		1/1 (100)
2.1A	0/2 (0)	0/2 (0)	0/1 (0)	1/2 (50)	0/1 (0)		1/1 (100)	1/1 (100)	1/1 (100)
2.1B	0/1 (0)	0/1 (0)							
2.2	1/2 (50)	1/2 (50)	0/2 (0)				1/1 (100)	1/1 (100)	1/1 (100)
2.3A	2/2 (100)	1/1 (100)	1/2 (50)	1/1 (100)			1/1 (100)		1/1 (100)
2.3B	1/2 (50)	0/1 (0)		0/1 (0)	0/1 (0)				
2.7		1/1 (100)	1/1 (100)						
3.1A	2/2 (100)	1/1 (100)	1/2 (50)				1/1 (100)		1/1 (100)
3.1B	0/2 (0)	0/2 (0)		0/1 (0)	0/1 (0)				
4.1	1/4 (25)	1/4 (25)	0/2 (0)	1/2 (50)	0/1 (0)		1/1 (100)	1/1 (100)	1/1 (100)
4.2	0/1 (0)	0/1 (0)	0/1 (0)				0/1 (0)		0/1 (0)
5.1	0/1 (0)	0/1 (0)		1/2 (50)	0/1 (0)				
5.3		1/1 (100)	0/1 (0)						
6.1	1/3 (33)	1/3 (33)	1/3 (33)	0/1 (0)	0/1 (0)		2/2 (100)	2/2 (100)	2/2 (100)
8.1	3/6 (50)	1/4 (25)	1/3 (33)	1/2 (50)	0/1 (0)		2/3 (67)	1/2 (50)	2/2 (100)
8.6	2/5 (40)	1/4 (25)	0/2 (0)	1/2 (50)	0/1 (0)		1/1 (100)	1/1 (100)	1/1 (100)
8.7	3/4 (75)	1/2 (50)	1/2 (50)	0/1 (0)	0/1 (0)		1/1 (100)		1/1 (100)
9.1	2/5 (40)	1/4 (25)	0/2 (0)	1/2 (50)	0/1 (0)		1/1 (100)		1/1 (100)
10.3	1/1 (100)		1/1 (100)				1/1 (100)		1/1 (100)
11.2	0/2 (0)	0/1 (0)	0/1 (0)				0/1 (0)		0/1 (0)
12.4	0/2 (0)	0/1 (0)	0/1 (0)				0/1 (0)		0/1 (0)
12.5	1/2 (50)	0/1 (0)		0/1 (0)	0/1 (0)				
12.6	2/5 (40)	1/4 (25)	0/2 (0)	1/2 (50)	0/1 (0)		1/1 (100)	1/1 (100)	1/1 (100)
15.4	0/1 (0)	0/1 (0)	0/1 (0)				0/1 (0)		0/1 (0)
TOTALS	12/15	7/21	9/15	10/5	0/15	0/1	16/5	10/1	18/4

Key: BCT part of statistically effective intervention/BCT part of all interventions (effectiveness ratio %); Blank areas indicate where no PA adherence data was available for this domain/ timeframe

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is defined by RCTs of medium to high RoB with poor intervention reporting. Further heterogeneity of BCTs and PA adherence outcome measures meant meta-analysis was not appropriate and limited the evidence-based recommendations that could be made.

The BCT taxonomy was found to have excellent inter-rater agreement (Kappa = 0.83) [46], which showed similar reliability to other systematic reviews where the coders undertook training [16–20,22–25,27,34,51] (range 0.68–0.92) and the 31 BCTs identified across interventions (mean (SD): 11.2(2.9)) were consistent with the most closely related systematic reviews [27,28,52]. Most BCTs had effectiveness ratios of <50% across time-frames and outcome domains, meaning that they were components of interventions that were statistically no more effective than comparator groups at optimizing PA adherence. This overall lack of effect could

be due to several reasons. Firstly, to be included, RCT interventions had to incorporate a BCT which would promote PA adherence when away from the clinic and possess at least one BCT which was distinct from its comparator group (when coded on the V1 taxonomy) to enable for its effectiveness ratio to be calculated. Despite this, of the 24 RCTs, only 13 reported PA adherence data between groups post baseline to enable effectiveness ratios to be calculated. This was reflected in the RCTs primary treatment aims objectives and outcome measures which generally focused on pain and function. The assessment of pain and function might not reflect changes in patient PA adherence as physical activity interventions generally aim to teach patients coping and self-management skills rather than trying to ameliorate their clinical symptoms [78].

Secondly, in order to determine individual BCT effectiveness on PA adherence, it was essential to code both the behavioural physiotherapy intervention and any active comparator groups. As several RCTs used physiotherapy comparison groups, the number of unique BCTs in the behavioural physiotherapy interventions that were used to calculate effectiveness ratios was reduced. Previous research has shown that greater numbers of unique BCTs are associated with increased effect sizes and therefore this may have contributed to the modest results [52].

Overall, five BCTs demonstrated effectiveness ratios of ≥50% in more than one outcome domain in both the short and long-time periods. These were 1.1A Patient led goal setting, 1.8 behavioural contract, 2.3A self-monitoring of behaviour, 3.1 A social support unspecified, and 10.3 non-specific reward. The most effective BCTs across time points were behavioural contract and non-specific reward (e.g. a reward was given to the patient if PA goals were met), both of which have been highlighted as effective in previous systematic reviews on PA [20,34]. However, these BCTs were only present in a single intervention in 1 high RoB RCT [40], therefore these results should be interpreted cautiously. The 3 further BCTs identified were the 'a' variations used specifically in this systematic review. Therefore, items which promote self-monitoring (e.g. activity diaries) and the provision of social support, which are explicitly intervention components may be more effective at promoting changes in PA adherence than if they are used for monitoring purposes only. This review showed that of the 26 interventions that incorporated the BCT goal setting (behaviour), only five reported it in a patient-led manner. Patients are more likely to adhere to health behaviours if their goals are related to activities they enjoy and fit with their values [79], therefore promoting intrinsically motivated autonomy and subsequently PA adherence [7].

Further BCTs that demonstrated high short-term effectiveness ratios were 1.4 action planning, 2.2 feedback on behaviour, 8.1 behavioural practice/rehearsal which have been shown effective on PA in other systematic reviews [16]. Overall, the BCTs that had the highest short-term effectiveness ratios were characterised as patient reminders to do their prescribed PA, either from the therapist directly (e.g. phone calls for monitoring purposes) or as physical items that were taken home (e.g. logbooks/diaries or handouts including detailed information about exercises). In the behaviour change literature, the initial period where patients learn new habits and health behaviours is termed the 'adoption' phase [7]. During adoption, new behaviours are enhanced by extrinsic factors, so the addition of BCTs that help form new habits likely optimised short-term PA adherence.

The period of longer-term behaviour change is commonly referred to as the 'maintenance' phase [79]. There are varying opinions in the literature about when a patient achieves maintenance, with authors using time scales or when the behaviour becomes the patients 'dominant' response [79] as key indicators. Interestingly the 6-month medium-term time period when BCT effectiveness ratios were reduced corresponds to the Transtheoretical model of changes' [80] definition of maintenance, which is the most widely used in the behaviour change literature [79], and may explain the drop off in effectiveness at this point. Maintenance is theorised

to require different skills and habits from adoption to prevent patients from relapsing to their previous behaviours [7]. However, most BCTs that had the highest effectiveness ratios at short-term follow up were the same techniques with the highest ratios at long-term time points. Further BCTs which demonstrated effectiveness ratios of $\geq 50\%$ in at least two domains at long-term follow up were 1.2 problem solving, 1.5 review behaviour goals, and 8.7 graded tasks. Taken together, These BCTs are thought to be important at promoting self-regulation and habits (problem-solving, behavioural contract, self-monitoring of behaviour, graded tasks) or sustaining motivation (patient led goal setting, reviewing behaviour goals, non-specific reward, social support (unspecified)) which have been identified as critical factors that help maintain behavioural changes [79]. Therefore, the increase in BCT effectiveness ratios from medium to long-term follow up may be due to patients with lower limb OA overcoming their relapses using the identified BCTs. Although these techniques show promise, these results should be interpreted cautiously as the effectiveness ratios of these BCTs were generally modest and there was insufficient data to draw firm conclusions. However, they were the only techniques for which the ratios demonstrated effectiveness at both short and long-term follow ups and warrant further investigation in physiotherapy practice, especially their use and effect around the 6-month post baseline time period.

RCT intervention fidelity demonstrated poor reporting. Although the domains receipt of treatment and enactment of skills were judged present in all RCTs, the only other systematic review that has used the NIHBCC checklist [78] judged these to be much lower. The high percentage reported in this review is likely due to its focus on targeting PA adherence in the community and home as several components within these domains focused on the performance of the target behaviour and skills outside from the clinic. The delivery of treatment and provider training domains were identified as poorly reported in both reviews. 12 RCTs reported that some form of training or monitoring took place but only 8 reported any timing with the majority lacking detail to enable replication (S1 Table). Therefore, limited conclusions can be drawn on BCT effectiveness and replicating them in clinical practice is problematic [42]. Similarly to Toomey et al., (2015) [78], fidelity assessment demonstrated a lack of use of theoretical models of behaviour change used to underpin their interventions. Although several RCTs mentioned behavioural models [40,56,57,61], only one (Schlenk et al., 2011) [67] explicitly used theory to inform their intervention. Theoretically derived interventions are thought to be more effective than non-theoretical interventions at increasing patient adherence [31] as they address specific determinants of health behaviour to enable treatment effects to be attributed to intervention techniques and therefore further refinement over time [27]. However, Schlenk et al., (2011) [67] was assessed as high RoB and therefore, the results from this RCT must be viewed with caution. Interestingly, the BCTs that showed the most consistently high effectiveness i.e. patient-led goal setting [81], self-monitoring [82], and social support [83] are key constructs of several theories of health behaviour change. Therefore, as physiotherapists have demonstrated a lack of knowledge of theoretical models of behavioural change and confidence in putting them into practice [14], this represents a gap in the professional knowledge base and literature.

Strengths and limitations

The strengths of this thoroughly conducted systematic review include its rigorous methodology conducted according to a published protocol. The key limitation was the limited number of RCTs that were characterised by poor intervention reporting and moderate to high RoB combined with heterogeneity of BCTs and PA adherence outcomes. This meant meta-analysis was not indicated, therefore limiting the evidence-based recommendations that could be

made. Furthermore, despite several BCT effectiveness ratios showing statistically significant increases in PA and adherence, it was not possible to determine whether the results were clinically significant. As PA [84] and adherence [85] outcomes are measured heterogeneously, no standardised process exists to convert the data into clinical meaningful parameters. This remains a gap in the literature and requires further investigation.

Conclusions

Overall, BCTs have limited effectiveness at promoting PA adherence as part of physiotherapy interventions with the medium term (6 months post baseline) the most difficult period to target. The BCTs patient-led goal setting, behavioural contract, self-monitoring of behaviour, social support (unspecified), and non-specific reward were the most effective at optimising PA adherence across time points. Future research should include low RoB and transparently reported RCTs incorporating physiotherapy interventions with pre-specified BCTs aimed at optimising PA adherence in patients with lower limb OA. The inclusion of interventions underpinned by behaviour change theory is a research priority.

Supporting information

S1 Checklist. PRISMA checklist.
(DOC)

S1 Table. Characteristics of Included RCTs.
(DOCX)

S2 Table. Physical activity and adherence outcomes in included RCTs.
(DOCX)

S3 Table. Fidelity domain assessment of included RCTs.
(DOCX)

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Appendix 1.3: Article, BMJ Open, Barriers and facilitators to recommended physical activity in lower-limb osteoarthritis: protocol for a qualitative study exploring patients and physiotherapist perspectives using the theoretical domains framework and behaviour change taxonomy

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Protocol

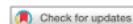
BMJ Open Barriers and facilitators to recommended physical activity in lower-limb osteoarthritis: protocol for a qualitative study exploring patients and physiotherapist perspectives using the theoretical domains framework and behaviour change taxonomy

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ABSTRACT

Introduction Osteoarthritis (OA) is the leading cause of disability and pain in older adults. Although increasing physical activity (PA) can help reduce symptoms, patients with lower-limb OA are less active than the general public. Although physiotherapists commonly deliver PA programmes, they lack knowledge of key barriers and facilitators to adherence to prescribed PA that patients with lower-limb OA experience while attending physiotherapy appointments (treatment period) and after discharge (post-treatment period). This study aims to explore the perspectives of patients with lower-limb OA of barriers and facilitators to adherence to physiotherapy prescribed PA in the treatment and post-treatment time periods to inform the development of intervention underpinned by behaviour change theory.

Methods and analysis A qualitative study, based on phenomenology, will purposively recruit patients with lower-limb OA who have had physiotherapy. In-depth semi-structured interviews will be undertaken following discharge from physiotherapy at a single time point. Participants' perspectives of physiotherapy interventions, including barriers and facilitators to prescribed PA and techniques that they felt optimised adherence to physiotherapist PA prescription will be explored (phase I). The acceptability and feasibility of delivering a physiotherapy intervention incorporating the techniques identified in the semi-structured interviews will then be explored through focus groups conducted with physiotherapists (phase II). Data will be coded following thematic analysis, with barriers and facilitators mapped to the constructs on the theoretical domains framework, and behaviour change techniques identified following definitions from Michie's V1 taxonomy. **Ethics and dissemination** Findings from this study will inform development of a physiotherapy intervention underpinned by behaviour change theory aiming to optimise adherence to PA prescription in patients with lower-limb OA during the treatment and post-treatment

Strengths and limitations of this study

- This qualitative study is the first to seek an in-depth understanding of the barriers and facilitators to adherence to physiotherapy prescribed physical activity in both treatment and post-treatment time periods in patients with lower-limb osteoarthritis (OA).
- Patient and public involvement has been utilised in the design of the study and will inform data analysis ensuring that the perspectives of patients with lower-limb OA is captured throughout the study.
- Seeking the opinion of physiotherapists who currently treat patients with lower-limb OA on the acceptability and feasibility of delivering a pilot intervention enhances the clinical applicability of the study.
- This study has a relatively small sample size and excluding patients with lower-limb OA who do not speak English or who not attended physiotherapy will further limit its generalisability and applicability.

time periods. This study has ethical approval (IRAS 247904) and results will be disseminated through publications in peer-reviewed journals and presentations at conferences and to study participants.

INTRODUCTION

In the UK, osteoarthritis (OA) is the leading cause of individual level disability and the most common cause of pain in older adults¹ with one-third of patients over 45 years old, equating to almost 9 million individuals, having sought treatment for OA related symptoms.² Lower-limb OA is particularly problematic in the UK, with 4.1 and 2.5 million

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6

individuals experiencing knee and hip OA related symptoms, respectively.³

Physical activity (PA), incorporating both structured exercise and broader concepts such as leisure activities, is advocated by international healthcare guidelines and is used extensively as part of non-surgical management of lower-limb OA-related symptoms.⁴ However, patients with lower-limb OA have reduced PA levels compared with the general population⁵ and interventions incorporating PA strategies generally only facilitate short-term management of pain and function.^{6,7} This short-term time frame generally corresponds to when the patient is attending sessions under the supervision of a healthcare professional (eg, a physiotherapist) and doing prescribed PA away from the clinic as part of the treatment regime (treatment-period). The primary reason for decreased long-term effectiveness of PA interventions is related to reduced adherence to PA prescription from patients with lower-limb OA^{8–10} when they are required to maintain their prescribed PA independent of input from the healthcare professional (post-treatment period).

The behaviour change literature outlines that learning and consolidating new behaviours, such as PA, requires individuals to go through several phases of behaviour change including initiation^{11–13} or adoption^{14,15} and maintenance.^{16–17} It is likely that most treatment periods occur during the 'adoption' phase,¹⁶ when the individual would be learning new habits and techniques to enhance their PA levels. The post-treatment period would coincide with the 'maintenance' phase,¹⁷ where the individual consolidates their PA behaviours. The skills required to maintain a behaviour are distinct from those that enables an individual to adopt it^{16,17} and a healthcare intervention aimed at optimising adherence to PA likely requires unique techniques that match the changing needs of its target patients. This may in part explain the drop off in effectiveness in clinical outcomes during the post-treatment phase.

The Medical Research Council advocates that interventions that alter participant behaviours (such as PA) should be underpinned by behaviour change theory¹⁸ as they are thought to be more effective than non-theoretical interventions and specific determinants of behaviour can be tested with subsequent refinement of the intervention.¹⁹ However, few intervention studies exist that are underpinned by behaviour change theory.¹⁹

Physiotherapists are the primary healthcare professionals responsible for providing PA prescription in the National Health Service (NHS),²⁰ and well placed to provide PA interventions to patients with lower-limb OA.²¹ Although physiotherapists believe that they have the necessary skills to promote PA,²² recent systematic review evidence suggested that physiotherapists do not possess the requisite knowledge of behavioural theories or techniques to apply them effectively in their clinical practice.²³

The theoretical domains framework (TDF) synthesises different theories of behaviour change into one

framework and enables the mapping of barriers and facilitators against theoretically derived domains that influence patient behaviour.²⁴ The original TDF²⁴ has been validated and updated to include 14 domains incorporating 84 theoretical constructs.²⁵ The domains include knowledge, skills, social/professional role and identity, beliefs about capabilities, optimism, beliefs about consequences, reinforcement, intentions, goals, memory, attention and decision processes, environmental context and resources, social influences, emotion and behavioural regulation.²⁵ The TDF has been used extensively in the behaviour change literature with over 800 citations in peer-reviewed journals.²⁶

Interventions underpinned by behaviour change theory can be developed by identifying behavioural techniques relevant to the TDF domains.²⁷ Behaviour change techniques (BCTs) are the theoretically derived, active components found within behaviour change interventions.²⁸ Michie *et al.*²⁸ (p82) define a BCT as 'an observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour' and include techniques such as 'reinforcement', 'self-monitoring' and 'feedback'. The taxonomy contains 93 distinct BCTs grouped into 16 hierarchies²⁹ and has been used extensively in the literature.²⁹ Our recent systematic review (Willett *et al.*, under review) of randomised controlled trials examining the effectiveness of BCTs used in physiotherapy interventions to optimise adherence to prescribed PA in patients with lower-limb OA identified the BCTs 'behavioural contract', 'non-specific reward', 'goal setting (behaviour)', 'self-monitoring of behaviour' and 'social support (unspecified)' as effective at optimising adherence to prescribed PA across all measured time points (from ≤3 to ≥12 months post-baseline). The results also suggested that certain BCTs may be more useful during the treatment period (eg, 'action planning') while others more effective during the post-treatment periods (eg, 'graded tasks' and 'problem solving'). However, the overall effectiveness of these BCTs was modest and based on results from RCTs graded as medium-high risk of bias and with poor intervention reporting. Therefore, further research is needed to verify and expand on these results.

To develop a physiotherapy intervention aimed at optimising adherence to prescribed PA that is underpinned by behaviour change theory and incorporates the most appropriate BCTs, key barriers and facilitators that patients face need to be identified. Barriers and facilitators to adherence to prescribed PA in patients with lower-limb OA have been outlined in the literature and include fear of pain with movement, reduced motivation for PA engagement and limited access to facilities to promote PA.^{30,31} However, only one study³² has identified determinants at a specified point in the behaviour change process and this study focused exclusively on PA maintenance. No research to date has sought to gain an in-depth understanding of patients with lower-limb OAs' perceptions of barriers and facilitators to physiotherapist prescribed PA

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during both the treatment and post-treatment timeframes or identified the most important BCTs to include as part of a physiotherapy programme aimed at optimising PA adherence. Furthermore, no research has examined the perspectives of physiotherapists on whether a pilot intervention that is underpinned by behavioural theory and includes BCTs which have been identified by patients with lower-limb OA as important at optimising PA in the treatment and post-treatment time periods would be acceptable and feasible to be delivered consistently in their clinical setting.

Aims

The studies aim is to explore the perspectives of patients with lower-limb OA of barriers and facilitators to adherence to physiotherapy prescribed PA in the treatment and post-treatment time periods to inform the development of intervention underpinned by behaviour change theory.

Objectives

Phase I

1. To explore patients' perceptions of barriers and facilitators to adherence to PA prescribed within physiotherapy sessions during the treatment and post-treatment time period.
2. To identify which BCTs patients with lower-limb OA perceive to be most important to include in a physiotherapy programme aimed to optimise adherence to prescribed PA in the treatment and post-treatment period.

Phase II

3. To determine physiotherapists' perspectives on the feasibility and acceptability of incorporating the identified BCTs into a real-world pilot physiotherapy intervention.

METHODS AND ANALYSIS

Research team and reflexivity

Phase I

The semi-structured interviews will be undertaken by the lead researcher (MW), an advanced practice physiotherapist with over 15 years of experience in managing patients with lower-limb OA. Although no specific relationship will be established prior to the commencement of the interviews, MW will outline that the interviews are part of a programme of research that intends to develop a physiotherapy intervention aiming to promote adherence to prescribed PA in patients with lower-limb OA. The participants will be informed of MW's professional background to ensure full disclosure but will be assured that MW is there as a researcher rather than a clinician.

Phase II

The focus groups will be led by the chief investigator (AR), an experienced musculoskeletal physiotherapist who has a PhD and extensive experience conducting qualitative research; with MW as the observer who will record who is

speaking at each time point and participants' reactions. AR will be familiar to many of the participating physiotherapists. The focus group participants will be told that the study forms part of a programme of research and that it will be used to develop a physiotherapy intervention based on behaviour change theory that seeks to optimise adherence to PA prescription during the treatment and post-treatment period in patients with lower-limb OA.

Study design

Theoretical framework

Patient perspectives are integral to determining the effectiveness of complex clinical interventions³³ and qualitative research is becoming more influential in NHS guidelines for clinical practice.³⁴ As the perspectives of patients and physiotherapists are central to developing an intervention³⁵ and an in-depth understanding is sought,³⁶ this qualitative study is based on a phenomenological framework. This study is designed and will be reported in line with the Consolidated Criteria for Reporting Qualitative Studies.³⁷

Participant selection and setting

Phase I

Adults (≥18 years) with a diagnosis of unilateral or bilateral lower-limb OA who are attending physiotherapy at one site (The Royal Orthopaedic Hospital NHS Trust, Birmingham, UK) will be invited to take part in a single one-to-one, semi-structured interview (figure 1). Diagnosis of OA can be through self-report of symptoms (≥45 years old, activity-related joint pain and morning stiffness ≤30 min duration) as per National Institute for Health and Care Excellence (NICE) guidelines or imaging.¹ Participants are required to be able and willing to give informed consent, and able to communicate fluently in English. Patients who have coexisting articular pathology affecting their hip or knees for example, gout, ankle arthritis, rheumatoid arthritis, have had or on a waiting list for hip or knee joint replacement, or are wheelchair dependent/have an inability to transfer will be excluded.

Consenting participants will be offered a choice of having their interview at their home or at the Royal Orthopaedic Hospital or the University of Birmingham. Purposive sampling will be used gain a wide variety of opinions and recruitment will continue until data saturation has been reached (minimum of 10 participants) which is defined by no additional themes emerging from the analysis³⁸ (please see figure 1 for detail). In the UK, ~60% of patients with lower-limb OA have knee OA³⁹ and 60% are females. Therefore, initially stratified purposive sampling will target participants based on these ratios.⁴⁰ The initial purposive sampling framework is outlined in table 1. As sampling progresses, theoretical purposive sampling will be utilised to target key secondary factors to ensure that those who work/do not work and those from different ethnic and educational backgrounds are also captured within the sample.⁴¹

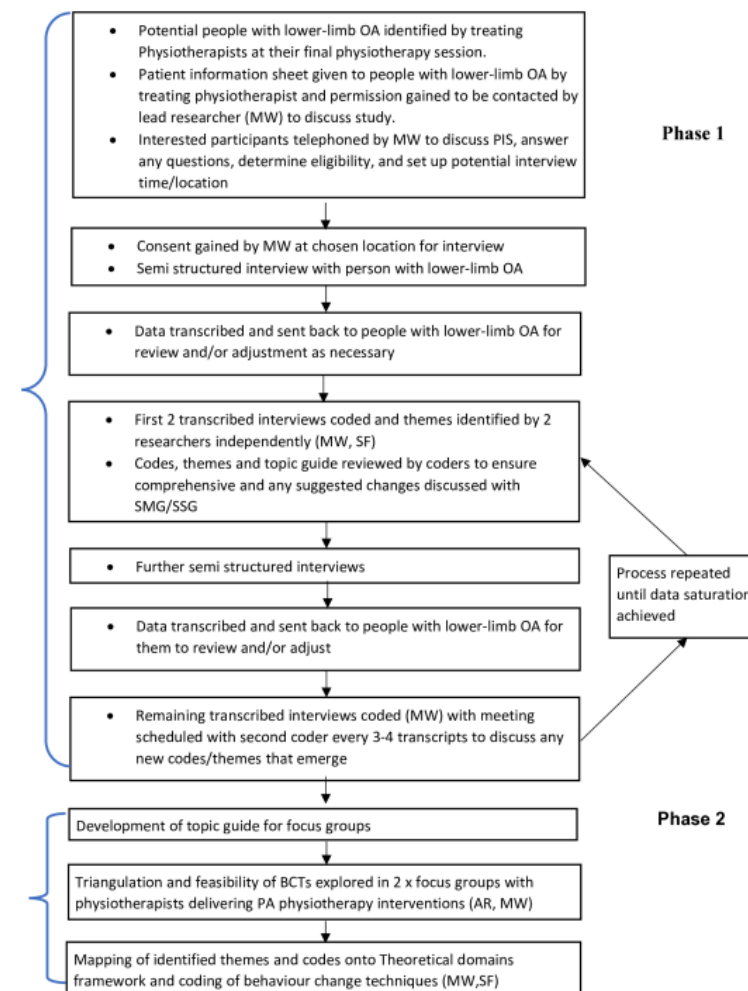


Figure 1 Study flowchart. BCTs,behaviour change techniques; OA, osteoarthritis; SMG,Study Management Group; SSG, Study Steering Group.

Table 1 Purposive sampling framework target

	Male	Female
Hip	2	3
Knee	4	6

The site lead researcher (DR), who is an advanced physiotherapy practitioner within the trust, will outline the study to physiotherapists who treat patients with lower-limb OA at the Royal Orthopaedic Hospital. Participants will then be identified by their treating physiotherapist and the study will be outlined with them at their final physiotherapy appointment. If they show interest in the study, the patient with lower-limb OA will be given a participant information sheet (PIS), and consent to contact will be sought for the lead investigator (MW) to contact them by telephone. Potential participants will then be contacted by telephone ~1 week after the date of their final appointment, so they have time to think about the study and consult with family and friends. During the telephone call, MW will confirm eligibility, discuss the participant information sheet and answer any questions about the study before arranging a time and location for the interview.

Phase II

Physiotherapists who have delivered PA interventions for patients with lower-limb OA within the last 6 months at the Royal Orthopaedic Hospital will be eligible to participate. The site lead researcher (DR), will use convenience sampling to approach and recruit the physiotherapists in person. Focus groups will be conducted at the Royal Orthopaedic Hospital for pragmatic reasons, time commitments and convenience of the clinicians. There are ~16 physiotherapists who regularly treat patients with lower-limb OA, therefore, it is anticipated that 2 focus groups will be conducted (based on 6–8 in each group). The total number of physiotherapists approached compared with those who attended the focus groups will be recorded.

Data collection

Phase I

Semi-structured interviews were chosen for the phase I data collection to enable patients with lower-limb OA to go into great depth when discussing their perceptions of PA,⁴² to provide a rich account of their perspectives, while allowing for flexibility within the session.⁴³ Questions will initially be asked in an open manner with prompts given or clarification sought if key points are identified with participants encouraged to identify new ideas during the interview. The topic guide (please see online supplementary appendices for the phase I topic guide) has been developed by including perspectives of patients with lower-limb OA (through patient and public involvement), and incorporating systematic review data, contemporary interview research,^{41 43–45} and surveys exploring perspectives⁴⁶ of patients with

lower-limb OA. The guide includes questions regarding a participant's current PA, their perspectives of physiotherapy interventions including barriers and facilitators to (objective 1), and BCTs they believe would optimise (objective 2), adherence to physiotherapist PA prescription during the treatment and post-treatment time periods. Demographic data including participants gender, age, Body Mass Index (BMI), ethnicity, educational level, length of time since OA diagnosed and the number of times they have been referred for referred to physiotherapy for management of their lower-limb OA symptoms will be collected. Further detail on participants functional level (Short-form Knee Injury and Osteoarthritis Outcome Score^{47 48}/Hip Injury and Osteoarthritis Outcome Score^{47 49} and PA (3-day physical activity recall interview^{50 51}) will be collected as part of the interviews. MW will take supplementary field notes during the interview process to enable triangulation during data analysis. Interviews will be audio recorded and transcribed verbatim and are anticipated to last ~60 min. Repeat interviews will not be conducted but the transcripts will be posted or emailed to participants (according to their preference) for member checking. Any adjustments or additional comments which arise from member checking, including contradictory statements, will not be included in the main data analysis but will be presented to the study steering and management groups when presenting the emerging themes to challenge the robustness of the barriers and facilitators identified. The member checking will also be used to verify approval of quotations to use in the final write up.⁵² The topic guide will be pilot tested prior to use with members of the Centre for Precision Rehabilitation Spine's Patient and Public Involvement Group at the University of Birmingham who have lower-limb OA and are not part of the main study. The topic guide can be found in the online supplementary appendices.

Analysis and findings

Data analysis and reporting

Development of the pilot physiotherapy intervention

The pilot physiotherapy intervention will follow a modified version of the guidance outlined by French *et al*⁵³ to develop complex interventions which are underpinned by behaviour change theory.

Identification of barriers and facilitators

Data from the semi-structured interviews and focus groups will be analysed inductively following the six stages from Braun and Clarke.⁵⁴

1. Familiarise yourself with the data.
2. Generate initial codes: coding for as many patterns as possible with surrounding words included to maximise contextual factors
3. Searching for themes: sort codes into potential themes.
4. Reviewing themes.
5. Defining and naming themes.

6. Producing the report.

This is an established method,⁵⁵ having been utilised extensively in qualitative studies, and enables flexibility⁵⁴ to analyse the research topic while developing unexpected themes that emerge from the transcripts during coding.⁵⁵ The first transcript from the semi-structured interview will be coded by two researchers (MW, SF who has expertise in behaviour change) in tandem to develop a coding strategy with the second transcript used to ensure the researchers are comfortable with the coding.⁵⁶ The remaining semi-structured interviews will be coded independently by MW and the coders will meet every 2–3 semi-structured interviews to review any new codes and themes that emerge from the transcripts and emerging themes will be presented to the Study Steering Group (SSG) to iteratively discuss any emerging themes. The coders will actively read the entire transcription before beginning to code the data and will attempt to suspend any presuppositions. To enable transparency within the audit trail, NVivo software will be used to store information and coders will keep a reflexive journal to identify their initial thoughts and perceptions.

To identify the most important themes to target in the developing intervention, the coders will pay specific attention to:⁵⁷

1. High frequency of specific beliefs and/or themes.
2. Presence of conflicting beliefs.
3. Strongly emphasised beliefs that may affect adherence to physiotherapy prescribed PA.

Quotations from participants will be presented to highlight key themes (participants will be identified with an assigned code) that emerge from the thematic analysis, with major and minor themes clearly delineated in the study report. Finally, the themes will be categorised as barriers or facilitators to adherence to physiotherapy prescribed PA in the treatment and post-treatment period. The barriers and facilitators will then be mapped onto relevant domains of the TDF^{25 27} by the same two researchers who conducted the thematic analysis.

Identification of BCTs to overcome barriers and aid facilitators

BCTs (from the BCT taxonomy)²⁸ will be coded from the identified domains on the TDF by the same two researchers following established guidelines.^{37 38} Important and priority BCTs will be related to the barriers and facilitators from which they were coded based on the criteria outlined in the thematic analysis (ie, frequency, presence of conflicting opinions and those that are strongly emphasised). The phase I topic guide (please see online supplementary appendices) is divided into treatment and post-treatment time frames to enable sequencing of BCTs. The timing and means of delivery of the BCTs will be further informed by reviewing the interventions from the low risk of bias RCTs (identified in our systematic review) which demonstrated effect of adherence to prescribed PA.

Phase II

The pilot physiotherapy intervention will then be explored in focus groups (objective 3) (figure 1). The focus group topic guide will seek the physiotherapists' perspectives on the structure and content of the pilot intervention including its acceptability, feasibility and practicality (capability, opportunity, challenges to delivery)⁴⁵ and the incorporated BCTs. The focus groups will be used to maximise insight of physiotherapist perspectives through an interactive group process providing multiple perspectives.⁴⁶ This will enable physiotherapists to propose and, through challenging and adding to others' points,⁵⁹ to articulate logistical issues around implementation of the outlined physiotherapy intervention within their trust that are not apparent to the researchers.⁴⁹ Prior to the focus group, basic demographic data will be recorded from the participating physiotherapists (gender, age, total time in clinical practice since graduation and amount specifically treating patients with lower-limb OA, their level of education, frequency treating patients with lower-limb OA, and how often they use strategies to target adherence to prescribed PA and their perceived effectiveness during the treatment and post-treatment time periods). Each focus group is anticipated to last ~90 min and the discussion will be audiotaped and transcribed verbatim, with the transcripts emailed to participating physiotherapists to enable further review and feedback. Please see online supplementary appendices for the phase II topic guide. Data from the focus groups will be analysed following the same processes by the same two researchers as the semi-structured interviews from phase I.

Implications of results

The BCTs and key barriers and facilitators identified from the semi-structured interviews will be synthesised to develop a pilot physiotherapy intervention aimed at optimising adherence to physiotherapy prescribed PA in patients with lower-limb OA. The focus groups will enable the feasibility and acceptability of delivering the identified BCTs as part of an intervention to be determined and enhance its clinical applicability. Comparison of the findings with our systematic review (Willett *et al*, under review) will enable incorporation of the most effective BCTs identified across both research projects to develop the physiotherapy intervention for a proposed pilot and feasibility study.

Patient and public involvement

This study is informed by suggestions made by a patient with lower-limb OA who is an integral member of the research team (member of both Study Management Group (SMG) and SSG). This has ensured that their perspective has contributed to the development of the phase I interview topic guide, participation information sheet and consent forms, and will further inform the data analysis and production of a lay summary of findings for dissemination. Members of the Centre for Precision



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Rehabilitation Spine Patient and Public Involvement group will be used to pilot the phase I topic guide.

LIMITATIONS

The lead investigator, who will conduct the interviews, code transcript data for themes, identify barriers and facilitators, and code BCTs is a musculoskeletal physiotherapist with extensive experience with patients with lower-limb OA. Therefore, it will be problematic to remove all presuppositions and some researcher bias is expected. As this study focuses on patients with lower-limb OA who have already attended physiotherapy, it will not identify barriers that patients with lower-limb OA who are invited but do not attend physiotherapy sessions experience. Therefore, specific BCTs that could facilitate patients with lower-limb OA attending physiotherapy will not be identified and could be explored in future studies.

Furthermore, this study also has a relatively small sample size and excluding patients with lower-limb OA who do not speak English will further limit its generalisability and applicability.

ETHICS AND DISSEMINATION

Research governance

The study will be conducted in accordance with the principles of the Research Governance Framework for Health and Social Care. The study protocol (IRAS 247904) has received Health Research Authority and site confirmation of capacity and capability approval, and a favourable opinion has been given by a research ethics committee (18/WM/0363). Pseudonymised participant data will be stored confidentially for 10 years in the protected REDCap data storage system in the Centre for Precision Rehabilitation of Spinal Pain at the School of Sport and Exercise, Rehabilitation Sciences, at the University of Birmingham, in accordance with General Data Protection Regulation (GDPR) and the Data Protection Act 2018 and University of Birmingham's research governance frameworks. The study will be coordinated by a SMG and overseen by a SSG. The SMG includes the researchers involved in designing the study, the site principle investigator (DR), and the patient and public involvement representative and will discuss and resolve any logistical issues that occur. The SSG is responsible for the analyses of results and will include the chief and lead researcher, the patient and public involvement representative, the site principle investigator and academics from the University of Birmingham with expertise in designing and conducting PA interventions.

Any protocol deviations will be documented, and the sponsor and chief investigator will be notified instantly. All investigators and site staff will comply with GDPR and the Data Protection Act 2018 when gathering, storing and dispensing of personal participant information. Only the chief investigator, who will also be the data custodian, the lead investigator, and second coder (SF) who is part of

the SMG, will have access to the data to enable quality inspection and data analysis. Although there are minimal risks involved with this study, a management plan is in place should any problem arise. During the semi-structured interviews or focus groups if the researchers are concerned for the participants well-being, mechanisms for safeguarding the participant and managing any distress will be implemented, including discussion (with permission from the participant) with the site lead physiotherapist (DR) to mitigate harm.

Peer review

As part of the funding application, the study rationale, methodology and intended analysis have been independently peer reviewed by the Musculoskeletal Association of Chartered Physiotherapists' research committee. Therefore, this protocol has been peer reviewed by an appropriate, independent professional body. The findings will be presented in an article in an open access peer-reviewed journal and conferences nationally and internationally. The funder will be provided with a study report and a lay summary of the report (led by the patient and public involvement representative) will be written for patients with lower-limb OA. Phase I participants will be invited to attend a presentation of the results which will provide a further opportunity for them to provide critical feedback.

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Contributors MJW is a PhD student and AR is the lead supervisor, and JD and CAG are supervisors. AR (chief investigator) and MJW (lead investigator) led on development of the protocol and gaining approvals (eg, ethics). AR, CAG and JD provided critical guidance on the conception, methodological decisions, design, and proposed analyses and dissemination. MJW and SF will be involved in data analysis and interpretation. DR is the principal investigator at the clinical site and is involved in data acquisition. All authors will contribute to data interpretation and conclusions. MJW drafted the initial version of the protocol manuscript. All authors have read, contributed to and agreed the final manuscript. AR is the guarantor of the study.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval NHS ethical and HRA approval and site capacity and capability have been obtained (IRAS 247904).

Provenance and peer review Not commissioned; externally peer reviewed.

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Appendix 1.4: Article, BMC Musculoskeletal Disorders, Utilising the perspectives of patients with lower-limb osteoarthritis on prescribed physical activity to develop a theoretically informed physiotherapy intervention

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RESEARCH ARTICLE

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Utilising the perspectives of patients with lower-limb osteoarthritis on prescribed physical activity to develop a theoretically informed physiotherapy intervention

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Abstract

Background: Lower-limb osteoarthritis (OA) causes high levels of pain and disability. Physiotherapists are the primary healthcare provider of non-pharmacological treatments, and incorporate strategies to optimise physical activity (PA) to aid patients with lower-limb OA to moderate their clinical symptoms. However, patients with lower-limb OA have low adherence to PA recommendations both during treatment and after discharge. This study aimed to use knowledge of identified barriers and facilitators to physiotherapy prescribed PA (during treatment and post-discharge) to develop a theoretically informed intervention to optimise adherence to PA for patients with lower-limb OA during treatment and post-discharge.

Methods: 1) A purposive sample of 13 patients with lower-limb OA participated in semi-structured interviews following physiotherapy treatment. Inductive analysis identified themes/subthemes reflecting barriers and facilitators to physiotherapist prescribed PA, which were organised deductively according to personal factors, treatment and post-discharge phases.

2) Themes/subthemes were mapped onto the *theoretical domains framework* (TDF).

3) Behaviour change techniques (BCTs) were coded from the key identified domains and a theoretically informed physiotherapy intervention addressing barriers and using facilitators, was developed.

(Continued on next page)

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Willett et al. BMC Musculoskeletal Disorders (2021) 22:155

Page 2 of 13

(Continued from previous page)

Results: Themes of patient confidence, mind-set, motivation, OA symptoms and PA experiences were primary personal factors that influenced PA adherence; with the TDF domain 'Beliefs about capabilities' most important to target. During treatment, the theme of routine formation was the major driver of personal factors; and primarily influenced by developing a positive physiotherapist-patient relationship. Post-discharge, physical factors, psychosocial factors and ongoing access to resources were important themes influencing PA maintenance. 'Environmental context and resources' and 'social influences' emerged as the key TDF domains to target during treatment and post-discharge. The proposed theoretically informed intervention included 26 BCTs delivered across conceptual phases of adoption, routine formation, and maintenance.

Conclusion: A theoretically informed physiotherapy intervention was proposed to optimise PA adherence in patients with lower-limb OA. The included BCTs primarily target patients' perceived beliefs about their capabilities, by developing a PA routine during treatment and facilitating appropriate psychosocial support and access to resources for PA maintenance post-discharge. The feasibility of delivering the intervention in clinical practice will now be evaluated.

Keywords: Theoretical intervention, Osteoarthritis, Physiotherapy, Behaviour change

Background

Osteoarthritis is a leading cause of pain and reduced function and quality of life [1]. In the United Kingdom (UK), OA is a burden on health services and the greatest cause of individual level disability in people aged 45 years or older, with approximately 2 million general practitioner (GP) visits each year related to OA symptoms [2]. The large synovial joints of the lower-limb (hip and knee) are the most common cause of OA related pain, accounting for approximately 70% of symptoms [3]. As there is currently no cure for OA [2], and with increased life expectancy [4], it is likely that greater numbers of patients with lower-limb OA will be required to self-manage their symptoms to reduce the load on healthcare systems in the coming years.

Promoting physical activity is a key non-pharmacological strategy that healthcare guidelines recommend to aid patients with lower-limb OA to manage their symptoms [1, 2, 5, 6]. However, the majority of patients with lower-limb OA are less active than asymptomatic populations [7], and healthcare PA interventions are generally only effective at reducing short-term (≤ 3 months post baseline) [8] symptoms, with pain and loss of function returning after about 6 months [9]. This is likely associated with a gradual reduction in patient adherence to prescribed PA after discharge, when approximately 90% of patients with lower-limb OA do not maintain their PA [10].

People undergo several 'phases' of behaviour change when integrating new behaviours into their lifestyle [11]. The most important phases are 'adoption' [12, 13], which occurs while people are receiving treatment from a health professional, and 'maintenance' [14] which would be ongoing post-discharge and occurs after 6 months of behavioural practice. While adoption and maintenance have several overlapping influences, they

also possess unique determinants [11, 15, 16]. Therefore, a healthcare intervention needs to incorporate specific behaviour change techniques (BCTs) to match these phases in the behaviour change process to optimise PA adherence.

Physiotherapists are the primary healthcare provider of non-pharmacological treatments for patients with lower-limb OA [17]. As such, they are in an optimal position to promote PA adherence [18]. However, physiotherapists and patients with lower-limb OA do not necessarily agree with the most effective BCTs to promote PA adherence [19]. Furthermore, patients with lower-limb OA believe they require more support and can perceive prescribed PA (e.g. exercise) as unsafe [20]. Physiotherapists also perceive they do not have sufficient understanding of BCTs to deliver them consistently in practice [21].

The Medical Research Council (MRC) advocates that interventions should be informed by behaviour change theory [22] to enable a greater understanding of the assumed intervention mediators (e.g. self-efficacy) effects on the target behaviour to enable refinement for future testing, and therefore, greater clinical effectiveness over time [23]. The Theoretical Domains Framework (TDF) is a validated framework which synthesises constructs from 33 theories of behaviour change into 14 overarching domains [24, 25]. By mapping barriers and facilitators to specific domains, the TDF can be used to identify key determinants of behaviour change [26] and important BCTs to develop theoretically informed interventions [27, 28].

Qualitative methods are utilised to provide an in-depth understanding of patients experiences and identify barriers and facilitators to treatment [29]. Although previous qualitative studies [30–38] have determined barriers and facilitators to PA for patients with lower-limb OA, only one study has considered stages of behaviour

change in their analysis [39]. Hammer et al. [39] found that patient self-efficacy and severity of symptoms were highly influential on PA maintenance. However due to their long-term focus, it was problematic to identify similarities or differences in determinants that occurred while under treatment (related to adoption) or post-discharge (related to maintenance) and their results were not utilised to develop a behaviour change intervention. Currently there are no theoretically informed interventions that incorporate BCTs that target the overlapping and unique features of PA adherence during the adoption and maintenance phases. Therefore, this study aimed to gain an in-depth understanding of the overlapping and unique barriers and facilitators to physiotherapist prescribed PA that patients with lower-limb OA experience during treatment and post-discharge to develop a theoretically informed physiotherapy intervention.

Objectives

- 1) To explore patients' in-depth experiences of barriers and facilitators to physiotherapist prescribed PA within sessions that effect adherence while receiving treatment and post-discharge.
- 2) To use the barriers and facilitators to identify themes/subthemes that influence patient's adherence to prescribed PA during treatment and post-discharge.
- 3) To map themes/subthemes to the TDF to identify key domains that effect adherence to PA during treatment and post-discharge.

- 4) To identify appropriate BCTs from the TDF domains to propose a theoretically informed intervention aimed at optimising PA adherence.

Methods

Theoretical framework

The in-depth perspectives of patients with lower-limb OA and their individual experiences of attending physiotherapy for the management of their OA related symptoms were sought to propose a theoretically informed intervention [40]. This study utilised a phenomenological framework [41], which followed a published protocol [42], and was reported using the Consolidated criteria for REporting Qualitative research (COREQ) [43]. A summary of the study processes is outlined in Fig. 1.

Research team and reflexivity

One-to-one semi structured interviews were conducted by the lead researcher (MW); an experienced physiotherapist who has treated patients with lower-limb OA for > 15 years. Participants were informed of MW's occupation, but his role as a researcher was emphasised. Participants had not met MW prior to the interview.

Participant selection

Adult patients (≥18 years) with hip or knee OA (diagnosed through NICE guidelines [2] or imaging), who had attended physiotherapy at the Royal Orthopaedic Hospital (ROH), in Birmingham, England, were recruited. The target sample comprised those who had experienced the phenomenon of interest (i.e. patients with lower-limb OA who had received physiotherapy

treatment and would likely have perceptions of the barriers and facilitators to prescribed PA) and therefore, purposive sampling was utilised [44]. Initially, stratified purposive sampling [45] aimed to recruit approximately 60% of participants with knee OA and 60% being female [46] (based on UK epidemiological data). Theoretical purposeful sampling [45] was then utilised in the final stages of recruitment to ensure secondary demographic factors (e.g. working status, age, educational background) that may influence patient perspectives could be included in the analysis [47]. Sampling continued until data saturation (the point where no new themes emerge from the data analysis) had been achieved [48]. Within phenomenology, a sample of up to 10 is generally accepted to reach data saturation [44]. However, Francis et al. [48] advocated that a further three interviews should be conducted post saturation, to ensure no new themes emerge. Therefore, a sample of 10–15 participants was anticipated which was consistent with previous phenomenological studies on patients with lower-limb OA [30, 31, 39].

Potential participants were identified by their treating physiotherapist and the study was outlined at the final treatment session. Each interested patient was given a participant information sheet (PIS) and asked to sign a consent to contact form passed to the site lead investigator (DR) who sent the form to MW by encrypted email. MW telephoned potential participants to verify eligibility, outline the study, answer any queries, and negotiate a time and place for the interview to take place. Potential participants were given at least 1 week to enable them to make an informed decision regarding participation. Participants could have interviews at their home, the ROH or at the University of Birmingham.

Data collection

The interview schedule (Additional file 1) was developed by integrating content from contemporary research examining the perspectives on PA in patients with lower-limb OA [30, 34, 35, 49] and refined by piloting with the study's patient and public representation (ED) who has lower-limb OA. The schedule included questions on patients' current levels of PA (adapted 3 day Physical Activity Recall interview [50, 51]) and key demographic data (gender, age, Body Mass Index (BMI)), ethnicity, length of time since OA diagnosis and their highest educational level. Several patient reported outcome measures were integrated into the interview schedule: bothersomeness [52] and average pain [53] of their symptoms over the previous week, and either the short form Hip [54] or Knee [55] Injury and Osteoarthritis Outcome Scores (HOOS/KOOS). Open questions (with prompting where required) were used to gain participants' in-depth opinions on: the received

physiotherapy intervention and key barriers and facilitators or BCTs that influenced their prescribed PA during treatment and post-discharge. Participants were invited to offer any further perspectives that they felt were not addressed in the topic guides. Interviews were audio-recorded, transcribed verbatim, and mailed/emailed (dependent on preference) to participants for member checking so researcher interpretation of the data could be reviewed [56]. No follow up interviews were planned.

Data analysis and development of intervention

Development of the theoretically informed physiotherapy intervention followed a modified version of the steps outlined by French et al. [57].

Step 1: identification of barriers and facilitators and thematic analysis

Barriers and facilitators to physiotherapist prescribed PA were identified and synthesised to generate themes and subthemes following thematic analysis guidance as outlined by Braun and Clarke [58] (Objectives 1 and 2).

Familiarisation with the data and generating initial codes

MW took field notes to summarise key thoughts at salient points of the semi-structured interviews which enabled initial familiarisation with the data. Transcribed verbatim interviews were uploaded into NVivo software and read several times by two researchers (MW, SF) who attempted to put aside their pre-conceived thoughts to maintain the unique experiences of the participants in the analysis [44]. MW and SF coded the first transcript in tandem and the second independently to establish consistency [59]. The researchers included additional text so that each code maintained its own meaning [44], with as many examples as possible included to ensure contextual factors were recorded [58]. Any explicit details outlining participants perspectives on specific BCTs and/or their mode of delivery or perspectives on sessions (i.e. number, frequency or duration) that appeared in the transcript were noted by the coders to ensure that the proposed intervention matched participants suggestions. MW and SF worked collaboratively to arrange codes (with quotations) from the first transcript into preliminary themes/sub-themes with several follow up meetings used to iteratively update the emerging results from the second transcript. The remaining transcripts were coded by MW.

Searching for themes The interview topic guide included questions outlining barriers and facilitators during treatment and post discharge, and those which were intrinsic to the participants experience. Therefore, a deductive framework was utilised initially to cluster preliminary codes and quotations (including both barriers

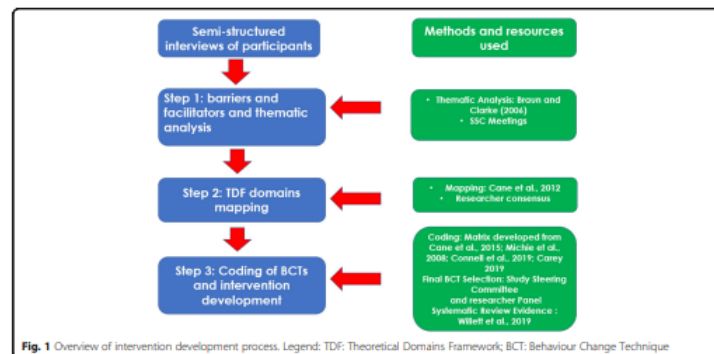


Fig. 1 Overview of intervention development process. Legend: TDF: Theoretical Domains Framework; BCT: Behaviour Change Technique

and facilitators) into three overlapping groupings of themes.

- 1) 'Personal factors' grouping encompasses themes which could influence PA adherence across both during treatment and post-discharge.
- 2) 'Treatment factors' grouping encompasses themes that primarily influenced PA adoption including effects that the physiotherapist and treatment sessions had on patients.
- 3) 'Post-discharge factors' grouping encompasses themes that primarily influenced PA maintenance beyond the clinic after the patient is discharged from care.

Reviewing, defining and naming themes Data on NVIVO were reviewed by MW who grouped barriers and facilitators to develop preliminary themes and sub-themes. MW wrote all subthemes and supporting quotations on post-it notes and generated an initial inductive mind-map which enabled visual exploration of patterns of themes and subthemes including any overlap and delineation of individual perspectives and experiences [60]. Common subthemes and deviant cases were sought to ensure individual perspectives were captured within the analysis [44]. The mind-maps were videoed with theme associations outlined for later review. Emerging themes/subthemes and mind maps were audited and clarified through presentations to the chief investigator (AR) and results, supported by quotations, were developed iteratively through presentations and feedback at Study Steering Committee (SSC) meetings. The SSC included researchers, clinicians, and patient and public involvement and the in-depth, collaborative feedback aided the analyses' value and the studies reflexivity [61].

Step 2: mapping to the theoretical domains framework

To provide a comprehensive overview of associated domains, all subthemes were mapped onto the TDF (objective 3). TDF Mapping was piloted by two researchers (MW, SF) over a series of meetings and supported by a modified manual from a previous study [62]. Mapping was completed by MW and audited by SF with any issues discussed. In the case of any mapping disagreements, an expert in behaviour change theory (JD) mediated. If agreement of mapping a subtheme to single domain could not be reached, it was mapped onto all domains identified by either coder [26]. Each subtheme was evaluated across three criteria to clarify its relative importance [63]: The number of participants who identified each subtheme; the presence of strong beliefs; the presence of conflicting beliefs. The domains outlined from the subtheme mapping were synthesised to identify

the most important domains for each theme for the intervention to target.

Step 3: behaviour change technique identification and intervention development

A coding matrix (Additional file 2), synthesising research linking BCTs to theoretical constructs [27, 28] and mechanisms of action [64, 65] was used to identify all potential BCTs from the key TDF domains within each theme (objective 4). BCTs were categorised as 'unique' if they were coded exclusively/primarily to a one grouping, or 'overlapping' if they were identified consistently across groupings (Additional file 2). To reflect clinical practice and enable capture of the phases of behaviour change, the proposed intervention was split into early (adoption), middle, and late (maintenance) sessions. BCTs coded to the treatment or post-discharge grouping were incorporated into the early-middle sessions to target PA adoption, or middle-late sessions to target PA maintenance respectively. Those that were coded to the personal factors grouping, or across groupings, were generally considered reoccurring and repeated across sessions. Although the aforementioned studies [27, 28, 65] offer a useful way to identify BCTs, there is currently no guidance regarding prioritisation or mode of delivery [66]. Therefore, if conflicts were identified during BCT identification, Cane et al. [28] was preferentially used as it is the only study that has demonstrated reliability and validity when linking BCTs to behavioural domains. The final selection of BCTs, including their mode of delivery and physiotherapy session detail (i.e. suggested number of sessions, duration, and frequency), was further informed by: repeated review of participants transcripts; collaborative discussions at SSC meetings; the lead investigators clinical experience; the BCTs most commonly used in clinical practice [28]; the most effective BCTs from low risk of bias trials identified in our systematic review [9].

Results

Participants

All 13 patients ($n = 4$ males) who were approached agreed to participate and interviews were conducted March–November 2019 and lasted 46–70 min (mean 56 min). All participants were of White British descent, ninthwith knee OA, three with unilateral hip OA, and one with severe hip and mild bilateral knee OA (considered as a hip participant in the analysis). Although two participants had family members in the house during their interview, no person other than the participant and interviewer were present in the interview room. Saturation of themes was reached after 10 participants, and a further three interviews ensured no further themes emerged [48]. Participants' ages ranged between 44 and

76 years (mean 63; standard deviation 10.7) and BMI ranged between 24 and 42 (31.9; 5.3). Participants' average pain intensities ranged from 1 to 6 (3.9;1.9) and six participants rated their bothersomeness as 'moderately' over the past week. The SF-KOOS and HOOS scores ranged from 24.9–66.6 (38.77;11.35) and 33.9–46.1 (40.9; 4.4) respectively. PA levels ranged from 1975 to 4250 kcal/day for the previous 3 days with a mean of 2920.8 (660.0) kcal/day. Twelve participants had their diagnosis confirmed with an X-ray and one with patient history and clinical examination data. Symptom duration varied from < 1 year to 48 years. Participant data are shown in Table 1. Transcripts were sent to six participants at their request, but none responded with comments.

Step 1: identification of barriers and facilitators and thematic analysis and step 2: mapping to the theoretical domains framework

Due to the integrative nature of the data analysis, and to avoid repetition, the results for Steps 1 and 2 are presented together. A summary of themes within each deductive grouping, and their associated primary TDF domains are presented in Table 2. Overall, 13 of 14 TDF domains (all accept 'attention and decision-making processes') were identified as important influences of PA adherence in at least one theme. Nine TDF domains were identified within the personal factors grouping with 'Beliefs about Capabilities' influential to all themes. The treatment phase grouping identified ten TDF domains as important with 'Environmental Context and Resources' and 'Social Influences' associated across three themes. Seven TDF domains were identified in the post-discharge grouping with domain 'Environmental Context

and Resources' important across all themes. Additional detail on subthemes and TDF mapping, with example supporting quotations are included for the personal factors, treatment and post-discharge groupings in Additional file 3: Tables 1–3 respectively and further detailed below.

Personal factors grouping

Five interrelated themes contributed to the personal factors grouping: participant's motivation, confidence, mindset, arthritic symptoms, and experiences of PA (Additional file 3: Table 1).

Motivation theme Patients motivation to adhere to PA was influenced by a continuum of factors and included internal and external sources. Subthemes related to internal sources of motivation included: enjoyment (or not) of PA; seeing progress; having a purpose; wanting to maintain function or moderate arthritic symptoms; fear of functional decline or need of invasive surgery; and a sense of personal-responsibility or guilt at not doing prescribed PA. Subthemes related to external sources of motivation were: use of the physiotherapist or reminders (e.g., use one's Theraband) as motivators. The most important TDF domains associated with motivation were 'Intentions', 'Goals', and 'Emotion', and 'Beliefs about Capabilities'.

Confidence theme Participant confidence was highly influential in promoting PA adherence. Subthemes included: the effect of PA on symptoms and function; feelings of PA capability; and fear avoidance. The most important TDF domains associated with this theme were

Table 1 Participant demographic features

Participant no	Gender	Age	BMI	Joint	NPRS	BSM	SF KOOS	SF HOOS	PA	HEL	TSSB	TSD	EM
1	F	60	26	Right knee	1	Slightly	35.3	N/A	2155	O levels	2	0.5	N
2	F	75	35	Right knee	2	Moderately	46.1	N/A	2588	PG Diploma	25	25	N
3	M	75	33	Both knees	6	Very much	42	N/A	3800	High School	30	0.75	N
4	F	63	28	Right knee	3	Moderately	33.6	N/A	2692	UG degree	1.5	0.5	Y
5	M	76	25	Left knee	5	Slightly	35.3	N/A	2580	Left school at 14	48	3	N
6	F	53	42	Right knee	6	Very much	66.6	N/A	4250	Left School at 16	12	1	Y
7	F	75	35	Right hip; both knees	4	Moderately	37	41.7	2672	College	6	4	N
8	F	63	24	Left knee	6	Moderately	42	N/A	2376	UG degree	4	1	Y
9	F	67	37	Left hip	3	Slightly	N/A	33.9	3197	UG degree	0.5	0.5	Y
10	F	53	27	Left knee	2	Slightly	24.9	N/A	1975	College	6	5	
11	F	67	N/G	Both knees	1	Slightly	24.9	N/A	N/G	High School	10	10	Y
12	M	44	30	Left hip	6	Moderately	N/A	41.7	3201	College	2.5	0.5	Y
13	M	48	29	Right hip	6	Moderately	N/A	46.1	3564	Master's Degree	6	3	Y

N/A Number, BSM Body Mass Index, NPRS Numerical Pain Rating Scale, BSM Bothersomeness, SF KOOS Short Form Knee Injury and Osteoarthritis Outcome Score, SF HOOS Short Form Hip Injury and Osteoarthritis Outcome Score, PA Physical Activity level (mean kcal/day for past 3 days), HEL Highest Education Level Achieved at time of interview, TSSB Time since symptoms began, TSD Time Since diagnosis of OA, EM Employed at time of interview

Table 2 Key theoretical domains frameworks domains that influenced themes

Grouping	Theme	TDF Domain													
		Kn	Sk	SPRI	BACap	Op	BACon	Rein	Intent	Goals	MAD	ECR	Soci	Em	Behf
Personal factors	Motivation				✓				✓	✓				✓	
	Confidence	✓	✓		✓		✓								
	Mindset				✓	✓						✓		✓	
	Pain	✓				✓								✓	
	Previous Experience		✓		✓		✓								
Treatment Phase	Routine	✓	✓					✓	✓	✓		✓			✓
	Access														
	Value											✓	✓		
	Relationship					✓								✓	
Post-Discharge Phase	Personalised Rx	✓	✓		✓			✓	✓	✓				✓	✓
	Access							✓				✓	✓	✓	
	Psychosocial factors			✓	✓	✓								✓	
	Physical factors				✓		✓					✓			

TDF Theoretical Domains Framework, Kn Knowledge, Sk Skills, SPRI Social/Professional Role and Identity, BACap Beliefs about Capabilities, Op Optimism, BACon Beliefs about Consequences, Rein Reinforcement, Intent Intention, MAD Memory, Attention and Decision Processes, ECR Environmental Context and Resources, SocI Social Influences, Em Emotion, BehR Behavioural Regulation

'Knowledge', 'Skills', 'Beliefs about Capabilities', and 'Beliefs about Consequences'.

Mindset theme Several participants outlined the importance of a positive mindset, or having the mental energy or headspace to engage with prescribed PA. This theme was very closely linked with participant confidence to undertake PA and included the subthemes: psychological effects of symptoms and PA; mental and emotional resources; and comfort zone. The most important TDF domains were 'Beliefs about Capabilities', 'Optimism', 'Environmental Context and Resources', and 'Emotions'.

Arthritic symptoms Pain and other arthritic symptoms (e.g. articular stiffness) were key influences of PA adherence. Subthemes included the effect of symptoms on: Undertaking PA; mood; enjoyment of PA; and the effect of pharmacology on pain. The key associated TDF domains were 'Beliefs about Capabilities', 'Knowledge', 'Optimism', and 'Emotion'.

Experiences of PA Participants' previous PA experiences influenced their PA adherence. Sub-themes included: PA effects on participants wellbeing, mind-set, arthritic symptoms and function; and participants identifying oneself as physically active; their expectations of treatment; and frustration at loss of function. The most important associated TDF domains were 'Skills', 'Beliefs about capabilities', 'Beliefs about Consequences', and 'Reinforcement'.

Treatment phase factors grouping

The treatment phase grouping included the themes: routine formation; person-centred treatment; the patient-physiotherapist relationship; access; and value of physiotherapy sessions (Additional file 3: Table 2).

Routine formation PA routine formation emerged as the primary mechanism to promote patient confidence, motivation, and a positive mindset. Subthemes were grouped into barriers and facilitators. Facilitators included: having a PA plan; integrating PA into daily life; promoting habits; and the effects of routine on motivation and well-being. Barriers to routine included: health concerns; memory; other commitments; and time. The primary associated TDF domains were 'Knowledge', 'Skills', 'Intentions', 'Goals', and 'Behavioural Regulation' which contained both barriers and facilitators and 'Environmental Context and Resources' which was exclusively identified as a barrier to this theme.

Person-centred treatment A collaborative, person-centred treatment approach was important to developing a PA routine. Subthemes included: a personalised treatment plan; a detailed PA routine; ongoing assessment and reassessment; and understanding of OA. The primary associated TDF domains were 'Knowledge', 'Skills', 'Reinforcement', 'Intention', 'Goals', and 'Behavioural Regulation'.

Relationship with the physiotherapist Participants outlined the importance of their relationship with the physiotherapist in adhering to prescribed PA. Subthemes

included: personal level knowledge; collaborative relationship; familiarity; encouragement (from physiotherapist); motivation (from physiotherapist); communication; and the physiotherapist's attitude. The most important TDF domains were 'Optimism' and 'Social Influences'.

Access to physiotherapy sessions Participant's access to their physiotherapist influenced the development of a PA routine. Subthemes included: other commitments; appointment flexibility; number and of sessions; and referral process. The primary associated TDF domain theme was 'Environmental Context and Resources'.

Value of physiotherapy sessions PA adherence was influenced by how valuable participants perceived their physiotherapy sessions to be. Subthemes include: motivation from sessions; empowerment from sessions; too much talking; and PA within sessions. The primary associated TDF domains were 'Environmental Context and Resources' and 'Social Influences'.

Post-discharge factors grouping

The post-discharge grouping included the themes: access to resources; psychosocial factors; and physical factors (Additional file 3: Table 3).

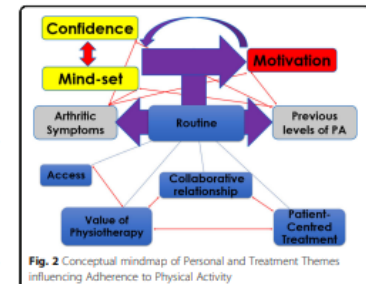
Access to resources Access to a community facility or physical space influenced post-discharge PA maintenance. Subthemes included: Follow-up with the physiotherapist; Appropriate facilities and; Ease of access. The primary associated TDF domains were 'Environmental Context and Resources' and 'Social Influences'.

Psychosocial factors Ongoing psychosocial support influenced PA post-discharge. Subthemes included: Relatedness to others; Fear of judgement; and Psychosocial support. The most important TDF domains were 'Environmental Contexts and Resources', 'Social Influences', 'Social Identity', 'Beliefs about Capabilities', and 'Optimism'.

Physical factors Physical factors impacted participants adherence to PA post-discharge. Subthemes included: Perceived physical capability; intrinsic physical factors (e.g. age, weight); and extrinsic physical factors (e.g. hills, weather). The primary associated TDF domains were 'Beliefs about Capabilities', 'Beliefs about Consequences' and 'Environmental Context and Resources'.

Interrelationship of themes across groupings

The relationships of the themes within the personal factors and treatment and post-discharge groupings can be visualised in Figs. 2 and 3 respectively. The conceptual mind-maps demonstrate the importance of the


Fig. 2 Conceptual mindmap of Personal and Treatment Themes influencing Adherence to Physical Activity

participant's mindset and confidence to adhere with prescribed PA and their influence on motivation. The smaller curved arrow details the feedback and ongoing relationship between these personal factors. The figure also takes into account the interrelation of patients unique PA experiences and OA symptoms with the other personal factors. The main vertical arrows demonstrate PA routine as the key mechanism in the adoption (Fig. 2) and maintenance (Fig. 3) of the key personal factor themes. The bottom of each model outlines the interacting themes of each grouping and their influence on PA routine adoption and maintenance.

Step 3: behaviour change technique identification and intervention development

A proposal of the theoretically informed intervention is outlined in Table 3 and includes 26 BCTs with two additional BCTs (body changes and credible source) naturally occurring due to the sessions being delivered. The conceptual phases of adoption, routine formation, and

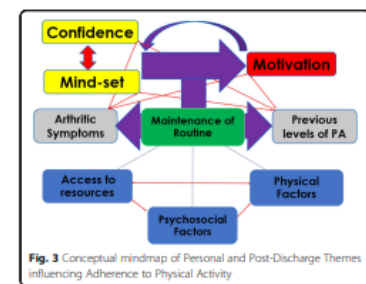

Fig. 3 Conceptual mindmap of Personal and Post-Discharge Themes influencing Adherence to Physical Activity

Table 3 Theory-informed physiotherapy intervention outlining phases targeted by behavioural change techniques

Session Number	Targeted Phase	Specific BCTs	Reoccurring BCTs
1–2	Adoption	- Goal setting (behaviour and/or outcome) - Action planning (including implementation intentions) - Information on health consequences of performing the behaviour - Information on social and environmental consequences - Rewards (one of: Material, non-specific, social, self-reward, or outcome)	- Review behaviour goals (and/or outcome) - Feedback on behaviour (and/or outcomes) - Self-monitoring of behaviour (and/or outcomes of behaviour) - Social support (unspecified) - Social support (practical) - Instruction in how to perform the behaviour
3–4	Routine Formation	- Prompts/cues - Habit formation - Generalisation of a target behaviour - Adding objects to the environment (e.g. objects to facilitate behaviour)	- Modelling/demonstration of behaviour - Behavioural rehearsal/practice - Graded Tasks - Pharmacological Support - Body changes^a - Credible source^a
5–6	Maintenance	- Problem Solving - Behavioural Contract - Reduce negative emotions - Restructuring of social environment - Verbal persuasion about capability - Social comparison - Information about others' approval	

BCT Behaviour Change Technique

^aDenotes associated BCT occurrences naturally from delivering the intervention as planned

maintenance were based on the inductive thematic analysis and behaviour change literature with the number of sessions informed by the interview transcripts. Of the included BCTs, 11 were recurrent, five were primarily coded to adoption, five to routine formation, and eight to the maintenance phases respectively. BCTs with a 'behaviour' and 'outcome' variant (e.g. goal setting) were listed as a single BCT and the final selection will be determined by patient's preference when the intervention is delivered. For example, if the patient's goal is to lose weight as a result of optimising PA, then the BCT would become goal-setting (outcome) as weight would be the outcome of consistently applying the behaviour.

Discussion

This is the first qualitative study to gain in-depth perspectives of the barriers and facilitators to physiotherapist prescribed PA during the treatment and post-discharge phases in patients with lower-limb OA. Inductive thematic analysis synthesised barriers and facilitators and themes and subthemes were collated into an a priori deductive framework which included three overarching groupings: personal factors; treatment factors and; post-discharge factors. Subthemes were mapped to the TDF and results synthesised to outline the key domains to target for each theme. Thirteen TDF domains were identified and 26 BCTs were included in the proposed intervention, which represents the first theoretically informed physiotherapy intervention to target adherence to prescribed PA during treatment and post-discharge.

Personal factors

Personal factors that influenced participants' perceptions of PA adherence were consistent with previous literature, specifically: motivation [30, 33, 67], confidence [30, 34, 35, 39, 68], mindset [30, 34, 35, 39, 68] and experiences of arthritic symptoms [33, 34, 39] and/or PA [30, 34, 39]. Themes relating to personal factors were highly interactive and participants could be categorised into two broad profiles;

- Those with higher levels of arthritic symptoms and/or decreased physical capabilities, or who experienced symptoms as a result of PA reported less confidence, motivation and/or a negative mindset reported difficulty adopting and/or maintaining PA behaviours and required ongoing practical and social support [30].
- Participants who had internalised PA behaviours [16] or had high levels of social support reported feeling greater confidence, motivation and/or a positive mindset to adopt and maintain their PA post-discharge without additional need of support [30].

The TDF domain 'Beliefs about Capabilities' was influential for all personal factor themes. This domain includes constructs such as of 'self-confidence', 'empowerment', 'perceived competence', and 'perceived behavioural control'. These constructs relate closely with participant confidence, mindset, and the theoretical cognition of self-efficacy [69] which is a salient

correlate of overall PA behaviours in patients with lower-limb OA [39]. Participants discussed that positive PA experiences increased their confidence and generated a positive mindset, which facilitated motivation to engage with prescribed PA. Therefore, self-efficacy may act as an antecedent to motivation in the behaviour change process [15] and BCTs that targeted the 'beliefs about capabilities' construct (e.g. instruction in how to perform the behaviour and demonstration of the behaviour) were introduced early in the proposed intervention with several reoccurring.

Treatment factors

Forming a PA routine was the key mechanism to promote PA behaviours during treatment. Participants felt that physiotherapists could optimise their routine by instructing prescribed PA and enabling participants' to practice/rehearse within sessions [31, 32, 35, 36, 39, 68], slowly increasing PA in a graded manner, and providing feedback about PA or its associated outcomes (e.g. weight loss). Participants suggested that providing a demonstration of the behaviour (e.g. exercise sheet or video) and/or integrating self-monitoring of PA (e.g. pedometers or exercise diaries) into programmes would help regulate PA outside of the clinic during the treatment phase [70]. Interestingly, participants linked these BCTs to promoting confidence and purposeful PA. However, they are underutilised in clinical practice [70, 71] suggesting that physiotherapists may not be effective at utilising strategies which encourage PA adherence [72]. Therefore, these BCTs were introduced in sessions to and reinforced in sessions three-four to facilitate behavioural adoption and routine formation respectively.

The beneficial effects of a positive patient-physiotherapist relationship are in line with previous studies, as participants commented that encouragement [73], reassurance [36], and developing a strong personal connection enhanced adherence to PA [30, 74]. The proposed intervention therefore, utilises the reoccurring BCTs *social support (unspecified)* and *(practical)* respectively. Participants discussed how patient-centred treatment that involved collaboratively generated PA goals, led to feelings of empowerment and enhanced motivation to engage with PA [31, 75]. The use of a collaborative approach is associated with advanced clinical reasoning and expert physiotherapist practice [76]. Moreover, goal setting techniques with recurring review, were identified as important BCTs to promote PA adherence by patients with lower-limb OA [19], and were included in the adoption phase of the proposed intervention.

Post-discharge factors

Several participants believed their physiotherapist could provide additional support post-discharge, as they perceived negative reactions from family/friends or peer PA

groups [30, 38] due to their reduced physical capacity. As intervention time is limited for physiotherapists, it would be beneficial if community resources for post-discharge PA provision were integrated with the physiotherapy provider [34]. In line with previous studies, participants discussed that any post-discharge PA group needed to be exclusive to individuals of similar physical abilities [32, 34, 36, 38, 39, 68] and diagnosis to enhance relatedness [32, 36] and reduce feelings of anxiety or embarrassment [32, 39, 68]. Therefore, the proposed intervention incorporated BCTs relating to *problem solving*, and an in-depth discussion on *how to structure the social environment* during the maintenance phase [28, 64, 65]. Community facilities primarily target those with decreased physical ability and lower income and need to be highly accessible [30, 31] and at minimal cost [19, 21]. However, participants discussed that they found access to services highly problematic. Therefore, the proposed intervention included BCTs that alter the home environment, in order to prompt routine formation and maintenance post-discharge (e.g. using prompts and cues, or leaving Theraband in a prominent place to act as a reminder to their PA).

Reflections on TDF mapping and BCT coding

With the exception of the motivation theme, TDF mapping was intuitive and consistent with all discussion points clarified by the two researchers. Motivation has a multi-faceted influence on PA adherence [30, 33, 67] that may change at different parts of the behaviour change process [16]. This is perhaps reflected in the refined TDF [28] which separated the original 'goals and motivation' domain [27] into the distinct 'goals' (preferred outcome), and intentions (determination to act in a certain way). While it is acknowledged that motivation is a distinct mechanism or process of action in current research [64, 65] further clarification of its definition within the TDF domains would likely increase consistency during mapping. These difficulties may also be linked to the topic guide design which was not informed by the TDF domains.

The TDF domains 'environmental context and resources' and 'social influences' were highly influential across both treatment and post-discharge phases. While the separation of themes into the personal factors, and treatment and post-discharge phases enabled some clarity of sequencing of BCTs, there was considerable overlap of domains across groupings. This suggests that behavioural adoption and maintenance have both unique and similar determinants.

Although the constructed matrix provided a useful tool, several BCTs did not overlap between studies and further work to establish agreement of the coding of BCTs from behavioural domains and mechanisms of action is required.

Strengths and limitations

Strengths include the transparent methodology [77] to identify barriers and facilitators of PA adherence, which incorporated a valid and reliable framework to map them to determinants of behaviour change [24], and an extensively utilised strategy of identifying BCTs [28]. These strengths may enhance the interventions effectiveness at optimising adherence to PA. The study design facilitated an in-depth understanding of participant views and incorporating patient and public involvement further aided participants perspectives to be integrated during the intervention's initial development.

A key limitation is that all participants were familiar with the person who recruited them, which may have influenced the findings. Furthermore, all participants were fluent English speakers of White British descent. While this reflected the hospital demographics, findings may not be generalisable beyond this population. In addition, participants recall PA levels were higher than those typically reported for patients with lower-limb OA [7]. Although the sample may have included only active participants, inconsistent and over-reporting of PA levels with patient reported methods of data collection is widely outlined in the literature [78], and perhaps strengthens the need for validated measures of objective PA in patients with lower-limb OA.

The theoretically informed physiotherapy intervention represents the initial proposal only. Prior to implementation, further data is required on the intervention's feasibility to other stakeholders to clarify points on BCT mode of delivery, session lengths and frequency, and training needs of physiotherapists. Therefore, the feasibility and acceptability of delivering the intervention will now be tested in focus groups of physiotherapists working clinically prior to a phase two feasibility study.

Conclusions

A proposed theoretically informed physiotherapy intervention to optimise PA adherence in patients with lower-limb OA during treatment and post-discharge was developed through a transparent and rigorous methodology. The intervention BCTs primarily target patients' perceived beliefs about their capabilities, by developing a PA routine during treatment and facilitating appropriate psychosocial support and access to resources for PA maintenance post-discharge. The feasibility of delivery of the proposed intervention now requires evaluation.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12991-021-04036-6>.

Additional file 1. Semi-structured interview topic guide.
Additional file 2. BCT assigned to matrix and groupings.
Additional file 3. Themes mapped to TDF across groupings.

Abbreviations

OA: Osteoarthritis; PA: Physical activity; TDF: Theoretical Domains Framework; BCT: Behaviour Change Technique; UK: United Kingdom; GP: General practitioner; COREQ: Consolidated criteria for Reporting Qualitative research; ROH: Royal Orthopaedic Hospital; SF HOOS: Short-form Hip Injury and Osteoarthritis Outcome Scores; SF KOOS: Short-form Knee Injury and Osteoarthritis Outcome Scores; SSC: Study Steering Committee

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Authors' contributions

MW is a PhD student who conceived the study. AR is the lead supervisor, and JD and CAG are co-supervisors. MW and AR applied for study funding. MW, AR, JD and CG developed the research idea and contributed to study design including content of the interview topic guides. DR was the principal investigator at the clinical site and was involved in data acquisition. MW collected the data. MW and SF were involved in initial data analysis and interpretation. MW, AR, JD, CG and DR gave critical feedback on emerging themes during the analysis as part of the Study Steering and/or Management Committees respectively. MW drafted the manuscript, then circulated it to other authors for comments and revisions. All authors read and approved the final manuscript.

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Availability of data and materials

All data generated or analysed during this study are included in this published article [and its supplementary information files].

Ethics approval and consent to participate

National Health Service ethical and Health Research Authority approval and site capacity and capability were obtained (IRAS 247904) prior to the study. All methods were performed in accordance with the relevant guidelines and regulations. Informed Consent to participate was gained from all participants verbally and in written form prior to their involvement in the study. All participants were over 18 years of age. Informed Consent included the permission for the interview data to be presented in publications in an anonymized format.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Appendix 1.5: Article, Pilot and Feasibility Studies, Feasibility of a theoretically grounded, multicomponent, physiotherapy intervention aiming to promote autonomous motivation to adopt and maintain physical activity in patients with lower-limb osteoarthritis: protocol for a single-arm trial

Willett et al. *Pilot and Feasibility Studies* (2023) 9:54
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Pilot and Feasibility Studies

STUDY PROTOCOL

Open Access

Feasibility of a theoretically grounded, multicomponent, physiotherapy intervention aiming to promote autonomous motivation to adopt and maintain physical activity in patients with lower-limb osteoarthritis: protocol for a single-arm trial

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Abstract

Background Lower-limb osteoarthritis (OA) causes high levels of pain and disability in adults over 45 years of age. Adopting and maintaining appropriate levels of physical activity (PA) can help patients with lower-limb OA self-manage their symptoms and reduce the likelihood of developing secondary noncommunicable diseases. However, patients with lower-limb OA are less active than people without musculoskeletal pain. This single-arm feasibility trial seeks to determine the feasibility and acceptability of a complex multicomponent physiotherapy behaviour change intervention that aims to aid patients with lower-limb OA to adopt and maintain optimal levels of PA.

Methods This trial will be conducted at one site in a National Health Service physiotherapy outpatient setting in the West Midlands of England. Up to thirty-five participants with lower-limb OA will be recruited to receive a physiotherapy intervention of six sessions that aims to optimise their PA levels during phases of behavioural change: adoption, routine formation and maintenance. The intervention is underpinned by self-determination theory (and other motivational frameworks) and seeks to foster a motivationally optimal (empowering) treatment environment and implement behaviour change techniques (BCTs) that target PA behaviours across the three phases of the intervention. Physiotherapists ($n = 5-6$) will receive training in the why and how of developing a more empowering motivational environment and the delivery of the intervention BCTs. Participants will complete patient-reported and performance-based outcome measures at baseline and 3-month (to reflect behavioural adoption) and 6-month (maintenance) post-baseline. Feasibility and acceptability will be primarily assessed through semi-structured interviews (purposively recruiting participants) and focus groups (inviting all physiotherapists and research staff). Further evaluation will include descriptive analysis of recruitment rates, loss of follow-up and intervention fidelity.

Discussion A novel complex, multicomponent theoretical physiotherapy behaviour change intervention that aims to create a more empowering motivational treatment environment to assist patients with lower-limb OA to adopt

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Willett et al. *Pilot and Feasibility Studies* (2023) 9:54

Page 2 of 17

and maintain optimal PA levels has been developed. Testing the feasibility and acceptability of the intervention and its associated physiotherapist training and related trial procedures is required to determine whether a full-scale parallel group (1:1) randomised controlled trial to evaluate the interventions effectiveness in clinical practice is indicated.

Trial registration Trial register: International Standard Randomised Controlled Trial identification number: ISRCTN12002764.

Date of registration: 15 February 2022.

Keywords Feasibility, Acceptability, Physical activity, Physiotherapy, Osteoarthritis, Adoption, Maintenance

Background

Osteoarthritis (OA) is the leading cause of individual level disability for elderly adults [1] and a significant socioeconomic burden [2] which is anticipated to continue to increase [3] and engulf global healthcare systems within 10 years [4]. Lower-limb (hip and knee) OA is of primary concern, with over 300 million global cases reported, which represents an increase of over 9% from figures detailed in 1990 [5]. In the United Kingdom (UK), approximately one-in-three people over 45 years, equating to 6.6 million individuals, experience lower-limb OA symptoms [1].

Strategies to promote physical activity (PA), including planned exercises and lifestyle activities [6], are fundamental aspects of non-pharmacological interventions to help patients reduce pain and optimise function in several international OA guidelines [1, 7–9]. Physiotherapists are specialists in the assessment and management of musculoskeletal conditions and the primary healthcare provider of PA interventions within the National Health Service (NHS) in the UK [10]. However, physiotherapy PA interventions help patients with lower-limb OA to moderate their clinical symptoms only over short time periods (≤ 3 -month post-baseline) with symptom recurrence about 6-month post-baseline [11, 12]. Therefore, patients with lower-limb OA may seek further treatment, which places additional strain on the healthcare services. Clinical symptom regression and subsequent re-referral are likely associated with difficulties that patients with lower-limb OA experience when maintaining their prescribed PA behaviours post-discharge [13].

The Medical Research Council (MRC) [14] recommends that behaviour change theory should be utilised when developing complex interventions. Using theory enables specific behavioural determinants (e.g. self-efficacy for PA) to be targeted by the interventions' treatment techniques [i.e. behaviour change techniques (BCTs)] [15]. Therefore, the interventions active ingredients can be modified over time, leading to potential increased clinical effectiveness on the target behaviour [15]. However, there is a lack of theoretical behaviour change interventions tested on patients with musculoskeletal pain [15].

Researchers postulate that individuals undergo several 'phases' of behaviour change when incorporating new behaviours into their lifestyle, with the most important phases for intervention delivery being *adoption/initiation* and *maintenance* [16]. In regard to the promotion of PA by physiotherapists, it is assumed that patients will be *adopting* PA behaviours, while receiving physiotherapy treatment and *maintenance* will be manifested and hopefully ongoing post-discharge. While it is likely that several BCTs are consistently relevant to the behaviour change process overall, others are more pertinent to either the adoption or maintenance of PA phase [17].

Randomised controlled trials (RCTs) are considered the gold standard procedure to evaluate the clinical effectiveness of an intervention. However, due to the complex processes and costs that occur when delivering and evaluating behaviour change interventions, robust scoping work prior to a definitive RCT is essential [18]. Feasibility trials are advocated to test implementation of the interventions' procedures [19] and trial design [18], thus informing whether a full-scale RCT is warranted [20]. To date, one theoretical physiotherapy behaviour change feasibility trial has been undertaken on patients with lower-limb OA. Hurley et al. (2020) [21] evaluated the feasibility and acceptability of a complex group intervention that aimed to promote self-management behaviours in patients with musculoskeletal pain. Although the intervention was highly acceptable, eligible participants preferred to be managed individually (i.e. one to one). Low recruitment rates and delays in commencing the group intervention led to a full-scale trial being unfeasible to deliver [21]. These issues have also been highlighted in research where patients and physiotherapists did not feel they received, or were unable to deliver, effective personalised treatment within the current time slots employed in the National Health Service (NHS) [22]. Furthermore, physiotherapists most commonly treat patients with lower-limb OA 1 to 1 in clinical practice [23], and this delivery may be more effective than group classes at aiding patients' self-management of their levels of pain and function [24].

To address these issues, an individually delivered, complex, multicomponent theoretical behaviour

change physiotherapy intervention has been developed. Briefly, the intervention and associated training programme (*Empowering Physio*[™]) are underpinned by self-determination theory (SDT) which focuses on the underlying reasons for individuals' behavioural engagement [25]. The overarching aim of the intervention is to create a more motivationally empowering treatment climate to deliver BCTs that target the determinants of PA adoption and maintenance in patients with lower-limb OA.

Aim

The trial has two primary aims:

- 1) To investigate the feasibility and acceptability of a complex, multicomponent theoretical behaviour change physiotherapy intervention in the view of patients with lower-limb OA and treating physiotherapists
- 2) To evaluate the feasibility and acceptability of trial-related procedures to participants and research-related staff

Objectives

Intervention feasibility and acceptability

To determine the feasibility and acceptability of the complex and multicomponent behaviour change intervention to participants and treating physiotherapists

To determine the acceptability of the bespoke *Empowering Physio* training programme to treating physiotherapists

To evaluate fidelity of intervention delivery by treating physiotherapists

Trial feasibility and acceptability

- To measure the recruitment rates of participants
- To measure the completeness of data collection of performance-based and patient-reported outcome measures at baseline, 3- and 6-month post-baseline
- To determine the feasibility and acceptability of trial-related procedures (recruitment, outcome assessment) to participants and research staff
- To determine the feasibility and acceptability of utilising an accelerometer as the primary outcome in a definitive randomised controlled trial
- To determine the acceptability of the patient-reported and performance-based outcome measures to participants

Methods

Ethics

The trial protocol has received a favourable ethical approval from the Health Research Authority via the Integrated Research Application System (IRAS number: 303710). This will ensure that the trial is conducted following best practice ethical guidelines. It will follow guidance from the Research Governance Framework for Health and Social Care and comply with the Data Protection Act 2018. Although clarification will be sought from the research team if a participant withdraws, they may do so without offering one, and their normal care will not be affected in anyway. If a person withdraws, data collected up to the point of withdrawal will be used to inform the analysis unless the participants specifically withdraw consent for this.

Trial design

The trial will utilise a single-centre mixed-methods feasibility design including a quantitative prospective, single-arm feasibility trial with a 6-month follow-up [18, 26] and a qualitative component to provide an in-depth examination of the intervention's feasibility and acceptability [20] in the view of participants, physiotherapists and research staff. Six months are the planned primary end point of the anticipated future definitive RCT. This is based on the generally accepted definition of behavioural maintenance in the literature [27] and large drop off in reported clinical effectiveness on PA behaviours [12] around this time point. This trial is registered with the International Standard Randomised Controlled Trial Number (ISRCTN) database (Trial ID: ISRCTN12002764) and follows Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) guidelines [28]. The trial is reported in accordance with the CONSORT Statement for Pilot and Feasibility studies [29] and the Consolidated criteria for REporting Qualitative research (COREQ) guidelines for quantitative and qualitative components respectively [30]. Figures 1 and 2 outline the flow of patients with lower-limb OA through the trial and the schedule of enrolment, intervention and assessments, respectively.

Trial setting and participant eligibility criteria

Patients referred for physiotherapy treatment of their hip or knee OA symptoms at the Royal Orthopaedic Hospital (ROH), Birmingham, will be invited to participate (please see Table 1 for eligibility criteria).

All intervention procedures will take place in the ROH physiotherapy clinics or virtually via phone or 'Attend Anywhere', the secure NHS video call service.

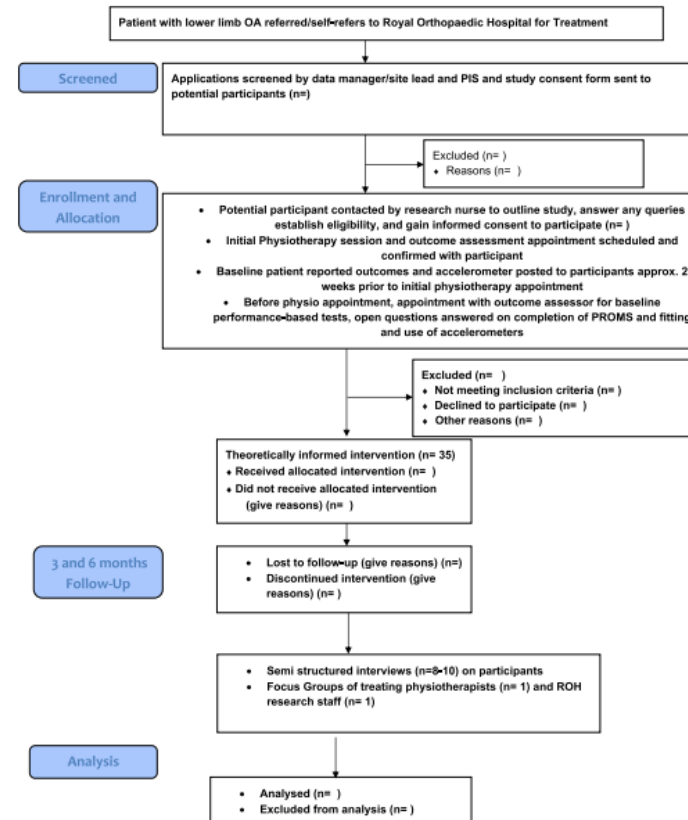


Fig. 1 Feasibility trial flow diagram

TIMEPOINT	STUDY PERIOD									
	Enrolment	Baseline	Treatment		Follow up		Intervention*	Focus groups**	Close-out	
	T0	T0	T1, T2	T3, T4	T5, T6	T7, T8	T9, T10	T11, T12	T13, T14	T15
ENROLMENT:										
Eligibility screen	X									
Informed consent	X									
Allocation	X									
INTERVENTION:										
ASSESSMENTS:										
Acceptability of intervention								X	X	
Acceptability of training									X	X
Intervention safety										X
Recruitment rates		X								
Completion rates of outcomes		X				X	X			
Feasibility and acceptability of procedures and outcome measures							X	X		
Feasibility and acceptability of accelerometer in future RCT							X			
Demographic characteristics		X								
Accelerometer		X			X	X				
Physical Activity and adherence		X			X	X				
Pain		X			X	X				
Function: Self-report and performance based		X			X	X				
Botheromeness/Quality of life		X			X	X				
Self-Efficacy		X			X	X				
Motivation Regulation and psychological needs satisfaction		X			X	X				
Perceptions of autonomy support					X					

Fig. 2 Schedule of enrolment, interventions and assessments

Table 1 Eligibility criteria

Inclusion criteria
Diagnosis of unilateral or bilateral lower-limb OA based on the NICE guidelines [1]
Males or females ≥ 45 years old as follows:
• Morning joint-related stiffness lasting ≤ 30 min or no morning joint-related stiffness
• Activity-related joint pain
Exclusion criteria
• A further joint-related pathology that could affect the biomechanics of the hip or knee, e.g. rheumatoid arthritis or lumbar nerve root lesion
• Previously had or awaiting knee or hip joint replacement
• Wheelchair dependent
• Unwilling/unable to give informed consent for treatment
• Unable to communicate fluently in English
• Diagnosed with a psychiatric illness (e.g. schizophrenia)
• Diagnosed with an upper motor neuron lesion, e.g. multiple sclerosis
• Unwilling/unable to attend physiotherapy sessions

Ongoing PA will be undertaken by people with lower-limb OA in their own home or the community.

Participant identification and consent

Feasibility trial

Potential participants will be identified from the physiotherapy waiting lists at the ROH by a member of the

research team. If the patient appears to meet the eligibility criteria, they will be sent a participant information sheet (PIS) and trial consent form via post. Each potential participant will be phoned by a research nurse a minimum of 1 week later. Potential participants will be asked if they have reviewed the PIS and if they are interested in trial participation. If they report being interested, the research nurse will confirm eligibility, outline the trial and answer any outstanding questions. Consent will be taken by the research nurse during the phone call and witnessed by another ROH staff member. During the meeting, the research nurse will reiterate that participants are free to withdraw from the trial at any time, and that this will not impact on their current or future healthcare [31].

Semi-structured interviews with participants

A purposive sample of patients who undergo the physiotherapy intervention ($n = 8-10$) will be invited to attend individual semi-structured interviews. Participation in the semi-structured interviews will be discussed at the 3-month post-baseline assessment with the research nurse, and consent will be gained in the same manner as for the main trial. If the participant consents to having an interview, the lead researcher (MW) will contact the participant approximately 1 week later. If participants choose not to engage with the interviews, the research

nurse will gently probe for any underlying reasons. If the participant chooses to divulge their reasons, these will be anonymously fed back to the lead researcher for data recording and further discussion in study steering meetings. Interviews will be offered either by telephone or skype/zoom depending on the participant's preference and will be scheduled as close to the end of their treatment sessions as convenient for the participant.

Focus groups with Royal Orthopaedic Hospital physiotherapists and research staff

All physiotherapists who deliver intervention ($n = 6-7$) and the ROH trial research staff team will be invited to attend focus groups. The participating ROH physiotherapists and research staff will be approached by the site lead researcher (GS), an advanced physiotherapy practitioner within the ROH. Prior to the focus groups, participants will be given the opportunity to ask any questions, and the PIS will be reviewed in real time. MW will conduct all semi-structured interviews and focus groups and establish informed consent prior to focus groups (intervention physiotherapists and ROH research staff, respectively). GS is experienced in clinical practice, establishing consent (has in-date GCP training), and conducting and analysing qualitative data obtained from semi-structured interviews and focus groups.

Multicomponent behaviour change intervention

The complex, multicomponent theoretical behaviour change intervention was developed iteratively through several interconnecting projects including the following:

- A systematic review that identified the most effective BCTs used in physiotherapy interventions to promote PA adherence in patients with lower-limb OA [12, 32]
- Semi-structured interviews with patients with lower-limb OA [17, 33]
- Focus groups with outpatient physiotherapists
- A scoping review and mapping exercise to identify appropriate theories of behaviour change to underpin the intervention delivery and physiotherapy training

The resulting intervention, which is underpinned by self-determination theory (SDT), has the overarching aim of creating a more motivationally empowering treatment climate and to implement particular BCTs to support patients with lower-limb OA to adopt and maintain appropriate individual levels of PA. Briefly, SDT outlines three universal psychological needs (competence, relatedness and autonomy) which influence the quality of an individuals' motivation (i.e. how self-determined that

motivation is) [34]. An individual's competence relates to their ability to effectively do the behaviour; autonomy refers to whether the engagement is voluntary and the degree of agency that an individual has with regard to the behaviour; relatedness involves feelings of being associated and optimally supported by others in regard to the behaviour [25]. SDT postulates that fulfilment of the 3 psychological needs leads to more autonomous forms of motivation and facilitates behaviour adoption and maintenance. A primarily SDT-based training programme *Empowering Coaching*, [35, 36], which has been adapted for delivery to physiotherapists (i.e. the bespoke *Empowering Physio* training), was selected to guide the training of the trial physiotherapists in regard to the motivational aspects of the intervention delivery. A brief overview of the sequential development of the intervention and associated training programme is outlined in the additional file 2, Appendix 1 and further detail will be provided in a subsequent paper.

Intervention materials and associated behaviour change techniques

Support material has been developed and will be utilised to assist delivery of intervention BCTs. Participants will be given two paper-based workbooks. The first workbook targets facilitating PA adoption by encouraging the patient to reflect on their PA preferences to identify appropriate patient-centred PA goals ('goal setting'; 'review behaviour goals') and includes a weekly activity planner ('action planner'). Each participant will be given a Yamax pedometer (Tokyo, Japan) to keep that will act as a self-monitoring device ('self-monitoring of behaviour'; 'feedback of behaviour') and as a thanks for partaking in the trial.

Participants will be given the second workbook in session 4. This workbook aids participants to identify necessary modifications to their physical and/or social environment ('problem-solving'; 'restructuring of the social environment') to help develop a PA routine and then maintain these behaviours ('habit formation'; 'generalisation of the target behaviour'). A detailed list of local PA services and supports is also included ('social support (practical)'). Each workbook is written using needs supportive language to aid participants' feelings of competence, autonomy and relatedness towards establishing PA as a lifestyle behaviour.

The trial-specific workbooks will be supported by the *Versus Arthritis* information booklets on knee or hip OA which outline general information on OA epidemiology, pathophysiology, management strategies (exercise and medication) and appropriate support services ('information on health consequences of performing the

behaviour'; 'information on social and environmental consequences'). An outline of the intervention materials, their intended sequencing and associated BCTs is outlined in Table 2.

The use of manual therapy techniques and supportive braces/walking devices will be incorporated into the intervention at the discretion of the treating physiotherapist [1]. Participants will be asked to not seek any additional treatments for their OA symptoms for the duration of the trial and to maintain their standard medications. Any co-interventions will be recorded in the assessment appointments with the research nurses.

Intervention delivery

Participants will attend individual intervention sessions (approximately six based on patient preference reflected in previous work related to the intervention development [33] and the standard number of physiotherapy sessions offered by the ROH) with the trained physiotherapists. Physiotherapy sessions will be conducted in person, via phone or 'Attend Anywhere' (based on participant preferences). Appointment frequency will depend on the participants' availability and related PA goals and the

physiotherapists' clinical schedules. The ROH's standard physiotherapy sessions are 45 min for an initial appointment and 30 min for a follow-up session.

Physiotherapist training

The bespoke *Empowering Physio*TM training programme aims to enhance physiotherapists' understanding of differences in the quality of patient motivation (and implications) and awareness of the treatment climate they create and how it can influence patients' psychological needs of competence, autonomy, relatedness and their subsequent autonomous motivation to adopt and maintain their PA goals. The training will involve presentations, and interactive exercises to convey why, when and how physiotherapists interact and provide feedback with patients during their treatment sessions may influence participants' levels of controlled and autonomous motivation to engage in PA. Delivery of the BCTs across PA adoption, routine formation and/or maintenance will be addressed including their theoretical background. The physiotherapists will receive printed and electronic versions of the *Empowering Physio*TM training workbook, a handbook with BCT definitions

Table 2 Intervention materials delivered across sessions and outline of content with associated theoretical constructs and behaviour change techniques

Session numbers	Intervention material	Intervention content	SDT constructs targeted	Associated behaviour change techniques
1–2	Activity Adoption Workbook	Aims of physiotherapy information on benefits of PA Exercises to identify patient-centred PA goals Activity diary	Autonomy Competence	• Goal setting (behaviour and outcome) • Problem-solving • Review behaviour goals (and/or outcome) • Action planning • Self-monitoring of behaviour (and/or outcomes of behaviour)
	Pedometer	Pedometer to self-monitor number of steps	Autonomy Competence	• Self-monitoring of behaviour (and/or outcomes of behaviour) • Feedback on behaviour (and/or outcomes)
	Versus Arthritis Book: Osteoarthritis of the Knee/Hip General Information	Epidemiology of OA Pathophysiology of OA General treatment strategies		• Information on health consequences of performing the behaviour • Information on social and environmental consequences • Modelling/demonstration of behaviour
3–4	Routine Formation and Maintenance Booklet	Problem-solving exercises to identify barriers and solutions to physical and social environment as needed to maintain PA Detail of local physical activity resources and support	Competence Autonomy Relatedness	• Problem-solving • Social support (practical) • Habit formation • Generalisation of a target behaviour • Restructuring of the social environment
Any	Theraband	Resistance band to enhance or make prescribed exercises more difficult	Autonomy Competence	• Prompts and cues • Habit formation • Adding objects to the environment

Legend: SDT Self-determination theory

and clinical examples and key research articles relevant to the intervention.

Intervention physiotherapists ($n=6-7$) will be trained by two members of the research team, Professor Joan Duda (JD), the founder of the *Empowering Coaching* programme who possesses a PhD in psychology and is an internationally renowned expert in motivational processes, and MW, whose PhD has focused on the development of the intervention. Training will include two 3-h, in-person group training sessions conducted on consecutive weeks and a follow-up 2-h 'top-up' session approximately 1 month later.

Trial outcomes and success criteria

Once data analyses are complete, the overall trial's success (i.e. trial-related procedures and intervention feasibility and acceptability) will be determined by evaluating the results against a priori established criteria for success (Table 3). The criteria were established by the Trial Management Group, which includes experts in musculoskeletal physiotherapy, ROH physiotherapists and researchers with expertise in trial methodology and behaviour change supported by contemporary literature in contemporary feasibility trial methodology [37]. Each criterion will be evaluated against guidance outlined by Thabane et al. (2010) [38] to determine if progression to a definitive trial is recommended. Possible outcomes include the following:

- Stop: A definitive trial is not feasible.
- Continue with modification: Modification of the protocol is required to make definitive trial feasible.
- Continue without modification: Modification of the protocol is not required to make definitive trial feasible but requires close monitoring.
- Continue without modifications: A definitive trial appears feasible.

Once it has been established if each criterion has been met, further consultation with patient and public involvement (PPI) at Trial Steering Group meetings will be utilised to determine if and what modifications the intervention requires to progress to the full-scale RCT (e.g. adaptations to intervention to enable delivery in alternative NHS physiotherapy departments).

Methods of data collection

Patient-reported and performance-based outcomes during trial

Participants will complete outcome assessment at baseline, 3-month post-baseline and 6-month post-baseline. Baseline outcome assessment appointments will

be scheduled immediately prior to participants' initial physiotherapy session. Outcome assessments are anticipated to be conducted virtually in the participants' own homes via phone or 'Attend Anywhere'. However, if participants do not feel confident about completing their performance-based outcomes at home, they will be offered a choice of having their baseline assessment done in person. Outcomes to be assessed include the use of an accelerometer to measure daily PA, patient-reported outcome measures (PROMs) and performance-based outcomes. Accelerometers and PROMs will be posted to participants' home addresses 1 week prior to outcome assessment appointments. A 150-cm tape measure will be included for standardisation of one of the performance-based tests (figure-of-8 walking test: Table 4) [47]. Participants will be asked to complete PROMs prior to assessment appointments so the session can be used to collect performance-based outcomes and answer any questions. A stamped, addressed envelope will be included for return of accelerometers (including simple fitting instructions and a belt to secure the accelerometer) and PROMs to the ROH. If accelerometers and PROMs are not returned within 2 weeks of their assessment appointment, participants will be contacted via text/telephone and asked to send them back at their earliest convenience.

The accelerometer will be fitted over the right anterior superior iliac spine [45, 46, 67]. Following a standardised and widely used protocol [68], participants will be asked to wear accelerometers for 7 consecutive days [43, 69–71] with removal for sleep or when in water (e.g. swimming or shower) [45, 46, 71, 72]. The patient-reported and performance-based outcomes to be assessed, including their rationale, are detailed in Table 4.

Collection of qualitative data

As the main aim of the qualitative component of the trial is to gain in-depth perspectives on the feasibility and acceptability of the trial intervention and associated processes, the epistemological stance is based on phenomenology [73]. Questions will initially be asked in an open manner with clarification sought if key points are identified. Participants, physiotherapists and research staff will be invited to introduce new topics and/or issues as the discussions progress. The respective topic guides have been developed a priori with questions determined through collaboration of the trial management team which includes clinical physiotherapists, researchers with expertise in qualitative research methods and behaviour change and PPI [74].

Table 3 Trial outcomes and success criteria

Aim 1: Intervention feasibility and acceptability		
Objective	Method of assessment	Success criteria
Objective 1.1: To determine the feasibility and acceptability of the complex and multi-component behaviour change intervention to participants and treating physiotherapists (P)	• Participants: Semi-structured interviews • Physiotherapists: Focus group	Continue without modifications Thematic analysis identifies that trial participants and treating physiotherapists found the intervention acceptable and feasible to deliver in the setting. In semi-structured interviews and focus groups respectively. Stop Thematic analysis suggests that trial participants and treating physiotherapists did not find the intervention satisfactory (i.e. it was unfeasible and/or unacceptable)
Objective 1.2: To determine the acceptability of the bespoke Empowering Coaching training programme (Empowering Physio) to treating physiotherapists (P)	• Focus group	Continue without modifications Thematic analysis identifies that intervention physiotherapists perceived that the EC training programme developed their understanding and enactment of behaviour change strategies and that the Empowering Physio programme was acceptable to deliver. Thematic analysis suggests that intervention physiotherapists perceived that the EC training programme was insufficient to develop their understanding or enactment of how to create an empowering treatment climate • Essential pre-specified BCIs are delivered with at least mean moderate levels of fidelity (≥ 50%) [40] • At least 80% of participants completed the programme and evaluate treatment climate [41]
Objective 1.3: To evaluate fidelity of intervention delivery by treating physiotherapists (S)	• Two members of the research team will assess transcripts of one intervention session from the adaptation, routine formation and maintenance phases from first and third participants for the following: 1) Intervention content by coding of BCIs 2) Treatment climate using the SPACOT [39]	
Aim 2: Trial feasibility and acceptability		
Objective	Method of assessment	Success criteria
Objective 2.1: To measure the recruitment rates of participants (P)	• Recording number (n) of participants who were sent a participant information sheet, number who agreed to participate and number recruited per month	Continue without modification • Target of n = 35 participants recruited in 9 months (approx. 4/ month) • Conversion rate of ≥ 30% (number sent PSY/ number who agreed to participate) Stop • Target of n = 15 participants recruited in 3 months (less than 3/ month) • Conversion rate of ≤ 15% (number sent PSY/ number who agreed to participate)
Objective 2.2: To measure the completeness of data collection of performance-based and patient-reported outcome measures at baseline, 3- and 6-month post baseline (P)	• Record number of PROMs returned to trial team and number of participants who completed performance-based outcomes during virtual outcome assessments at each timepoint	Continue without modification • ≥ 80% PROM and performance-based data collected at 3-month post baseline • ≥ 80% PROM and performance-based data collected at 6-month post baseline Stop • ≤ 50% PROM and performance-based data collected at 3-month post baseline • ≤ 50% PROM and performance-based data collected at 6-month post baseline

Table 3 (continued)

Objective	Method of assessment	Success criteria
Objective 2.3: To determine the feasibility and acceptability of trial-related procedures (recruitment, outcome assessment) to participants and RCH research staff (P)	• Participants: Semi-structured interviews • RCH research staff: Focus groups	Continue with modification • Thematic analysis identifies that trial participants and RCH research staff are satisfied (i.e. feasible and acceptable) with trial procedures (eg. recruitment, outcome assessment) in semi-structured interviews and focus groups respectively Stop • Thematic analysis identifies that trial participants and RCH research staff are not satisfied (i.e. they do not perceive it is feasible and/or acceptable) with trial procedures (eg. recruitment, outcome assessment) in semi-structured interviews and focus groups respectively
Objective 2.4: To determine the feasibility and acceptability of utilising an accelerometer as the primary outcome in a definitive randomised controlled trial (S)	• % of accelerometers returned to research staff with valid data • Semi-structured interviews	• ≥ 70% of accelerometer data collected at 6-month post-baseline • Accelerometer data will be considered valid if it has been recorded for at least 3-4.5 h for ≥ 47 days, with at least one falling within the range of 144-660 • Participants state that they believe that accelerometer is feasible and acceptable to use as the primary outcome measure in future definitive trial
Objective 2.5: To determine the acceptability of the patient-reported and performance-based outcome measures to participants (S)	• Semi-structured interviews	• Participants report that they found the patient-reported and performance-based outcomes feasible and acceptable, and the time taken to complete was satisfactory for use in a definitive randomised controlled trial

Legend: SPACOT: Interpersonal support in physical activity consultations: observational; Primary feasibility outcome related to progression to definitive trial; Secondary feasibility outcome

Table 4 Planned participant secondary outcome measures for randomised controlled trial

Outcome domain	Instrument	Administered at	Rationale
Physical activity	Short-Form-7 (questions) International Physical Activity Questionnaire [48]	Baseline, 3 months, 6 months	Primary aim of physiotherapy intervention. Has demonstrated reliability and validity [48]
Adherence to PA/Exercise recommendations	Section B of the Exercise Adherence Rating Scale (6 items) [49]	Baseline, 3 months, 6 month post-baseline	Primary aim of the physiotherapy intervention. Has demonstrated reliability [49] and validity [50]
Pain	11-point Numerical Pain Rating Scale [51]	Baseline, 3 months, 6 months	Suggested to include as a core outcome domain in international guidelines [51]. Shown excellent reliability [52] and suggested as more reliable than a visual analogue scale in patients who are older or have more pain and more useful for demonstrating change [53]
Function: Self-report	Short-Form Hip Disability and Osteoarthritis Outcome Score-SF-HOOS/Short Form Knee Injury and Osteoarthritis Outcome Score (SF-400S) [51]	Baseline, 3 months, 6 months	Suggested to include as a core outcome domain in international guidelines [51]. Have shown good levels of reliability [54, 55]
Function: Performance based	Fivetimes sit-stand test	Baseline, 3 months, 6 month post-baseline	Has demonstrated excellent validity and reliability. Direct, observable measure of physical function. When tested in home setting [56]
	Figure of 8 walking test	Baseline, 3 months, 6 months	Has demonstrated excellent validity and reliability when tested at home [47]
Both/Perceptions	Both/soresness index: 5-point Likert scale	Baseline, 3 months, 6 months	Outlined as important outcome domain by public involvement representative
Quality of life	EuroQol-5-domain instrument (EQ-5D) [51]	Baseline, 3 months, 6 months	A domain recommended by international guideline. Has shown good reliability and validity [57]
Self-efficacy for physical activity/exercise	Self-Efficacy for Exercise Scale 9 items [58]	Baseline, 3 months, 6 months	Outlined as an important influence on behaviour in international guidelines [51]. Validity and aspects of self-efficacy including perceived barriers to exercise [59]. Valid and reliable [58]
Motivation/regulations to participate in physical activity/exercise	Behavioural Regulation in Exercise Questionnaire-3, 24 items [60, 61]	Baseline, 3 months, 6 months	Motivation was outlined as important influence on behaviour change in preliminary work. Grounded in SDT. Important stage of intervention process model. Valid [60, 62] and reliability [63]
Psychological needs: satisfaction	A modified version of the Psychological Need Satisfaction in Exercise Scale [64, 65]	Baseline, 3 months, 6 months	Grounded in SDT. Important stage of intervention process model. Valid and reliable [64, 65]
Social/psychological environment/perceptions of autonomy support	Health Care Climate Questionnaire 15 items [66]	3-month post-baseline	Assesses the participants' perceptions of five motivational social constructs provided in physiotherapy intervention. Validity and reliability of the intervention process model. Identified as an important influence on behaviour change in preliminary work. Reliable

Two researchers will use the Interpersonal Support in Physical Activity Consultations Observational Tool (ISPACOT) [39], a 21-item tool that is grounded in SDT, which will be used to evaluate the treatment climate of the physiotherapy sessions. The tool assesses four aspects of the motivational climate created as follows: autonomy support, involvement, structure and interpersonal

control and has demonstrated moderate to high levels of inter-rater reliability when assessments are carried out by trained users [39]. A 7-point Likert scale, ranging from 1 'not at all true' to 7 'very true', will be used to determine the degree of need support. The mean Likert scores will be calculated for all physiotherapists and reported for the adoption, routine formation and maintenance phases, respectively. In line with previous research, scores of $\geq 4/7$ will be considered the minimum required to deliver a need supportive treatment climate [41, 79].

Qualitative data analysis

The interviews and focus groups will be audio recorded and transcribed verbatim. Interviews and focus groups will not be repeated. However, transcripts will be returned to participants/physiotherapists/research staff for member checking and any supplementary comments which are highlighted will be presented to the Trial Steering Group, noted and integrated with the main analysis [80]. MW will take supplementary field notes during the interview process to enable triangulation during data analysis.

All transcripts will be analysed following a six-step deductive method as outlined in Braun and Clarke (2006) [81]. To analyse the semi-structured interviews, two researchers will code the first transcript together to establish a preliminary framework and identify initial themes using NVivo 11 software (QSR International, Melbourne, Australia). A second transcript will be coded independently by the same two researchers with in-depth meetings planned to test the initial framework. The remaining transcripts will be coded by both researchers, with codes and emerging themes clarified through researcher meeting (approximately every two–three transcripts). Focus groups will be undergo the same analysis by two researchers. Iterative results from semi-structured interviews and focus groups, supported by direct quotations, will be presented to the research team and at Trial Steering Group meetings for feedback and challenge.

Additional information

Further trial information, including data storage, monitoring of adverse events and intended dissemination of findings, can be viewed in the additional file 2, Appendix 2.

Discussion

Lower-limb OA is a prevalent and painful condition that impacts the quality of life in adults ≥ 45 years old. International guidelines support optimising PA to help manage clinical symptoms associated with OA. However, people with lower-limb OA are generally less active

than other people of a similar age. Optimising PA levels requires people to alter their behaviours, and this is thought to be most easily accomplished if the treatment incorporates behaviour change theory. Theoretical interventions have demonstrated significant improvements in PA levels in several populations with secondary noncommunicable diseases. Therefore, the main aim of this trial is to determine the acceptability and feasibility of delivery of a complex, multicomponent theoretical physiotherapy behaviour change intervention that aims to optimise adoption and maintenance of prescribed PA in patients with lower-limb OA.

The behaviour change intervention has been developed targeting the specific behavioural determinants of PA adoption and maintenance. It has been developed sequentially over a series of projects including a systematic review and a qualitative project incorporating the views of patients with lower-limb OA and heavily influenced from feedback from PPI.

Key methodological considerations were discussed extensively within the SSC at the trial planning stage. These included the primary data collection end point and choice of a single-arm or randomised parallel two-arm trial design.

Within the behaviour change literature, the concept of behavioural 'maintenance' suffers from considerable heterogeneity [16]. However, the most utilised definition in empirical studies is that proposed in the transtheoretical model, which suggests behavioural maintenance occurs after approximately 6 months of behaviour change practice (i.e. when a behaviour change intervention commences) [82]. Although this definition is based on addictive behaviours, it has also been utilised in previous systematic reviews examining PA in healthy young and middle-aged [83] and inactive adult populations [84].

Interestingly, the effectiveness of physiotherapy delivered BCTs on PA behaviours (as measured by effectiveness ratios) was lowest at 6-month post-baseline compared to other time points in our systematic review [12]. Furthermore, there appeared to be a drop off in the amount of available data for analysis at this timepoint. Therefore, a 6-month post-baseline was chosen as the primary end point for our feasibility study. However, if a definitive RCT is indicated once analysis is complete, it is anticipated that the interventions effectiveness will be measured at further time points post-baseline (e.g. 9 and/or 12 months) to capture this data for further analysis.

There have been an extensive number of RCTs conducted on patients with lower-limb OA, and methodological aspects such as randomisation have already been established. As information on these features exists, and STAPLO feasibility trial does not aim to test the interventions effectiveness, adding a parallel arm was considered

unresourceful and potentially unethical. To this end, a single-arm study with a sample size great enough to provide a normal distribution of patients was planned [85].

This trial design should enable purposive sampling to gain a wide range of opinions on the feasibility and acceptability of the intervention from participants, intervention physiotherapists and research staff. Furthermore, study research nurses were not informed of the trials' overall design (single arm versus parallel arms) or primary aims during training. Therefore, they are considered blind assessors in the STAPLO trial. The results of several large scales, low risk-of-bias RCTs, from those identified in our systematic review, [12, 86] and conducted locally, [87] will be used to inform methodological decisions, such as a sample size calculation, if a full-scale definitive trial is indicated.

The proposed intervention protocol has been concept tested against physiotherapists working clinically and further refined to encompass theories of behaviour change. Feasibility examination is required prior to its effectiveness being determined.

Abbreviations

OA	Osteoarthritis
PA	Physical activity
BCT	Behaviour change technique
UK	United Kingdom
NHS	National Health Service
MRC	Medical Research Council
SDT	Self-determination theory
CONSORT: ISRCTN	International Standard Randomised Controlled Trial
SPRIT	Number
	Standard Protocol Items Recommendations for Interventional Trials
COREQ	Consolidated criteria for REporting Qualitative research
ROH	Royal Orthopaedic Hospital Birmingham
PIS	Participant information sheet
PROM	Patient-reported outcome measure
EC	Empowerment coaching
V1	Version 1
ISPRACOT	Interpersonal Support in Physical Activity Consultations Observational Tool

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s40814-023-01274-6>.

Additional file 1: The Staying Active with Physiotherapy in patients with Lower-limb Osteoarthritis (STAPLO) Feasibility Trial – Consent Form. The Staying Active with Physiotherapy in patients with Lower-limb Osteoarthritis (STAPLO) Feasibility Trial – Interview Consent Form. Physiotherapist focus group consent form. Research staff focus group consent form.

Additional file 2: Appendix 1. Overview of intervention development. **Appendix 2.** Additional Trial Information, Table 1: Adverse Event Definitions.

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Authors' contributions

MW is a PhD student. JD, AR and CG are the academic supervisors of MW. JD is the CL and MW is the PI of the trial. MW, JD, AR and CG conceived the trial. MW and JD contributed to the underpinning theory of the intervention. MW applied for funding and ethical approval. GS is the site lead, and SR is the trial co-ordinator and will assist in data collection. GS and SR advised on trial design and site-specific feasibility parameters. SF advised and will assist on accelerometry collection and data analysis. MW drafted the protocol. Critical feedback was provided by JD, AR, CG, GS and SF. MW, AR, JD, ED, GS and SF will contribute to Trial Steering and Management Groups respectively. MW, GS and SR will be responsible for data monitoring. MW will be responsible for data analysis. The authors read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analysed during the current trial will be available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Ethics approval was granted on the 10/11/2021 from the Health Research Authority reference number (21/09/1490). Written informed consent will be obtained from all participants.

Consent for publication

Not applicable. No identifiable details (including images and videos) relating to an individual person will be published.

Competing interests

The authors declare that they have no competing interests.

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Appendix 2.1 Fidelity domains and components assessed in trials

Fidelity Domain	Conceptual Definition (Borelli et al., 2011)(172)	Components evaluated (Borelli et al., 2011)	Example where component would be coded as present
Study Design (16 components)	Determines whether the trial protocol satisfactorily evaluates its proposed hypotheses through appropriate underlying theory /mechanisms of action influence	Provide information about treatment dose in the intervention condition - Length of contact (minutes) - Number of contacts - Content of treatment - Duration of contact over time Provide information about treatment dose in the comparison condition - Length of contact (minutes) - Number of contacts	Providers complete an intervention checklist after each participant contact indicating the length of the visit. Number of intended intervention sessions clearly described in protocol or trial paper and mean/median number reported. Providers complete intervention checklist after each participant contact indicating the components delivered. Providers complete intervention checklist after each participant contact indicating the length of the visit Providers complete an intervention checklist after each participant contact, indicating the length of the visit. Number of intended intervention sessions clearly described in

• Content of treatment	protocol or trial paper and mean/median number reported. Intervention techniques and materials of intervention clearly described in protocol or trial paper Providers complete intervention checklist after each participant contact indicating the components delivered.
• Duration of contact over time	Providers complete an intervention checklist after each participant contact indicating the length of the visit
Method to ensure that dose is equivalent between conditions.	Dose of intervention and comparator interventions are equivalent based on methods (protocol and trial paper) and reported in final write up.
Method to ensure that dose is equivalent for participants within conditions	Paper reports mean/median number of treatment sessions within in each intervention group. Where two active interventions are compared, the number of sessions are approximately equivalent.
Specification of provider credentials that are needed	Protocol or trial paper outlines minimum qualifications/experience required to deliver interventions e.g. 'each treating physiotherapist was required to have a MSc in musculoskeletal physiotherapy.'
Theoretical model upon which the intervention is based is clearly articulated.	

• The active ingredients are specified and incorporated into the intervention • Use of experts or protocol review group to determine whether the intervention protocol reflects the underlying theoretical model or clinical guidelines • Plan to ensure that the measures reflect the hypothesized theoretical constructs/mechanisms of action • Potential confounders that limit the ability to make conclusions at the end of the trial are identified	The techniques included within interventions (i.e. BCTs) are clearly described in the intervention or protocol paper. Designers of the intervention are renowned experts in the theory of behaviour change that the intervention is based upon and theoretical model is articulated linking constructs to techniques in the protocol/trial write up. Outcome measures are explicitly linked to the behaviour change techniques (e.g. self-efficacy is evaluated and linked to the BCT demonstration of behaviour/modelling). Other interpretations for interventions effectiveness/or lack of on intended constructs are included in the write up (usually in discussions or limitations sections)
Plan to address possible setbacks in implementation	Trial or protocol paper outlines plan to recruit and train further physiotherapists if current providers leave trial prior to completion.
If more than one intervention is described, all described equally well.	Both intervention and any equivalent comparator groups (active interventions) described in equivalent details.

Provider Training (7 components)	Outlines provider training and determines the interventions providers	Description of how providers will be trained (manual of training procedures)	Trial outlines a training manual of procedures was given to intervention providers

ability to deliver the intervention throughout study.

Standardization of provider training

Standardised training (content of training, timing of training, identity of training providers) is detailed in trial paper and consistent across sites.

Assessment of provider skill acquisition.

Training involves monitoring or role play with feedback from instructor
Measurement of skill acquisition from training e.g. Kirkpatrick methods

Assessment and monitoring of provider skill maintenance over time

Physiotherapist audio records intervention session and sends to trainer via encrypted email. Trainer reviews recording and provides feedback to physiotherapist of their performance.

Characteristics being sought in a treatment provider are articulated a priori. Characteristics that should be avoided in a treatment provider are articulated a priori.

Protocol details level of physiotherapy experience (e.g. minimum of 5 years) treating patients

At the hiring stage, assessment of whether or not there is a good fit between the provider and the intervention

Intervention presented to physiotherapists in local setting prior to implementation to determine acceptability for delivery

There is a training plan that takes into account trainees' different education and experience and learning styles

Training details appropriate additional -individualised top up training (e.g. feedback on patient encounter) as required by physiotherapist.

Treatment Delivery
(9 components)

Assessment/monitoring of the intervention's delivery within the trial

Method to ensure that the content of the intervention is delivered as specified.

Observation/assessment of provider delivering intervention via appropriate means (direct

Method to ensure that the dose of the intervention is delivered as specified	observation, use of digital recordings). Raters code whether intervention content delivered and provide feedback to intervention providers. Monitoring of number of intervention session delivered by individual physiotherapists throughout trial. If specific physiotherapist is providing greater/few number of sessions than expected, feedback provided by trial team.
Mechanism to assess if the provider actually adhered to the intervention plan or in the case of computer delivered interventions, method to assess participants' contact with the information	Observation/assessment of provider delivering intervention via appropriate means (direct observation, use of digital recordings). Feedback provided to physiotherapists as required.
Assessment of non-specific treatment effects.	Intervention sessions are audio recorded and communication style rated on 5-point Likert scale
Use of treatment manual	Trial or protocol details that a treatment manual was supplied to intervention providers for reference.
There is a plan for the assessment of whether or not the active ingredients were delivered.	• Observation/assessment of provider delivering intervention via appropriate means (direct observation, use of digital recordings).

There is a plan for the assessment of whether or not proscribed components were delivered. (e.g., components that are unnecessary or unhelpful)

- Raters code for protocol behaviour change techniques.
- Observation/assessment of provider delivering intervention via appropriate means (direct observation, use of digital recordings).
- Raters code for non-protocol behaviour change techniques.

There is a plan for how contamination between conditions will be prevented

Provider training includes an education/discussion of the importance of preventing treatment contamination

There is an a priori specification of treatment fidelity

The protocol or trial paper outlines that providers are required to adhere to delivering >80% of intervention behaviour change techniques.

Treatment Receipt
(5 components)

Determines whether the patient understood the treatment received and their accuracy of that understanding.

There is an assessment of the degree to which participants understood the intervention

After physiotherapist instructs their patient in an exercise, the patient rates their confidence (e.g. from 1-10) that they can perform it at home.

The physiotherapist asks what could make the patient feel more confident to complete exercise at home.

There is specification of strategies that will be used to improve participant comprehension of the intervention.

Physiotherapist supplies patient with a video of prescribed exercises.

The participants' ability to perform the intervention skills will be assessed during the intervention period

A strategy will be used to improve subject performance of intervention skills during the intervention period

Multicultural factors considered in the development and delivery of the intervention

The participant demonstrates their prescribed exercises during their session and is monitored by the physiotherapist

The participant demonstrates their prescribed exercises during their session and is monitored by the physiotherapist who provides feedback on performance

Intervention materials are reviewed by patients with lower-limb OA at the trial set up stage.

Treatment
Enactment
(2 components)

Assessing whether the intervention facilitates use of skills/practice in general day to day activities

Participant performance of the intervention skills will be assessed in settings in which the intervention might be applied.

Virtual call from physiotherapist where participant completes exercises

A strategy will be used to assess performance of the intervention skills in settings in which the intervention might be applied.

Virtual call from physiotherapist where participant completes exercises and receives feedback on performance.

Appendix 2.2: Characteristics of Included Trials

Trial /Country	Type of OA	Comparison Group		Behavioural Physiotherapy intervention		Delivery and training	
		N, (M/F), Mean age	Content	N, (M/F), Mean Age	Content and PA adherence BCT:	Delivery	Training in BCT delivery
Bennell 2005, Australia	Knee	67 (23/44), 69.8	Sham Ultrasound, no detail on dose or timings	73, (23/50), 67.4	4 x 30-45 minute weekly sessions, followed by 4 x fortnightly sessions with the physiotherapist with HEP and taping provided. Log book given to measure HEP adherence.	Physiotherapist only	Trial mentions training and treatment manual given to physiotherapists by one researcher but no detail on timing or additional content
Bennell 2010, Australia	Knee	44(24/20), 64.6	No Intervention	45, (22/23), 64.5	5 weekly and 2 fortnightly (7 total) Physiotherapy sessions (30-minute initial and 15 minutes follow up) with HEP provided. Diary of home exercises (% of 60 days) to measure adherence	Physiotherapist only	Both protocol and trial mention training but no detail provided by whom, timing or content
Bennell 2014, Australia (Original trial not included)	Knee	38, (18/20), 63.7	Participants asked to continue with HEP from original RCT – outcomes assessed via questionnaire at 24 weeks (mail out	40, (24/16), 60.5	Control + 2 x individual booster sessions with physiotherapist with HEP adherence counselling and problem solving encouraged at weeks 8 and 16	Physiotherapist only	3-hour training during original RCT.
Bennell 2014b, Australia	Hip	53, (17/36), 62.7	Sham Ultrasound	49, (23/26), 64.5	10 sessions of 30-60 minutes over 12 weeks with HEP provided. Log book given to measure HEP adherence. Phone calls to monitor adherence (treatment manual)	Physiotherapist only	2-day workshop with treatment manual and DVD provided
Bennell 2016, Australia	Knee	PSCT: 74, (45/29), 63.0; Exercise: 75, (44/31), 62.7;	PSCT: 10 x 45-minute sessions with physiotherapist over 12 weeks; Sessions were PCST and training and homebased practice encouraged, Physiotherapists telephoned patients to discuss progress and adherence in weeks 22,38 and 46. Exercise: 10 x 25-minute sessions with physiotherapists over 12 weeks. HEP given to patients. Physiotherapists telephoned patients to discuss progress	73, (44/29), 64.6;	10 x 70-minute sessions with physiotherapists over 12 weeks teaching both HEP and PCST to patients. Physiotherapists telephoned to discuss progress and adherence to the home program in weeks 22, 38 and 46.	Physiotherapist only	PCST: Psychologist led 4-day group workshop, followed by group tutorials and individual practice, feedback provided from Audio recordings Exercise: 4-hour workshop with treatment manual and DVD of workshop provided

			and adherence in weeks 22,38 and 46				
Bennell 2017, Australia	Knee	84, (27/57),61.1	5 x 30-minute sessions over 6 months with physiotherapist focusing on HEP and education. Log book and Pedometer given to patient to monitor adherence.	84, (35/29), 63.4	Physiotherapy control + 6-12 telephone-delivered coaching sessions (30-45-minute initial; 15-30 minute follow up) with nurse over 6 months to encourage adherence to PA and adherence behaviours	Physiotherapist s: Exercise component Health coach (nurse, occupational therapist, psychologist): Telephone component	Physiotherapists: One-day training and provision of treatment manual Health coaches: One-day training of health coaches with no experience had additional 3 day 'Health change Australia' training with lead researcher. Practice sessions between days 2-3 of course with one face to face session with lead researcher and 3 practice patients provided. Initial 2 patients reviewed and feedback given. Further feedback as needed.
Crossley 2015, Australia	Knee	48, (19/29), 53	8 x 60-minute education sessions delivered with physiotherapist	44, (20/24), 56	8 x 60-minute (1/week for 4 weeks, then 1/week fortnightly for 8 weeks) Physiotherapy sessions with HEP, manual therapy and taping. Log book to monitor adherence to HEP.	Physiotherapist only	6 hours of training provided to physiotherapists by lead researcher and treatment manual given. Monitoring mentioned but no detail provided
Deyle 2000, USA	Knee	36, (18/18), 62.4	Sub therapeutic ultrasound. 8 x 30minute sessions (2/ week for 4 weeks) with physiotherapists	33, (12/21), 59.6	8 x 30-45-minute sessions (2/ week for 4 weeks) with physiotherapist with HEP. Logbook given to monitor HEP adherence.	Physiotherapist only	No detail on training provided
Dincer 2016, Turkey	Knee	16, (3/11),52.9,	15 sessions x 30 minutes (5/ week for 3 weeks) with physiotherapist providing TENS and hot-pack	19, (3/13), 49.5	Placebo + 15 sessions x 30 minutes (5/ week for 3 weeks) with physiotherapist, with HEP followed by 9 x weeks of home exercises. Adherence checked by phone fortnightly	Physiotherapist only	No detail on training provided
EMPART (French) 2013, Ireland	Hip	43 (20/23), 60.8	Waitlist control	Group 1: Exercise Physiotherapy 45 (11/34), 61.8	Group 1: Exercise Physiotherapy 6 – 8 x 30 min sessions over 8 weeks with physiotherapist. HEP taught. Activity and home exercise diaries to monitor adherence.	Physiotherapist only	Training in exercises and manual therapy provided in 2 sessions by lead researcher and treatment manual given to participating

				Group 2: Exercise and manual Physiotherapy: 43(16/27), 64.8	Group 2: Exercise and manual Physiotherapy: 6-8 x 45-minute sessions over 8 weeks with physiotherapist including 30 min of exercise therapy and up to 15 min of manual therapy; Activity and home exercise diaries to monitor HEP adherence.		therapists. No detail on length of sessions.
Hiyama 2012, Japan	Knee	20, (0/20), 73.8	4 weekly sessions including exercises and cryotherapy	20, (0/20), 71.9	Physiotherapy control plus PA walking goal set.	Physiotherapist only	No detail on training provided
Hunt 2013, Australia	Knee	10, (NS), 59.8	10 x 60-minute sessions with physiotherapist with HEP plus NDC.	10, (NS), 66;	10 x 60 minute weekly sessions with physiotherapist focusing on HEP plus PCST training to change patients PA behaviours.	Physiotherapist only	PCST: Psychologist led two-day training workshop with follow up tutorials and practice with feedback. Physiotherapists had to meet written criteria prior to accreditation. NDC plus exercise: one-day training session with practice integrated into session.
Jones 2012, Brazil	Knee	32, (NS: 11/89 total) 62.6	Control, no cane intervention – instructed to use no gait devices	32, (NS: 11/89 total) 61.8	1 x 5-minute physiotherapy session for provision on Cane and education on its use. Adherence to cane use in intervention group documented via chart	Physiotherapist only	No detail on provider training given
Kawasaki 2009, Japan	Knee	42, (0/42), 69.5	9 Hyaluronate injections (1/week for 5 weeks; 1 / month for 4 months).	45, (0/45), 71.2	2 sessions (initial plus 1 month) with Physiotherapist instructed on HEP. Diary measured adherence to HEP.	Physiotherapist only	No detail on provider training given
Kuru- Colak 2017, Turkey	Knee	23, (9/24), 60 .	18 sessions of 40-45 mins (3/ week for 6 weeks) focused on HEP	23, (15/8), 59	Home based exercise programme; 1 x physiotherapy session where HEP taught. Weekly Follow up telephone call to monitor adherence for 6 weeks.	Physiotherapist only	No detail on provider training given
Lim 2008, Australia	Knee	54 (25/29), 63.6	No intervention	53, (23/30), 65.6	7 sessions over 10 weeks with a physiotherapist focused on HEP. Diary measured HEP adherence.	Physiotherapist only	No detail on provider training given
MOA (Abbott) 2013, New Zealand	Hip and Knee	51, (26/25), 66.1	No Intervention	Group 1: Exercise physiotherapy 51 (19/32), 66.9 Group 2: Exercise physiotherapy plus Manual Therapy	Group 1: Exercise physiotherapy 11 x 50-minute sessions (1 /week for 9 weeks + 2 booster sessions at week 16) focused on HEP. Diary measured HEP adherence. Group 2:	Physiotherapist only	3 days of training by lead researcher including treatment protocol, monthly team meetings and feedback

				50, (21/29), 66.0	Exercise physiotherapy plus Manual Therapy 11 x 50-minute sessions (1 /week for 9 weeks + 2 booster sessions at week 16) focused on HEP with addition as manual therapy. Diary measured HEP adherence.		
Odole 2013, Nigeria (includes Odole¹)	Knee	25, (14/11), 55	18 sessions (3 x week for 6 weeks) with physiotherapist focused on exercise in clinic only.	25, (14/11), 56	1 x Physiotherapy session with Physiotherapy focused on HEP. 18 sessions of Tele-physio (3 / week for 6 weeks) exercise log book given to monitor HEP adherence.	Physiotherapist only	No detail on provider training given
Schlenk 2011, USA	Knee	13, (NS Overall: 1/25) NS Overall: 63.2	1 session with physio at end of 6 months intervention phase.	13, (NS Overall: 1/25) NS Overall: 63.2	6x 60-minute physiotherapy sessions physio focussing on HEP and 9 fortnightly phone calls (15-30 Mins) with registered nurse focusing on PA adherence and behaviour change. PA diary given to monitor PA adherence and reviewed during telephone consults.	Exercise component: Physiotherapist Telephone Component: Nurse	No detail on provider training given
Segal 2015, USA	Knee	19 (9/10), 69.6	Arthritis Foundation symptom diary	29, (7/22), 69.1	24 x 45 min (2/ week for 12 weeks) sessions with physio focused on walking education. 4 x telephone motivational interviewing counselling sessions with physiotherapist (months 4,5,8 and 10) to monitor and encourage PA adherence.	Exercise component: Physiotherapist Telephone Component: Not clear ('researcher')	No detail on provider training given
Teirlinck 2016, The Netherlands	Hip	102, (46/56), 67	Usual care given by patients GP and brochure about hip OA	101, (38/63), 64	UC + 12 x 30-minute sessions over 3 months with Physiotherapist focusing on HEP. 3 x Booster sessions in month 5, 7, 9. Physiotherapist recorded PA adherence at each session.	Physiotherapist only	Training at consensus meeting of Dutch physiotherapy guide lines and treatment manual mentioned but no detail on length of training or by whom.
Van Baar 1998, The Netherlands (Includes Van Baar, 2001)	Hip and Knee	102, (21/81), 67.7	GP only	98, (22/76), 68.3	UC + Physiotherapy sessions: Up to 3/ week for 12 weeks (30-minute duration) focused on HEP. Telephoned to check adherence to HEP in weeks 6 and 12.	Physiotherapist only	2 training sessions in protocol given. Exercises reviewed and practiced. No detail on length of sessions or who provided training (assumed lead researcher based on

Veenhof 2006, The Netherlands (Includes Pisters, 2010^{1, 2, 3})	Hip and Knee	103, (22/81), 64.5	18 x 30-minute sessions over 12 weeks with a physiotherapist focused on HEP based on the Dutch physiotherapy guidelines.	97, (24/73), 65.1	18 x 30-minute sessions over 12 weeks with 5-7 x 30-minute booster sessions between weeks 18-55 with physiotherapist. Sessions based integrated operant conditioning and exercise therapy focusing on PA adherence.	Physiotherapist only	protocol development). Behavioural Physiotherapy: 2-day training with supervision via telephone throughout trial Control Physio: 4-hour workshop on Dutch guidelines. No details on who provided training.
Wallis 2017, Australia	Knee	23, (12/11), 67	No intervention	23, (14/9), 68	1x 30-minute session with a physiotherapist to plan walking location/ time/ duration. Weekly session with Physiotherapist to monitor walking. SMS and telephone monitoring with physiotherapist. Pedometer and log book given to monitor PA adherence.	Physiotherapist only	No detail on provider training given

Key:

BCT: Behaviour Change Technique ; OA: Osteoarthritis ; ACR: American College of Rheumatology; HEP: Home exercise programme; RCT: Randomized controlled trial; PCST: Pain Coping Skills Training; BL: Baseline ; NDC: Non-directive counselling.

Appendix 2.3: Physical Activity and Adherence outcomes in Included Trials

Outcome Measure (PA/ adherence measure domain)		Outcome Timings / Effect sizes (Continuous outcome; SMD (95% CI); Dichotomous; PR (95% CI))		
Trial		Short	Medium	Long
Bennell 2005	Adherence: Diary to measure HEP done in intervention group. Not measured between groups.	12 Weeks	24 Weeks	NM
Bennell 2010	Physical Activity (self-report): - PASE Adherence: - Diary to measure percentage of HEP (n/60) done in intervention group. Not measured between groups.	13 weeks -0.49 [-0.94, -0.03]+	NM	NM
Bennell 2014	Adherence: Patient report of home exercises in previous week (%) (week 16) 11 -point NRS over previous 8 weeks (Week 24)	16 weeks -0.14 [-0.58, 0.31]+	24 weeks -0.60 [-2.09, 0.89]+	NM
Bennell 2014b	Physical activity (self-report): PASE Physical Activity Recorded (direct measure): Steps per day (Pedometer) Adherence: - Adherence to home exercises (%). Not measured between groups	13 weeks -0.07 [-0.47, 0.33]+ 0.16 [-0.25, 0.56]+	36 weeks -0.15 [-0.58, 0.29]+ -0.19 [-0.62, 0.24]+	NM
Bennell 2016	Physical Activity (self-report): PASE Physical Activity (direct measure): - Pedometer (NR) Adherence: Adherence to home exercises (%) reported in log books - Self-rating on NRS at during treatment and average throughout 52 weeks follow up - Therapist rated adherence during treatment phase	12 weeks -0.07 [-0.41, 0.26]+ 0.30 [-0.04, 0.64]+	22 weeks -0.36 [-0.72, -0.00]+	52 weeks -0.10 [-0.45, 0.25]+ -0.11 [-0.47, 0.25]+
Bennell 2017	Physical Activity (self-report): PASE AAS Physical Activity (direct measure): Total no of steps per day (accelerometer)	NM	6 months -0.41 [-0.74, -0.08]+ -0.20 [-0.53, 0.13]+	12 months -0.08 [-0.41, 0.26]+

	No of step hours / day			
	Adherence: HEP sessions completed in past 2 weeks in log book (%) - Self-rated adherence to home exercise (NRS) - Therapist rated home exercises		-1.97 [-2.38, -1.57]+	-0.42 [-0.76, -0.08]+
Crossley 2015	Adherence: Diary to measure HEP done in intervention group only. Not measured between groups	3 months	9 months	NM
Deyle 2000	Adherence: Diary to measure HEP done in intervention group only. Not measured between groups	8 weeks	NM	1 year
Dincer 2016	Adherence: Diary to measure HEP done in intervention group only. Not measured between groups	12 weeks	NM	NM
EMPART 2013	Physical Activity (self-report): IPAQ Short Form Adherence: - Diary to measure HEP done in intervention group only. Not measured between groups	9 weeks -0.44 [-0.81, -0.07]+	NM	NM
Hiyama 2012	Physical Activity (direct measures): Step count (pedometer)	4 weeks -1.96 [-2.73, -1.19]+	NM	NM
Hunt 2013	Adherence: HEP recorded in log book (%)	11 weeks -0.02 [-0.92, 0.88]	NM	NM
Jones 2012, Brazil	Adherence: Cane use as walking aid recorded in log book. Not measured between groups.	60 days	NM	NM
Kawasaki 2009, Japan	Adherence: HEP recorded in log book and monitored in treatment sessions. Not measured between groups	NM	24 weeks	NM
Kuru-Colak 2017, Turkey	Physical Activity: - IPAQ (in methods but not reported) Adherence: - Intervention group received telephone calls to monitor compliance to HEP. Not measured between groups.	6 weeks	NM	NM
Lim 2008	Adherence: HEP recorded in log book (%). Not measured between groups.	13 weeks	NM	NM

MOA 2013	Adherence: HEP recorded in log book in intervention group. Not measured between groups.	9 weeks	6 months	1 year
Odole 2013	Adherence: HEP recorded in log book in intervention group only. Not measured between groups.	6 weeks	NM	NM
Schlenk 2011	Physical Activity (Self-Report): Total volume exercise per week by diary - Participation in fitness walking and other aerobic physical activities by diary	NM	6 months -1.10 [-2.03, -0.16]+	11 months -0.83 [-1.73, 0.07]+
Segal 2015	Physical Activity: PASE only done at baseline. Not measured between groups during or post intervention	3 months	6 months	12 months
Teirlinck 2016	Physical Activity (self-report): Minutes per day of PA - Days per week of PA Adherence: Self-report of whether doing prescribed PA over past 3 months (dichotomous)	3 months 0.10 [-0.31, 0.51]+ 2.42 [1.79, 3.26]%	6 months -0.28 [-0.70, 0.15]+ 2.73 [2.01, 3.71]%	12 months 0.13 [-0.31, 0.57]+ 2.80 [1.87, 4.19]%
Van Baar 1998	Physical Activity (Self-report): Zutphen PAQ - Number who improved in each group (dichotomous) Adherence: - Patient and physiotherapist reported on 5-point scale then dichotomised. Not measured between groups.	6 Weeks 0.24 [-0.04, 0.53]+	36 weeks 0.20 [-0.09, 0.49]+	NM
Veenhof 2006, (Includes Pisters, 2010^{1, 2,3})	Physical Activity (self-report): Number of days per week moderate to vigorous physical activity (Pisters¹) Adherence: Self-rated home exercises 5-point scale. 4-5 classified as yes; 1-3 as no. Results then dichotomised - Self-rated home exercises 5-point scale. 4-5 classified as yes; 1-3 as no. Results then dichotomised	7 Weeks -1.40 [-2.11, -0.69]+ 1.66 [1.24, 2.21]%	39 weeks	65 weeks -1.40 [-2.21, -0.59]+ 1.75 [1.20, 2.54]%
Wallis 2017	Physical Activity (direct measures): Steps per Day - Time walking > 80 steps/min per week (Moderate Intensity) - Minutes walked per day	13 Weeks -0.83 [-1.48, -0.19]+	NM	NM

Key:

SMD: Standardised Mean Difference for continuous data; PR: Probability ratio for dichotomous data; CI: Confidence interval; NM: Not measured; Measure in each domain that was written in bold was used to determine effect sizes; NR: No results available; Results in bold show statistically significant effect in favour of behavioural physiotherapy intervention ($P < 0.05$); No results were able to be calculated if Physical activity or adherence was not measured between groups; HEP: Home exercise programme; PASE: Physical Activity Scale for the Elderly; AAS: Active Australia Survey; IPAQ: International Physical Activity Questionnaire; ZPAQ: Zutphen Physical Activity Questionnaire; SQUASH: Short Questionnaire to Assess Health Enhancing Physical Activity; NRS: Numerical Rating Scale; + indicates continuous data; % indicates dichotomous data

Appendix 2.4: Fidelity Domain Assessment of included RCTs

Trial	Domains					Components % of individual components present
	Treatment Design	Training Provided	Delivery of Treatment	Receipt of Treatment	Enactment of skills	
Bennell 2005	A	A	A	P	P	33
Bennell 2010	P	A	A	P	P	28
Bennell 2014	P	A	A	P	P	44
Bennell 2014b	P	P	P	P	P	68
Bennell 2016	P	P	P	P	P	66
Bennell 2017	P	P	A	P	P	62
Crossley 2015	P	A	A	P	P	37
Deyle 2000	P	A	A	P	P	33
Dincer 2016	A	A	A	P	P	21
EMPART 2013	P	A	A	P	P	41
Hiyama 2012	P	A	A	A	P	21
Hunt 2013	P	P	A	P	P	55
Jones 2012	P	A	A	P	P	28
Kawasaki 2009	P	A	A	P	P	36
Kuru-Colak 2017	P	A	A	P	P	30
Lim 2008	P	A	A	P	P	28
MOA 2013	P	P	P	P	P	63
Odole 2013	A	A	A	P	P	19
Schlenk 2010	P	A	A	P	P	41
Segal 2015	P	A	A	P	P	28
Teirlinck 2016	P	A	A	P	P	44
Van Baar 1998	P	A	A	P	P	32
Veenhof 2006	A	A	A	P	P	43
Wallis 2017	P	A	A	P	P	32
Total (N/24)	20	5	3	23	24	MCP 38.9 SD:14.1

Key: MCP- Mean components present; P- Present; A- Absent

Appendix 2.5- Checklist PRISMA 2009 checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	27
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	27
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	28-31
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	31
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	31, Appendix 1.1
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	32
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	32-33
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	33-34
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	34-35
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	35

Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	35
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	36
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	39-40
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	40

Appendix 3.1 Semi structured Interview schedule

Study title: **STaying Active after Physiotherapy** in patients with Lower-limb **Osteoarthritis** (STAPLO)

Semi-structured interview topic guide

Background data:

- How many times have you been referred to physiotherapy before? How many times was this for your osteoarthritis?

- Male/Female: _____
- How old are you? _____
- Do you remember how tall and heavy you were the last time you checked?

- Where does your family originate from? _____
 - Do you identify as being English?
- When did you exit education? _____
 - Did you finish your GCSEs/O levels/A levels?
 - How old were you when you left school?
 - Did you go to University?
 - Did you finish your undergraduate degree/MSc/PhD?

*Note: Person with lower-limb Osteoarthritis will now be asked to complete the Pain Numerical Pain Rating Scale (below), the bothersome index (below), and either SFKOOS/SFHOOS questionnaire as appropriate.

- Please mark on the following scale the average amount of pain felt over the PAST WEEK in your most painful joint:

No pain possible Worst pain

() 0 () 1 () 2 () 3 () 4 () 5 () 6 () 7 () 8 () 9 () 10

- In the last week, how bothersome has your osteoarthritis been in this joint?

not at all () slightly () moderately () very much () extremely ()

After Pain numerical rating scale, bothersome index, and SFKOOS/SFHOOS completed, interviewer will fill out 3-day Physical Activity Recall form (appendix 1) while asking questions on physical activity level.

I would like to know a bit more about the amount and type of physical activity that you engage in your everyday life.

- Were you employed in the last 3 day? _____
- How many days of the last three did you work? _____ days
- How many total hours did you work in the last three days? _____
- What two days do you consider your weekend days? _____

Sleep:

- Now I would like to look at the time you spent sleeping in the 3 days. By sleeping, I mean the time you went to bed one night and the time that you got out of bed the next morning. You may not necessarily have been asleep the entire time you were in bed. You may have been reading or watching television.
- Today is _____ so yesterday was _____. What time did you go to bed last night/the night before and get up this morning/morning before? (Note: This question will be repeated for each day, beginning with preceding day and going back for a total of three days).

Physical Activity:

- Physical activity refers to any bodily movement that is performed by your skeletal muscles and requires energy, such as walking.
- Please think of the physical activities you have done in the past 3 days, starting with yesterday and going back. Please remember, this is a recall of actual activities for the past 3 days, not a history of what you usually do.
- We are not considering light activities, such as desk work, standing, light housework, strolling, and stop-and-go walking such as grocery or window shopping.
- We are interested in occupational, household, and sports activities that make you feel similar to how you feel when you are walking at a normal pace.

Intensity:

- I will ask you to categorize the intensity of each physical activity you do into one of three groups; moderate, hard, or very hard. The moderate category is similar to how you feel when you are walking at a normal pace. The very hard category is similar to how you feel when you are running. The hard category just falls in between. In other words, if the activity seems harder than walking but not as strenuous as running, it should go in the hard category

Segments of the day:

- I am going to ask you about the physical activities you engaged in during three segments of the day, which includes morning, afternoon, and evening. Morning is considered from the time you get up in the morning to the time you have lunch; afternoon is from lunch to dinner; and evening is from dinner until the time you go to bed

Today is _____ so yesterday was _____. Think about what you did yesterday morning/afternoon/evening. (Note: This question will be repeated for each day, beginning with preceding day and going back for a total of three days).

Potential Prompts:

Where were you? Think about what you usually do. Did you do anything unusual? Did you do any physical activity?

Duration:

How long did you do that activity? How much of that time was spent standing still or taking breaks?

Intensity:

Did that activity feel similar to how you feel when you are walking or running or is it somewhere in between?

How would you rate the intensity of that activity?

At end of first day recall:

Now I am going to ask you about activities you might do for building strength or improving flexibility. Strength activities include push-ups, pull-ups, sit-ups, lifting free weights, and using weight machines. Flexibility activities include holding stretches for several seconds or an activity like yoga.

For each subsequent day:

Did you do any strength or flexibility activities? How many minutes did you spend on each?

After all 3 days have been reviewed:

Are there any physical activities that you might have forgotten? Did you do any physical activity at work? any other recreational or sport activities? housework or gardening? Were there any other walks that you might have taken?

Compared to your physical activity over _____ the past three months, was the last three days of physical activity more, less, or about the same? _____

Facilitators and barriers to physical activity and perceptions of physiotherapy

We are also interested in knowing about your thoughts on things that make it easier and harder for you to be generally physically active

- What makes it easier for you to be more physically active in your daily life?
 - How does it help?
 - What are the facilitators?
- What makes it harder for you to be physical active?
 - How do these make it harder to be physically active?

- Any other barriers that you can think of?
- Has osteoarthritis effected your ability to be physically active?
 - If so, how?
 - How does this make it harder to be physically active?
 - So how physically active were you before you had osteoarthritis?
- With what you are doing now how, has physiotherapy made a difference to how physically active you are today?
 - Why? Why not?
 - Did you enjoy it? Why? Why not?
 - What might help improve it further?
 - Did you attend all the sessions? Why not?

During Treatment period

The next series of questions is dealing with how physiotherapy effected your physical activity levels while you were being treated. By that I mean your physical activity levels from your first appointment to when you were discharged including the time spent in between sessions.

- In your sessions, did the physiotherapist prescribe any exercises for you to do?
 - If so, what?
 - Did they make sure you were doing them correctly?
 - Did you find this effected your activity levels? Why/why not?
- Did the physiotherapist give you any further advice on how to be as physical activity as possible in between sessions?
 - What advice did they give you? E.g. setting goals, not doing too much when you had reduced pain, health benefits of physical activity, weight management, smoking etc
 - Did they give you any additional information? If so, what? e.g. sheet with exercises on it, TheraBand, activity diary, pedometer etc
 - Did it work? Why/ Why not?
- What made it difficult for you to make the changes to your physical activity in between your sessions that the physiotherapist suggested?
 - Why was this difficult?
 - What made it difficult?
- What helped make it easier for you to make the changes to your physical activity in between sessions that the physiotherapist suggested?
 - How did it make it easier?
 - What else could your physiotherapist have done to help you be more physically active?
 - Anything else you could think of?
- Can you think of any additional support, suggestions, or advice the physiotherapist could provide that would help you to be as physically active as possible in-between your sessions?

- e.g. provision of a physical activity diary, education on appropriate levels of physical activity, knowledge about your condition, advice on pain management, setting goals, how to solve problems, further advice etc.
- How would that help you be more physically active?
- Anything else you can think of?

Post-treatment period

Now we are going to focus on your physical activity since you have been discharged from physiotherapy.

- Did the physiotherapist do anything or offer any advice to help you maintain your physical activity after you had finished your course of treatment?
 -
 - What did they do/suggest? E.g. reviewing your goals, education on health benefits of maintaining physical activity, use of 'buddy' to motivate, contact details of community support.
 - Did it work?
 - What was the most effective thing they did/suggested?
 - Why was this effective/ineffective?
- Is there anything that the physiotherapist suggested or did that makes it easier for you to be physically active now?
 - What did they say/do?
 - How does it make it easier for you to be more physically active?
- Is there anything that the physiotherapy suggested or did that makes it more difficult for you to be physically active now?
 - What were they?
 - How do they make it more difficult to do your physical activity?
- Can you think of any additional support, suggestions, or advice the physiotherapist could provide that would help you to be as physically active as possible now your sessions have ended?
 - e.g. reviewing your goals, education on health benefits of maintaining physical activity, use of 'buddy' to motivate, contact details of community support .etc.
 - How would that help you be more physically active?
 - Anything else you can think of?

Focused questions on session delivery preferences

Ok now look at your programme overall, now you have been through it from start to finish

- Would there have been anything else you would have wanted included in the physiotherapy programme which would help you be as physically active as possible?
 - What?
 - How would this help with your activity levels?

- What are the most important things to include in the physiotherapy sessions to help you be as physically active when you first start physiotherapy treatment in between your sessions?
 - E.g. More education around your condition, use of physical handouts, diary, pedometer, advice on rearranging your physical space at home, incorporation of peer support etc
 - How would they help?
 - Anything else you can think of?
- What are the most important things to include in the physiotherapy sessions to help you be as physically active as possible now you have finished your sessions?
 - E.g. Follow up texts or telephone calls, referral to a community group? Further follow up with the physiotherapist? Dedicated phone line that you can call?
 - How would they help?
 - Anything else you can think of?
- How many physiotherapy sessions do you think you would require before you feel confident that you could maintain your physical activity levels (i.e. self-manage)?
- How would you like these sessions delivered?
 - *How long/often/ specific time of the day*
 - In person?
 - Could any be done over phone/skype?
 - Are there any other things you can think of which you would make these sessions better?

Conclusion:

Thank you for speaking with me. I enjoyed our discussion. Any other points you would like to make on any of the topics we discussed?

Appendix 1: 3-day Physical Activity Recall Form (filled out by interviewer during semi-structured interview)

	Days			
Sleep	Time in bed			
	Time out of bed			
Morning	Moderate			
	Hard			
	Very Hard			
Afternoon	Moderate			
	Hard			
	Very Hard			
Evening	Moderate			
	Hard			
	Very Hard			
	Strength			
	Flexibility			
Total mins per day				

Appendix 3.2 Behaviour Change Technique and Domains Matrix

	Domain	Kn	Sk	SPRI	BOCap	Op	BOCon	Rein	Intent	Goal	MAD	ECR	Socl	Em	BehR	Mot
BCT																
1.1 A			X						X x	X xX					X	
1.2			X		x x				X	x	X			X		X
1.3			X						X	x xX						
1.4										X						
1.5										XX						
1.6										X						
1.7										XX						
1.8									X Y	X						
1.9									Y							
2.1			X													
2.2		X			X		X									X
2.3			X		X		X				X				X	
2.4															X	
2.5			X													
2.6		xY														
2.7					X		X									
3.1				X	X				X	X			x x X			
3.2				X	X				X	X		X	x x X			
3.3				X	X				X	X			X Y	Y		
4.1		X	X		X											
4.2		XY													X	
4.4																
5.1		X xX					X		X							
5.2							X Y									
5.3		X x					x x Y		X	X						
														Y		
5.5							X Y									
5.6							X Y							Y		

6.1			X		X								X X			
6.2													XX			
6.3													X Y			
7.1											X x	x X				
7.2												Y				
7.5												X				
7.8								Y								
8.1			x x X		x x											
8.2															X	
8.3			Y													
8.4			Y													
8.6			X													
8.7			x x Y		x x				X	X						
9.2			X		X		X Y		X	X						X
9.3							X Y									
10.1							X	XX								
10.2								XX								
10.3			X					X Y	X	X						
10.4								X Y					X Y			
10.5								X								
10.6			X					XX	X x	X						
10.7								X								
10.8							X	XX								X
10.9								Y								
10.10							X	X								X
10.11							Y	Y								
11.2														x x Y	X	
11.3											x				X	
12.1													X X x			
12.2													X x Y	Y		
12.3													X Y			

Coding Decisions

Michie 2008:

- Goal setting and Monitoring separated into behaviour and outcome
- Rewards; incentives: coded as 10.3/10.6 Non specific
- Increasing skills: coded as problem solving and pros and cons (decisional balance)
- Stress management: coded as Reduce Negative Emotions
- Coping skills: coded as problem solving
- Rehearsal of relevant skills: coded as behavioural practice/rehearsal
- Role play: coded as demonstration of target behaviour
- Implementation: coded as action planning
- Prompts, triggers, cues: coded as Prompts and cues
- Environmental changes: coded as 12.2 Restructuring the social and physical environment; 12.5. Adding objects to the environment
- Social Processes of encouragement, pressure, support: coded as Social support (all)
- Persuasive communication: coded as Verbal persuasion about capability
- Information regarding behaviour, outcome: Information about health consequences, Information about social and environmental consequences
- Personalised message: not coded
- Modelling/demonstration of the behaviour: coded as demonstration of the behaviour
- Homework: not coded
- Personal experiments: coded as behavioural experiments
- Experiential: not coded
- Feedback: coded as feedback on behaviour; feedback on outcomes of behaviour
- Use of imagery: not coded
- Perform behaviour in different setting: coded as generalisation of the target behaviour
- Shaping of the behaviour: coded as Instruction in how to perform the behaviour
- Motivational interviewing: coded as Social support unspecified
- Relapse prevention: coded as problem solving

- Cognitive restructuring: coded as Framing/reframing
- Relaxation: coded as body changes
- Desensitisation: not coded
- Time management: not coded
- Identify/prepare for difficult situation/problems: not coded
- Increasing skills: problem solving and pros and cons (decisional balance)
- Stress management: Reduce Negative Emotions

Cane et al., 2015:

- Vicarious reinforcement: coded as vicarious consequences
- Incentive: coded as all of 10.1. Material incentive (behaviour) 10.5. Social incentive 10.6. Non-specific incentive 10.7. Self-incentive 10.8. Incentive (outcome)
- Self-assessment of affective consequences: coded as Monitoring of emotional consequences

Initial Behaviour Change Techniques coded to Groupings		
Grouping	Coded from	Potential BCTs
Personal factors	Matrix	1.2, 2.2, 2.3, 2.6, 2.7, 3.1, 3.2, 3.3, 4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.6, 6.1, 8.1, 8.3, 8.4, 8.7, 9.2, 9.3, 10.11, 11.2, 15.1, 15.3, 15.4, 16.1, 16.2, 16.3
	Transcripts	1.4, 2.2, 2.3, 2.4, 3.1, 3.2, 4.1, 6.1, 8.1, 8.7, 11.1
Treatment Phase	Matrix	1.1, 1.3, 1.4 ^a , 1.5, 1.7, 2.2 ^a , 2.4, 2.6, 3.1 ^a , 3.2 ^a , 3.3 ^a , 4.2, 5.1, 6.1 ^a , 6.2, 6.3, 7.1, 7.2, 7.5, 7.8, 8.1 ^a , 8.3, 8.4, 8.7 ^a , 10.1, 10.2, 10.3, 10.4 ^a , 10.5, 10.6, 10.7, 10.8, 10.9, 10.11, 12.1, 12.2, 12.3, 12.5, 12.6, 14.1, 14.2, 14.3, 14.4, 14.6, 14.7, 14.8, 14.9, 14.10, 13.1, 16.3
	Transcripts	1.1, 1.3, 1.4 ^a , 5.1, 5.3, 4.1 ^a , 6.1 ^a , 8.3, 8.6, 8.7 ^a , 10.4, 10.6, 12.5
Post-Discharge Phase	Matrix	1.2, 2.2 ^a , 2.3 ^a , 2.7, 3.1 ^a , 3.2 ^a , 3.3 ^a , 4.1 ^a , 6.1 ^a , 6.2, 6.3, 7.1, 7.2, 7.5, 8.1 ^a , 8.7 ^a , 9.2, 10.4 ^a , 12.1, 12.2, 12.3, 12.5, 13.1, 15.1, 15.3, 15.4, 16.3
	Transcripts	1.2, 1.8, 11.2 ^a , 12.2, 15.1

Legend: BCT: Behaviour Change Technique; ^a: denotes commonly identified overlapping Behaviour Change Techniques

Appendix 3.3: Themes and subthemes with examples quote and corresponding Theoretical Domain Framework (TDF) Domain

Table 1: Personal factors

Theme/sub-theme	Example of quotation (participant no; 'quotation')	Associated TDF Domains	Participant No's	Conflicting Belief (y/n)	Strong Belief (y/n)
Motivation					
Seeing progress	(4) 'You need to feel that you are making progress, and as I have, this is definitely affected my motivation and made me do my exercises.'	Skills Beliefs about capabilities Intentions Reinforcements	1,2,3,4,7,8,9,11,13		Yes
Having a purpose	(2) 'I suppose it's motivation, it's having something to do and the need to get out because I make that, when I don't have to go out, I make a point of going out for a walk and having that 11:00 cup of coffee. I think it's that motivation'	Goals Intentions	2,4,8,10		
Wanting previous level of functional ability	(1) 'Because I used to be ever so quick, you know what I mean... For me it was more of like, to get physically back to where I wanted to be.'	Goals	1,2,7, 8,9,10,11,12,13		yes
Fear of functional decline/ need for invasive treatments	(9) 'I know that I'm going to carry on doing it because I've got a very simple goal: over my dead body am I going to need a hip replacement...it's an absolute motivator for me. I do not want to go down the road of needing opioids, steroid injections or a referral for surgery. I absolutely loathe hospitals.'	Goals Intentions Emotions	1,2,7,9,10,11		yes

Wanting to reduce or control symptoms	(7) 'What made me do them was because I thought, "I've got to get rid of this pain and that, I'll have to do them." (11) 'regards the arthritis, I was going to rule it, it wasn't going to rule me...there's two ways of dealing with it. It could rule me and say right I can't do that I've got this, or I could say right, I'm not letting this stop me from doing what I want to do and do my exercises.'	Goals Intentions	1,2,3,7,8,9,10,11		
Enjoyment of physical activity/Exercise	(8) 'For me, the motivation would just have been to carry on doing the things I wanted to do which was ride, walk ideally, and that's changes more to cycling now.'	Goals Intention Emotion	2,3,4,8,9,12,13	Yes	Yes
External sources of motivation					
Using the physiotherapist as a motivator	(9) 'I wanted to show the physiotherapist I could do the exercises properly'	Knowledge Skills Intentions Goals (goals) Social Influences	6, 8, 9,10		
Using items to provide motivation (TheraBand, pedometer)	(6) because of the steps, the amount of steps that you do a day, you sort of keep up and you'd look at it and you'd think, right okay, I've done 2,000 steps today, tomorrow I want to do 2,050, I think it would push yourself to do more'	Intentions Environmental context and resources Self-regulation Reinforcement	3,6,13	Yes	
Guilt	(2) 'I feel guilty if I do not do my exercises.'	Beliefs about consequences Emotion	2,8		
Self-discipline/personal responsibility					
Need to take personal responsibility for own PA/Exercise	(12) 'You've got to give it a go, at the end of the day if you want it to work; again, that's just personal preference. If	Intentions	2,4,7,8,9,10,11,12		Yes

	you want it to work, you've got to put a bit of effort in yourself.'				
Excuses to not do PA/Exercises	(6) 'In a way I sort of use it as a bit of an excuse, I know he can't walk as well as he used to'	Intentions	1,6		
Perceived Capability					
Confidence					
Realisation that PA/Exercises reduce symptoms and improve function	(13) 'By doing the exercises...it made me realise, I suppose, that I could do something about it and it gave more confidence'	Knowledge Skills Beliefs about capabilities Beliefs about consequences Reinforcement	1,2,3,4,7,8 11,12,13		Yes
Increased feelings of capability from doing PA/exercises	(1) 'You've gone through the exercises and that and I don't know, you just feel so much more capable of doing everyday things'	Knowledge Skills Beliefs about capabilities Optimism Reinforcement	1,3,4,8,9,10 11,13		
Confident in skills to maintain activity	(2) It's all about maintaining, I think. What do I need to maintain? It's being confident that I've got the tools (exercises) necessary	Knowledge Skills Belief about capabilities Beliefs about Consequences	2,3		
Fear-avoidance	(3) 'The noises in my joints are horrendous. It makes me nervous to be active.' (9) 'Most of the time I don't need a stick, but the thing is, when...I can have times when this hip is so painful and my leg feels as if it's going to support me. The stick isn't to help me walk properly. The stick is to give me confidence that, if I get that feeling in my leg, that I am not going to fall over.'	Knowledge Skills Beliefs about capabilities Beliefs about consequences Optimism Environmental context and resources	2,3,7,9,13	Yes	Yes
Mindset					

Psychological effects of improvement of symptoms'	(2) 'It was quite a psychological boost to feel that one part of me, physically, could improve so quickly and so helpfully and I wasn't on the downward spiral. Psychologically that is so important, it really is.	Knowledge Skills Beliefs about capabilities Optimism Beliefs about consequences Reinforcement Emotion	2,6,7,8		Yes
Mental and emotional resources	(8) 'Maybe that was part of why it was hard to do myself, but part of my motivation for stopping treatment was because I just felt like I hadn't got any more, you know, space to do stuff really.'	Beliefs about Capabilities Optimism Memory attention and decision processes Environmental Context and resources Emotion	1,8		Yes
Comfort zone	(1) 'It was quite difficult at first. I think I was out of my comfort zone being in a room with people you didn't know, but then after the first week, when I went back the second week, I found it much easier.	Beliefs about capabilities Optimism Environmental context and resources Social influences Emotion	1,6,8,9		
Arthritic symptoms					
My pain stops me from being active	(12) 'Personally, I'm thinking, as I am at the moment, because I have been in quite a bit of pain I haven't been as active now because I want to come home and rest.'	Knowledge Beliefs about capabilities	1,2,3,4,7,8,9 10,11,12,13	Yes	Yes
Pain stops me doing my exercises	(7) I was lying on the bed and I mean, that was painful because my hip was playing me up at the time and I couldn't do them' (exercises)	Knowledge Beliefs about capabilities	4,5,7,8,9,10 11	Y	Y
Pain affecting mood and reducing PA	(2) I was getting very depressed with the pain I was in and starting to not go out and starting to not walk. I felt this is it.'	Beliefs about Capabilities Optimism Emotion	2,7,12		Y
Pain affecting enjoyment of PA	(4) 'because obviously if it doesn't hurt so much (laughter) you enjoy it a bit	Optimism Emotions	4,8,10,12		Yes

	more'				
Other symptoms in joints (apart from pain)	(12) 'I am stiff in the morning because of my arthritis.' (3) 'The stiffness controls me while I'm playing golf.' (2) my flexibility has gone; I'm just generally walking with a limp and so on	Beliefs about capabilities Beliefs about consequences	2,3,8,12		
Pharmacology reducing symptoms to enable PA	Injection therapy: (10) When my knee had the injection, it just lessens and takes the pain away. Without the injection, my knee aches constantly though the day, aches, pains, I'll get a sudden jolt like electric jolt of pain Oral Medication: (3) When I play golf, I take a painkiller, I must admit. I don't because I'm not into painkillers. But I take one before I leave, co-codomol. It might be one, it might be two and then that kicks in by the time I'm up and running and that gets me round then I'm all right Topical Gel: (8) 'If I do walk, I have to use a gel, an ibuprofen gel, and if I do that, I can walk without too much discomfort.'	Knowledge Environmental context and resources	1,3,4,8,10,12		Yes
Experience of PA					
Benefits of activity (well-being/general health)	(2) 'I know that for my health I need to get out, fresh air, walk, so I make it like, it's almost as important as having lunch, do you know what I mean? That's my daily exercise and I make sure I get it in. If I don't, I miss it.'	Skills Beliefs about Capabilities Beliefs about consequences Reinforcement Emotion	2,4,10,12,13		Yes

	(2) 'Once I'm active there's less problems really. The more active I am, the better I am, I know that'				
Effects of PA/Exercise (mind-set)	(2) 'The exercises made me more positive. Instead of thinking, I can't do this, I started, it's psychological, I can do this. It's not going to be a burden; it actually could be a pleasure.'	Skills Beliefs about Capabilities Beliefs about consequences Reinforcement Emotion Optimism	1,2,11		Yes
Effects of PA/Exercise (symptoms)	(4) 'I think it's to do with less pain from the exercises, because at one time it was like a knife going through my knee, as I was trying to put the weight on the right knee. So, it's less pain, and more strength.' (10) 'It was just that one exercise when my knee actually didn't like and, well stiffened. It wouldn't bend. I couldn't walk. Something happened. So, I don't know what happened to my knee, but I just could use it, I couldn't drive, I couldn't walk.'	Skills Beliefs about capabilities Beliefs about consequences Reinforcement	1,2,4,6,7,9, 10,11,12,13	Yes	Yes
Effects of PA/exercise (function e.g. stairs, walk, balance)	(11) 'I used to go upstairs one at a time, you know. One, one, one and now I can go one, two, one, two.'	Skills Beliefs about capabilities Beliefs about consequences Reinforcement	2,4,7,11		Yes
Increased symptoms from too much PA	(3) 'I can only do what I'm doing. I wouldn't try to do something above that because I've just got to pay the price for it, so...I just do what I know I'm capable of doing without making myself suffer really.'	Intentions Beliefs about capabilities Beliefs about consequences Reinforcement	1,3,4,5,7,9, 10,12,13		Yes
Previous levels of Physical activity					

Identifying as physically active	(13) Being very physical, has always been part of my USP, I suppose, as a person it's been quite difficult to come to terms with the fact that I can't do that anymore	Skills Social or professional role or identity Beliefs about capabilities	8,9,10,12,13		Yes
Adjusting expectations	(12) 'I think sometimes you've got to have a hard conversation with yourself and say look, you've got this, with best will in the world you may never get to the stage that you were before'	Beliefs about capabilities Intentions Goals	7,12		
Frustration at loss of function	(12) 'things I used to be able to do, which I think was really easy, even walking now, long walking, I'm starting to hurt quite a bit in my leg. I used to walk for miles. It's frustrating because I know what I could do and what I want to do, but I can't	Beliefs about Capabilities Optimism Emotion Reinforcement	7,12		yes

Table 2: Physiotherapy Specific Factors

Theme/sub-theme	Example of quotation (participant no; 'quotation')	Associated TDF Domains	Participant Numbers	Conflicting Belief (y/n)	Strong Belief (y/n)
Access					
Other obligations (work)	(10) 'And when I was working and I'd got the hectic schedule and so much going on in my life, it did make it more difficult. And it made it difficult to get to the actual physiotherapy session,	Environmental context and resources	6,10,11		

	because as I say, they give you a time and the you think, 'oh, no I can't do that one, I'm in a lesion that day.' Or they'd change my timetable at work, and I was having to try and swap things, it was a nightmare.'				
Appointment flexibility	(13) 'I thought they were really flexible actually. My first appointment was 7:40, so I did it before work and it was utterly fine. All my other ones have been early-ish, so I could get into work. I didn't realise that that was a thing, so that's quite useful.'	Environmental context and resources	1,12,13		
Number of sessions	(2) 'You go there and then you start doing the physio and you just get to that, she says to have five and I actually, and they gave me six, which I was really, you know, thankful for. I would like to say I could have done with a few more.'	Environmental context and resources	1,6,10		
Duration of sessions	(7) 'I was called in, my husband came with me and he was sitting where I met you, he was sitting there. And I come out and	Environmental context and resources	5,7,12		Y

	he says, "Where are you going?" I said, "I'm finished." I do think they should really spend a bit longer.'				
Long referral process	(12) 'Excuse me, I'm sitting here with pain every day, 24/7 for the last six months and I'm coming back and badgering you saying it's still hurting. It took quite a while to get to that stage as well.'	Environmental context and resources	2,9,12,13		
Value of sessions					
Increased motivation	(2) 'Every time I attended one of those sessions, I came out feeling more motivated and more hopeful because nobody said, "Go away, you're old, live with it.'	Optimism Reinforcement Emotion Social influences Environmental context and resources	1,2,5,6		
Empowered/ control of symptoms	(13) The experience has had has been really, It's been really kind of empowering, because I know how to take control, of what I'm working with (9) When she first said those words "osteoarthritis", my heart absolutely sank because I know an awful lot about arthritis, but she was able	Knowledge Beliefs about capabilities Social influences Environmental contexts and resources	2,3,5,9,13		yes

	to make me feel that I was in control of it				
Too much talking	(12) 'There's been a lot of turning up at appointments, talking about something and I'll go away and just, okay, you've talked about it, but you've actually done nothing for me.'	Environmental context and resources Social influences	3,5,7,9,12		Yes
Physiotherapist didn't do anything	(5) 'I just don't understand that, when I came out, I spoke to them, who I seen in the...she said "It's a load of bloody rubbish, they didn't do nothing." And they just said, Well, that's it now..." I thought bloody hell.	Environmental context and resources Social influences	3,5,7,12		Yes
Doing exercises in the sessions	(7) 'But I don't do the exercises there. Not now. That's what makes me think, "Is it worth coming all the journey?" I might as well do them at home. And I do them better at home. Because I'm only coming now to talk to her.' (12) One of the things I was doing was stretching, lying down and stretching the leg out...coming away from that session is like, oh, that's great. I walked	Skills Environmental context and resources Social influences Reinforcement Intentions Emotions	6,7,9,12	Yes	

	out of here and I thought, oh, I really felt a sense that it eased up.'				
Relationship with physiotherapist					
Getting to know patient as an individual	(13) 'She got the lay of the land, on a personal level pretty quickly. She identified through an examination and also through conversation, that I was quite active anyway.'	Social influences	1,2,4,6,7,8,9,13		
Collaborative relationship	(8) 'there's something about the engagement in that process, engaging in your own recovery and feeling that some else is also engaged in that and it's not just their job, you know...'	Optimism Social influences	1,2,4,8,9,10,13		Yes
Familiarity	(7) 'Yeah at least I know she's there. But I think for my hip, I think the more I do the exercises, but I feel safer if it's with (name).'	Social influences Beliefs about capabilities Reinforcement	7,10,11,12		
Physiotherapist was motivating	(4) 'He is absolutely fantastic in all ways, because I have seen other physios before and found them useful, be he is so motivating and so kind....And I think that his input has been particularly	Optimism Social influences	1,2,4,6,7,10,12,13		

	important, because there are other physios I've seen that I thought oh.'				
the physiotherapist was friendly/encouraging	(2) 'They were absolutely brilliant. I cannot think of anything negative about them. They were encouraging, honest, personable and I couldn't wish for better people.'	Optimism Social influences	1,2,4,6,8,10,11		yes
Encouragement from the physiotherapist helps with mental well-being	(1) 'I think having encouragement from them (is the most important thing)...I think sometimes when you've had things like that, it's not just physically, its mental as well.'	Optimism Social influences	1,4,8,6,10,11		
Communication	(2) 'I suppose it's down to communication. He would ask what the problem was and then he would offer some solution... they can remember some of the conversation we had last time and they speak to me as a human being and there's humour and they're just brilliant.'	Optimism Social influences	2,4,8,9,13		
Attitude of healthcare professional	(10) 'He has a bit of an attitude...he made me feel like I was wasting his time...I'm quite stoic, I will	Optimism Social influences	3,10,13		

	put up with pain and I was thinking, maybe I'm not putting up with pain as much as I should. So, I wouldn't go back. And I was in absolute agony and my husband was pleading with me, "Go back, go back." And I'm like, "No, no." Because they just made me feel that big'				
Person centred Treatment					
Patient centred treatment	(8) 'I suppose to explore what you enjoy and to try and make that into thing that, you know, your regime is built around or your exercise is built around. I don't know, to not have a formula of easy exercises you do if you got an arthritic knee, to personalise it really.'	Knowledge Skills Goals Social influence	2,4,8,9,12,13		Yes
Type of exercise					
Resistance work	(10) 'Using the TheraBand helps. Because you can definitely feel the difference when you're not using them, because you have got that extra tension and can feel it working.'	Knowledge Skills Beliefs about capabilities	6,9,10	Yes	

	(9) 'Yes, the resistance work, I know it's helpful. It isn't always easy but them...you're trying to work a joint and get it doing something that, you know...It's not always physically easy.'				
Reducing Impact	(12) 'I had to lay off any hard impact training.... I couldn't anyway. I'd had to stop the cycling, running was a no-no, all that sort of stuff.'	Knowledge Skills Beliefs about capabilities	6,10,12		
Detailed assessment and Reassessment					
(Re) Assessment of joint	(2) 'I had (name) who figured out what was wrong with me and then he realised the back of my leg was all very, very stiff because of what has happened.' (7) 'She didn't even check my knee. She did once, check my knee, the bending on it and all that. But you can't see anything.'	Knowledge Skills Beliefs about capabilities Social influence Reinforcement	1,2,4,7,8,9,10,12	Yes	Yes
(Re) Assessment of function and overall ability	(12) 'It would have been good to say, right, let's do a session where we can see, actually can you do	Knowledge Skills Beliefs about capabilities Social influence	3,4,5,7,8,12		Yes

	this now? Can you bend over and pick up that item up, can you stretch, can you walk up and down, what are you looking like?....you wouldn't fix a car and then not take it out for a test drive to see it's fixed. You wouldn't say, right, I've fixed this, just leave it sitting in the garage and expect that it's worked. You've got to take it for a test drive and see it's working.'	Reinforcement			
Assessment of exercises/PA	(2) 'he checked and asked me to do the exercises as he prescribed, to make sure I was doing it properly...this made me feel much more positive'	Knowledge Skills Beliefs about capabilities Optimism Social influence Reinforcement	1,2,4,7,8,9,10,12		Yes
Feedback on exercises	(9) 'She showed them to me and got me to do them in each session, and critiqued what I as doing and made suggestions for how I could do them better'	Knowledge Skills Beliefs about capabilities Social influence Reinforcement	1,6,7,8,9,10,12,13		
Personalised Treatment plan					
Instruction and demonstration	(11) 'Well, really, I'd say the exercises and showing me how to do them (most	Knowledge Skills Beliefs about capabilities	2,3,6,9,11,12,13		Yes

	important thing that the physio did) they need to ensure I know how do them.'	Social influences			
Explanation of what PA/exercises are supposed to do	(3) 'I don't know what else, other than an operation, they could do that would make it better. I don't know. I don't know whether the exercises, or what different sort of exercises would do it. Like I say, I think, what I was doing was to strengthen the muscles in the knees and thighs, and when you do that it pulls and it's all strength muscles and I don't know whether, in my particular case, the muscles needed strengthening' (9) 'She was also very good in terms of explaining why the exercises were important and what they were designed to do.'	Knowledge Skills Beliefs about capabilities Social influences	3,6,9,11	Yes	
Having a detailed plan	During treatment (8) 'also making a plan. I do quite like having a plan or a to-do list for something which might incorporate activity and exercise.'	Knowledge Skills Goals Behavioural Regulation	1,2,6,7,8,9,12,13		yes

	Maintenance: (2) 'I think it's just, the word 'schedule' comes to mind...if they just said this amount of walking every day, this is a place you can go to a couple of times a week to get the stretches in, then this would go to maintain where you are.'				
Written or visual instructions	(1) 'If they had to put it down in black and white, this is what you need to really do and then you can progress after a week two or three. I think to have something in black and white really.' (13) 'They were quite simple exercises initially and honestly, the second set of exercises, she didn't write down and I couldn't remember one of them. A visual aid is quite useful just to...yeah particularly if you're unfamiliar with the routine of it and how far you can go.'	Knowledge Reinforcement Skills Goals Behavioural Regulation	1,3,5,6,12,13		
Detail on Dose/frequency etc	(9) 'One of the things that really confused me when I first started doing the exercise was, I said,	Knowledge Skills Goals	2,8,9,12,13		

	“(Name), how many repetitions should I do?” She said, “Do whatever you’re happy with.”....I think they should be saying...”Look, to keep your hip in a reasonable state, you need to be doing 10 repetitions a day,” something like that.’	Behavioural Regulation			
Level of PA/exercise	(4) ‘I think to assess your ability and set it (exercises) at the right level to start with because if they set it too high, you're not going to do it.’	Knowledge Skills Beliefs about Capabilities Goals Behavioural Regulation	1,4,6,8,9,10,11, 12,13		Yes
Gradual Progression	(13) ‘I suppose it’s how that relationship kind of grows in terms of, there’s some exercise, some simple exercise to start, then it gets a bit more complicated. Then is gets more complicated and then she’s saying, “keep doing that and now and then go for a swim.” It’s kind of that build up, I suppose of instruction.’	Knowledge Skills Beliefs about Capabilities Goals Behavioural Regulation	1,2,4,8,9,12,13		Yes
New exercises	(4) ‘Every time I go back, and he gives me a new exercise, I'm like, "I'm going to do new exercises." And I have done them, I can honestly say I have done them.’	Knowledge Skills Beliefs about Capabilities Intentions Behavioural Regulation	4,12,13		

Knowledge and Understanding of OA					
Knowledge about OA	(13) 'I like to know, it is about education, I want to know what the problem is. In terms of what I can and can't do, what I might expect, what the prognosis is, what is this pain that I'm experiencing, what is it? I'm very familiar with how it feels, but what actually is it? What's causing it? What's the problem?'	Knowledge	2,9,12,13		Yes
Education about OA	(13) 'I like to know, it is about education, I want to know what the problem is. In terms of what I can and can't do, what I might expect, what the prognosis is, what is this pain that I'm experiencing, what is it? I'm very familiar with how it feels, but what actually is it? What's causing it? What's the problem?'	Knowledge	1,2,5,10,12,13		Yes
Advice about OA (treatment options, none-physiotherapy management)	(9) 'It sounds daft to say that I need to be told what sort of exercise to avoid, because you would think that, if it was an exercise you should avoid, it would be blooming painful, but I	Knowledge Beliefs about Capabilities	1,2,5,9,12,13		

	know that it's quite possible to do something that's very bad for your joint. It doesn't actually cause pain at the time. It causes pain afterwards, so some general advice about good joint self-care, things to be thinking about.'				
Routine					
routine effect on PA adherence	(2) 'the word 'schedule' comes to mind. If they just said, this amount of walking every day, this would help me do my exercises.'	Knowledge Skills Beliefs about capabilities Reinforcement Intentions Goals Behavioural regulation	1,2,4,5,6, 8,10,13		yes
Integrating PA/exercise into daily life	(9) 'You see, the thing is I combine lots of things, so I'll be standing in the kitchen, I'll be... I'll do one of the exercises, which probably takes two minutes, two/three minutes-ish, but then I'll stand and finish the washing up. Then I might do another of the exercises.'	Knowledge Skills Reinforcement Intentions Goals Environmental contexts and resources Behavioural regulation	2,3,5,6,7,9, 10,11,12,13		
Ways to promote routine	(8) 'something like a thing where you had to score every day even what your level of pain was and what exercise you'd done,	Knowledge Skills Goals Reinforcement Behavioural regulation	2,7,8,10,11, 13		

	something like a diary or something that you were in a habit... because if you establish a habit, don't you, the likelihood is that you'll keep doing it.'				
Effects of routine (well-being/ general health)	(2) 'I think it's routine/discipline because I know that for my health I need to get out, fresh air, walk, so I make it like, it's almost as important as having lunch, do you know what I mean? That's my daily exercise and I make sure I get it in. If I don't, I know I miss it.'	Knowledge Skills Beliefs about consequences Reinforcement Intentions Goals Behavioural Regulation	1,2		
Effects of routine (motivation)	(2) 'I suppose it's motivation, it's having a routine and something to do and the need to get out because I make that, when I don't have to go out, I make a point of going out for a walk and having that 11:00 cup of coffee. I think it's that motivation.'	Skills (practice) Beliefs about consequences Reinforcement Intention Goals Behavioural regulation	2,4		
Barriers to routine					
other health concerns	(8) 'I've not been very well as well; I've got diagnosed with kidney stones two weeks ago. The paramedics had to come; I was in so much pain.'	Environmental context and resources Emotion	1,8		

	Although I'm not using it as an excuse, when things are suddenly thrown at you like that, it sort of puts all your routine out really, of doing stuff and that.'				
Memory	(4) 'One of the things that was really hard though was actually remembering them properly because they gave me sheets of diagrams, but it was quite hard'	Environmental context and resources Memory, attention and decision processes	2,4,7,8,10, 11,13		
Other commitments (work)	(10) 'And because there were times, I was rushing off to work and I'd come back physically tired and mentally tired, because I was doing sign language. And I was coming home so shattered, I just wasn't always doing the exercises.' (12) 'I've done them in the mornings, I've done them, it's awkward for me with shifts. I've done them at various different times of the day. I wouldn't say I've got a set pattern where I get up in the morning and I do them and I think, I feel great through the day.'	Environmental context and resources	6,10,12,13	yes	

Other commitments (non-work)	(4) 'If you've got too many obligations, like mother and grandchildren, that would stop you getting in a routine.'	Environmental context and resources	1,4		
Time	(4) Well, in terms of the amount of times, yes, because at first, I was doing them every day. And then, when I came back on about the fourth visit and he was adding, adding, I said, "Well, it takes quite a long time now, it's taking about half an hour to do them." (12) they've not been strenuous what they've given me. You can fit it in with five or 10 minutes. He said, "Just do a few reps at a time," he hasn't given me drastic amounts. It's not like he said, I want you to do half an hour or an hour.	Environmental context and resources	2,4,10,12,13	yes	

Table 3: Maintenance Related Factors

Theme/sub-theme	Example of quotation (participant no; 'quotation')	Associated TDF Domains	Participant numbers with similar statements	Conflicting Belief (y/n)	Strong Belief (y/n)
Access to resources					
Further follow up/review with physiotherapist as needed	(10) 'then at least you know you can go back if something happens, because she says to me, "If anything happens in between then come back."'	Knowledge Skills Environmental context and resources Social influences	2,10,7,11,12		
Facility to maintain PA	(2) 'I think it's a niche and it seems to be, provision for people who, for older people to do arm stretches and things like that. Then there's a gym for people who are younger and physically active, but where you get access to those pieces of equipment and that sort of expertise, I don't know anywhere else apart from this, which is why it's a goldmine....If they had information like that, I would grab it with both hands.'	Knowledge Reinforcement Environmental context and resources Social influences	1,2,4,5,6,10,11		yes
Ease of Access: (Convenience, cost, special equipment needed etc)	(9) 'It's been a little bit more than normal because I've got the bike. I've deliberately got it set up so that, if I'm in the mood, I can just get on the bike, and sit and watch TV. So, rather than just sitting and watching TV or whatever I'm doing, I can sit there and I'm exercising my hip.'	Reinforcement Intentions Environmental context and resources	2,9,10		
Psychosocial support					
Relatedness to peers	(2) 'There's a new swimming baths opening in Northfield and there's a gym. I watch people who go in and	Environmental contexts and resources Social influences Social identity	1,2,4,5,6,10,13		Yes

	out to see if any of them look like me and so far, I haven't seen anybody look like me.' (10) 'A group, where people with knee pain, for instance, get invited to a session to do something. People with back pain and it would be sessions aimed at their specific problem, to help as a group. And also, that you'd be able to sit and chat about what you're having, that you're not the only one that's getting that pain or, "I'm getting the pain and I do this and that helps me." Like for instance, with my gel. If I say to people, "I use that." "Oh, I'll give that a go." You might be able to help people out that way.'	Beliefs about capabilities Optimism			
Fear of judgement by others	(8) 'Because nobody really is interested in someone who's got chronic pain because it's quite boring isn't it? It's not like you've broken your leg and people go, "Oh, how long have you got that cast on for?" You know, in your circle of friends, I mean. Nobody wants to hear that your knee hurts, do they?' (2) 'I don't want to feel stupid or embarrassed when I exercise.'	Social identity Environmental context and resources Social influence Beliefs about Capabilities Optimism Emotion	2,7,8,10		Yes
Fear of decreased support post-treatment	(2) 'I suppose I've got an image in my mind that I'd been given all this amazing care and suddenly I'm going to go out, you can't see what I do there. It's outer darkness really and having to go and it's not having that support and vital information, I think.'	Social identity Environmental context and resources Social influence Optimism Emotion	2,8,10		Yes

Family support	(10) 'It's usually not too long because my husband doesn't like walking, I think it's probably about half an hour'	Environmental context and resources Social influence	8,10,11	Yes	
Perceived Physical Capability					
Physical Capability	(4) 'I know I'll hold them up and what happens is you struggle up the hill towards them, where they've been waiting for you for five minutes. As soon as you get there, they've had their rest, so off they go again, and you have to carry on up the hill. Yeah, so that does stop me doing things.'	Beliefs about Capabilities Beliefs about Consequences Environmental context and resources Social influence Emotion	4,7,8		
Fear avoidance of going out.	(9) 'Most of the time I don't need a stick, but the thing is, when...I can have times when this hip is so painful and my leg feels as if it's going to support me. The stick isn't to help me walk properly. The stick is to give me confidence that, if I get that feeling in my leg, that I am not going to fall over.'	Beliefs about Capabilities Beliefs about Consequences Environmental Context and resources	2,7,9	Yes	Yes
Intrinsic Physical factors (age, weight)	(6) 'My weight is stopping me, because since I have stopped, the weight has piled on. I wasn't nowhere near as big then as I was now. Also, I gave up smoking and that's when the weight started to pile on as well.'	Beliefs about Capabilities Beliefs about consequences	2,5,6,7,8		
External physical factors (hills, uneven ground, stairs, heavy equipment)	(6) 'Whilst I'm okayish walking on the flat, one guy who organises our walks always says' "No, no, there's no hill, it's fine." And I say, "Well, yes, that's fine for you because your legs don't hurt, you don't even know that it's a hill." To me a hill is like that, to him a hill's like that.'	Beliefs about Capabilities Beliefs about Consequences Environmental Context and resources	1,4,6,8		Yes
Weather (e.g. amount of light, cold)	(6) 'I think if I try and use my car less because I do only work down the road. The only reason I do use my car	Beliefs about Capabilities Environmental context and resources	2,5,6,11		

	in the mornings is because it's so dark and I don't really like walking down there.' (5) 'The only thing I'll do out in the garden is I'll feed the birds, fill up the bird bath. But if it's too cold I'm back in. I don't like doing it when it's cold, it's worse now.'				

Appendix 3.4 COREQ checklist, Patient Semi-Structured Interviews

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

YOU MUST PROVIDE A RESPONSE FOR ALL ITEMS. ENTER N/A IF NOT APPLICABLE

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
<i>Personal Characteristics</i>		
1. Inter viewer/facilitator	Which author/s conducted the inter view or focus group?	64
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	64
3. Occupation	What was their occupation at the time of the study?	64
4. Gender	Was the researcher male or female?	64
5. Experience and training	What experience or training did the researcher have?	64
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	64
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	64
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	64
Domain 2: study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	64,66
<i>Participant selection</i>		
10. Sampling	How were participants selected? e.g.	65

	purposive, convenience, consecutive, snowball	
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	66
12. Sample size	How many participants were in the study?	65-66
13. Non-participation	How many people refused to participate or dropped out? Reasons?	72
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	66
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	72
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	73-75
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Appendix 3.1, 67
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	67
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	67
20. Field notes	Were field notes made during and/or after the inter view or focus group?	68
21. Duration	What was the duration of the inter views or focus group?	72
22. Data saturation	Was data saturation discussed?	66
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	72
Domain 3: analysis and findings		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	68
25. Description of the coding tree	Did authors provide a description of the coding tree?	67-69
26. Derivation of themes	Were themes identified in advance or derived from the data?	67-69
27. Software	What software, if applicable, was used to manage the data?	NVivo 68
28. Participant checking	Did participants provide feedback on the findings?	72
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Appendix 3.3

30. Data and findings consistent	Was there consistency between the data presented and the findings?	74-80
31. Clarity of major themes	Were major themes clearly presented in the findings?	74-80
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	74-80

Appendix 4.1 COREQ checklist, physiotherapy focus groups

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

YOU MUST PROVIDE A RESPONSE FOR ALL ITEMS. ENTER N/A IF NOT APPLICABLE

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
<i>Personal Characteristics</i>		
1. Inter viewer/facilitator	Which author/s conducted the inter view or focus group?	96
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	96
3. Occupation	What was their occupation at the time of the study?	96
4. Gender	Was the researcher male or female?	96
5. Experience and training	What experience or training did the researcher have?	96
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	96
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	96
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	96
Domain 2: study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	97
<i>Participant selection</i>		

10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	97
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	97
12. Sample size	How many participants were in the study?	97
13. Non-participation	How many people refused to participate or dropped out? Reasons?	100
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	97
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	100-101
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	101
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	98
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	98
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	98
20. Field notes	Were field notes made during and/or after the inter view or focus group?	98
21. Duration	What was the duration of the inter views or focus group?	100
22. Data saturation	Was data saturation discussed?	113
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	100-101
Domain 3: analysis and findings		
<i>Data analysis</i>		
24. Number of data coders	How many data coders coded the data?	99
25. Description of the coding tree	Did authors provide a description of the coding tree?	99-101
26. Derivation of themes	Were themes identified in advance or derived from the data?	99-101
27. Software	What software, if applicable, was used to manage the data?	NVivo 100
28. Participant checking	Did participants provide feedback on the findings?	98
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	104-105

30. Data and findings consistent	Was there consistency between the data presented and the findings?	101-103
31. Clarity of major themes	Were major themes clearly presented in the findings?	101-105
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	101-105

Appendix 4.2- STAPLO Physiotherapy focus group topic guide

Study title: STaying Active after Physiotherapy in patients with Lower-limb Osteoarthritis (STAPLO)

Focus group topic guide

Presentation of Structure & Content of the physiotherapy programme (MW)

- We are now going to outline the physiotherapy programme aimed at optimising physical activity adherence in people with lower-limb osteoarthritis
- By **physical activity (PA)** we mean any bodily movement produced by skeletal muscles that requires energy expenditure and can be done at any level of skill and for enjoyment. A good example of this might be a walking programme but can include a home exercise programme that you prescribe.
- By **adherence** we mean the extent to which the person with lower-limb OA regularly engages in the agreed physical activity recommendations promoted within your sessions.
- We are interested optimising PA adherence in two distinct time-frames.
- The first occurs while the person with lower-limb OA is being treated by you and adopting new PA habits and behaviours (the '**treatment phase**'). The second phase we are interested in is when the person with lower-limb has finished their physiotherapy and they need to maintain their levels of PA (the '**post-treatment phase**').
- As most PA will take place with-in the home or community, we are primarily interested in BCTs which will optimise adherence to PA away from the clinic during the treatment phase and foster maintenance to PA recommendations post-treatment.
- Population – Lower-Limb OA of hip knee
- Structure of suggested physiotherapy programme identified in semi-structured interviews including:
 - 1 to 1 treatment with physiotherapist
 - Number of sessions, timings etc
- Content of physiotherapy programme identified in semi-structured interviews including
 - suggested BCTs
 - mode of delivery
- Are there any specific questions for clarification?

Discussion Topics

We are now interested in hearing your feedback about the outlined physiotherapy programme

Structure of programme:

- What are your initial impressions about the structure of the physiotherapy programme?
 - What aspects did you like? Why?
 - What aspects did you not like? Why?
- Do you think this number of sessions and frequency will enable you to optimise adherence to physical activity in the people with lower-limb osteoarthritis that you see?
 - How many do you think you would need to deliver this programme?
- What do you think about the duration of sessions?
 - Are they long enough to enable you to help people with lower-limb to adhere to your physical activity recommendations?
 - How long would you like to have with the patients?
- Are there any further suggestions on the structure of the programme?
 - What are they?
 - How will they help you deliver the programme?

Content of programme:

- What are your initial impressions about the content of the physiotherapy programme?
 - What aspects did you like? Why?
 - What aspects did you not like? Why?
- Were there any BCTs that you think should be included?
 - Which ones?
 - How would they help facilitate adherence to physical activity?
- Out of the ones you have suggested, which BCTS are the most important to include to optimise adherence to physical activity?
 - Any others that you can think of?
 - How do you think they will encourage adherence to physical activity
- Were there any BCTs that you think should be taken out?
 - Which ones?
 - Why?
- What are your impressions on the mode of delivery? (e.g. follow up phone call, skype conversations etc)
 - Can you think of any other ways of delivering these BCTs?
 - How will they help optimise adherence to physical activity?

Acceptability:

- Is this programme acceptable to you?
 - Why? Why not?
- Would you be willing to deliver this physiotherapy programme as it has been outlined today?
 - If not, why not?
- What changes would need to be made for you to be willing to deliver it?

- Of these changes, which are the most important?
- How will these changes make it more acceptable to you?

Feasibility of delivery:

- What do you think about the feasibility of delivering this intervention within your current role?

Capability:

- Do you feel that you as an individual could deliver the programme as it has been outlined?
 - Why/Why not?
 - What changes would you make?
- Do you have the required knowledge and skills to deliver the suggested BCTs to optimise adherence to physical activity as part of the programme?
- What training or support do you feel you would require to successfully provide the physiotherapy programme? (MW to note responses on flip chart)
- Is there anything you would need to feel confident providing education and delivering these BCTs (MW put up slide with BCTs and options on mode of delivery)
 - Can you think of anything else? Anything at all?

Opportunity:

- Do you think there are sufficient numbers of appropriate people with lower-limb OA to conduct a trial at the Royal Orthopaedic Hospital? (population)
- Do you think the structure of this programme as outlined can be delivered at the Royal Orthopaedic hospital? (specific BCTs, mode of delivery, no of sessions, timings)
 - What changes do you think needs to be made?
- Do you have the appropriate facilities to deliver this programme?
 - What additional facilities do you think you might need?
 - Anything else?
- Do you have the appropriate resources and equipment to deliver this programme resources?
- Which, of these resources and facilities, are absolutely essential – for example you could not provide this intervention without them?
- Do you feel you have adequate managerial support to deliver this intervention? (e.g. service managers, referral sources)
- Is there any (other) specific feedback you have on the feasibility of implementing this intervention in your service setting with people with lower-limb OA?

Challenges to delivery

- What aspects of the programme would be relatively easy to deliver?
- What parts do you think would be more difficult to deliver?
 - What about them is difficult?
- What changes do you think need to be made?
 - How will this help?
- Of all of the challenges you have mentioned, which ones are the biggest or most important?
- How might the most important challenges be addressed?
 - How will these help?
 - Any other challenges you can think of?

Appendix 1: Background information (to be filled in by focus group participants after informed consent gained)

1) What is your gender? _____

2) What is your age? (in years) _____

3) How many years have you been qualified as a physiotherapist? _____

4) Of these, how many have you been treating people with lower-limb Osteoarthritis (OA)? _____

3) Do you have any post-graduate qualifications? If so, what is your highest level of qualification? _____

4) How frequently do you treat people with lower-limb OA? (Please select one box only)

- () Very Infrequently; 1 in the last 6 months
- () Infrequently; between 2 and 5 in the last 6 months
- () Somewhat frequently; at least 1 per month
- () Frequently; at least 1 per week
- () Very frequently; 5 or more per week

How frequently do you use strategies to promote adherence to physical activity in people with lower-limb OA?

- () Never () occasionally () 50% of the time () usually () always (100%)

Which strategies do you tend to use? _____

How effective do you believe that these strategies are at optimizing adherence to physical activity in people with lower-limb OA while they are seeing you?

Very ineffective

Very effective

() 0 () 1 () 2 () 3 () 4 () 5 () 6 () 7 () 8 () 9 () 10

How effective do you believe that these strategies are at optimizing adherence to physical activity after the person with lower-limb OA has stopped seeing you? (i.e. in the post-treatment phase)

Very ineffective

Very effective

() 0 () 1 () 2 () 3 () 4 () 5 () 6 () 7 () 8 () 9 () 10

Appendix 5.1- Reason for exclusion of Behaviour change theories (n=48)

Theory	Reason for exclusion
Action Theory Model of consumption	Theory focuses on processes involving in purchases
Affective Events Theory	Theory focuses on how effective experiences influence job satisfaction and performance
Aids Risk Reduction Model	Theories primary aim is to explain HIV protective behaviours
Behavioural-Ecological Model of Adolescent Aids Prevention	Theories primary aim is to understand adolescent sexual behaviours
Change Theory	Primary focus is on social change so not relevant
Classic Conditioning	Based on behaviourism and stimulus which not relevant Excluded by Hale et al., (2020) due to lack of behaviour
Consumption as social practices	Primary focus on consumer behaviour
Containment Theory	Primary focus on deviant behaviour/crime
Differential Association Theory	Primary focus on criminal behaviour
Diffusion of Innovations	Primary focus on individuals /groups accept or reject new ideas so very limited relevance
Ecological Model for Preventing Type 2 diabetes in Minority Youth	Primary focus on type 2 diabetes in youths
Extended Information Processing Model	Primary focus on mass media campaigns Excluded by Hale et al., (2020): Integrated into the Theory of Triadic Influence
Extended Parallel Processing Model	Primary focus on response to fear/threat not relevant
General Theory of Crime	Primary focus on criminal behaviour
General Theory of Deviant Behaviour	Primary focus on deviant behaviour
Information-Motivation-Behavioural skills (for aids risk reduction)	Primary focus is on aids reduction
Information-Motivation-Behavioural Skills Model of Adherence (to anti-retroviral therapy)	Primary focus on adherence to anti-retroviral therapy
Integrated Theoretical Model of Alcohol and Other Drug Abuse Prevention	Primary focus on drug abuse prevention
Integrated theory of Drinking Behaviour	Primary focus is on alcohol consumption in youths
Integrative Model of Factors Influencing Smoking Behaviours	Primary focus on smoking behaviours in young people Excluded by Hale et al., (2020) Excluded by Hale et al., 2020: Integrated into the Theory of Triadic Influence
Integrative Model of Health Attitude and Behaviour Change (Mass media campaigns)	Primary focus on mass media health promotion campaigns Excluded by Hale et al., (2020) Excluded by Hale et al., 2020: Integrated into the Theory of Triadic Influence
Integrative Model of Factors Influencing Smoking and Attitude and Health Behaviour Change	Primary focus on smoking behaviours Excluded by Hale et al., 2020: Integrated into the Theory of Triadic Influence

Model of Pro-environmental behaviour	Primary focus on pro-environmental behaviour
Motivation-Opportunities-Abilities Model (Impact on the environment)	Primary focus on consumer behaviours and environmental impact
Needs-Opportunities-Abilities Model (consumer Behaviour)	Primary focus on consumer behaviour
Norm Activation Theory	Primary focus on altruistic behaviours
Operant Learning Theory	Focus on 'punishment' not relevant
Problem behaviour theory (Adolescents)	Primary focus on deviant behaviour in young people
Prospect Theory	Primary focus on decision making in uncertain circumstances not relevant
Prototype Willingness Model (adolescent risk behaviour)	Primary focus on adolescent risk behaviour
Rational Addiction Model	Primary focus on economic addiction
Relapse Prevention Model	Primary focus on addictive substances/behaviours
Risk of Feeling Theory	Primary focus on responses to difficult/risky situation which has very limited application to study
Six-Staged Model of Communication	Primary focus on Mass media influence of behaviour
Social Action Theory (Ewart, 1991)	Primary focus on a population level rather than individual so limited value
Social Action Theory (Weber, 1978)	Excluded by Hale et al., (2020): Relationships between constructs not clear
Social Change Theory	Primarily aimed at altering the community level to influence individuals so not relevant to intervention
Social Consensus Model of Health Education	Focuses on a population level rather than individual so not relevant to intervention
Social development model	Primarily focused on criminal behaviours in young people
Social Identity Theory	Primary focus on groups interactions does not fit with the interventions
Social Influence Model of Consumer Participation	Primary focus on consumer practices
Social Learning Theory	Primary focus on imitation of limited relevance to intervention
Social Norms Theory	Focus on perceptions of perceptions/behaviours of others in social group of limited relevance to intervention
Technology Acceptance Mode	Primary focuses on use of technology
Terror Management Theory	Primarily focuses is on self-esteem and mortality not relevant to intervention
Terror Management Health model	Focus is on mortality not relevant to intervention
Theory of Normative Social Behaviour	Primary focus is on alcohol consumption
Value belief Norm Theory	Primary focus is on environmentalism/conservation

Appendix 5.2- Mapping of intervention behaviour change techniques to Self Determination Theory constructs

MBCT (Texiera et al., 2020)	SDTT (Gillison et al., 2019)	Associated V1 BCTs (Gillison et al., 2019)	Corresponding V1 BCTs from prototype intervention
Autonomy			
MBCT 1 Elicit Perspectives on condition or behaviour	SDT2: Acknowledge participant's perspective		
MBCT 2 Prompt identification of sources of pressure for behaviour change	SDT8 Explore reasons		
MBCT 3 Use non-controlling, informal language	SDT 4: Use of non-controlling language		
MBCT 4 Explore life aspirations and values	SDT 5: Intrinsic Goal orientation		1.1 Goal setting (behaviour) 1.3 Goal setting (outcome)
MBCT 5 Provide a meaningful rationale	SDT3: Provide a rationale	BCT 4.2 Information about antecedents BCT 5.1 Information about health consequences BCT 5.2 Salience of consequences BCT 5.3 Information about social and environmental consequences BCT 5.6 Information about emotional consequences	5.1. Information about health consequences 5.3. Information about social and environmental consequences
MBCT 6 Provide choice	SDT1: Choice		1.1 Goal setting (behaviour) 1.3 Goal setting (outcome) 1.4 Action planning
MBCT 7 Encourage the person to experiment and self-initiate the behaviour	SDT7: Emphasise responsibility SDT6: Structure	BCT 12.2 Restructuring of the social environment BCT 1.1 Goal setting (behaviour) BCT 1.3 Goal setting (outcome) BCT 1.4 Action Planning BCT 4.1 Instruction on to perform the behaviour BCT 6.1 Demonstration of the behaviour	12.2 Restructuring the social environment 1.1 Goal setting (behaviour) 1.3 Goal setting (outcome) 1.4 Action Planning 4.1 Instruction on how to perform the behaviour 6.1 Demonstration of the behaviour 8.1 Behavioural practice/rehearsal

SDT9: Motivational Interviewing

BCT 8.1 Behavioural practice/rehearsal
3.3 Social Support (Emotional)
Motivational interviewing

Relatedness

MBCT 8 Acknowledge and respect perspectives and feelings			
MBCT 9 Encourage asking of questions			
MBCT 10 Show unconditional regard			
MBCT 11 Demonstrate interest in the patient	SDT16: Involvement		3.3 Social support (unspecified)
MBCT 12 Use empathetic listening			
MBCT 13 Provide opportunities for ongoing support	SDT15: Provide support and encouragement	15.1 Verbal persuasion about capability	3.3 Social support (unspecified) 15.1. Verbal persuasion about capability
MBCT 14 Prompt identification and seek available social support	SDT17: Encourage social support seeking	3.1. Social support (unspecified) 3.2. Social support (practical) 3.3. Social support (emotional)	3.1. Social support (unspecified) 3.2. Social support (practical) 3.3. Social support (emotional)
	SDT18: Group cooperation		3.2. Social support (practical)
	SDT19: Use of incentives**	10.1 Material incentive (behaviour) 10.2 Material reward (behaviour) 10.3 Non-specific reward 10.10 Reward (outcome)	10.1 Material incentive (behaviour) 10.2 Material reward (behaviour) 10.3 Non-specific reward 10.10 Reward (outcome)

Competence

MBCT 15 Address obstacles for change	SDT14: Barrier identification	1.2 Problem Solving	1.2 Problem Solving
MBCT 16 Clarify expectations			
MBCT 17 Assist in setting optimal challenge	SDT11: Provide optimal challenge	8.7 graded tasks	1.1 Goal setting (behaviour) 1.3 Goal setting (outcome) 8.7 graded Tasks
MBCT 18 Offer constructive, clear and relevant feedback	SDT12: Provide informational feedback	1.7 Review behaviour goals 2.2 Feedback on behaviour 2.3 self-monitoring of behaviour	1.5 Review behaviour goal(s) 1.7 Review outcome goal(s) 2.2 Feedback on behaviour 2.3 Self-monitoring of behaviour

		2.4 Self-monitoring of outcomes of behaviour 2.6 Biofeedback 2.7 Feedback on outcome (s) of behaviour 1.1 Goal setting (behaviour) 1.3 Goal setting (outcome) 1.4 Action Planning 4.1 Instruction on to perform the behaviour 6.1 Demonstration of the behaviour 8.1 Behavioural practice/rehearsal	2.4 Self-monitoring of outcome(s) of behaviour 2.7 Feedback on outcome(s) of behaviour 1.1 Goal setting behaviour 1.3 Goal setting outcome 1.4 Action planning 4.1 Instruction in how to perform the behaviour 6.1 Demonstration of the behaviour 8.1 behaviour practice/rehearsal 2.3 Self-monitoring of behaviour 2.4 Self-monitoring of outcome(s) of behaviour 1.2 Problem solving
MBCT 19 Help develop a clear and concrete plan of action	SDT 6: Structure		
MBCT 20 Promote self-monitoring			
MBCT 21 Explore ways of dealing with pressure			
	SDT19. Use of incentives		10.1 Material incentive (behaviour) 10.2 Material reward (behaviour) 10.3 Non-specific reward 10.10 Reward (outcome)
	SDT10: Task climate SDT13 Provide information	4.2 Information about antecedents 5.1 Information about health consequences 5.3 Information about social and environmental consequences 5.6 Information about emotional consequences	5.1 Information about health consequences 5.3 Information about social and environmental consequences
	SDT15: Provide support and encouragement	15.1 Verbal persuasion about capability	15.1 Verbal persuasion about capability

Legend: MBCT: Motivational Behaviour change technique as identified in Teixeira et al., (2020)(437); SDTT: Self-determination Theory technique as identified in Gillison et al., 2019(428). Note: SDTT were mapped against to the specific Self-Determination Theory Need/Construct of Autonomy, Relatedness or Competence. MBCTs and SDTTs appear in the same row if they were considered equivalent. V1 BCT: Behaviour Change Technique from Michie et al., (2013) V1 taxonomy(123); SDT: Self-Determination Theory;

1. Teixeira PJ, Marques MM, Silva MN, Brunet J, Duda JL, Haerens L, et al. A classification of motivation and behavior change techniques used in self-determination theory-based interventions in health contexts. *Motivation Science*. 2020;6(4):438-55.
2. Gillison FB, Rouse P, Standage M, Sebire SJ, Ryan RM. A meta-analysis of techniques to promote motivation for health behaviour change from a self-determination theory perspective. *Health Psychol Rev*. 2019;13(1):110-30.

3. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Ann Behav Med*. 2013;46(1):81-95.

Appendix 6.1: Schedule of enrolment, interventions, and assessments

	Enrolment	Baseline	Treatment			Follow up			Close-out
TIMEPOINT**	$-t_1$	t_0	t_1-t_2	T_3-t_4	T_5-t_6	$t_0 + 3 \text{ Mo}$	$t_0 + 6 \text{ Mo}$	Interview S^*	t_x
ENROLMENT:									
Eligibility screen	X								
Informed consent	X								
Allocation	X								
INTERVENTION:									
ASSESSMENTS:									
Acceptability of intervention								X	
Acceptability of training									X
Intervention fidelity									X
Recruitment rates		X							
Completion rates of outcomes		X				X	X		
Feasibility and acceptability of procedures and outcome measures								X	

Feasibility and acceptability of accelerometer						X	X	
Demographic characteristics	X							
Accelerometer	X				X	X		
Physical Activity	X				X	X		
Adherence					X	X		
Pain	X				X	X		
Function: Self report and performance based	X				X	X		
Bothersomeness	X				X	X		
Quality of Life	X				X	X		
Self-Efficacy	X				X	X		
Motivation Regulations and psychological needs satisfaction	X				X	X		
Perceptions of autonomy support					X			

*Interviews were conducted on a purposive sample of patients with lower-limb Osteoarthritis at completion of their treatment, approximately 4-5 months post baseline. Interviews with physiotherapists and research staff occurred prior to individuals completing tasks associated with the trial

Appendix 6.2: Overview of intervention development

The complex, multi-component theoretical behaviour change intervention has been developed sequentially as outlined below.

Systematic review

A systematic review evaluated the effectiveness of BCTs within physiotherapy interventions aimed at optimising adherence to PA in patients with lower-limb OA.(277, 374) Most BCTs demonstrated modest effects (measured by likelihood ratios) at optimising PA adherence. Findings also revealed specific techniques (i.e., 'Action planning' and 'Feedback on behaviour') to be most effective over the short-term ($\leq$ three months post baseline) while others (i.e., 'Problem solving' and 'Review behaviour goals') were more effective over the longer-term ($\geq$ six months). Some behaviour change techniques (i.e., 'Behavioural contract' and 'Non-specific reward') were potentially effective across all time points. Overall, BCTs were least effective at promoting PA adherence at six months post-baseline before a slight recovery at 12 months post-baseline.(277)

Qualitative Studies

Interviews with Patients

Semi-structured interviews(300, 340) examined the views of patients with lower-limb OA regarding the barriers and facilitators to adherence to physiotherapist prescribed PA during treatment (adoption) and post-discharge (maintenance). The results revealed that the promotion of a PA routine within a positive, supportive, patient-centred physiotherapy environment was integral to behavioural adoption and the facilitation of confidence and motivation to initially engage with prescribed PA when outside the clinic. Modifying the patient PA environment to ensure it is positive and supportive and ongoing access to appropriate resources deemed important to facilitate PA maintenance post-discharge. Pulling from these findings, a theoretically informed physiotherapy intervention which incorporated 26 BCTs was developed.

Focus Groups of physiotherapists

The proposed intervention was presented to physiotherapists to assess their perspectives on its acceptability and feasibility for implementation in clinical practice. Although the physiotherapists found the intervention highly acceptable and did not suggest any alteration of intervention BCTs, they believed that they required further training in behaviour change theory, especially in strategies for creating a more supportive motivational treatment environment and how to optimally deliver the BCTs.

Selection of theory and choice of training programme

Theories of behaviour change were reviewed to provide a conceptual framework to support training of physiotherapists in intervention delivery. Self-determination Theory (SDT),(280, 422) a prominent theory of behaviour change which focuses on an individuals' underlying reasons (i.e motivations) for behavioural engagement, was chosen as an appropriate theory to underpin the intervention.(443) The resulting intervention has the overarching aim of creating a more motivationally empowering treatment climate and to implement particular behaviour change techniques (BCTs) to support patients with lower-limb OA to adopt and maintain appropriate individual levels of PA.

The *Empowering Coaching* programme,(425, 535) which is grounded in SDT, was adapted for delivery for physiotherapists (*Empowering Physio™*). The overarching aim of the bespoke training programme is to enhance physiotherapists' understanding of differences in the quality of patient motivation (and implications), and awareness of the treatment climate they create and how it can influence patients' psychological needs of competence, autonomy, and relatedness their subsequent more autonomous motivation to adopt and maintain their PA goals.

Appendix 6.3 Overview of physiotherapist training

- 1) **Intervention Introduction (1 hour):** MW outlined the rationale and developmental steps of the intervention and overviewed the conceptual phases and protocol BCTs. The intervention manual (Appendix 6.) which outlined the BCTs [as defined by the V1 taxonomy (123)] and provided examples of how to deliver them to create an empowering treatment climate, and key research articles, were distributed to physiotherapists for reference.
- 2) The *Empowering Physio*TM training programme: Previous work by Duda (2013) (425) synthesised key principles from leading motivational theories [Self Determination Theory (SDT) (384) and Achievement Goal Theory (AGT) (545)] to propose a conceptual model of an empowering or disempowering motivational climate. The conceptual model informed the creation of *The Empowering Coaching*TM training programme (425, 535), which aimed to assist sports coaches to develop motivationally empowering climate to promote well-being and optimise performance in athletes. The essential features of the *Empowering Coaching*TM training programme have been adapted for healthcare professionals and were delivered to intervention physiotherapists in the trial. Based on the model proposed by Duda (2013) (425, 535) (please see Figure 7.1 in main thesis), a motivationally empowering treatment climate can be created when physiotherapists provide choices for PA (autonomy support) and social support (care and respect/ unconditional regard) to help patients to reconceptualise their feelings for PA to be based on the exertion expended to complete it (task involvement). However, physiotherapists would produce a motivationally disempowering treatment climate if their exchanges were controlling/coercive, or if their favour was based on the patient's ability to achieve their PA goals in comparison to others with lower-limb OA (ego driven). The *Empowering Physio*TM training programme aimed to help physiotherapists conceptualise how their communication style and the immediate environment could create a more motivationally empowering or disempowering treatment climate for patients with lower-limb OA. Training linked how the promotion or thwarting of SDTs (384) constructs of autonomy, relatedness (belonging), and competence could foster an empowering or disempowering treatment climate and its influence on the quality of patient motivation to adopt and maintain PA and impact on clinical outcomes.
- 3) Delivery of protocol BCTs (3 hours): MW defined each protocol BCT and linked them to intervention materials. Videos of how BCTs could be delivered in physiotherapy practice were presented. Further discussion critically reviewed the videos and collaboratively agreed strategies in how to deliver BCTs in an empowering way.
- 4) Top up training (2 hours): MW met with physiotherapists for problem-solving discussions to trouble shoot any issues identified during initial intervention delivery. Points that were unclear from the initial phase of training were reviewed and clarified.

STaying Active with Physiotherapy in patients with Lower-limb Osteoarthritis (STAPLO)

Study booklet 1: How you can become more active



Authors: Matthew Willett, Joan Duda, Alison Rushton, Carolyn Greig, Eric Deeson, Gareth Stephens.

Email any questions to [REDACTED]

RESEARCH SHOWS THAT OSTEOARTHRITIS CAN REDUCE YOUR LEVELS OF PHYSICAL ACTIVITY. THIS CAN AFFECT YOUR HEALTH AND HOW MUCH PAIN YOU FEEL.

The aim of this booklet is to explain why being physically active is important. Physical activity includes two main parts. The first is doing general lifestyle activities that you may enjoy, like going for a walk with your friends. The second is doing structured exercises, like sitting down and standing up ten times, that may make your stronger legs. There are many benefits to doing both types of physical activity and some of these reasons may be particularly important to you. Our goal is to support you in becoming more physically active and, in turn, help you manage your osteoarthritis.

Initial Thoughts

When were you first diagnosed with osteoarthritis?

How do you think you are managing your osteoarthritis? (circle the word that best describes your situation)

Very Well Quite Well Just Coping Not Coping At All

How active is your life style currently? (circle one):

Very Active Quite Active Not Very Active Not Active At All

How important do you think activity and exercise are to more effective management of your osteoarthritis symptoms? (circle one):

Very Important Quite Important Not Very Important Unimportant

BECOMING MORE ACTIVE

Being more physically active has the potential to result in a number of benefits.

These include:

- Reduced pain
- Increased function
- Increased feelings of confidence
- Increased well-being and mood
- Increased concentration and memory
- Weight loss

OUR PHYSIOTHERAPY TREATMENT

The aim of our physiotherapy treatment is to support you to be as physically active as possible. We will do this by helping you to identify activities you could enjoy and work out how they might fit into your lifestyle. This could enable you to develop your physical skills, become fitter, and adopt an active lifestyle that you can continue after you have finished your physiotherapy treatment.

A key factor that determines how active we are is our motivation to do that particular activity

WHAT IS MOTIVATION?

Motivation relates to why we want to do things. What are the reasons, for example, for why we personally might want to become more active?

If a particular form of physical activity is meaningful to you, it is more likely that it will be beneficial for your wellbeing. You are also more likely to choose to start and keep doing it if you enjoy it. This is referred to as ‘autonomous’ motivation as you choose the physical activity that you will do and provide your own motivation. Developing autonomous motivation is likely to give you the best opportunity to start and keep up your activity levels.

There are three key areas that we can target to help you develop your autonomous motivation for physical activity.

- 1) Where possible, we know that most people find it beneficial to have **choice** in, and take ownership of their activities.
- 2) If doing your activities with others, it may be beneficial to feel a sense of **belonging**. No one is an island; we know you are more likely to start and continue with an activity if you feel connected to others that do the activity. This can make the activity more meaningful to you and more enjoyable.
- 3) It may be beneficial to feel **competent** or that you have the ability to do your chosen activity.



Our physiotherapy treatment has been specifically designed to help promote your feelings of Choice, Belonging, and Competence to help develop your autonomous motivation to be as active as possible.

In order to enable us to give you the best support, please take some time to answer the following questions before you start. Your physiotherapist will work through these with you in your treatment sessions. This may help you understand why you do different activities. This will likely help them to advise you on what you can do and how you can do it. Please feel free to ask for any advice or inspiration!

IMPORTANT POINT: When filling in the points below, it is good to remember all those activities that you enjoy the most!



Questions	Comments
It might be helpful to write down if you personally wish to become more physically active and consider why/why not	
For you personally, in what ways would becoming and staying more active benefit you?	
For you personally, what might be the barriers to starting to become more physically active?	

For you personally, what might be the barriers or challenges to continuing being physically active after you have finished physio?	
It might be helpful write down what physical activity/ activities you already do? (Up to 3).	Activity 1)
In the space provided it might be helpful to consider how often you do each of them and how you could make each more enjoyable and/or interesting?	Activity 2)
	Activity 3)
It might be beneficial if you could suggest any new activities you would like to try over the next week or two? (Up to 3)	Activity 1)
We know most people find it helpful to consider and write down details of: • How many times per week you could do each activity • For how long • When and where you could do each activity • Think of anybody you could do the activity with	Activity 2)
	Activity 3)
Note: It may be helpful to use the activity diary on the next page to help you plan your activity and form a routine.	

Weekly Physical Activity Planner for week beginning
copies or ask your physio for some!)

(Make a few

		Monday	Tuesday	Wednesday	Thursday	Friday
Sleep	bedtime last night					
	getting up time					
Morning	What will I be doing?					
	Potential Activity					
Afternoon	What will I be doing?					
	Potential Activity					
Evening	What will I be doing?					
	Potential Activity					
Total Daily Steps						

STaying Active with Physiotherapy in patients with Lower-limb Osteoarthritis (STAPLO)

Study booklet 2: How to keep your activity going



Authors: Matthew Willett, Joan Duda, Alison Rushton, Carolyn Greig, Gareth Stephens, Eric Deeso

Email any questions to [REDACTED]xxxxxxx

Forming a routine and continuing with activity

The first booklet hopefully helped you to identify activities that you enjoy and make an initial plan to form a routine in terms of when, where, and with whom to do them....and perhaps, identify some new physical activities you would like to try!

Now that you have been doing physiotherapy for a while, it may be important to think how you can sustain your physical activity levels once you have finished your treatment. It can also be worthwhile to consider how you might modify your current activity practices so that you keep your autonomous motivation to continue with each activity.

There are **two** key aspects of your environment that affect your confidence and motivation to keep doing activities: your **physical** environment and your **social** environment.

To help identify important aspects of these, you might want to increase your awareness of what you do, both when you are by yourself and with others.

You can do this by monitoring your types and amounts of activity and seeing how much you enjoy each and/or how interesting and engaging they might be. You may also find it helpful to use the self-monitoring diary attached at the end of the booklet to help with this.

This booklet will also ask you several questions to help you look at both your physical and social environment. This will help you consider how you can change things so that you feel competent to continue with your chosen activity.

A list of local resources is provided within this booklet to give you choices and help keep you active. You may find it useful to look into them in between your treatment sessions so you can discuss the best options with your physiotherapist.



Activity Questions (e.g. swimming, walking with your friends, gardening)

Can you give examples of activities you have done this week? Give up to three.	1)
It may also be useful to consider why you choose to do these activities	2)
	3)
Which activity did you enjoy the most? Why did you enjoy it the most?	
Can you think of anything that could be done to make it more engaging or make you want to do it again?	
How did you feel when you were doing the activity?	

How did you feel when you were finished?	
Next week, what might you do differently? What will you do the same?	
What other activity could you do next week?	
When and where will you do this?	

Thinking ahead: Why not build this up over the next few weeks?

For you personally, what is your favourite form of physical activity?	
For you personally, where do you enjoy doing physical activity the most?	
Do you have space at home that you can be physically active in?	
For you personally, do you enjoy being physically active with others?	
If so, can you think of anyone who you do, or could do, physical activity with regularly?	
It may be beneficial to review the list of local resources below: Do you like the look of any?	
Could you try any of them? If so, which ones?	
Alternatively, are you aware of any other such resources available nearby that you would like to try? (e.g. walking groups, gyms, aqua jogging classes)	
When could you try one of these?	

Is there anyone you know who could do them with you?	
If you are planning on using these resources, how could you access them?	
Do you feel that you will be able to keep on doing your activity/exercises after you have finished your physiotherapy sessions?	
For you personally, what might be the barriers or challenges to continuing being physically active after you have finished physio?	
Can you think of any solutions?	
Can you think of any additional support that you need to stay active? If so, what?	

Final important messages

You have done really well with your physical activity. Remember most people with osteoarthritis are less active than others. However, we know that other people with osteoarthritis and your family and friends usually think it is great that you are becoming more active. This way you can do more and it should help reduce your pain over the long-term.

Remember, just because you have osteoarthritis, this does not mean that you have to stop doing things you enjoy! You can maintain or increase your level of physical activity slowly over time by keeping a record and listening to your body. If you have an increase in symptoms that lasts longer than a few hours after your exercises, just take a break and reduce how much you are doing. An increase in symptoms does not mean that your arthritis is getting worse. It is much more likely that you have done a bit too much and just need to slow down.



Local Resources to help you to get active

It may be useful to have a look at the sources listed below and see if they are right for you to help plan how to stay active.

Birmingham Council:

Active Parks: Did you know that 84% of Birmingham's population is defined as inactive, but a whopping 60% say they'd like to do more exercise? Look at the link below for more information:

<https://www.birmingham.gov.uk/activeparks>

Walking

Walking for health Walking for Health is England's largest network of health walks with over 360 active walking schemes, helping people across the country lead a more active lifestyle. The walks are short and over easy terrain, and are open to everyone but are especially aimed at those who are least active.

<https://www.walkingforhealth.org.uk/walkfinder>

The Urban Walking Route Planner Get a route map between any two points, including your journey time, calorie burn, step count and carbon saving. It's quick, free, healthy and green. Search for walking directions using the journey planner or try one of the suggested walks.

<http://walkit.com/>

The Active Wellbeing Society provide a wide range of activities at all levels from absolute beginners to more confident, through to advanced and they are all FREE. Activities range from cycling and rambles to Tai Chi and sports like rounders and basketball, boules, tennis, rowing, and canoeing to community projects such as gardening, conservation and bushcraft.

<https://theaws.co.uk/activities/>

Passport to Leisure (PTL) card gives you up to 20% off most activities at council-run leisure centres, Wellbeing Centres and swimming pools. The card also gives you discounts at some museums, theatres and other attractions in Birmingham.

You can get a Passport to Leisure Card if you are a Birmingham resident and are either:

- aged 60 or over
- a full-time student
- an asylum seeker
- a carer
- receiving certain benefits (ask at your local leisure centre), or
- a child in care

You can also apply for a card if you have a disability and are receiving incapacity benefit, tax credits or disability living allowance.

[REDACTED]

[REDACTED]xxxxxxxxxxxxxxxxxx

https://www.birmingham.gov.uk/info/50041/sport_and_leisure_memberships/688/passport_to_leisure

https://www.birmingham.gov.uk/info/20177/sport_and_leisure

Community Centres Various community centres across Birmingham have classes aimed at older adults such as over 50's exercise classes, needlecraft and yoga.

https://www.birmingham.gov.uk/directory/59/community_centres_in_birmingham/category/1177

Further Treatment Advice

Chartered Society of Physiotherapy,

14 Bedford Row London WC1R 4ED Phone: [REDACTED] www.csp.org.uk

If none of these options appear right for you, please don't worry. Please discuss these issues with your physiotherapist for further advice and contacts on things such as: Pain, Gardening, Mental Health or dietary advice.

Weekly Physical Activity Planner for week beginning
some!)

(Make a few copies or ask your physio for

	Days	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Sleep	Time in bed							
	Time out of bed							
Morning	Activity							
	Whom did I do it with?							
	How much did I enjoy it?							
Afternoon	Activity							
	Whom did I do it with?							
	How much did I enjoy it?							
Evening	Activity							
	Whom did I do it with?							
	How much did I enjoy it?							

STaying Active with Physiotherapy in patients with Lower-limb Osteoarthritis (STAPLO)

Investigators:

Mr Matthew Willett

Professor Joan Duda

Mr Gareth Stephens

Professor Alison Rushton

Professor Carolyn Greig

Dr Eric Deeson

Contact details: [REDACTED]

Treatment Manual 2022

- 1. Background**
- 2. Methods**
- 3. What is being asked of you**
- 4. The intervention**
- 5. Physiotherapy training**
- 6. Other important information**
- 7. Key Personnel**
- 8. Appendix 1: STAPLO consort Flow diagram**
- 9. Appendix 2: Intervention materials delivered across sessions and outline of content and associated theoretical constructs and behaviour change techniques**
- 10. Appendix 3: Behaviour Change Techniques to be delivered during the STAPLO Intervention**

Thank you for agreeing to helping deliver our physiotherapy intervention. The information below outlines the study and will provide key guidance of what is required from you.

In the United Kingdom (UK), Osteoarthritis (OA) is the leading cause of disability and pain in older adults, with one-third of patients over 45 years old, equating to almost 9 million individuals, having sought treatment for OA related symptoms. Lower-limb OA is particularly problematic with 4.1 and 2.5 million individuals experiencing symptoms associated with knee and hip OA respectively.

Musculoskeletal physiotherapists are the primary healthcare provider of non-pharmacological treatments for patients with lower-limb OA. Evidence-based physiotherapy interventions follow international guidelines and incorporate strategies to optimise physical activity (PA) to aid patients with lower-limb OA to moderate their clinical symptoms (i.e. reduce pain and increase function and quality of life). However, physiotherapy interventions are effective at improving short-term pain and function only (approximately 3 months), with symptoms returning around six months post baseline. This is likely associated with a gradual reduction in patient adherence to prescribed PA after discharge, when approximately 90% of patients with lower-limb OA do not maintain their PA.

The Medical Research Council (MRC) advocates that interventions should be informed by behaviour change theory to enable a greater understanding of the intervention mediators (e.g. self-efficacy) effect on the target behaviour and therefore, the intervention can be refined for future testing. However, there is currently a lack of theoretically informed behaviour change interventions in both OA and wider pain populations.

The literature outlines that individuals go through several phases of behaviour change when integrating new behaviours, such as PA adherence, into their lives. The most important phases are '*adoption*', which would occur during physiotherapy treatment, and '*maintenance*' which would be ongoing post-treatment and is considered to be evident approximately 6 months of behavioural practice. Importantly, factors that influence patients' adoption and maintenance of PA are distinct and therefore, a physiotherapy intervention needs to incorporate specific behaviour change techniques (BCTs) to match these conceptual phases to optimise PA adherence.

Our systematic review of the effectiveness of behavioural physiotherapy interventions on adherence to PA supported this concept and demonstrated that some BCTs were most effective over the short-term (≤ 3 months post baseline) or longer-term (≥ 6 months) time points with others potentially effective across all time points. Our qualitative study of patients with lower-limb OA suggested that promotion of a PA routine was an important transitional stage linking PA adoption and maintenance. The formation of a PA routine developed patients' feelings of competence and motivation and was best achieved through a more positive, supportive, patient-centred physiotherapy treatment environment.

We developed a theoretically informed physiotherapy intervention which incorporated BCTs that targeted the determinants of PA adoption, routine formation, and maintenance and presented it to focus groups of physiotherapists. The physiotherapists found the intervention highly acceptable and feasible, therefore, the next step was to test the interventions feasibility within physiotherapy clinical practice.

Although the intervention was deemed acceptable to physiotherapists, they perceived a need for further training in ways of creating a more positive, supportive, and patient-centred treatment environment to promote feelings of patient competence and motivation and how to deliver the intervention BCTs.

Therefore, further work was undertaken to identify potential theories of behaviour change and associated training programmes to support intervention delivery and training of the trial physiotherapists. Self-determination Theory (SDT) was identified as an appropriate theory to underpin the behaviour change intervention due to its theoretical associations linking feelings of confidence/competence to task motivation and empirical base of clinical trials targeting PA behaviours. The *Empowering Coaching* (EC) framework was further identified for its conceptual linkages to SDT and expanded understanding of the features of the environment linked to the promotion of resilient participant competence and quality (i.e., autonomous) motivation. The EC training programme has been modified, based on the results of our qualitative studies, to provide bespoke training for physiotherapists (i.e., *Empowering Physio*). The training aims to help physiotherapists produce a more positive, supportive, and patient-centred treatment environment by developing their understanding of the rationale for and features and determinants of such an environment.

Therefore, our pragmatic single arm feasibility trial will be the first theoretical physiotherapy intervention designed to promote a supportive and patient-centred treatment environment to enable patients with lower-limb OA to develop feelings of competence and motivation to PA utilizing BCTs targeting PA adoption, routine formation, and maintenance.

Aim

This trial has two primary aims:

- 3) To investigate whether a complex, multi-component theoretical behaviour change physiotherapy intervention is feasible and acceptable for patients with lower limb OA and treating physiotherapists.
- 4) To evaluate the feasibility and acceptability of trial related procedures to participants and research related staff

Study Methods

Trial Design

The trial will utilize a mixed-methods feasibility design including a quantitative prospective, single-arm feasibility trial with a 6 month follow up and a qualitative assessment to provide an in-depth examination of the intervention's feasibility and acceptability for participants, physiotherapists and research staff at the Royal Orthopaedic Hospital. An overview of the trial flow can be seen in Appendix 1.

Trial Participants

30-35 participants will be recruited at the Royal Orthopaedic Hospital Based on the following criteria:

Inclusion Criteria
Adults (≥ 45 years) with a diagnosis of unilateral or bilateral lower-limb (hip or knee) OA as per NICE guidelines(273) who have been referred to the ROH for physiotherapy (either self-referral or consultant referred) to aid their related symptom management.
Exclusion Criteria
• No co-existing articular pathology effecting their hip or knees e.g. gout, ankle arthritis, rheumatoid arthritis, serious spinal pathology or lumbar nerve root impingement • Having had or on a waiting list for hip or knee joint replacement • Wheel chair dependence/inability to transfer • Participants are required to be able to give informed consent and communicate and understand the English language. • Physiotherapy for the management of their OA related symptoms within the last 6 months • Currently enrolled or involved in a concurrent PA/exercise programme • Previous participation in a physiotherapy behavioural intervention • Mental health conditions (e.g. high levels of anxiety, current clinical depression) or psychiatric illness (e.g. schizophrenia) • Upper motor neuron lesions e.g. previous CVA, Multiple sclerosis, parkinson's disease • Inability or unwilling to attend physiotherapy sessions

What is being asked of you?

Intervention delivery

The intervention will be delivered in one-to-one physiotherapy sessions. There will be approximately six sessions which is based on patient preference from the intervention

development and current trust parameters. The sessions will be conducted in person or via phone/skype and be based on the patient's preferences. Session timings will be dependent on patient availability and your work schedule. Assessment of the patient reported and performance-based outcome measures will be performed on three occasions: once at the commencement of the study period, 3 months and then again after 6 months. These will be collected by the research nurses at virtual appointments. Therefore, you will not be required to collect any official data during the trial.

Length of sessions

The intervention is designed to be delivered within the established trust physiotherapy timeslots.

Recording of intervention sessions

One of our key objectives relates to how the intervention is being delivered during the trial. Therefore, we will ask you to audio record one session from each phase (adoption, routine formation, maintenance) of the intervention of the first and third patient that you see. The session number will be randomized and you will be directed on which session to record. Please record these on the digital voice recorder provided and then send a copy of the recording to MW via encrypted email.

The STAPLO intervention

Behaviour change intervention

The intervention has the overarching aim of providing a supportive and patient-centred treatment environment to assist patients with lower-limb OA to adopt and maintain their PA goals. It is hypothesised that the treatment environment and intervention BCTs will influence patients' perceptions of autonomy support, relatedness, and competence and their motivation regulation to facilitate the adoption and maintenance of prescribed PA. The adoption and maintenance of PA is hypothesised to impact on patients' outcomes of pain, function, and self-efficacy for PA.

To support patients to adopt and maintain the prescribed activities they will be given

- A pedometer
- Two trial related work books
- Hip or knee versus arthritis book
- Theraband (optional)
- Exercise sheets (optional; can be printed or used from versus arthritis booklets)

Appendix 2 outlines the intervention materials and their linkages to specific BCTs.

Adoption (Sessions 1-2)

The aim of the adoption phase is to facilitate the patient to develop physical activity goals and outline a clear, detailed plan of how they can achieve them. To help with patients' feelings of competence and autonomy try to use this time to explore the patients' goals and values, explain about osteoarthritis and why PA can help with symptom management and their well-being, and discuss activity options based on their preferences. It is also important at this stage to only prescribe activities that the patients feel that they can do fairly easily that will not make their symptoms worse.

Please give the patient their adoption workbook, their pedometer, and the associated versus arthritis information booklet at their first appointment. This workbook is fairly short and has been written using autonomy supportive language. It outlines the aim of the treatment programme, gives a bit of background information about motivation, and asks a series of questions to help the patient identify their activity goals and consider ways they can enhance their enjoyment. There is also an optional weekly physical activity planner that the patient can use to track their activity. The versus arthritis booklet provides educational material about OA and basic management strategies. The patient should work through their workbook and read the versus arthritis booklet between sessions 1 and 2. In session two please ask them if they have identified anything that they think will help them become as physically active as possible.

Routine formation (Sessions 3-4)

The main of these sessions is to help promote the patients' feelings of competence so they can apply their chosen activities in different aspects of their daily life in preparation for when they will need to continue independently.

You may want to consider giving the patient an item like some TheraBand and asking them to keep it in a place where it can act as prompt or cue to do their activity to create a habit. Alternatively, they could set an alarm on their computer/phone or could magnetize their exercise sheet to the fridge.

You can also provide important social support by ensuring you encourage the patient to ask questions and include their perspectives when prescribing activities. Demonstrating interest in the patient and respect regardless of whether they have done their prescribed activity is important to

develop a collaborative relationship and provide a patient-centred treatment environment. Please give the patient their second workbook during session 4.

Recurring Techniques

Throughout the adoption and routine formation phases you will repeat several strategies to help patients develop feelings of competence for their chosen activity. It is important that during sessions you have the schedule some time to:

- Ask the patient how they are getting on with their activity goals and review and adjust as needed.
- Ask the patient to demonstrate any activities they are having difficulty with and offer clear constructive feedback.
- Ask about the patients' pedometer or activity diary to promote self-monitoring of their activity

Importantly, please commence with levels of activity within the patients' physical capability and then progress them as fitness and symptoms allow. Give them a physical copy which outlines their activities or exercises. This could be an exercise sheet from physio tools, or the Royal Orthopaedic website, a video them doing their activity/exercise taken from their phone during your session, or a youtube link if delivered remotely.

Maintenance phase

The main aim of this phase is to identify potential barriers within the patients physical and social environment that could impact on their motivation to continue with their chosen activities and consider potential solutions if needed. You may want to discuss whether your patient has had the opportunity to review the list local resources and completed their second workbook. Hopefully this will have helped your patient clarify any activities they may wish to try or identify another person or peer group to support them after discharge.

It might be useful to explore things that the patient may perceive as pressure and encourage them to experiment with the activity in-between your final few sessions. Your patient may need further convincing from you that they are capable to continue with their OA. Therefore, it might be a good idea to establish a detailed post discharge activity plan and discuss the concept of pacing themselves.

Physiotherapist training

In order for you to be able to deliver the intervention, you will be trained in how to create a motivational treatment environment. In the training, we will explore your understanding of how the treatment environment can influence patients' feelings of competence, autonomy, relatedness and their subsequent motivation to adopt and maintain prescribed PA. The training will involve presentations and interactive exercises to highlight why, when, and how you interact and provide feedback with patients during treatment sessions can facilitate or thwart autonomous motivation to participate in PA.

You will reflect on your own motivational philosophies and experiences in clinical practice to identify barriers and develop strategies to promote a collaborative and patient-centred treatment environment. Aspects of delivery of core BCTs across physical activity adoption, routine formation, and maintenance will be discussed how they can influence on patients' feelings of competence, relatedness, and autonomy and subsequent motivation.

Training in the *Empowering physio* programme will be provided by two members of the research team; Professor Joan Duda (JD), the founder of the original *Empowering Coaching* programme who possesses a PhD in psychology and is an internationally renowned expert in motivational processes and Matthew Willett, whose PhD has focused on the development of the intervention.

Training will take approximately 8 hours and consist of two three-hour sessions one week apart with a further top up session approximately one month later. These times will be scheduled in your work diary for you. In addition to training in behaviour change theory there will be the opportunity to practice delivery of intervention BCTs. Detail on intervention BCTs, including definition and examples of mode of delivery can be found in Appendix 3. To assist clarity BCTs have been grouped as either 'essential' or 'optional' and further divided into their respective phases of adoption, routine formation and maintenance or identified as recurring.

Focus groups with treating physiotherapists

At the end of the trial you will be invited to give your opinions on the behaviour change intervention, including the BCTs and how useful the training was. This will give us greater insight into whether we need to change anything to conduct a full scale randomized controlled trial. This will take about 90 minutes and will be scheduled in your work diary.

Other important information

Safety of the treatment protocols

Could you please advise the patient that they may feel pain/discomfort when doing their exercises or increasing their activity levels and that this is normal. If increased pain following exercise lasts

for more than a few hours or if the patient has night pain that is worse, then this could indicate that they have overdone the exercises.

Concurrent treatments

All participants will be requested to refrain from seeking other forms of treatment (other physical modalities) during the trial. This will be confirmed by research nurse at the baseline assessment. Patients who are currently taking medications will be allowed to continue taking stable doses throughout the study. For ethical reasons, analgesia will be permitted for pain relief and will be recorded at the virtual outcome assessments. Patients who are already wearing orthotics or insoles will be permitted to continue using them during the trial. Patients will be requested not to commence orthotic use during the trial or change or modify their current orthotics.

Non attendance

Patients who fail to attend need to be contacted. Therefore, if the patient does not attend their appointment, please let a member of the research team know.

Physiotherapy Treatment notes

For all treatment sessions, Project Physiotherapists will complete their usual Treatment notes

Ethical Considerations

This study is partially funded by the Musculoskeletal Association of Chartered Physiotherapists. It has been approved by a Research Ethics Committee (REC) for the study protocol, informed consent forms, Participant Information Sheet, and all other relevant documents. The sponsor is the University of Birmingham which assumes overall responsibility for the initiation and management of the study.

Key Personnel

Mr Matthew Willett [REDACTED] xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Professor Joan Duda is the Chief Investigator [REDACTED]xxxxxxxxxxxxxxxxxxxxxxxxxxxx

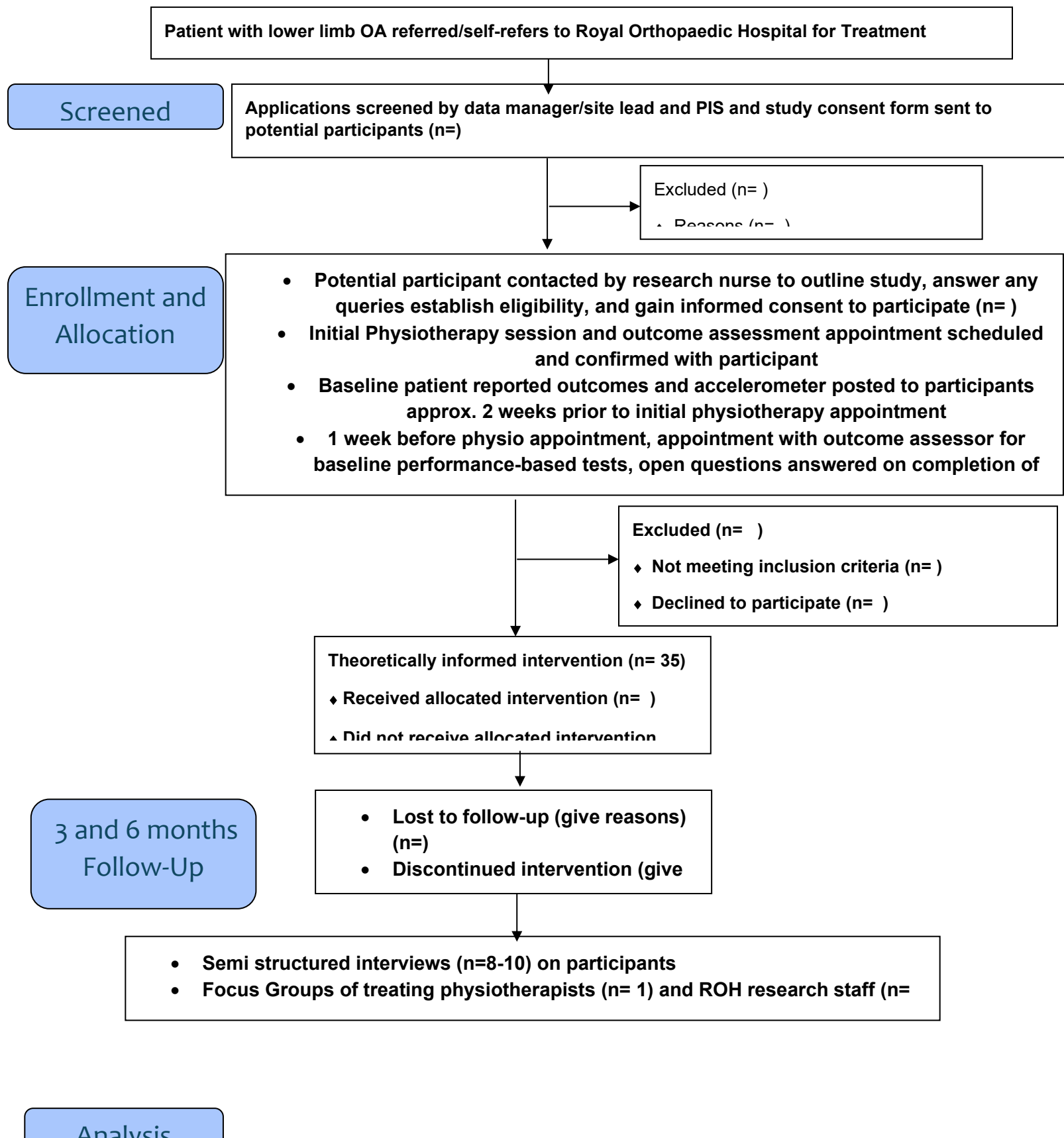
Mr Gareth Stephens [REDACTED]xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Professor Alison Rushon [REDACTED]xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Professor Carolyn Greig [REDACTED]xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Dr Eric Deeson [REDACTED]xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Appendix 1: STAPLO intervention CONSORT flow diagram



1 Appendix 2: Intervention materials delivered across sessions and outline of content and associated behaviour change techniques

2

Session numbers	Intervention Material	Intervention Content	Associated Behaviour Change Techniques
1-2	Activity Adoption Workbook	Aims of physiotherapy Information on benefits of PA Problem solving exercises to identify patient centred PA goals Activity Diary	Goal Setting (behaviour and outcome) Problem solving Review behaviour goals (and/or outcome) Action planning Self-monitoring of behaviour (and/or outcomes of behaviour)
	Pedometer	Pedometer to self-monitor number of steps	Self-monitoring of behaviour (and/or outcomes of behaviour) Feedback on behaviour (and/or outcomes)
	Versus Arthritis Book: Osteoarthritis of the Knee/Hip General Information	Epidemiology of OA Pathophysiology of OA General treatment strategies	Information on health consequences of performing the behaviour Information on social and environmental consequences Modelling/demonstration of behaviour
3-4	Routine Formation and Maintenance Booklet	Problem solving exercises to identify barriers and solutions to physical and social environment as needed to maintain PA. Detail of local physical activity resources and support	Problem Solving Social Support (practical) Habit formation Generalisation of a target behaviour Restructuring of the social environment
Any	Theraband	Resistance band to enhance or make prescribed exercises more difficult	Prompts and Cues Habit formation Adding objects to the environment

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STAPLO Feasibility Trial

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Appendix 3: Behaviour Change Techniques to be delivered during the STAPLO Intervention

Essential BCTs				
Phase	Behaviour change techniques	V1 Definition of technique (Michie et al., 2013)	Example of behaviour change technique	Example of wording within treatment session
Adoption	Goal setting (behaviour and/or outcome)	Set or agree on a goal defined in terms of a positive outcome of wanted behavior Note: This may be seen alongside ‘action planning’ which includes detail of when, how often and amount of physical activity. A goal is any physical activity behaviour that the patient identifies as something they wish to do. Within the exercise component of the physiotherapy session, this may include the exercises that they wish to complete that day	Behaviour: Agree on a daily walking goal (e.g. 3 miles) with the person and reach agreement about the goal. Outcome: Set a weight loss goal (e.g. 0.5 kilogram over one week) as an outcome of walking programme.	Behaviour/outcome: <i>“Is there a particular physical activity goal that you would like to try to achieve over the next few weeks?”</i>

	Action planning (including implementation intentions)	Prompt detailed planning of performance of the behavior (must include at least one of context, frequency, duration and intensity). Context may be external/ environmental (physical or social) or internal (physical, emotional or cognitive)	Prompt planning the performance of a particular physical activity (e.g. walking) at a particular time (e.g. before work) for a particular distance on certain days of the week	<i>“Have you thought about how often you might be able to walk or how long you might walk for?”</i> <i>“Have you thought what time of the day would be easiest for you to walk?”</i>
	Information on health consequences of performing the behaviour	Provide information (e.g. written, verbal, visual) about health consequences of performing the behavior	Explain that regular physical activity can decrease the risk of developing secondary non-communicable diseases such as type 2 diabetes and heart disease.	<i>“It may be beneficial for you to do your exercises regularly to strengthen the muscles around your hip. We know that this usually strengthens your muscles and reduces the load going through the joint.”</i>
	Information on social and environmental consequences	Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behavior Note: consequences can be for any target, not just the recipient(s) of the intervention	Inform the patient that if they can improve their fitness levels, they are more likely to be able to go out with their family for walks and social outings.	<i>“If you are able to do a few walks a week, after a while, you may be able to go with your daughter when she walks Charlie.”</i>
Routine Formation	Prompts/cues	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behavior. The prompt or cue would normally occur at the time or place of performance	Put a sticker on the bathroom mirror to remind people to do their squats while brush their teeth	<i>“Stickers sometimes are helpful when trying to remember to do your exercises. If you think this strategy might work for you, have you thought about where you could put a sticker up to remind you to do your squats?”</i>
	Habit formation	Prompt rehearsal and repetition of the behavior in the same context repeatedly so that the context elicits the behavior	Prompt patients to do their prescribed physical activity before brushing their teeth every morning or evening	<i>“Some people find it useful to create a routine to help them do their exercises. Would you like to try doing your squats before and after you brush your teeth each</i>

				<i>morning and before you go to bed?"</i>
	Generalisation of a target behavior	Advise to perform the wanted behaviour, which is already performed in a particular situation, in another situation	Advise to repeat strengthening exercises learned in the physiotherapy session when at home	<i>"If you are able to try and fit your exercises in at home, you could expect your muscles around your hip to gradually get stronger."</i>
	Adding objects to the environment (e.g. objects to facilitate behaviour)	Add objects to the environment in order to facilitate performance of the behavior Note: Provision of information (e.g. written, verbal, visual) in a booklet or leaflet is insufficient.	Provide TheraBand to facilitate physical activity routine	<i>"Would you like to have a theraband to help you do your knee exercises?"</i>
Maintenance	Problem Solving	Analyse, or prompt the person to analyse, factors influencing the behavior and generate or select strategies that include overcoming barriers and/or increasing facilitators	Identify specific triggers (e.g. feeling anxious about the presence of others) that generate the need to not leave the home and develop strategies for avoiding environmental triggers or for managing negative emotions, such as anxiety. Prompt the patient to identify barriers preventing them from starting a new exercise regime e.g., lack of motivation, and discuss ways in which they could help overcome them e.g., going to the gym with a buddy	<i>"Is there anything that you found stopped you from realizing your walking goal this week?"</i> <i>"Have you considered if there is any other way you could do that exercise?"</i> <i>"Some people find....'Have you thought about whether there are other people who have retired who you could go out walking with?"</i>
	Reduce negative emotions	Advise on ways of reducing negative emotions to facilitate performance of the behavior (includes 'Stress Management')	Advise on the use of stress management skills, e.g. to reduce anxiety about joining	<i>"It sounds like you are worried about joining the walking club. I can understand why you feel like</i>

			a community physical activity programme.	<i>this...I think we all feel like this when we start something new. How would you feel about taking a friend along with you? Would that make you feel less nervous?"</i>
	Restructuring of social environment	Change, or advise to change the social environment in order to facilitate performance of the wanted behavior or create barriers to the unwanted behavior (other than prompts/cues, rewards and punishments)	Advise to minimise time spent with friends who do excessive/ too little physical activity.	<i>"So, it sounds like you found your walking class difficult because they were going too fast? How would you feel about walking with a friend or neighbour instead?"</i>
	Verbal persuasion about capability	Tell the person that they can successfully perform the wanted behavior, arguing against self-doubts and asserting that they can and will succeed	Tell the person that they can successfully increase their physical activity, despite their osteoarthritis related pain.	<i>"You're making great progress with your walking. If you keep going, you will be able to make it all the way to the shops quicker than you think."</i>
Recurring BCTs	Review behaviour goals or outcome	Review behaviour goal(s) jointly with the person and consider modifying goal(s) or behavior change strategy in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of (or in addition to) the first, or no change	Behaviour: Examine how well a person's performance corresponds to agreed goals e.g. whether they kept to their walking target of 6000 steps per day, and consider modifying future goals accordingly e.g. by increasing or decreasing walking goals or considering the terrain. Outcome: Examine how strong muscles are for a particular area and consider modifying outcome goal(s)	<i>"How did you get on the past week with your walking goal?"</i> <i>"I think you mentioned that you wanted to lose a stone of weight. How have you been getting on with that?"</i>

			accordingly e.g. by increasing or decreasing strength target	
	Feedback on behavior or outcomes of behaviour	Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g. form, frequency, duration, intensity)	Inform the person of how many steps they walked each day (as recorded on a pedometer).	<i>“Well done, you’ve made your target of 6000 steps three times this week, that is great progress. How does it make you feel that you reached this goal?”</i>
	Self-monitoring of behaviour	Establish a method for the person to monitor and record their behavior(s) as part of a behavior change strategy	Ask the person to record daily, in a diary, whether they have achieved their walking goals or completed their home exercises (doing 10 repetitions and 3 sets). Give patient a pedometer and a form for recording daily total number of steps	<i>“How would you feel about using a pedometer to track your daily steps? You could consider writing them down in your log book and then after a week or two you could see how you’re getting on.”</i>
	Social support (unspecified) or encouragement	Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues, ‘buddies’ or staff) or non-contingent praise or reward for performance of the behavior. It includes encouragement and counselling, but only when it is directed at the behavior	• Advise the person to call a ‘buddy’ when they experience anxiety or low feelings about their osteoarthritis • Arrange for a spouse or family member to encourage continuation with walking. Give information about a local activity resources to help maintain activity after discharge from physiotherapy	<i>“Well done, you are doing really well. How would you feel about calling your neighbor to come with you on your walk and you can discuss how they manage their arthritis?”</i> <i>“Yes, so you can join the group for free and it is a great service.”</i>

	Social support (practical)	Advise on, arrange, or provide practical help (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behavior	Ask the spouse of the patient to put their theraband on the breakfast table so that the patient remembers to do their prescribed physical activity	<i>"If you cannot walk all the way to the shops, could you walk their and then get your husband to pick you up?"</i> <i>"If you're worried about whether your walking will cause more pain, why don't you chat to the other members of your walking group to see if they manage their symptoms?"</i>
	Instruction in how to perform the behaviour	Advise or agree on how to perform the behavior	Advise the patient how to do their prescribed exercises with the correct technique	<i>"If you hold on the back on the chair, you will have more support and it will make your squats easier to do."</i>
	Modelling/demonstration of behaviour	Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate	Demonstrate to patients how to do their prescribed exercises Give patients a video or sheet of exercises with instructions of their exercises.	<i>"See how when you lift your bottom off the bed, your back arches, it is usually most effective if you can keep it as flat as possible. This is important to make your bottom muscles do most of the work and should take the strain off your hip when you walk."</i>
	Behavioural rehearsal/practice	Prompt practice or rehearsal of the performance of the behavior one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill	Enable your patient to practice their exercises during the treatment session and then when they get up first thing in the morning.	<i>"How would you feel about showing me the exercises you have been doing since our last session? If you feel comfortable, we may be able to progress them to help make the muscles around your knee stronger."</i>
	Graded Tasks	Set easy-to-perform tasks, making them increasingly difficult, but achievable, until behavior is performed	Ask the person to walk for 100 yards a day for the first week, then half a mile a day	<i>"How would you feel about doing an additional short walk over the</i>

			after they have successfully achieved 100 yards, then two miles a day after they have successfully achieved one mile.	<i>next week? This may help build up your exercise tolerance.”</i>

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Optional BCTs				
Adoption	Rewards	Arrange delivery of a reward if and only if there has been effort and/or progress in performing the behavior (includes ‘Positive reinforcement’)	One of: Material Reward Arrange for the person to receive money that would have been spent on smoking if and only if they have done their prescribed physical activity for one month Non-specific: Identify something (e.g. an activity such as a visit to the cinema) that the person values and arrange for this to be delivered if and only if they have done their prescribed physical activity for one month Social reward: Congratulate the person for each day they achieve their prescribed physical activity Self-reward: Encourage to reward self with material (e.g., new clothes) or other valued objects if and only if they have adhered to their prescribed physical activity. Reward (outcome) Arrange for the person to receive money if and only if a certain distance of walking is achieved.	Material/non-specific/self-reward: <i>“How about rewarding yourself if you achieve your goal. You could go to the cinema to watch a movie if you walk all the way to there?”</i> Social Reward: <i>“Well done, that’s really good progress, you are walking further and your legs are becoming stronger.”</i>

Routine Formation	Reward approximation	Arrange for reward following any approximation to the target behavior, gradually rewarding only performance closer to the wanted behavior (includes 'Shaping')	Arrange reward for any increase in daily steps, gradually requiring the daily steps to become closer to the planned final number.	<i>"What do you think to allowing yourself to buy a new coat if you can increase your steps to half way?"</i>
Maintenance	Behavioral Contract	Create a written specification of the behavior to be performed, agreed on by the person, and witnessed by another	Sign a contract with the person e.g. specifying that they will do their prescribed physical activity three times per week for one month.	<i>"If you want, you can write down how far you will walk this week on your exercise sheet and sign it."</i>
	Social comparison	Draw attention to others' performance to allow comparison with the person's own performance <i>Note: being in a group setting does not necessarily mean that social comparison is actually taking place</i>	Tell the patient about previous cases where increasing physical activity has reduced pain and increased function.	<i>"Recent research suggests that most people with osteoarthritis could do about 6000 steps per day, where do you think you are in comparison with that?"</i>
	Information about others' approval	Provide information about what other people think about the behavior. The information clarifies whether others will like, approve or disapprove of what the person is doing or will do	Tell the patient that their family and friends will approve of them increasing their physical activity levels as they will be able to do more as a group.	<i>"If you do your walking regularly, your friends will probably be really pleased as you are taking care of yourself and more likely to be able to go around the national trust properties with them."</i>
	Rewarding completion	Build up behavior by arranging reward following final component of the behavior; gradually add the components of the behavior that occur earlier in the behavioral sequence (includes 'Backward chaining')	Reward doing prescribed physical activity for one week; then make reward contingent on them generating own physical activity goals and doing them.	<i>"How would it work for you, now that you are doing your 6000 steps per day regularly, that you only get your latte if you walk to the coffee shop?"</i>
Recurring	Pharmacological Support	Provide, or encourage the use of or adherence to, drugs to facilitate behaviour change	Suggest the patient asks the family physician for nicotine replacement therapy to facilitate smoking cessation	<i>"If your pain increases after you have done your walking for the day, its</i>

				<i>absolutely fine to use your medication to bring it under control again.”</i>

STaying Active with Physiotherapy in patients with Lower-limb Osteoarthritis (STAPLO): Treatment Fidelity Training Manual

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Fidelity Assessment Training Manual

STAPLO Feasibility Trial

44	Table of Contents
45	11. Background
46	12. Methods
47	13. What is being asked of you
48	14. The intervention
49	15. Physiotherapy training
50	16. Other important information
51	17. Key Personnel
52	18. Appendix 1: Intervention materials delivered across sessions and outline of content and
53	associated theoretical constructs and behaviour change techniques
54	19. Appendix 2: BCT coding manual
55	20. Appendix 3: The Interpersonal Support in Physical Activity Consultations Observational
56	Tool
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66	Thank you for agreeing to helping to evaluate the fidelity of delivery of our
67	physiotherapy intervention. The information below outlines the study and
68	will provide key guidance of what is required from you.

70 Background

71 In the United Kingdom (UK), Osteoarthritis (OA) is the leading cause of
72 disability and pain in older adults, with one-third of patients over 45 years
73 old, equating to almost 9 million individuals, having sought treatment for
74 OA related symptoms. Lower-limb OA is particularly problematic with
75 4.1 and 2.5 million individuals experiencing symptoms associated with
76 knee and hip OA respectively.

77 Musculoskeletal physiotherapists are the primary healthcare provider of non-pharmacological
78 treatments for patients with lower-limb OA. Evidence-based physiotherapy interventions follow
79 international guidelines and incorporate strategies to optimise physical activity (PA) to aid patients
80 with lower-limb OA to moderate their clinical symptoms (i.e. reduce pain and increase function
81 and quality of life). However, physiotherapy interventions are effective at improving short-term pain
82 and function only (approximately 3 months), with symptoms returning around six months post
83 baseline. This is likely associated with a gradual reduction in patient adherence to prescribed PA
84 after discharge, when approximately 90% of patients with lower-limb OA do not maintain their PA.

85 The Medical Research Council (MRC) advocates that interventions should be informed by
86 behaviour change theory to enable a greater understanding of the intervention mediators (e.g. self-
87 efficacy) effect on the target behaviour and therefore, the intervention can be refined for future
88 testing. However, there is currently a lack of theoretically informed behaviour change interventions
89 in both OA and wider pain populations.

90 The literature outlines that individuals go through several phases of behaviour change when
91 integrating new behaviours, such as PA adherence, into their lives. The most important phases are
92 '*adoption*', which would occur during physiotherapy treatment, and '*maintenance*' which would be
93 ongoing post-treatment and is considered to be evident approximately 6 months of behavioural
94 practice. Importantly, factors that influence patients' adoption and maintenance of PA are distinct
95 and therefore, a physiotherapy intervention needs to incorporate specific behaviour change
96 techniques (BCTs) to match these conceptual phases to optimise PA adherence.

97 Our systematic review of the effectiveness of behavioural physiotherapy interventions on
98 adherence to PA supported this concept and demonstrated that some BCTs were most effective
99 over the short-term (≤ 3 months post baseline) or longer-term (≥ 6 months) time points with others
100 potentially effective across all time points. Our qualitative study of patients with lower-limb OA
101 suggested that promotion of a PA routine was an important transitional stage linking PA adoption
102 and maintenance. The formation of a PA routine developed patients' feelings of competence and
103 motivation and was best achieved through a more positive, supportive, patient-centred
104 physiotherapy treatment environment.

105 We developed a theoretically informed physiotherapy intervention which incorporated BCTs that
106 targeted the determinants of PA adoption, routine formation, and maintenance and presented it to

focus groups of physiotherapists. The physiotherapists found the intervention highly acceptable and feasible, therefore, the next step was to test the interventions feasibility within physiotherapy clinical practice.

Although the intervention was deemed acceptable to physiotherapists, they perceived a need for further training in ways of creating a more positive, supportive, and patient-centred treatment environment to promote feelings of patient competence and motivation and how to deliver the intervention BCTs.

Therefore, further work was undertaken to identify potential theories of behaviour change and associated training programmes to support intervention delivery and training of the trial physiotherapists. Self-determination Theory (SDT) was identified as an appropriate theory to underpin the behaviour change intervention due to its theoretical associations linking feelings of confidence/competence to task motivation and empirical base of clinical trials targeting PA behaviours. The *Empowering Coaching* (EC) framework was further identified for its conceptual linkages to SDT and expanded understanding of the features of the environment linked to the promotion of resilient participant competence and quality (i.e., autonomous) motivation. The EC training programme has been modified, based on the results of our qualitative studies, to provide bespoke training for physiotherapists (i.e., *Empowering Physio*). The training aims to help physiotherapists produce a more positive, supportive, and patient-centred treatment environment by developing their understanding of the rationale for and features and determinants of such an environment.

Therefore, our pragmatic single arm feasibility trial will be the first theoretical physiotherapy intervention designed to promote a supportive and patient-centred treatment environment to enable patients with lower-limb OA to develop feelings of competence and motivation to PA utilizing BCTs targeting PA adoption, routine formation, and maintenance.

Aim

This trial has two primary aims:

- 5) To investigate whether a complex, multi-component theoretical behaviour change physiotherapy intervention is feasible and acceptable for patients with lower limb OA and treating physiotherapists.
- 6) To evaluate the feasibility and acceptability of trial related procedures to participants and research related staff

The STAPLO intervention

Aims

The intervention has the overarching aim of providing a supportive and patient-centred treatment environment to assist patients with lower-limb OA to adopt and maintain their PA goals. It is hypothesised that the treatment environment and intervention BCTs will influence patients' perceptions of autonomy support, relatedness, and competence and their motivation regulation to facilitate the adoption and maintenance of prescribed PA. The adoption and maintenance of PA is hypothesised to impact on patients' outcomes of pain, function, and self-efficacy for PA.

The intervention has been split into three overlapping conceptual phases (outlined below)

Phase	Primary Aim
Adoption (Sessions 1-2)	Facilitate the patient to develop physical activity goals and outline a clear, detailed plan of how they can achieve them.
Routine formation (Sessions 3-4)	Promote the patients' feelings of competence so they can apply their chosen activities in different aspects of their daily life in preparation for when they will need to continue independently.
Maintenance (Sessions 5-6)	to identify potential barriers within the patients physical and social environment that could impact on their motivation to continue with their chosen activities and consider potential solutions if needed.

What is being asked of you?

Intervention delivery

Part of determining whether the intervention is feasible or not, is to evaluate the treatment fidelity. In this case, treatment fidelity is reviewing whether the intervention has been delivered as intended by the physiotherapists. Before they started treating trial patients with, the physiotherapists had three training sessions. The the bespoke training programme (*Empowering Physio™*) aimed to enhance physiotherapists' understanding of differences in the quality of patient motivation (and implications), and awareness of the treatment climate they create and how it can influence patients' PA goals.

The training was provided by two members of the STAPLO team; Professor Joan Duda, the founder of the *Empowering Coaching* programme who possesses a PhD in psychology and is an internationally renowned expert in motivational processes and MW, whose PhD has focused on the behaviour change processes involved in PA adoption, routine formation, and maintenance and the development of the intervention package

Recording of intervention sessions

The physiotherapists were asked to audio record one session from each phase (adoption, routine formation, maintenance) of the intervention of their first and third patient. The session number was randomized. These recordings were then transcribed/audio for analysis.

Intervention Fidelity

Fidelity assessment of delivery of the intervention includes evaluation of two key aspects; what was delivered (e.g., the BCTs) and how these BCTs were delivered/overall exchanges between the physiotherapist and patient (i.e., the physiotherapy treatment motivational climate) in regard to promoting the patient's feelings of competence, autonomy and relatedness.

What was delivered: Evaluation of Behaviour Change Techniques delivered

- Could you please code the provided transcripts to identify the physiotherapist's use of BCTs as defined within BCTTv1 which has been sent to you. The 26 embedded BCTs (18 core and 8 optional) and their definitions are included in the appendix 1.

Important points:

- BCTs should only be coded once per session
- Each BCT should be coded as either
 - 1 Fully present: BCT is present beyond all reasonable doubt; clear evidence available
 - 2 Partially present: BCT is present in all probability, but evidence not clear. BCTs within this category will not fully support the definition provided within BCTTv1.
- Please also note code BCTs that were present but not part of the specific protocol will also be noted.

A BCT coding form is included in appendix 2

How was it delivered: Evaluation of the Treatment Motivational Climate

You will use the Interpersonal Support in Physical Activity Consultations Observational Tool (ISPACOT), a 21-item tool that is grounded in SDT, to evaluate the treatment climate of the physiotherapy sessions. The tool assesses four aspects of the motivational climate created: Autonomy Support, Involvement, Structure, and Interpersonal Control and has demonstrated moderate to high levels of inter-rater reliability when assessments are carried out by trained users. A 7-point Likert-scale, ranging from 1 'not at all true' to 7 'Very True', will be used to determine the degree of each need support.

Brief summary of coding steps

- Please listen to the **audio recording/read transcript** of each intervention session.
- Once you have listened to the whole audio recording of the class, please complete the IPSACOT taking the whole intervention session into account when answering statements. You can provide a short justification for each in the noted section.
- Please use the seven point likert scale to rate how empowering the treatment climate was that provided by the physiotherapist.

Training and timelines

- 1 Please complete the online BCT training available at: <https://www.bct-taxonomy.com/> (this should take approximately 5 hours)
- Please read the familiarise yourself with the IPSACOT (This should take approximately 1 hour). The reference article will be sent to you.
- You will be invited to pilot code a few video recordings of Patient interview/management sessions (This should take about 1 hour)
- You will pilot an initial intervention script/audio recording and a further one in parallel with the lead researcher to optimise consistency (this should take about 2 hours).
- The forms will be reviewed by an expert in behaviour change (JD) with feedback provided.
- There will be approximately 30 transcripts to review. It is anticipated that each will take about 1 hour to complete.

Ethical Considerations

This study is funded by Private Physiotherapy Education Fund and the Musculoskeletal Association of Chartered Physiotherapists. It has been approved by a Research Ethics Committee (REC) for the study protocol, informed consent forms, Participant Information Sheet, and all other relevant documents. The sponsor is the University of Birmingham which assumes overall responsibility for the initiation and management of the study.

Key Personnel

Mr Matthew Willett [REDACTED]xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Professor Joan Duda is the Chief Investigator [REDACTED]xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Mr Gareth Stephens [REDACTED]xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Professor Alison Rushon [REDACTED]xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Professor Carolyn Greig[REDACTED]xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Appendix 1: Behaviour Change Techniques to be delivered during the STAPLO Intervention

Essential BCTs			
Phase	Behaviour change techniques	V1 Definition of technique (Michie et al., 2013)	Example of behaviour change technique
Adoption	Goal setting (behaviour and/or outcome)	Set or agree on a goal defined in terms of a positive outcome of wanted behavior Note: This may be seen alongside 'action planning' which includes detail of when, how often and amount of physical activity. A goal is any physical activity behaviour that the patient identifies as something they wish to do. Within the exercise component of the physiotherapy session, this may include the exercises that they wish to complete that day	Behaviour: Agree on a daily walking goal (e.g. 3 miles) with the person and reach agreement about the goal. Outcome: Set a weight loss goal (e.g. 0.5 kilogram over one week) as an outcome of walking programme.
	Action planning (including implementation intentions)	Prompt detailed planning of performance of the behavior (must include at least one of context, frequency, duration and intensity). Context may be external/ environmental (physical or social) or internal (physical, emotional or cognitive)	Prompt planning the performance of a particular physical activity (e.g. walking) at a particular time (e.g. before work) for a particular distance on certain days of the week
	Information on health consequences of performing the behaviour	Provide information (e.g. written, verbal, visual) about health consequences of performing the behavior	Explain that regular physical activity can decrease the risk of developing secondary non-communicable diseases such as type 2 diabetes and heart disease.
	Information on social and environmental consequences	Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behavior Note: consequences can be for any target, not just the recipient(s) of the intervention	Inform the patient that if they can improve their fitness levels, they are more likely to be able to go out with their family for walks and social outings.
Routine Formation	Prompts/cues	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behavior. The prompt or cue would normally occur at the time or place of performance	Put a sticker on the bathroom mirror to remind people to do their squats while brush their teeth
	Habit formation	Prompt rehearsal and repetition of the behavior in the same context repeatedly so that the context elicits the behavior	Prompt patients to do their prescribed physical activity before brushing their teeth every morning or evening

	Generalisation of a target behavior	Advise to perform the wanted behaviour, which is already performed in a particular situation, in another situation	Advise to repeat strengthening exercises learned in the physiotherapy session when at home
	Adding objects to the environment (e.g. objects to facilitate behaviour)	Add objects to the environment in order to facilitate performance of the behavior Note: Provision of information (e.g. written, verbal, visual) in a booklet or leaflet is insufficient.	Provide TheraBand to facilitate physical activity routine
Maintenance	Problem Solving	Analyse, or prompt the person to analyse, factors influencing the behavior and generate or select strategies that include overcoming barriers and/or increasing facilitators	Identify specific triggers (e.g. feeling anxious about the presence of others) that generate the need to not leave the home and develop strategies for avoiding environmental triggers or for managing negative emotions, such as anxiety. Prompt the patient to identify barriers preventing them from starting a new exercise regime e.g., lack of motivation, and discuss ways in which they could help overcome them e.g., going to the gym with a buddy
	Reduce negative emotions	Advise on ways of reducing negative emotions to facilitate performance of the behavior (includes 'Stress Management')	Advise on the use of stress management skills, e.g. to reduce anxiety about joining a community physical activity programme.
	Restructuring of social environment	Change, or advise to change the social environment in order to facilitate performance of the wanted behavior or create barriers to the unwanted behavior (other than prompts/cues, rewards and punishments)	Advise to minimise time spent with friends who do excessive/ too little physical activity.
	Verbal persuasion about capability	Tell the person that they can successfully perform the wanted behavior, arguing against self-doubts and asserting that they can and will succeed	Tell the person that they can successfully increase their physical activity, despite their osteoarthritis related pain.
Recurring BCTs	Review behaviour goals or outcome	Review behaviour goal(s) jointly with the person and consider modifying goal(s) or behavior change strategy in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of (or in addition to) the first, or no change	Behaviour: Examine how well a person's performance corresponds to agreed goals e.g. whether they kept to their walking target of 6000 steps per day, and consider modifying future goals accordingly e.g. by increasing

			or decreasing walking goals or considering the terrain. Outcome: Examine how strong muscles are for a particular area and consider modifying outcome goal(s) accordingly e.g. by increasing or decreasing strength target
	Feedback on behavior or outcomes of behaviour	Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g. <i>form, frequency, duration, intensity</i>)	Inform the person of how many steps they walked each day (as recorded on a pedometer).
	Self-monitoring of behaviour	Establish a method for the person to monitor and record their behavior(s) as part of a behavior change strategy	Ask the person to record daily, in a diary, whether they have achieved their walking goals or completed their home exercises (doing 10 repetitions and 3 sets). Give patient a pedometer and a form for recording daily total number of steps
	Social support (unspecified) or encouragement	Advise on, arrange or provide social support (e.g. <i>from friends, relatives, colleagues, 'buddies' or staff</i>) or non-contingent praise or reward for performance of the behavior. It includes encouragement and counselling, but only when it is directed at the behavior	- Advise the person to call a 'buddy' when they experience anxiety or low feelings about their osteoarthritis - Arrange for a spouse or family member to encourage continuation with walking. Give information about a local activity resources to help maintain activity after discharge from physiotherapy
	Social support (practical)	Advise on, arrange, or provide practical help (e.g. <i>from friends, relatives, colleagues, 'buddies' or staff</i>) for performance of the behavior	Ask the spouse of the patient to put their thera-band on the breakfast table so that the patient remembers to do their prescribed physical activity
	Instruction in how to perform the behaviour	Advise or agree on how to perform the behavior	Advise the patient how to do their prescribed exercises with the correct technique

	Modelling/demonstration of behaviour	Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate	Demonstrate to patients how to do their prescribed exercises Give patients a video or sheet of exercises with instructions of their exercises.
	Behavioural rehearsal/practice	Prompt practice or rehearsal of the performance of the behavior one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill	Enable your patient to practice their exercises during the treatment session and then when they get up first thing in the morning.
	Graded Tasks	Set easy-to-perform tasks, making them increasingly difficult, but achievable, until behavior is performed	Ask the person to walk for 100 yards a day for the first week, then half a mile a day after they have successfully achieved 100 yards, then two miles a day after they have successfully achieved one mile.

Optional BCTs			
Adoption	Rewards	Arrange delivery of a reward if and only if there has been effort and/or progress in performing the behavior (includes 'Positive reinforcement')	One of: Material Reward Arrange for the person to receive money that would have been spent on smoking if and only if they have done their prescribed physical activity for one month Non-specific: Identify something (e.g. an activity such as a visit to the cinema) that the person values and arrange for this to be delivered if and only if they have done their prescribed physical activity for one month Social reward: Congratulate the person for each day they achieve their prescribed physical activity Self-reward: Encourage to reward self with material (e.g., new clothes) or other valued objects if and only if they have adhered to their prescribed physical activity

			Reward (outcome) Arrange for the person to receive money if and only if a certain distance of walking is achieved.
Routine Formation	Reward approximation	Arrange for reward following any approximation to the target behavior, gradually rewarding only performance closer to the wanted behavior (includes 'Shaping')	Arrange reward for any increase in daily steps, gradually requiring the daily steps to become closer to the planned final number.
Maintenance	Behavioral Contract	Create a written specification of the behavior to be performed, agreed on by the person, and witnessed by another	Sign a contract with the person e.g. specifying that they will do their prescribed physical activity three times per week for one month.
	Social comparison	Draw attention to others' performance to allow comparison with the person's own performance <i>Note: being in a group setting does not necessarily mean that social comparison is actually taking place</i>	Tell the patient about previous cases where increasing physical activity has reduced pain and increased function.
	Information about others' approval	Provide information about what other people think about the behavior. The information clarifies whether others will like, approve or disapprove of what the person is doing or will do	Tell the patient that their family and friends will approve of them increasing their physical activity levels as they will be able to do more as a group
	Rewarding completion	Build up behavior by arranging reward following final component of the behavior; gradually add the components of the behavior that occur earlier in the behavioral sequence (includes 'Backward chaining')	Reward doing prescribed physical activity for one week; then make reward contingent on them generating own physical activity goals and doing them.
Recurring	Pharmacological Support	Provide, or encourage the use of or adherence to, drugs to facilitate behaviour change	Suggest the patient asks the family physician for nicotine replacement therapy to facilitate smoking cessation

Appendix 2: Behaviour Change Techniques coding sheet

[illegible]

Appendix 3: The Interpersonal Support in Physical Activity Consultations Observational Tool

Subject	Description	
Autonomy support		
Acknowledging feelings	The physiotherapist acknowledged negative affective states that the client has experienced/may experience regarding physical activity	
Acknowledging feelings (2)	The physiotherapist acknowledged any positive affect that the client has experienced/may experience regarding physical activity	
Provide Rationale	A meaningful rationale was provided for setting goals in a physical activity program	
Encouraging self-initiative	The physiotherapist encouraged the client to put forward solutions to barriers.	
Effective non-verbal skills	The physiotherapist listened carefully to how the client wanted to do things	
Providing choice	The client was provided with choice over the types, pace and frequency of the physical activity program where possible.	
Taking perspective	The physiotherapist really understood how the client felt before making any suggestions (e.g., appreciated his /her personal barriers and his /her past experiences with physical activity)	
Enhancing self-worth	The physiotherapist enhanced the client's sense of importance	
Involvement		
Demonstrating affection	The physiotherapist demonstrated dedication to and care for the client.	
Accepting all behaviours and beliefs	The physiotherapist accepted the client unconditionally.	
Structure		
Non-controlling reinforcement	The physiotherapist gave positive informational feedback to the client for effort, improvement and task mastery	
Encouraging questions	The physiotherapist encouraged the client to ask questions and answered any posed, fully and carefully.	
Appropriate goal setting	The physiotherapist helped the client to identify and formulate realistically achievable goals	
Informative	The physiotherapist made sure the client understood the risks of an inactive lifestyle	
Informative (2)	The physiotherapist clarified the benefits of an active lifestyle	
Controlling		
Over authoritative	The physiotherapist sought to dominate the consultation talking and monopolizing the interaction.	
Enforcing compliance	The physiotherapist pressured the client to adhere to the physical activity program	
Forcing change	The physiotherapist sought to change the client's attitudes, values and perceptions without rationale or discussion	
Controlling language	The physiotherapist used controlling language with the client (e.g., "should, have to, must and ought to").	
Using deadlines	The physiotherapist established deadlines without consulting the client.	
Highlighting external benefits	Rewards (e.g., passes) and/or extrinsic benefits were offered to initiate exercise behaviour.	
Using conditional acceptance	Praise and positive non-verbal language was used when the physiotherapist heard what he/she wanted to hear.	
Encouraging specific beliefs and behaviours	The client was told how they should think, feel and act.	

Key References

- Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Annals of behavioral medicine : a publication of the Society of Behavioral Medicine* 2013;**46**(1):81-95. https://digitalwellbeing.org/wp-content/uploads/2016/11/BCTTv1_PDF_version.pdf
- Rouse PC, Duda JL, Ntoumanis N, et al. The development and validation of the Interpersonal Support in Physical Activity Consultations Observational Tool. *European journal of sport science* 2016;**16**(1):106-14. <https://www.tandfonline.com/doi/abs/10.1080/17461391.2014.987320?journalCode=tejs>
[20](#)

Appendix 6.8: Additional Trial Information

Data Storage

The acquisition, storing and processing of all personal data will be conducted in accordance with GDPR, the Data Protection Act 2018, and University of Birmingham's research governance frameworks. All participants will be pseudonymised by assigning a trial number upon initial consent being gained which will only be known to the chief and lead investigators and essential members of the ROH research team. The numerical code assigned to each participant will allow for identification of the participant and will only be used to establish contact to arrange and conduct outcome assessment, to invite to semi-structured interviews if needed, or to send a lay summary of results if of interest to the participant.

PROM data and accelerometers will be sent by participants to the research team at the ROH in the provided pre-addressed and stamped envelopes via post after their assessment sessions. PROMS, feasibility trial and semi-structured interview consent forms, performance-based outcome results, and accelerometers will be collected from the ROH by MW. Physiotherapists and ROH trial staff will complete focus their consent forms prior to the respective focus groups and MW will collect the physical copies of focus group consent forms. MW will scan all collected documents at the University of Birmingham. The semi-structured interviews and focus groups will be audio recorded using a digital recording device. If conducted via zoom, the video will not be recorded. The audio recording of the interview/focus groups and intervention sessions (for fidelity assessment) will contain no personal data when uploaded to the transcription website. All scanned documents, accelerometer data, pseudonymised interview/focus group transcripts, and intervention sessions will be uploaded and stored electronically on the secure REDcap system at the University of Birmingham by MW.

The original physical copies of all documents forms will be placed in a secure, locked filing cabinet in the office of the chief investigators (JD). The Accelerometer data and audio files on the digital recording device will be deleted after upload to REDcap. When not in use, the digital recording device used in semi-structured interviews and focus groups will be stored in the secure, locked filing cabinet in the office of the lead investigator. Therefore, only the chief (JD) and lead (MW) researchers will have access to participant data.

Adverse Events

Good Clinical Practice (GCP) defines two primary types of adverse events (Table 1)

Table 1: Adverse Event Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant to whom a medicinal product has been administered, including occurrences which are not necessarily caused by or related to that product.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening

	• requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

No adverse events are expected beyond minor musculoskeletal pain which may arise from new and progressive PA /exercises prescribed at physiotherapy sessions. The physiotherapists will be mindful of any such events and the intervention will be modified as appropriate to reduce any symptoms. Any adverse events will be recorded at participant outcome assessments with research nurses and reported to the PI who will document the specifics of the event and duration. When an AE has occurred, which is suspected to be a potential SAE, the PI, lead and Chief investigator will discuss the causality and severity of the AE with the chair of the Trial Steering Committee. If the AE is confirmed as being a SAE, the CI will complete a SAE form, which will be scanned and emailed to the ROH, REC, and sponsor for review, where a local incident form will also be completed. For each SAE the following information will be collected:

1. Full details and case description of event.
2. Event duration.
3. Action taken.
4. Outcome.
5. Level of severity.
6. Causality

Dissemination of findings

The results are intended to be disseminated through publications in peer reviewed journals and presentations at appropriate physiotherapy and inter-disciplinary conferences. A lay summary of findings will be completed and sent to participants and interested members of the public (supported by the Patient and Public Involvement representative) and to the ROH, and a summary report will be produced for the sponsor (University of Birmingham) and research funders (Private Physiotherapy Educational Foundation and Musculoskeletal Association of Chartered Physiotherapists).

List of Abbreviations

HRA: Health Research Authority; IRAS: Integrated Research Application System; REDcap: Research Electronic Data capture; PPI: Patient and Public Involvement; MACP: Musculoskeletal Association of Chartered Physiotherapists; GCP: Good Clinical Practice. PALS: Patient advice and Liaison Service

Appendix 6.9: Reasons for patient ineligibility identified during screening.

Total patients screened (n=537)

Potentially eligible: (n=191)

Reasons for ineligibility at screening (n= 346)

- Other diagnosis (hip/knee pain not due to OA) n=71
- Previous surgery n=80
- Physio App user: n=61
- Awaiting surgery n=7
- Has appt booked n=1
- Prisoner n=1
- Interpreter required/language barrier n=10
- Mobility assistance user n=4
- No longer on waiting list n=55
- Other health condition (exclusion/contraindication) n=20
- Already contacted by physiotherapy department n=14
- Reason not recorded n=8
- Hydro requested n=2
- Transferred to other trust n=7
- Unable to attend appts n=5

Appendix 6.10: Reasons for ineligibility and declined participation in potential participants who were sent a participant information sheet

Participant information sheets sent out (n=152)*	Reasons for ineligibility (n= 42)	Reasons declined to participate (n=25)
- Consented n= 36 - Deceased n=1 - Did not reached top of wait list prior to end of recruitment n=39 - Unable to contact n=44 - Outcome not recorded n=3 Declined n=25 Not eligible n=42	- Awaiting surgery n=3 - Already had non STAPLO appt booked n=1 - Prisoner n= 1 - Interpreter required/language barrier n=3 - Mobility assistance user n=2 - No longer on waiting list n=3 - Other diagnosis (hip/knee pain not due to OA) n=7 - Other health condition (exclusion/contraindication) n=6 - Transferred to other trust n= 7 - Unable to attend appts n= 5 - Reason not recorded n=4	- Doesn't want physio n=4 - Doesn't want to commit to sessions n=2 - Undergoing treatment for another health condition n=1 - Wants physio nearer to home: n=2 - Reason not stated: n=16

*39 participants had not reached the top of the waiting list prior to recruitment closing. Therefore 152 of 191 participant information sheets were sent out.

Appendix 6.11 - CONSORT extension for Pilot and Feasibility Trials Checklist, Feasibility Trial

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	143
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	143
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	144-146
	2b	Specific objectives or research questions for pilot trial	146-148
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	148-149
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	149-150, 152, 156,159
Participants	4a	Eligibility criteria for participants	150
	4b	Settings and locations where the data were collected	149
	4c	How participants were identified and consented	150-152
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	152-156
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	157-162

	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	157-162
Sample size	7a	Rationale for numbers in the pilot trial	165
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	NA
Generation	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	160-162
Results			
	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	170-172, 174

Participant flow (a diagram is strongly recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	174
Recruitment	14a	Dates defining the periods of recruitment and follow-up	170-171
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	171-172
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	175-191
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	175
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	176-191
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	172
	19a	If relevant, other important unintended consequences	172
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	202-203
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	203
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and	196-202

		considering other relevant evidence	
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	202
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	149
Protocol	24	Where the pilot trial protocol can be accessed, if available	Appendix 1.5,
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	204
	26	Ethical approval or approval by research review committee, confirmed with reference number	149

Appendix 6.12 COREQ checklist, Feasibility Trial

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
<i>Personal Characteristics</i>		
1. Inter viewer/facilitator	Which author/s conducted the inter view or focus group?	151-152
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	151-152
3. Occupation	What was their occupation at the time of the study?	151-152
4. Gender	Was the researcher male or female?	151-152
5. Experience and training	What experience or training did the researcher have?	151-152
<i>Relationship with participants</i>		
6. Relationship established	Was a relationship established prior to study commencement?	151
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	151
8. Interviewer characteristics	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	151
Domain 2: study design		
<i>Theoretical framework</i>		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	164

<i>Participant selection</i>		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	151-152
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	151-152
12. Sample size	How many participants were in the study?	151
13. Non-participation	How many people refused to participate or dropped out? Reasons?	177, 184-185, 188
<i>Setting</i>		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	177-178, 185, 189
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	N/A
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	177-178, 184-185
<i>Data collection</i>		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	164
18. Repeat interviews	Were repeat inter views carried out? If yes, how many?	152
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	169-170
20. Field notes	Were field notes made during and/or after the inter view or focus group?	169-170
21. Duration	What was the duration of the inter views or focus group?	177, 184-185, 188
22. Data saturation	Was data saturation discussed?	177-178
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	169-170
Domain 3: analysis and findings		
<i>Data analysis</i>		

24. Number of data coders	How many data coders coded the data?	170
25. Description of the coding tree	Did authors provide a description of the coding tree?	170
26. Derivation of themes	Were themes identified in advance or derived from the data?	Derived from data
27. Software	What software, if applicable, was used to manage the data?	NVivo p170
28. Participant checking	Did participants provide feedback on the findings?	169-170
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	183-184, 188, 192
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Y
31. Clarity of major themes	Were major themes clearly presented in the findings?	Y
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Y

Appendix 6.13 TIDieR-Checklist-Word, Feasibility Trial

Item number	Item	Where located ** Primary paper (page or appendix number)
1.	BRIEF NAME Provide the name or a phrase that describes the intervention.	Chapter 6: __143__
2.	WHY Describe any rationale, theory, or goal of the elements essential to the intervention.	Chapter 6: 152-157
3.	WHAT Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Chapter 6: _152-158
4.	WHO PROVIDED Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Chapter 6: _152-157__
5.	HOW For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Chapter 6: _156-157
6.	WHERE Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Chapter 6: _157__

7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Chapter 6: 157
WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	_ Chapter 6: __156-157
TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Chapter 6: __154-157_
MODIFICATIONS		
10. [‡]	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Chapter 6: _157_
HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Chapter 6: 167-169; Chapter 7: 216-219__
12. [‡]	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Chapter 7- 220-227_

Appendix 6.14 SPIRIT_Checklist, Feasibility Trial

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	p143; Appendix 1.5
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	p149; Appendix 1.5
	2b	All items from the World Health Organization Trial Registration Data Set	_____ N/A
Protocol version	3	Date and version identifier	_____ N/A
Funding	4	Sources and types of financial, material, and other support	P205; Appendix 1.5
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Appendix 1.5
	5b	Name and contact information for the trial sponsor	Appendix 1.5
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	p205; Appendix 1.5

5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	P159, p165, Appendix 6.3_____

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	_ p144-146 ;Appendix 1.5 _____
	6b	Explanation for choice of comparators	____ N/A _____ —
Objectives	7	Specific objectives or hypotheses	____p_146-147_ ; Appendix 1.5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	P148-149; Appendix 1.5

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	_P149_____

Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	P150_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	P152-157; Appendix 15
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	_Appendix6.3; Appendix 1.5
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	P167-169; P216-219; Appendix 1.5 _____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	P155; Appendix 1.5
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	P158-166; Appendix 1.5
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Appendix 6.1 _____

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	P151,166
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	P150-151: Appendix 1.5

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	_____N/A_____ _____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	_____N/A_____ _____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	_____N/A_____ _____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	_____N/A_____ _____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_____N/A_____ _____

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	P158-166
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_____P159-60; Appendix 1.5 ____
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Appendix 6.3 _____ —
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	P167; Appendix 1.5
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	P167-170
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_____N/A as feasibility trial _____

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	___Appendix 6.3___
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	___N//A___
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___P 155; Appendix 6.3___
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___Study Steering and Committee Meetings; Appendix 6.3

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	P148; Appendix 1.5
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	N/A as feasibility trial___
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	150-152; Appendix 1.5

	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Appendix 6.3; Appendix 1.5_
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Appendix 1.5
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____N/A
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_____None____ _____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Appendix 1.5
	31b	Authorship eligibility guidelines and any intended use of professional writers	Appendix 1.5
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____N/A____ _____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Consent forms included in Appendix 6.10

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	____N/A____ _____

Appendix 6.15: Trial Participant Information Sheet and Consent Forms

The STaying Active with Physiotherapy in patients with Lower-limb Osteoarthritis (STAPLO): Feasibility Trial - Summary

Participant Information Sheet

We would like to invite you to join our research study. This leaflet tells you what the STAPLO research trial is about and what it involves. One of our research team will go through it with you and answer your questions. Do not be afraid to ask!

What is the study for?

Lower-limb (hip or knee) osteoarthritis (OA) is the most common cause of pain in people who are 45 years of age or over. Being active is a great way to manage this pain and help with function. However, lower-limb OA makes people less active. STAPLO's new physiotherapy course aims to keep people with lower-limb OA as active as possible.

Why ask me and what will I do?

You have lower-limb OA and can have physiotherapy at ROH (the Royal Orthopaedic Hospital). That is why we sent you this sheet. If you wish, you can chat with a research team member either by phone or online who will discuss STAPLO and answer your questions.

If you agree to take part, the team member will talk you through the study and establish consent with you in real time. The consent process will be witnessed by another member of the ROH staff who will be monitoring the call.

We will send you a booklet containing questionnaire forms to fill in about your levels of pain, confidence and motivation for physical activity. The team member will also book you a session with a researcher so they can answer any questions you have about the questionnaire forms and so they can get you to do a few simple activities. For convenience, this can be done in your own home. One of the things we are studying is whether we can 'blind' the researcher assessing you. Therefore, please try to not discuss your treatment with the researcher who is assessing you.

You will also receive an appointment with one of our specially trained physiotherapists to start the new course, which has about six sessions spread over a time-period to suit you. During these sessions, you will discuss your activity with the

physiotherapist and come up with a plan to help you be as active as possible. These sessions can be done in person or remotely via phone or 'Attend Anywhere', the secure NHS video call service.

We will ask you to fill in the same questionnaire forms again after three months, and then six months. This lets us track how you are getting on and how much the new course is helping. At the end of your treatment sessions, if you are interested, you may be invited to an interview to give your opinions about the physiotherapy course.

We may audio record up to three of your physiotherapy sessions. We will type out what you say and destroy the audio recording. We will then review the typed words to see whether the treatment is being given to you as planned. The recording and typed words will not contain any personal information about you.

Do I have to take part?

It is entirely up to you whether to take part or not: you can withdraw at any time, without a reason. Doing this will not affect your treatment in any way.

The use of personal data

In this research study we will use information from you and your medical records. We will only use information that we need for the research study.

We will let very few people know your name or contact details, and only if they *really* need it for this study as part of our research team. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study, we will save some of the data for future research. We will make sure no-one can work out who you are from the reports we write.

The annex tells you more about this.

Annex: The key details

What is the study for?

Lower-limb (hip or knee) osteoarthritis (OA) is the most common cause of pain in people 45 years of age or over. Maintaining your physical activity levels is one of the best ways to manage this pain. However, people with lower-limb OA tend to be less active than others. We have developed a new physiotherapy course of treatment that aims to keep people with lower-limb OA as active as possible.

You are eligible for the new physiotherapy course at the Royal Orthopaedic hospital because you have lower-limb OA (hip or knee or both). You will have been sent this sheet by one of the members of our research team.

If you take part in the study, we will give you a gift of a pedometer to keep as a thank you for participating, however it will be your responsibility to change the batteries when they run out!

What are the possible advantages and disadvantages of taking part in the study?

There are no known risks of taking part. Sometimes people get some pain or stiffness once they start increasing their activity levels but this usually goes away very quickly. We cannot promise that taking part will help you directly, but usually the more active you are, the less pain you will feel! If we become concerned for your well-being or safety while you are being treated, we will ask your permission to discuss this with the site-lead physiotherapist at the Royal Orthopaedic Hospital to ensure appropriate management.

What if there is a problem (contact details below)?

It is highly unlikely that the physiotherapy course will cause any problems for you. If you are worried about anything please speak to the Lead Investigator, Matthew Willett and he will do his best to answer any of your questions. If you remain unhappy, you can complain by following the NHS or University complaints procedures by obtaining advice from the Patient Services Teams at the Hospital or Research Governance and Ethics department at the University. Their contact details are outlined below.

Who is organising and funding this study?

The study is part of PhD research at the University of Birmingham in collaboration with physiotherapists at The Royal Orthopaedic Hospital. It is sponsored by the University and funded by the Musculoskeletal Association of Chartered Physiotherapists Research Council.

Who has reviewed the study?

Like all research in the NHS, an independent group of people called a Research Ethics Committee, has given a favourable opinion to this study, this is to protect your interests and ours.

Contact for further information about this study:

Matthew Willett, Lead Investigator, [REDACTED]

Tel: [REDACTED]

Email: [REDACTED]

Contact details if you wish to seek advice:

The Patient Services Teams at the Trust

[REDACTED]

Research Governance and Ethics at the University of Birmingham:

In case of complaint please contact [REDACTED] for the University of Birmingham.

How will we use information about you?

We will need to use information from you and your medical records for this research project. All information will be stored in accordance with the Data Protection Act 2018.

This information will include your:

- Name
- Contact details
- Level of pain
- Level of knee/hip function
- Amount of physical activity that you undertake
- Confidence and motivation to do physical activity.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will destroy all information that could be used to identify you. We will keep the data on the forms you filled in so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. This information will be stored for 10 years before being destroyed.

If you wish, you can chat with a team member either by phone or online who will discuss STAPLO and answer your questions.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason. We will immediately destroy all personal information about you but the data collected will be included in the study.

- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.
- OPTION if data will be used for future research: If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team or by sending an email to the [REDACTED]

Please refer to the following for further information: www.hra.nhs.uk/patientdataandresearch

The STaying Active with Physiotherapy in patients with Lower-limb Osteoarthritis (STAPLO): Feasibility Trial – Consent Form

Please initial each box

- 1) I have read and understand the Patient information sheet V01 dated xxxxxx,
for the above study. I have had the opportunity to consider the information,

to ask questions and have had these answered satisfactorily. ☐
- 2) I understand that my participation is voluntary and that I am free to withdraw at any time, ☐ without giving any reason, without my
medical care or legal rights being affected. ☐
- 3) I understand that I will be attending the physiotherapy treatment programme which aims to help me be as active as possible. The
sessions will take place at the Royal Orthopaedic Hospital or via phone or the 'Attend Anywhere' virtual platform ☐
- 4) I understand that all data will be anonymised and securely stored at the University of Birmingham. My contact details or any
identifiable data will be stored for the duration of the study and then destroyed. My data will be stored for 10 years ☐
- 5) I agree for some of my treatment sessions to be audio recorded and what I say transcribed unidentifiably. ☐
- 6) I agree for the University of Birmingham trial researchers, NHS sites and regulatory bodies to ☐ have access to the anonymised data ☐
- 7) I agree to take part in the above study ☐

- 8) We would be interested in hearing your feedback about the physiotherapy course. If you interested in attending an interview and giving your opinion about the physio course, please initial the box alongside this statement

_____	_____	_____
Name of Participant	Date	Signature

_____	_____	_____
Name of staff member taking consent	Date	Signature

For witnessed verbal consent: I witnessed accurate reading of the consent form to the patient, who could ask any questions and was happy with the responses.

_____	_____	_____
Name of staff who witnessed consent	Date	Signature

When completed, 1 for participant; 1 for Uni of Birmingham; 1 for the site file

Appendix 8.1- Characteristics of included trials in updated review

Comparison Group				Behavioural Physiotherapy		Delivery and training	
Trial /Country	Type of OA	N, (M/F), Mean age	Content	N, (M/F), Mean Age	Content	Delivery	Training in BCT delivery
Alasfour, 2022, Saudi Arabia	Knee	20, (0/20),55.15	9 prescribed exercises overseen by physiotherapist plus paper copy of exercises	20 (0,20), 53.65	9 prescribed exercises overseen by physiotherapist plus 'My Dear Knee' APP	Physiotherapist only	No detail on training provided
Allen, 2018, USA	Knee	Internet Based Exercise Training: 142, (98,44) 65.3 Waitlist Control: 68 (54,14) 64.3	IBET: Information about OA, visual demonstration of exercises, self-monitoring, and self-management strategies Waitlist control: no intervention	140 (100,40), 65.7	Up to 8 one-hour sessions focusing on education and HEP and manual therapy	Physiotherapist only	Received training from investigators in 'standard treatment' but no detail as what this entails.
Allen, 2021, USA	Knee	155, (98/17), 60.2	Educational materials via mail every 2 weeks for 9 months	230, (194,36), 59.9	Stepped Knee Osteoarthritis intervention Stage 1: Internet Based Exercise Training Stage 2: 6 Telephone calls every two weeks focused on physical activity coaching. Stage 3: 1 x 1 hour physio visit followed by 2-6 x 30-minute physiotherapy sessions	Only in behavioural intervention: Stage 2: 'Physical Activity Coach' Stage 3: Physiotherapy	Stage 2: Training from investigators No detail on timings Stage 3: 1 initial session, followed by fidelity checks. No further detail on timing.
Bendrik, 2021, Sweden	Hip and Knee	69, (46,23),60.9	Advice Group (physiotherapist delivered) 1 hour physiotherapy session focussing on	72, (56,16),59.7	Prescription group (physiotherapist delivered) 1 hour physiotherapy session focussing on	Physiotherapist delivered both groups	No detail on training provided

			information and advice about physical activity		information and advice about physical activity. 3 x Individual physiotherapy follow up sessions at 3 weeks, 3 months, and 6 months (15 mins- 1hour in duration) One physiotherapy group session at 6 months		
Bennell, 2018, Australia	Hip	71, (37,34), 61.3	Comparison Group: Online educational material OA for 8 weeks. 5 x 30-minute physiotherapy sessions (approximately every 3 weeks) for HEP.	73, (45,28), 61.2	Comparison group plus: Access to internet based automated PCST program for 8 weeks. Each session anticipated to be 35–45-minute duration.	Physiotherapist delivered all in person sessions across both groups.	Physiotherapists received half a day of training.
Hay, 2018, United Kingdom	Knee	175 (87,88), 62	UPC: 4 physiotherapy sessions over 12 weeks	ITE: 176 (91,85), 63 TEA: 163 (84,79), 64	ITE:6-8 physiotherapy sessions over 12 weeks. HEP tailored and activity diary given to patients. Targeted exercise adherence: 8-10 physiotherapy sessions over 6 months following cognitive behavioural principles and adherence enhancing tool kit. Pedometer given to patients.	Physiotherapist delivered all groups	All physios attended day one. ITE and TEA physios attended days 2-3. TEA physios attended day 4-5.
Kloek, 2018, Netherlands	Hip and Knee OA	99, (67,32), 62.3	Usual Care: Unspecified number of face-to-face physiotherapy sessions following Dutch guidelines,	99, (74,35), 63.8	E-Exercise: 5 face-to-face physiotherapy sessions and an internet delivered education, HEP and graded activity based on Dutch OA guidelines over 12 weeks.	All in person sessions delivered by physical therapists. All else on internet	All physiotherapists received half day of training.
Knoop, 2022, Netherlands	Knee	177 (114,63), 64	Usual Care: Unspecified number of face-to-face physiotherapy sessions	151 (95, 56), 66	Patients split into 3 subgroups. High muscle strength: 3-5 individual physiotherapy	Physiotherapist delivered all treatment apart from Obesity	Control group physiotherapists: 2-hr training session

			following Dutch guidelines,		session over 12 weeks and 1 booster session focusing on specific education and HEP. Obesity subgroup: 12-18 individual physiotherapy sessions over 12-week period and 2-3 booster sessions focusing on specific education and HEP. 5-8 individual sessions with dietician (150 mins total)	subgroup which included input from dietician.	Behavioural physiotherapists: 4 hours of training session. Also given e-learning course based on Dutch guidelines. Dieticians: instructed in current guidelines
Li, 2018, Canada	Knee	31 (28,3), 62.1	Delayed group: Same content as behavioral intervention with 2-month delay.	30 (22,8), 61.3	1.5-hour physiotherapy session and 4 x phone call every second week. Patients given Fitbit flex.	Physiotherapist delivered all treatment	2-day training in motivational interviewing course. 2 x 2 hours 'orientation session'
Li, 2020, Canada	Knee	25 (19, 6), 64.8	Delayed group: Same content as behavioral intervention with 14-week delay	26 (23,3), 65.0	50-minute physiotherapy session and 4 x phone call every second week. Patients given Fitbit flex. Reminder emails from weeks 9-12.	Physiotherapist delivered both interventions.	2-day training in motivational interviewing course. Orientation session including shadowing a counselling session.
Schlenk 2021, USA	Knee (and hypertension)	91 (25/66), 64.96	6 x weekly and 9 x fortnightly 15–20-minute educational telephone calls with nurse	91, (24/67), 64.4	6 x 60-minute weekly in person physiotherapy sessions. 9 x fortnightly 15-20 minutes with nurse for goal setting.	Behavioural intervention: Physiotherapist and nurse Comparison group: Nurse	Training given to all 'interventionalist s' using 'teach back/show back' methods. No detail on timing.

Stanton, 2020, Australia	Knee	10, (2,8), 64.8	4 x 60-minute physiotherapy sessions with walking programme, education, and sham ultrasound Educational Workbook 4 x 15-20-minute phone calls with physiotherapist	10, (4,6), 69.2	4 x 60-90-minute physiotherapy pain education and graded walking sessions Interactive pain science and workbook. 4 weekly 15-20-minute phone calls with physiotherapist	Physiotherapist s delivered all interventions	Behavioural intervention: 20 hours pain science education Control physiotherapist: 8 hours of training on educational content and 1 hour on walking program

Key:

BCT: Behaviour Change Technique; OA: Osteoarthritis; HEP: Home exercise programme; RCT: Randomized controlled trial; PCST: Pain Coping Skills Training; BL: Baseline; ITE: Individually tailored exercise; TEA: Targeted Exercise Adherence; UPC: Usual Physiotherapy Care; IBET: Internet based Exercise training

Appendix 8.2- Physical Activity and Adherence outcomes in updated review

Outcome Measure (PA/ adherence measure domain)		Outcome Timings / Effect sizes (Continuous outcome; SMD (95% CI); Dichotomous; PR (95% CI))		
Trial		Short	Medium	Long
Alasfour, 2022	Adherence: Percentage of exercises completed out of the total number prescribed	6 weeks 0.98 [0.27, 1.69] +	NM	NM
Allen, 2018	Physical Activity (self-Report) PASE - minutes per week of stretching, strengthening and aerobic exercise	4 months Vs Waitlist control 6.95 (-12.31, 26.22) + Vs IBET -13.77 (-29.73, 2.19) +	NM	1 year Vs Waitlist control 7.11 (-9.69, 23.91) + Vs IBET -0.09 (-14.41, 14.23) +
Allen, 2021	Physical Activity (Self-Report) PASE	3 Months -0.5 (-18.3 to 17.3) +	6 Month -8.6 (-28.4 to 11.1) +	9 Month 10.3 (-9.5 to 30.1) +
Bendrik, 2021	Physical Activity (Self-Report) Activity minutes - Leisure time physical activity - Sedentary time (IPAQ) Physical Activity (direct measure) Accelerometer Steps per day - Average daily moderate-vigorous physical activity (mins/day) - Average sedentary time (mins/day) - Average light physical activity time (mins/day) - METs (average/day)	NM	0.64 (0.27-1.00) + 1.21 (0.81-1.61) +	NM

Bennell, 2018	Physical Activity (self-report) PASE - Amount of exercise done on Likert scale Adherence Adherence to Exercise in logbooks (%) - Therapist-rated 11-point NRS of participant's adherence to home exercise at final exercise session - Self-reported number of home exercise sessions in the previous 2 weeks (maximum: 6) - Self-rated 11-point NRS adherence to home exercise	8 -0.02 (-0.35, 0.3) + NM	24 0.03 (-0.31,0.37) + -0.13 (-0.47, 0.21) +	52 0.05 (-0.30,0.39) + -0.06 (-0.40, 0.29) +
Hay, 2018	Physical Activity (self-report) PASE - Amount of exercise done on Likert scale Physical Activity (Direct Measure) - Accelerometer worn on the hip. Subset measured only. No data to enable meaningful comparison between groups. Adherence - Exercise frequency in the last month (likert scales): Not measurable across groups	3 months ITE Vs UPC -0.09 (-0.30,012) + TEA Vs UPC -0.03 (-0.25, 0.18) +	6 months ITE Vs UPC 0.01 (-0.2, 0.22) + TEA Vs UPC 0.09 (-0.12,0.30) +	9 months ITE vs IPC -0.1 (-0.31,0.11) + TEA Vs UPC 0.21 (-0.01, 0.42) +
Kloek, 2018	Physical Activity (self-report) - SQUASH (mins/day total exercise) Physical Activity (direct measure) Accelerometer - Average daily moderate-vigorous physical activity (mins/day)	3 Month -0.09 (-0.39, 0.20) + 0.00(-0.30, 0.30) +	NM	12 month -0.18 (-0.52, 0.16) + -0.08 (-0.42, 0.25) +

Knoop, 2022	Adherence • Patient-reported adherence to home exercises and moderate and vigorous physical activities (Y/N)	NM	NM	12 months 1.05 (0.84,1.32) %
Li, 2018	Physical Activity (direct measure) Accelerometer: • Average daily bouts moderate-vigorous physical activity (mins/day) • Average daily steps (number/day) • Average daily bouts Sedentary time (mins/day)	8 weeks 0.46 (-0.05, 0.97) +	NM	NM
Li, 2020	Physical Activity (direct measure) Accelerometer: • Average daily bouts moderate-vigorous physical activity (mins/day) • Average daily steps (number/day) • Average daily bouts Sedentary time (mins/day)	13 weeks 0.26 (-0.30,0.83) +	NM	NM
Schlenk 2021	Physical Activity (self-report) • Lower limb extremity exercises reported by participant (mins/day) • Fitness walking (mins/day) Physical Activity (direct measure) Accelerometer: • Average daily moderate-vigorous physical activity (mins/day) • Average sedentary time (mins/day) • Average light physical activity time (mins/day)	NM 	24 Weeks 0.92 (0.58,1.26) + -1.81 (-2.19, -1.42) +	50 weeks 3.23 (2.73,3.73) + -2.49(-2.93,-2.05) +
Stanton, 2020	Physical Activity (direct measure) Accelerometer: • Daily steps (number/day) • Average daily moderate-vigorous physical activity (mins/day) • Average sedentary time (mins/day) • Average light physical activity time (mins/day)	8 weeks NR	26 weeks NR	NM

Key:

SMD: Standardised Mean Difference for continuous data; PR: Probability ratio for dichotomous data; CI: Confidence interval; NM: Not measured; Measure in each domain that was written in bold was used to determine effect sizes; NR: No results available; Results in bold show statistically significant effect in favour of behavioural physiotherapy intervention ($P < 0.05$); PASE: Physical Activity Scale for the Elderly; IBET: Internet Based Exercise Training; ; IPAQ: International Physical Activity Questionnaire; MET: Metabolic Equivalent of Task; NRS: Numerical Rating Scale; ITE: individually tailored exercise; UPC: usual physiotherapy care; TEA: : targeted exercise adherence ; SQUASH: Short Questionnaire to Assess Health Enhancing Physical Activity; HEP: Home exercise programme; + indicates continuous data; % indicates dichotomous data

Appendix 8.3 - Updated systematic review PRISMA_2020_checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	235
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	235
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	236-238
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	237
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Same as original review
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Same as original review
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	237
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	238
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Same as original review
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Same as original review
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Same as original review
Study risk of bias	11	Specify the methods used to assess risk of bias in the included studies, including	239

Section and Topic	Item #	Checklist item	Location where item is reported
assessment		details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Same as original review
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Same as original review
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	Same as original review
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Same as original review
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Same as original review
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Same as original review
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N/A
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	N/A
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	239
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	240
Study characteristics	17	Cite each included study and present its characteristics.	241
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	242-243
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g.	243-245

Section and Topic	Item #	Checklist item	Location where item is reported
		confidence/credible interval), ideally using structured tables or plots.	
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	N/A
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	246, Appendix 2.4
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	N/A
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	250
	23b	Discuss any limitations of the evidence included in the review.	259-260
	23c	Discuss any limitations of the review processes used.	259-260
	23d	Discuss implications of the results for practice, policy, and future research.	260-261
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Same as original review
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Same as original review
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Same as original review
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	N/A
Competing interests	26	Declare any competing interests of review authors.	Appendix 1.2
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Appendix 1.2

Appendix 9.1- AMSTAR 2 Checklist for systematic review (Chapter 2, Chapter 8)

	AMSTAR 2 Criteria	Y/N/PY
1	Did the research questions and inclusion criteria for the review include the components of PICO?	Y
2	Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Y
3	Explanation of selection of the study designs?	Y
4	Did the review authors use a comprehensive literature search strategy?	Y
5	Did the review authors perform study selection in duplicate?	Y
6	Did the review authors perform data extraction in duplicate?	Y
7	Did the review authors justify exclusions?	Y
8	Did the review authors describe the included studies in adequate detail?	Y
9	Did the review authors use a satisfactory technique for assessing the risk of bias (RoB)/quality in individual studies that were included in the review?	Y
10	Did the review authors report on the sources of funding for the studies included in the review?	Y
11	If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	N/A
12	If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	N/A
13	Did the review authors account for RoB/quality in individual studies when interpreting/ discussing the results of the review?	Y
14	Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Y
15	If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	N/A
16	Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Y

Appendix 9.2 - Self assessed Risk of Bias of Qualitative study - Patient Semi structured interviews

Critical Appraisal Skills Program Qualitative Checklist	Y/N/?
1) Was there a clear statement of the aims of the research?	Y
2) Is a qualitative methodology appropriate?	Y
3) Was the research design appropriate to address the aims of the research?	Y
4) Was the recruitment strategy appropriate to the aims of the research?	Y
5) Was the data collected in a way that addressed the research issue?	Y
6) Has the relationship between researcher and participants been adequately considered?	Y
7) Have ethical issues been taken into consideration?	Y
8) Was the data analysis sufficiently rigorous?	Y
9) Is there a clear statement of findings?	Y
10) How valuable is the research?	N/A

Lincoln and Guba Trustworthiness Criteria	Examples where criteria applied.
Credibility	• Prolonged engagement • Researcher triangulation • Peer discussion • Negative case analysis
Dependability	• Research audit: Raw data, Audio recordings, field notes, transcription, NVIVO and reflexive journal. • Transparent reporting (COREC)
Confirmability	• Reflexive journal • Reasons for theoretical, methodological, and analytic choices outlined. • Raw data included
Transferability	• Thick description

Appendix 9.3 - Self assessed Risk of Bias of Qualitative study - Physiotherapist Semi focus groups

Critical Appraisal Skills Program Qualitative Checklist	Y/N/?
11) Was there a clear statement of the aims of the research?	Y
12) Is a qualitative methodology appropriate?	Y
13) Was the research design appropriate to address the aims of the research?	Y
14) Was the recruitment strategy appropriate to the aims of the research?	Y
15) Was the data collected in a way that addressed the research issue?	Y
16) Has the relationship between researcher and participants been adequately considered?	Y
17) Have ethical issues been taken into consideration?	Y
18) Was the data analysis sufficiently rigorous?	Y
19) Is there a clear statement of findings?	Y
20) How valuable is the research?	?

Lincoln and Guba Trustworthiness Criteria	Examples where criteria applied.
Credibility	• Prolonged engagement • Researcher triangulation • Peer discussion • Negative case analysis
Dependability	• Research audit: Raw data, Audio recordings, field notes, transcription, NVIVO and reflexive journal. • Transparent reporting (COREC)
Confirmability	• Reflexive journal • Reasons for theoretical, methodological, and analytic choices outlined.

	• Raw data included
Transferability	• Thick description

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