INTERVENTIONS TO REDUCE SEDENTARY TIME IN OLDER ADULTS WITH AND WITHOUT MOBILITY LIMITATION

By JUSTIN AVERY AUNGER

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School of Sport, Exercise, and Rehabilitation Sciences

College of Life and Environmental Sciences

University of Birmingham

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Abstract

Older adults are a growing portion of the population and are most at-risk of the negative health effects of sedentary behaviour. In this PhD, a systematic review was presented which assessed existing interventions to reduce sedentary behaviour in older adults and found that to date, none have recruited older adults with co-morbidities or mobility limitations, and have not assessed clinical outcomes. Older adults with osteoarthritis are highly sedentary, and thus reducing their sedentariness prior to hip or knee replacement surgeries may be pertinent to improve their health and post-surgical outcomes. A randomised controlled feasibility study based on Self-Determination Theory was conducted in 35 patients waiting for surgery using a range of behavioural techniques to increase activity and reduce sitting. It was found that the study was feasible to patients, and that it had potential to improve physical function and reduce sedentary behaviour but required some modification to be feasible to deliver. More robust trials to test efficacy of the intervention are required; thus, the design of a future RCT was presented, requiring multi-site design and 188 participants to detect meaningful changes in physical function post-surgery.

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List of abbreviations

AE – Adverse Event
ANOVA – Analysis of Variance
BCT – Behaviour Change Technique
BMI – Body Mass Index
CI – Confidence Interval
CRF – Cardiorespiratory Fitness
CRP – C-Reactive Protein
CVD – Cardiovascular Disease
GCT – Goal Contents Theory
HDL – High Density Lipoprotein
INTEREST – INTErvention to REduce Sedentary Time in older adults undergoing orthopaedic surgery
IPAQ-SF – International Physical Activity Questionnaire Short Form
LDL – Low Density Lipoprotein
LPA – Light Physical Activity
MET – Metabolic Equivalent of Task
MI – Motivational Interview
MOST – Measure of Older Adults' Sedentary Time
MPA – Moderate Physical Activity
MVPA – Moderate-to-Vigorous Physical Activity
NHS – National Health Service (of the United Kingdom)
OIT – Organismic Integration Theory
PA – Physical Activity
PANINI – Physical Activity and Nutritional INfluences In ageing (research network)
PIS – Participant Information Sheet
QoL – Quality of Life
RCT – Randomised Controlled Trial
RN – Research Nurse
SAE – Serious Adverse Event
SD – Standard Deviation
SDT – Self-Determination Theory
SF-MNA – Short Form Mini Nutritional Assessment
SMART – Specific, Measurable, Achievable, Realistic, and TImely
SPIRIT - Standard Protocol Items Recommendations for Interventional Trials
SPPB – Short Physical Performance Battery
TV - Television
VPA – Vigorous Physical Activity

CHAPTER 1: INTRODUCTION

1.1. Summary

Older adults are a highly sedentary population subgroup that is particularly susceptible to the negative health effects of sitting. In the UK, the older population is growing, both in absolute and relative terms, which is already putting immense pressure on healthcare services to develop strategies to alleviate the burden on resources. Although evidence is still mixed with respect to whether the negative health impact of sedentary behaviour is truly independent of PA, the focus of research in the field of sedentary behaviour regarding older adults should remain on reducing sedentary behaviour. This is because it may be more achievable to reduce sedentary behaviour rather than increase moderate-to-vigorous physical activity (MVPA), as performance of MVPA is dependent on being physically capable. In older adults, sedentariness is negatively associated with physical and mental function, cardiometabolic health, and activities of daily living, and has a complex relationship with health that requires consideration of factors such as sedentary bout length, overall sitting time, sit to stand transitions, and the performance of specific behaviours such as TV watching. However, the mechanisms underlying the health effects of sedentary behaviour remain to be fully understood; limited evidence has explored the effects of sedentary behaviour on lipoprotein and glucose metabolism.

Furthermore, older adults have specific lifestyle factors which need to be considered when designing interventions to diminish sedentariness, such as their typical behaviours and morbidities. For example, a patient suffering from osteoarthritis (another growing population subgroup) endures further barriers to being active. Despite the complexities inherent in designing interventions to reduce sedentariness in older adults, it should be a research priority to determine the efficacy and effectiveness of interventions, and, consequently, to inform policy-makers and health service providers about which behaviour change strategies are optimal to use when tackling this pressing contemporary healthcare issue.

1.2. Defining concepts

Sedentary behaviour is a complex, multifaceted construct often considered to be synonymous with inactivity, i.e. someone is 'sedentary' when they do not perform enough exercise. According to the Oxford English Dictionary, sedentary (in terms of lifestyle) means "characterised by much sitting and little physical activity", or (in terms of position), "sitting; seated", and when referring to a person, means "tending to spend too much time seated; somewhat inactive" (Oxford Dictionaries, 2019). Therefore, sedentary can represent a multitude of different concepts. However, in the context of whether a person can be considered sedentary, sedentariness should not be defined according to the absence of a different construct, namely, physical activity. Rather, it should be defined as a distinct concept in its own right: i.e. by prevalence of sitting or lying, non-moving behaviours. For example, one could engage in only 30 minutes of sitting per day but stand up and do chores for 10 hours. Although in this case there is an absence of what is traditionally considered exercise, one should not consider that individual to be sedentary, as they are not engaging in sedentary behaviour for long periods. Therefore, sedentary behaviour should be defined as a distinct construct within the spectrum of day-to-day movement patterns, rather than by an absence of physical activity (figure 1).

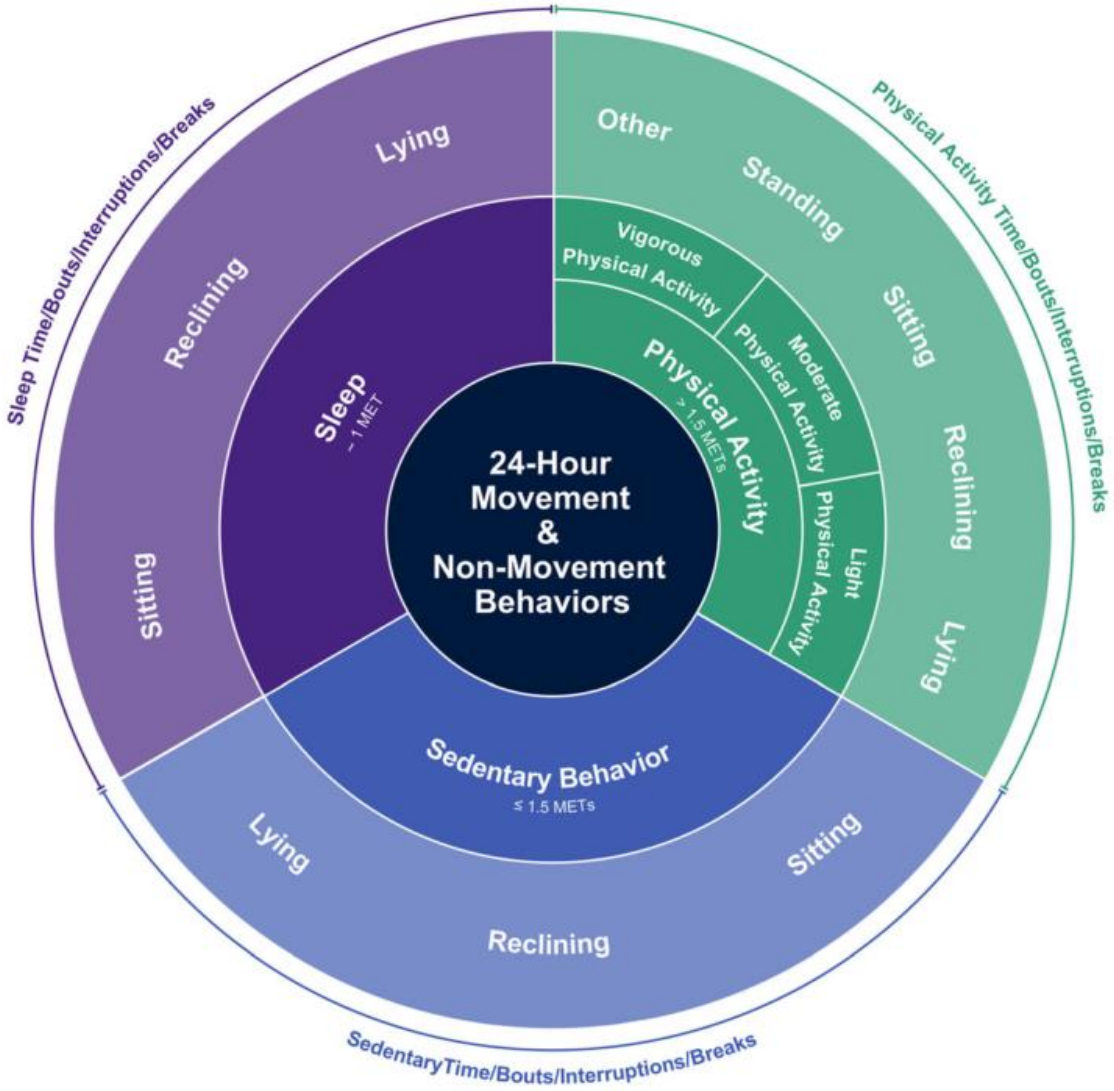

Figure 1 - Conceptual model of movement-based terminology. From Tremblay et al. (2017).

However, there is debate about where sedentary behaviour lies in the energy expenditure spectrum. The Sedentary Behaviour Research Network (SBRN, 2013) has therefore proposed an operationalised definition of sedentary behaviour, in which sedentary behaviour is defined as "any waking behaviour characterised by an energy expenditure of ≤1.5 metabolic equivalent of tasks (MET)s while in a sitting or reclining posture." This definition treats sedentary behaviour as a distinct concept, existing within the physical activity (PA) energy expenditure continuum with an additional postural component, and provides an operationalisation that is useful for scientific practice. In research prior to the release of a consensus statement by the Sedentary Behaviour Research Network (2013), the definition of

sedentary behaviour often differed. A recent publication by the SBRN in 2017 outlined how these definitions differed, with some papers defining sedentary behaviour as any behaviour with an energy expenditure below 2.0 METs, another simply as “non-upright activities”, or as vaguely as “a distinct class of behaviours characterised by low energy expenditure” (Tremblay *et al.*, 2017). Thus, the need for consensus was strong.

Sitting is the most common waking form of sedentary behaviour and many studies focus on and measure the effect of waking SBs such as watching TV, reading books, etc., on an aspect of health. Standing is also an area of contention, as it can also be within the MET range of the definition of sedentary behaviour. To clarify this, the Sedentary Behaviour Research Network has recently released a statement that makes a distinction between passive standing (≤2.0 METs) and active standing (>2.0 METs) as independent concepts from sedentary behaviour, lying between sedentary behaviour and light PA (LPA) in the activity spectrum (Tremblay *et al.*, 2017). In interventions to reduce sedentary time, displacements of sedentary behaviour are most frequently to LPA or standing rather than more vigorous forms of activity (Aunger, Doody and Greig, 2018).

Both sedentary behaviour and PA are related to aspects of health and function in unique and independent ways, and both exist within the spectrum of energy expenditure (see figure 1 for the spectrum in METs) (Dickie *et al*., 2016; Ekblom *et al*., 2015; Green *et al*., 2014). For example, performance of light PA, considered as any activity between 1.5 and 3.0 METs, has been found to have an independent impact on arterial stiffness in older adults (where higher stiffness increases risk of cardiovascular disease (CVD)), even after controlling for more vigorous activity and sedentary behaviour (Gando *et al.*, 2010). The impact of different energy-balanced physical activity and sedentary behaviour scenarios on insulin action and plasma lipids have been investigated in n=18 healthy younger adults who were randomly assigned to either sitting for 14 hours a day, sitting 13 hours/day with 1 hour of vigorous exercise, or a longer period of walking (LPA) (4 hours) and standing (2 hours)

with 8 hours of sitting (Duvivier *et al.*, 2013). It was found that the latter condition, the lightest but longest level of physical activity, significantly lowered insulin (8320.4 vs. 6727.3 min/ml; p=0.005) and triglycerides (0.70 vs. 0.85 mmol/L; p=0.007) more than 1 hr of vigorous PA (VPA) (Duvivier *et al.*, 2013). This suggests that LPA should be considered its own class of activity within the 24-hour spectrum due to its own unique physiological effects. An additional conclusion is that a shorter period of intense exercise may not be enough to offset the negative impact of prolonged sedentarism on insulin action and plasma lipids. However, further studies of this kind are needed to verify this finding.

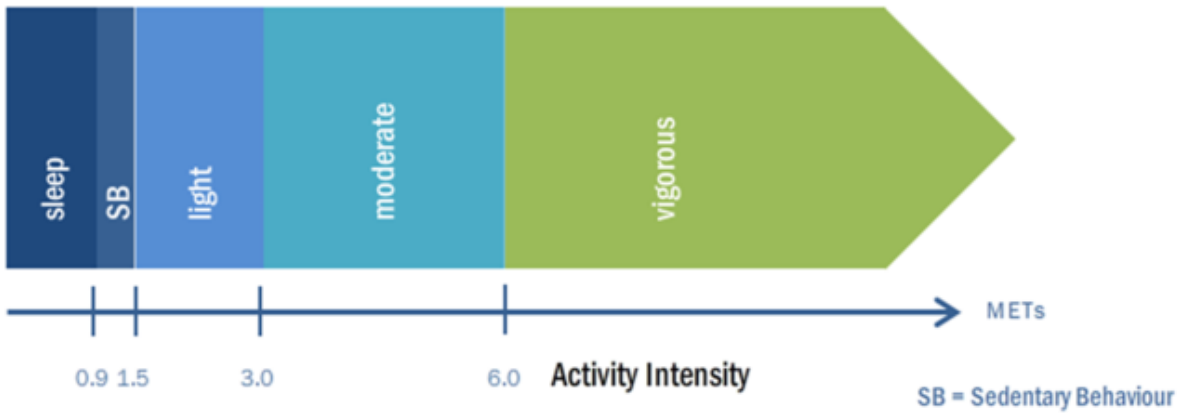

Figure 2. MET levels for sedentary behaviour and physical activity. From Trinity College Dublin, (n.d.).

Moderate physical activity (MPA) is equivalent to an energy expenditure between 3.0 and 6.0 METs, and includes gardening, cleaning the house, or light tennis. Performance of VPA that constitutes activity of greater than 6.0 METs, has been found to have the strongest positive impact on cardiorespiratory fitness (CRF). CRF is defined as "the highest rate at which oxygen can be taken up and consumed by the body during intense exercise" (Dalleck and Dalleck, 2008), and in energy-matched scenarios, more intense PA is more effective at increasing CRF than less intensive PA (O'Donovan *et al.*, 2005). Since CRF is an objective measure of physiological organ capacity that is very strongly positively related to CVD risk, performance of VPA has a strong positive impact on the cardiorespiratory system, and reduces risk of coronary heart disease and type 2 diabetes (O'Donovan *et al.*, 2005; Swain and Franklin, 2006). Even though CRF is approximately 25-47% genetically

determined, PA of sufficient intensity can raise CRF over untrained levels by up to 20% (Bouchard *et al.*, 1999). According to a critical review investigating the associations between PA, sedentary behaviour, and CRF, CRF may moderate the relationship between sedentary behaviour, PA, and disease risk, meaning that low CRF may increase the risk of the negative effects of sedentary behaviour (Figure 3) (Després, 2015). The study emphasises that CRF is an objective physiological measure that reflects cardiorespiratory health, rather than simply being performance of a behaviour, and is the factor most strongly associated with morbidity and mortality risk from noncommunicable diseases throughout the lifespan (Després, 2015).

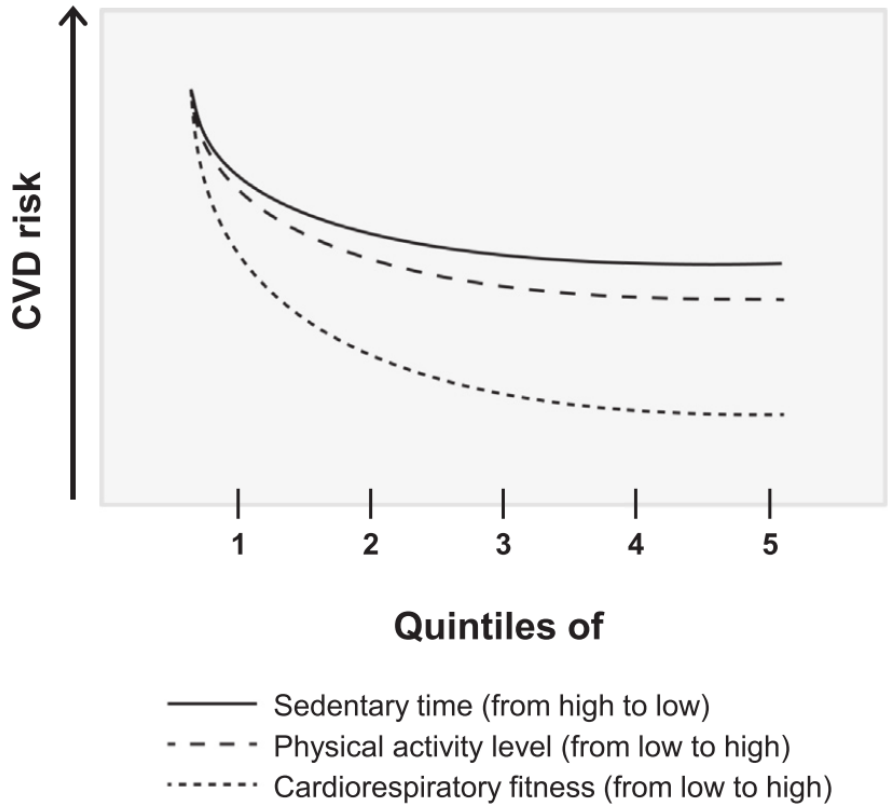

Figure 3. Figure depicting the independent relationships between sedentary time, PA level, and CRF and CVD risk. From Després (2015).

In terms of the amount of physical activity needed to prevent a significant negative health impact, public health recommendations from the World Health Organisation (WHO) suggest performing at least 150 minutes/week of MPA or 75/week of VPA (WHO, 2010). However, as of yet, few worldwide

organisations recommend putting specific limitations on sitting time. One exception to this is the (Department of Health and Social Care, 2019) of the United Kingdom, which has emphasised that ”older adults should break up prolonged periods of being sedentary with light activity when physically possible, or at least with standing, as this has distinct health benefits for older people“ (Department of Health and Social Care, 2019). These recommendations are based on a range of findings, such as a report of evidence relating to prevalence and health effects of sedentary behaviour across different age groups provided by the Sedentary Behaviour and Obesity Expert Working Group (Biddle *et al.*, 2010), as well as the findings of a harmonised meta-analysis including over 1-million individuals from Ekelund *et al.*. (2016) and a narrative review of the health effects of sedentary behaviour in older adults by Copeland *et al.* (2017). However, the evidence is still premature and too dependent upon other factors, such as engagement in physical activity, to give quantitative estimates of risk for engagement in sedentary behaviour (Department of Health and Social Care, 2019).

1.3. Older adults: sociodemographic factors and the ageing process

Older adults generate more burden than other age groups on health services in the western world, due to the associated co-morbidities of ageing (Prince *et al.*, 2015). Currently, in the UK, expenses from caring for adults ≥65 years account for two fifths (40%) of the total National Health Service (NHS) budget, even though over-65s are only 17.7% of the population as of mid-2014 (HM Treasury, 2015; ONS, 2015). At the same time, older adults are growing significantly as a proportion of the population in the UK (Office of National Statistics, 2015). By 2050, adults 65 years and older are expected to comprise approximately 25% of the total UK population (Cracknell, 2010). This ongoing increase is proportionally increasing the burden on the NHS in the UK, causing great financial and logistical strain. Hence, efforts to improve the health of older adults through lifestyle means, such as by reducing the prevalence of sedentary behaviour in older adults, could both help to improve the health of older adults and thereby reduce their reliance on NHS services.

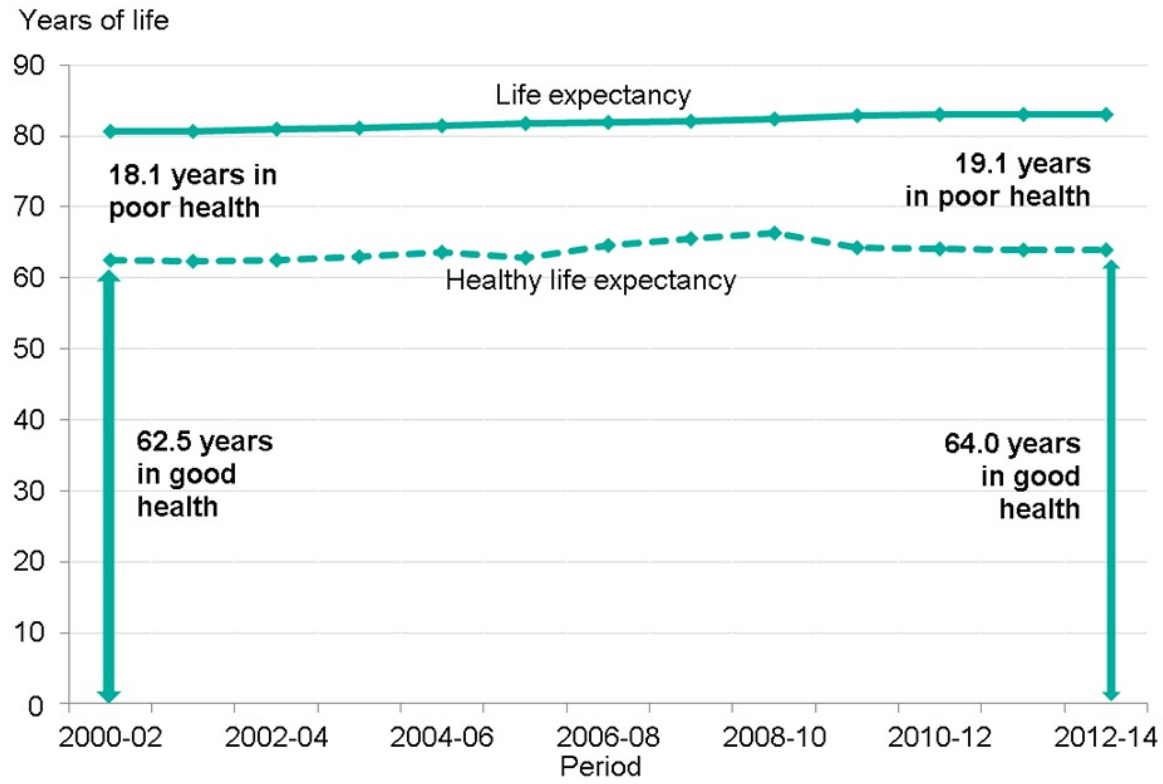

Figure 4. Healthy state life expectancies at birth, females, United Kingdom, 2000 to 2014. From Office for National Statistics (2016).

Alongside this, lifespan is also still increasing, largely due to improvements in healthcare. In the period 1980-2013, male lifespan from birth has increased by 8.3 years, and by 6.0 years for women. Expected lifespan at the age of 65 years has also risen from 13 years in 1980 in men to 18.5 years in 2013, and from 16.9 years in 1980 in women to 20.9 in 2013. However, *healthy life expectancy*, that is, the length of one's life during which one expects to be healthy, is not increasing as rapidly as the increase in lifespan (Figures 3 and 4) (Salomon *et al.*, 2012). This means that older adults are living for longer with ill-health, due to a decline in physical function, and many are below the thresholds for physical independence that have drastic negative effects on their quality of life (Young, 1997; Marques *et al*., 2014). Ageing is characterised by a decline in physiological reserve across a number of bodily systems. Few aspects of this physiological decline, however, are as debilitating as the loss of muscle, which occurs at a rate of approximately 1% per year after middle age (50 and onwards) (Young, 1997). A sufficient decline in muscle power constitutes the crossing of a threshold that signals the end of healthy

life expectancy, whereby activities of daily living are impaired and require aid from others (Young, 1997; Salomon *et al.*, 2012). Finding methods to enable older adults to enjoy a longer 'healthspan', the portion of life spent in good health, by improving muscle function or through other means, is therefore an important goal that would reduce the burden on health care services, carers, and older adults themselves (Marques *et al.*, 2014).

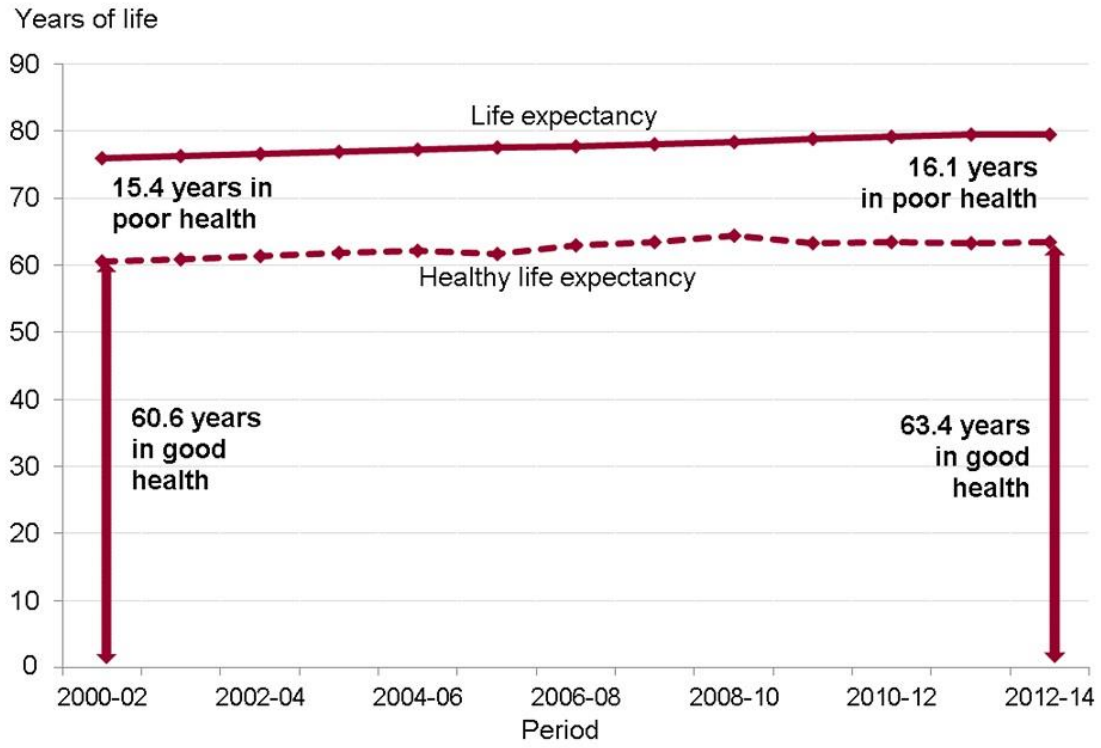

Figure 5. Healthy state life expectancies at birth, males, United Kingdom, 2000 to 2014. From Office for National Statistics (2016).

1.4. The risks of being older and highly sedentary

The prevalence of sedentary behaviour in older adults is high. A review of objectively-measured sedentary behaviour in older adults >60 years in the United States reported that they spent an average of 8.5 hours per day sitting (Evenson, Buchner and Morland, 2012). Other studies reported higher average daily sitting times; in a sample of 1403 older men with a mean age of 78.4 years, the participants were found to spend approximately 72% of waking time in sedentary behaviours (10.3 hours) over 7 days (Jefferis *et al.*, 2015). Similarly, a study of older women found that they spent about

65.5% of the day being sedentary (9.7 hours) (Shiroma *et al.*, 2013). Additionally, Jefferis *et al*. (2015) have shown that after the age of 65 years, mean sedentariness increases every year, with additional medical factors also found to be associated with a further increase in sedentariness (Jefferis *et al.*, 2015).

Compounding this issue is ageing. Since ageing primarily manifests as a decline in physiological reserve throughout bodily systems, older adults have a phenotype characterised by low CRF and low muscular strength, low adherence to guidelines relating to PA, and high sedentary behaviour, i.e. a trio of risk factors for CVD and mortality (Matthews *et al.*, 2008; Sandbakk, Aspvik and Stensvold, 2016). Evidence suggests that if one is already highly sedentary, sitting for even longer will further amplify the negative health effects of sedentary behaviour (Després, 2015). The association has important implications, as it means that certain populations are at greater risk than others for morbidity and mortality if they already have low CRF. Similarly, elite athletes are likely to be mostly protected from the negative effects of sedentary behaviour due to having high CRF from chronic performance of VPA.

sedentary behaviour is associated with a number of non-communicable diseases, such as cardiovascular disease (CVD) and type II diabetes, as well as all-cause mortality (M. T. Hamilton, Hamilton, & Zderic, 2007; Wullems *et al*, 2016). A recent investigation of the relationship between CVD, PA, and sedentary behaviour, controlling for CRF, was conducted in a sample of 1398 adults with a mean age of 53.4 years (Vasankari *et al.*, 2017). CVD risk was determined using the Framingham risk model, which is a composite score comprised of age, total cholesterol, HDL cholesterol, smoking history, and systolic blood pressure (Wilson *et al.*, 1998). Increased CVD risk was most significantly associated with waist circumference, followed by the number of sedentary behaviour bouts >10 mins per day, and the latter association was maintained with CVD risk even after adjustment for PA and CRF. High CRF was found to be the most negatively associated factor with CVD risk (Vasankari *et al.*, 2017). This study is particularly rigorous as it is relatively uncommon for the role of CRF to be accounted for

in the relationship between sedentary behaviour and CVD risk in studies such as this one, even though CRF is purported to be a key mediator. However, the authors only estimated CRF based on a sub-maximal walk test, which is not as valid a measurement of CRF in comparison to a maximal CRF test (Grant *et al.*, 1995).

With respect to mortality, a recent study followed n=2635 Spanish older adults, aged 60 and over, using a prospective cohort design, to investigate the relationship between sedentariness and mortality (León-Muñoz *et al.*, 2013). This study found that individuals who became sedentary at follow-up, i.e. went from below to above the median for self-reported sitting time over follow-up from 2001-2003, had a hazard ratio for all-cause mortality of 0.91 (95% CI = 0.76, 1.10) compared to those consistently sedentary (León-Muñoz *et al.*, 2013). Conversely, individuals who were consistently non-sedentary (i.e. below the median) across this whole period, had a hazard ratio for all-cause mortality of 0.75 (95% CI = 0.62, 0.90) (León-Muñoz *et al.*, 2013).

According to a systematic review of 24 studies investigating the relationship between health outcomes and sedentary behaviour in older adults, there is moderate evidence of associations between sedentary behaviour and metabolic syndrome, waist circumference, and overweight/obesity, all of which negatively impact mortality (Rezende *et al.*, 2014). However, the evidence thus far has been based on mostly cross-sectional or longitudinal research designs. Nonetheless, these findings highlight the associations between sedentary behaviour, CVD risk, and mortality risk, and that the risk is sensitive to change with variations in sedentary behaviour over time.

1.5. The independence of the health effects of sedentary behaviour and moderate-to-vigorous physical activity

As both sedentary behaviour and PA exist as independent constructs within the spectrum of daily physical movement, the notion that one can be a sedentary exerciser emerges, as an individual can

perform 1 hour of MVPA per day and then spend the remainder of waking time in various sedentary behaviours (Hamilton *et al.*, 2008). This same individual is both active and sedentary, even meeting many PA recommendations, and such a phenotype has been coined "an active couch potato" (Hamilton *et al.*, 2008). From this conundrum, the question arises as to whether it is possible for an individual to 'protect' themselves against the consequences of their sedentariness by exercising more.

A recent, harmonised meta-analysis investigated the association of PA and sedentary behaviour with mortality and included 16 studies encompassing 1,005,791 individuals over 18 years of age who were followed up for 2-18 years (Ekelund *et al.*, 2016). Ekelund *et al*. reported that, in those individuals sitting >8 hours a day who also engaged in greater than 35.5 MET hours/week of activity, there was no increased risk of mortality (1.04 hazard ratio (HR), $p<0.0001$) (figure 6), unless those individuals were also watching >5 hours of TV per day as a portion of that sitting activity (1.15 HR; 95% CI = 1.05, 1.27). However, those individuals who were highly sedentary *and* highly inactive, with >8 hours of sitting per day and ≤2.5 MET hours per week of PA, had a mortality HR of 1.27 (95% CI = 1.22, 1.32). Additionally, those performing ≤2.5 MET hours per week of PA and watching over 5 hours of TV per day had a HR of 1.44 (95% CI = 1.34, 1.56). These data suggest that a high degree of PA can indeed be protective against the negative effects of sitting on health (figure 6), and that TV watching is a form of sedentary behaviour particularly detrimental to health. However, Ekelund *et al*. relied heavily on self-reported data about sedentary behaviour and PA, thus the results are likely to suffer from self-report bias. The authors also did not investigate the role of CRF in this relationship.

Ekelund *et al.* (2019) published a more stringent follow-up paper which also employed a harmonised meta-analysis methodology, and relied on fewer studies (six rather than 16), however the authors included only studies which used objective measurement of sedentary time. In total, 36,383 participants were included with a median follow-up of 5.8 years, and the included studies were of high quality. Interestingly, they found that simply moving from the lowest quartile (1.00 HR) of physical

activity to the second reduced hazard ratio to a HR of 0.48 (95% CI = 0.43 to 0.54), whereas being in the top quarter lowered the hazard ratio to nearly a quarter of the lowest (HR 0.28, 95% CI = 0.23 to 0.32). With respect to time spent sedentary, risk of death also increased; hazard ratios for the second quartile was 1.28 (95% CI = 1.09 to 1.51) and 2.63 (95% CI = 1.94 to 3.56) for the top quartile. This means that spending 9.5 hours per day or more sedentary leads to a significantly elevated risk of death (Ekelund *et al.*, 2019).

Despite these findings, in the field of sedentary behaviour research, there is still ongoing debate as to whether PA may be protective against the negative impact of sitting time, particularly for older adults (Copeland *et al.*, 2017). Nevertheless, the results of these studies by Ekelund et al. suggest that a sufficiently high degree of MVPA may be protective against the negative effects of sedentary behaviour.

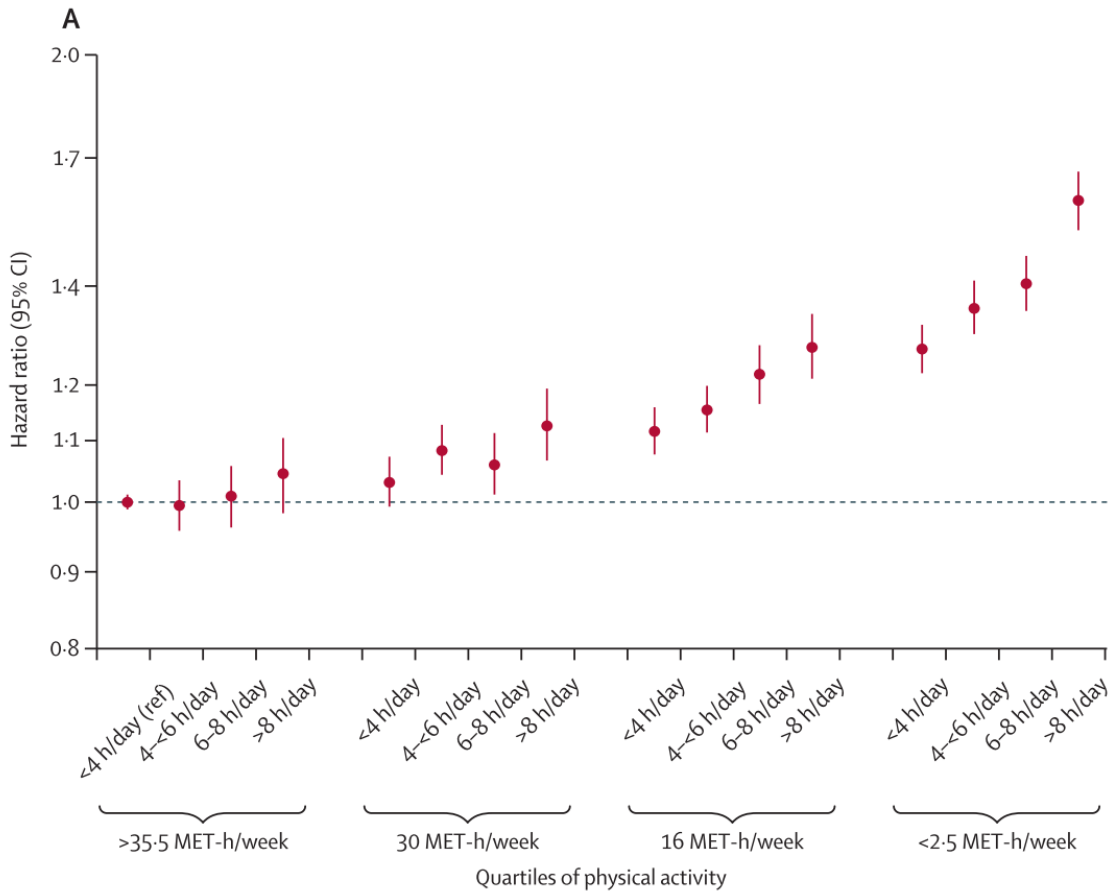

Figure 6. Risk for mortality stratified by amount of sedentary behaviour in hours per day within different quartiles of PA expressed in MET hours per week. From Ekelund et al. (2016).

Ekelund *et al*. (2016) reported that a high MET-h/week could offset the negative impact of sedentary behaviour on mortality. This may be because these individuals exercise frequently and vigorously enough to increase or maintain their CRF. This begs the question: can performance of VPA alone allow one to maintain their CRF even if they are otherwise a 'couch potato'?

There is evidence to suggest that sedentary behaviour is associated with reductions in CRF, even in individuals who otherwise exercise (Santos *et al.*, 2013). A study including n=2024 participants with a mean age of 59.7 years in the Netherlands found that each one hour period of objectively-measured sedentary time per day corresponded with 1.2% lower CRF values for men and 0.9% lower CRF values for women ($p<0.05$) (van der Velde *et al.*, 2017). It is important to note that replacing 1hr of sedentary behaviour with 1hr of LPA in their statistical models was associated with a higher CRF ($\beta=0.08$; 95% CI = 0.03-0.14; $p<0.05$) (van der Velde *et al.*, 2017).

These findings are particularly important for older adults, as older adults may not always be physically capable of (or comfortable with) performing VPA (van der Velde *et al.*, 2017). Ecologically, a displacement of sedentary behaviour usually occurs to LPA – a form of PA not traditionally considered to be 'exercise', rather than MVPA (Matthews *et al.*, 2015). However, in this study, VPA was still found be the most powerful effector of CRF, as five daily minutes of VPA was found to exert the same degree of effect on CRF as 1 daily hour of sedentary time (van der Velde *et al.*, 2017). Additionally, sedentary behaviour patterns (i.e. how sedentary behaviour was accumulated), were found to have no significant effect on CRF. Nonetheless, van der Velde *et al*. (2017) suggest that at least some of the mechanisms through which sedentary behaviour may negatively affect CRF could potentially be different to the vascular changes which positively affect CRF as a result of performing MVPA, and may not simply be the result of detraining (Thijssen, Green and Hopman, 2011; van der Velde *et al.*, 2017). However, it is important to note that CRF was assessed using a submaximal cycle ergometer test in this study, thus it must be considered only an estimate of maximal CRF. Evidently, more research is needed to

determine whether the negative effects of sedentary behaviour can be fully attenuated by PA of any particular intensity, and whether this effect is mediated by CRF, glucose or lipoprotein metabolism, the ghrelin-leptin-adiponectin axis, or more (Ryan, Stebbings and Onambele, 2015).

In older adults, VPA may not necessarily be realistically achievable for many, depending on mobility levels. One recent study investigated the relationship between sedentary behaviour, PA, and mortality using a prospective cohort design that included 7985 participants aged >45 years with a median follow-up of 4.0 years (Diaz *et al.*, 2017). The authors reported that, even in those performing MVPA, sedentary behaviour was significantly associated with increased mortality, with HRs of 2.63 (95% CI = 1.60, 4.30) for the greatest tier of sedentary time (≥12.5 hours), while HRs of 1.96 (95% CI = 1.31, 2.93) were reported for those with the greatest mean sedentary bout duration (≥10 mins/bout) (figure 7). Likewise, those individuals both in the highest quartile for sedentary behaviour bout length and the highest quartile for having the greatest total sedentary behaviour were most at risk of death (Diaz *et al*., 2017). Unlike the Ekelund *et al*. (2016) study, which included predominantly younger adults, the study by Diaz *et al*. (2017) indicates that in older adults, either MVPA may be less protective against the negative effects of sedentary behaviour, or there is such little MVPA being performed that it makes no difference. In older adults, the discussion of whether MVPA can prevent against the negative effects of sedentary behaviour may be more readily focused on what is realistically achievable by them in their day-to-day lives: namely focusing on a reduction of sedentary behaviour itself, and a subsequent displacement of time to standing mixed with LPA.

Current evidence suggests that performance of LPA in older adults can provide many benefits. LPA is associated with reduced arterial stiffness (Gando *et al.*, 2010), improved insulin concentrations, and reduced plasma lipid concentrations when compared to shorter, energy-matched periods of MPA (Duvivier *et al.*, 2013): LPA has also been found to be associated with a reduced risk of loss of one's physical independence (Marques *et al.*, 2014).

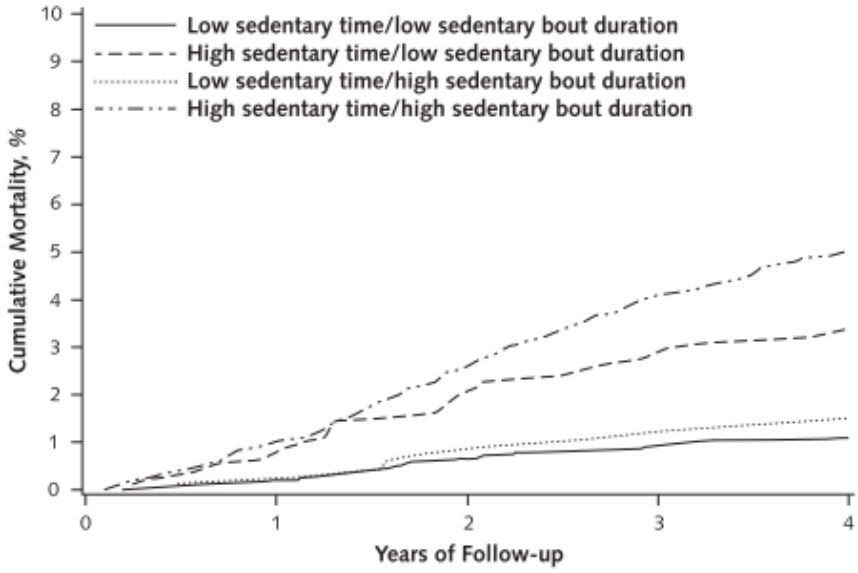

Figure 7. Cumulative mortality according to high/low sedentary time, and high/low sedentary bout duration. From Diaz et al. (2017).

Overall, these data suggest that there is some evidence for an independent effect of sedentary behaviour on health, however, this is based on mostly low-quality evidence. Although highly relevant to adults in good health, the question of whether MVPA provides benefit to the highly sedentary may not be as relevant in older adults who suffer from mobility limitations.

1.6. How does sedentary behaviour affect health?

A high degree of sedentary behaviour influences disease and mortality risk (Copeland *et al.*, 2017). Television (TV) viewing is often considered the most hazardous type of sedentary behaviour (perhaps due to associated eating behaviours and the prolonged nature of the bouts) (Kim *et al.*, 2013; Ekelund *et al.*, 2016). TV viewing is associated with an odds ratio of 2.2 for metabolic syndrome in those who watch >7hrs of TV per day compared with those watching <1hrs (Gao, Nelson and Tucker, 2007). Likewise, Stamatakis *et al*. (2012) found associations between time spent in sedentary behaviour and body mass index (BMI), waist circumference, cholesterol ratio, and type 2 diabetes (T2D) in older adults. The associations in this study remained after adjusting for performance of MVPA.

The negative health impact of sedentary behaviour has been found to extend beyond cardiometabolic diseases and into physical function. A high degree of sedentary behaviour can accelerate the decline toward dependency in older age, as frequent bouts of sedentary behaviour has been found to accelerate functional decline (Dogra and Stathokostas, 2012). In this cross-sectional analysis by Dogra & Stathokostas (2012), covering 9,478 older adults 65 years or greater, the least sedentary (self-reported as <2hrs per day) had an odds ratio of 1.43 (95% CI = 1.23, 1.67) for successful ageing (defined as a composite of physical, psychological, and social factors), compared with sedentary older adults (self-reported >4hrs per day). In contrast to increasing sedentary behaviour, performance of LPA and MVPA was found to predict better health (Dogra and Stathokostas, 2012). However, as this study used self-reported sedentary behaviour data (which suggests an underestimation of true sedentary behaviour), and due to potential for reverse causality, these findings must be considered with caution (Copeland *et al.*, 2017). Yet, further studies have supported these results; a study in n=117 males and n=195 females aged 65-103 years investigated the relationship between sedentary behaviour, PA using accelerometery, and functional fitness using the Senior Fitness Test (Santos *et al.*, 2012). This study found that time spent in sedentary behaviour was associated with reduced performance in the Senior Fitness Test in older adults, independently of performance of MVPA, and vice versa (Santos *et al.*, 2012). In terms of subsets of the functional scores, sedentary behaviour was negatively associated with upper and lower body strength, agility/dynamic balance, and lower body flexibility. Conversely, MVPA was positively associated with MVPA, aerobic endurance, and upper body flexibility (Santos *et al.*, 2012). Additionally, research suggests that activities of daily living (ADLs) are also negatively associated with sedentary behaviour. An assessment of the U.S. National Health and Nutrition Examination Survey (NHANES) 2003-2006 data by Dunlop *et al*. (2015) has found that the odds ratio for ADL disability was 46% greater for each additional daily hour spent in sedentary behaviour, even after adjustment for MVPA. This means that there is potential for sedentary behaviour to exert a real negative effect on the

daily lives of older people. A potential explanation for this could be the potential negative effect of sedentary behaviour on physical function.

The associations between sedentary behaviour and physical function are significant: for example Rosenberg *et al*. (2016) showed that in n=307 older adults living in retirement communities, objectively-measured sedentary behaviour was negatively associated with a plethora of both objective and subjective measures of physical function, including the Short Physical Performance Battery (SPPB), balance task scores, 400m walk time, chair stand time, and gait speed - even after adjustment for physical activity. Each one-hour increase in daily sedentary time was equivalent to a 21-second increase of 400m walk time, and a 0.55 decrease in SPPB score ($p<0.001$) (where the maximum is 12 points). Rosenberg *et al*. (2016) states that this relationship is indicative of a "clinically meaningful effect", as these figures fall within range of what are considered meaningful changes in physical performance sufficient to impact people's lives (Kwon *et al.*, 2009).

In terms of data from interventions, Gibbs *et al*. (2016) have conducted a small-scale RCT that allocated older adult participants to either a 12-week intervention to reduce sedentary behaviour (n=19), or an intervention to increase MVPA (n=19). They found that the sedentary behaviour reduction group increased their SPPB score by 0.5 points ($p<0.05$), mostly from increases in chair-stand and balance performance, demonstrating that it is possible to achieve a meaningful improvement in physical function as a result of an intervention. The intervention to increase MVPA had no significant improvements in physical function. However, this trial was not powered to detect these differences.

Sedentary behaviour in older adults has also been found to be associated with cognitive function. A longitudinal study by Lee *et al*. (2013) in 550 older adults aged 60 years and over investigated the relationship between sedentary time over the previous 12 months (assessed by questionnaire) and cognitive function (assessed using the Mini Mental State Examination (MMSE)). For those individuals reporting ≥14.3 hours of sedentary time per day, there was a 3.03 OR (95% CI = 1.29, 7.14) for

significant cognitive decline compared with 1.0 for those reporting <11.5 hours per day. Sedentary behaviour has also been found to be associated with brain structure. Arnardottir *et al*. (2016) found that, in a study of 352 older adults with a mean age of 79.1 years over a 5-year follow-up, brain white matter quantity was significantly negatively associated with sedentary time (β=-0.10; p=0.001). This suggests that spending a large amount of time in SBs could lead to greater brain atrophy in older age, contributing to a decline toward psychological dependency. However, the potential for reverse causality in these epidemiological studies cannot be ruled out.

1.7. Factors affecting the relationship between sedentary behaviour and health

The way sedentary behaviour is accumulated over the course of a day or week can have a substantial effect on health. Patterns of sedentary behaviour over time may vary just as much as within an individual as between individuals, with afternoon and mornings or weekdays and weekends being very different in terms of sedentary behaviour accumulation (Marshall *et al.*, 2015a). For example, in a single sedentary bout, an individual can sit for 10 minutes, 20 minutes, or 4 hours at a time. In a sample of 1566 older men between 71 and 91 years of age, individuals were found to accumulate sedentary behaviour in an average of 72 bouts per day, with an average of 7 breaks per hour of sedentary behaviour (Jefferis *et al*., 2015). The study also found that both being older and having a greater number of chronic health conditions increased the average length of each sedentary bout, showing that poorer health predicts further sedentary behaviour (and demonstrates the risk for reverse causality if unaccounted for). In older women with an average age of 71.8 years it has been found that their sedentary behaviour is accumulated in average of 85.9 bouts per day with 9.0 breaks per sedentary hour (Shiroma *et al.*, 2013). Older men have thus, on average, been found to have longer bouts and fewer breaks than older women, however, neither study reported data about PA in their samples (Shiroma *et al.*, 2013; Jefferis *et al.*, 2015). Just as the length of a bout of exercise is important for its effect on health (where longer is typically better), it has been found that the longer the

uninterrupted bout of sedentariness, the greater the conferred health risk (Honda *et al.*, 2016). This means that breaking up long bouts of sitting with more frequent breaks may confer health benefits.

The influence of fragmenting sedentary time on health has been investigated by Healy *et al*. (2008) in a cross-sectional study in n=168 Australian adults with a mean age of 53.4 (range 30-87) years, finding that an increase in breaks in 7-day objectively-measured sedentary time was beneficially associated with BMI (β −0.19, 95% CI = −0.35, −0.02), waist circumference (β −0.16; 95% CI = −0.31, −0.02), triglycerides (β −0.18; 95% CI = −0.34, −0.02), and 2-h plasma glucose (β −0.18; 95% CI = −0.34, −0.02) ($p<0.05$). Breaking up sedentary time has also been associated with improved physical function in older adults. A study by Sardinha *et al*. (2015) demonstrated that more breaks were found to be significantly positively associated with both upper and lower body strength (physical function composite z-score) assessed by the Senior Fitness Test battery, independently of MVPA performance and other potential cofounders (β 0.180; 95% CI = 0.052, 0.310). Likewise, another cross-sectional study found that in a sample of n=240 older adults ≥70 years, each additional break per hour in objectively-assessed sedentary time was associated with a 0.58 increase in SPPB score: a clinically significant amount (Kwon *et al.*, 2009; Davis *et al.*, 2014). This may be because breaking up sedentary time leads to many more muscular contractions throughout the course of the day, which may provide muscular and metabolic adaptations, conferring a benefit to health (Sardinha *et al*., 2015). Breaks in sedentary time assessed using accelerometery have been found to be significantly associated with bone density in the femoral neck in n=44 older women, such that a single additional break in daily sedentary behaviour has been found to be associated with a 10% reduced risk of osteopenia or osteoporosis (Braun *et al.*, 2017).

In a similar manner, there has been much research into sit-to-stand transitions, which are somewhat indicative of a break in sitting, but also reflect minor acute contractile activity of the lower body musculature (Júdice *et al.*, 2016). Sit-to-stand transitions are an important target in interventions, as it is possible that increases in the number of sit-to-stand transitions per day would provide benefit to

lower body muscle mass and strength, which may help to improve balance and prevent falls, and to reduce disease risk by preventing lengthy sitting bouts. In older participants, sit-to-stand transitions have been shown to elicit substantial activation of trunk and leg musculature, with force production equivalent to 40% of body mass required to complete the movement (Millington, Myklebust and Shambes, 1992). Efforts have been made to incorporate increases in sit-to-stand transitions in multiple existing interventions in older adults (Fitzsimons *et al.*, 2013; Rosenberg, Gell, *et al.*, 2015; Kerr *et al.*, 2016). Rosenberg *et al*. (2015) accomplished a non-significant increase of 2 sit-to-stand transitions per day ($p=0.13$) in a study of n=25 overweight and obese adults 60 years and older using a mostly phone-call-based intervention approach. Likewise, Kerr *et al. (*2016) reported, in a study of n=15 adults aged 50-70 years, achieving an increase of 13 transitions per day ($p<0.001$) in an intervention designed specifically to increase sit-to-stand transitions. This discrepancy in results between these studies could be explained by the differences in both the health of the participants and the intervention designs.

Certain contexts and times may also modulate the risk of sedentary behaviour to health. Firstly, being highly sedentary in the postprandial period is associated with a higher health risk, as uninterrupted sitting increases postprandial lipidaemia by 18% compared with walking ($p=0.015$) (Miyashita *et al.*, 2013). Secondly, prolonged sitting (6.9; 95% CI = 5.5, 8.7), as measured by glucose incremental area under the curve (iAUC) (mmol/L) significantly increases postprandial hyperglycaemia in comparison to periods of sitting with light (5.2; 95% CI = 4.1, 6.6; $p<0.01$)) or moderate (4.9; 95% CI = 3.8, 6.1; $p<0.01$) walking breaks (Dunstan *et al.*, 2012). Thirdly, breaking up prolonged sitting with light or moderate walking in the postprandial period can significantly alter skeletal muscle gene expression, particularly in genes relating to anti-inflammatory and triglyceride metabolism pathways, according to a study using muscle biopsies from the vastus lateralis (Latouche *et al.*, 2013). These findings are very important, as in a typical 3 meal/day plus snacking western diet pattern, up to three quarters of the day can be spent in a postprandial period (Miyashita *et al.*, 2013). Even non-diabetic levels of hyperglycaemia have been associated with an increased risk of cardiovascular disease (Levitan *et al.*,

2004), and LPA in the postprandial period has been shown to reduce postprandial blood sugar spikes effectively (figure 8) (Bailey and Locke, 2015; Henson, Davies, *et al.*, 2015). Thus, breaking up sitting, particularly around mealtimes, can have very beneficial effects on inulin action and lipid concentrations, which has the potential to translate meaningfully to CVD risk.

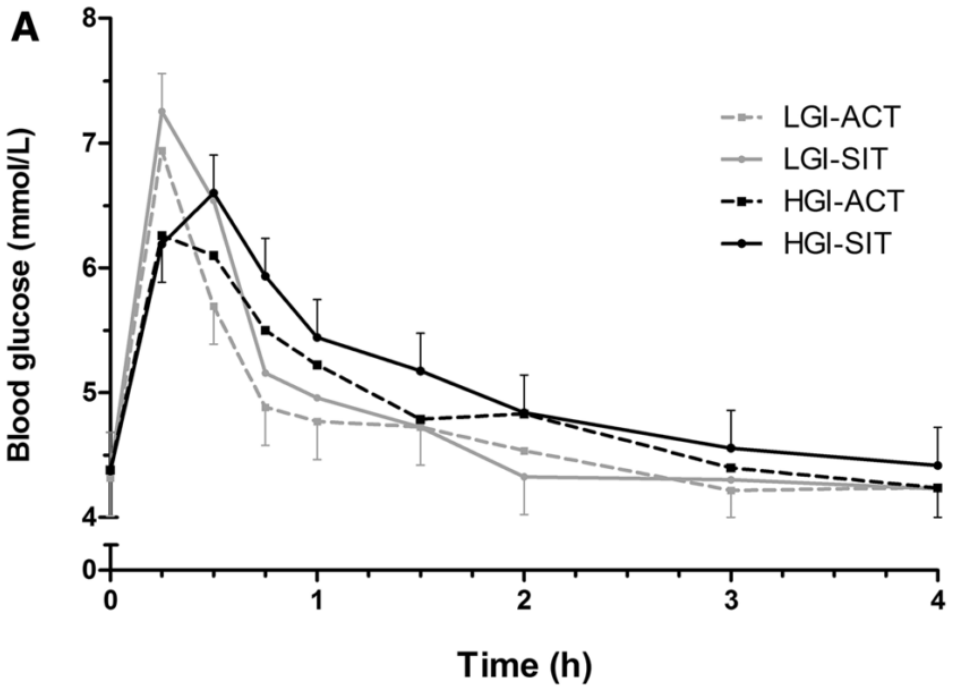

Figure 8. Association of low glycaemic index food and activity breaks (LGI-ACT), low glycaemic index food and uninterrupted sitting (LGI-SIT), high glycaemic index foods and activity breaks (HGI-ACT), and high glycaemic index and uninterrupted sitting (HGI-SIT) with blood glucose over a 4 hour period. From Bailey et al. (2017).

The behaviour performed while sitting or lying can also change the relationship between sedentary behaviour and health. It has been shown in epidemiological analyses that leisure-related sitting time is more strongly associated with mortality risk than work-related sitting time (Kim *et al.*, 2013). Specifically, TV-viewing, a type of leisure-based sitting activity, appears to have a very strong relationship with mortality risk (Kim *et al.*, 2013). This may be because sedentary TV bouts tend to be particularly prolonged when compared with other activities, but this has not yet been investigated, or it may be because TV-viewing has been found to be associated with snacking, which essentially turns TV viewing into one long eating bout, and thus, an extended postprandial period (Cleland *et al.*, 2008). Some studies have suggested that the strength of the negative health impact of TV viewing may be due to the impact of snacking on weight gain, thereby increasing mortality risk (Cleland *et al.*, 2008). Therefore, specifically decreasing TV viewing time would also be likely to reduce incidence of associated unhealthy habits, such as snacking, making it an attractive context of sedentary behaviour to target. TV viewing has also been shown to be associated with conversion rate to dementia (OR =

1.8; 95% CI = 0.9, 3.4; P = 0.053), and reduced executive function, in a 5-year prospective cohort study of 75-year old community-dwelling older adults who did not have dementia at baseline (Blasko *et al.*, 2014). Other, more mentally-active sedentary pursuits such as reading (OR = 0.77; 95% CI = 0.63, 0.95) and writing (OR = 0.73; 95% CI = 0.55, 0.96) were found to decrease conversion rate to dementia and improve executive function over the 5-year period (Blasko *et al.*, 2014). TV viewing has also been found to be significantly associated with lower MMSE scores in n=1383 older adults aged 65 and over ($p < 0.001$) (Da Ronch *et al.*, 2015). Leask *et al*. (2015) have shown that TV time can occupy 30.3% of total sedentary time in older Scottish adults, and Gardiner *et al*. (2011) has demonstrated a similar figure of 37% using a self-report method in Australia. Thus, due to its prevalence and relatively severe health impact, specific targeting of TV viewing time should be a goal for behaviour change interventions.

1.8. Sedentariness and energy balance

sedentary behaviour is a low energy-expenditure state that, when chronic and frequent, may lead to dysregulation of the body's natural hunger and satiety signalling, and disruption of other metabolic processes such as stem cell health and immune function (Thyfault *et al.*, 2015). Eating in state of substantial caloric surplus has been found to increase sedentary behaviour and reduce walking behaviour in both healthy lean and obese individuals in an 8-week study, so the positive relationship between caloric intake and sedentary behaviour is likely to be reciprocal (Levine *et al.*, 2008). BMI is associated with both increased sedentary behaviour and increased CVD risk, so taking caloric intake into account when investigating the link between sedentary behaviour and CVD is a key consideration (Chaput *et al.*, 2011).

Evidence suggests that sedentary behaviour can even influence the storage location of excess calories. A recent study has shown that there is a significant positive association between each additional objectively-measured 30-minute period of sedentary behaviour, and 15.7cm^3 greater pericardial ($p=0.008$), 1.2% greater liver ($p=0.026$), and 183.7cm^3 higher visceral fat deposition ($p=0.039$)

measured using MRI in n=66 participants at risk of T2D with an average age of 47.9 years, even after adjustments for glycaemia, whole-body adiposity, and MVPA (Figure 9) (Henson, Edwardson, *et al.*, 2015). Likewise, a similar study has assessed this phenomenon in 539 healthy older adults (mostly women, but with a very ethnically diverse sample) with a mean age of 65 years, where fat deposition was measured cross-sectionally using computed tomography (B. A. Larsen *et al.*, 2014). This study used self-report measurement of sedentary behaviour and PA, however other CVD risk factors were factored into the statistical model such as diabetes, hypertension, triglycerides, and cholesterol, finding that each hour of additional weekly PA was associated with 1.85cm^2 less visceral fat ($p<0.01$), but not other fat depositions. Moreover, each hour of daily sitting was significantly associated only with pericardial fat ($p<0.05$), because, once adjustments were made for CVD risk factors and BMI, sitting time was no longer associated with visceral fat.

The relationship between pericardial fat, and objectively-measured sedentary behaviour and PA was studied in a sample of 446 men and women with a mean age of 66 years (Hamer *et al.*, 2012). Consistent with the findings of B. A. Larsen *et al*. (2014), any significant association between sedentary behaviour and pericardial fat was diminished when MVPA was added to the statistical model. The difference in results between these studies could be due to multiple factors, including the differences in measurement of sedentary behaviour and PA, healthy vs. diabetic and diversity of samples, or different covariates used in statistical models. It is clear that the relationship between fat deposition and sedentary behaviour needs further investigation, and that doing so should take into account both CRF and total PA (rather than only MVPA), as CRF is the factor most strongly (inversely) associated with visceral fat deposition in overweight individuals (Després, 2012). However, if sedentary behaviour can increase fat storage in the heart and in the viscera, then this represents a mechanism through which sedentary behaviour can directly increase CVD risk (Després, 2012).

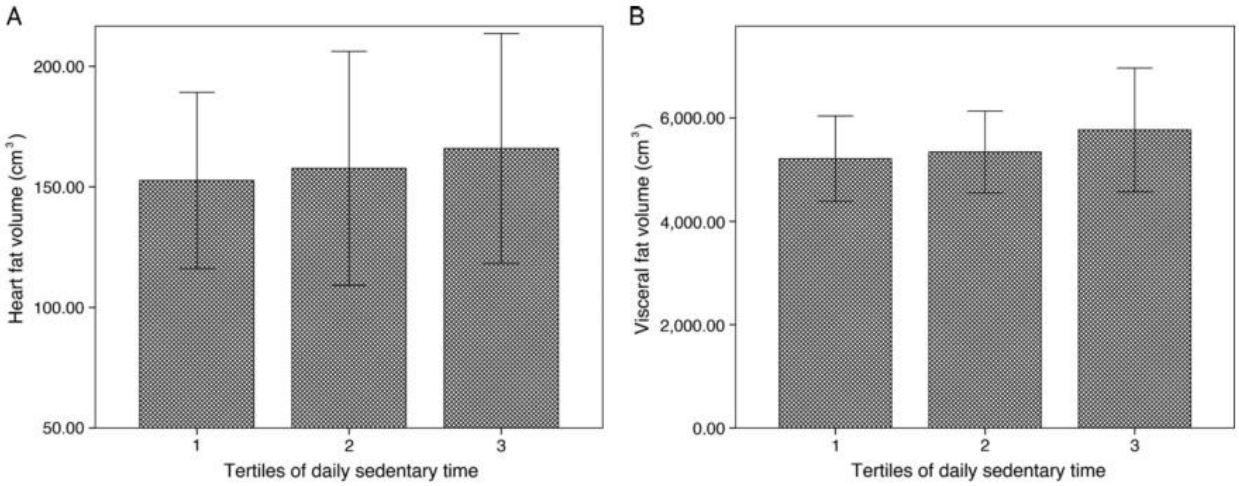

Figure 9. Heart fat (A) and visceral fat (B) volume stratified by tertile of daily sedentary time. From Henson, Edwardson et al. (2015).

Most of the observed effects of sedentary behaviour on the body discussed throughout this chapter are not likely to affect all populations equally. As discussed earlier, older adults are particularly affected by the consequences of most unhealthy behaviours, including sedentary behaviour (Whalen, Carter and Steele, 1988). Due to the effects of ageing on the robustness and function of the musculoskeletal system, older adults react in a particularly sensitive manner to any detriments in PA. The same may apply to sitting, independently of performance of PA. One study has investigated the associations between sedentary behaviour, body composition, muscle function, and sarcopenia (age-related loss of muscle mass and function) in a cross-sectional study of 162 community-dwelling older adults aged 60-86 years (Gianoudis, Bailey and Daly, 2014). This study measured body regional lean and fat mass using dual-energy X-ray absorptiometry (DXA), sitting time using a validated self-report questionnaire and 7-day recall, PA using a PA questionnaire, lower limb strength using a bilateral leg press and timed stair climb, 30s sit-to-stand, four square step test, and timed-up-and-go for functional muscle power. Sarcopenia was operationally defined as being in the lowest quartile for relative appendicular skeletal muscle mass and leg muscle strength and gait speed (Gianoudis, Bailey and Daly, 2014). Food intake was also considered using 24-hr food diaries. Each 1-h increment in daily sitting time was associated

with a 33% increased risk of sarcopenia (OR 1.33; 95% CI = 1.05, 1.68). However, no significant association was reported between sitting time and any other outcome measure, except for TV viewing time, which, after adjustment for fat mass, was negatively associated with lower leg lean mass.

Lean mass and adipose tissue are not the only aspects of body composition that have been investigated for associations with sedentary behaviour. Bone mineral density (BMD) has been shown to be negatively associated with sedentary behaviour in women in a cohort of older adults (S F M Chastin *et al.*, 2014). It is plausible that bone may remodel to be less dense in the absence of signals that indicate that they are being loaded for extended periods of time, just as density increases when exposed to chronic PA. However, whether sedentary behaviour can induce bone remodelling independent of PA is unclear. Interestingly, the first study to investigate this hypothesis using NHANES data comprising n=2117 individuals found that the relationship between BMD and sedentary behaviour may be sex-dependent. In their sample of 2117 individuals aged 23-90 years, a significant negative relationship was found between each additional 10-minute increment of sedentary behaviour per day and BMD of the femur (β=-0.159g/cm^2; 95% CI = -0.241, 0.076) and all other hip sub-regions in women (S F M Chastin *et al.*, 2014). No significant associations were found between sedentary behaviour and BMD in men, but there was a positive association between BMD and each 10-minute increment of MVPA (β=0.306g/cm^2; 95% CI = 0.021, 0.0591). This suggests that women may be more sensitive to the skeletal unloading effect of sedentary behaviour (S F M Chastin *et al.*, 2014). Although this evidence is not causal, these data nonetheless suggest that older people may benefit from sitting less to optimise their health and function.

1.9. Physiological mechanisms underlying the adverse health effects of sitting

Clearly, there is accumulating evidence linking sedentary behaviour to health and physical and psychological function. However, the physiological evidence for mechanisms underpinning the health

effects of sedentarism is currently sparse and hypothetical in nature, and very little is based on experimental data.

Some of the initial experimental research in this area has been in rat models, investigating how triglyceride metabolism is altered in response to hind limb immobilisation (figure 10) (Bey and Hamilton, 2003; Hamilton, Hamilton and Zderic, 2004). This research has focused on the enzyme lipoprotein lipase (LPL), which has already been extensively studied in the PA literature and is inversely associated with risk for coronary heart disease (CHD), a form of CVD. The role of LPL is to bind to and hydrolyse circulating lipoproteins in the blood stream, releasing the lipid contained within. Loss of function of this enzyme results in hyperlipidaemia, leading to increased CHD risk (Hamilton, Hamilton and Zderic, 2004).

Limb immobilisation is reported to downregulate LPL activity, and this downregulation occurs through transcriptional mechanisms, whereas LPL upregulation caused by movement occurs through translational mechanisms (Hamilton, Hamilton and Zderic, 2004). This evidence is consistent with the independence of mechanistic effects of sedentary behaviour versus PA on LPL activity, affecting CVD risk in different ways. However, total LPL activity may be associated more with total contractile activity across the entire daily spectrum of activity than to individual periods of sedentariness, since periods of sedentary behaviour, like those of PA, can both upregulate and downregulate genes (Hamilton, Hamilton and Zderic, 2004). In reality, the metabolomic effects of sedentary behaviour have not yet been sufficiently investigated beyond the investigation of LPL regulation. It must be considered that the current evidence is from one study and relies upon laboratory methodology; not only is 'hind limb immobilisation' not an ecologically-valid model of sedentary behaviour in a human context, but the use of rats potentially further reduces its applicability to human physiology.

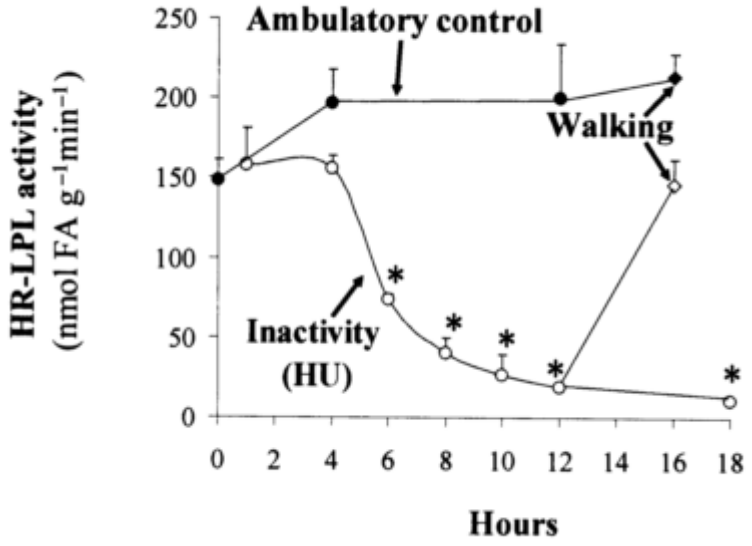

Figure 10. Heparin-releasable LPL activity after hours of either inactivity, walking, or in ambulatory controls (data from rats). From Bey & Hamilton, 2003.

Care must be taken when investigating the effects of sedentary behaviour to differentiate between the impact of acute sedentariness versus chronic sedentarism in individuals who have been inactive for years. For example, measuring the effects of subjecting active people to prolonged sedentary behaviour may be measuring detraining in addition to sedentary behaviour itself, rather than the isolated effect of sedentarism. For example, muscle may atrophy because of an absence of PA, rather than a prevalence of sedentary behaviour, yet LPL can be downregulated due to sedentary behaviour regardless of hypotrophy or atrophy (Hamilton, Hamilton and Zderic, 2004). Thus, separating the effects of cessation of PA from the negative effects of sedentary behaviour on the body is a particular challenge for sedentary behaviour research. Separation of these aspects would give great insight into the ageing process as it is currently very difficult, particularly in epidemiological studies, to separate observed effects of ageing (e.g. declines in CRF) from the effects of chronic sedentary behaviour.

One other relevant recent mechanistic research area is the effect of sitting on macrovascular and microvascular function. Vascular function is directly related to CVD. One study assessed popliteal artery reactive hyperaemia and flow-mediated dilation before and after a 3-hour sitting period in 12

young women and 8 men (Vranish *et al.*, 2017). Men predominantly suffered reduced macrovascular function as assessed using flow-mediated dilation (5.5 to 1.6 in men ($p<0.001$), 4.4 to 3.6 ($p=0.29$) in women), whereas both sexes showed similar popliteal artery reactive hyperaemia (microvascular) reductions. This acute effect of sitting lowered vascular reactivity, which may have serious repercussions as endothelial dysfunction is a progenitor to atherogenesis and deep-vein thrombosis (figure 11) (Widlansky *et al.*, 2003). To counter this, a recent study of 12 young adults reported that lower limb fidgeting for 20% of sitting time was sufficient to prevent microvascular dysfunctions through simple non-activity energy thermogenesis (NEAT), i.e., small daily movements not considered activity in their own right (Widlansky *et al.*, 2003; Morishima *et al.*, 2016). In n=12,778 'excessive sitters' sampled from the UK Women's Cohort Study (>7 hrs/day), which included a 12 year follow-up for mortality, fidgeting has been found to be associated with a reduced risk of all-cause mortality in comparison to those that do not fidget (HR=0.63; 95% CI = 0.43, 0.91) (Hagger-Johnson *et al.*, 2016). Evidently, this hypothesis is in need of more investigation, as if it can reverse vascular changes, then fidgeting may be able to affect other metabolic processes and signalling pathways as well.

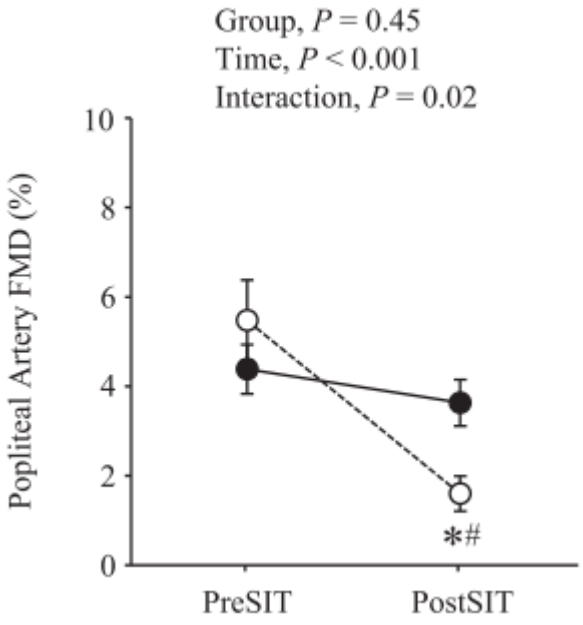

Figure 11. Popliteal Artery FMD after Women are shown by closed circles (n = 12) and men with open circles (n = 8) after a 3-hour sitting bout. From Vranish et al. 2017.

1.10. Experimental evidence on the effect of sedentary behaviour on health

Despite the overall lack of experimental research into the physiological mechanisms underlying the negative health effects of sedentary behaviour, there are some studies that provide some insight into which metabolic processes may be involved. One area of significant research is glycaemic control and its consequent impact on the likelihood of T2D (Thyfault *et al.*, 2015). Previous studies have experimentally fragmented sitting time with walking and/or MPA, and have measured resultant glucose and insulin responses (e.g., Dunstan *et al*., 2012). A similar study conducted by Bailey *et al*., (2017) subjected 14 adult males through four conditions: either high glycaemic index (GI) or low GI breakfast combined with either 4 hours of uninterrupted sitting, or 4 hours sitting with 2 minutes of activity every 20 minutes. It was found that postprandial glucose responses were independently reduced by both interrupting prolonged sitting (2.07 iAUC vs. 2.56 iAUC in uninterrupted sitting; p=0.004) and by reducing dietary GI (2.13 iAUC in low GI vs. 2.51 iAUC in high GI; p=0.022). This demonstrates that sitting for long periods after eating both low GI and high GI foods can prolong exposure to heightened blood glucose levels, increasing risk for CVD and T2D. However, this study relied on a very small sample size, which may affect the validity of the results.

A previous review of 17 experimental studies which reduced sitting in the postprandial period, accounting for the activity level of the participants in included studies, allowed for interesting conclusions to be drawn regarding differential effects of sitting relative to PA status and age (Benatti and Ried-Larsen, 2015). This review included healthy individuals as well as those with conditions such as T2DM. Younger, more active participants in the included experimental studies were more responsive to more vigorous forms of PA to break up sitting, but also had more delayed positive metabolic responses as compared to inactive subjects with T2DM. In T2DM participants, results indicated a different response to exercise stimuli, as both LPA and MPA were effective at reducing postprandial glucose and insulin responses. However, this may have occurred in a dose-response style

relationship, rather than in the young/fit who required higher intensities of PA. In other studies, standing was found to slightly but significantly reduce blood glucose in office workers, and this effect persisted overnight (Benatti and Ried-Larsen, 2015).

Two studies were also identified that reduced sitting in office workers over long periods of time. One 9-month study reduced sitting in n=12 overweight adults using treadmill workstations and found improvements in LDL (by 16 mg/dl), total cholesterol (by 15 mg/dl), waist circumference (5.5cm reduction), and glycosylated haemoglobin (all $p<0.05$) with no corresponding changes to food intake (John *et al.*, 2011). Another 3-month study with a control group in n=32 adults reported only significant benefits to HDL pre-to-post (0.26 mmol/L; 95% CI = 0.10, 0.42), and a reduction in sitting time (97 mins/day; 95% CI =-144, -50) (Alkhajah *et al.*, 2012).

Evidence from a subsample of participants from Dunstan *et al*. (2012)'s study by Latouche *et al*. (2013) suggests that breaking up sitting can modify gene expression in such a way that increases carbohydrate oxidation. Additionally, there was evidence of increased glucose transport into the muscle (Latouche *et al.*, 2013). In contrast to previous research on LPL, the breaks in sitting were found to reverse the effects of chronic inactivity in expression of certain genes (Latouche *et al.*, 2013). However, it may be the case that some alterations in gene expression that occur due to sedentarism are the reverse of those that occur due to PA, while others may be independent. Similarly, of course, lipid and glucose metabolism are likely to differ in terms of how they are genetically regulated in relation to PA and sedentary behaviour performance.

1.11. The need for bespoke lifestyle interventions for older adults

To effectively reduce sedentary behaviour in older adults, robust interventions that produce lasting behaviour change must be developed. To assist in this aim, a review of existing interventions in this population is presented in chapter 2.

According to a systematic review by Manini *et al*. (2015), interventions to reduce sedentary behaviour are most effective when they consider the life course in their design (Figure 12). Another systematic review, comprising n=24 eligible studies, of the most effective behaviour change techniques for increasing PA in older adults, found that the techniques which were most effective in older adults were not the same as those that were effective for younger and middle-aged adults (French *et al.*, 2014). This means that the unique lifestyles of older adults must be considered. Older adults, ≥60 years of age are often retired, they may live in different housing depending on their age and functional status, and they more often have specific morbidities that must be considered. They may also have differing abilities when it comes to usage of technology. All of this may impact the activities that they choose to engage in when compared with a younger population. Older adults also have differing attitudes towards and barriers to engagement in physical activity, which should also be considered when developing interventions (Crombie *et al*., 2004; Elena *et al*., 2011).

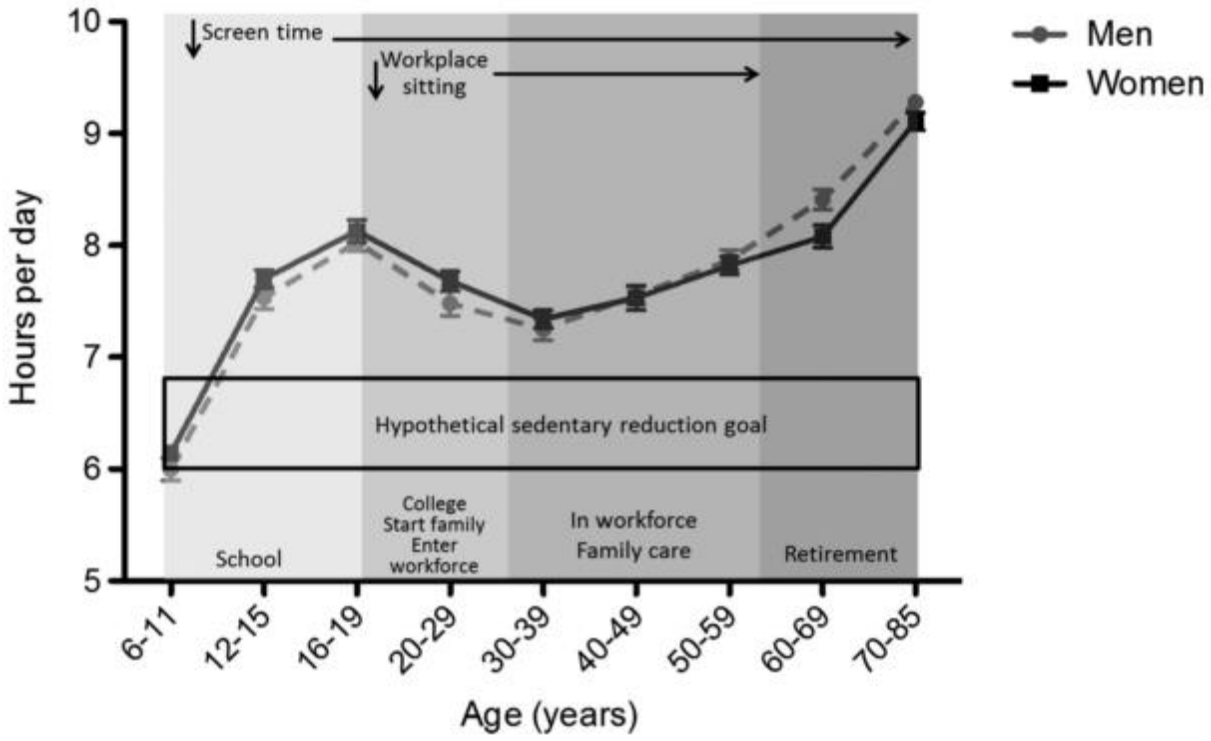

Figure 12. Data from the National Health and Nutrition Examination Survey depicting sedentary behaviour across the lifespan according to age. It also depicts major life transitions, as stage of life is an important lifestyle consideration when designing interventions. From Manini et al. (2015).

There is some evidence relating to the lifestyles of older adults and the manner in which sedentary behaviour behaviour is accumulated. With 33 Scottish community-dwelling older adults, Leask *et al*. (2015) have used an innovative (but relatively intrusive) combination of an ActivPal3 inclinometer and time-lapse camera, which, by taking pictures 5x per minute, could detect the contexts in which sitting occurred. The results showed that 63.9% of sedentary time was accumulated by non-screen time which mostly comprised of miscellaneous behaviours that could not be properly identified, followed by screen-based sedentary behaviour at 36.1%, 84.04% of which was TV-viewing. Other than miscellaneous behaviours, reading was the most common non-screen-based activity. Most sedentary behaviour (70.1%) was accumulated at home, which is in contrast to adults of working age, who accumulate a great deal of sedentary behaviour within the workplace (Owen *et al.*, 2011).

Regarding motivations for being sedentary, most sedentary activities were performed for leisure purposes, and the majority of leisure sedentary behaviour occurred when participants were alone, suggesting loneliness may increase the likelihood of sedentary behaviour (Leask *et al.*, 2015). This, again, is in contrast to working adults, who are likely to be sitting with others in meetings or office-spaces in their work environments (Owen *et al.*, 2011). There are several key differences between retired older adults and working older adults, and these lifestyle factors must be considered when designing interventions. This extends from considerations of the built environment, such as office settings, which can have effects on behaviour, to behavioural expectations evident in the workplace which restrict what can be achieved in comparison to free-living scenarios.

1.12. Sedentary behaviour and arthritis: interactions with chronic musculoskeletal illness

Older adults are more likely to suffer from one or more morbidities than younger populations (Yazdanyar and Newman, 2009; Lozano *et al.*, 2012). This may affect the level of sedentary behaviour in which an older adult will engage. One such population are orthopaedic patients living with

osteoarthritis. The lifetime risk of developing hip or knee osteoarthritis is 25% and 45% respectively (Murphy *et al.*, 2008, 2010). In severe cases, joint replacement surgery (arthroplasty) is an effective way to reduce the pain and allow individuals to continue living their lives. In the UK alone every year, over 160,000 hip or knee replacement surgeries are carried out (National Joint Registry, 2016). Given the rising prevalence of osteoarthritis, the number of joint replacement procedures is expected to increase by 50% (figure 13) by the year 2026 (Culliford *et al.*, 2012). Perhaps due to the impact of this disease on the lower body musculature, individuals who suffer from hip or knee osteoarthritis tend to be even more inactive than disease free age-matched counterparts. Osteoarthritis presents specific sequelae that require even more bespoke intervention design when trying to reduce sedentary behaviour.

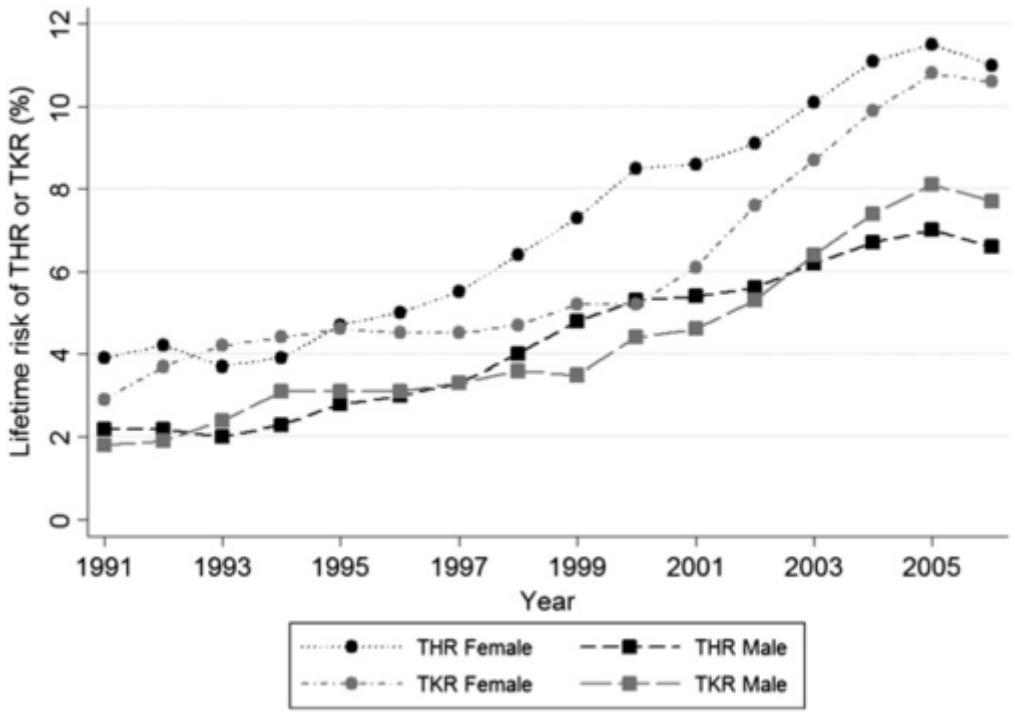

Figure 13. Lifetime risk of total hip replacement (THR) or total knee replacement (TKR) stratified by sex in the UK. From Culliford et al. (2012).

Non-arthritic older men spend 72% of waking time in SBs and non-arthritic older women spend 65.5% of the day sedentary (Shiroma *et al.*, 2013). In contrast, one study in orthopaedic patients undergoing

total hip or knee arthroplasty showed that 82% of the day was spent sedentary prior to surgery and 83% of the day being sedentary thereafter (Harding *et al.*, 2014). Similarly, an analysis of the NHANES 2003-2006 data has determined an average of 9.9 hours per day spent sedentary in those who have a mobility disability compared with 9.2 hours for those who do not (Manns *et al.*, 2015). Data from the Osteoarthritis Initiative, a longitudinal study conducted in the USA collecting data from individuals with osteoarthritis, has also investigated the effect of sedentary behaviour on physical function in their cohort objectively with accelerometery (Lee *et al.*, 2015; Semanik *et al.*, 2015). In a subset of 1,168 individuals from their cohort aged 49-83 with osteoarthritis of the knee, in which physical function was assessed with 20-meter walk and chair stand test, it was identified that the most sedentary quartile had gait speed of 3.88 feet/second and chair rises of 25.9 stands/minute, whereas the least sedentary quartile had a gait speed of 4.33 feet/second and 31.1 stands/minute (Lee *et al.*, 2015). These findings were adjusted for MVPA. Similarly, another study in 1,659 adults aged 49-83 in the same cohort identified that sedentary time was significantly associated with loss of physical function independently of performance of MVPA over the duration of follow-up, equivalent to -1.66 feet/min decrease in gait speed per 10% of waking hours spent sedentary, and -0.75 repetitions per minute in chair stand test (Semanik *et al.*, 2015).

Of particular concern is that the data suggest that after surgery, individuals typically do not change in their level of sitting time or physical activity (figure 14) (Harding *et al.*, 2014; Kahn and Schwarzkopf, 2015; Arnold, Walters and Ferrar, 2016; Webber, Strachan and Pachu, 2017). A recent systematic review comprising of n=8 studies with a total of 373 patients who had either total knee (n=238) or hip (n=135) replacements, reported that even one year post-surgery, physical activity was still largely unchanged and still much lower compared to healthy controls (total hip replacement standardised mean differences, –0.25 to –0.77; total knee replacement standardised mean differences, –1.46 to –1.80). (Arnold, Walters and Ferrar, 2016). This puts individuals at unnecessary health risk and is contrary to advice from healthcare authorities that urge maintenance of physical activity before and

after surgery (Arnold, Walters and Ferrar, 2016). It is possible that, once having become used to being highly sedentary due to pain or for another reason, it becomes habitual and is very difficult to change even if function improves. Supporting this, a recent study by Stubbs *et al*., (2014) has found that, in older adults with musculoskeletal pain, avoidance of activities due to a fear of falling contributes highly to increased sedentariness. Similarly, Rosenberg *et al*. (2016) also found that higher sedentary behaviour is associated with greater fear of falling. Thus, interventions are required to intervene preferably both prior to and after surgery in orthopaedic patients. One component in such interventions may be to address patient concerns about falling.

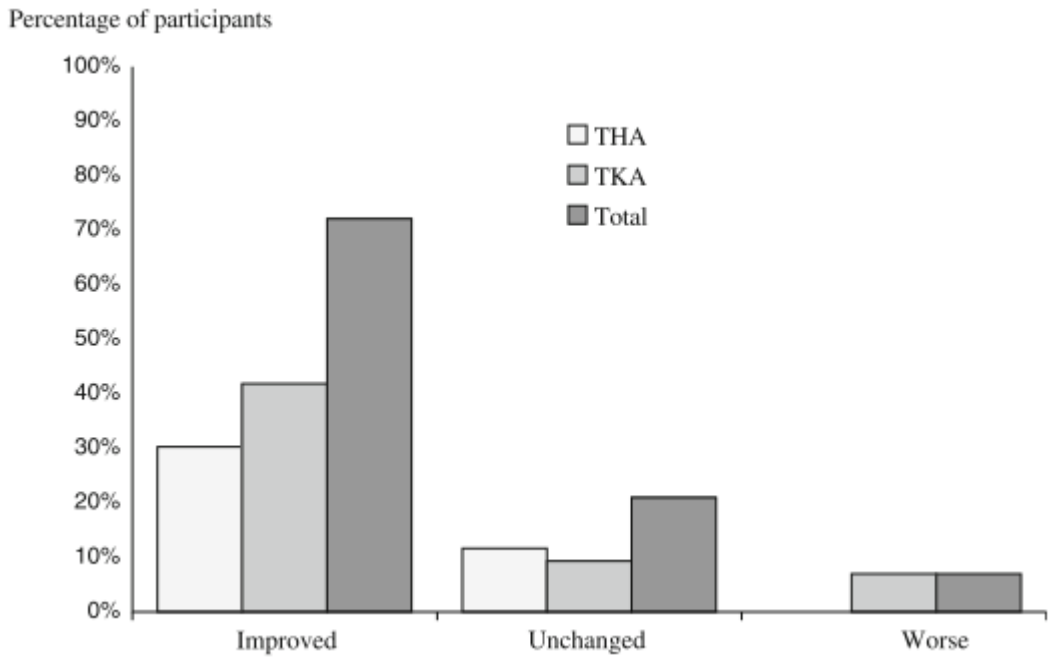

Figure 14. Percentage of participants reporting changes in their PA levels post-surgery after total hip arthroplasty (THA) and total knee arthroplasty (TKA). From Harding et al. (2014).

1.13. The basics of behaviour change programming

To date, sedentary behaviour intervention research in older adults has underused behaviour change theories despite trying to change a particularly complex mode of behaviour (Gardner *et al.*, 2015). Sedentary behaviour is difficult, as the posture in which we perform specific activities are performed is often secondary to the purpose and implications of the action we perform (Gardner *et al.*, 2019). To

most effectively reduce sedentariness, a sophisticated methodology is required so that the intervention is informed by a clear understanding of why alterations in the targeted behavioural output(s) should occur as a consequence of the intervention components (Michie and Johnston, 2012).

Typically, behaviour change interventions can target either a very specific action, such as taking a pill, or, in the case of "sedentary behaviour", a wider variety of activities. Thus, it is important to determine exactly which behaviour is the desired outcome due to a need to measure precisely what is needed to change. In the case of sedentary behaviour, this can be a range of indicators discussed in this chapter, such as total time spent sedentary, number of breaks in sedentary bouts, sit to stand transitions, and also the antithesis of these behaviours, i.e. physical activity, to acquire a full perspective on daily 24hr movement patterns.

To develop an effective intervention, a number of approaches can be taken. These can include partnerships (such as co-creation with stakeholders), evidence-based (e.g. combining theories and evidence in rigorous process to maximise external and internal validity), stepped or phased (development through systematic review and evidence based testing of modifiable contextual factors, mechanisms of change and pilot studies) (O'Cathain *et al.*, 2019). The most rigorous techniques such as intervention mapping involve consultation with stakeholders, experts, and multiple cyclical stages of development to ensure rigour and validity (Eldredge *et al.*, 2016). However, all approaches involve identifying what needs to be changed (conception), selecting which individuals need to be involved in development (planning), identifying a theory (or processes/a logic model) which can aid in explaining how a behaviour arises and selecting behaviour change techniques and how to deliver them (designing), making mock-ups/prototypes of the intervention (creating), testing/optimising for efficiency (refining), documenting the intervention effectively, and planning for future evaluation (O'Cathain *et al.*, 2019).

Criteria exist for assessing how well interventions implement behaviour change theory. One such aspect is the Theory Coding Scheme by Michie and Prestwich (2010). Developed in a series of 13 iterative stages using 29 papers describing interventions to improve physical activity and eating, 19 criteria were identified to evaluate the theoretical base of interventions. These criteria form six major categories, namely: is the theory mentioned, are the relevant theoretical constructs targeted, is theory used to select participants or tailor interventions, are relevant theoretical constructs measured, is theory tested, and is it refined based on the findings (Michie and Prestwich, 2010)? Together, these assess the quality of implementation of theory.

A solid implementation of theory is important because meta-analyses have identified that having a theoretical framework is a significant predictor of positive behavioural change (Dombrowski *et al.*, 2012; Ma and Martin Ginis, 2018). However, use of theory still is not a wide-spread practice in all fields. For example, in the sedentary behaviour intervention field, a recent review of interventions to reduce sedentary behaviour in adults identified that only 11 out of 26 studies (42%) mentioned a theoretical framework of any kind. So, many interventions in this field as of yet do not use described systematic and rigorous approaches to their development (Gardner *et al.*, 2015). Additionally, the studies included in the above review focused on capability and opportunity and ignored the role of motivation in determining behaviour (Gardner *et al.*, 2015; Michie, Atkins and West, 2015). It is clear that more rigorously-designed theoretically-informed interventions are required.

However, choosing the right theory is not a trivial task; there are at least 82 in use in the behavioural and social sciences alone (Davis *et al.*, 2015). In the sedentary behaviour field, common theoretical frameworks include the Transtheoretical Model (Prochaska and DiClemente, 1983), Social Cognitive Theory (Bandura, 1986), and Self-Determination Theory (Deci and Ryan, 1985). Part of the reason for this continued profusion is that there is not yet enough evidence as to which theories most effectively predict behaviour.

There is more evidence supporting the "active ingredients" of interventions. Interventions tend to target the behaviour using one or more "behaviour change techniques" (BCTs), which are essentially the proposed mechanisms of change. Use of these BCTs should be embedded within a theoretical framework, or theories which inform the researchers how the intervention should work. Theoretical frameworks and BCTs should be integrated together to form theories of change which allow for a clear causal chain and prediction of outcomes to result in a predicted change in behaviour. With respect to BCTs, the rigorously-developed and widely-used taxonomy developed by Michie et al. contains 93 techniques which are arranged into categories, such as goals and planning, feedback and monitoring, regulation, self-belief, and social support (Michie *et al.*, 2013). The BCTs included in an intervention should be theoretically coherent, e.g. "behavioural rehearsal/practice" would only be coherent if it is related to a barrier that can be removed by this BCT, such as a lack of skill to perform the behaviour (Michie *et al.*, 2013; Cadogan *et al.*, 2016).

Therefore, selection of BCTs for an intervention requires a concrete understanding of the barriers and enablers of the behaviour in question according to the theoretical framework. Due to the complexity of sedentary behaviour, the range of contexts in which it occurs, and the activities it encompasses, this results in a wide range of barriers, enablers, and, consequently, BCTs that can be selected. According to recent research, sitting is largely "invisible" to people doing it, with actions performed whilst sitting being more memorable (Gardner *et al.*, 2019). As such, intervention designers can seek to raise awareness of sitting into the conscious realm, or target sitting whilst also not disrupting the activities that need to be performed - which may require different considerations in individuals who work vs. are retired, for example (Gardner *et al.*, 2019). Although there are a large number of potential BCTs, there are ongoing investigations into which BCTs are most effective in particular circumstances, such as reviews of the efficacy of the self-monitoring BCT in sedentary behaviour interventions

(Compernolle *et al.*, 2019), or reviews of which BCTs are more promising in these studies (Gardner *et al.*, 2015).

1.14. Summary and gaps in the literature

To conclude, there is epidemiological evidence linking sedentary behaviour to CVD, reduced physical function, metabolic syndromes, and overall mortality. However, this evidence is currently tenuous as it relies mostly on associational data and the likelihood for reverse causality is high. There is some mechanistic data linking sedentariness with certain health outcomes, however, these data come from murine models. Additionally, interventional data, although promising, is sparse. As such it is hard to make any recommendations to policy-makers, etc., based on these findings. Likewise, it was shown that interventions are required that integrate robust behavioural science to achieve changes to these lifestyle habits.

This chapter has identified several of these knowledge gaps. There has been no comprehensive review of existing interventions in older adults to reduce their sedentary behaviour. Such a review should be conducted to determine what approaches to the problem have thus far been taken, how successful they have been, and what could be done to improve their effectiveness in the future. Additionally, no interventions in mobility limited patient groups such as orthopaedic patients have been conducted to reduce their sedentary time, despite the possible benefits. The impact of a sedentary behaviour reduction intervention on cardiometabolic health and function in older adults has only been rudimentarily assessed, despite the large amount of cross-sectional data available, while the mechanisms underlying the associations between sedentary behaviour and health are still unclear.

1.15. Aims, objectives, and research questions

Several research questions emerge from the areas explored in this chapter, namely: (1) What is the existing evidence regarding interventions to reduce sedentary behaviour in older adults? (2) How can

this inform us to design ideal behavioural interventions to reduce sedentary behaviour in this demographic? And (3) How should a definitive trial to reduce sedentary behaviour in older adults be designed? Answering these questions could inform policymakers and health service providers on optimal behaviour change strategies to employ to tackle this pressing healthcare issue.

Aims of this PhD:

1. To design and conduct a systematic literature review of existing interventions to reduce sedentary behaviour in non-working older adults (Chapter 2).
2. Use the results of the systematic review and other available evidence to aid the design of an intervention and feasibility study to reduce sedentary behaviour in older adults undergoing orthopaedic surgery (Chapter 3).
3. Use the results of the feasibility study (Chapter 4) to (a) refine the intervention, and (b) inform the design of a full-scale definitive clinical trial to assess the effectiveness of the intervention on lower limb physical function recovery post-surgery (measured using the SPPB) (Chapter 5).

CHAPTER 2: INTERVENTIONS TARGETING SEDENTARY BEHAVIOR IN NON-WORKING OLDER ADULTS: A SYSTEMATIC REVIEW

Published as "Aunger, J.A., Doody, P. and Greig, C.A., 2018. Interventions targeting sedentary behavior in non-working older adults: a systematic review. *Maturitas*, *116*, pp.89-99."

2.1. Abstract

Sedentary behaviour has been found to be associated with negative health outcomes independently of physical activity in older adults. Thus, this systematic review aimed to evaluate evidence from interventions to reduce sedentary behaviour in non-working older adults, assessing whether they are effective, feasible, and safe. A systematic search identified 2560 studies across five databases. Studies were included where participants were ≥60 years on average with none younger than 45, and participants did not work >2 days per week. A total of six studies were identified, three of which included control groups; the other three were repeated measures pre-post designs. Only one study randomised participants. The overall level of quality of included studies was poor. A narrative synthesis was conducted, as heterogeneity in outcomes and outcome reporting was too high for a meta-analysis to be performed. The narrative synthesis suggested that interventions have the potential to reduce sitting time in non-working older adults. Included studies reported feasible implementations of their interventions in most samples, except for one subsample from a study of sheltered housing residents. All were found to be safe. Objectively-measured reductions in sitting time were between 3.2 and 5.3% of waking time (up to 53.9 minutes per day). Future studies should use fully powered, theory-based randomised trial designs with objective outcome measures to assess the effects of reducing sedentary behaviour on health and physical function, and should include follow-ups to measure the duration of behaviour change achieved.

Keywords: sitting, elderly, behaviour change, aging, sedentary, older adults

2.2. Introduction

2.2.1. Rationale

Sedentary behaviour is defined by the Sedentary Behavior Research Network [1] as any activity performed in a sitting or reclining posture with an energy expenditure equivalent to ≤1.5 Metabolic Equivalent of Tasks (METs). Interventions to reduce sedentary behaviour are important, as sedentary behaviour has been found to be a risk factor for multiple metabolic diseases, independent of the degree of moderate-to-vigorous physical activity a person performs (MVPA) (Hamilton, Hamilton and Zderic, 2007; Katzmarzyk *et al.*, 2009). Specific populations are at greater risk than others for the negative consequences of sedentary behaviour, particularly because these populations have low cardiorespiratory fitness and activity levels, both of which have been found to be independently related to risk for cardiovascular disease (Bouchard, Blair and Katzmarzyk, 2015). A demographic fitting these criteria is older adults aged >60 years.

Older adults are growing significantly both as a segment of the UK and global population (Office of National Statistics, 2015). Globally, the number of people over 60 is expected to increase by 56% by 2030, and, is expected to double by 2050 (United Nations, Department of Economic and Social Affairs, Population Division, 2015). This means that in the UK, in 2050, older adults are expected to constitute approximately 25% of the total population (Cracknell, 2010). In older people, objectively-measured sedentary behaviour manifests its negative health effects in terms of reduced physical function, greater risk for cardiovascular disease and type 2 diabetes, and increased mortality, independent of performance of MVPA (Stamatakis *et al.*, 2012; Rezende *et al.*, 2014; Rosenberg, Bellettiere, *et al.*, 2015). Additionally, sedentary behaviour is related to disease risk in a multitude of ways. For example, the manner in which sitting time is accumulated, such as in longer or shorter bouts, is differentially associated with cardiovascular disease risk in adults >45 years (R. N. Larsen *et al.*, 2014). In this sample, interrupting bouts of sitting time every 20 minutes had a significant enough effect on systolic blood

pressure to lower all-cause mortality risk by 3-4% (R. N. Larsen *et al.*, 2014). The morbidities of this population combined with the ongoing relative growth makes this segment of the population highly burdensome to healthcare facilities of their respective countries (Office of National Statistics, 2015; Prince *et al.*, 2015). For example, in the UK, healthcare for older adults over-65s account for 2/5ths of the total National Health Service's budget (HM Treasury, 2015). Thus, designing, testing, and implementing interventions in older adults that target sedentary behaviour specifically is important, and has been found to have beneficial impacts on physical function, and is associated with improvements to cardiometabolic health (Stamatakis *et al.*, 2012; Rosenberg, Gell, *et al.*, 2015). Although there are many published studies focusing on reducing sedentary behaviour, not many have specifically targeted older adults, and no systematic reviews of sedentary behaviour interventions exclusively in older adults have yet been published (Martin *et al.*, 2015). Therefore, the aim of this review is to assess the feasibility, safety and efficacy of interventions targeting sedentary behaviour in older adults.

2.2.2. Objectives

The objectives of the review are as follows:

1. To assess the efficacy of interventions to reduce sedentary behaviour in older adults.
2. To investigate how sitting time is displaced to other behaviours in older adults.
3. To identify design methodologies and theoretical frameworks used in interventions to reduce sedentary behaviour in older adults.
4. To assess the feasibility and safety of interventions to reduce sedentary behaviour in older adults.
5. To analyse the current state of the research and propose future directions.

2.3. Methods

2.3.1. Prospero registration

The review was registered on PROSPERO (https://www.crd.york.ac.uk/PROSPERO/) on 20/01/2017 with registration number CRD42017054932.

2.3.2. Search

Systematic searches were run on the following databases: EMBASE including Epub, Ovid MEDLINE®, CINAHL Plus SportDiscus, and PsychInfo. The searches were run on the 13th of January 2017 and included papers from 1946 onwards.

A systematic search strategy was primarily developed for the OVID platform with EMBASE in mind, was checked by a senior librarian at the University of Birmingham, and then adapted for the other databases. The search strategy for Ovid is supplied in the appendix as Item C. Additional articles were sought by reference-list and primary author searching of identified articles. After running the searches, articles were retrieved and imported into a citation manager and duplicates were removed. Two reviewers, JA and PD, screened all titles and abstracts for relevance and resulting articles were compared. Any disagreement was resolved through discussion. Full-text articles were then independently screened against inclusion criteria and any ineligible articles were removed.

2.3.2.1. Inclusion criteria

1. All participants aged 45 years or older with a mean age of 60 years or older.
2. In voluntary or paid employment ≤ 2 days per week (e.g. a typical retirement lifestyle).
3. Interventions specifically designed to reduce sedentary behaviour.
4. Randomised controlled trials (RCTs), quasi-experimental studies, controlled before-and-after studies, interrupted time series designs, and feasibility or pilot studies (pre-post) designs.

5. Studies must measure sitting time (mins/day, mins/week, mins/weekday, mins/weekend-day, percentage change), standing time (mins/day), stepping time (mins/day), number of breaks in sitting time and sitting time in bouts >30 minutes measured using either self-report or objective tools.

2.3.2.2. Exclusion criteria

1. Articles not written in English.

2.3.3. Data extraction

Data extraction was performed on a custom-designed, piloted form tested by one reviewer. Data extracted included: (1) study, participant, and intervention characteristics (such as theoretical framework, intervention components, and which device was used to measure sedentary behaviour); (2) outcome measures including sitting time, number of breaks in sedentary time, lengths of sedentary bouts, time spent in sitting bouts ≥30 or <30 minutes, and data relating to physical activity, such as walking, stepping, standing time, and time spent in light, moderate, and vigorous physical activity; data for outcome measures were extracted for any type of measurement tool used (e.g. ActivPal or IPAQ), and the measurement tool used was recorded. Feasibility and safety data were also extracted where possible.

2.3.4. Risk of bias in individual studies

Preliminary searching identified a very heterogeneous pool of potentially eligible studies; therefore, two assessment tools of methodological quality were selected. For RCTs and non-randomised CTs, the Delphi Quality Assessment (Verhagen *et al.*, 1998) tool was employed, but was modified by removing items 5 and 6 due to the inability to blind the participant and researcher in these studies. For simple pre-post style feasibility or pilot studies, the National Heart, Lung and Blood Institute's Quality Assessment of Before-After Studies With No Control Group (QABAS) tool was used, with the caveat that even high quality studies of this type are likely to be highly biased (NHLBI, 2014). Quality

assessment was performed by two independent reviewers, JA and PD, and discrepancies were resolved with discussion. A third reviewer (CAG) was available to resolve issues of contention, but all issues were resolved through discussion.

2.3.5. Method of synthesis

A quantitative synthesis was not possible due to the insufficient number of eligible studies, and heterogeneity of outcome measure reporting and assessment tools. A narrative synthesis was performed according to guidance from Popay *et al*. (2006) and the Centre for Reviews and Dissemination (2009). All aspects of narrative synthesis were performed: developing a theory of why the interventions work, a preliminary synthesis of included studies, an exploration of relationships within and between studies, and an assessment of the robustness of the synthesis. No additional analyses were performed.

2.4. Results

2.4.1. Study selection

Only six studies were eligible for inclusion in the data analysis including n=222 total completing participants (Paul A. Gardiner *et al.*, 2011; Chang, Fritschi and Kim, 2013; Matei *et al.*, 2015; English *et al.*, 2016; Lewis *et al.*, 2016; Maher, Sliwinski and Conroy, 2016). Most studies were screened out in the title and abstract stage as they did not focus on older adults or were not intervention studies (figure 15). Of 12 items identified by the title and abstract screening, a further six items were removed at the full-text stage, five due to including adults in employment >2 days/week, and one as the study was an exercise, not sedentary behaviour, intervention. No additional studies were identified via additional web-searching outside of the main systematic search, or through examination of authors' publications and reference lists.

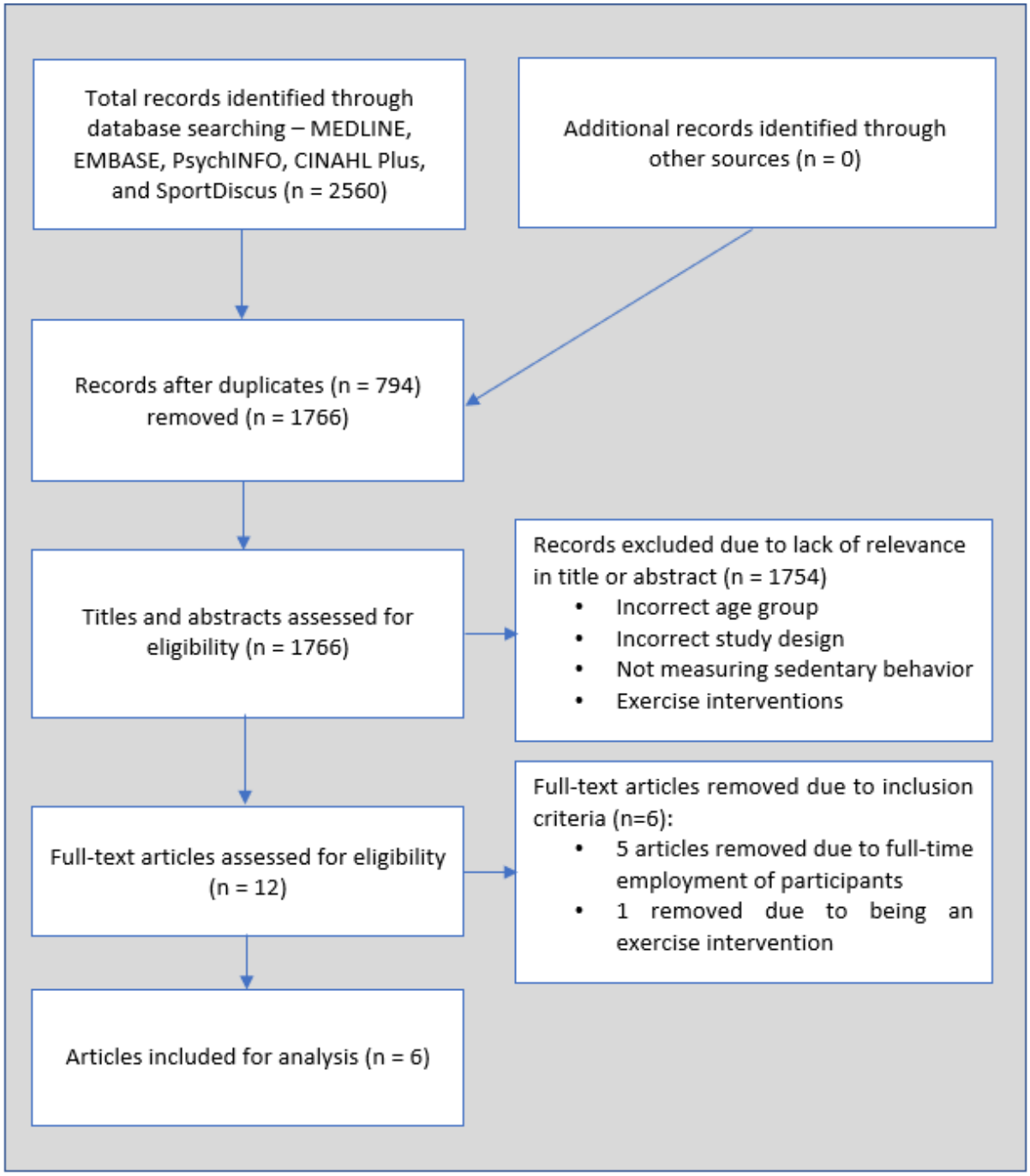

Figure 15. PRISMA flow diagram of the study selection process.

2.4.2. Preliminary synthesis of findings of included studies

The synthesis adopted in this review involved a tabulation of study characteristics (table 2) and the following textual description.

2.4.3. Study characteristics

2.4.3.1. Study design. One study was quasi-experimental in design, meaning a control group was included, but randomisation was not performed (Chang, Fritschi and Kim, 2013). Only one 'true' RCT was identified (English *et al.*, 2016), with the four remaining studies all feasibility or pilot studies (Paul A. Gardiner *et al.*, 2011; Matei *et al.*, 2015; Lewis *et al.*, 2016; Maher, Sliwinski and Conroy, 2016), of which only one utilised a comparison group (Maher, Sliwinski and Conroy, 2016).

2.4.3.2. Risk of bias within studies. Overall quality of the identified studies was poor. Three studies were assessed with the modified Delphi tool as they included control groups (Chang, Fritschi and Kim, 2013; English *et al.*, 2016; Maher, Sliwinski and Conroy, 2016), and the other three were before-after designs and were thus assessed with the QABAS tool (Paul A. Gardiner *et al.*, 2011; Matei *et al.*, 2015; Lewis *et al.*, 2016). Of the modified Delphi-assessed studies (table 1), one scored a 6/7 (English *et al.*, 2016), and the other two scored 3/7 (Chang, Fritschi and Kim, 2013; Maher, Sliwinski and Conroy, 2016). Regarding the QABAS-assessed studies, the scores were all determined as fair for pre-post designs. Independent quality assessment agreement was 100% for Delphi-assessed studies, and agreement was 97.2% for the QABAS-assessed items.

Table 1. Delphi quality assessment of included study with control groups.

Criteria ID	Question	Chang *et al*. (2013)	English *et al*. (2016)	Maher *et al*. (2016)
1a	Was a method of randomisation performed?	No	Yes	Yes
1b	Was the treatment allocation concealed?	No	Yes	No
2	Were the groups similar at baseline?	Yes	Don't Know	No
3	Were the eligibility criteria specified?	Yes	Yes	Yes
4	Was the outcome assessor blinded?	No	Yes	No
5*	Was the care provider/interventionist blinded?			
6*	Was the patient/participant blinded?			
7	Were the point estimates and measures of variability presented for the primary outcome measures?	Yes	Yes	Yes
8	Did the analysis include an intention-to-treat analysis?	Don't Know	Yes	Don't Know
Total score		3	6	3
Other comments				90% female sample

2.4.3.3. Samples. Sample sizes were small, ranging from 30 (Lewis *et al.*, 2016) to 59 (Paul A. Gardiner *et al.*, 2011). Recruitment sources of older adults varied; one study recruited from a Public Health Centre in Korea (Chang, Fritschi and Kim, 2013), another from outpatient clinics and previous trials due to the focus on hypertensive patients (English *et al.*, 2016), one from senior centres (Maher, Sliwinski and Conroy, 2016), two were convenience samples of community-dwelling older adults (Paul A. Gardiner *et al.*, 2011; Lewis *et al.*, 2016), and one compared two samples from among both sheltered housing and community-dwelling older adults (Matei *et al.*, 2015). Five studies included participants that were at least 60 years and older (Paul A. Gardiner *et al.*, 2011; Chang, Fritschi and Kim, 2013; Matei *et al.*, 2015; Lewis *et al.*, 2016; Maher, Sliwinski and Conroy, 2016). Only one study included participants younger than 60 years, however it should be noted that for this study, the mean age was 66.9 years with a SD=12.7 years (Matei *et al.*, 2015).

2.4.3.4. Duration. Duration of interventions varied from 2 to a maximum of 8 weeks, with a mean of 5.5 weeks.

2.4.4. Exploring relationships within and between studies

Methods adopted for this section of the narrative synthesis included the vote counting of study features (table 3), tabulation of differences in study outcomes for sedentary behaviour variables, standing, and stepping, (table 4) and the following textual analysis outlining the variations in methodologies and effects within and between included studies.

2.4.4.1. Intervention components. All included interventions focused on decreasing sedentary behaviour. Common intervention components included goal-setting, which all interventions incorporated to some degree, and individualised feedback (Paul A. Gardiner *et al.*, 2011; Lewis *et al.*, 2016). Motivational sessions were also employed, designed to inspire behaviour change (Chang, Fritschi and Kim, 2013; English *et al.*, 2016) and phone calls to achieve the same aim (English *et al.*, 2016; Lewis *et al.*, 2016).

2.4.4.2. Theoretical frameworks. Theoretical frameworks employed included empowerment theory (Chang, Fritschi and Kim, 2013), social cognitive and behavioural choice theories (Paul A. Gardiner *et al.*, 2011), self-determination theory (Lewis *et al.*, 2016), the health action process approach and a habit dual-process framework (Maher, Sliwinski and Conroy, 2016), and a habit-formation model (Matei *et al.*, 2015). Only one study did not mention a theoretical underpinning (English *et al.*, 2016).

2.4.4.3. Sedentary behaviour reduction targets. Of the included studies, one mentioned a 30 min/day reduction in sitting time as their minimum target that they would consider clinically significant, but did not support this with references (English *et al.*, 2016) and another cited 60 minutes/day (Lewis *et al.*, 2016). A further study cited a 5.6% reduction in sitting as a target, but gave no rationale for this (Paul A. Gardiner *et al.*, 2011), and another targeted keeping sedentary behaviour to an 8 hour/day maximum with standing or moving for at least 10 minutes per hour (Maher, Sliwinski and Conroy,

2016). The remaining two studies did not set specific targets (Chang, Fritschi and Kim, 2013; Matei *et al.*, 2015).

2.4.4.4. Sedentary behaviour measurement. Three of the included studies used self-report methods alone for assessing sedentary behaviour, with the International Physical Activity Questionnaire (IPAQ) being most common (Chang, Fritschi and Kim, 2013; Matei *et al.*, 2015). However, the IPAQ has not been well validated for sedentary behaviour measurement as it was originally designed to assess physical activity (Chastin, Culhane and Dall, 2014). Other studies used the Measure of Older Adults' Sedentary Time (MOST) (Paul A Gardiner *et al.*, 2011; Matei *et al.*, 2015; Maher, Sliwinski and Conroy, 2016), and the Multimedia Activity Recall for Children and Adults (MARCA) (English *et al.*, 2016; Lewis *et al.*, 2016). Three studies used accelerometers to measure sedentary time, such as the ActiGraph GT1M (Paul A. Gardiner *et al.*, 2011), or an inclinometer such as the ActivPal3 (English *et al.*, 2016; Lewis *et al.*, 2016).

2.4.4.5. Sedentary behaviour outcomes. There was large heterogeneity in outcome measures and how they were reported in the studies (table 4). All studies reported total sitting time, but some did so in minutes/week (Chang, Fritschi and Kim, 2013; Matei *et al.*, 2015; Maher, Sliwinski and Conroy, 2016), mean minutes/day (English *et al.*, 2016; Lewis *et al.*, 2016), and as a percentage of waking time reduction (Paul A. Gardiner *et al.*, 2011; Lewis *et al.*, 2016). Only one study standardised measures for accelerometer wear time (Matei *et al.*, 2015) and for another it was unclear whether they did so or not (Chang, Fritschi and Kim, 2013). However, those studies which used the ActivPal3 inclinometer (Matei *et al.*, 2015; Maher, Sliwinski and Conroy, 2016) have accounted for sleeping behaviour in their analyses, and one used the Actigraph GT1M, accounting for waking time (Paul A. Gardiner *et al.*, 2011). Most included studies were powered to detect significant differences in sitting time (Paul A. Gardiner *et al.*, 2011; Chang, Fritschi and Kim, 2013; English *et al.*, 2016; Lewis *et al.*, 2016), thus, five studies detected a significant positive reduction in sitting time (Paul A. Gardiner *et al.*, 2011; Chang, Fritschi

and Kim, 2013; Matei *et al.*, 2015; Lewis *et al.*, 2016; Maher, Sliwinski and Conroy, 2016). However, Lewis *et al.* (2016) report that their large number of secondary outcomes may have inflated the significance of their results. Additionally, in the study by Matei *et al.* (2015), a significant difference was found only in the sample of community-dwelling older adults and not in the sheltered housing residents. In the studies using accelerometery to assess sitting time where a significant difference occurred, reductions were 3.20% (p<.001) of waking time (Paul A. Gardiner *et al.*, 2011) and 5.3% (p=.004) (Maher, Sliwinski and Conroy, 2016). English *et al.* (2016) also reported a 30 minute (SD=50.6) average reduction in daily sitting time, but these results were not statistically significant. Both English *et al.* (2016) and Lewis *et al.* (2016) reported a larger displacement of sedentary behaviour to standing time rather than walking time post-intervention.

Other sedentary behaviour variables were also included in more than one study. Both English *et al.* (2016) and Lewis *et al.* (2016) included the variable 'sitting time accumulated in bouts of ≥30 minutes per day'. For English *et al.* (2016), there was a non-significant reduction of 36.1 (SD=65.0) mins, and for Lewis *et al*. (2016) a significant reduction of 53.9 mins (p=0.003) for this variable.

Three studies used objective measures (Paul A. Gardiner *et al.*, 2011; English *et al.*, 2016; Lewis *et al.*, 2016), but in studies utilising self-report measures, both Chang, Fritschi and Kim. (2013) and Matei *et al.* (2015) used the IPAQ to measure sitting time. Chang *et al.* (2013) reported a 534.33 (SD=494.79) minute reduction in weekly sitting time (p=0.004), and Matei *et al.* (2015) reported a post-intervention reduction of 1,055.86 minutes per week (p<0.001) in their sample of community-dwelling older adults, but a non-significant increase in sitting time of 340.5 minutes per week (p=0.76) in sheltered housing participants. Maher *et al*. (2016) reported a significant reduction of weekday sedentary time of 132.6 minutes (SD=28.5, p<0.001) using the MOST, which is more suited to measuring change in sedentary time than the IPAQ (Heesch *et al.*, 2010). Matei *et al.* (2015) also used the MOST tool, and reported a

reduction from 3534.13 (SD=1895.25) minutes/week to 2530.43 (SD=1416.67) minutes/week in their sample of community-dwelling older adults.

Effect sizes for sitting time were reported only by Chang, Fritschi and Kim (2013), English *et al.* (2016), and Lewis *et al.*, (2016), and these were 0.83, 0.62, and 0.53 respectively, which are all considered a moderate-to-large effect.

2.4.4.6. Feasibility and safety outcomes. Five out of six included studies assessed either feasibility or safety, except for the study by Chang *et al*. (2013). Common methods of assessing feasibility included adherence to intervention components (Matei *et al.*, 2015; English *et al.*, 2016; Maher, Sliwinski and Conroy, 2016), attendance (Maher, Sliwinski and Conroy, 2016), completion of measurements (English *et al.*, 2016; Maher, Sliwinski and Conroy, 2016), retention (Paul A. Gardiner *et al.*, 2011; Lewis *et al.*, 2016), reach (defined as amount of participants recruited as a proportion of those screened and eligible) (Paul A. Gardiner *et al.*, 2011), satisfaction (Paul A. Gardiner *et al.*, 2011; Chang, Fritschi and Kim, 2013; Lewis *et al.*, 2016), burden (Matei *et al.*, 2015; English *et al.*, 2016; Lewis *et al.*, 2016), completion of questionnaires relating to acceptability (Matei *et al.*, 2015; Maher, Sliwinski and Conroy, 2016), and semi-structured interviews (Matei *et al.*, 2015). Most of these measures were qualitative in nature and thus were difficult to synthesise.

Safety was assessed by English *et al*. (2016), and Maher *et al*. (2016). In both, safety was measured by reporting of adverse events and, by English *et al.* (2016) with assessment of self-reported pain, spasticity, and fatigue with the Checklist Individual Strength Questionnaire (Vercoulen *et al.*, 1994).

All included interventions reported a high degree of feasibility based on their qualitative assessments. Only Matei *et al.* (2015) reported low feasibility in their sample of older adults from sheltered housing, due to the unique circumstances of their lifestyles. However, these individuals still reported benefits to wellbeing due to the intervention. For other aspects of feasibility, the quantitative measure of satisfaction was reported between 8.2 (Lewis *et al.*, 2016) to 9 (Paul A. Gardiner *et al.*, 2011) out of 10.

Compliance (or adherence) was also assessed by Lewis *et al.* (2016), who achieved 90% adherence to goals. Likewise, Matei *et al.* (2015) achieved 40% adherence to goals as assessed using tick-sheets in their sample from sheltered housing. In the sample of community-dwelling older adults, adherence was 58%, in line with the greater efficacy achieved in this group (Chang, Fritschi and Kim, 2013). However, in comparison with Lewis *et al*. (2016), the goals were pre-specified (not individualised), and some lacked social desirability, which could explain the poorer outcome. Maher *et al.* (2016) achieved 98% adherence to session attendance, and data completion was 98%. English *et al.* (2016) reported 100% compliance to counselling sessions. These data suggest that overall compliance with the interventions was high.

Few safety concerns were reported. Maher *et al.* (2016) reported that the most severe effect of the intervention was mild soreness from increasing standing and walking, and English *et al.* (2016) reported that four non-injurious falls occurred, but that they were unrelated to the intervention. Participant ratings of pain improved in the intervention group, but this study was not powered to detect significant differences in safety measures (English *et al.*, 2016). Gardiner *et al*. (Paul A. Gardiner *et al.*, 2011) reported no adverse events, and Matei *et al.* (2015) reported one death, and three illnesses, unrelated to study participation.

Table 2. Characteristics of included studies

Study	Design	Completing *N* per group (experimental, control)	Intervention	Study Duration (weeks)	Comparator	Participant characteristics	Mean age of participants	Outcome Measures (efficacy)	Outcome Measures (feasibility)	Study was powered	Study used objective measurement and specific device
Chang *et al*. (2013)	Quasi-experimental	27, 21	One 110-minute empowerment session per week & normal care	8	Standard hypertension education & normal care	Older adults >60 years with hypertension	66.3	Sitting (total min.week^{-1}), Total physical activity (MET min.week^{-1}), Perceived health, Depression, Self-efficacy for physical activity	N/A	Yes	No
English *et al*. (2016)	Randomised Controlled Trial	19, 14	Four counselling sessions	7	Calcium supplement & attention-matching	Stroke survivors	66.9	Total sitting time (min.day^{-1}), Sitting time accumulated in bouts ≥30min (min.day^{-1}), Standing time (min.day^{-1}), Stepping time (min.day^{-1}), MVPA, ≥1952 cpm (min.day^{-1})	Pain, spasticity, fatigue, no. of falls, no. valid wear days activPAL3, waking wear hours activPAL3 (hr.day^{-1}), no. of valid wear days Actigraph, waking wear hours Actigraph (hr.day^{-1})	Yes	Yes (Actigraph GT3+ and ActivPal3)
Gardiner, Eaken *et al*. (2011)	Feasibility or pilot study	59	One session of individual and normative feedback, goal setting, and formulation of an action plan	2	None	Older adults >60 years	74.3	Sedentary time, breaks, and physically active time	Reach, retention, and participant satisfaction	Yes	Yes (ActiGraph GT1M)
Lewis *et al*. (2016)	Feasibility or pilot study	27	"Small Steps" - individual goal-setting, normative	6	None	Older adults >60 years	71.7	Total sitting time (min.day^{-1}), Sitting <30 (min.day^{-1}),	Satisfaction, burden, feasibility	Yes	Yes (ActivPal3)

			feedback, phone calls					Sitting ≥30 (min.day^{-1}), % of waking time sitting, No. of bouts sitting ≥30 min (n), Standing (min.day^{-1}), Stepping (min.day^{-1}), TST1.5a (sitting time accrued with activities at less than 1.5 METs) (min.day^{-1}), TV (min.day^{-1}), Computer (min.day^{-1}), Reading (min.day^{-1}), Passive transport (min.day^{-1}), Light physical activity (min.day^{-1}), moderate-to-vigorous physical activity (min.day^{-1}), Total Daily Energy Expenditure (TDEE) (MET minutes)	(uptake and retention)		

Maher *et al*. (2016)	Feasibility or pilot study	25, 17	Focus group, video segment about risks, enhancement of outcome expectancies, action plan formulation	2	Social isolation intervention	Older adults >60 years in senior centres	76.9	Sedentary behaviour (separated into weekday and weekend for each sub-item) made up of following domains: total sedentary behaviour, TV time, computer time, reading time, socialising time, transportation time, hobbies time, paperwork time, eating time, and 'other'	Feasibility (participation, adherence, and measurement completion), participation (no. of centres with meaningful recruitment), acceptability, and safety.	No	No
Matei *et al*. (2015)	Feasibility or pilot study	12 (sheltered housing), 23 (community dwelling)	Booklet with tips & goals	8	None	Sample 1 from sheltered housing, sample 2 from community-dwelling older adults. Over 55 years of age.	66.42 (sample 1); 66.91 (sample 2)	Sitting time (IPAQ; min.week^{-1}), sitting time (MOST; min.week^{-1}), sitting habit (1-7 scale), walking (min.week^{-1}), moderate PA (min.week^{-1}), vigorous PA (min.week^{-1}), PA habit (1-7 scale)	Adherence to tips (tick-sheets). Qualitative semi-structured covering experiences using leaflets, barriers to adherence, habit-formation, whether further support was required, and suggestions for improvement.	No	No

Table 3. Intervention components, measurements, and presence of comparison groups.

Studies	Intervention components					Measurement			Study had a comparator group
	Goal setting	Individualised Feedback on Sedentary Time	Motivational Sessions	Phone Calls	Sedentary behaviour education	Study used objective measurement of sedentary behaviour	Study assessed feasibility	Study assessed safety	
Chang *et al*. (2013)	✓		✓		✓				✓
English *et al*. (2016)	✓		✓	✓		✓	✓	✓	✓
Gardiner, Eaken *et al*. (2011)	✓	✓				✓	✓		
Lewis *et al*. (2016)	✓	✓		✓	✓	✓	✓	✓	
Maher *et al*. (2016)	✓				✓		✓	✓	✓
Matei *et al*. (2015)	✓				✓		✓		

Table 4. Tabulation of outcomes in included studies.

Outcome			Study	Value (SD)	Significance
	Reporting Method	Measurement Tool			
Change in sitting time	Minutes/week	International Physical Activity Questionnaire	Chang *et al*. (2013)	-534.33 (494.79)	0.004
			Matei *et al*. (2015) Sample 1	+340.5 (NR)	0.76
			Matei *et al*. (2015) Sample 2	-1055.86 (NR)	<0.001
		Measure of Older Adults' Sedentary Time	Matei *et al*. (2015) Sample 1	+565.59 (NR)	0.33
			Matei *et al*. (2015) Sample 2	-1003.7 (NR)	0.047
	Minutes/day	ActivPal3 Inclinometer	Lewis *et al*. (2016)	-51.5 (NR)	0.006
			English *et al*. (2016)	-30.2 (50.6)*	0.018
	Minutes/weekday	Measure of Older Adults' Sedentary Time	Maher *et al*. (2016)	-132.6 (NR)	<0.001
	Minutes/weekend-day	Measure of Older Adults' Sedentary Time	Maher *et al*. (2016)	-87.4 (NR)	0.65
	Percentage change	ActiGraph GT1M Accelerometer	Gardiner, Eaken *et al*. (2011)	-3.2%	<0.001
Change in sitting time (mins/day) – effect size (Cohen's *d)*			Chang *et al*. (2013)	-0.83	N/A.
			English *et al*. (2016)	-0.62	N/A.
			Lewis *et al*. (2016)	-0.58	N/A.
Change in sitting time (mins/weekday) – effect size (Cohen's *d*)			Maher *et al*. (2016)	-0.83	N/A.
Change in sitting time (total mins) – effect size (Cohen's *d*)			Maher *et al*. (2016)	-1.02	N/A
Change in sitting time in bouts ≥30 minutes (mins/day)			English *et al*. (2016)	-36.1 (65.0)*	0.026
			Lewis *et al*. (2016)	-53.9 (NR)	0.003
Change in number of breaks in sedentary time			Gardiner, Eaken *et al*. (2011)	+4.0 (NR)	0.003
Change in standing time (mins/day)		ActivPal3 Inclinometer	English *et al*. (2016)	+22.4 (35.5)*	0.013
			Lewis *et al*. (2016)	+38.5 (NR)	0.006
Change in stepping time (mins/day)		ActivPal3 Inclinometer	English *et al*. (2016)	+7.8 (19.2)*	0.096
			Lewis *et al*. (2016)	+9.3 (NR)	0.148

Outcomes for experimental groups only
**Data standardised to accelerometer wear time*
NR = not reported
Note: P-values here must be interpreted with caution due to small sample sizes and feasibility nature of the studies

2.5. Discussion

The aim of this review was to assess the feasibility, safety and efficacy of interventions targeting sedentary behaviour in older adults living a typical retirement lifestyle. As evidenced by this review, most of the included studies were of low methodological quality with respect to assessing efficacy. Thus, the overall evidence pool is limited. Additionally, the discrepancy in reporting style, methodology, and subpopulations of included studies mean it is difficult to be conclusive about efficacy, feasibility, and safety. Nevertheless, since significant reductions in sitting time were attained by a few studies using objective measurements with good effect sizes, there is some indication that sedentary behaviour interventions may be effective in older adults. It seems theoretically and ecologically possible to achieve reductions in sitting time of approximately one hour per day in older adults, as a 51.5 minute reduction was reached by one of the included studies (Lewis *et al.*, 2016). This is similar to a previous review in adults of all ages, which found a mean of 42 mins/day reduction in studies that focused on reducing sedentary behaviour (Martin *et al.*, 2015). Although feasibility was largely qualitatively-assessed, evidence suggests these interventions are feasible, at least in samples of community-dwelling individuals. The same is found in relation to safety, as reducing sedentary behaviour should not expose individuals to more substantial risk than any other day-to-day activity.

2.5.1. A theory of interventions to reduce sedentary behaviour in older adults

All the included studies had primary aims of reducing sedentary behaviour. The most common technique used was goal-setting to reduce contextual sedentary behaviour. Accomplishing this involves the displacement of time spent sitting to other slightly more active behaviours such as light physical activity or standing. Sitting time, light physical activity, and standing were measured in the included studies, and therefore are placed in figure 16 as intermediate outcomes.

However, the ultimate purpose of interventions to reduce sedentary behaviour relates to the detrimental association of sedentary behaviour with disease risk and physical function. All included

studies mentioned the distinct effects of sedentary behaviour on an aspect of health, most typically cardiovascular health, and that the effects of sedentary behaviour are more severe in older adults. All included studies reiterated this as the purpose of their intervention, either in the discussions or conclusions of their studies. Additionally, Maher *et al.* (2016) mentioned that benefits could be attained for physical function because of a decrease in sedentary behaviour. Therefore, these aspects can be included in a theory of change as ultimate outcomes as depicted in figure 16. However, longer-term ultimate outcomes which result from improved health and function, namely a healthier ageing process and a reduction in the burden of older adults on healthcare services, were not mentioned in the included studies. These ultimate outcomes rely on the assumption that the achieved reductions in sitting time and/or subsequent increases in light physical activity are clinically meaningful (i.e. provide a detectable improvement to health or physical function) (figure 16). However, intermediate outcomes such as health and physical function, despite being repeatedly mentioned as key assumptions, have not yet been investigated as outcomes in interventions, meaning that field is left in an intermediate stage where the effect of interventions on sitting time is being investigated, whereas the intended effect on ultimate outcomes, such as effects on disease risk, healthy ageing, healthy lifespan, and quality of life, remains unassessed (figure 16).

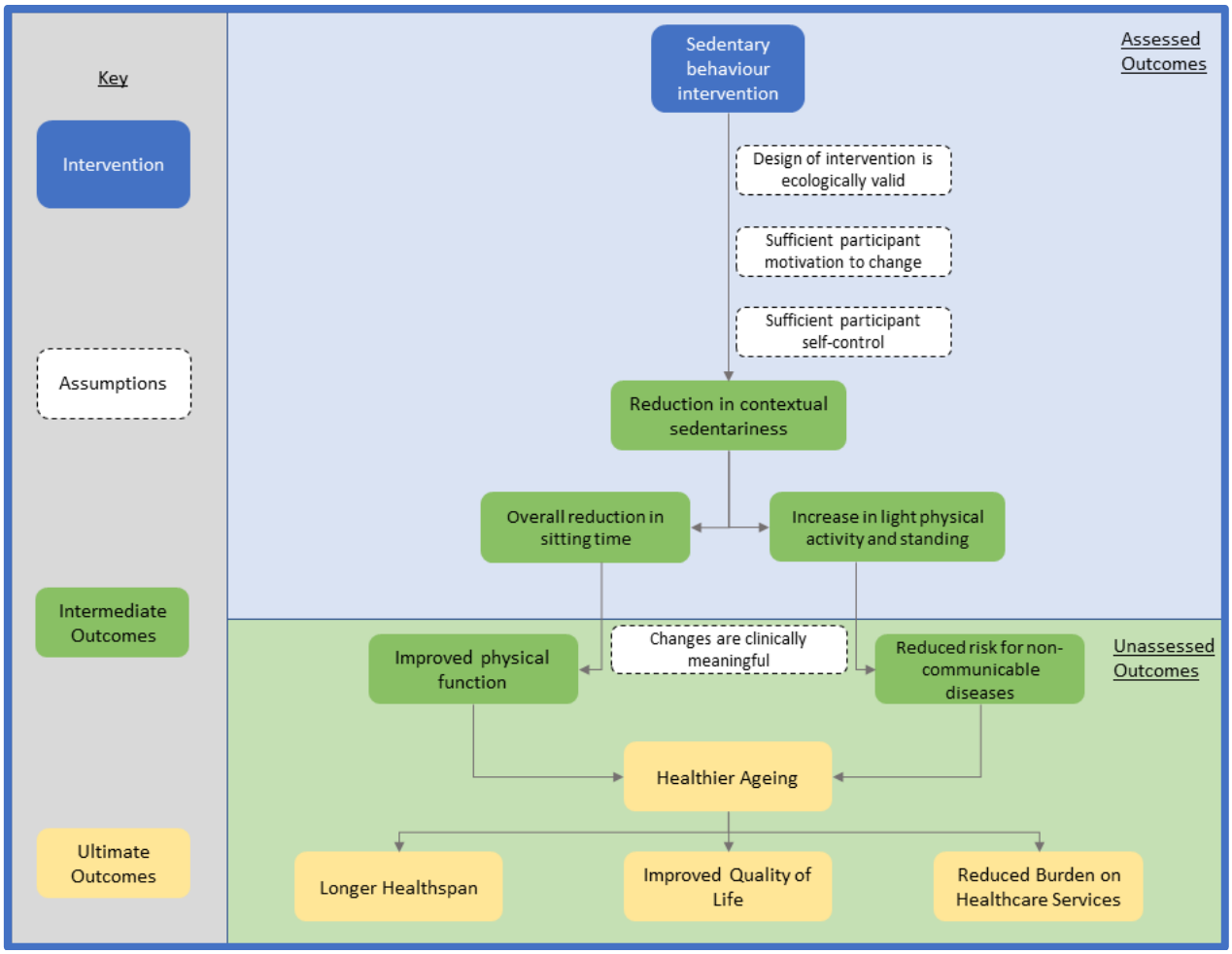

Figure 16. - Interventions to reduce sedentary behaviour in older adults: an implicit theory of change model. Assessed outcomes are those investigated in the included studies of this review; unassessed outcomes represent the implicit purpose of the interventions and the future direction of the field.

2.5.2. Robustness of the narrative synthesis

Overall robustness of this narrative synthesis is low, due to both the low methodological quality of included studies and the lack of quantitative synthesis methods included in this review. Certain elements of the narrative synthesis were subjective, such as which information was chosen for inclusion in table 2. Additionally, heterogeneity of study designs was very high, precluding the use of quantitative techniques, increasing risk of bias. Therefore, the results cannot be considered conclusive and must be interpreted with caution.

2.5.3. Future directions and recommendations

Since five out of six of the included studies were published between 2013 and 2016, there is clearly a spotlight moving within the research community towards sedentary behaviour, particularly with research into the demographic of older adults. However, this review identified a lack of studies with RCT designs of sufficient sample size and ecological validity. Although the included studies were powered to detect significant differences in sedentary behaviour variables, sample sizes were limited to between 30 and 59 participants. Larger sample sizes are needed in future clinical trials to increase rigour and detect smaller differences, as individual variation in magnitude of behaviour change can be substantial (English *et al.*, 2016). Increasing sample sizes would also increase the sensitivity of analyses within studies, enabling the individual components of interventions to be assessed proportionally for their role in the degree of behaviour change achieved. Adequate sensitivity of intervention subcomponents was lacking in the included studies, as it was not clear which part of the multicomponent interventions contributed most to the observed effects. Where possible, such an analysis should be incorporated, so that ineffective aspects of interventions can be discarded and overall efficiency of design can be improved moving forward.

Despite efforts from organisations such as the Sedentary Behavior Research Network (2013), there is still large heterogeneity in reporting and assessment of outcomes within the field of sedentary behaviour research. Half of the included studies used only self-report methods of sedentary behaviour: either the IPAQ or MOST (Chang, Fritschi and Kim, 2013; Matei *et al.*, 2015; Maher, Sliwinski and Conroy, 2016). In these studies, there were substantially greater effects reported on sitting time; for one a 28% reduction was reported (Matei *et al.*, 2015) which far exceeds the maximum of 5.3% reported in the objectively-measured studies (Lewis *et al.*, 2016). The sizeable reductions reported by these studies are likely due to response bias and information bias (bias resulting from measurement error) which are common in self-report methods compared with objective ones (Matthews *et al.*, 2012; Aguilar-Farías *et al.*, 2015). Half of the studies used at least one objective measurement tool such as

an accelerometer or inclinometer. However, there are also problems with heterogeneity of objective measures: an accelerometer such as the ActiGraph GT1M or an inclinometer such as the ActivPal3 do not have complete cross-comparability. For example, in direct observation of sitting, the ActiGraph GT3X+ has been found to have a correlation of r^2=0.39, whereas the ActivPal3 achieved a correlation of r^2=0.94 (Kozey-Keadle *et al.*, 2011; Aguilar-Farías, Brown and Peeters, 2014). Likewise, the GT3X+ can misclassify standing activity as sitting or lying (Steeves *et al.*, 2015). Although any kind of objective measurement device is considered more valid and reliable than self-report methods for measuring sedentary behaviour, inclinometers such as the ActivPal3 are considered superior as they can detect and record the posture of the individual (Busschaert *et al.*, 2015; van Nassau *et al.*, 2015). A recent critical review of sedentary behaviour in older adults, that also covered measurement techniques, found that self-report methods significantly underestimate sedentary time in comparison to objective measures, whereas inclinometers are the current gold standard (Copeland *et al.*, 2017). Inclinometers allow for more accurate measurement of sedentary behaviour, as it includes the postural component of the definition. A recent review of interventions to reduce sedentary behaviour in adults of all ages found that a combination of ActivPal3 to capture objective postural information, as well as at least one self-report measure to assess context, provides the optimal detection of a beneficial intervention effect (Martin *et al.*, 2015). Thus, pooling the data could lead to substantial problems if the assumption is that the data are based on a comparable measurement, since the tools have substantially different validity. This heterogeneity extends to how outcomes are reported, meaning that performance of any kind of statistical analysis when systematically reviewing such articles is obfuscated. For example, one study reported in minutes of sitting time per week (Chang, Fritschi and Kim, 2013), while another reported a reduction in average minutes per day (Lewis *et al.*, 2016) (table 4). Future studies should endeavour to gravitate towards better-suited measurement tools that are directly applicable to sedentary behaviours as the primary outcome, such as inclinometers which assess posture as well as inactivity, and not be satisfied with the use of self-report measures alone. Additionally, greater

consensus within the field as to reporting of outcome measures is desirable; for example, reporting sedentary time in average $min.d^{-1}$ is more useful than $min.wk^{-1}$ as it is more sensitive. This would allow for better synthesis of results within the field.

Older adults have varied lives – some are retired, some working, looking after grandchildren, or living in care homes. These lifestyle factors will have large effects on sedentary time and how it is accumulated. This means that differences in participant lifestyle are key considerations that should be addressed when designing interventions in these groups. For this reason, the decision was made not to include older adults in full-time employment in this review, as other studies have mixed working and non-working participants in their analyses despite their very different lifestyles (Rosenberg, Gell, *et al.*, 2015; Kerr *et al.*, 2016). If half of the participant base spends eight hours a day in the office whereas the rest are retired, and participants with both lifestyles are included, then there is significant heterogeneity in lifestyle within the same study. This presents a problem because the behaviour change strategies used will need to be different, as one group will likely be sitting out of necessity at work, and the other for leisure purposes. If it is still necessary to include participants with different lifestyles in a single study, then subgroup analyses are suggested based on these lifestyle types (e.g., working and non-working). Likewise, motivations and lifestyle may change substantially within the week, as weekday versus weekend behaviour patterns are very different in older adults, causing substantial changes in sedentariness within a single 7-day period [36]. Therefore, given this substantial difference, researchers suggest that sedentary behaviour outcomes should be reported separately for both weekends and week-days (Marshall *et al.*, 2015b).

Since the overall trend of the included studies suggests that interventions have the potential to be safe, effective, and feasible in non-working older adults, it is now time for studies to assess physical function and cardiometabolic health following reduction of sedentary time. The assumption is that interventions will improve these health factors. However, currently, the estimated magnitude of

improvement to health and function is based largely on epidemiological studies that employ statistical techniques such as isotemporal modelling to estimate improvements from hypothetical reductions in sedentary behaviour, or is based on cross-sectional data (Matthews *et al.*, 2015). Two studies (identified in the search, but not eligible due to including working participants) assessed a measure of function using the Short Physical Performance Battery (Rosenberg, Gell, *et al.*, 2015; Gibbs *et al.*, 2016). One did not detect a significant difference pre-to-post intervention (Rosenberg, Gell, *et al.*, 2015), and another found a significant improvement (Gibbs *et al.*, 2016). No study, thus far, has experimentally assessed the impact of a sedentary behaviour reduction in older adults on blood markers such as cholesterol, fasting insulin, triglycerides, or low-density lipoproteins, all of which are associated with disease factors influenced by sedentary behaviour (Thorp *et al.*, 2009). Thus, it is not yet clear from the interventional data what the required change in sedentary behaviour would be to confer clinically meaningful health benefits. However, studies utilising isotemporal substitution modelling, a statistical technique that allows the effect of displacing time spent in one activity to another, suggest that replacing 30 mins/day of sedentary behaviour with MVPA, or even light physical activity in individuals with co-morbidities, could have positive effects on frailty in older adults (Mañas *et al.*, 2018). Another isotemporal substitution study suggests that replacing 30 mins/day of sedentary behaviour with light physical activity could reduce all-cause mortality by 11% and cardiovascular disease risk by 24% (Dohrn *et al.*, 2018). Based on interventional data alone, however, it is currently undetermined whether reducing sedentary behaviour is a powerful enough stimulus to confer a definite improvement in health and physical function in older adults.

Furthermore, follow-up measurements were not included within the included studies, making it impossible to assess whether lasting behavioural change can be achieved by the interventions. To be able to inform policy design and clinical practice accurately and properly, sedentary behaviour research must reliably demonstrate that interventions arising from the field have the potential to confer lasting positive behavioural change with a resultant impact on health and function.

2.5.4. Limitations

This review has several limitations. Firstly, due to the infancy of this specific field there were too few studies with too high a degree of measurement heterogeneity to undertake meta-analysis, which means the efficacy of sedentary behaviour interventions in older adults could not be estimated with statistical means. Secondly, the review was of studies published only in the English language, thus other potentially eligible studies may have been missed. Thirdly, although every effort was made to distinguish between studies relying solely on self-report and those involving objective measurement of sedentary behaviour according to the definition, this review nonetheless relies partially on studies utilising self-report methodologies, as well as accelerometers rather than inclinometers for objective measurement (which could not provide postural information). Finally, even in those studies which used objective measures, they often were of feasibility design or included small sample sizes, making them unsuitable for estimating effectiveness.

2.6. Conclusion

This systematic review is the first to assess sedentary behaviour interventions in older adults, who are one of the most sedentary demographics, whilst simultaneously being most at-risk for its negative health effects. Although the evidence is both limited in quantity and quality, sedentary behaviour interventions in non-working older adults have the potential to lead to meaningful reductions in sedentary time. However, there is not yet experimental evidence for any impact of sedentariness on clinical outcomes such as physical function and cardiometabolic health. Additionally, a lack of follow-up in these studies means there is no evidence of the likely duration of behaviour change that can be achieved by this type of intervention. As multiple pilot studies of sedentary behaviour interventions indicate that sedentary behaviour can be reduced by up to 1 hour/day in this demographic, future studies should be of RCT design, and should endeavour to assess changes in function and health as primary outcomes, with adequate follow-up assessment for measuring duration of behaviour change.

In this manner, the underlying assumptions of the field can be tested, and it can be established what dose of sedentary behaviour reduction is required to improve health and physical function in older adults, as well as what types of intervention are suitable for achieving the long-term behavioural changes required.

CHAPTER 3: A NOVEL BEHAVIOURAL INTERVENTION TO REDUCE SITTING TIME IN OLDER ADULTS UNDERGOING ORTHOPAEDIC SURGERY (INTEREST): A RANDOMISED CONTROLLED FEASIBILITY STUDY

Published as "Aunger, J.A., Greaves, C.J., Davis, E.T. and Greig, C.A., 2019. A novel behavioural INTErvention to REduce Sitting Time in older adults undergoing orthopaedic surgery (INTEREST): protocol for a randomised controlled feasibility study. *Pilot and feasibility studies*, *5*(1), p.54.

3.1. Summary

Osteoarthritis is a highly prevalent condition in older adults, that causes many sufferers to require a hip or knee replacement in order to reduce pain and improve quality of life. Individuals waiting for hip or knee replacements are often highly sedentary; thus, it is pertinent to assess whether reducing their sedentariness prior to surgery may aid in improving post-operative outcomes. The study was a randomised controlled feasibility trial design, with 2:1 randomisation into an intervention and usual care group respectively. A target of 45 participants aged 60 years or older waiting for hip and knee replacements were to be recruited from Russells Hall Hospital, Dudley, UK, approximately 8-10 weeks before surgery. The intervention, informed by Self-Determination Theory (SDT), was composed of multiple behaviour change techniques; namely, motivational interviewing, feedback on current objectively-measured sedentary behaviour and activity, goal-setting, environmental modification, self-monitoring, and social support. Assessments were at baseline, 1-week pre-surgery, and 6-weeks post-surgery, with the study duration being variable according to participant surgery schedules. The primary outcome was the feasibility of intervention delivery and of the trial procedures, assessed quantitatively based on rates of recruitment and retention, measures-completion, and intervention fidelity assessment, and with mixed-methods assessment of acceptability, practicality, adaptation, satisfaction, and safety. Exploratory outcomes included physical function, cardiometabolic biomarkers,

measurement of SDT constructs, and both objective and subjective measurement of average daily activity and sitting time.

3.2. Background

Evidence suggests there is an association between sedentary behaviour and reduced physical function, as well as cardiovascular disease, type II diabetes risk, and all-cause mortality in older adults (de Rezende *et al.*, 2014; Copeland *et al.*, 2017). A further study found that each additional 1-hour period of sitting time per day is associated with a clinically significant reduction in physical function of 0.55 points of the Short Physical Performance Battery (SPPB) score (Kwon *et al.*, 2009; Rosenberg *et al.*, 2016). This is of particular concern as a review of 18 surveys including over 500,000 adults ≥60 years of age has found that they spend an average of 8.5 hours per day sitting when objectively measured (Harvey, Chastin and Skelton, 2013).

Given the high degree of sedentariness in older adults, in combination with the mounting evidence of the associated health risks, several interventions aiming to reduce sitting time in older adults have been developed. These include interventions to displace sedentary time to light physical activity such as walking, or simply other standing activities (Aunger, Doody and Greig, 2018). However, existing interventions have suffered several shortfalls. They are often feasibility trials with small sample sizes that lack objective measurement of sedentary behaviour using an inclinometer or accelerometer. Often, they have not assessed changes in blood biomarkers or physical function post-intervention, nor have they included follow-up to assess the duration of behaviour change conferred. Very few such trials have adequately reported the theoretical basis or logic model underpinning their behaviour change intervention (Aunger, Doody and Greig, 2018). Additionally, they have all included healthy older adult populations without significant co-morbidity.

However, older adults do often have morbidities which can lead to even greater sitting time due to pain or other factors (Sebastien F M Chastin *et al.*, 2014). One such condition is osteoarthritis, which

is extremely prevalent in older adults. In the UK, 18.2% of adults ≥45 years have osteoarthritis of the knee, and 10.9% have osteoarthritis of the hip (Arthritis Research UK, 2013). Osteoarthritis causes chronic pain and further predisposes participants to be more sedentary. According to an analysis of objective sedentary behaviour data, individuals with mobility limitations have more sedentary time, less active time, and longer sedentary bouts compared with healthy controls (Manns *et al.*, 2015). Likewise, a recent review has identified that after total hip or knee replacements, older adults do not return to being as active as their healthy counterparts, despite decreases in pain post-surgery (Harding *et al.*, 2014).

Despite these findings, no intervention to date has attempted to reduce sedentary time in older adults with mobility limitations, despite the benefits it may bring to this at-risk population. One previous intervention has found it possible to improve the SPPB score by 0.5 points, a clinically meaningful increase, after a 12-week sedentary behaviour reduction intervention in healthy older adults 60 years and over (Barone Gibbs *et al.*, 2016). These data suggest that it may be possible to improve physical function simply by reducing sedentary behaviour. However, no study to date has examined the impact of reducing sedentary behaviour in an older clinical population with mobility limitations who are awaiting hip or knee surgery.

3.3. Aims

The overall objectives were (1) to assess the feasibility and acceptability of delivering an intervention to reduce sedentary time using a novel behaviour change intervention in a population of adults ≥60 years awaiting hip or knee arthroplasties and (2) assess the feasibility and acceptability of conducting the procedures required to deliver a full-scale RCT.

The study aimed to:

a) Estimate variance in outcome measures
b) Assess feasibility of delivering outcome measures
c) Test the feasibility/acceptability (to patients) of delivering the INTEREST intervention
d) Test the feasibility of recruitment via research nurses
e) Test the feasibility of study processes through quantitative means, by assessing retention rates, recruitment rates, and adherence to the study
f) Assess intervention fidelity
g) Analyse content of action plans to identify common behaviours in which older adults engage, that could be displaced to other forms of activity
h) Assess feasibility against criteria for progression to a definitive trial

3.4. Theoretical framework

Changing human behaviour is a challenging endeavour and changing the ingrained habits of older adults dealing with the burden of morbidity, particularly so. When developing complex interventions, it is considered best-practice to establish a clear logic model and explicit theoretical underpinnings to allow for explanation of the mechanisms of action (Craig *et al.*, 2008). However, a recent review of behaviour change strategies to reduce sedentary behaviour in adults found that 58% of included interventions (15 out of 26) did not mention a theoretical framework (Gardner *et al.*, 2015). Of those that did, seven mentioned using a Transtheoretical Model, four used Social Cognitive Theory, three used the Theory of Planned Behaviour, and one used Empowerment theory (Gardner *et al.*, 2015). Despite this lack of clearly defined theory, interventions were found to generally assume that sedentary behaviour is largely determined by the external environment, or problems in self-regulation by individuals. However, as Gardner *et al*. (2015) point out, none of the interventions included in their review paid any attention to individual motivation when attempting to change behaviour (Gardner *et al.*, 2015).

A recent systematic review of interventions in older adults extracted the theoretical frameworks used in the included studies (Aunger, Doody and Greig, 2018). Of the six included, one did not include a theoretical framework, and each of the five others used a different theory. These included

empowerment theory, social cognitive and behavioural choice theories, the health action process approach, a habit dual-process framework, and a habit formation model. However, the most successful trial used a multi-componential design based upon Self-Determination Theory (SDT). This theory emphasises motivation as being key to behaviour, a missing consideration in all sedentary behaviour interventions developed to date (Gardner *et al*., 2015).

3.4.1. Application of Self-Determination Theory

SDT has been found to be successful when used in previous sedentary behaviour and exercise interventions in adults (figure 17). To maximise behaviour change, SDT states that intrinsic motivations (including self-generated motivation or internalisation (integration) of externally-generated instructions or ideas) are more powerful than extrinsic (externally generated, but not internalised) motivations (Ryan and Deci, 2000; Silva *et al.*, 2010). Fundamental to the generation of intrinsic motivation are three psychological needs proposed by Ryan & Deci (2000) in their Basic Psychological Needs theory. These three needs; autonomy, competence, and relatedness, serve as useful targets for enhancement when designing interventions. Autonomy is the desire to be the agent of one's self; competence refers to a desire to feel control over the outcomes of one's own actions; and relatedness is the desire to connect to and be approved of or accepted by others (Ryan & Deci, 2000). Enhancing these needs leads to greater internalisation of goals into "integrated regulatory processes", greater personal growth and development, and the resulting accomplishment of one's own goals.

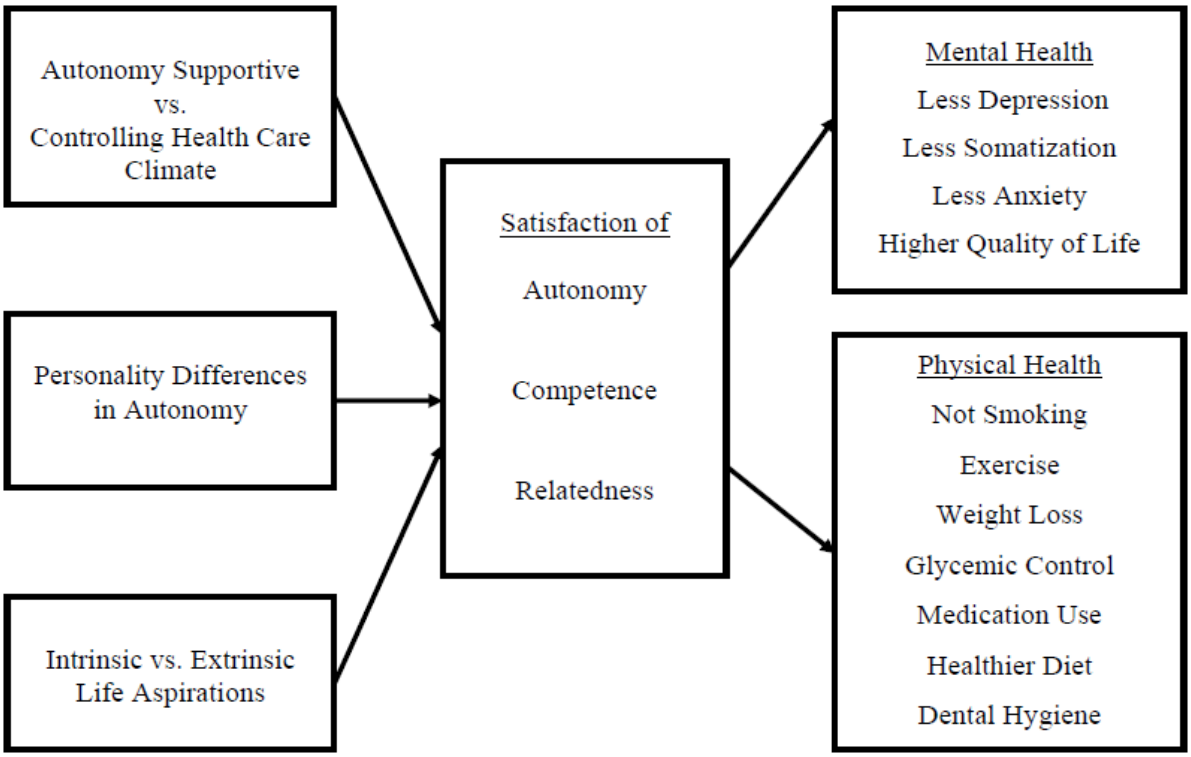

Figure 17. Self-Determination Theory model of health behaviour change (Ryan et al., 2008).

Linking psychological needs and extrinsic motivational processes is Organismic Integration Theory (OIT), a sub-theory of SDT that describes the process by which external motivators regulate behaviour (Deci and Ryan, 1985). OIT posits that when external motivators appeal to basic psychological needs, they are more likely to be internalised, thus driving behaviour change that is stronger and more persistent. This involves moving along a spectrum from external regulation, in which people are motivated purely by extraneous factors, to integrated regulation, whereby they have thought about their long-term goals and integrate behaviours that fulfil their personal beliefs and values, and long-term goals. Another sub-theory, Goal Contents Theory, supports this, stating that if these external motivators relate to intrinsic aspirations (long term life goals) such as health and wellbeing, then this will also facilitate behavioural change (Kasser and Ryan, 1996).

3.5. Behaviour change techniques

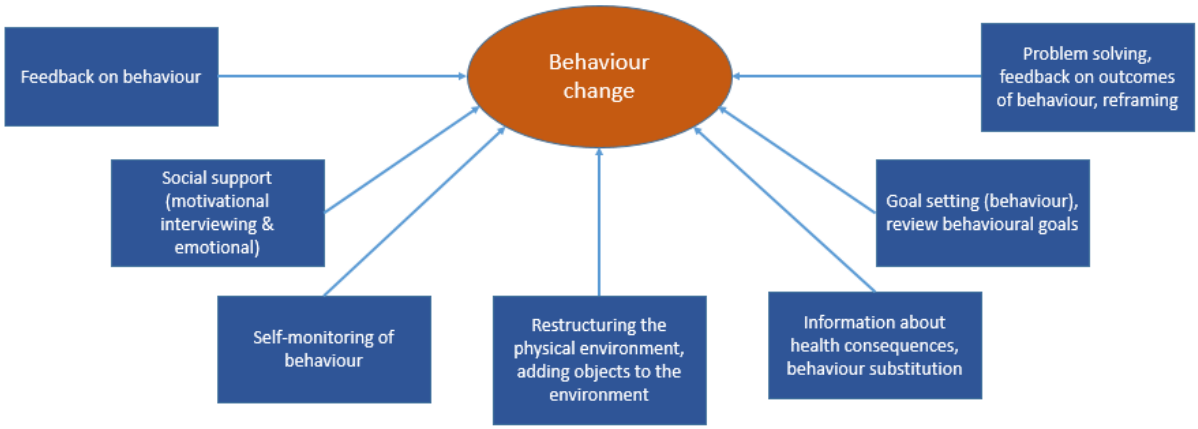

Figure 18. Behaviour change techniques used in INTEREST.

3.5.1. BCTs used by the researcher with the participant

3.5.1.1. Supporting the basic psychological needs

As Self-Determination Theory is the theoretical framework of the study, every opportunity was taken to enhance the participants' basic psychological needs (figure 18). Opportunities were taken to enhance participant autonomy by emphasising participant choice and minimising control (i.e. by emphasising that each of the goals are the participant's own choice), to highlight the participants' strengths and agency, to emphasise their feelings and perspectives, and to support them to overcome their own barriers and to achieve their goals (Williams, Deci and Ryan, 1998). Competence was supported by providing participant with the tools they need to feel a sense of achievement, by recognising efforts towards achieving goals, by supporting change talk, and praising participant achievements. Relatedness was aided by engaging in a person-centred manner with the researcher, by encouraging spousal/familial involvement where possible, and by supporting or suggesting activities that occur in a social context. This included addressing any negative social influences on achievement of the participants' action plans.

3.5.1.2. Health education

Health education in this session comprised of a brief discussion prior to the motivational interview about the health effects of sedentary behaviour. This was delivered in an ask-tell-discuss format to ensure that it adhered to a participant-centred format and to maintain participant autonomy.

3.5.1.3. Social support (motivational interviewing)

Motivational interviewing is by definition a very open process that is intended to follow a specific direction, but this occurs very much at the behest of the participant. It involves four generally-chronological stages, namely (1) engaging, where the investigator establishes a relationship with the participant, next is (2) focusing, in which the investigator and participant hones in on the problem behaviour in question, then (3) evoking, during which the investigator tries to elicit "change talk" from the participant, which reflects the individual's internal desires to change. The planning stage (4), shifts from talking to making the change. In this study, motivational interviewing (MI) was used primarily with the following general structure in mind:

1. Engaging:
    a. To start, the participant was encouraged to talk about their own relationship with sitting behaviour and physical activity.
    b. The participant was encouraged to talk about their hip or knee problems and how it impacts them in their day-to-day lives.
2. Focusing:
    a. What benefit the participant aims to gain from their hip or knee replacement surgery was discussed.
    b. The investigator asked the participant whether there may be a link between sitting and physical activity behaviour, and their envisaged benefits/desire to recover well post-operatively.
3. Evoking:
    a. The investigator aided the participant in understanding that by reducing their sitting and increasing other physical activities such as standing and walking, even if acutely painful, they may benefit themselves after surgery, thus reducing ambivalence towards reducing their sitting behaviour.

b. Change talk was encouraged from the participant with respect to reducing their sedentary behaviour.

4. Planning:

    a. This fed into the goal-setting and the development of an action plan.

Throughout this process, MI techniques were used to elicit change talk, namely open questions, affirmations, reflective listening, and summaries (OARS). Additionally, the investigator always avoided confrontation. During MI, open questions are posed to allow people to tell their own story about their experiences and not to force them in any direction. Affirmations are statements that acknowledge the participant's strengths and ability to change, such as "you have managed this very well", "you are clearly a person who cares a lot about their health", etc. This guides the participant in the direction of change whilst enhancing the aspects of their character that would enable such change. Reflective listening involves listening very closely to what the participant is saying, and making 'reflections', which are statements that try to continue down a line of thought and discovery with a participant, while perhaps changing the tone towards change. At least three different types of reflection exist, including repeating (simple repetition back to the speaker), paraphrasing (rephrasing but keeping the same meaning), and a reflection of feeling (rephrasing with emphasis on the underlying emotional impact of what is being said).

Summaries are another key aspect of MI. These summaries are often also reflective in nature but are most useful when conversation has naturally died down or at a transitional period between one topic and another (especially when moving from discussions about motivation to action-planning). Summaries involve reflecting to the participant the topics discussed, and with a specific focus on any statements made by the participant about the importance of change and confidence to change (i.e. statements about readiness to change). When ambivalence is indicated by the participant, summaries can include, for example, phrases such as "on the one hand…. and on the other hand", and a summary can end with an invitation to the participant for them to correct or add to anything the investigator

has said, which can feed into further discussion. Together, the OARS strategy is a comprehensive set of tools for supporting participant autonomy whilst simultaneously eliciting change talk.

The end of the MI process integrates well into the individualised goal-setting session as a natural extension of the motivation phase. The MI session covers the willingness to change of the participant, whereas the individualised goal setting provides the action plan that enables them to change their behaviour in a measurable and specific fashion.

3.5.1.4. Individual feedback on walking, standing, and sitting behaviour

Participants were given individualised feedback on their activity patterns based on a measurement taken using an ActivPal3 activity monitor at baseline (see Measures below). This included stepping, standing, sitting time, and length of sedentary bouts of differing lengths. The feedback provided was in the form of ActivPal daily summaries and posture allocation reports, which the researcher explained to the participant for optimal understanding. Using these data, it was possible to make goals that targeted specific times of day where individuals were more sedentary (e.g. the afternoon/evening) and agree upon specific step count targets that were tailored to their individual performance. It was also a possibility to talk about altering recurring behaviours based on time-specific recordings to increase activity levels (e.g. going shopping more frequently if conducive to increasing activity or adding an extra session of tennis per week).

3.5.1.5. Action planning - individualised, incremental goal setting (behaviour), behavioural substitution

Also, in visit 3, participants worked collaboratively with the researcher to formulate an action plan consisting of 6 goals and 3 environmental modifications that were each designed to either reduce the length of sedentary bouts, reduce total sedentary time, increase physical activity, or increase sit-to-stand transitions. In the first week, participants were asked to choose the first goal and attempt to reduce that specific behaviour. In the second week, the next goal was added concurrently with the

first, and so on, until in the 6th week, all 6 goals were being concurrently worked towards. In addition, at the goal-setting session, three environmental changes were identified that the participant could make in their own home. These modifications were added to the participant's regime during weeks 1, 3, and 5 of the intervention, and encouraged movement within the home (reducing sitting time, increasing sit-to-stand transitions, and breaking up sedentary bouts).

3.5.1.6. Social support (emotional)

As the goals for INTEREST were bespoke and tailored to the individual, this meant that individual living arrangements could be integrated into the design. Older adults have large variations in living conditions, including living alone, with a spouse, or in multi-generational households. This meant, particularly when older adults lived with their spouses or family, that it was possible to integrate social support into the goals or environmental modifications themselves. One such goal could be *"go for a walk outside after lunch every day with my wife".*

3.5.1.7. Prompts/cues, restructuring physical and social environment

Participants were encouraged to make three modifications to their home or personal environment, in a manner that enhanced individual autonomy in line with SDT principles, personalising the experience, and minimising any ethical pitfalls. The participant was encouraged to identify contexts and areas in which they sit the most and make changes to their home environment. This could vary from removing a chair from a room where they liked to sit, thus forcing them to stand instead (modifying physical environment), to putting up posters (prompts) reminding them of their goals, or changing the social environment (going to see a friend more often with whom walks frequently occur). By devising techniques to modify their environment themselves, participants could make these modifications more achievable and specific to their own individual level of physical function, lifestyle, and home, thereby enhancing autonomy.

3.5.1.8. Review of behavioural goals, and illumination of discrepancies between current behaviour and goals

Problem solving was delivered by the researcher in collaboration with the participant, to find means with which to solve issues they were facing in their action plans. This led to review of behavioural goals in most cases, and discrepancies between current behaviour and goals were discussed.

3.5.1.9. Problem solving

Problem solving was a two-step process, and initially involved using reframing techniques to alter participant perspectives towards viewing setbacks as opportunities for change, rather than as personal failures. Participants were also informed about coping plans as a strategy for managing setbacks, to help sustain the change. Problem solving was the second step in the process that ensured that support was given to the patient and that goals were also revised and reformulated where necessary, so that action plans continued to be achievable. Techniques such as identifying barriers; breaking problems down and exchanging information in an ask-tell-discuss manner (e.g. to address misconceptions or to stimulate ideas for overcoming barriers) were also utilised.

3.5.2. Other BCTs used by participants between visits

3.5.2.1. Self-monitoring of behaviour

Self-monitoring in behaviour change refers to “the systematic observation and recording of target behaviour” and often relies on self-regulatory processes (Kanfer, 1970). The modes through which individuals performed self-monitoring in INTEREST were via active monitoring of performance towards goals and recording their goal adherence in the sedentary behaviour booklet (available in the supplementary files of the published protocol). Since INTEREST used a Yamax SW200 Digiwalker Pedometer (https://www.yamax.co.uk/yamax-pedometers/sw200-digi-walker/), provided to participants at the start of intervention phase (visit 3), the most relevant goal focused on increasing the participant’s step count. Many participants were able to set goals aiming for their minimum steps

per day during the intervention to be close to their highest-step day from their baseline ActivPal measurement. Many participants recorded and noted down their daily steps for their own reference, to see whether they had been achieving their step target.

3.6. Logic model and combination of intervention components

3.6.1. Explaining the logic model

Figure 19 depicts the overall rationale for the implementation of SDT in INTEREST, providing an overview of how the selected behaviour change techniques (the intervention components) were used to address the intended theoretical processes of change. The components were chosen to target specific basic psychological needs and the primary target for each component is shown in figure 19. It is worth noting that some components, such as individualised goal-setting, would likely enhance both competence and autonomy. In figure 19, in line with OIT, satisfaction of the Basic Psychological Needs moves individuals along a spectrum towards integrated regulation of the new behaviours introduced as part of the study. Likewise, GCT is represented in the logic model, by showing that the goals in the study were supportive of lifetime intrinsic aspirations, such as improved physical function and maintenance of independence. By actively achieving their goals, participants were expected to gain feelings of achievement/competence (and autonomy), leading to greater persistence of behaviour change and enhanced well-being.

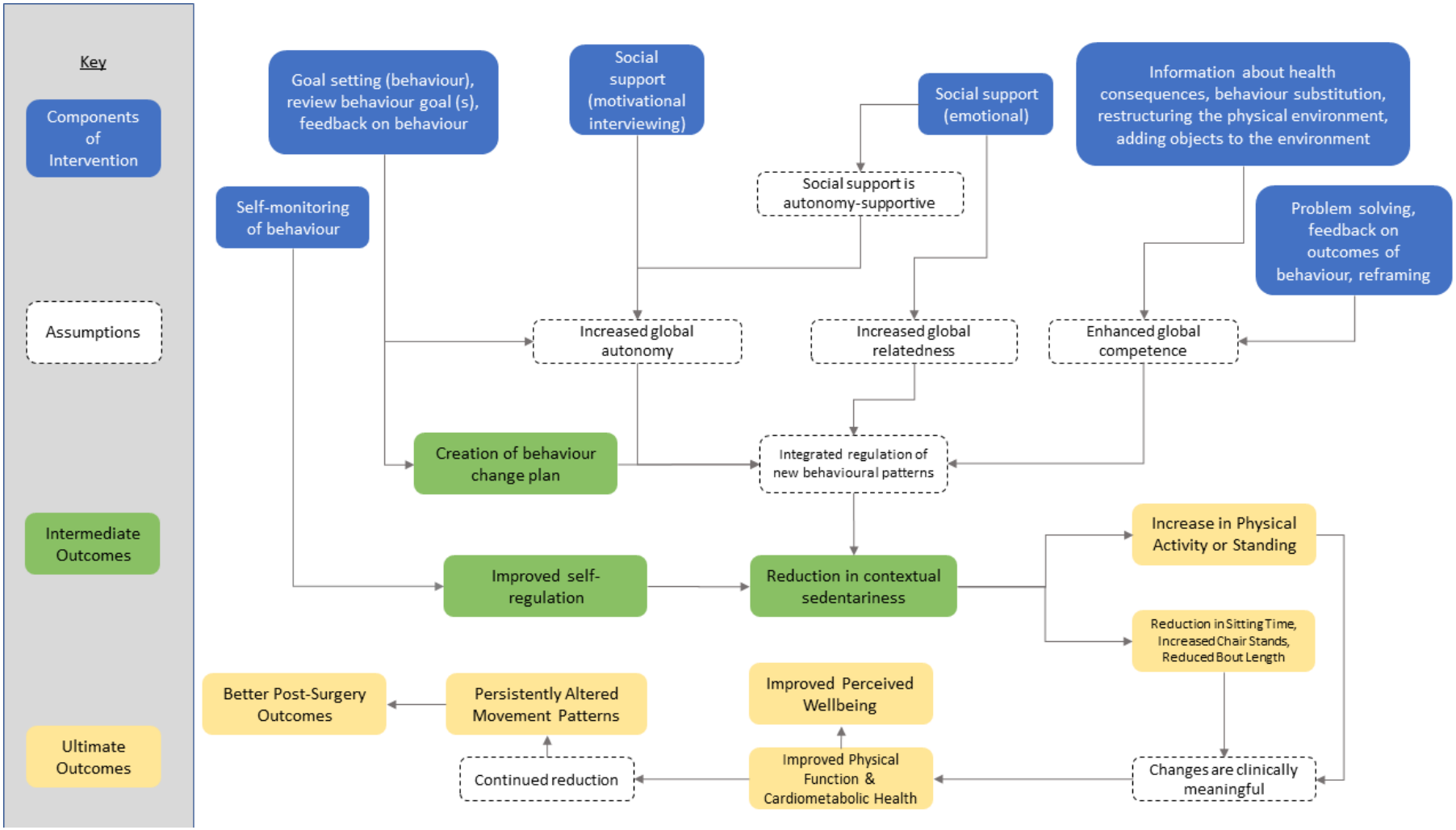

Figure 19. Logic model for INTEREST based upon Self-Determination Theory.

3.7. Rationale for intervention components

All the intervention components in INTEREST, outlined in the prior section, were chosen for their suitability for addressing the theoretical processes of Self-Determination Theory. These are described according to BCTs present in the behaviour change technique taxonomy (v1) or indicated otherwise (Michie *et al.*, 2013)

3.7.1. Participant-centred delivery style

As the Basic Psychological Needs are integral constructs within Self-Determination Theory, the intervention is based upon the concept that supporting autonomy, competence, and relatedness within participants will lead to maximised motivation. The primary focus was on supporting participant autonomy; a review of 32 interventions for problem drinkers found that the most important determinants of change were giving non-evaluative feedback, encouragement of participant responsibility, and empathetic delivery, all of which are indicative of a person-centred delivery style (Bien, Miller and Tonigan, 1993). Healthcare investigators that create controlling contexts have also been found to lead participants on a path towards introjection rather than integrated regulation of new behaviours, meaning that motivational processes will not be maximised (Williams, Deci and Ryan, 1998). Unfortunately interpersonal style is not included in the behaviour change taxonomy and is thus referred to here as simply “participant-centred delivery style” (Hagger and Hardcastle, 2014).

Phone calls were considered to be an important component of the intervention to engage with participants in a person-centred manner, to enhance motivation and feelings of relatedness. This is supported by findings from Deci (1971), who found that giving people unexpected positive feedback not only acts as a reward, but also increases feelings of competence, thus increasing intrinsic motivation and reinforcing the behaviour. Therefore, during the phone calls, positive encouragement was given.

3.7.2. Social support (motivational interviewing)

Motivational interviewing and SDT share many fundamental assumptions (Markland *et al.*, 2005). Motivational interviewing is primarily a participant-centred counselling technique aimed at reducing a patient's ambivalence about making a change. This is achieved by supporting their sense of agency and helping them to decide to make changes of their own accord, by mobilising their own internal motivations (Letourneau, 2014). Both SDT and MI emphasise the role of personal autonomy as a driving force of human behaviour (Markland *et al.*, 2005). However the ability for motivational interviewing to support the basic psychological needs is dependent upon the skilfulness with which it is delivered (Deci and Ryan, 2012b).

According to a review of 15 studies investigating the efficacy of MI in older adult populations with acute and chronic illnesses, aiming to improve physical activity participation or quit smoking or alcohol, or a combination of lifestyle behaviours, MI was found to be effective at increasing PA, reducing smoking and alcohol behaviours, and improving health markers (Cummings, Cooper and Cassie, 2009). However, results were conflicting about whether the behaviour changes achieved persisted in the long-term (Cummings, Cooper and Cassie, 2009).

MI was successfully employed in a RCT of 56 community-dwelling older adults of 65 years and above (95.7% women), living with chronic pain in Hong Kong, with the intention of reducing their pain and increasing their participation in physical activity (Tse, Vong and Tang, 2013). MI was delivered in a group setting for 30 minutes weekly over the course of 8 weeks. The pain intensity at baseline was not significantly different between groups, but after intervention and MI delivery, 8 weeks later, pain was significantly reduced in the intervention group compared with the control group (Tse, Vong and Tang, 2013). This study demonstrates that MI, used appropriately, may be effective in community-dwelling older adults with chronic lower body pain. MI has also been used in an intervention to reduce

sedentary time in n=23 frail older adults in Scotland, however, sedentary time was not reduced in this small pilot study (Harvey, Chastin and Skelton, 2018).

To ensure that the MI was delivered to a proper standard, the investigator underwent two training courses by Pip Mason Consultancy (a Beginner and an Intermediate Motivational Interviewing Training Course), and to assess quality of the use of MI techniques, an expert member of the study team (CJG) reviewed the fidelity of MI sessions.

3.7.3. Individual feedback on walking, standing, and sitting behaviour

According to a review which taxonomised different types of feedback in health behaviour interventions, there are three main types of feedback (Diclemente *et al.*, 2001). The first is generic feedback, which is relevant to an entire population. Second is targeted feedback, based on demographic characteristics. Finally, personalised feedback provides specific information for an individual based on either normative (relating to what behaviour or performance or outcome is 'normal' for others) or ipsative (comparing someone to their own prior performance) comparisons. In INTEREST, feedback was given after the baseline visit about their sedentary behaviour and physical activity as measured by the ActivPal3. This feedback was personalised and ipsative, as it was considered unfair to compare osteoarthritic individuals with healthy or even other osteoarthritic older adults. Participants were heterogeneous with respect to physical function and had different severities of osteoarthritis or other co-morbidities, which meant that normative comparisons could have been unattainable and thus discouraging for some.

Individual feedback has been shown to be effective in other behaviour change interventions, e.g., increasing hand hygiene behaviours in n=24 nurses (Chun *et al.*, 2014). Behaviour was monitored with direct observation, and participants were given a score based on their individual frequency of handwashing in comparison to the required amount of handwashing. Hand washing quality was also assessed by making bacterial cultures from each person's right hand after handwashing and showing

these to participants. In combination with education about handwashing, feedback on handwashing behaviour was able to increase handwashing frequency from 46.8% to 71.4% (Chun *et al.*, 2014). Given the efficacy of this approach and its utility to goal-setting, feedback was an integral component of the INTEREST design.

3.7.4. Individualised, incremental goal setting (behaviour) and action planning

Goal-setting is well established in behaviour change interventions, and a recent meta-analysis of 141 papers has found it to be highly effective, particularly so when the goal was challenging to achieve, set in a group, or publicly (Epton, Currie and Armitage, 2017). Originating in Goal Setting Theory, goal setting has been used to change a range of health behaviours (Locke and Latham, 1990; Epton, Currie and Armitage, 2017). For example, a combination of personalised feedback and individualised goal setting has been used to increase weekly running distance in healthy adults (Wack, Crosland and Miltenberger, 2014) and to aid obese older adults in weight loss and to prevent weight regain (Nicklas *et al.*, 2014). Goal Setting Theory maintains that goals should be conscious and specific, rather than vague, such as “do x when y occurs”, rather than “be better at x” (Epton, Currie and Armitage, 2017). Four modifiers are postulated that enhance behaviour change as a result of goal setting, namely (1) intention to adhere to the goal, (2) low degree of complexity of the goal (not the same as difficulty), (3) feedback about progress towards the goal, and (4) adequate resources available/few constraints (Locke and Latham, 2006; Epton, Currie and Armitage, 2017). Goal Setting Theory originally did not consider older adults as a specific case, however, more recently, the authors have elaborated that older adults have a number of specificities that synergise well with goal setting (Epton, Currie and Armitage, 2017).

The approach in this study added two other aspects, inspired partly by SDT; namely, the individualised and incremental aspects of goal setting. These operate upon two main assumptions: firstly, that by individualising the goals, the goals were more specific to an individual’s lifestyle and thus more

achievable for them, again enhancing their autonomy; and, secondly, that by incrementally introducing them over the course of weeks it was less difficult for people to adjust to their goals as it was less cognitively demanding and impactful on people's lifestyles. In addition to being personalised, the goals are created using SMART principles, which were originally developed for application in a business context and have since expanded to healthcare contexts as a way to make behaviour change more personalised and manageable in a real-world context (Doran, 1981; Shaw *et al.*, 2015). By ensuring they are SMART (Specific, Measurable, Achievable, Relevant, and Time-specific), the goals fulfil the conclusions of the systematic review, namely that the goals are formulated with the intention of adherence and ensuring availability of enough resources to achieve them. This also satisfies the criteria for classification as "action planning" in the Behaviour Change Taxonomy (Michie *et al.*, 2013). Finally, in combination with the self-monitoring, the participants were able to self-feedback on and review their own goal achievement, especially in combination with the weekly monitoring of goal adherence encouraged by the INTEREST sedentary behaviour booklet (available in the supplementary files of the published protocol) (Aunger *et al.*, 2019).

3.7.5. Information about health consequences

As the field of sedentary behaviour research is relatively new, it is very possible that many older adults are not aware of the potential health ramifications of sitting. A recent study found that only 14 percent of older adults aged 55 years or over in the UK had accurate knowledge about physical activity guidelines (Knox *et al.*, 2013). Given these low figures regarding the better-established guidelines around physical activity, knowledge about the health effects of sedentariness is likely to be even lower. Although education by itself is not sufficient to drive behaviour change, informing participants about the health impact of sitting may serve as additional motivation for them to sit less (Michie, Van Stralen and West, 2011).

3.7.6. Prompts/cues, restructuring physical and social environment

The built environment is acknowledged in a large number of behavioural theories as a key determinant of behaviour, and has been found to be another key driver of sedentariness (Owen *et al.*, 2014; Sallis, Owen and Fisher, 2015). Therefore, environmental modification as a tool for behaviour change has been identified by reviews to be a highly promising component of sedentary behaviour interventions (Gardner *et al.*, 2015). Environmental modification has also been used in other interventions to good effect, such as in interventions to drive eating behaviour change to elicit weight loss (Carels *et al.*, 2011; Gorin *et al.*, 2013). A recent RCT found that a behavioural weight loss program was less effective than a behavioural weight loss program combined with environmental modification, in which modifications included providing participants with exercise equipment in the home, giving them scales and full-body mirrors, health focused magazines, and incorporating partner support (Gorin *et al.*, 2013). In a pilot study, environmental modification has also been used to reduce TV viewing by turning off power to TVs after an allotted time period (Gorin *et al.*, 2006).

3.7.7. Self-monitoring of behaviour

Self-monitoring is a technique that involves use of self-regulatory behavioural processes (Bandura, 2005). Self-monitoring may increase engagement and feelings of self-control when working towards achieving behavioural targets and enhance self-regulatory abilities. It was envisioned for the sense of achievement through self-monitoring to lead to enhanced feelings of competence. In this study, self-monitoring was performed with use of a pedometer provided to participants as well as through recording of achievement of their goals.

3.7.8. Social support (emotional)

In healthcare interventions, it is integral for the concept of relatedness for the client/patient to feel that they are respected, understood, and cared for, by the practitioner and by their family and friends (Ryan *et al.*, 2008). Without these factors in place, it is less likely that the patient will accept and want

to work toward the recommendations of a healthcare practitioner. Within the framework of SDT, social factors can have both positive and negative effects in terms of the satisfaction of the basic psychological needs (Deci and Ryan, 2012a). Social support can be either autonomy-supportive, or controlling, in nature, however, the former has been found to be supportive of the basic psychological needs of competence and relatedness (Deci and Ryan, 2012a). Social support has been found to be generally autonomy-supportive, and therefore beneficial to be included in interventions (Deci *et al.*, 2006; Deci and Ryan, 2012a). Social support was often incorporated into the goals set by participants, such as to go on walks with their spouse, or to ask family/friends for support in achievement of their targets.

3.7.9. Problem solving, review of behavioural goals, and illumination of discrepancies between current behaviour and goals

These aspects of the intervention were facilitated during the phone calls by the investigator. These BCTs do not have literature available to support their integration into SDT, however, use of these techniques were delivered in an autonomy-supportive, person-centred style and aimed to emphasise the competence of the participant.

3.8. Coding the use of behaviour change theory in the intervention

Interventions can incorporate behaviour change theory to varying degrees. The degree to which they implement them can be assessed using tools such as the Theory Coding Scheme published by Michie and Prestwich (2010). As discussed in Chapter 1, this coding scheme was devised through a rigorous process of 13 iterations based on an analysis of healthy eating interventions. The scheme assesses integration of theory into the design of an intervention, as well as how well it is tested and revised. The scheme has been used to successfully demonstrate that better incorporation of theory leads to improved efficacy, and this is especially true for the selection of participants based on a theoretical criterion (category 3, table 5) (Prestwich *et al.*, 2014).

The scoring of the present study and its reporting was performed by JA and a secondary coder, CG. The full scoring can be viewed in Appendix I. However, table 5 shows the scoring according to category. Although theory was well-implemented in the design, it was not rigorously tested, or refined, which is what might be expected from a feasibility study that was not powered to detect differences in theoretical constructs. However, Chapter 5 explores what aspects of SDT could have been integrated into the present study to improve theoretical integration and what could be done to improve inclusion of categories five and six.

Table 5. Theory Coding Scheme scoring.

Category	**Score**
Category 1: Is theory mentioned?	Yes
Category 2: Are the relevant theoretical constructs targeted?	Yes
Category 3: Is theory used to select recipients or tailor interventions?	No
Category 4: Are the relevant theoretical constructs measured?	Yes
Category 5: Is theory tested?	No
Category 6: Is theory refined?	No

3.9. Study design

Experimental single-centre mixed methods feasibility study with 2:1 randomisation to experimental and control group respectively. The study was intended to last up to 18 weeks per participant with a 1-year recruitment period.

3.9.1. Location

The primary recruitment site for this study was at Russells Hall Hospital (RHH), Dudley, Birmingham, in the UK. Participants were recruited from the orthopaedic clinics at this site, and participant visits could occur at participants' own homes, at Russells Hall Hospital, or at the School of Sport, Exercise, and Rehabilitation Sciences, University of Birmingham. Assessments, such as motivational interviewing and goal-setting, took place predominantly at participants' own homes, although having them at RHH or

the School of Sport, Exercise, and Rehabilitation Sciences at the University of Birmingham were offered as options.

3.9.2. Eligibility criteria

3.9.2.1. Inclusion criteria:

1. Men and women aged ≥60 years.
2. Listed for elective hip or knee surgery.
3. Capable of providing informed consent.
4. Regular access to a phone at pre-specified times.
5. Able to speak and understand English.

3.9.2.2. Exclusion criteria:

1. Neuromuscular impairments that preclude participating in physical activity, visual, hearing, or moderate/ severe cognitive impairments as indicated by the research nurse prior to recruitment.
2. Significant co-morbid disease that would pose a safety threat, affect blood measures significantly, or impair ability to participate such as coronary artery disease, severe hypertension, peripheral vascular disease, stroke, congestive heart failure, chronic obstructive pulmonary disease, insulin-dependent diabetes, psychiatric disease, renal disease, liver disease, or an active cancer other than skin cancer.
3. Unwillingness or inability to comply with the intervention.

3.10. Study procedures

3.10.1. Recruitment process

Orthopaedic participants ≥60 years were identified from waiting lists and screened for eligibility from medical notes by a research nurse at Russells Hall Hospital. Eligible participants were sent a participant information sheet (PIS). The PIS is available in the supplementary files of the published protocol (Aunger *et al.*, 2019). After a week, the research nurse could re-contact the potential participant again by phone to remind them about the study and to ask if they were interested in taking part. The participant could respond using the reply slip provided (along with a stamp addressed envelope) or alternatively could contact them directly via the email address or phone number provided on the PIS. Depending on information that either the RN or participant received about the likely date of surgery,

the first visit could be scheduled either promptly or further in advance to make it more likely that the 6-8-week ideal intervention length was achieved.

Given the potential difficulties of recruiting participants from this target group, convenience sampling was used; all eligible participants were recruited if they expressed interest and fulfilled the eligibility criteria.

3.10.2. Randomisation and group allocation

Due to the nature of the intervention it was not possible to blind participants nor the data-collecting researcher to group allocation (as, due to resource constraints, the researcher also delivered the intervention). Randomisation was conducted using 2:1 permuted block randomisation by a third-party who retained allocations in confidence. The researcher was blinded to the allocation until the first participant visit.

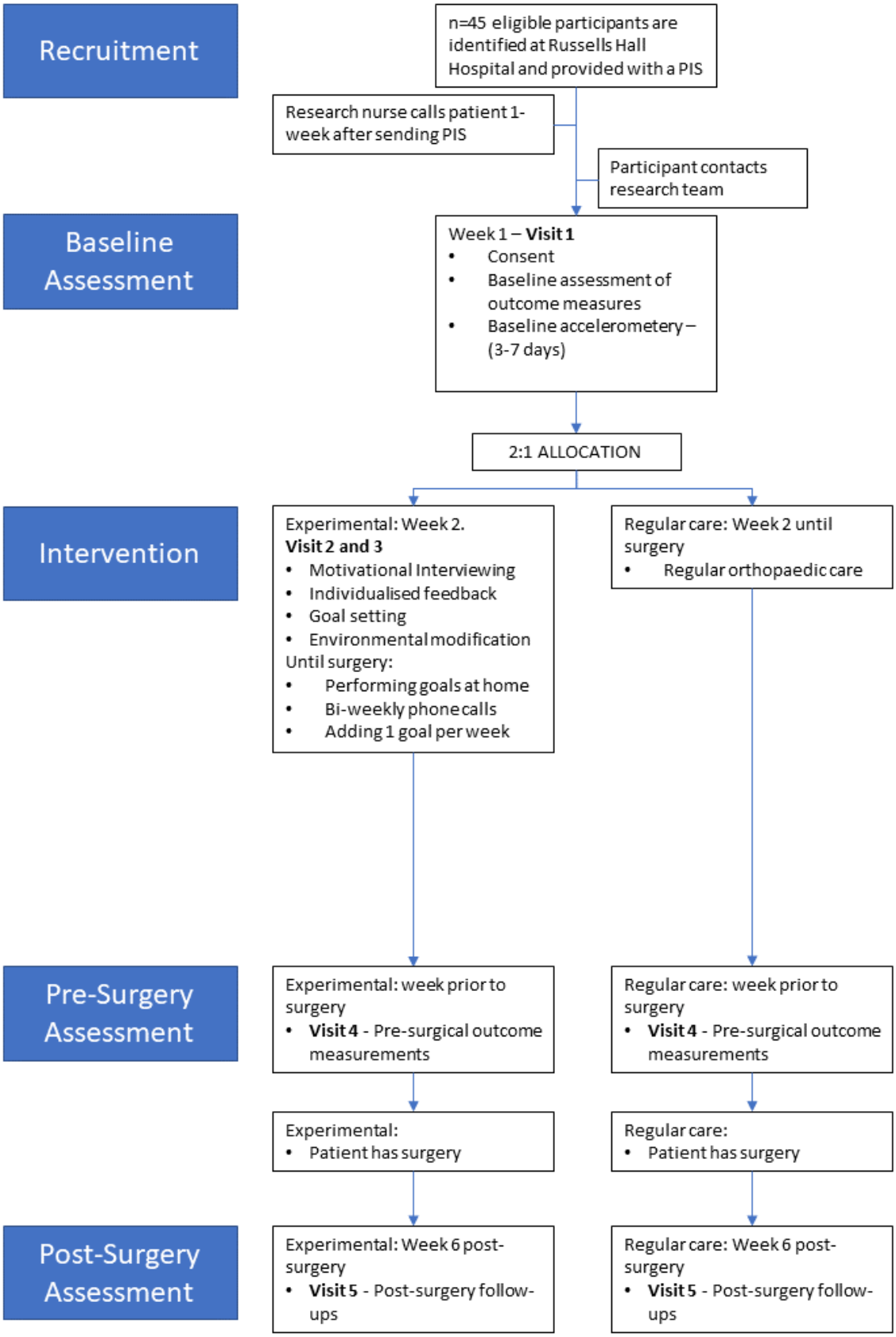

Figure 20. Study flow chart, with visits highlighted in bold.

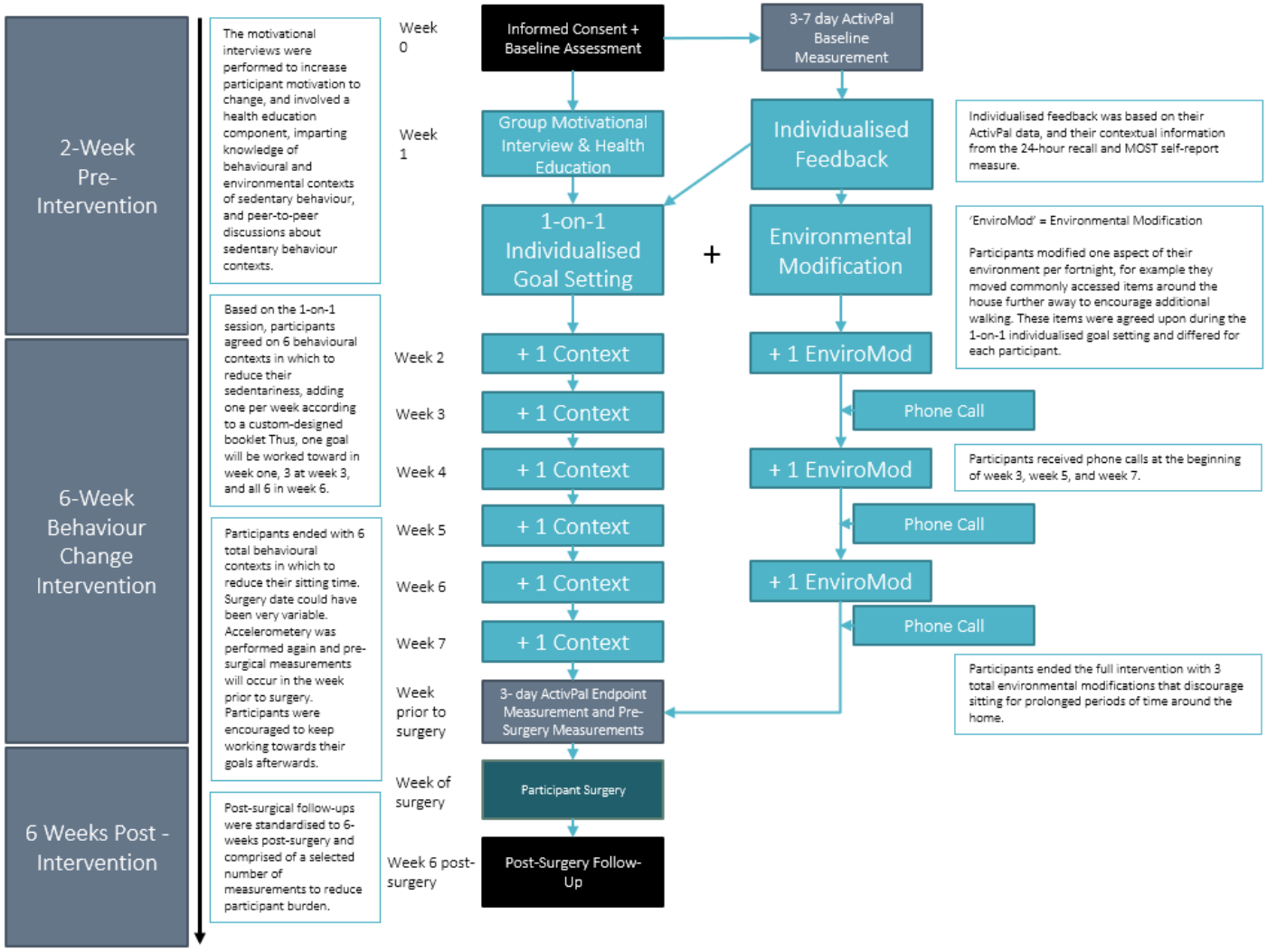

Figure 21. Study procedures in experimental group.

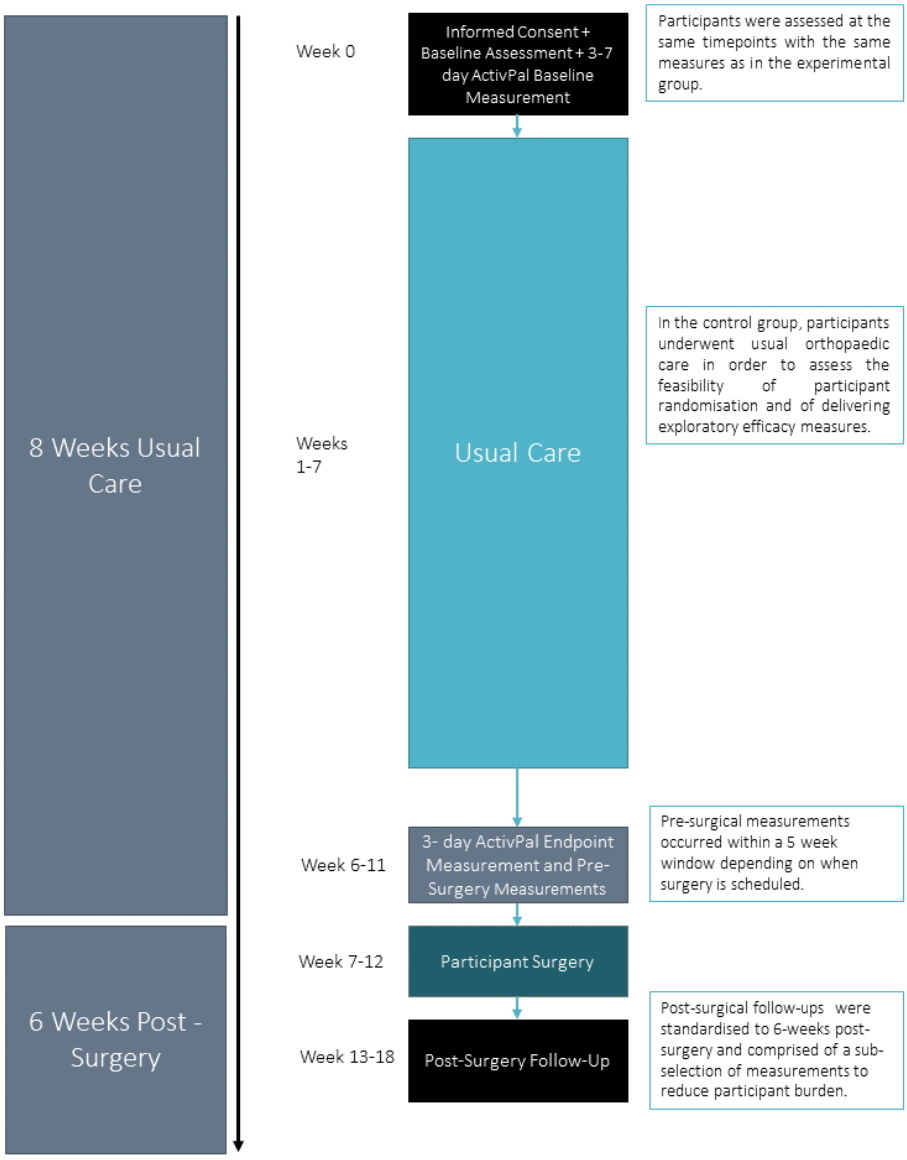

Figure 22. Study procedures in the usual care group.

3.10.3. Study visits and delivery of BCTs

INTEREST featured several BCTs delivered over the course of two visits (which could be condensed into a single 90-120-minute visit) and three phone calls, each lasting 5-20 minutes. Figure 19 depicts the included BCTs.

3.10.3.1. Visit 1 (60-120 mins) - assessments

At this meeting, informed consent was obtained with a Participant Informed Consent Form (available in the supplementary files of the published protocol (Aunger *et al.*, 2019)), all measures were taken,

and at the end of this visit, an ActivPal physical activity monitor was attached to the participant's upper thigh and worn for between 3 to 7 days to determine baseline activity, amount of sedentary behaviour, sit-to-stand transitions, average length of sedentary bouts, and number of sedentary bouts >30 minutes . For the baseline session it was necessary for the participant to fast overnight after eating dinner prior to the meeting for the correct measurement of metabolites. All samples were taken either by a phlebotomy-trained member of the research team adhering to University of Birmingham SOPs. Additionally, 2 millilitres of whole blood were obtained at baseline and pre-surgery to be sent for epigenetic analysis at the University of Bologna to aid in their research investigating epigenetic changes as a result of physical activity interventions in older adults. At this point the participant's GP were informed of their participation in the study. Full details of the protocols for data collection are available in Appendix D.

In the experimental group, the ActivPal data gathered from this visit were used to provide individualised feedback to the participant. This ActivPal data were shown to the participant during the individualised goal-setting meeting (visit 3).

3.10.3.2. Visit 2 (45 mins) – intervention delivery

BCTs used in this visit:

1. Information about health consequences
2. Social support (motivational Interviewing)

MI sessions were conducted during visit 2. Health education was provided during this session, entailing a brief discussion about the health effects of sedentary behaviour, followed by the MI session. Visits 2 and 3 were often combined, in which case, the planning phase began immediately by formulating the action plans.

3.10.3.3. Visit 3 (45 mins) – intervention delivery

BCTs used in this visit:

1. Individual feedback on behaviour
2. Action planning and goal setting (behaviour)

3. Prompts, restructuring physical and social environment
4. Social support (emotional)

In weeks 1-2, individualised goal setting sessions took place with a member of the study team, either at the participant's home, the clinic, or at the School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham.

3.10.3.4. Phone calls (5-15 mins) – intervention delivery

BCTs used during phone calls:

1. Social support (motivational interviewing)
2. Problem solving
3. Review behaviour goals
4. Discrepancies between current behaviour and goal

Phone calls were delivered at the beginning of week 2, week 4, and week 6 of the intervention. They provided an opportunity to review progress, offer encouragement to use MI techniques, to ask about any problems/challenges encountered and offer solutions, and to revise goals according to the discussion.

3.10.3.5. Visit 4 (60-90 mins) - assessments

Visit 4 comprised the pre-surgical measurements and occurred at or within 7 days prior to surgery. The ActivPal was sent in the mail in advance and was worn for a minimum of three days prior to this meeting in both the Intervention and usual care groups. The other pre-surgical measurements also occurred at this meeting point, which included the same measures as baseline except for the SF-MNA and demographic questions (visit 4). The pre-surgical outcome measurements were conducted at either the participant's home, or at the hospital or the School of Sport, Exercise, and Rehabilitation Sciences (table 5).

Due to variations in surgery scheduling, it was likely that some participants would not have surgery as scheduled. If in the intervention group, the participant was encouraged to continue with their goals for whichever length of time was necessary. If a participant's surgery was significantly delayed, the

pre-surgical measurements were taken per protocol, but the participant was no longer eligible for the post-surgical follow-up due to the effect of the intervention (sedentary behaviour reduction) potentially being lost. Thus, this participant would leave the study at this point although the data from the first two timepoints were still included. These occurrences were noted to inform the feasibility of the study.

3.10.3.6. Visit 5 (30-60 mins) - assessments

The final point of contact in both the usual care and intervention groups was the post-surgical follow-up, which was standardised for each participant, occurring at 6-weeks post-surgery (visit 5). Visit 5 also occurred at a location of the participant's choosing. A reduced set of outcome measures were conducted at this point to reduce participant burden and as performing them would not further inform the feasibility of the study (table 6). A further questionnaire to assess whether the participant considered it feasible to continue behaviour change in the absence of phone calls and other intervention components was also delivered (see Figure 21 and 22 for complete depictions of participant flow in the intervention and usual care groups respectively).

Table 6. Study visits and assessments.

Visit Number	Week(s)	Purpose	Location
1	0	Informed consent	Participant's home or clinic or UoB
1	0	Baseline assessments	Participant's home or clinic or UoB
2 (intervention group only)	1	Motivational interview	Venue at RHH (or home or UoB)
3 (intervention group only)	1	Individual feedback, action planning, environmental modification	Participant's home or clinic or UoB
4	7-12	Pre-surgery assessment	Participant's home or clinic or UoB
5	13-18	Post-surgery follow-ups	Participant's home or clinic or UoB

3.10.4. Outcomes

3.10.4.1. Primary outcome assessment

3.10.4.1.1. Feasibility (study statistics)

Feasibility was assessed primarily using the following measures:

- Study uptake rate – percentage of participants receiving a PIS who were subsequently enrolled in the study (%).
- Recruitment rates – average number of participants recruited per month.
- Intervention adherence – average self-reported goal adherence (scale 1-5) per week (recorded in the sedentary behaviour booklet).
- Percentage of participants whose surgery occurs 8 or more weeks after visit 3 (%).
- Percentage of participants whose surgery is scheduled 4 or fewer weeks after visit 3 (%).
- Percentage of participants with indefinitely delayed or cancelled surgery – proportion of participants who did not have surgery within the lifetime of the study (%).
- Retention rates – percentage of participants who remained in the study (i.e. provided measures) and did not drop-out at each follow up time point (%).
- Average duration of intervention – average number of weeks of participation in the intervention prior to surgery.
- Session attendance – number of intervention sessions attended, and the associated total contact time.

3.10.4.2. Secondary outcome assessment

3.10.4.2.1. Feasibility questionnaire

Feasibility was assessed secondarily by use of bespoke questionnaires that comprise both open and closed questions, one for usual care, and one for intervention group. Each question is designed to

target an aspect of feasibility based on guidance by Bowen *et al.* (2009). The questionnaires assess acceptability, practicality, adaptation, satisfaction/feedback, and safety/risk for the participant. These questionnaires are available in the supplementary files of the published protocol (Aunger *et al.*, 2019).

3.10.4.2.2. Qualitative interviews with health care staff

Semi-structured qualitative interviews were conducted with the research nurses after cessation of recruitment to assess how feasible the recruitment process was from their perspective.

3.10.4.3. Exploratory outcomes

To assess the feasibility of collecting outcomes data in this population, data were collected at the baseline, pre-surgery, and post-surgery visits. The outcomes assessed were sedentary behaviour, physical function, body composition (weight, height, BMI, waist-to-hip ratio), nutritional status, quality of life, activities of daily living, hip and knee pain and its resulting impact, blood biomarkers, and basic psychological needs (see table 6 for a comprehensive list). These data informed the design of a definitive trial by helping to identify which outcomes are feasible, and which demonstrated the greatest responsiveness to the intervention.

3.10.4.4. Other data

Demographic data was also captured at the baseline visit, and included age, date of birth, gender, country of origin, all spoken languages, marital status, ethnicity, education level, school years, prior main occupation, living arrangements, housing arrangements, pets, alcohol behaviour, former alcohol behaviour, smoking status, and former smoking status. Furthermore, medication information and participant history were also captured.

Table 7. Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) diagram to show the participant schedule, including enrolment, allocation, interventions, visits, and assessments (Chan et al., 2013). R = researcher. PC = Phone Call. CRP = C-Reactive protein.

	Study period										
	Recruitment	Baseline	Allocation	Post-allocation							Close-out
Visit	Pre-enrolment	Visit 1	Allocation between visit 1 and 2	Visit 2	Visit 3	PC 1	PC 2	PC 3	Visit 4	Visit 5	Post-study
Timepoint (weeks)	1	2	3	3	3	5	7	9	1 wk prior to surgery	6 wks post-surgery	
Study member	Research nurse	R	Third party	R	R	R	R	R	R	R	R
Enrolment											
Eligibility screening	X										
Informed Consent		X									
Allocation			X								
Study Groups											
Sedentary behaviour reduction	X	X	X	X	X	X	X	X	X	X	
Usual care	X	X	X						X	X	
Assessments											
Feasibility (study statistics)											X
Feasibility (questionnaire; acceptability, practicality, adaptation, satisfaction, safety)									X	X	
Socio-demographic questions, medication info, medical history		X									
ActivPal measurements (sitting time, sit-to-stand transitions, no. of sedentary bouts ≥30 mins, avg. length of sedentary bouts,		X							X	X	

	Study period										
	Recruitment	Baseline	Allocation	Post-allocation							Close-out
Visit	Pre-enrolment	Visit 1	Allocation between visit 1 and 2	Visit 2	Visit 3	PC 1	PC 2	PC 3	Visit 4	Visit 5	Post-study
Timepoint (weeks)	1	2	3	3	3	5	7	9	1 wk prior to surgery	6 wks post-surgery	
Study member	Research nurse	R	Third party	R	R	R	R	R	R	R	R
stepping time, standing time, steps per day)											
International Physical Activity Questionnaire Short Form (IPAQ-SF) (Craig *et al.*, 2003)		X							X		
Measure of older adults' sedentary behaviour (MOST) (Paul A Gardiner *et al.*, 2011)		X							X	X	
Quality of life (QoL) (EuroQoL 5D-5L, EuroQoL-Visual-Analogue Scale) (EuroQol Group, 1990)		X							X	X	
Oxford Hip and Knee Score(s) (Dawson, Fitzpatrick and Carr, 1996; Dawson *et al.*, 1998)		X							X	X	
Basic Psychological Needs in General Scale (Ryan and Deci, 2000; Gagne, 2003)		X							X	X	
Activities of Daily Living (ADL) (Katz-ADL) (Katz *et al.*, 1970)		X							X		
Physical function - Short Physical Performance		X							X	X	

	Study period										
	Recruitment	Baseline	Allocation	Post-allocation							Close-out
Visit	Pre-enrolment	Visit 1	Allocation between visit 1 and 2	Visit 2	Visit 3	PC 1	PC 2	PC 3	Visit 4	Visit 5	Post-study
Timepoint (weeks)	1	2	3	3	3	5	7	9	1 wk prior to surgery	6 wks post-surgery	
Study member	Research nurse	R	Third party	R	R	R	R	R	R	R	R
Battery (SPPB) (Guralnik *et al.*, 1994)											
Short form mini nutritional assessment (SF-MNA) (Rubenstein *et al.*, 2001).		X									
Weight		X							X	X	
Height		X									
Body mass index		X							X		
Waist-to-hip ratio		X							X		
Blood measures (Albumin, High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), cholesterol, triglycerides, Vitamin D., Cortisol, Transferrin, HBA1c, CRP, full blood count)		X							X		

3.11. Rationale for choice of outcome measures

3.11.1. Objective measurement of movement and sedentary behaviour (ActivPal)

The ActivPal developed by PAL Technologies, Glasgow, United Kingdom, is an activity monitor that is well-validated and highly suited to measuring sedentary behaviour variables, such as sitting time and sit-to-stand transitions (Ryan *et al.*, 2006; Lyden *et al.*, 2012). It was selected for this study because of its inclinometer and sedentary behaviour monitoring functions and was used at multiple timepoints to assess a number of variables. Due to the ability to measure both posture and movement, it is possible to extract data relating to sedentariness, including sitting time, physical activity, average length of sedentary bouts, sit-to-stand transitions, and the number of sedentary bouts beyond a certain duration. It can also capture stepping time (walking) but can only estimate the intensity of the physical activity being performed. The ActivPal is an objective measurement tool of sedentary behaviour/activity, and thus cannot determine what behaviours are being performed at specific times or which are being reduced. For that reason, a self-report method was used in conjunction with it. Although it cannot determine the context of behaviours, the ActivPal is accurate in terms of measurement of sedentariness and activity when compared with direct observation, with 100% accuracy for standing, and over 95% accuracy for stepping and sitting behaviours, and accurate detection of cycling as activity 93% of the time in healthy adults (Steeves *et al.*, 2015).

3.11.2. Physical function - Short Physical Performance Battery (SPPB)

The SPPB is a multicomponent physical function test that assesses gait speed, balance, and lower limb power and strength with a possible score between 0 and 12, where 12 is maximal functionality (Guralnik *et al.*, 1994). It is sensitive to events such as hospitalisation and rehabilitation and thus is an appropriate measure of change in physical performance in older adults undergoing surgery (Bunout *et al.*, 2006; Volpato *et al.*, 2010). The SPPB is also effective at predicting which individuals are likely to lose their ability to perform a 400m walk test, which makes it a useful tool for identifying individuals

most at need for intervention (Vasunilashorn *et al.*, 2009). In a previous study of a 12-week intervention to reduce sitting in older adults, the SPPB improved by 0.5 points, mostly due to increases in the chair stand portion of the test (Gibbs *et al.*, 2016). A 0.54 point increase is likely to be indicative of a significant improvement to wellbeing in many individuals, as a secondary analysis of observational data and clinical trials in 692 people has shown that an increase in score of 0.54 is a useful target indicative of a clinically meaningful difference (Perera *et al.*, 2006). For these reasons, it was used at all three assessment points of the study to assess whether a change in physical function had occurred. An improvement in physical function as measured by the SPPB is also the intended primary outcome variable for the proposed future clinical trial.

3.11.3. Self-reported physical activity - International Physical Activity Questionnaire Short Form (IPAQ-SF)

The IPAQ-SF assesses physical activity behaviours through self-report methods. The IPAQ-SF has been reported to lack validity in comparison with objective measures of activity in a recent systematic review which included n=23 validation studies, overestimating by an average of 84 percent (Lee *et al.*, 2011). The IPAQ-SF has been found to have acceptable validity for measuring vigorous physical activity and walking (Lee *et al.*, 2011). Validity and reliability data are lacking for the assessment of sedentary behaviours (Rosenberg *et al.*, 2008). For this reason, the Measure of Older Adults Sedentary Time (MOST) was used in INTEREST, in addition to the IPAQ-SF, to determine which sedentary behaviours were performed in which contexts. However, the IPAQ-SF nonetheless provided valuable data about the quantity of light, moderate, and vigorous physical activity undertaken by participants. A study comparing n=225 chronic musculoskeletal disorder patients with n=350 control participants using the IPAQ-SF found that these two groups differed mostly on vigorous physical activity (VPA), where the patient group reported 0 MET/hours of VPA per week, compared with 240 for the controls (Moseng *et al.*, 2014). The other reported indices of physical activity were not significantly different according to

group, which means that musculoskeletal limitations may limit people mostly in terms of the intensity of exercise with which they can engage.

3.11.4. Self-reported sedentary time - Measure of Older Adults' Sedentary Time (MOST)

The measure of Older Adults' Sedentary Time was developed specifically for the measurement of older adult's sedentary time, offering a number of domain-specific measures of behaviour, such as reading, watching television, or doing hobbies, and has been validated in older adults (Paul A Gardiner *et al.*, 2011). It has good test-retest reliability on most subdomains, with a score of 0.78 for TV time, but less so for socialising and transport, and was acceptable for overall sedentary time (0.52). However, in this study, objective measurement was used alongside the MOST, thus providing both accurate measurement of overall activity and sedentariness, whilst using the MOST to acquire contextual information. The MOST has been used in a recent sedentary behaviour intervention in older adults, and was found to consistently be more accurate for reporting overall sitting time than the IPAQ, which typically underreported (White *et al.*, 2017).

3.11.5. Nutritional status - Short-Form Mini Nutritional Assessment (SF-MNA)

The SF-MNA was specifically developed to assess whether older adults eat a sufficiently nutritious diet, and has a 0.94 correlation with the full Mini Nutritional Assessment tool (Rubenstein *et al.*, 2001). It was included in this study as a validated tool for assessing malnutrition in participants, enabling nutritional status to be controlled as a covariate when performing analyses. When a participant with malnourishment was identified, then the study team would inform the medical team of the patient.

3.11.6. Activities of daily living - Katz Index of Independence in Activities of Daily Living (Katz ADL)

Developed in 1979, the Katz ADL was developed specifically to address the growing need for a tool which can assess functional capacity for everyday tasks in older adults (Katz, 1979). The Katz ADL asks several questions of the older individual, namely whether they can perform several daily tasks on their own, such as bathing, dressing, toileting, and feeding. It is scored from 0-6, with 6 being most independent. In this study, the Katz ADL was used to assess whether individuals change in terms of dependence over the course of the study, particularly as a result of their surgery. The Katz ADL is sensitive to changes as a result of interventions. A 1-year RCT of an intervention in n=134 patients in nursing homes with Alzheimer's disease using two weekly, 1 hour exercise sessions, found that the patients had significantly lower reduction of independence over the 1-year period in the exercise group (Rolland *et al.*, 2007).

3.11.7. Basic Psychological Needs in General Scale (BPNS)

This intervention was designed using the principles of Self-Determination Theory (SDT). Thus, it was important to assess whether some of the constructs within the theory change as a result of taking part in the intervention, namely the Basic Psychological Needs of autonomy, relatedness, and competence. As there is no validated sedentary-behaviour specific version of this scale available, the Basic Psychological Needs in General scale was used, which is a global assessment of these constructs. The BPNS questionnaire includes 7 items per psychological need (21 items in total), and asks questions such as "*I feel pressured in my life*" to assess autonomy, "*I get along with people I come into contact with*" to assess relatedness, and "*I often do not feel very capable*" to assess competence. These questions are answered on a 1-7 Likert scale. Satisfaction of the three basic needs has been shown to be associated with positive well-being, life satisfaction, self-esteem, and negatively linked to depression (Johnston and Finney, 2010). In the INTEREST study, this measure was used to identify

whether participants in the study felt like their basic psychological needs (competence, autonomy, and relatedness) were enhanced as a result of the intervention. A sample questionnaire is available in Appendix E.

3.11.8. Quality of life - EuroQol-5D-5L (EQ-5D-5L) and EQ-VAS

The EQ-5D-5L is a measure of QoL and overall health, and includes five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 possible levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The EQ-5D-5L is regularly used in orthopaedic care in the UK, and is a common tool in research (Ng *et al.*, 2012). A review of instruments for assessing quality of life in older adults has emphasised that since QoL is a multi-dimensional concept, there is no one tool that yet adequately measures all aspects, but the EQ-5D-5L is found to be the best for assessing quality-adjusted life years (QALYs). It is expected that if physical function improves as a result of participation in the study, this would likely impact the EQ-5D-5L positively. In addition to the EQ-5D-5L, the EuroQol Visual Analogue Scale (EQ-VAS) was used, which allows for the participant to rate their overall health with a number from 0-100, where 0 is the worst health that they can imagine, and 100 the greatest.

3.11.9. Hip and knee pain and recovery - Oxford Hip/Knee Score

The Oxford Hip and Knee scores have been in use since the late 1990s, and today are an integral part of orthopaedic care where they are used in clinical audits to judge the success of hip and knee replacements (Dawson, Fitzpatrick and Carr, 1996; Dawson *et al.*, 1998). This assessment is delivered in the form of a self-completed questionnaire delivered to the participant (Murray *et al.*, 2007). The questions asked are on a 1-5 scale and mostly relate to pain or obstructions to daily life caused by the hip or knee issues. For example, items include: “could you do household shopping on your own?”, and, “how much has pain interfered with your usual work (including housework)?”. Both are scored from 0-60, where 60 is perfect hip or knee function without any pain. Other studies have found that a change

in score of 5 points is indicative of a clinically meaningful improvement to the impact of a hip or knee condition on one's life (Beard *et al.*, 2015).

3.11.10. Cardiometabolic blood biomarkers

One of the most unique aspects of this study is the assessment of cardiometabolic biomarkers. To date, no study in older adults has assessed the impact of an intervention to reduce sitting time on cardiometabolic biomarkers (Aunger, Doody and Greig, 2018). It is not yet clear whether a reduction in sitting time is potent enough to meaningfully change these markers. This intervention includes blood sampling at baseline and pre-surgery timepoints for analysis of Albumin, HDL, LDL, triglycerides, Vit. D3., CRP, Cortisol, DHEA/S, and Transferrin. These measures have been chosen due to their strong associations with cardiovascular disease processes (Duarte *et al.*, 2009).

3.11.11. Waist to Hip Ratio (WHR)

Many studies measure waist circumference as a means of assessing weight status /weight-related health risk, as it is strongly related to abdominal adiposity (the most dangerous form of fat distribution) (Janssen, Katzmarzyk and Ross, 2004). However, in terms of CVD risk, a meta-regression analysis of 15 articles including over 250,000 participants found that WHR predicts CVD events than better WC alone (De Koning *et al*., 2007). This may be because it considers differences in bone structure and therefore may be a better proxy for abdominal adiposity. A more accurate measure would be measurement of body composition via DXA scanning, but this study was not sufficiently resourced for this. In a study following 14,833 older adults over the age of 75 years, recruited from family practices in the UK, WHR has been found to be more strongly associated with overall mortality than BMI or WC (Price *et al*., 2006). In relation to osteoarthritis, a population-based cohort study of Swedish adults with OA found that there is an increasing relative risk (RR) for OA with increases in BMI, WC, weight, body fat percentage, and WHR (Lohmander *et al.*, 2009). Given the benefits of WHR over WC, and the small

amount of extra time required to do the hip measurement, WHR was felt to be the best measurement of adiposity for this study.

3.12. Intervention fidelity

All goals and environmental modifications made during the intervention were recorded and qualitatively coded after the end of the study. Ratings of skill used while delivering the intervention utilised purpose-built checklists based on the five-stage model of adult skill acquisition by Dreyfus *et al*. (2004), which has been used successfully in prior trials (Dreyfus, 2004; Stathi *et al.*, 2018; Thompson *et al.*, 2018). Scales for skill ratings were on a 0-5 basis, whereby 0 was an absence of the skill, and 5 "expert" usage of the skill, and applied to motivational interviewing, supporting of basic psychological needs, problem solving, progress monitoring, managing setbacks, and action plan creation. The complete description of the fidelity tool, scoring, and interpretation of scores is available as Item A in the appendices.

Skills were assessed on a per-session basis where relevant. Action plans were also reviewed for content, quality (adherence to SMART principles) and suitability for improving participant physical function. Additionally, these action plans were independently rated by a third-party who was not a member of the study team. The researcher also self-rated 33.3% of action planning sessions for proper utilisation of all the relevant skills (e.g. whether participant autonomy was supported). The same third of the motivational interviews were audio-recorded and checked for quality of delivery by an expert member of the study team (CG) using the same checklist. A third of the phone calls were also self-rated by the investigator immediately after delivery on checklists for the usage of problem solving, progress monitoring, and setback managing skills.

3.13. Statistics and data analysis

3.13.1. Sample size calculation

A power calculation demonstrated that a sample size of 44 is enough to allow estimation of the retention rate of a future clinical trial with 95% confidence intervals of +/- 11%, given an expected retention rate of 80%. For this reason, this study aimed to recruit 45 participants, with 30 randomised to the intervention group and 15 to the usual care group. This sample size was also consistent with advice from clinicians about expected uptake rate, and sample sizes used in prior feasibility studies to reduce sedentariness in older adults (Aunger, Doody and Greig, 2018). This sample was to be recruited over a 12-month period.

3.13.2. Planned recruitment rate

Participants were informed of the study as they were listed for surgery at the RHH. The recruitment rate was dependent on the number of participants listed for surgery, the proportion who were invited and their rate of uptake of the study invite. We aimed to recruit 45 participants over the course of 12 months, which meant a required recruitment rate of at least 6 participants/month.

3.13.3. Statistical analysis plan

All data were entered from case report forms into a database programme. Questionnaires were scored according to designer's instructions, qualitative data were transcribed either into Microsoft Word of Excel and loaded into NViVo 12 for analysis. For analysis, the SPSS version 24.0 (IBM Corp.) was used and analyses were conducted by the Chief Investigator (CI). Analyses were performed on a complete case analysis basis, as missing data at post-surgery was >50%, meaning imputation could not be reliably performed (Jakobsen *et al.*, 2017). Quantitative feasibility variables are reported in table 8.

The feasibility questionnaires which assess acceptability, practicality, satisfaction, and safety of the intervention used Likert scales and other modes of quantitative response. There were also qualitative elements arising from semi-open questions.

3.13.4. Primary outcome analysis

The primary outcome for this study was feasibility of study delivery. Quantitative assessment of the various elements comprising study feasibility are shown in table 8.

Quantitative Variables:

Table 8. Statistical analysis of primary quantitative feasibility outcomes.

Variable	Type	Reporting method	Statistical test
Study Uptake Rate	Percentage	%	N/A
Recruitment Rates	Participants/month	N/mth	Mean and SD
Intervention Adherence (goal adherence in experimental group)	Score 1-5 (mean of all weeks assessed)	Score 1-5; %	Mean and SD; N/A
Percentage of participants whose surgery is scheduled 2 weeks prior to the end of the intervention	Percentage	%	N/A
Percentage of participants whose surgery is scheduled up to three weeks after the end of the intervention	Percentage	%	N/A
Percentage of participants whose surgery is cancelled or delayed for too long	Percentage	%	N/A
Retention rates (% of participants making it from baseline to follow-up)	Percentage	%	N/A
Average duration of intervention	Avg. weeks	n	Mean, SD
Session attendance	Avg. proportion of sessions attended	%	N/A

Alpha level = 0.05

3.13.5. Analysis of feasibility data

The mixed methods assessment of feasibility included questionnaires with scales ranging from 1-3 to 1-7, and some open questions. Responses to the closed questions were reported in terms of mean and SD, and narrative analysis was used for the semi-open questions.

Goal adherence data, recorded on the booklet, were summarised for each week using means and SDs. Feasibility questionnaires for Intervention and usual care groups were analysed separately due to each having some different questions.

Qualitative questionnaire data were transcribed verbatim from the relevant booklet pages into Excel and imported into NVivo 12 for inductive thematic analysis (Thomas, 2006). An inductive approach was chosen to capture what emerged as a result of the participants' unique and subjective experiences. Subthemes were subsequently identified that were largely equivalent to two main areas of feasibility according to Bowen *et al*. (2009): practicality and satisfaction.

For the qualitative interview with the research nurse, a deductive, realist form of thematic analysis was chosen, in order to avoid over-simplifying the data and to ensure that all aspects of the recruitment process were captured to ensure future replication and to better inform the design of a future definitive trial (Braun and Clarke, 2006). These data were coded with a deductive, realist perspective, as the researcher had a pre-existing expectation and experience within the recruitment and study processes, and the intent was to focus on the individual level. The deductive process incorporated a familiarisation with the data, verbatim transcription of the interview, generation of initial codes based on this first-pass, then review and refinement of the codes (Braun and Clarke, 2006). Themes were established based on the following questions that the researcher used with the aim of obtaining specific answers from the data relating to practicality, satisfaction, and adaptation, namely:

1. What were the problems that arose during recruitment? (practicality)
2. How could recruitment have been improved? (adaptation)

3. How would such a study scale to another research site or a definitive trial? (adaptation)
4. What were the positive aspects of the design of the INTEREST feasibility study? (satisfaction)

These main questions guided both the construction of the interview topic guide, and the deductive thematic analysis. Subthemes were identified inductively as they became evident within the data.

Additionally, goals that were set were recorded and coded into different categories for analysis, along with comments made and recorded within the booklet in the goal adherence section. These goals were qualitatively coded using a mix of deductive and inductive strategies. Initially, a first pass was made to inform the development of a higher-order matrix of themes focused around common behaviours and modification types. This matrix was subsequently refined during the coding process as more novel categories emerged from the data. The themes and subthemes were tested for inter-coder reliability by providing the files to an independent coder for assessment.

3.13.6. Exploratory analysis of outcomes for use in the definitive trial

Exploratory analysis of efficacy-related variables used independent T-tests performed on the differences of measures taken only at baseline and pre-surgery and 2x3 ANOVAs for the data taken at all timepoints to estimate between-groups differences. Within-group differences were also tested for, using paired t-tests for variables where differences were normally distributed, and no outliers were present (as assessed using the Shapiro-Wilk test where $p>0.05$). Within group comparisons were performed using Wilcoxon Signed-Rank Tests where differences were not normally distributed. If differences between timepoints were not symmetrical according to visual inspection of a histogram, then the Sign rank test was again used. All tests were performed with an alpha level of 0.05 in IBM SPSS Statistics 25.0. For Wilcoxon Signed-Rank Tests, the distribution of difference scores was approximately symmetrically distributed, checked using a histogram with a superimposed normal curve. Bonferroni adjustments were not conducted due to the small sample size and potential for over-conservatism leading to type II error (Nakagawa, 2004). For within and between-group analyses, thirty

out of thirty-five participants were included in the analysis (all those that had at least some data present at both baseline and pre-surgery). All 35 are included in the baseline data analysis.

For independent T-tests, difference variables were calculated according to "[Pre-Surgery Variable Value] minus [Baseline Variable Value]". The independent t-tests were performed upon this difference variable with group as the factor variable where data were normally distributed as assessed by a Shapiro-Wilk test ($p>0.05$). Where data were not normal, Independent t-tests were still performed as they are robust to violations of normality, however, these violations were reported in the text in the results chapter (Sawilowsky and Blair, 1992). Statistical significance was reported with equal variances assumed where Levene's test reports $p>0.05$, and Welch's T-Test values were used where equal variance assumption was violated.

Two-way mixed ANOVAs (2x group, 2x time) were also performed on a subset of these variables; however, as they both require satisfaction of more assumptions and produced identical *p*-values, Independent t-tests were used and reported instead.

3.14. Ethical considerations

This study was intended to reduce sitting time and was not expected to expose participants to any undue harm. The highest-risk procedure in the study was the blood sampling, which is already a part of regular orthopaedic care. Additionally, it was possible that increased standing and moving around could have predisposed people to having a fall. Overall, the study was deemed to be low risk by clinician members of the study team. Adverse events were recorded and are reported in the results section.

3.14.1. Ethical approval and amendment history

A favourable ethical opinion was obtained from the Solihull Research Ethics Committee in November 2017 (research ethics committee ref. number 17/WM/0371 and IRAS ID 228033), and the study was given approval by Dudley NHS Research and Development to begin on the 29th of January 2018.

CHAPTER 4: RESULTS

Submitted as "Aunger, J.A., Greaves, C.J., Davis, E.T., Asamane E.A. and Greig, C.A., 2019. A novel behavioural INTErvention to REduce Sitting Time in older adults undergoing orthopaedic surgery (INTEREST): results of a randomised controlled feasibility study. *Aging Clinical and Experimental Research."*

4.1. Summary

Thirty-five participants aged 60 years and over waiting for hip or knee replacements were recruited a mean of 8-weeks prior to surgery. Randomisation allocated 24 participants into the intervention group and 11 into usual care. The study was found to be feasible with some modifications and was negatively affected only by unpredictable surgery scheduling. Suggestions were given by participants and research nurses to improve study processes. Within-group comparisons found that the intervention group significantly improved their physical function (SPPB) score by 0.71 (p=0.032) points, a clinically significant increase, compared to 0.38 (p=0.504) points in the usual care group. Additionally, the intervention group non-significantly reduced mean sedentary time by up to 66 $min.d^{-1}$ in those retained to post-surgery. This study has found that it is feasible to intervene to reduce sedentary time in this older surgical population with mobility limitations, and may have potential to improve physical function by displacing sedentary time to other forms of activity. Future trials should further assess the effect of reducing sedentary time on health in mobility limited older adults.

4.2. Structure

This thesis and chapter is structured to address the aims of the study in the following sections:

Aim		Section
a)	Estimate variance in outcome measures	4.3., 4.9., Appendix F.
b)	Test the feasibility of study processes through quantitative means, by assessing retention rates, recruitment rates, and adherence to the study	4.4.
c)	Assess feasibility of delivering outcome measures	Appendix F.3.
d)	Test the feasibility/acceptability (to patients) of delivering the INTEREST intervention	4.5. - 4.6.
e)	Test the feasibility of recruitment via research nurses	4.7., Appendix G.
f)	Assess feasibility against criteria for progression to a definitive trial	4.14.
g)	Assess intervention fidelity	4.10.
h)	Analyse content of action plans	Appendix. H.

4.3. Baseline participant characteristics

A total of 35 participants were recruited, comprising 20 women and 15 men, of whom 17 were hip and 18 were knee patients. This sample size is consistent with the median for feasibility studies conducted in the UK (Billingham, Whitehead and Julious, 2013). Data are presented as mean (SD). All participants were 64 years or older with a mean age of 73.1 (SD 5.8) years. They were almost all British-white, with one participant of Pakistani origin. The mean BMI was 30.7 (4.15) $kg.m^{-2}$, above the threshold for obesity, and the median number of medical conditions was three, indicating a high prevalence of multimorbidity. In addition, the mean waist-to-hip ratio (WHR) was 0.92 (SD 0.11), which is above the 0.9 cut-off for abdominal obesity in men (and 0.85 for women). The sample was diverse in terms of physical function, with the Short Physical Performance Battery (SPPB) score ranging from 2-12, with a mean of 6.9 (SD 2.9), indicating the presence of mobility limitation in most of the sample. Twenty-nine participants (82.8%) scored <10, which is indicative of one or more mobility limitations and an increased risk of mortality (Guralnik *et al.*, 1994). The mean Oxford Hip/Knee score (scoring range 0-48, lower number indicates worse function) including both groups was 20.0 (SD 8.0), which is indicative

of severe arthritis that requires surgical intervention (Dawson, Fitzpatrick and Carr, 1996; Dawson *et al.*, 1998).

In terms of objectively measured physical activity and sedentary time, 32 (91.4%) individuals had at least three days of valid measurements at baseline. Mean (SD) sedentary time (consisting of a computed variable comprising both sitting and non-sleeping lying time, in line with the definition of sedentary behaviour) was 590.18 (113.91) $min.d^{-1}$ (9.84 $hr.day^{-1}$); standing time was 257.03 (100.49) $min.d^{-1}$ (4.28 $hr.d^{-1}$), stepping time was 72.26 (40.42) $min.d^{-1}$ with mean steps per day at 5088 (3374), sleeping time was 519.16 (98.79) $min.d^{-1}$ (8.65 $hr.d^{-1}$), and mean sit-to-stand transitions were 39.5 (15.4) per day. Mean time spent in sitting bouts >30 mins/day was 317.18 (144.04) $min.d^{-1}$, and mean time spent in sitting bouts >60 mins/day was 175.11 (138.16) $min.d^{-1}$. In comparison with data from 'healthy' older adults ≥60 yrs (n=30, mean age 71.7 (SD 6.5)), a similar intervention study using ActivPal3s found that they spent 534.1 (114.1) $min.d^{-1}$ in sedentary time, indicating that the sample in INTEREST is more sedentary (Lewis *et al.*, 2016). Subjective data from the Measure of Older Adults' (MOST) sitting time questionnaire (35) produced a mean of 8.85 (2.9) hours for sitting per day. A Pearson's correlation was performed to compare MOST data to the objective ActivPal data. A scatterplot indicated a linear relationship between variables with both normally distributed, as assessed by Shapiro-Wilk's test (p>0.05) and there were no outliers. There was no association in 32 participants between the two variables (r=-0.062, p=0.735, n=32). Self-reported International Physical Questionnaire Short-Form (IPAQ-SF) walking data reported an average of 62.7 (85.5) $min.d^{-1}$ of walking. There was no correlation between these data and objective measurement of stepping time (r=0.062, p=0.735, n=32). Statistical hypothesis testing for significant differences between groups at baseline was not performed as it is evident that any differences that may be present could be due to chance (Altman, 1985; Elkins, 2015).

Baseline characteristics are summarised in Table 9. Data are expressed in terms of mean (SD), or *N* (%). Data relating to physical function, physical activity, cardiometabolic biomarkers, and sedentary time are presented in the exploratory analysis of outcomes section.

Table 9. Baseline characteristics of sample.

Variable		**Intervention (n=24)**	**Usual Care (n=11)**
Age	Mean (SD)	73.25 (5.55)	72.91 (6.54)
Surgery Type	Knee, *n (%)*	13 (54.2)	5 (45.5)
	Hip, *n (%)*	11 (45.8)	6 (54.5)
Sex	Men, *n (%)*	10 (41.7)	5 (45.5)
	Women, *n (%)*	14 (58.3)	6 (54.5)
Marital Status	Married, *n (%)*	15 (62.5)	10 (90.9)
	Separated, *n (%)*	4 (16.7)	1 (9.1)
	Widowed, *n (%)*	5 (20.8)	0 (0)
Education	Primary, *n (%)*	0 (0)	1 (9.1)
	Secondary, *n (%)*	18 (75.00)	8 (72.7)
	University, *n (%)*	5 (20.8)	2 (18.2)
	Post-graduate, *n (%)*	1 (4.2)	0 (0)
Living Status	Alone, *n (%)*	7 (29.2)	2 (18.2)
	Not Alone, *n (%)*	17 (70.8)	9 (81.8)
Housing Type	Privately-Owned, *n (%)*	21 (87.5)	10 (90.9)
	Family-Owned, *n (%)*	1 (4.2)	0 (0)
	Public Rental, *n (%)*	2 (8.3)	0 (0)
	Sheltered Housing, *n (%)*	0 (0)	1 (0)
Pets	No Pets, *n (%)*	16 (66.7)	6 (54.5)
	Dog(s), *n (%)*	2 (8.3)	2 (18.2)
	Other Pet(s), *n (%)*	6 (25)	3 (27.3)
Drinking	Yes, *n (%)*	11 (45.8)	6 (54.5)
	No, *n (%)*	13 (54.2)	5 (45.5)
Smoking	Yes, *n (%)*	1 (4.2)	0 (0)
	No, *n (%)*	23 (95.8)	11 (100)
Former Smoking	Yes, *n (%)*	9 (37.5)	6 (54.5)
	No, *n (%)*	15 (62.5)	5 (45.5)
School Years	Mean (SD)	11.5 (2.27)	11.36 (1.5)
Weight (kg)	Mean (SD)	83.89 (12.82)	83.29 (16.46)
Medical Conditions	Mean (SD)	3.13 (1.48)	3.73 (1.74)
BMI (kg/m^2)	Mean (SD)	31.00 (4.36)	30.03 (3.76)
Waist-to-Hip Ratio	Mean (SD)	0.92 (0.11)	0.92 (0.13)
KATZ Activities of Daily Living (0-6)	Mean (SD)	5.62 (0.71)	5.00 (1.18)
Mini Nutritional Assessment (0-14)	Mean (SD)	12.08 (2.36)	12.27 (1.9)

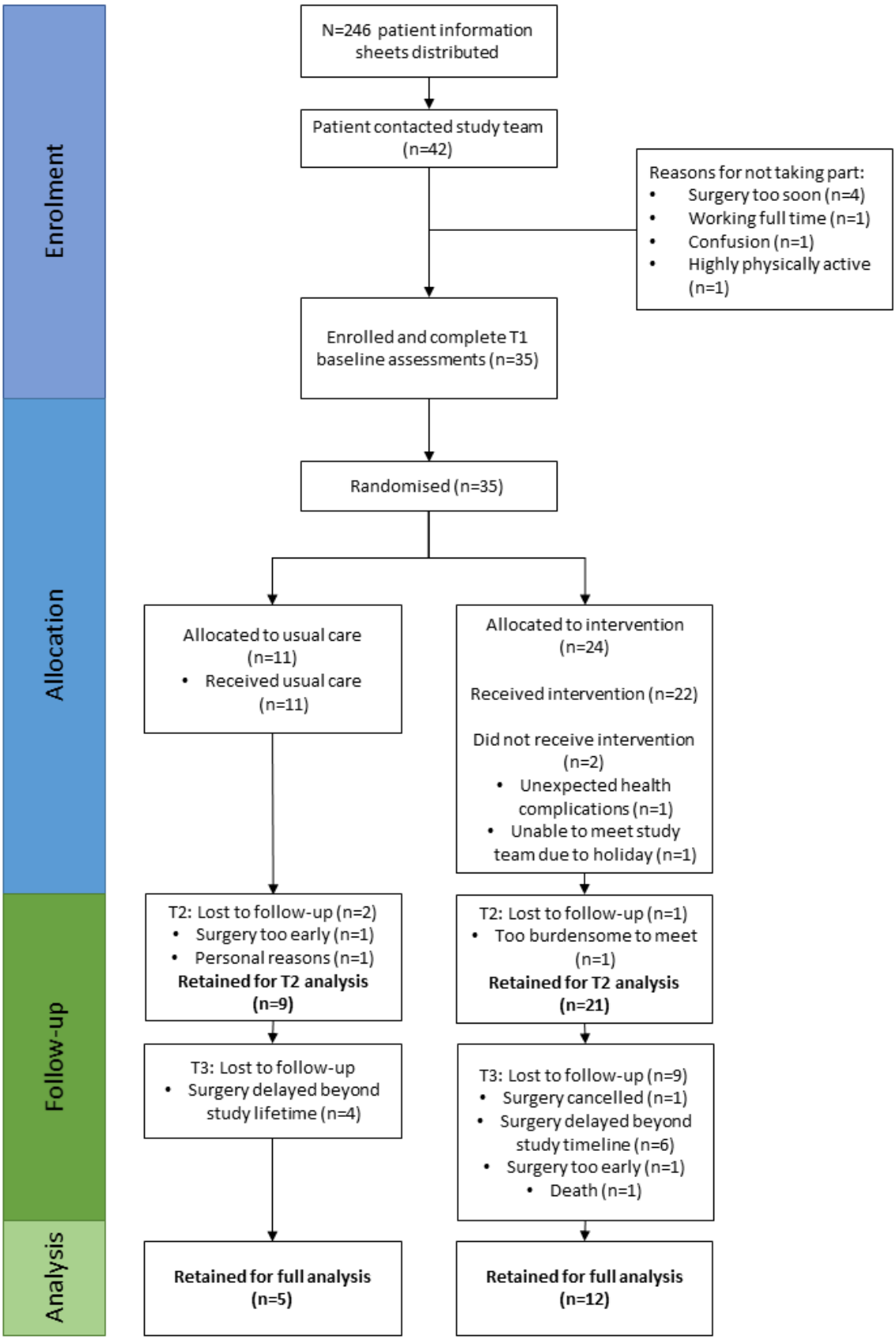

Figure 23. Consort 2010 Participant Flow Diagram (Schulz, Altman and Moher, 2010).

4.4. Feasibility – study statistics

4.4.1. Recruitment and uptake rate

Recruitment began on the 29th January 2018 and ceased on the 14th January 2019; study assessments continued until the 16th April 2019. Thirty-five participants were recruited over this period with a mean recruitment rate of 2.99 (2.52) participants per month (figure 24). Over this time period, 246 participant information sheets were sent to potential participants, yielding an uptake rate of 14.2% (95% CI, 10.2% to 19.4%) (figure 24). Twenty-four participants (68.6%) were allocated to the intervention group, and eleven to the usual care group (31.4%). A total of 112 visits were conducted by the primary researcher in the period Mar 2018 – Apr 2019 inclusive, 111 of which occurred at participants' own homes.

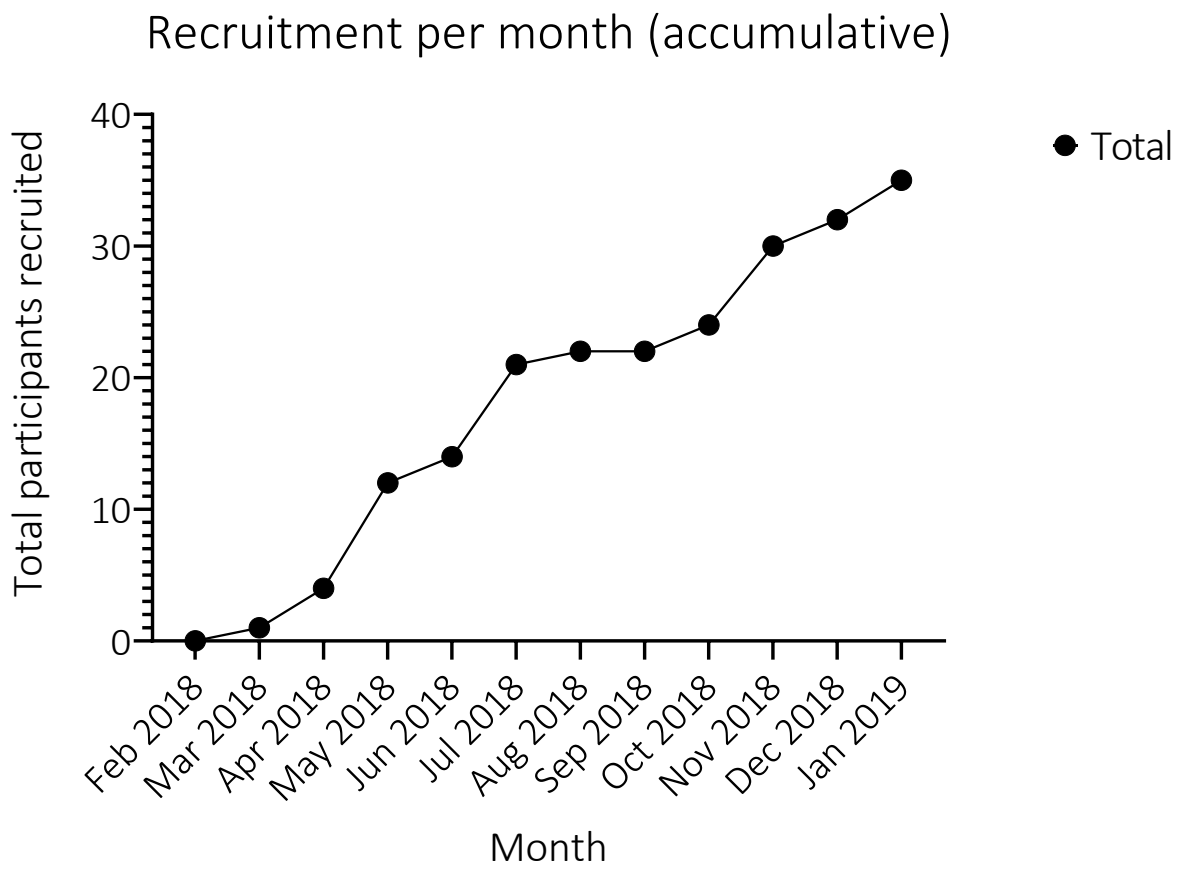

Figure 24. Recruitment over time.

4.4.2. Intervention duration

The scheduling of surgeries caused intervention duration to vary. The researcher was told the month in which the surgery was likely to take place, but only 10 patients (28.57% of total) had surgery within the month that was indicated to the research team prior to recruitment.

The mean duration (time between intervention delivery visit (2/3) and visit 4) was 59.76 (32.43) days, which was almost ideal for the planned 8-week intervention time. However, the minimum amount of days was 11, and the maximum 119, which reflects the range of deviation from the expected surgery date. This may also not be reflective of the final time to surgery, as in 10 cases, visit 4 was conducted without any expectation of the possibility of follow-up, because surgeries were delayed beyond the lifetime of the study.

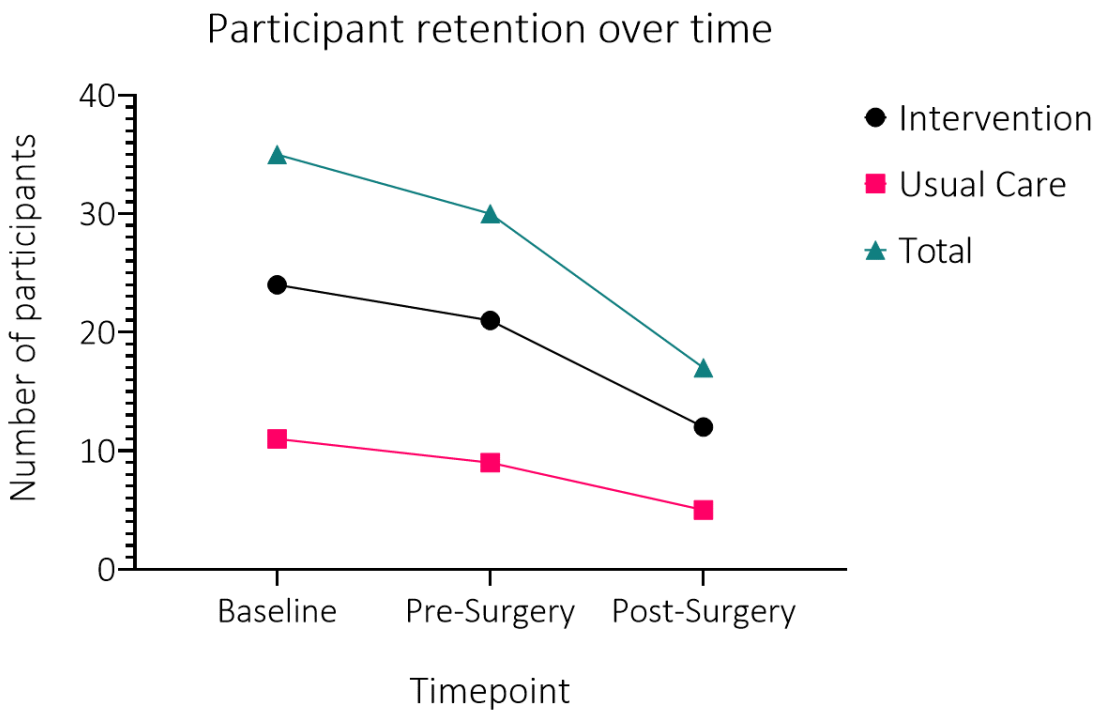

Figure 25. Retention to study stratified by group and total.

4.4.3. Goal adherence

Out of 21 participants in the intervention group that attended the pre-surgery visit, 16 (76.2%) (Visit 4) entered information in the adherence section in the sedentary behaviour booklet given to participants as part of the intervention. Of these, there was an 87.95% completion rate for goal adherence. This shortfall was due either to non-reporting (50% of missing data) or illegibility (50%). Completion rate when zeros were coded for the other five complete non-responders (i.e. intention-to-treat analysis) was 55.78%. For the entries where data were provided, the overall mean of the per-participant average weekly goal adherence was 3.92 (0.65) out of a maximum of 5.

The completion rate for environmental modification adherence recording was lower, with only 52.38% of entries being complete, all due to non-reporting. Completion rate when zeros were coded for complete non-responders was 16.67%. For adherence where data were provided, the overall mean of the per-participant average was 4.16 (0.67) out of 5.

4.4.3.1. Achievement of step targets

As part of the intervention, nineteen participants formulated goals to improve their step counts as part of their action plans, and also provided a follow-up ActivPal measurement at the pre-surgical timepoint (Visit 4) (figure 26).

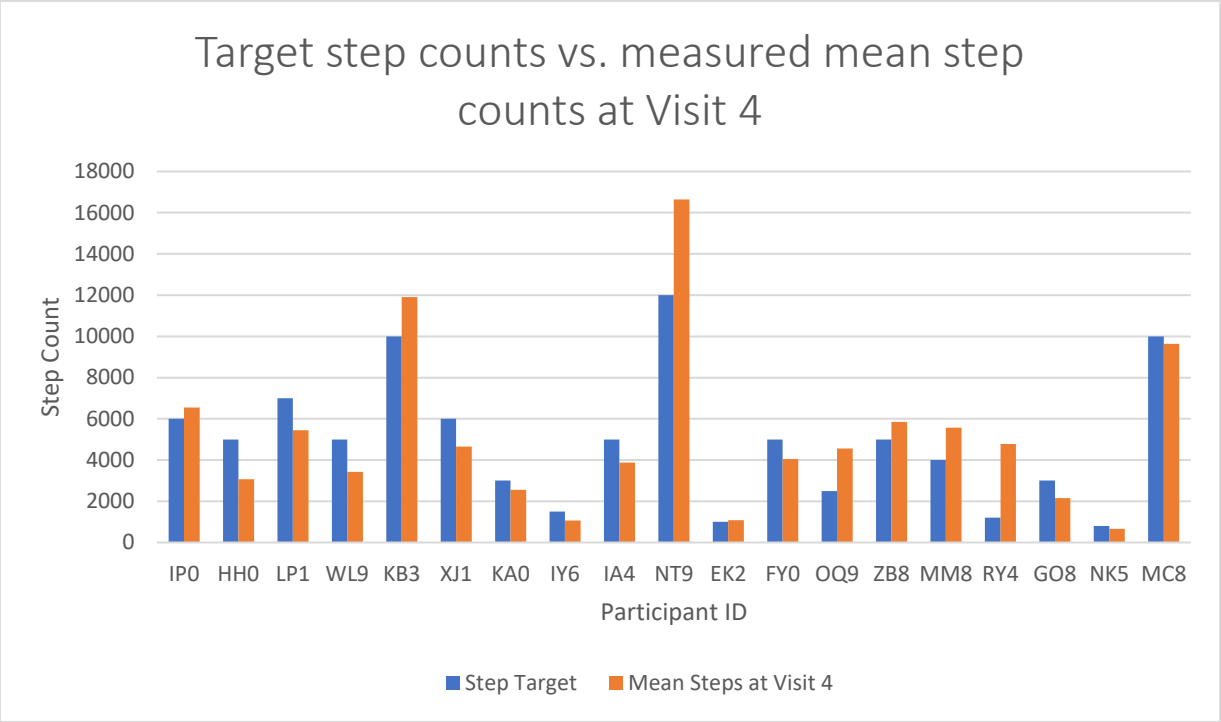

Figure 26. Step count targets set during intervention, versus mean daily step counts measured at pre-surgery (Visit 4).

Eight (42.1%) achieved or exceeded their step targets. This indicates low adherence to the step count targets; however, the close mirroring of the variables suggests that the step targets, based on measurements at Baseline, were realistic for almost all the participants at Visit 4 (figure 26).

4.4.4. Overall feasibility statistics

Table 10 displays the study statistics relevant to an assessment of feasibility. The significant rate of attrition between Visit 4 and Visit 5 (post-surgical follow-up) was mostly due to significant delays to the scheduled time of surgery (n=10 of 13 lost between Visit 4 and Visit 5) (table 10, figure 26), rather than unwillingness of participants to attend subsequent visits.

Table 10. Overall feasibility statistics. Data are mean (SD), or %.

Statistic	Value
Study uptake rate	14.2% (95% CI, 10.2% to 19.4%)
Recruitment rate	2.99 (2.56) participants per month
Intervention adherence	Goal data completion: 55.78% Environmental modification completion: 16.67% Mean goal adherence (where complete): 3.92 (0.65) out of 5 Mean environmental modification adherence (where complete): 4.16 (0.67) out of 5
Percentage of participants whose surgery occurred eight or more weeks after visit 3 (or visit 1 in Usual Care)	66.7%
Percentage of participants whose surgery was scheduled four or fewer weeks after visit 3 (or visit 1 in Usual Care)	16.7%
Percentage of participants with indefinitely delayed or cancelled surgery	31.4%
Retention rates	85.7% (95% CI, 69.0% to 94.6%) at Visit 4, 48.6% (95% CI, 31.7% to 65.7%) at Visit 5
Mean duration of intervention	Intervention: 8.54 weeks (59.76 (8.54) days) Usual Care: 16.46 weeks (115.22 (68.23) days)
Session attendance	100%

In cases where surgeries were obviously delayed, the pre-surgery visit (visit 4) was performed and follow-up (visit 5) was cancelled.

4.5. Feasibility - qualitative

4.5.1. Qualitative analysis of open-ended adherence comments

A total of 16 participants providing adherence data in the sedentary behaviour booklet also provided qualitative data in the "comments" sections next to the quantitative adherence rating. These varied in length from short phrases or sentences, to entire paragraphs of text. A sample page is shown in Appendix B. The comments provided reflections and reasoning for the quantitative assessments underlying the participants' goal and environmental modification adherence, as well as an understanding of the practical issues that faced participants in the intervention group.

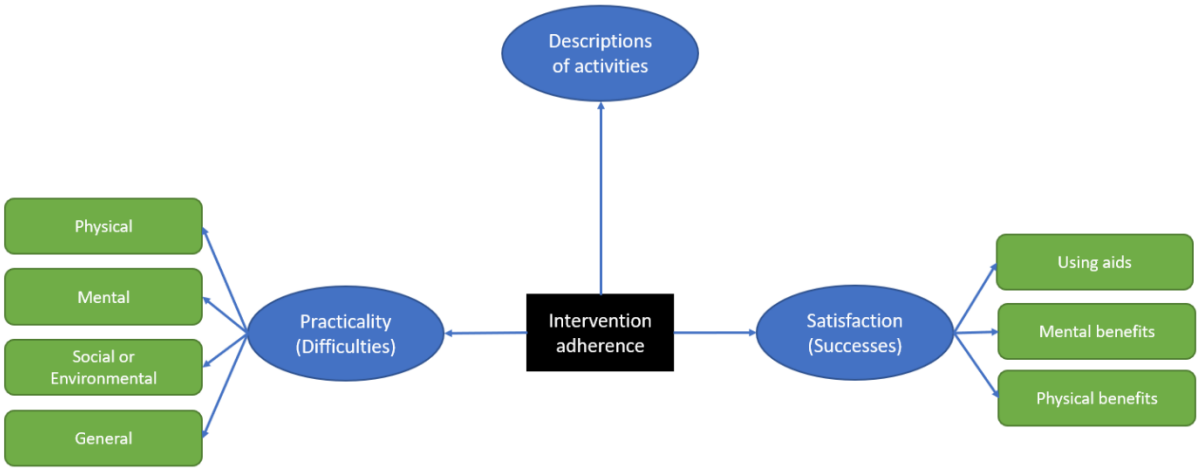

Figure 27. Schema depicting themes and subthemes present in qualitative analysis of participant comments regarding intervention adherence.

4.5.1.1. Analysis

After a first pass of the transcripts, three main themes were identified in the comments: difficulties, successes, and descriptions of activities (figure 27). Difficulties and successes were mapped to practicality and satisfaction respectively. The theme of difficulties included common occurrences that constituted a setback or barrier to achievement of goals; successes included comments regarding perceived benefits to physical or mental health, improvements to motivation, and aids that participants used in achievement of goals they had set; and descriptions of activities included strategies, ideas, and reported behaviours in relation to achieving goals. Figure 28 depicts the number of codes for each difficulty identified by participants.

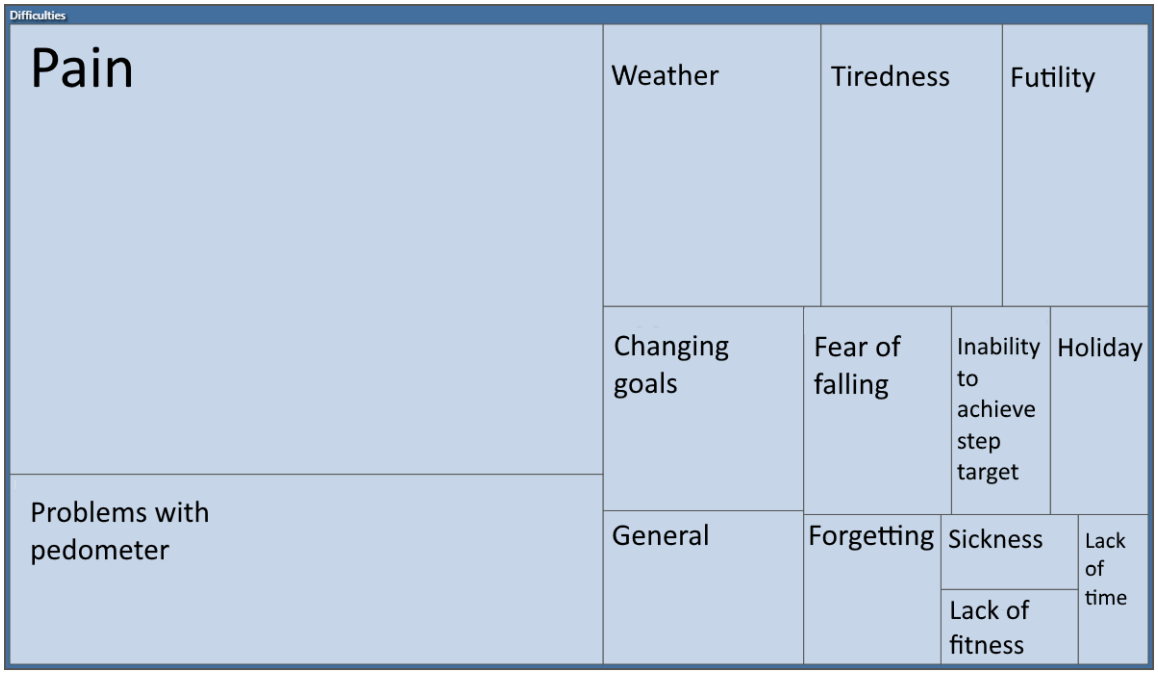

Figure 28. Hierarchy chart displaying the most common difficulties put forward by participants. Size of the boxes represents number of codes.

4.5.1.1.1. Practicality (difficulties)

Present in this category were physical, mental, social and environmental, and general subthemes.

Physical difficulties. The largest subtheme within difficulties was pain, comprising 28.3% of total codes. Participants frequently cited pain as the primary barrier to achieving their goals, with 10 out of 16 reporting pain-related problems. Often, participants related it directly to trying to achieve their goals:

> *"I have done this goal for 3 days but found the extra walk led to extra pain" (woman, 68 y, hip replacement)*

> *"Friday night after Rome unable to sleep due to pain – both knees and hip and lower back" (woman, 79 y, knee replacement – after walking on holiday)*

> *"Went shopping on Thursday. I did 1379 steps, but on Friday my hip and knees were aching more" (woman, 71 y, hip replacement)*

Four participants mentioned strategies that could allow them to achieve their goals whilst avoiding some of the resulting additional pain:

> *"Walking not so far, but more often, seemed to be better" (man, 67 y, hip replacement)*

> *"Struggling with discomfort on walking, finding back pain is increasing, but increased painkiller and plodding onwards" (woman, 67 y, knee replacement)*

Additionally, three participants reported that tiredness and lack of physical fitness were something they needed to overcome.

> *"Don't see how I can reach 3000 steps. Met many goals but not gardening, felt very tired if I did all 6 goals" (woman, 81 y, hip replacement)*

> *"Breathlessness an issue when using slight inclines" (woman, 67 y, knee replacement)*

Environmental and social difficulties. The next most common barrier preventing goal achievement was weather. Five participants cited hot, cold, and rainy weather as preventing them from achieving their walking:

> *"Weather too hot for walking" (man, 79 y, hip replacement)*

> *"Very hard to go into garden in wet. Think of alternative" (woman, 81 y, hip replacement)*

> *"When weather is bad this [goal] is not done, but OK when dry" (woman, 74 y, knee replacement)*

Other subthemes were identified on the same level as physical, and environmental and social difficulties subthemes, namely: going on holiday, forgetfulness, a sense of futility or pointlessness to certain goals, fear of falling, and lack of time.

General issues. Another common area of difficulty included problems with the pedometer, the model of which, unfortunately, did not seem to be well-suited to individuals with severe mobility limitations who are not able to walk at pace. Six participants reported issues with the pedometer on this form:

> *"I now think my shuffling steps do not register - so I am not sitting but not recording movement either" (woman, 81 y, hip replacement)*

> *"Been counting my steps walking around but step counter does not pick up every step" (woman, 71 y, hip replacement)*

However, some more technologically minded participants were able to use other solutions to more effectively self-monitor their steps:

> *"Pedometer didn't operate effectively, spoke to [the researcher] and downloaded [a] health app on [my] mobile" (woman, 67 y, knee replacement)*

4.5.1.1.2. Satisfaction (successes)

Physical benefits. Although participants predominantly focused on what stopped them from reaching their goals, they also commented on benefits attained from engaging with the intervention:

> *"Weight loss is continuing very well which does have an impact". "Overall I feel my physical activity is well improved and I feel better for it, have control over pain" (woman, 67 y, knee replacement)*

Mental benefits. Mental benefits were also reported, specifically with motivation and additional self-control:

"Feel I have improved and mentally more aware of the benefits after exercise."

"Not always 100% happy with results but use it as a motivation" (woman, 67 y, knee replacement)

"Difficult to start, but now motivated" (man, 69 y, knee replacement)

"In pain a lot of the week. Have had to cut walks due to pain but feel better for the movement" (man, 67 y, hip replacement)

4.5.1.2. Adherence conclusions

Overall, activity goal and environmental modification adherence means were above 3.9 (out of 5) for both metrics, indicative of good adherence and this was borne out by close mapping of objectively-recorded measures of adherence to step targets. Participants reported their adherence was affected mainly by pain, the weather, and problems with the provided pedometers. To avoid pain while still achieving their goals, some participants used pro-active coping strategies such as increasing painkillers and using sticks. Management of pain and additional fatigue seem to be the main barriers to reducing sedentary time in this population of older adults with osteoarthritis; these are factors that would likely not affect interventions in otherwise healthy older adults. However, when goals were achieved, this conferred a potentially motivational perception of physical and mental benefits to the participants.

4.5.3. Feasibility - questionnaire (qualitative)

Feasibility data were coded using deductive, realist thematic analysis (Braun, Clarke and Weate, 2016). Highest-order themes were pre-specified according to feasibility criteria specified in the protocol and informed by Bowen *et al*. (2009), namely: acceptability, adaptation, practicality, safety, and satisfaction and feedback (figure 29). However, subthemes were inductively created based on patterns within the responses by the participants during the familiarisation process, comprising a first-pass of the data, followed by review and refinement of these codes (Braun and Clarke, 2006). Data are presented per-theme and highlighted where there were differences between groups and timepoints.

Figure 29. Schema depicting themes and primary sub-themes arising from thematic qualitative analysis of feasibility questionnaire data.

4.5.3.1. Questionnaire items stratified by feasibility elements

All questions on the questionnaire were intended by design to correspond to different feasibility themes. However, some participants wrote answers to some questions that did not fit into the intended theme for the question and thus were coded to another theme instead. Table 11, following, depicts the overall planned areas covered by each of the questionnaire questions at each time point.

Table 11. Questionnaire feasibility themes.

Feasibility Theme	Question
Pre-Surgery	
Acceptability	1. Which part(s) of the intervention did you find most difficult?
Practicality	2. If you found it burdensome, how could it have been improved? *(both groups)*
Satisfaction	3. Which part(s) of the intervention did you find most enjoyable?
Adaptation	4. Do you have any suggested improvements for the booklet?
	5. Is there anything you would change about the assessments? *(both groups)*
	6. Do you have any suggested improvements for the study?
Safety	7. If you found an aspect of the study more painful or harmful than usual, how? (*both groups*)
Post-Surgery	
Satisfaction/Practicality	1. How have you found the assessments in the study so far (e.g. the questionnaires, physical tests, etc.)? *(both groups)*
Adaptation	2. Do you have any suggested improvements for the study? *(both groups)*
	3. Is there anything you would change about these assessments? (*both groups*)
Safety	4. If you found an aspect of the study more painful or harmful than usual, how? (*both groups*)

4.5.4. Analysis

4.5.4.1. Acceptability

Burden. As reported in the quantitative data regarding burden, overall burden was higher in the intervention group. Only one participant in the usual care group commented at the pre-surgery timepoint that *"due to mental issues"*, partaking in the study was *"too much" (*man*, 67, knee replacement).*

Difficulties. Most participants reported some in achieving the intervention goals. Pain and weather, as seen in the adherence analysis, were common barriers, with participants reporting that *"the pain barrier has to be overridden" (*man*, 87 y, knee replacement),* as well as social responsibilities: "s*ocial responsibilities/commitments and some weather condition interruptions" (wo*man*, 67 y, knee replacement).* There was a wide range in what was purported to cause difficulty, ranging from

"attaining the steps", to *"opening the pedometer"*, as the pedometer had a screen that was difficult to gain access to in individuals with arthritic hands. Others also mentioned that *"the step monitor failed after [2] weeks (so I purchased a monitor)"*, and that *"it did not work with the steps I now take (a slow shuffle). This made keeping the record of steps inaccurate" (wo*man*, 81 y, hip replacement).* These issues suggest that the pedometer was not friendly for the older people in the study who walked at a slower pace.

A number of participants (3) also stated that the chair rises were most difficult, as some formulated goals to do several of these in sequence at certain times of the day. Other specific goals were mentioned as causing difficulty, such as *"standing for breakfast, leaving TV until after 9pm" (wo*man*, 72 y, hip replacement)*, *"remembering to stand up whilst on the phone" (wo*man*, 79 y, knee replacement)*, and *"using the exercise bike" (wo*man*, 68 y, hip replacement).* Certain times of day were also more difficult for some people, with *"evening exercise"* being specified as being difficult, due to fatigue and a desire to relax in the evening.

Others reported mental aspects being the most difficult to contend with, reporting *"more self-discipline and better weather"* would have improved things for them, or simply that *"motivation"* in general was the most difficult aspect of the study for them.

Pain on exercising was a further barrier for many participants:

> *"My right knee became much worse so I had to rest for a few days on advice from my doctor" (woman, 66 y, knee replacement)*

Another found that implementing their goals led to greater pain:

> *"I found taking the dog for an extra walk made my pain worse, as did using the exercise bike" (woman, 68 y, hip replacement)*

One participant mentioned that, in relation to pain, "*evening activity is worst to achieve*" (man, 74 y, knee replacement).

4.5.4.2. Practicality

Decline in physical function. One participant mentioned that from baseline to pre-surgery, *"getting up from chairs/toilet became progressively more difficult" (wo*man*, 79 y, knee replacement)*. This may be because some participants were increasingly feeling the impact of arthritis over time or many other reasons.

Health complications. Five participants in the intervention group mentioned other health conditions as well as consequences of the operation that had affected achievement of their goals. One mentioned the following after surgery:

> *"I have not achieved all my goals since surgery because I have quite severe oedema. My doctor is investigating - apparently I am anaemic and have low levels of protein in the blood. I also have problems with low blood pressure." (woman, 79 y, knee replacement).*

Others also had additional joints that still had osteoarthritis (other than the one to be operated on during the study) that also needed to be replaced, which affected them both in pre-surgery and post-surgery phases:

> *"I am waiting to have my other hip replaced which is more problematic, so cannot walk without aids" (man, 79 y, hip replacement).*

One participant mentioned that they found the study "*burdensome because of other difficulties I have had with severe shoulder pain due to a tear in my tendon*" *(woman, 73 y, hip replacement).* Another couldn't keep up with the goals of the study due to being "*unwell for two weeks*" *(woman, 74 y, knee replacement)*.

Health issues arose during the study that also affected goal achievement, which should have led to greater action by the researcher to alter their goals. One participant mentioned that *"because of my other health issues I found my goals should have been changed half way through"* and said that it was difficult *"keeping to the goals first set due to my other health issues" (woman, 73 y, hip replacement)*. This indicates that in some cases, goals should have been adapted//refined following review of progress but were not.

4.5.4.3. Satisfaction and feedback with the study procedures

Assessments. For assessments, participants mentioned that they "*find questions difficult*" and that they had "*lots of repetitiveness*", and that "*questions [were] sometimes ambiguous and could be answered in many ways depending on one's interpretation*" *(woman, 67 y, knee replacement).* Additionally, one mentioned that the physical tests were not so applicable to the daily life of older people, and that "*it would be good to have a wider range of physical tests, e.g. put in some housework and general activity tests*" *(woman, 81 y, hip replacement).* However, overall, there were more positive comments than negative. One individual had a number of comments to make about the assessments:

> *"i) Designed to promote self-awareness. Ii) Responsibility for promotion of self-betterment. Iii) Encouraging. Iv) Hopefully promote academic success" (man, 70 y, hip replacement)*

Some people enjoyed the psychological aspects of the assessments, as they made them self-reflect, and *"found them interesting and achievable" (woman, 68 y, hip replacement)*. However, the following comment was from an individual in the usual care group:

> *"Made me think how much time I sit. Been very useful. Felt very relaxed with the study" (woman, 69 y, knee replacement)*

This comment suggests that, even in the usual care group, the additional self-reflection caused by the assessments alone could have the potential to go on to affect behaviour.

Dissatisfaction. One participant was unhappy with being in the usual care group and *"would have preferred to be more 'active'" (man, 70 y, hip replacement).*

Enjoyable Aspects. There was great variation in what participants found enjoyable about the study. Many participants mentioned mental benefits, such as increasing awareness and self-reflection in terms of being *"more aware of activity levels" (man, 73 y, knee replacement)* or that it gave *"confidence in achievement, helped me concentrate on doing more" (man, 79 y, hip replacement).* According to another, it also enhanced *"natural daily activity and being conscient of movement – more focus and awareness" (woman, 81 y, hip replacement)*. In some, it helped them realise for the first time the importance of physical fitness:

> *"Changing attitude towards the phrase fitness/activity which I began to realise were different. It was good to find myself 'fitter' rather than chasing being 'active'" (woman, 67 y, knee replacement).*

Participants seemed happy with the goals, and how they provided "*targets to walk towards, e.g. getting up from a sitting position without using hands*" *(woman, 79 y, knee replacement)*. Another mentioned that "*aims set were appropriate to stretch me and motivate me to take a step back and look how I had let my physical side deteriorate. These issues I was able to address*" *(woman, 67 y, knee replacement)*.

A few were also happy with social benefits, whether it was to have the chance to talk to the researcher, saying that *"chatting to the researcher"* was also a benefit of taking part in the study, or with family and friends. Another said that benefits were obtained in the form of *"encouragement from partner and family. Study has provided me with an outlook to discuss with others." (man, 79 y, hip replacement).*

Physical benefits were also mentioned, as well as the positive effect of resulting successes on perceptions of strength, mobility, and general wellbeing. One participant mentioned that their *"legs have become stronger"*, and another that they were *"glad to have achieved the chair rises. Glad to be a bit more active" (woman, 71 y, hip replacement)*. One participant mentioned at post-surgery that "*It has been very helpful considering other operations I have had and time it has taken for recovery" (woman, 74 y, knee replacement)*. One participant felt no need to use their mobility aid any longer:

> *"The fact that a short time into the intervention I was able to walk further and felt much more mobile. I have not used my walking stick once since starting the study - great!" (woman, 68 y, hip replacement).*

Using achievement as a motivation was a common theme, as was reported by these participants:

> *"I found it great taking a look at myself and the achievements I have made (I really enjoyed the pedometer)" (woman, 66 y, knee replacement).*

> *"Initially [the main benefit] was achievement. It became obvious that I was not as active as I thought I was and needed to do more 'physical activity' on a daily basis" (woman, 67 y, knee replacement).*

People also found specific activities particularly enjoyable, rather than any benefits attained. Just as some said *"chair rises"* or the pedometers as the main difficulties, others mentioned them as aspects they enjoyed.

Motivation. Motivation was also mentioned as being positively affected. One participant mentioned that it *"gave me motivation to look round at myself and to start to get things in order, make changes" (woman, 79 y, hip score)*, and another that it *"purely motivated me to push harder and get overall fitness higher" (woman, 67 y, knee replacement).*

4.5.4.4. Adaptation of the study

Changes to goals. Participants made changes to their goals throughout the study, which they mentioned in the questionnaire. Most common was reducing the step count, specifically *"to make them more achievable" (woman, 74 y, knee replacement)*, and, in another case, to *"stop when it hurts" (man, 67 y, hip replacement)*. One other person wanted to start doing *"sit to stands each day"* of their own volition, suggesting good engagement with the notion of increasing their activity.

Adaptive strategies used to achieve goals. It became evident from responses that participants in the intervention group adopted several strategies in the achievement of their goals, both at pre-surgery (Visit 4) and post-surgery (Visit 5) time points. At Visit 4, participants mentioned, *"when the pain was too severe, I did exercises sitting down, lowering myself to the chair slowly gave less pain" (man, 87 y, knee replacement)*. One participant had a goal of 5 chair rises after every meal, however, they commented that they *"could have done chair rises before meals to avoid indigestion" (woman, 77 y, hip replacement)*. Further participants used different strategies to achieve the purpose of their goals. In one case, they mentioned that *"[keeping the] TV remote [far away] was not done, but used timer instead" (woman, 77 y, hip replacement)*, thus still prompting themselves to stand up whilst watching TV. At Visit 5, a participant mentioned that they *"should have used the pedometer more because it helped me to walk more" (man, 73 y, knee replacement)*, indicating that they regretted not keeping up with it since surgery.

Suggestions for the study. Participants mainly had suggestions for the assessments in the study and the booklet (other than issues with the pedometers, mentioned under "difficulties"). For the booklet, participants mostly found it to be good, however, a few mentioned that the "worksheets" section was confusing and needed *"more writing room"* to be able to complete it properly.

4.5.4.5. Safety

Increased risk. One participant mentioned that one of their goals made them afraid of falling, saying that *"[the] target of gardening was not a good choice (too problematic underfoot). Did not feel safe" (woman, 81 y, hip replacement)*. This suggests this goal could have been changed as it was not realistically achievable.

4.5.4. Summary of qualitative feasibility questionnaire data

Qualitative assessment in the feasibility questionnaires covered all key themes of feasibility. In terms of acceptability, participants focused on recording the barriers and difficulties that they encountered, which were generally pain, the weather, specific activities, and problems with the pedometer. For adaptation, it was evident that participants wanted to see a more appropriate pedometer for those with mobility limitations to be used in a future study, as well as better monitoring of goals throughout the study so that they can be more effectively altered as appropriate. Additionally, the booklet could use additional design changes to allow for more writing space and clarity on how to fill out certain elements. With practicality, not too many issues were faced by participants, except for further declines in physical function and other co-morbidities that these patients undergo. For safety, the only concern was that certain activities may present additional risk for falling, particularly on wet ground (e.g. in the garden). With respect to satisfaction and feedback, participants were mostly very satisfied with the study, reporting benefits to physical and mental health, improved motivation, and enhanced self-reflection.

4.6. Feasibility - questionnaire (quantitative)

4.6.1. Pre-surgery (Visit 4)

These data are based on responses to the feasibility questionnaire delivered to participants pre-surgery (post-intervention) at Visit 4. These responses comprise were available for 21 people in the intervention group and nine in the usual care group. Completion rate of these questionnaires was

100% for those attending the visit. Means are reported for questions with 1-5 response scales, and medians reported for questions with 1-3 response scales.

4.6.1.1. Practicality

These questions were all delivered to the intervention group only and assessed practicality.

1. Did you have any problems achieving the goals you set at the beginning of the study? *(scale 1-3: "No problems", "Some problems", or "Many problems").*

a. Most participants answered that they did have at least have "some problems" achieving the goals they set, giving a median score of 2.

2. Did you have any problems achieving the environmental modifications? *(scale 1-3: "No problems", "Some problems", or "Many problems").*

a. Most (52.4%) participants reported having no problems achieving their environmental modifications with a median score of 1. This suggests the modifications were easier to achieve than the goals.

3. How difficult was it to achieve your goals physically? *(scale 1-5, 5 is "very difficult")*

a. This question was asked on a scale of 1-5, where 5 was "very difficult", 3 was "neither easy nor difficult", and 1 was "very easy". The mean answer was 3.29, indicating that participants tended towards answering that goals were difficult to achieve and 42.9% reported achievement being at least "difficult".

4. How easy was it to achieve your goals mentally? *("scale 1-5, 5 is "very difficult")*

a. This question was asked on a scale of 1-5, where 5 was "very difficult", 3 was "neither easy nor difficult", and 1 was "very easy". Participants tended to report that their goals were mentally "quite easy" to achieve, with a mean score of 2.44. Only 14.3% reported it being mentally difficult to achieve their goals. This indicates goals were physically more difficult to achieve than mentally.

5. Did you find the goals to be well-suited to your individual circumstances? *(scale 1-5, 5 is "very well-suited").*

a. This question was on a 1-5 scale, with 5 being "Very well suited", 3 "Neither well-suited nor not well-suited", and 1 being "Very not well-suited". The mean answer was 3.95, which indicates that participants found their action plans to be well-suited in general. Only 9.5% reported their goals being "quite unsuitable".

6. How useful did you find the goal booklet? *(scale 1-5, 5 is "very useful")*

a. This question was on a 1-5 scale, whereby 1 was "not useful at all", 3 was "neither useful nor not useful", and 5 was "very useful". 85.7% of participants reported the booklet being at least "useful", and 42.9% reported it being "very useful". Only 1 participant found it not useful.

7. Could you have changed your goals to make them more achievable? *(yes or no)*

a. Most participants could not have changed their goals to make them more achievable, however, 33.3% reported that they could have changed them. This indicates that for the most part, participants found their goals to be well-suited.

8. How likely are you to continue working towards your goals in the future? *(scale 1-5, 5 is "very likely").*

a. This question was on a 1-5 scale, with 1 being "not likely at all", 3 "neither likely nor not likely", and 5 "very likely". Most participants reported continuing to want to work towards their goals, demonstrated by the mean score of 4.5.

4.6.1.2. Acceptability

The following questions assessed acceptability and were delivered to both intervention and usual

care groups.

1. Have you found taking part in the study burdensome? *(scale 1-5; 5 is most burdensome; both groups)*

a. This question was on a 1-5 scale, with 1 being "not burdensome at all", 3 "neither burdensome nor not burdensome", and 5 "very burdensome. Neither group found the study burdensome, with the median answer in both groups being 1. However, 19.0% of participants in the intervention group responded with a score ≥3 (mean: 1.39), versus 11.1% in the usual care group (mean 1.22). The intervention group also had to commit much more time and effort in changing their daily routines. One participant in the usual care group rated the study a "3", as the questions in the study exacerbated their ongoing mental health problems.

2. Do you feel that taking part in the study has exposed you to more pain? *(scale 1-3, "no pain", "some more pain", "a lot more pain"; both groups)*

a. The intervention group reported greater increases in pain in comparison to the usual care group. The median score in the usual care group was 1, and in the intervention group it was 2. This discrepancy is likely due to the intervention group pushing themselves to engage in more physical activity.

3. How likely would you be to suggest taking part in such a study to friends or family? *(scale 1-5, both groups)*

a. One participant reported a "1" as they did not like to recommend participation in such activities in general. The mean in the usual care group was 4.88, and 4.28 in the intervention group.

4.6.1.3. Satisfaction

The following questions assessed satisfaction. They were delivered in both groups.

1. How do you feel about being randomised into the group you are in in the study? *(scale 1-5, 5 is "very satisfied", both groups).*
a. Both groups were satisfied or very satisfied with being randomised into their respective groups, with means of 4.4 and 4.8 in the intervention and usual care groups respectively.

2. How would you rate your overall satisfaction with the study? *(scale 1-5, 5 is "very satisfied"; both groups)*
a. All participants in both study arms reported a score ≥4 for study satisfaction, with means of 4.5 and 4.9 in the intervention and usual care groups respectively.

4.6.1.4. Safety

The following questions assessed safety in both groups.

1. Do you feel that taking part in the study has exposed you to risk of physical harm? *(scale 1-3; both groups).*
a. Participants did not report that the study exposed them to any risk of physical harm. All participants responded, "no risk".

4.6.2. Post-surgery (visit 5)

These data are based on responses to the feasibility questionnaire delivered to participants 6-weeks post-surgery, during visit 5. There were 12 responses in the intervention group and 5 in the usual care group. Completion rate of these questionnaires was 100%.

4.6.2.1. Practicality

The following questions assessed practicality and were given to the intervention group only.

1. Since you had your surgery, have you been working towards achieving the goals set in the study? *(scale 1-3).*
a. All participants reported working towards their goals at least "a little".

2. Have you continued to achieve your environmental modifications since surgery? *(scale 1-3).*
a. All participants reported achieving their modifications at least "a little" after surgery. The data may suggest that, after surgery, participants kept working towards goals more so than the environmental modifications.

3. Have you continued to use the sedentary behaviour booklet since surgery? *(scale 1-3).*
a. Most participants seemed to use the booklet not at all, or a little, after surgery.

4. How difficult has it been to work towards the goals set earlier in the study in the absence of the phone calls, etc.? *(scale 1-5, 5 is "very difficult").*

a. Most often, participants reported it being “quite easy” to achieve their goals since surgery. No participant reported it being more difficult than “neither difficult nor easy”. The mean was 2.08.

5. Could your goals have been easier to achieve since surgery? *(yes or no)*
a. Only one participant reported that their goals could have been altered to have been easier to achieve after surgery.

6. How likely are you to continue working towards your goals in the future? *(scale 1-5)*
a. All participants reported being at least “likely” to continue to work towards their goals in the future. The mean was 4.7.

4.6.2.2. Acceptability

The following questions assessed acceptability and were in both groups.

1. Have you found taking part in the study burdensome? *(scale 1-5, both groups)*
a. Neither group found the study burdensome at this timepoint, however, the intervention group found the study less burdensome at this time compared to the prior timepoint due to the absence of the frequent phone calls and lifestyle changes in this post-surgery period. The means were 1.08 in the intervention group and 1.00 in the usual care group.

4.6.2.3. Satisfaction

The following questions assessed satisfaction and were in both groups.

1. Do you feel that taking part in the study has influenced your recovery after surgery? *(scale 1-5, 5 is “very positive impact”, both groups)*
a. All participants reported that the study had at least a “positive impact” (a 4 or above) on their recovery after surgery. The mean was 4.5, and the median 4.5 for the intervention group, and 4.25 and 4 respectively for the usual care group.

2. How would you rate your overall satisfaction with the study? *(scale 1-5, both groups)*
a. Satisfaction with the study at the post-surgery timepoint was very high, with all participants rating the study a 4 or 5 out of 5.

3. How likely would you be to suggest taking part in such a study to friends or family? (*scale 1-5, 5 is “very likely”; both groups)*
a. Participants were very likely to recommend taking part in such a study to their friends and family. The mean for the intervention group was 4.58 and for usual care was 4.5.

4.6.2.4. Safety

The following question assessed safety and was only in the usual care group.

1. Do you feel that taking part in the study has exposed you to risk of physical harm? *(scale 1-3, “no risk”, “some risk”, “a lot more risk”).*
a. All participants answered 1, “No risk”, for this question.

4.7. Feasibility of recruitment (interview with RNs)

A single interview was conducted with the primary research nurse assigned to the project in March 2019. A second research nurse was not able to perform significant duties on the study due to an unexpected leave of absence from work, so only one interview was performed. The purpose of the interview was to assess satisfaction, practicality and ideas for adaptation of the recruitment process in INTEREST, from the perspective of the primary deliverer of recruitment. The full analysis is available in Appendix G, however, a summarised version with key messages is presented here.

4.7.1. Results

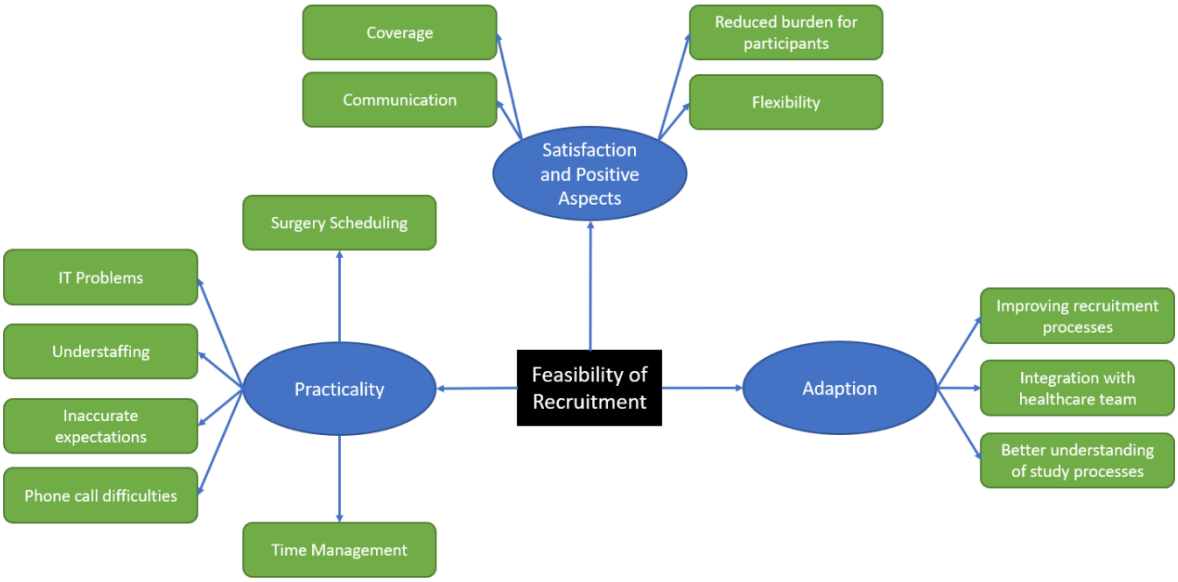

Figure 30. Schema of themes and subthemes relating to the feasibility of recruitment resulting from the qualitative analysis of the interview with the research nurse.

Figure 30 depicts an overall scheme of the themes and subthemes arising from the analyses.

4.7.1.1. Context

The research nurses in this study performed several tasks, including managing most recruitment-related processes, and dealing with communication from the research team regarding surgery scheduling. The recruitment process involved sending out participant information sheets to participants approximately 10-12 weeks before surgery, which required knowledge of an estimated

surgery date. Approximately a week after the PIS was sent, the RN could also call the participant directly to ask if they were interested in taking part in the study.

When sending the PIS, the expectation was that patients would have surgery approximately 16 weeks after seeing the clinician for the first time, so this date was used for surgery date estimation. After this point, the RN could request updated dates for surgery from the clinicians' secretaries, if asked to do so by the researcher.

4.7.1.2. Findings

The primary roadblocks perceived by the RN that affected practicality of the recruitment strategy were problems with operating theatres and the length of participant-facing documents. Recruitment could be improved by reducing the length of these documents, increasing the recruitment period and overall study length, and by affording the RNs a better understanding of activities within study visits. For adaptation of the study, the RN did not foresee any issues with scaling to other research sites, other than that the same caveats found in this study would be likely to remain. Lastly, for the category of satisfaction, the RN found that the recruitment processes in INTEREST were comprehensive, as it managed to reach all eligible patients, and the visits in participants' homes likely improved uptake rate due to reducing burden.

4.8. Synthesis of feasibility data and conclusions

4.8.1. Synthesis of quantitative and qualitative feasibility data

Table 12 shows feasibility results from the above quantitative and qualitative data organised by feasibility criteria (Bowen *et al.*, 2009).

Table 12. Summary of feasibility results for participants and healthcare staff according to feasibility criteria.

Criteria	For the participant	For healthcare staff
Satisfaction	Participants reported satisfaction ratings averaging over 4.75 and mentioned gaining physical and mental benefits from the study.	The main positives of the recruitment approach were that patients were contacted who were eligible to take part, and going to participant's homes reduced burden

Criteria	For the participant	For healthcare staff
		and increased uptake. However, there were issues with delivery.
Practicality	Quantitatively, the study was practical, as participants found their goals to be well-suited, and found them reasonable to work towards in the future. They did find the goals physically difficult to achieve, and qualitative data made it evident that pain and the weather were common barriers that were difficult to overcome for many. Health complications and ongoing decline in physical function further affected participants' ability to keep to the study goals.	Practicality was affected by understaffing, inaccurate expectations of uptake rate, IT problems, and unpredictable surgery scheduling that led to many participants not having surgery within the study lifetime.
Acceptability	Participants did not find the study overly burdensome, but it was more of a burden to those in the intervention group. The intervention group also reported more pain, and qualitative data suggested that there was a range of activities that participants found most difficult, which varied based on the participant's own experience(s).	n/a
Adaptation	Participants would like a clearer booklet design and a pedometer that works better with the mobility restricted.	A more face-to-face, active recruitment method may have increased uptake, as well as better integration with the healthcare team or better access to IT systems at the hospital.
Safety	Participants did not feel at additional risk of harm due to the study, although qualitative data suggested that some did report a fear of falling due to increased walking, particularly in bad weather. One serious adverse event occurred but it was not related to the study.	n/a

4.8.2. Adverse events and safety

One adverse event occurred during the study, which was identified on the 18th of February 2019. This AE was the death of a participant due to complications resulting from surgery. As such, it was classified as a Serious Adverse Event. This event was determined by the study medical expert (ETD) to be unrelated to any study procedures.

4.8.3. Criteria for progression to a definitive trial

Four out of five of the criteria for progression to a definitive trial were fulfilled. However, several items were not considered in the criteria (table 13). The retention rate at Visit 5 was 48.6%, much lower than at Visit 4. Most of the patients recruited in the period Nov 2018 – Jan 2019 were due for surgery in

Jan-Mar 2019, and only 2 out of 11 of these had surgery by Apr 2019. The reason for this was a shortage of beds and issues with surgical theatres at Russells Hall Hospital, which was out of the control of the study team. Additionally, only five participants who attended visit 5 had surgery within 4-8 weeks after the preceding visit as intended, which was 14.3% of the original total sample size, further highlighting the unpredictability of surgery scheduling.

Table 13. Summary of criteria for progression to a definitive trial.

Criterion	Assessment	Conclusion
A minimum of 75% of patients had their surgeries within 10 days of the 4-8-week intervention window between visit 1 (usual care) or 3 (intervention), and the pre-surgery visit (visit 4).	36.67% (n=11) of patients had visit 4 between 18 and 66 days after their preceding study visit. However, of these, only n=8 had surgeries that were scheduled in the week after this visit. This constitutes only 26.67% of those retained until Visit 4.	**This aspect was not feasible.**
Rate of uptake meets or exceeds 10%.	The rate of uptake was 14.2%.	**This aspect was feasible.**
Participant retention rate exceeds 75% between baseline and pre-surgery visits.	The retention rate at pre-surgery (Visit 4) was 85.7%.	**This aspect was feasible.**
Study satisfaction must be ≥4/5, and risk of harm should be <2/5, as assessed by the feasibility questionnaire given to participants.	All these criteria were met at both Visit 4 and Visit 5. Overall mean satisfaction for both groups was 4.75. Risk of harm was assessed no higher than 1 by any participant.	**This aspect was feasible.**
The frequency of adverse events does not call into question the safety of the trial as determined by the medical expert on the study (ETD).	One AE occurred. This was classified as a SAE, but it was not related to the study.	**This aspect was feasible.**

This unpredictability makes the prospect of post-surgery follow-up extremely difficult and would be likely to affect the internal validity of the trial by significantly varying intervention length. It is not clear whether such issues are specific to Russells Hall Hospital or would also arise in other research sites. A future multi-site research design may alleviate these problems.

The overall conclusion for the INTEREST study is that the study is *feasible with some modifications*. The study would require greater integration with hospital processes in order to better arrange the study around unpredictable healthcare processes, by perhaps allowing manual checking of surgery dates by the researcher. Additionally, the internal validity of the study could be improved by either:

1) Mandating that the pre-surgery visit occurs at 8-weeks after baseline and post-surgery visit is cancelled if surgery does not occur within 2 weeks of this visit.
2) Incorporating "top-ups" of the intervention, such that if surgery is delayed beyond a certain point, another meeting is made to refresh the motivational interviewing and set more advanced or applicable goals according to the progress and feedback made by the participant.

4.9. Analysis of outcome measures

The purpose of these analyses were to estimate variance in these outcome variables. The focus was primarily on baseline (T1) to pre-surgery (T2) to investigate this prehabilitative phase of the intervention, which would be where a definitive trial would be intended to focus. Section 4.9.1 assesses the within-group changes from baseline (T1) to pre-surgery (T2), in the 30 participants retained to this timepoint; three from the intervention group and two from usual care were not retained until this timepoint. Section 4.9.2 evaluates between-group differences in changes from baseline (T1) to pre-surgery (T2), and section 4.9.3 looks at changes from baseline (T1) through post-surgery (T2) both within and between groups in the 17 participants retained over all three visits.

4.9.1. Baseline (T1) to Pre-Surgery (T2), n=30

There were no significant differences present within groups for self-reported or objective sedentary time or physical activity measures (table 14). Please see Appendix F. for a full breakdown of baseline to pre-surgery outcome variables.

A significant increase was found between baseline and pre-surgery values within the intervention group for the SPPB Total Score (mean difference 0.71 points, 95% CI: 0.068 to 1.360), which is above the minimum clinically significant increase of 0.54 and is equivalent to a medium effect size of d=0.503

(Perera *et al.*, 2006). In the usual care group, there was a non-significant increase of 0.38 (95% CI, -1.63 to 0.88) points in SPPB score.

For EQ-5D-5L scores, both intervention and usual care groups reported a statistically significant increase in the mean mobility score (indicating an increase in mobility problems) of 1.05 (95% CI, 0.43, 1.66) points, and 1.56 (95% CI, 0.40, 2.72) points respectively, from baseline to pre-surgery. This is equivalent to moving from “no problems in walking about” to “moderate problems in walking about”. This worsening of perceived symptoms was also reflected by increases in pain score, particularly in the intervention group, wherein the mean increased by 1.33 (95% CI, 0.58, 2.09) Anxiety also decreased significantly in the intervention group by -1.76 (95% CI, -2.34, -1.19) points, with a smaller, non-significant trend in the usual care group of 1.22 (95% CI, -1.0, 2.54) points.

4.9.2. Between-group comparisons – baseline (visit 1) to pre-surgery (visit 4), n=30

This section uses independent T-tests to assess for statistically significant differences in magnitude of change between groups (table 14).

Table 14. Within and between-group changes from Baseline to Visit 4.

Outcome	Intervention Group					Usual Care Group					Mean difference in changes between groups		
	n	Baseline[a]	Pre-Surgery[a]	Mean Difference (95% CI)	*p*-value[d]	*n*	Baseline[a]	Pre-Surgery[a]	Mean Difference (95% CI)	*p*-value[d]	Mean difference (95% CI)[c]	*p*-value[e]	Effect size[f] - Klauer's *d*
BMI[b]	21	30.1 (3.77)	29.66 (4.01)	-0.44 (1.65, 0.77)	0.46	8	31.07 (3.57)	30.03 (3.93)	-1.04 (-3.50 to 1.41)	0.35	0.60 (-1.73 to 2.93)	0.60	*0.155*
Waist-to-Hip Ratio[b]	21	0.91 (0.10)	0.89 (0.10)	-0.02 (-0.05, 0.01)	0.22	8	0.88 (0.09)	0.90 (0.09)	0.02 (-0.01, 0.04)	0.21	-0.03 (-0.08, 0.02)	0.17	*-0.36*
SPPB total points (0-12)	21	6.95 (3.09)	7.67 (2.97)	0.71 (0.07, 1.36)	0.032*	8	6.75 (2.31)	7.13 (2.70)	0.38 (-0.88, 1.63)	0.50	0.34 (-0.89, 1.57)	0.586	*0.11*
MOST Total (min.d^{-1})	21	479.66 (141.00)	463.31 (182.53)	-16.35 (-107.48, 74.78)	0.71	9	623.65 (186.17)	502.14 (179.70)	-121.51 (-251.56, 8.55)	0.06	105.16 (-51.42, 261.73)	0.18	*0.71*
Mean sedentary time (min.d^{-1})	19	607.49 (132.62)	575.23 (84.27)	-31.26 (-87.42, 24.89)	0.26	6	557.28 (83.01)	562.08 (112.89)	4.80 (-90.42, 100.02)	0.90	-36.06 (-144.00, 71.87)	0.50	*-0.25*
Mean upright time (min.d^{-1})	19	322.06 (117.22)	327.89 (120.59)	5.83 (-25.15, 36.81)	0.70	6	326.90 (105.63)	338.13 (135.87)	11.22 (-42.37, 64.82)	0.61	-5.40 (-65.11, 54.32)	0.85	*-0.04*
Mean sleeping time (min.d^{-1})	19	509.74 (112.39)	511.15 (117.91)	1.42 (-39.52, 42.35)	0.94	6	550.78 (76.37)	495.26 (79.51)	-55.52 (-159.51, 48.48)	0.23	56.93 (-28.51, 142.38)	0.18	*0.53*
Mean steps per day	19	4949.26 (3732.46)	5060.05 (3967.73)	110.79 (-591.39, 812.97)	0.74	6	3811.17 (617.63)	3743.17 (1422.46)	-68.00 (-1560.67, 1424.67)	0.91	178.79 (-1225.32, 1582.90)	0.80	*0.03*
Mean time spent in sedentary bouts >30 (min.d^{-1})	19	314.20 (164.69)	310.68 (127.27)	-3.52 (-74.51, 67.46)	0.92	6	350.89 (103.67)	331.41 (107.14)	-19.49 (-108.22, 69.25)	0.60	15.96 (-115.90, 147.83)	0.81	*0.07*
Mean time spent in sedentary bouts >60 (min.d^{-1})	19	173.44 (154.82)	173.38 (85.83)	-0.07 (-69.14, 69.00)	1.00	6	232.00 (101.49)	199.59 (96.70)	-32.41 (-91.56, 26.74)	0.22	32.35 (-93.07, 157.77)	0.60	*0.11*
Mean sit-to-stand transitions	19	41.95 (17.28)	37.95 (11.57)	-4.00 (-9.10, 1.10)	0.12	6	33.33 (11.72)	34.17 (9.22)	0.83 (-6.95, 8.61)	0.79	-4.83 (-14.50, 4.83)	0.31	*-0.19*
Mean Oxford Hip/Knee Score (0-48)	21	20.52 (7.69)	22.67 (8.56)	2.14 (-1.11, 5.39)	0.18	8	18.00 (9.83)	19.50 (9.46)	1.50 (-4.38, 7.38)	0.57	0.64 (-5.42, 6.70)	0.83	*0.06*
EQ-5D-5L Mobility (1-5)	21	1.86 (1.01)	2.91 (1.00)	1.05 (0.43, 1.67)	0.002**	9	1.67 (1.12)	3.22 (0.67)	1.56 (0.40, 2.72)	0.002**	-0.51 (-1.65, 0.64)	0.22	*-0.53*

Outcome	Intervention Group					Usual Care Group					Mean difference in changes between groups		
	n	Baseline[a]	Pre-Surgery[a]	Mean Difference (95% CI)	*p*-value[d]	*n*	Baseline[a]	Pre-Surgery[a]	Mean Difference (95% CI)	*p*-value[d]	Mean difference (95% CI)[c]	*p*-value[e]	Effect size[f] - Klauer's *d*
EQ-5D-5L Pain (1-5)	21	2.00 (1.30)	3.33 (0.91)	1.33 (0.58, 2.09)	0.001**	9	2.11 (1.27)	3.33 (1.00)	1.22 (-1.0, 2.54)	0.001**	0.11 (-1.25, 1.48)	0.37	*0.09*
EQ-5D-5L Anxiety (1-5)	21	3.14 (1.24)	1.38 (0.59)	-1.76 (-2.34, -1.19)	<0.001**	9	3.33 (1.33)	2.22 (1.30)	-1.11 (-2.16, -0.06)	<0.001**	-0.65 (-1.71, 0.40)	0.87	*-0.83*
EQ-VAS (0-100)	21	67.57 (21.14)	72.86 (17.36)	5.29 (-4.97, 15.54)	0.30	9	60.56 (18.78)	59.44 (13.57)	-1.11 (-11.94, 9.72)	0.30	6.40 (-10.32, 23.11)	0.44	*0.48*
BPNS Autonomy Score (0-7)[b]	21	5.91 (0.96)	6.07 (0.74)	0.16 (-0.26, 0.58)	0.44	9	4.89 (1.12)	5.18 (1.32)	0.29 (-1.02, 1.60)	0.62	-0.13 (-1.11, 0.84)	0.78	*-0.07*
BPNS Competence Score (0-7)[b]	21	4.64 (1.13)	4.67 (0.96)	0.03 (-0.51, 0.57)	0.91	9	4.13 (1.12)	4.13 (1.16)	0.00 (-0.86, 0.86)	1.00	0.03 (-0.93, 0.98)	0.95	*0.07*
BPNS Relatedness Score (0-7)[b]	21	6.16 (0.90)	6.16 (0.74)	0.00 (-0.43, 0.44)	0.98	9	5.86 (0.62)	5.71 (1.17)	-0.15 (-0.86, 0.56)	0.63	0.16 (-0.62, 0.93)	0.68	*0.16*
Cholesterol ($mmol.l^{-1}$)[b]	14	4.36 (0.91)	4.29 (0.92)	-0.07 (-0.41, 0.27)	0.66	6	4.82 (1.42)	4.38 (0.89)	-0.43 (-1.46, 0.59)	0.33	0.36 (-0.37, 1.09)	0.31	*0.32*
HDL ($mmol.l^{-1}$)	14	1.39 (0.36)	1.47 (0.39)	0.07 (-0.04, 0.19)	0.18	6	1.51 (0.37)	1.48 (0.42)	-0.02 (-0.23, 0.18)	0.80	0.10 (-0.10, 0.30)	0.33	*0.27*
LDL ($mmol.l^{-1}$)	14	2.31 (0.75)	2.25 (0.77)	-0.06 (-0.26, 0.14)	0.54	6	2.77 (1.35)	2.28 (0.79)	-0.49 (-1.36, 0.38)	0.21	0.43 (-0.44, 1.30)	0.11	*0.44*
Triglycerides ($mmol.l^{-1}$)[b]	14	1.46 (0.79)	1.26 (0.57)	-0.19 (-0.58, 0.19)	0.30	6	1.20 (0.32)	1.37 (0.44)	0.17 (-0.12, 0.45)	0.20	-0.36 (-0.96, 0.24)	0.22	*-0.57*
HBA1c ($mmol.l^{-1}$)	16	39.13 (8.57)	39.44 (8.40)	0.31 (-0.46, 1.08)	0.40	5	39.40 (1.82)	39.40 (1.14)	0.00 (-2.91, 2.91)	1.00	0.31 (-1.49, 2.11)	0.72	*0.04*
Cortisol ($mmol.l^{-1}$)	13	334.38 (131.23)	374.62 (77.08)	40.23 (-35.39, 115.85)	0.27	3	315.00 (22.52)	526.00 (239.90)	211.00 (-435.21, 857.21)	0.30	-170.77 (-379.52, 37.98)	0.10	*-1.47*
DHEAS ($mmol.l^{-1}$)	13	1.36 (0.77)	1.30 (0.72)	-0.06 (-0.25, 0.13)	0.52	4	1.71 (1.18)	1.71 (1.08)	0.00 (-0.61, 0.60)	0.99	-0.06 (-0.45, 0.34)	0.77	*-0.10*

[a]Values are mean (SD); [b]Shapiro-Wilks test indicated these data were not normal in one or both groups (p≤0.05); [c]Calculated as "[Intervention Mean Difference Baseline to Visit 4] - [Usual Care Mean Difference Baseline to Visit 4]"; [d]Calculated with Paired T-test, Significance Level = 0.05; Some data were not normal as indicated by [b]; [e]Calculated with Independent T-test, Significance Level = 0.05; [f]Calculated using Klauer's g (Morris, 2008).

There were no significant differences between groups from baseline to pre-surgery for any of the above tested variables. However, the Intervention group had a non-significant reduction in mean daily sedentary time of 31.26 min.d^{-1} (95% CI, -87.42, 24.89, *p*=0.257), and the usual care group had a non-significant increase of 4.80 (95% CI, -90.42, 100.02), equivalent to a low-medium effect size of *g*=0.324 (Hedge's *g* for independent T-test). With respect to effect sizes, small effect sizes were seen for sedentary time (*d*=0.25), waist-to-hip ratio (d=-*0.36*), EQ-VAS (*d*=0.48), medium effect sizes for triglycerides (*d*=-0.57) and for self-rated mobility (*d*=-0.53), and large for self-rated anxiety (*d*=-0.83) and cortisol (*d*=-1.47) in favour of the intervention. However, there were also effects found that favoured the usual care group, such as LDL (*d*=0.44) and self-reported sedentary time (MOST, *d*=0.71).

4.9.3. Baseline (visit 1) to post-surgery – between-group effects (visit 5), n=17

The following analyses used two-way mixed ANOVAs to test for interactions between groups across all three timepoints. For each analysis presented in this section, data were normal at all three time point as assessed using a Shapiro-Wilks test (*p*>0.05) unless otherwise indicated and there was a linear relationship between SPPB score pre and post-intervention in both groups as determined by visual inspection of a scatterplot. Also, there were no outliers, as assessed by examination of studentized residuals for values greater than ±3, and residuals for SPPB score were normally distributed, as assessed by Normal Q-Q Plot. Additionally, there was homogeneity of variances, as assessed by Levene's test of homogeneity of variance (*p*>0.05). Furthermore, there was homogeneity of covariances, as assessed by Box's test of equality of covariance matrices (*p*>0.05). Lastly, Mauchly's test of sphericity indicated that the assumption of sphericity was met for the two-way interaction in these analyses (*p*>0.05).

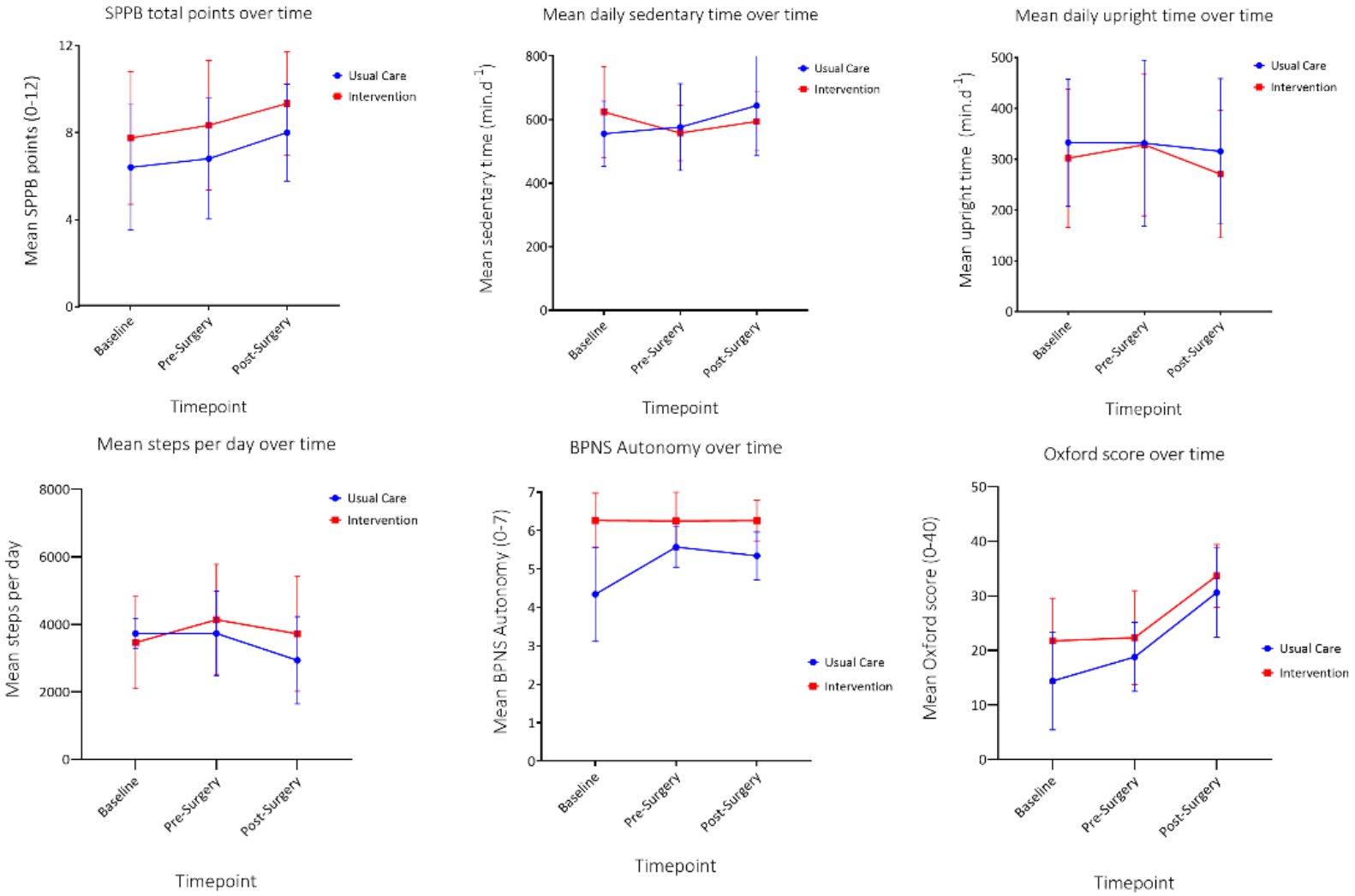

Figure 31. Graphs depicting changes over time in variables assessed within this section. Error bars are standard deviation.

Table 15. Means and 95% CIs of outcomes at each timepoint for individuals retained through all three timepoints.

Variable	Group	N	Baseline Mean (95% CI)	Pre-Surgery Mean (95% CI)	Post-Surgery Mean (95% CI)
Total SPPB (0-12)	Intervention	12	7.75 (5.90 to 9.60)	8.33 (6.54 to 10.13)	9.33 (7.89 to 10.78)
	Usual Care	5	6.4 (3.54 to 9.26)	6.8 (4.02 to 9.58)	8.0 (5.76 to 10.24)
Sedentary time ($min.d^{-1}$)	Intervention	8	623.85 (519.83 to 727.88)	557.84 (475.36 to 640.31)	594.31 (503.26 to 685.36)
	Usual Care	4	555.75 (408.64 to 702.86)	576.48 (459.85 to 693.12)	644.16 (515.40 to 772.93)
Upright time ($min.d^{-1}$)	Intervention	8	302.18 (197.54 to 406.81)	328.65 (212.70 to 444.61)	270.82 (167.61 to 374.03)
	Usual Care	4	332.91 (184.94 to 480.89)	331.79 (167.81 to 495.77)	315.62 (169.66 to 461.57)
Steps per day (n)	Intervention	8	3462.00 (2541.71 to 4382.29)	4138.75 (2930.16 to 5347.34)	3720.13 (2466.69 to 4973.56)
	Usual Care	4	3730.00 (2428.52 to 5031.48)	3732.50 (2023.29 to 5441.71)	2935.75 (1163.13 to 4708.37)
BPNS Autonomy (0-7)	Intervention	12	6.26 (5.72 to 6.80)	6.25 (5.82 to 6.68)	6.26 (5.92 to 6.60)
	Usual Care	5	4.34 (3.51 to 5.18)	5.57 (4.91 to 6.24)	5.34 (4.82 to 5.87)
Oxford (hip or knee) score (0-48)	Intervention	12	21.75 (16.74 to 26.76)	22.33 (17.37 to 27.30)	33.67 (29.67 to 37.66)
	Usual Care	5	14.40 (6.64 to 22.16)	18.80 (11.11 to 26.50)	30.60 (24.41 to 36.79)

ANOVAs were performed on all outcomes (figure 31). However, only the variables most relevant to the logic model of the study are presented (table 15). Analyses that identified large differences in means or a statistically significant effect of time or group are presented in the text.

Within the intervention group, there was a non-significant reduction in mean sedentary time of -66.02 (95% CI, -180.50, 48.46) $min.d^{-1}$ in those who were retained for all three timepoints (figure 31, table 15) which is equivalent to a medium-large effect size of 0.667 (Hedge's *g*). In the intervention group, increases in upright time and steps per day were identified from baseline to pre-surgery, means of which fell slightly again after surgery, although interactions for either group or time were not statistically significant. In the usual care group, no substantial or significant within-group effects were identified. For BPNS Autonomy score, there was a statistically significant interaction between group and time, $F(2, 30) = 0.800$, $p = 0.024$, partial $\eta 2 = 0.220$, however, in figure 31 it is apparent that Autonomy was unequal at baseline.

4.10. Intervention fidelity

4.10.1. Treatment delivery (motivational interview skill usage)

Twenty-one motivational interviews (MIs) were conducted, as one participant dropped out of the study prior to the motivational interview. One third (33.3%) of these interviews were recorded and rated for fidelity by two raters (self-rated by primary researcher and one independent expert). A further one was self-rated only.

Table 16. Treatment delivery skill assessment.

	MI Skills	Supporting Basic Psychological Needs
Self-rated (n=8)	3.63(0.48)	3.38(0.48)
Independently rated (n=7)	3.43(0.53)	2.07(0.63)
Total mean	3.53	2.73

While MI quality skill ratings were close, ratings of supporting the basic psychological needs were less congruent (table 16). There may be a few reasons for this. Firstly, this methodology had several

limitations. The primary issue was that the MI recording only covered the initial aspect of the discussion in visit 2, the formal motivational interview. As such, the independent rated only the first part of the participant visit, while the primary researcher self-rated the entire visit, which also consisted of action planning. The action planning phase contained further use of the supporting basic psychological needs skill that was not accounted for in the recording of the MI session, which was likely to have contributed to a discrepancy in ratings for the supporting basic psychological needs skill.

4.10.2. Treatment delivery (phone call skill usage)

A total of 75 phone calls were delivered as part of the intervention (3 calls each for 25 participants). One individual dropped out after randomisation but prior to receiving the first phone call. Of these, 33.3% (n=25) phone calls were self-rated for fidelity by the primary researcher. Goals were changed as a result of the phone calls in 12% of cases. Additionally, for some skills it was determined that they did not need to be used (i.e. patient didn't report any setbacks), so the "times not used" row reflects the occurrence of this. Fidelity ratings for skills used in the phone calls are shown in table 17.

Table 17. Phone skill usage assessment.

	Monitoring Progress	Managing Setbacks	Problem Solving	Motivational Interviewing	Supporting Basic Psychological Needs	Total
Mean (SD)	3.88(0.82)	3.38(1.05)	3.81(0.85)	3.75(0.83)	3.92(0.69)	3.79(0.19)
Median	4	3	4	4	4	4
Times not used	0 (0%)	4 (16%)	4 (16%)	9 (36%)	0 (0%)	n/a

Overall, the phone calls were delivered to a competent standard or greater, with some to "proficient". However, these ratings may be overestimated due to the impact of self-rating bias. Determinations of when certain skills were not required were made entirely by the primary researcher, hence certain skills may have not been used when it would have been more effective if they were.

4.10.3. Treatment receipt (ratings of action plan)

Action plans were rated by the main researcher as well as an independent rater according to the complete intervention fidelity assessment guide criteria (item A in the appendices). This constitutes rating all 132 goals for SMART criteria (Specific, Measurable, Achievable, Relevant, and Timely) and giving a total score out of 30, and then assessing the action plan for completeness and appropriateness to the physical function of the participant on a scale of 1-5.

Table 18. Action plan quality assessment. Data are mean (SD).

Goal Rating Scores		**Overall Action Plan scores**	
Rater 1	Rater 2	Rater 1	Rater 2
27.91 (1.28)	28.18 (1.77)	5 (0.00)	5 (0.00)

Overall, the action plans were assessed to have been constructed to a high standard (table 18). As such, it is unlikely that the results of the intervention would be negatively affected by the action plan formulation. The high ratings are likely due to these plans being actively checked by the researcher during their construction.

4.10.4. Treatment enactment

Treatment enactment was assessed with recording of goal adherence, which was already covered in the feasibility section.

4.10.5. Fidelity summary

A mean score of all skills used was computed, giving equal weighting to all skills and incorporating the independent rater for MI sessions equally as well. Overall fidelity of treatment delivery in the study was competent, with a mean of 3.12 (out of 5). According to the pre-defined criteria, all aspects of the study needed to be delivered to a standard of 3 or above to not call into question standard of the delivery of the study. The mean of the independently-rated and self-rated scores for supporting basic psychological needs during the MI session was 2.73 (out of 5), which may indicate that this aspect was (slightly) sub-optimally delivered, which could negatively impact the results of the study.

Quality of action plans was delivered to a good standard according to both the primary and independent rater, with all plans being rated at 5, the maximum score.

4.11. Intervention cost

The intervention itself did not require significant resource other than the cost of training personnel involved in the project and their time. Presuming retention for the entire study, each intervention participant cost approximately 16 hours of work for all study visits with data entry time, calling time, etc., and usual care participants cost 11.25 hours. The only material costs were printing and pedometers; £75.77 was spent on printing 30 booklets for the study, £21.25 on information sheets to be sent to participants, and £432.00 on 24 pedometers for the participants. No other costs were incurred, giving a total material cost of £529.02 to support the 35 participants in the study, or £15.12 per participant. Including both personnel costs of £26.02 an hour (including overhead for pension, etc.), and materials, an intervention participant cost £431.44 and a usual care participant cost £307.85, giving a total cost of £13740.91 for time spent if all participants were retained for the entire study period. The involvement of other staff and study set-up time, etc., was too complex to be considered in this analysis.

4.12. Discussion

Assessment of the criteria for progression to a definitive trial found that all were met except for one related to patient surgery scheduling. As a result, the study was deemed to be feasible with some modifications. This suggests that delivering the study with a focus on the pre-surgery prehabilitative phase may be a better approach for a definitive trial, with powering based on the baseline to pre-surgery changes one would expect to see. The pre-surgery measurements could either be taken at a specific cut-off point to increase internal validity, or ‘top-ups’ of components such as motivational interviewing and revised action plans could be provided after a certain amount of time.

From the participant perspective, they were very satisfied with the study, citing benefits in both physical and mental wellbeing, and found it largely practical, although difficult to achieve due to pain and health complications. Those in the intervention group found it more burdensome and more painful, and some recommended changes could be made to the study, such as a clearer design of study materials and more accurate pedometers for tracking of activity in an older population. The recruitment strategy was successful in identifying the target population (all participants were approached who were eligible) and home visits improved study uptake. However, a face-to-face strategy could have further enhanced recruitment.

There are at least ten sedentary behaviour interventions in older adults, eight of which are feasibility studies (Paul A. Gardiner *et al.*, 2011; Chang, Fritschi and Kim, 2013; Matei *et al.*, 2015; English *et al.*, 2016; Gibbs *et al.*, 2016; Lewis *et al.*, 2016; Maher, Sliwinski and Conroy, 2016; White *et al.*, 2017; Harvey, Chastin and Skelton, 2018; Koltyn *et al.*, 2019). Our feasibility results are similar to results from the aforementioned studies, which have also been found to be acceptable. However, our qualitative data suggests this mobility-limited sample suffers from additional barriers to engagement in physical activity, such as pain and lower physical function. This study also suffered from slower recruitment and reduced retention rates due to the post-surgical follow-up and clinical sample. This study demonstrates for the first time that is acceptable and safe to intervene to reduce sedentariness in older adults with mobility limitations awaiting hip or knee replacement surgery.

This study also included an exploratory assessment of the impact of the intervention on several outcome variables including objectively-measured sedentary behaviour at three timepoints. It also included for the first-time measurement of both physical function and blood-based cardiometabolic biomarkers. Although physical function has been measured by prior interventions to reduce sedentary behaviour in older adults, measurement of blood biomarkers has not been performed (Gibbs *et al.*, 2016; Aunger, Doody and Greig, 2018). The exploratory analysis of outcomes in this study should be

interpreted with caution due to the unpowered nature of this study, and the high likelihood of type I error.

The study found a nonsignificant decrease in mean daily sedentary time from baseline to pre-surgery in the intervention group, with a mean difference of -31.3 min.d^{-1}, and a statistically significant increase in total score SPPB score of 0.71 points over the same time period. It is worth noticing that the change in SPPB score is above the 0.54 threshold for a clinically significant difference (Perera *et al.*, 2006). This within-group improvement from baseline to pre-surgery is indicative of a medium effect size (d = 0.503) and arose mostly due to an improvement in chair stand score. This may be due to participants in the intervention group forming goals to perform many chair-rises throughout the day, however, no mean increase in objectively measured sit-to-stand transitions was found. Either participants did not perform these goals, or the ActivPal3 cannot pick up chair rises performed rapidly in succession. A prior intervention to reduce sedentary behaviour in older adults found an improvement of 0.53 points in SPPB (p=0.046), also arising from improvements in chair rise test performance, without a corresponding decrease in sedentary behaviour (Gibbs *et al.*, 2016). The specificity principle, which refers to an increase in function during specific frequently-performed movement patterns, was proposed as the underlying mechanism.

This study is also the first to incorporate follow-up after a sedentary behaviour reduction in older adults; in this case, occurring 6-weeks post-surgery. An analysis of 8 individuals who completed the intervention found that there was a non-significant mean reduction in sedentary time of 66 min.d^{-1} from baseline to pre-surgery. After surgery, sedentary time increased by 36.47 min.d^{-1} in the intervention group. Over the same three timepoints, the usual care group (comprising n=4 individuals) underwent a non-statistically significant increase in mean sedentary time at each follow-up timepoint, equal to 88.41 min.d^{-1} from baseline to post-surgery. Due to the very small sample size and lack of statistical significance, it is impossible to attribute this effect to the intervention. However, such a magnitude of reduction is consistent with, and slightly greater than, other studies in healthy older

adults (Lewis *et al.*, 2016; Aunger, Doody and Greig, 2018). Changes in cardiometabolic biomarkers were not found, either within- or between-groups in response to the intervention, which is in line with findings of prior RCTs and cross-sectional studies, as there is a multitude of factors that can affect these biomarkers, such as diet and medications, and it is impossible to take these all into account (Wirth *et al.*, 2016).

Statistically significant changes were also present within the intervention and usual care groups for EQ-5D-5L mobility score (which indicated worsening mobility), and for pain and anxiety in the intervention group only. However, these changes in both pain and anxiety are difficult to attribute to the intervention, as anxiety may be lowered by the imminence of surgery (whereas at baseline surgery was far in the future with more uncertainty), and increases in pain may be attributable to progression of osteoarthritis rather than the intervention itself, which seems likely as the usual care group also trended towards a pain increase of a similar magnitude. Finally, a two-way mixed ANOVA identified statistically significant between-groups and time interactions for BPNS Autonomy, but it was clear that there were already differences present in the mean in autonomy score at baseline. Small to large effect sizes were also identified in favour of the intervention in key variables such as sedentary time (*d*=0.25), waist-to-hip ratio (d=-*0.36*), EQ-VAS (*d*=0.48), self-rated anxiety (*d*=-0.83) and cortisol (*d*=-1.47) from baseline (T1) to pre-surgery (T2), however, as effects were also found which favoured the usual care group, it is difficult to attribute these effects to the intervention. A trial with more statistical power is required to draw more informed conclusions from these outcomes.

With respect to the theoretical integration of the study, an application of the Theory Coding Scheme by Michie and Prestwich (2010) identified that the intervention and study was robust with respect to integration of theory, and testing of theoretical constructs, but lacked a robust ability to test and refine its application of theory. However, testing and refining the theoretical basis of the study and/or assessing its logic model was not an aim of the present feasibility study, rather, the focus was on

assessing whether such a novel behavioural approach to reducing sedentary behaviour was feasible in this clinical population. A follow-up trial should consider the theoretical framework more heavily in the design and consider performing mediation analyses to identify what aspects of the intervention predict success.

A recent review recommends that prehabilitation programmes should be more personalised and include psychological support (Thomas *et al.*, 2019). As this study may have potential to improve physical function, a behavioural approach such could deliver a more personalised and similarly effective form of prehabilitation, as each participant was trying to achieve their own self-devised action plans. Such an approach may also provide other benefits such as reduced resource requirements. These findings warrant an adequately powered follow-up trial.

4.13. Strengths and limitations

Strengths of this study include the randomised design, which is more robust than a simple pre-post design. It is the first time an intervention to reduce sedentary behaviour in older adults has included cardiometabolic biomarkers as an outcome measure. The study also used both objective assessment of sedentariness and physical activity with ActivPal3 inclinometers, and subjective assessment with the MOST, which together provides both accurate measurement of sedentariness and captures contexts for the behaviour. The inclusion of a secondary follow-up after the end of the intervention, although affected by surgery and being relatively short at only 6-weeks, also allowed assessment of the short-term persistence of any behaviour change over the post-surgical period. The wide range of feasibility data, including interviews, questionnaires, and data recorded by the participants provided a more comprehensive assessment of feasibility. The study also had a strong theoretical design, including assessment of the basic psychological needs within self-determination theory, which was a further improvement on existing sedentary behaviour research within older adults (Aunger, Doody and Greig, 2018). Although limited in scope, the inclusion of the fidelity assessment was a further strength of this

study and is a first for interventions to reduce sedentary behaviour in older adults. Although the sample was small and lacking in diversity, it was well-balanced for sex and surgery type, and was reflective of the elevated degree of morbidity in this population.

This study had several limitations. First, the variable intervention length due to reliance on unpredictable surgery scheduling may have led to lack of comparability both between groups, and within groups, negatively affecting internal validity. Secondly, data collection did not use personnel blinded to group allocation and the assessment of intervention fidelity was (in part) self-rated and as such lacked robustness. The assessment of the delivery of the support of the basic psychological needs skill indicated that there was scope for improvement with the delivery of this element of the intervention. Thirdly, the small sample size, particularly at post-surgery, may have impacted the assessment of feasibility of the study, by potentially not supporting data saturation in the qualitative data analysis, and lack of statistical power likely also limits the conclusions that can be drawn from the analysis of exploratory outcomes. Additionally, the study was conducted over a 13-month period and thus seasonality may have affected physical activity and sedentary behaviour measurements. The relative homogeneity of the sample is also not reflective of the local (Birmingham) population, so the generalisability of findings to other populations may be limited. In addition, the study was carried out by one researcher, who was not blinded to group allocation at assessment points, which may have introduced measurement bias. Furthermore, the single-site nature of this study means that findings may not be generalisable to other research sites. Including both hip and knee patients may have resulted in differing recovery trajectories, which makes interpreting results in a single analysis more difficult, and multiple clinicians were performing the surgeries, which could have further affected post-surgery recovery.

4.14. Conclusion

The INTEREST feasibility study was found to be feasible with some modifications, with the main barrier being highly unpredictable patient surgery scheduling, affecting feasibility of follow-up and scheduling of the pre-surgery visit. This could be alleviated with small changes to the study design or better integration with healthcare services. Exploratory analysis of outcomes, although not powered to allow definitive conclusions, suggested that the intervention may have potential to reduce sedentary time and increase physical function in a definitive trial. Qualitative feedback from participants suggested that the pain and fatigue associated with osteoarthritis were key barriers affecting goal attainment; however, participants also reported gaining physical and mental benefits from the intervention. Given that such an intervention is acceptable and safe in patients undergoing hip and knee arthroplasty, further trials with adequate statistical power to detect improvements in physical function in older people awaiting joint surgery are warranted.

CHAPTER 5: RECOMMENDATIONS FOR A DEFINITIVE TRIAL, AND CONCLUSIONS

5.1. Synthesis of findings and implications

This PhD has encompassed several novel areas of research that have furthered sedentary behaviour research in older adults. First, a lack of systematic reviews of interventions to promote sedentary behaviours in older adult populations was identified, despite the additional risk that sedentary behaviour poses to older adults in comparison to younger, fitter demographics. As a consequence, a systematic review protocol was developed and subsequently undertaken to improve understanding of the current state of sedentary behaviour research, and to help inform the design of a feasibility study to be delivered in a population of highly sedentary older adults: those with severe osteoarthritis, awaiting surgery (Aunger, Doody and Greig, 2018). From the review it was evident that studies were lacking in terms of inclusion of objective measurement of sedentary behaviour, inclusion of a follow-up to assess duration of achieved behaviour change, and assessment of physical function and cardiometabolic biomarkers, these latter two being clinically relevant outcomes that are assumed to be affected by sedentary behaviour. However, some had potential to reduce sedentary behaviour.

To implement the recommendations of the review, the INTEREST randomised controlled feasibility study was developed, which was the first sedentary behaviour intervention in older adults to:

(1) be delivered to older adults with a co-morbidity causing mobility limitations;

(2) be used in a prehabilitative context;

(3) incorporate testing of cardiometabolic biomarkers in an older adult population;

(4) include a (post-surgical) follow-up to test for duration of behaviour change;

(5) incorporate and test the underlying theoretical behaviour change constructs into the design of the study as outcomes (in this case, Self-Determination theory);

(6) assess intervention fidelity.

This intervention targeted a population that is most at-risk of the negative health impacts of sedentary behaviour: older adults with mobility limitations. Additionally, the study served to move sedentary behaviour research in older adults towards testing its underlying assumptions (that reducing sedentary behaviour can have clinically relevant effects), and towards considering incorporating cutting edge behaviour change theory more seriously in such interventions. Future definitive trials should now endeavour to include these aspects in their design. Although not essential in a feasibility study, an assessment of intervention fidelity was shown to be feasible; it is recommended that inclusion of an assessment of intervention fidelity and a robust process evaluation should be a key aspect of any definitive trial of similar interventions.

5.2. Recommendations for a definitive trial

A follow-up definitive trial has a choice of either targeting mean daily sedentary time, or physical function (e.g. SPPB) as the primary outcome. Basing a power analysis on improvement of physical function would have two benefits: assessing a clinical outcome highly relevant to this population (which is an outcome which is further along the chain of causality) and would allow for a smaller sample. Additionally, several elements were identified in Chapter 4 that could be incorporated to improve efficacy of the intervention.

5.2.1. Sample size calculation

Sample size calculations were performed for mean daily total sedentary behaviour and total SPPB score variables using two-sided significance of 0.05 and 80% power (Kadam and Bhalerao, 2010); 90% power could also be used but increases sample size requirements by 34% (table 19). Effect sizes of 0.54 for change in SPPB total score, the smallest meaningful clinical difference (Perera *et al.*, 2006), was used, and -60 $min.d^{-1}$ was used for sedentary time, which according to data from the present study and others is achievable (Aunger, Doody and Greig, 2018). According to data from n=198,383 participants, a displacement of 1-h of sitting time to standing, or sitting to walking provides relative hazard ratios of

0.96 (95% CI, 0.95-0.97) and 0.84 (95% CI, 0.79-0.90) respectively, which is quite significant (Stamatakis *et al.*, 2015). However, these data were based on self-report methodologies.

For the sample size calculation, standard deviations of the change from Baseline to Visit 4 between groups from the INTEREST study were used, equivalent to 1.25 for the SPPB and 110.13 for sedentary time. As such, this calculation is powered on changes from baseline to pre-surgery to emphasise the prehabilitation aspect of the study. Although powering future trials using standard deviations obtained from pilot trials is not generally recommended, using deviations from trials in healthy older adults may also not be reflective of the osteoarthritic population either. Furthermore, there are no interventional studies published with data regarding SPPB or sedentary time in older adults with osteoarthritis to compare standard deviations to (Teare *et al.*, 2014)[1].

These calculations informed us that 85 and 53 participants would be required per arm with 1:1 randomisation for the SPPB and sedentary time respectively, meaning that with consideration for 10% loss to follow-up, a total sample of 188 or 118 would be required (94 or 59 per arm). A 10% loss to follow-up was used as this study experienced 14.3% loss from baseline to pre-surgery, which, with improvements to study design, could be lowered. A definitive trial with SPPB as primary outcome in a population waiting for surgery would therefore require a multi-site design with high patient throughput in order to provide sufficient uptake rate to complete the study in a reasonable timeframe.

A further consideration would be that if longer follow-ups were included in a definitive trial, the standard deviation for change in SPPB or sedentary time would also likely become much larger. As an example, a standard deviation of 2.0 rather than 1.255 for SPPB score would result in a required sample size of 635 participants, which is almost 3x higher.

[1] Calculating sample size based on feasibility trial data with samples where n≤70 may cause a lack of precision due to inflated estimates and can lead to over- or under-powering as a consequence (Teare *et al.*, 2014). Additionally, standard deviations found in the present study may not be as applicable to studies with healthy older adults.

Table 19. Sample size calculation according to power selection.

Variable	Effect size	Standard deviation	Power	Sample size per arm	Total sample size	Sample size plus 10% drop-out
SPPB	0.54	1.255	80%	85	170	188
			90%	114	228	250
Sedentary time	-60.0	110.138	80%	53	106	118
			90%	71	142	156
BPNS Autonomy	1.0	1.178	80%	22	44	48
			90%	30	60	66

5.2.2. Assessment of theoretical framework of the intervention

Self-determination theory was an appropriate choice as a theoretical basis for the INTEREST intervention, due to its close integration with motivational interviewing, strong track record of use in behaviour change interventions in physical activity and sedentary behaviour, and the availability of validated measures to test its theoretical structures (Fortier, Duda, *et al.*, 2012; Miller and Rollnick, 2012; Aunger *et al.*, 2019). It was hypothesised that the BCTs in the intervention would aid in enhancing all three aspects of the Basic Psychological Needs, which would thereby move participants along a continuum in line with organismic integration theory towards integrated regulation of the intervention aims as core beliefs, and behaviours as a means to achieve them (figure 32) (Deci *et al.*, 1994). However, there are a number of competing models and theories that could have been used, such as the COM-B framework by Michie, Atkins and West (2015), or the habit formation model by Gardner, Lally and Wardle (2012). Each has its own strengths and weaknesses, but any chosen approach should be able to measure changes in theoretical constructs throughout the intervention in line with a logic model.

As discussed in Chapter 3, the application of the Theory Coding Scheme to this study identified that the study was not well-designed for testing of the integration of SDT nor was it able to refine the theory used (Michie and Prestwich, 2010). Thus, it is more than possible that an alternative theoretical design

could be more effective in this population. One improvement that would allow for better assessment of the theoretical integration would be incorporating behavioural regulation as an outcome.

Although it is possible to measure both satisfaction of the basic psychological needs and behavioural regulation, in exercise interventions it is more common to assess the latter (Teixeira *et al.*, 2012). In the INTEREST study only needs satisfaction was measured, using the Basic Psychological Needs (BPNs) in General scale (Teixeira *et al.*, 2012). This was used to assess changes in the basic psychological needs as a domain-general measure (as no validated domain-specific type questionnaire for sedentary behaviour is available[2]). This limits the ability to infer that any changes in these basic psychological needs were due to the intervention itself, and could easily be a result of the patient surgery or other factors. Unfortunately, the data obtained were affected by imbalances at baseline, which led to difficulty in properly assessing changes in the variables of autonomy, competence, and relatedness. However, the means for autonomy, competence, and relatedness across all three timepoints using all participants' data show upwards trends in both groups for autonomy. This indicates potential for improvements in competence and relatedness in the intervention group as compared to usual care (figure 32). However, for proper identification of an effect of the intervention on autonomy using the current scale, a power calculation identifies that at least 66 participants are required overall (33 per group) with 90% power and an alpha of 0.05 (table 19), which would provide sufficient power to be incorporated as a sub-goal of a definitive trial powered on the SPPB.

[2] The Basic Psychological Needs in Exercise Scale is available, but many of the questions are not applicable to a sedentary behaviour intervention such as INTEREST and adapting it as required would require re-validation (Vlachopoulos and Michailidou, 2006).

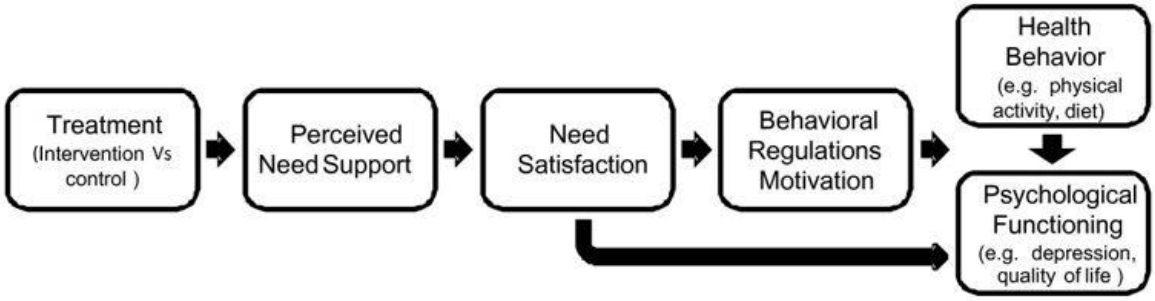

Figure 32. SDT process model for health behaviour change interventional research. Adapted from Fortier et al. (2012).

As is evident in figure 33, behavioural regulation was not assessed in the present study due to time constraints during study visits, which often exceeded 2-hours, and due to a lack of validated tools for assessing regulation of sedentary behaviour at the time of design. There are few tools available to measure whether a behaviour is internally regulated. There are scales that assess more 'global' motivation, such as the Global Motivation Scale, which is more applicable to global motivation, than contextual or specific motivation (Zycinska, 2019). A scale that assesses motivation on the contextual or specific level would be more applicable in this study due to the focus on sedentary behaviour (Vallerand, 1997). Efforts have even been made to develop a scale measuring integrated regulation in exercise, but, such scales often don't incorporate integrated regulation due to its similarity to and overlap with internal regulation (Mullan, Markland and Ingledew, 1997; Zycinska, 2019).

This extends to a recently-published paper, which has used a 15-item Behavioural Regulation in Exercise Questionnaire modified to cover sedentary behaviour to assess types of motivation for (only self-reported) sedentary behaviour among n=571 university students and staff (Gaston *et al.*, 2016). It found that intrinsic motivation is significantly positively associated with weekday and weekend leisure/recreation sedentary behaviour, indicating that people engage in it because they find it pleasurable and satisfying. However, work-related sedentary time was inversely associated with intrinsic motivation, but positively with external motivation, indicating that motives (autonomous vs. controlled) and desires are important in determining which form of motivation determines sitting

behaviour (Gaston *et al.*, 2016). In a largely occupationally retired sample such as in the INTEREST study, many of whom were in pain, it would indicate that they are likely to be internally motivated to sit, whereas a different strategy may need to be adopted if intervening in those externally regulated to sit (i.e. at work).

Although this adapted sedentary behaviour regulation scale also does not include integrated regulation, it does cover external regulation, introjected regulation, identified regulation, and intrinsic motivation, and the scale could be appropriate for inclusion in a follow-up pilot trial to assess changes in these constructs over time, alongside the measure of the BPNs. However, it would need to be interpreted negatively, i.e. the hypothesis would be that there would be a reduction in internal motivation towards sitting as a result of the intervention. The scale has been used in modified form in longer-term interventional exercise research of 3-6 months (Fortier, Sweet, *et al.*, 2012), and longitudinal studies in which it has demonstrated responsiveness over periods of 8 weeks in new exercisers (Rodgers *et al.*, 2010), but it is not yet clear whether the tool would be sufficiently responsive to change within a shorter-term intervention such as in INTEREST. Nonetheless, greater integration of SDT into the assessments within a follow-up trial would potentially be of great benefit.

5.2.3. A robust process evaluation

While the INTEREST feasibility study incorporated limited fidelity assessment, including treatment delivery, treatment receipt, and limited testing of treatment enactment, it would be more informative, if extra personnel were available, to perform a more comprehensive process evaluation to gain a full understanding of the mechanisms of action of the intervention. Medical Research Council process evaluation guidelines recommend having separation between process evaluators and data collectors in order to reduce potential bias in data analysis and to ensure proper blinding of data collectors (as process evaluators cannot be blinded) (Moore *et al.*, 2015). However, due to resource limitations, some skill usage was self-rated in the INTEREST feasibility study, which is highly susceptible to bias.

5.2.4. Expanded qualitative elements

In line with recommendations from the systematic review reported in Chapter 2, it would be ideal to have sufficient sample to be able to understand which intervention components were most effective at changing behaviour through sub-group analyses, however, more in-depth qualitative assessments (such as interviews) within the study could also effectively uncover participants' perceptions of which BCTs were most effective for them. In the INTEREST feasibility study, qualitative data did reveal some aspects that people found helpful, e.g. wearing the pedometer and tracking steps, but to better understand implementation and mechanisms of action, qualitative assessments in the form of participant interviews, or even interviews with intervention facilitators should be undertaken in a future trial.

The feasibility questionnaire left certain elements unaddressed when it came to optimal assessment of the intervention. For example, it would have been useful to explore which BCTs were most helpful from the participants' perspectives, and to obtain more detailed descriptions of the factors that withheld them from achieving their goals. Then strategies could be developed to more effectively deal with these, particularly if evaluations were ongoing throughout the delivery of the study. One of the concerns with using qualitative interviews was with respect to the time it would take to deliver such an interview in already long visits with participants that necessitated blood sampling, long questionnaires, and other discussion. In a larger study, it would be possible to include qualitative interviews with a subsample of participants that are randomly selected, but still sufficient to achieve data saturation. Alternatively, it could also be possible to invite participants to a focus group regarding their experiences after completion of the study, and that may be even more useful with respect to generating information about their shared or unique experiences.

5.2.5. Twelve-week follow-up

Due to time constraints, a 6-week follow-up was chosen for the present study. However, data shows that recovery trajectories for total hip or knee replacement often take 12 weeks to achieve maximal benefit to pain and physical function (Lenguerrand *et al.*, 2016). It may be optimal to incorporate an additional timepoint (a visit 6) at 12-weeks, in addition to the 6-week follow-up, to not only model whether trajectory of recovery is different (Δ of recovery), but also see whether changes in absolute maximal achieved recovery occur. This would greatly enhance the assessment of the length of the prehabilitative effect conferred by f the intervention.

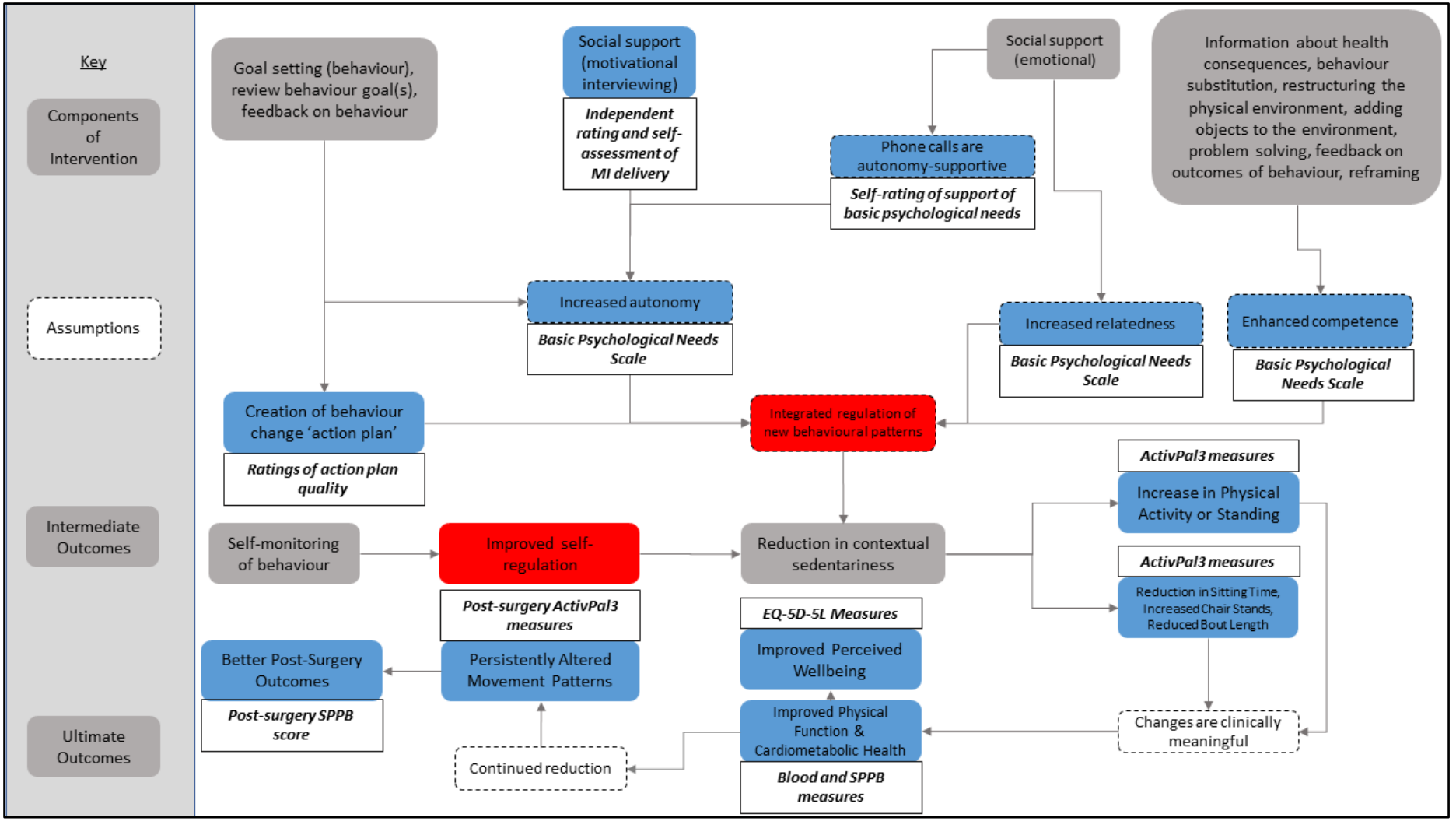

Figure 33. INTEREST logic model with areas assessed by an outcome measure indicated in blue, and those unassessed indicated in red. Bold, italic text indicates the outcome measure used to measure the attached outcome or assumption.

5.3. Improving study processes

5.3.1. Recruitment

As discussed in Chapter 4, the Research Nurse (RN) had offered several suggestions to improve recruitment in a follow-up trial. Chief amongst these were approaching participants face-to-face, reducing the length of study documents, and incorporating RNs more into study processes so that they have a greater understanding of the study procedures. As evidenced above in the sample size calculation, a future trial would either have to: (1) recruit for approximately 4 years with a recruitment rate of 2.9/month to achieve a sample size of 117 or greater (and not considering potential loss at post-surgery), or (2) require more personnel and a multi-site design. To achieve an unbiased process evaluation, an increase in personnel would also be required.

The first suggestion to improve recruitment was to approach patients face-to-face, as this more active approach to recruitment could enhance uptake. As researchers who are not on the primary care team are not permitted to directly approach a patient in-clinic, it may be possible for RNs to perform this task. The time at which patients go to clinic is usually for their initial consultation, meaning that they do not yet have a date for surgery. Although they could be recruited at this time point, it could be up to 4 months until their surgery, which would be too early to intervene. Therefore, they could either be informed of the study face-to-face at this time point and sent the PIS 10-12 weeks before their surgery as was done in INTEREST, or could be consented at that time point, with baseline assessments and intervention sessions organised as their surgery scheduling became clear.

To ensure maximal coverage, it may be best to employ multiple recruitment routes: this includes sending out the PIS as was done in the present study, approaching patients face-to-face, and asking clinicians to inform the patients about the study during their initial consultation. This would ensure that patients are informed through all avenues, likely enhancing the uptake rate.

5.3.2. Implementation

To save time from study visits and reduce cases of missing data, blood sampling for the study could be better planned by integrating with surgical procedures. Although the ability of RNs to take blood was added to INTEREST amendment 3.0, it was not used, as blood samples still needed to be collected from the research site by the primary researcher within a short period of time for processing at UHB Clinical Laboratory Services, several miles away. If blood samples were taken and automatically processed by research nurses at the research site, it would drastically shorten study visits, allowing the addition of further qualitative elements. Likewise, the presence of backup personnel would improve data completeness.

5.3.3. Assessment of prehabilitation-relevant variables

In a future trial within the same pre-surgical orthopaedic population, it would be ideal to acquire ethical approval for the gathering of variables relevant to their care, to better assess the prehabilitative potential of the intervention, as well as any potential economic impact of such a programme. This could include hospital length of stay, complication rate, and post-operative hospital admissions within a certain timeframe.

5.4. Revised booklet

In the qualitative feedback, participants also mentioned that they found the goal adherence recording quite confusing. As such, the booklet has been redesigned (figure 34). The new design features a description of what should be written in the comments section, more space for said comments, and now refers to the goals specifically by number when asking about how well they have been performed. This should be a lot less confusing for the participant. Additionally, to improve environmental modification adherence recording, the reminder at the bottom of the page has been amended to remind participants of this element, as the goals themselves are now numbered according to the week.

Figure 34. Old (left page) vs. new (right page) booklet goal adherence page design.

5.5. Use of pedometers in the study

The final recommendation evident in the feasibility questionnaire and adherence data was that the pedometer was inappropriate for older adults as it would not count steps accurately, particularly in those who could not walk quickly. The pedometer was chosen originally due to its frequent use in the NHS, however, it is clear that there are better options available on the market that use newer techniques, such as piezoelectric pedometers, which are not substantially more expensive. One such example is the Yamax EX210 3D, which is approximately £25 per unit rather than £18 used for the present study. These can be worn anywhere on the body and are more sensitive to smaller movements (Cruz, Brooks and Marques, 2016).

Updating the pedometer to a slightly more expensive version, such as that suggested above, would reduce a large amount of the frustrations experienced by the participants, and perhaps enhance efficacy by improving engagement with this self-monitoring component.

5.6. Summary of recommendations for definitive trial

Table 20 summarises the recommended additions and removals for the definitive trial of the INTEREST intervention.

Table 20. Recommended changes for follow-up studies using the INTEREST intervention.

Additions and enhancements	**Removals**
Process evaluation and post-completion focus groups to collect qualitative data	Feasibility questionnaire
Blood sampling by research nurses and analysis at research site	Blood sampling by researcher and analysis at university
Interviews with and observations of study deliverers	Self-rating of skill usage in the fidelity assessment
Face-to-face contact regarding study with (or recruitment of) participants by research nurse at initial consultation	Removal of Yamax SW200 Digiwalker Pedometer
Utilisation of all available recruitment routes: sending PIS, face-to-face, and through clinicians	
Shortening of participant facing documents by making language more concise and reduction of font size	
Assessment of behavioural regulation of sedentariness	
Revised booklet with clearer recording of adherence	
Incorporation of new piezoelectric pedometer	
Inclusion of prehabilitation-relevant variables: occurrence of complications, hospital length of stay, readmissions	
Multi-site design to ensure adequate uptake of participants to reach desired sample size	
Additional follow-up at 12 weeks	

5.7. Cost analysis of future trial

Cost per participant was calculated based on costs per participant of the present feasibility trial. This analysis assumes it would be delivered by an NHS staff member employed at Band 5, with hourly rate of £12.39 in the 2019/2020 pay scale. Current employer's national insurance and pension contributions (20.68% of pay) were factored in, which were current as of July 2019. Hours required for the delivery of the study were calculated using overestimates, with 10 hrs for patient data collection (including travel time), giving 2.25 hrs for each study visit. Four and two hours were allocated for patient-related paperwork and data entry, and for phone calls, respectively. The full breakdown can be viewed in Table 21.

Table 21. Cost analysis of such an intervention programme, from perspective of the NHS.

Item	**Cost breakdown per intervention group participant (£)**	**Cost breakdown per usual care group participant (£)**
Personnel data collection cost	148.68	111.51
Personnel paperwork cost	59.47	44.60
Personnel phone call cost	29.74	11.51
Booklet printing	2.53	n/a
Information sheet printing	0.10	0.10
Pedometer cost	25	n/a
Total cost per participant	265.52	167.37
Total for 94 participants in each group	24958.69	15732.31

In total, the cost for a definitive trial powered on the Short Physical Performance Battery would be £41,000, at a cost of £266 for an intervention group participant, or £168 for a usual care participant. There may be additional one-off training costs that are not factored into this analysis.

5.8. Summary of thesis

5.8.1. Chapter 1 - Introduction

In Chapter 1, an introduction to sedentary behaviour research in older adults was presented. It was argued that development of interventions should target the individuals most at-risk of the negative consequences of sedentary behaviour. In older adults, changing sedentary behaviour is more readily

achievable compared with increasing MVPA. This argument is even stronger in those with further mobility limitation, such as patients with osteoarthritis. It was evident from the analysis of sedentarism in the mobility restricted that greater focus in sedentary behaviour interventions should be in these at-risk population subgroups.

5.8.2. Chapter 2 – Systematic review

To this end, chapter 2 presented a systematic review of interventions to reduce sedentary behaviour in non-working older adults. Of 2560 articles screened, six were included, wherein 222 participants were 60 years or older on average with none <45 years, and participants did not work greater than two days per week. A narrative synthesis suggested that there are interventions with potential to meaningfully reduce sedentary time in healthy older adults, and that it is safe and feasible to do so. However, it was clear that the field needed to move towards assessing underlying assumptions (i.e. including clinical outcomes), to incorporate behaviour change theory in interventions and add follow-up to assess duration of behaviour change.

5.8.3. Chapter 3 – Intervention and feasibility study development

The INTEREST intervention and feasibility study was designed and presented in this chapter, targeting n=45 older adults ≥60 y waiting for hip and knee replacement surgeries with 2:1 randomisation into intervention and usual care groups respectively. Built upon Self-Determination theory, the INTEREST intervention used a wide number of BCTs, including motivational interviewing, goal-setting/action-planning, individualised feedback, etc. Three assessment points at baseline, pre-surgery, and post-surgery ensured that there would be a pre and post intervention phase, and a follow-up point at which the intervention effect on surgery recovery could be determined. Feasibility was assessed using mixed methods, with questionnaires given to participants, as well as adherence data and an interview regarding recruitment processes with the study's research nurses. Clinical outcomes, such as physical function (SPPB) and cardiometabolic biomarkers, were included, as well as basic psychological needs

satisfaction as part of self-determination theory and objective and subjective assessment of physical activity and sedentary time with an ActivPal3 inclinometer.

5.8.4. Chapter 4 - A novel behavioural INTErvention to Reduce Sitting Time in older adults undergoing orthopaedic surgery (INTEREST): results from a randomised controlled feasibility study

Thirty-five patients were recruited to the INTEREST feasibility study over a period of approximately 12 months. The study was found to be feasible with some modifications, as it was mostly negatively affected by unpredictable surgery scheduling. Suggestions were obtained from participants and research nurses on how to improve study processes. Within-group comparisons suggest that the intervention group significantly improved their physical function (SPPB) score by 0.71 (95% CI, 0.068, 1.360, p=0.032) points, a clinically significant increase, compared to 0.38 (95% CI, -1.63, 0.88, p=0.504) points, in the usual care group. Two-way mixed ANOVAs indicated that there were no significant between-group interactions, other than for BPNS autonomy, $F(1, 15) = 17.234$, $p = 0.001$. As this study was found to be feasible with modifications, it was recommended to pursue a further definitive trial of the intervention.

5.8.5. Chapter 5 - Recommendations for a definitive trial, and conclusions

The final chapter explored the modifications that could be made to a definitive trial based on the INTEREST intervention, utilising 1:1 randomisation. This included the recommendation to initially perform a trial in healthy older adults to assess the efficacy of the intervention at reducing sedentary behaviour in the absence of pain's interfering influence, to incorporate a full, robust process evaluation, revise documents and update pedometer used in the study, and employ more face-to-face recruitment techniques. A calculation of the required sample size for two outcomes was also presented, based on estimates of variance obtained from the INTEREST feasibility study.

5.9. Overall conclusions

This PhD has shown that sedentary behaviour interventions in older adults are still in relative infancy, consisting mainly of small feasibility studies, which are mostly not designed with robust psychological theory as a basis. It has also demonstrated that conducting a complex theory-based intervention to reduce sedentary behaviour in older adults awaiting knee or hip surgery is feasible, and safe and acceptable for participants. It also showed that it is possible to incorporate assessment of all aspects of a robust logic model, as well as an assessment of intervention fidelity, into such an intervention. Finally, it has identified that reducing sedentary behaviour may have potential to improve physical function, and thereby work as a form of prehabilitation prior to hip or knee replacement surgery. The findings of this PhD thesis warrant further theory-based sedentary behaviour interventions to be tested in older adults with mobility limitations, to improve physical function in a prehabilitative context.

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7.0. APPENDICES

Appendix A. Assessment of study fidelity

A.1.1. Types of fidelity assessment in INTEREST

Assessment of study fidelity was also essential to both understanding the feasibility of the study, in terms of whether any aspects of the study are presenting issues in terms of delivery and was also important when assessing the feasibility of the efficacy measures used in the study. The National Institute of Health Behaviour Change Consortium outlines several aspects of fidelity that can be assessed, such as treatment fidelity, treatment receipt, and treatment enactment (Bellg *et al.*, 2004). Treatment fidelity involves ensuring quality of the methodological practises used within the study, treatment receipt is whether participants understand and have taken into account the aspects of the intervention delivered to them, and treatment enactment refers to how well participants are utilising learned treatment techniques or skills in their daily lives (Bellg *et al.*, 2004). INTEREST aimed to measure all these constructs to some extent, but mostly focused on treatment fidelity. By measuring treatment fidelity, it is possible to gain additional insight into mostly the internal validity of the study, and to have a greater understanding of why expected outcomes may or may not have occurred in the actual delivery of the study components. If an intervention does not measure treatment fidelity and has negative results, it may be inaccurately attributed to the study's methodology, whereas actually the study may have been improperly delivered.

A.1.2. Fidelity assessment methodology

The INTEREST treatment fidelity measure for components delivered by a facilitator uses a six-point scale measuring adult skill acquisition to reflect the competence level of intervention component delivery (Dreyfus, 2004). This scale ranges from 0, indicating an absence of skill, up to 5, which would be considered an 'expert' level of delivery (table 4).

Table A1. The generic (non-applied) 6-point score of adult skill acquisition (Dreyfus, 2004).

Competence Level	Scoring	Description
Absence	0	Does not resemble the skill attempting to be used.
Novice	1	Minimal use of the skill and /or inappropriate performance of the skill.
Advanced Beginner	2	Evidence of competence, facilitator begins to understand the context involved, but numerous problems and inconsistencies. Detached involvement.
Competent	3	Competent, aware of and able to cope with different contexts and situations, but with minor problems. More engaged involvement.
Proficient	4	Minimal problems or inconsistencies. Able to adapt appropriately to a variety of contexts and situations. Involved understanding.
Expert	5	Highly appropriate and proficient with no problems. Able to make more subtle refined discriminations between contexts and able to adjust accordingly. Highly involved understanding.

At any time, the deliverer may encounter difficulties, for example due to resistance from the participant, etc. However, in these cases the assessor should have still focused on rating the delivery of the facilitator, whatever the response of the client may be.

A.1.2.1. Performance rating process

Separate documents were created for the rating of individual sessions in the intervention (visit 2/3, phone calls, and action plan rating). Using these forms, the initial assessment should have considered whether the key features of the skill are present (e.g. for motivational interviewing, does the facilitator use OARS, etc.). Secondly, the assessor should assess whether these skills are delivered in the

appropriate contexts rather than merely being present. If a facilitator utilised all the required skills in the appropriate contexts (i.e. doesn't miss many opportunities nor misuses opportunities), then they would be rated among the top competencies. INTEREST fidelity assessment covers motivational interviewing, problem solving, progress monitoring, setback managing, and action planning skills.

A.1.2.2. Performance standards

The intervention would be considered as having been delivered to a good standard if the mean competence of delivery was at level 3 or greater across all items, and if action plans scored a 3 or above.

A.1.3. Item 1: Motivational interviewing

A.1.3.1. Key features

The motivational interview should have been delivered in a client-centred manner, encouraging the patient to be the main driver of behaviour change in an *autonomous* fashion. The instructor should not have been dictatorial, judgemental, or disrespectful. Rather, they should have *supported the patient* and provide them with resources and *encouragement* with which they could realise their own capacity for change. The interaction should have demonstrated *a genuine sense of empathy and warmth* from the facilitator and should have been *individually tailored* to the patient's specific needs and should have *adapted* in response to new information. The patient should have been talking for *more than half of the time*. The facilitator could have shared their own experiences and provided *information/expertise*, but only in a manner that asks *permission*, and was *open-ended* and not dictatorial. MI techniques were also be used in the phone calls where appropriate, and the below skill table (Table 5) may also have been used to aid in skill rating after the phone calls where required. Review of the MI delivery should aid in assessing both treatment fidelity and treatment receipt.

A.1.3.2. Intervention techniques

1. In the initial phases of the MI (engaging, focusing), OARS (open questions, affirmation, reflective listening, summaries) should be used throughout to guide the discussion.
2. Reflective listening at minimum consists of simple reflections that repeat or rephrase elements of what the patient said, but a more skilled facilitator will use complex reflections that exaggerate/amplify the reflections, reframe, emphasise personal autonomy, or reinforce key theoretical components of the intervention /logic model (e.g. highlighting participant experiences of relatedness or their growing sense of competence).
3. Change talk should have been elicited from the patient, and the deliverer should have switched to EARS (elaborating, affirming, reflecting, and summarising).
4. Summaries should have been used throughout that reinforce/affirm/praise patient effort.
5. The responses of the facilitator should have exhibited specific tailoring to the responses of the patient and there should be evidence of a collaborative relationship. There should be no evidence of arguing, disagreements, judgment, blame, or persuasion.

Table A2: MI checklist. Place an X in the box for the highest competency level for which the facilitator fulfils all criteria.

Score	Proficiency	Description of characteristics
	0 – Absence of skill	An overly directing, practitioner-led, or dictatorial style of interaction without any evidence of change talk.
	1 – Novice	Little patient involvement. Minimal evidence of use of MI techniques. The facilitator talks for most of the session.
	2 – Advanced beginner	Some evidence of MI technique usage. Facilitator dominates the discussion. Numerous problems or inconsistencies. Detached involvement.
	3 – Competent	Appropriate use of basic MI techniques (OARS) and summaries. Change talk becomes evident. Evidence of a collaborative relationship. Difficulties in content or method of delivery.
	4 – Proficient	Exclusive use of client-centred delivery style. Participant and facilitator have a collaborative relationship. Little difficulty and few missed opportunities to use MI techniques. Some use of advanced MI skills, such as complex reflections, and summaries are delivered where appropriate, in a manner that furthers the discussion.
	5 – Expert	Highly proficient use of a wide range of advanced MI techniques, e.g. complex, strategic reflections, summaries, etc. No opportunities missed or evidence of problems. Smoothly transitions with new information and uses it in the MI techniques.
	N/A	Not relevant to this activity.

A.2. Item 2: Phone call delivery

A.2.1. Key features

The phone calls in INTEREST served the following purposes:

1. A motivational tool if the patient shows signs of reverting to a less motivated or more ambivalent state. This is on a case-by-case basis (where required).
2. To query the patient about goal adherence and offer opportunities for problem-solving collaboratively with the patient if any goals/environmental modifications are deemed as unachievable. This should result in changes to the goals to make them achievable (where required).
3. To monitor progress.
4. To manage setbacks (where required).

Given that many techniques could have been used in the phone calls, assessment of fidelity required a number of techniques to be assessed, including MI techniques (item 1) and problem-solving skills (item 2a), progress monitoring skills (item 2b), and setback management skills (item 2c).

A.2.2. Intervention techniques

The facilitator should have appropriately identified in which phone calls MI techniques are required and should have used problem solving skills as appropriate to work with the patient on a solution any problems that they have identified, monitor progress, and help manage setbacks (where needed).

Due to the private nature of these calls, the practitioner engaged in a self-rating exercise soon after the call is completed (Table 6). Changes to participant goals that emerged from discussion were recorded in Table 7 on the relevant document.

A.3. Item 2a: Problem-solving

A.3.1. Intervention techniques

Reframing should have been used in cases where there's a setback to focus on the opportunity to use it as a learning experience and help support the patient. Goals should have been revised and reformulated where necessary as part of problem solving and progress monitoring. Techniques such

as identifying barriers; breaking problems down (into easier chunks) and exchanging information in an ask-tell-discuss manner (e.g. to address misconceptions or to stimulate ideas for overcoming barriers) should have been utilised.

Table A3: Problem solving checklist

Score	Proficiency	Example
	0 – Absence of skill	Absence of discussion to suggest appropriate problem-solving strategies relating to the action plan.
	1 – Novice	Minimal discussion to suggest appropriate problem-solving strategies relating to the action plans and/or inappropriate delivery. Amendments to action plans are not made or made poorly despite being required.
	2 – Advanced beginner	Only a small part of the discussion is delivered to a competent level. Some discussion to suggest appropriate problem-solving strategies relating to the action plans, however, these may not be carried out to sufficient depth or detail. Adapting appropriately to context involved, but numerous problems and inconsistencies present. Detached involvement. Amendments to action plans are made poorly.
	3 – Competent	Competent and numerous discussions to suggest appropriate problem-solving strategies relating to prior action plan, however some difficulties are evident (e.g. opportunities to discuss missed, not all areas of problem covered). Able to cope with different context and situations. Minor problems or inconsistencies present. More engaged involvement. Action plans are amended satisfactorily where required, but problems evident, e.g. goals are no longer SMART.
	4 – Proficient	Numerous discussions to suggest appropriate problem-solving strategies with respect to the action plan, able to discriminate between a variety of contexts and situations with some minor problems or inconsistencies evident. Action plans are amended effectively where required.
	5 – Expert	Highly appropriate suggestion(s) of appropriate problem-solving strategies with respect to problems with the prior action plan. Able to make more subtle refined discriminations between contexts and able to adjust accordingly. Minimal or no discernible problems. Action plans amended without any problems.
	N/A	Not relevant to this activity.

Table A4: Goal amendments.

Old Goal or EnviroMod number	New Goal or EnviroMod	Reason for Amendment

A.4. Item 2b: Monitoring progress

A.4.1. Intervention techniques

The facilitator should have asked about progress against the action plans made, actively explored areas in which the patient had experienced benefits as a result of their behaviour change and sought to reinforce these benefits in order to help maintain patient motivation and achievement. The facilitator should also have encouraged ongoing self-monitoring of the targeted behaviours.

Table A5: Monitoring progress checklist

Score	Proficiency	Example
	0 – Absence of skill	Absence of discussion to monitor participant progress on the action plan.
	1 – Novice	Minimal or inappropriately delivered discussion to monitor participant achievement on the action plan.
	2 – Advanced beginner	Some evidence of competence. Some discussion to monitor participant progress towards achievement of the action plan, however, not in sufficient detail or depth. Detached involvement.
	3 – Competent	Competent and numerous discussions to monitor participant progress towards the action plan, however difficulties are evident (e.g. opportunities to discuss missed, not covering all aspects of the problem). Competent, aware of and able to cope with different contexts and situations. More engaged involvement.
	4 – Proficient	Involved discussion to monitor participant on the action plan, some minor problems or inconsistencies evident.
	5 – Expert	Highly appropriate and sufficient discussions monitoring participant progress towards the action plan. Minimal problems.
	N/A	Not relevant to this activity.

A.5. Item 2c: Managing setbacks

A.5.1. Intervention techniques

Setbacks should have been managed using reframing techniques, to change perspectives to allow for viewing of failures as opportunities for change. Participants should have been informed about coping plans as a strategy for managing the setbacks, to aid in the sustainability of change.

Table A6: Managing setbacks checklist

Score	Proficiency	Example
	0 – Absence of skill	Absence of discussion to review participant setbacks relating to action plans and/or highly inappropriate performance.
	1 – Novice	Minimal (or poorly delivered) discussion to review action plans and/or inappropriate performance.
	2 – Advanced beginner	Some evidence of competence. Some discussion to review participant setbacks relating to physical activity behaviours however, these may not be carried out to sufficient depth or detail. Adapting appropriately to context involved, but numerous problems and inconsistencies. Detached involvement.
	3 – Competent	Competent and numerous discussions to review participant setbacks in achievement of action plans. However, some difficulties are evident, such as minor inconsistencies. More engaged involvement.
	4 – Proficient	Numerous discussions to review participant setbacks when achieving action plans, able to discriminate between a variety of contexts and situations with some minor problems or inconsistencies evident. Some discussion of coping plans.
	5 – Expert	Highly appropriate and sufficient review of participant setbacks relating to achievement of action plans. Able to make more subtle refined discriminations between contexts and able to adjust accordingly. Minor or no discernible problems. Clear discussion of coping plans.
	N/A	Not relevant to this activity.

A.6. Item 3: Supporting the Basic Psychological Needs

A.6.1. Key features

The INTEREST study was designed using the theoretical framework of Self-Determination Theory (SDT). Within SDT is the sub-theory of basic psychological needs, which states that we all have three key needs: autonomy, competence, and relatedness. Individuals will maximally achieve behaviour change when these basic needs are most fulfilled. Thus, within the study, all activities should be supportive of the patient's basic psychological needs.

A.6.2. Intervention techniques

To enhance the basic psychological needs throughout the intervention, opportunities should have been taken to enhance participant autonomy by emphasising patient choice (i.e. by emphasising that each of the goals are their choice), highlighting their strengths and agency, and supporting them to overcome their own barriers and to achieve their goals. Competence should have been supported as well, by providing them with the tools they need to feel a sense of achievement, by recognising efforts towards achieving goals, by supporting change talk, and praising participant choices and achievements. Likewise, relatedness should have been aided by fostering an environment in which social interaction can occur, by encouraging spousal/familial involvement where possible, and by having supported or suggested activities that occur in a social context. This included addressing any negative social influences on achievement of the action plans.

Table A7: Supporting Basic Psychological Needs checklist

Score	Quality level	Description of characteristics
	0 – Absence of skill	None of the basic psychological needs were supported.
	1 – Novice	Slight support for one of the basic needs.
	2 – Advanced beginner	The patient was supported in most of the basic needs to some degree, however many opportunities were missed for reinforcement, encouragement, etc.
	3 – Competent	All of the basic psychological needs were supported, but some opportunities to support the patient were missed.
	4 – Proficient	Collaborative relationship between deliverer and patient was clear, and autonomy was highly supported. Few opportunities missed to emphasise autonomy, enhance relatedness, or to foster competence.
	5 – Expert	All needs were supported, no opportunities missed.

A.7. Item 4: Formulation of an appropriate action plan (action planning)

As the action plans are not purely reliant upon the skill of the deliverer, but also reliant upon the participant having a good understanding of their own context and behavioural patterns, the goal-plan was assessed in two stages. Firstly, quality of support for the action-planning process was self-rated by

the facilitator using a measure based on the six-point scale of adult skill acquisition (Dreyfus, 2004) (Table 11). Secondly, plan content and quality was assessed retrospectively at the end of the study. This was conducted with a custom-designed measure of plan content and quality according to the requirements of INTEREST (Table 12), and not the six-point scale of adult skill acquisition. This helped to assess treatment receipt, and goal adherence (self-recorded by participants) helped assess treatment enactment.

A.7.1. Key features

The facilitator should have worked with the participant to formulate an effective set of 6 goals and 3 environmental modifications with which the patient could have reduced their sedentary behaviour and increased their movement. All the goals and environmental modifications should clearly have targeted an aspect of sedentary behaviour or a behaviour with which sedentariness is commonly displaced: namely, they should be related to one of the following:

- Reduction in total sitting time.
- Reduction in the average length of sedentary bouts/greater frequency of breaks in sitting.
- Increased standing behaviour.
- Increased walking.
- Increased quantity of sit-to-stand transitions.
- To increase some other kind of physical activity.

The action plan should also have been appropriate to the level of physical function of the participant. The action plan should have been cross-referenced to the physical function or Short Physical Performance Battery (SPPB) score to ensure that the plan is suitably individualised. Each of the goals should have adhered to SMART principles (i.e. been specific, measurable, achievable, realistic, and timely).

To rate the action plan, the assessor should first have rated each of the goals made for a single participant according to the SMART principles using Table 12 below. Using Table 13 while looking at the whole of the action plan, plus the scoring in Table 12, the assessor should have then been able to

rate the overall level of quality of the action plan. Action plans were considered as delivered to a good level if the average score across the intervention was a 4 or above. Some SMART items, such as whether goals were achievable and realistic may have had to have been assumed or checked against the physical function level of the participant.

A.7.2. Intervention techniques

The facilitator should have ensured that the action plan was made as a collaborative process that was participant-focused and was supportive of their autonomy. The patient should have been heavily involved in the formulation of their own goals, and the purpose of the facilitator was mainly to ensure that the goals formulated are all SMART (as outlined above).

Table A8: Action plan delivery self-rating checklist

Score	Quality level	Description of characteristics
	0 – Absence of skill	No skills were used in the formulation of the action plan.
	1 – Novice	The deliverer dictated most of the goals to the patient with little regard for the patient's autonomy, and few of the goals meet SMART criteria.
	2 – Advanced beginner	The patient was partially supported in the goal making process. Some of the goals meet SMART criteria. Little evidence of a collaborative relationship between deliverer and patient.
	3 – Competent	The patient and deliverer had evidence of a collaborative relationship. Autonomy of the patient was mostly supportive and feedback was given for the majority of the goals as to whether they adhered to SMART criteria.
	4 – Proficient	Collaborative relationship between deliverer and patient was clear, and the patient confirmed that every goal adheres to SMART criteria. Autonomy of the patient was supported throughout the session. Small issues in delivery still present (e.g. couple opportunities missed to discuss an element of the SMART criteria).
	5 – Expert	Collaborative relationship between deliverer and patient was clear, and the patient confirmed that every goal adheres to SMART criteria. Autonomy of the patient was supported throughout the session. No discernible issues with delivery.

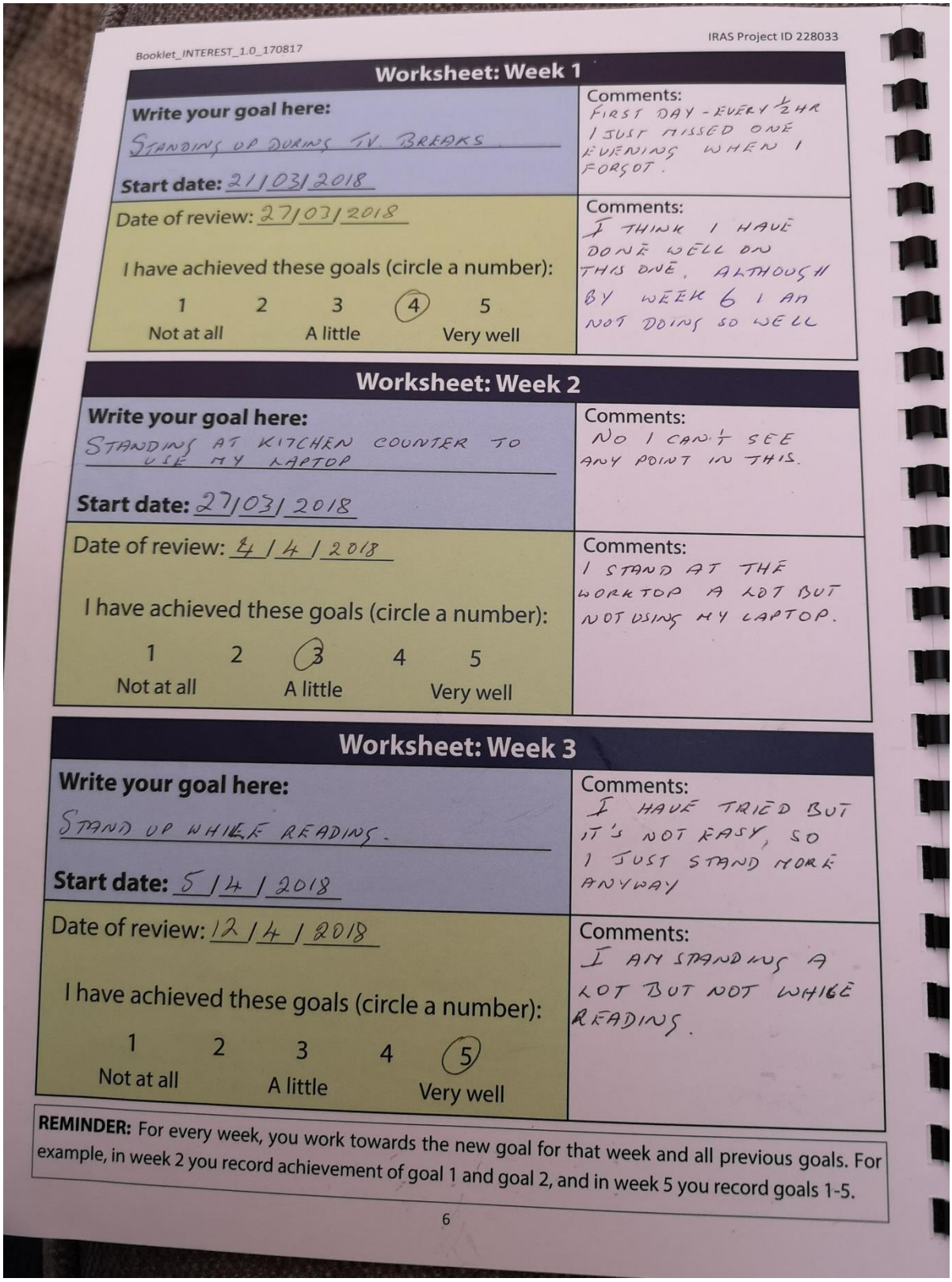
Table A9: Action plan scoring table

Score	Quality level	Description of characteristics
	0 – Non-existent	There is no evidence for an action plan for this participant.
	1 – Inadequate	In total, fewer than 6 goals and/or environmental modifications are created. This could be 3 goals and 2 environmental modifications, for example.
	2 – Adequate	Only one or two items are missing in total. For example, only 5 goals and 2 environmental modifications may be present. Total score for the SMART criteria is above 8.
	3 – Good	All goals and environmental modifications are present and the total score is above 12 on the SMART criteria.
	4 – Very good	All goals and environmental modifications are present, and the goals have been rated and all of them adhere to at least 3 of the SMART criteria, plus a total score of 18 or above for total action plan.
	5 - Excellent	All goals are present, score of 25 or above for SMART criteria, and all are suitable for the physical function level of the participant.

Table A10: Participant goal rating checklist

Goal number	SMART criteria					
	SPECIFIC	MEASURABLE	ACHIEVABLE	RELEVANT	TIMELY	Total score for goal (out of 5)
1						
2						
3						
4						
5						
6						
Total for action plan						

Appendix B. Sample booklet goal adherence page



Booklet_INTERREST_1.0_170817

IRAS Project ID 228033

Worksheet: Week 1

Write your goal here: STANDING UP DURING TV. BREAKS.

Start date: 21/03/2018

Comments: FIRST DAY - EVERY ½ HR I JUST MISSED ONE EVENING WHEN I FORGOT.

Date of review: 27/03/2018

I have achieved these goals (circle a number):

1 Not at all 2 3 A little (4) 5 Very well

Comments: I THINK I HAVE DONE WELL ON THIS ONE. ALTHOUGH BY WEEK 6 I AM NOT DOING SO WELL

Worksheet: Week 2

Write your goal here: STANDING AT KITCHEN COUNTER TO USE MY LAPTOP

Start date: 27/03/2018

Comments: NO I CAN'T SEE ANY POINT IN THIS.

Date of review: 4/4/2018

I have achieved these goals (circle a number):

1 Not at all 2 (3) A little 4 5 Very well

Comments: I STAND AT THE WORKTOP A LOT BUT NOT USING MY LAPTOP.

Worksheet: Week 3

Write your goal here: STAND UP WHILE READING.

Start date: 5/4/2018

Comments: I HAVE TRIED BUT IT'S NOT EASY, SO I JUST STAND MORE ANYWAY

Date of review: 12/4/2018

I have achieved these goals (circle a number):

1 Not at all 2 3 A little 4 (5) Very well

Comments: I AM STANDING A LOT BUT NOT WHILE READING.

REMINDER: For every week, you work towards the new goal for that week and all previous goals. For example, in week 2 you record achievement of goal 1 and goal 2, and in week 5 you record goals 1-5.

6

Appendix C. OVID MEDLINE search strategy

1. (sedentary adj1 (behaviour or time or behavior)).m_titl.
2. (sedentariness or sedentarity).m_titl.
3. (((sitting or screen) adj1 (time or behaviour or behavior)) or sitting-time or screen-time).m_titl.
4. Aging/
5. "Aged, 80 and over"/ or Aged/
6. (elder* or senior* or geriatric* or ?enarian or ag?ing).m_titl.
7. (("65" or >65 or over 65) adj2 (years or age* or old*)).m_titl.
8. (old* adj1 (adult* or people or person* or patient* or population* or men or women)).m_titl.
9. (intervention or trial or study or experiment*).m_titl.
10. ("clinical trial" or "clinical trial, phase i" or "clinical trial, phase ii" or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or "multicenter study" or "randomized controlled trial").pt. or double-blind method/ or clinical trials as topic/ or clinical trials, phase i as topic/ or clinical trials, phase ii as topic/ or clinical trials, phase iii as topic/ or clinical trials, phase iv as topic/ or controlled clinical trials as topic/ or randomized controlled trials as topic/ or early termination of clinical trials as topic/ or multicenter studies as topic/ or ((randomi?ed adj7 trial*) or (controlled adj3 trial*) or (clinical adj2 trial*) or ((single or doubl* or tripl* or treb*) and (blind* or mask*))).ti,ab,kw. or ("4 arm" or "four arm").ti,ab,kw.
11. case report.tw. or letter/ or historical article/
12. 9 or 10
13. 12 not 11
14. 4 or 5 or 6 or 7 or 8
15. Sedentary Lifestyle/
16. 1 or 2 or 3 or 15
17. 13 and 14 and 16
18. exp Infant/
19. exp Child/
20. 18 or 19
21. 17 not 20
22. 21 not animals/
23. remove duplicates from 22

Appendix D. Protocol for study assessments

This section will describe the specific protocols used when the assessments were delivered.

D.1.1. Short Physical Performance Battery

The SPPB was delivered according to the original test protocol (Guralnik *et al.*, 1994). First, the balance tests were conducted. This consists of the side-by-stand stand for 10s, the semi-tandem stand for 10s, and the tandem stand for 10s. For all the tests that required timing, a proper stopwatch was used to ensure the greatest accuracy. For the side-by-side and semi-tandem, one point was awarded if the participant could stand for 10s. For the tandem stand, 2 points are awarded for holding the position for 10s, and 1 point for 3-9.99s. None were awarded for <3s. Next the 4-meter walk was delivered, for which the participant could use a walking aid if required – this was recorded. The participant walked 4 meters at their regular daily pace, and this was performed twice to ensure the greatest accuracy. 4 points were awarded for a time <4.82s, 3 points for 4.82-6.20s, 2 points for 6.21-8.70s, and 1 point for >8.70s. 0 points were awarded if the 4-meter walk could not be achieved.

Next, the chair stand test was performed. This test involves the participant performing 5 chair rises as quickly as possible with the arms across the chest, where one chair rise is moving from a seated to a standing position with the knees and hips completely locked out. No points are awarded if the participant cannot do 5 chair rises, had to use their hands or if they take longer than 60 seconds to do 5. For a time under 11.19s, 4 points are awarded. Three points are awarded for 11.20-13.69s, two for 13.70-16.69s, and one for >16.69s. The total SPBB score is a maximum of 12 and this score is a summation of the described sub-scores.

D.1.2. Waist-to-hip-ratio

Waist and hip measurements were taken according to the World Health Organisation protocol. This means that the waist measurements are taken at the midpoint of the last rib and the top of the iliac

crest (World Health Organisation, 2005). Hip measurements are done at the widest portion of the buttocks with the tape measure parallel to the floor. Waist to hip ratio was computed by dividing the value for the waist by the hip.

D.1.3. Weight

Weight was measured using a SECA 875 scale. The participant was first asked whether they'd like to take off their shoes and any excessive clothing. Some opted not to do so, in which case this was recorded. The participant was asked to step on to their scale two times to ensure that no measurement error may have occurred. Only the second value was recorded, if both were in reasonable range of each other. If a discrepancy occurred twice, measurements continued until a repeatable number could be recorded.

D.1.4. Height

A SECA 213 stadiometer was used to standardise height measurements. Participants were asked to stand with their backs to the stadiometer with their feet on the marked feet locations with their shoes off. Some opted to keep their shoes on, in which case this was noted. Measurements were taken twice to account for the possibility of measurement error. All measurements were taken in the morning to account for variation throughout the day. The nose of the participant was aligned with the bottom of the ear following the National Health and Nutrition Examination Survey (NHANES) protocol (Centres for Disease Control and Prevention, 1988). The measurements were taken twice to account for any measurement error and were taken a third time if discrepancies occurred.

D.1.5. ActivPal physical activity and sedentary behaviour monitor

The ActivPal is designed to measure sedentary behaviour specifically, and as such can measure sitting time, lying time, standing time, stepping time, sit-to-stand transitions, and can output the length of sedentary bouts. An ActivPal was given to participants at the end of the respective assessment visits (visit 1, and 5), or for visit 4, sent via mail in advance for the patients to apply themselves. The ActivPal

was set up to record prior to the visit and then was affixed according to the ActivPal protocol. Tegaderm was applied first to the upper thigh, the ActivPal placed on top, and then a second layer of Tegaderm was added on top to create a semi water-resistant pocket for the device. In some cases, the researcher applied it directly to the participant themselves, and in other cases, the participant was thoroughly instructed on how to do so, and then attached the ActivPal themselves. The ActivPal was worn for 3-7 days to capture sufficient data.

D.1.6. Venepuncture

Phlebotomy was performed in accordance with local University of Birmingham standard operating procedures. Three tubes of blood were taken – 1 yellow-top 5ml SST tube and two lavender 4ml EDTA tubes. These were sufficient for all analyses. As most visits occurred at participants' homes, the blood samples were taken there. This means that initially the patient was asked which location within the home they'd be most comfortable having their blood taken at. The patient was then asked if they had any preferred arm from which to draw the blood, and how comfortable they were with the procedure. This was asked so that the researcher could foresee any issues that may occur. The researcher then identified a suitable vein and set up the patient with a pillow if available to ensure they were comfortable, and the sharps bin, cotton wipes, and tubes were positioned in an easily accessible location. The procedures for drawing the blood were then as follows:

1. A tourniquet was applied to the arm to a sufficient degree of tightness to improve blood flow, but not to the point of pain.
2. The researcher then applied gloves.
3. An alcohol wipe was used to cleanse the vein and immediate area.
4. The needle was then unsheathed and, after gently warning the patient, inserted at a 15-30-degree angle into the vein depending on its depth.
5. Blood tubes were then collected with yellow SST first, then the two lavender tubes.
6. When the last tube was full, the tourniquet was unclipped, and a cotton ball was placed at the site of blood draw while the needle was removed.
7. The needle was placed immediately into the sharps bin.
8. The patient was encouraged to keep pressure on the site to prevent haematoma formation.

9. The researcher inverted the blood tubes at this point to ensure adequate mixing of the blood with in-tube reactive agents.
10. The patient was asked if they'd like a plaster, and if desired, a plaster was applied.

If the initial blood draw was not successful, the patient was asked if they were willing to have another. If so, a maximum of 4 attempts were made before ceasing to try. A maximum of 4 attempts (2 per vein) were made per vein. Due to most visits occurring in people's homes, unfortunately there was no backup researcher available if required.

Appendix E. Basic Psychological Needs Scale (In General)

Please read each of the following items carefully, thinking about how it relates to your life, and then indicate how true it is for you. To give your answer, please circle the relevant number on the scale.

1. I feel like I am free to decide for myself how to live my life. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
2. I really like the people I interact with. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
3. Often, I do not feel very competent. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
4. I feel pressured in my life. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
5. People I know tell me I am good at what I do. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
6. I get along with people I come into contact with. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true

7. I pretty much keep to myself and don't have a lot of social contacts. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
8. I generally feel free to express my ideas and opinions. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
9. I consider the people I regularly interact with to be my friends. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
10. I have been able to learn interesting new skills recently. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
11. In my daily life, I frequently have to do what I am told. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
12. People in my life care about me. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
13. Most days I feel a sense of accomplishment from what I do. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true

14. People I interact with on a daily basis tend to take my feelings into consideration. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
15. In my life I do not get much of a chance to show how capable I am. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
16. There are not many people that I am close to. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
17. I feel like I can pretty much be myself in my daily situations. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
18. The people I interact with regularly do not seem to like me much. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
19. I often do not feel very capable. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true
20. There is not much opportunity for me to decide for myself how to do things in my daily life. 1 2 3 4 5 6 7 Not at all true Somewhat true Very true

21. People are generally pretty friendly towards me.

1 2 3 4 5 6 7

Not at all true Somewhat true Very true

Appendix F. Additional statistical and 'missing data' analysis.

F.1 Within-group comparisons – Baseline (Visit 1) to Pre-Surgery (Visit 4), n=30

F.1.1. Subjective measurement of daily sedentary and physical activities (MOST & IPAQ-SF)

Table F.1. Within-group comparisons of changes in subjective measurement of daily sedentary activities (MOST).

	Measure of Older Adults' Sedentary Time					
Outcomes	Intervention Group			Usual Care Group		
	Baseline (n=21)	Pre-Surgery (n=21)	*p*-value	Baseline (n=9)	Pre-Surgery (n=9)	*p*-value
TV Viewing Time (min.d^{-1})	188.44 (114.87)[a]	178.01 (87.69)[a]	0.653[a]	186.19 (92.94)[a]	171.67 (84.61)[a]	0.65[a]
Computer time (min.d^{-1})	25.71 (55.71)	17.14 (45.73)	0.842	120.00 (124.29)[c]	85.71 (120.00)[c]	0.219[c]
Reading time (min.d^{-1})	30.00 (72.86)	34.29 (100.71)	0.469	86.67 (57.41)[a]	65.71 (72.86)[a]	0.287[a]
Social activities (min.d^{-1})	108.57 (83.94)[a]	102.20 (83.49)[a]	0.797[a]	89.52 (61.97)[a]	77.14 (28.10)[a]	0.58[a]
Transport time (min.d^{-1})	42.86 (21.43)[c]	34.29 (60.00)[c]	0.481[c]	34.29 (36.43[c]	51.43 (62.14)[c]	1.00[c]
Hobby time (min.d^{-1})	17.14 (27.86)	8.57 (38.57)	0.875	43.33 (53.12[a]	33.33 (37.72)[a]	0.553[a]
"Other" time (min.d^{-1})	0.00 (64.29)	0.00 (18.21)	0.285	78.10 (110.39[a]	38.10 (49.82)[a]	0.272[a]
Total (min.d^{-1})	463.31 (182.53)[a]	479.66 (141.00)[a]	0.712[a]	623.65 (186.17)[a]	502.14 (179.70)[a]	0.063[a]

Note: values are shown only where both baseline and pre-surgery data are present.
[a]For these outcomes paired t-tests were used as data were normally distributed and means are shown; the unmarked values indicate that Wilcoxon Signed Rank nonparametric tests were used and the values are median plus inter-quartile range.
[c]For these outcomes a related measures signed rank test was used as differences were not symmetrical upon visual inspection of a histogram.

Table F.2. Within-group comparisons of changes in subjective measurement of daily sedentary and physical activities (IPAQ-SF).

Outcomes	IPAQ-SF					
	Baseline (n=20)			Usual Care Group		
	Baseline (n=20)	Pre-Surgery (n=20)	*p*-value	Baseline (n=8)	Pre-Surgery (n=8)	*p*-value
Walking (min.d^{-1})	32.14 (63.60)	60.00 (64.29)	0.481	39.64 (76.07)[c]	19.29 (32.13)[c]	0.453[c]
MPA (min.d^{-1})	0.00 (28.93)	3.21 (26.79)	0.919	30.00 (70.71)[c]	0.00 (19.29)[c]	0.375[c]
VPA (min.d^{-1})	0.00 (0.00)	0.00 (0.00)	0.655	0.00 (0.00)[c]	0.00 (0.00)[c]	1.000[c]
	Baseline (n=18)[b]	Pre-Surgery (n=18)[b]	*p*-value	Baseline (n=8)	Pre-Surgery (n=8)	*p*-value
Sitting Time (min.d^{-1})	360.00 (180.00)[c]	300.00 (180.00)[c]	0.322[c]	341.25 (125.18)[a]	343.13 (99.96)[a]	0.964[a]

Note: values are shown only where both baseline and pre-surgery data are present.
Abbreviations: MPA, Moderate Physical Activity; VPA, Vigorous Physical Activity
[a]For these outcomes paired t-tests were used as data were normally distributed and means are shown; the unmarked values indicate that Wilcoxon Signed Rank nonparametric tests were used and the values are median plus inter-quartile range.
[b]Items were excluded in line with IPAQ guidance where the participant answered "Don't know" for this question.
[c]For these outcomes a related measures signed rank test was used as differences were not symmetrical upon visual inspection of a histogram.

There were no significant differences present within groups for self-reported sedentary time or physical activity measures (table F.1. and F.2.).

F.1.2. Objective measurement of daily movement patterns

Table 22 Within-group comparisons of changes in objective measurements of daily movement patterns.

Outcomes	Intervention Group			Usual Care Group		
	Baseline (n=19)	Pre-Surgery (n=19)	*p*-value	Baseline (n=6)	Pre-Surgery (n=6)	*p*-value
Mean sedentary time ($min.d^{-1}$)	607.49 (132.62)	576.23 (84.27)	0.257	557.28 (83.01)	562.08 (112.89)	0.902
Mean standing time ($min.d^{-1}$)	252.04 (111.92)	256.25 (113.11)	0.761	269.18 (107.86)	283.11 (121.70)	0.420
Mean stepping time ($min.d^{-1}$)	70.02 (43.39)	71.64 (46.60)	0.692	55.72 (9.27)	55.02 (16.62)	0.730
Mean upright time ($min.d^{-1}$)	322.06 (117.22)	327.89 (120.60)	0.697	326.90 (105.64)	338.13 (135.87)	0.613
Mean steps/d	4949.26 (3732.46)	5060.05 (3967.73)	0.744	4907.40 (2977.70)	3811.17 (617.63)	0.911
Mean time spent in sitting bouts >30 ($min.d^{-1}$)	314.20 (164.69)	310.68 (127.27)	0.918	350.89 (103.67)	331.41 (107.14)	0.597
Mean time spent in sitting bouts >60 ($min.d^{-1}$)	173.44 (154.82)	173.38 (85.83)	0.998	232.00 (101.49)	199.59 (96.70)	0.218
Mean sleeping time ($min.d^{-1}$)	509.74 (112.39)	511.15 (117.91)	0.943	550.78 (76.37)	495.26 (79.51)	0.228
Mean sit-to-stand transitions	41.95 (17.28)	37.95 (11.57)	0.117	33.33 (11.72)	34.17 (9.22)	0.794

Note: values are mean (SD). Values are shown only where both baseline and pre-surgery data are present.
Paired T tests were used for all outcomes.

Objective physical activity and sedentary behaviour data were calculated using the CREA algorithm in ActivPal software 8.10.8.32 with minimum upright and non-upright periods of 10s. Differences between baseline and pre-surgery variables were all normally distributed in both groups as determined using the Shapiro-Wilk test, with no outliers present; thus, paired t-tests were used for all outcomes (table F.3.). There were no significant differences for objectively-measured sedentary time and physical activity variables in either group. However, sedentary time, and upright time all trended towards a reduction, and steps-per-day towards an increase in the Intervention group, and such trends were not present in the usual care group. Separate analyses for weekend/weekday effects were not

possible due to the limited number of days it was possible to record with some individuals prior to surgery (range 3-7).

F.1.3. Physical variables – BMI, waist-to-hip ratio, SPPB, Oxford Score.

Table F.4. Within group assessment of changes in physical variables.

Outcomes	Intervention Group			Usual Care Group		
	Baseline (n=21)	Pre-Surgery (n=21)	*p*-value	Baseline (n=8)	Pre-Surgery (n=8)	*p*-value
BMI	30.79 (5.66)[c]	29.22 (6.10)[c]	0.383[c]	31.71 (5.50)[c]	30.17 (6.95)[c]	0.688[c]
Waist-to-hip ratio	0.92 (0.12)[c]	0.94 (0.11)[c]	1.000[c]	0.90 (0.15)[c]	0.93 (0.16)[c]	1.000[c]
SPPB Balance Points (0-4)	4.00 (2.00)	4.00 (1.00)	0.317	4.00 (1.00)[c]	4.00 (1.00)[c]	0.508[c]
SPPB Walking Points (0-4)	2.00 (3.00)	2.00 (3.00)	1.000	2.00 (1.50)	2.00 (1.50)	0.564
SPPB Gait Speed ($m.s^{-1}$)	0.62 (0.29)[a]	0.65 (0.33)[a]	0.521[a]	0.54 (0.23)[a]	0.53 (0.19)[a]	0.731[a]
SPPB Chair Stand Points (0-4)	1.00 (1.00)	2.00 (3.00)	0.013*	1.25 (0.89)[a]	1.63 (1.06)[a]	0.285[a]
SPPB Total Points	6.95 (3.09)[a]	7.67 (2.97)[a]	0.032*[a]	6.75 (2.32)[a]	7.13 (2.70)[a]	0.504[a]
	Baseline (n=18)	Pre-Surgery (n=15)	*p*-value	Baseline (n=9)	Pre-Surgery (n=7)	*p*-value
SPPB Chair Stand Time (s)[b]	19.67 (15.24)[c]	14.53 (11.53)[c]	0.013*[c]	19.41 (6.45)[a]	16.22 (3.10)[a]	0.209[a]
	Baseline (n=21)	Pre-Surgery (n=21)	*p*-value	Baseline (n=8)	Pre-Surgery (n=8)	*p*-value
Oxford Score (Hip or Knee, 0-48)[c]	20.52 (7.69)[a]	22.67 (8.56)[a]	0.184[a]	18.43 (10.53)[a]	20.14 (10.02)[a]	0.565[a]

Note: Values are shown only where both baseline and pre-surgery data are present.
Abbreviations: BMI, Body Mass Index
[a]For these outcomes paired t-tests were used as data were normally distributed and means are shown; the unmarked values indicate that Wilcoxon Signed Rank nonparametric tests were used and the values are median plus inter-quartile range.
[b]For SPPB Chair Stand Time, some participants were unable to do any chair rises one or both timepoints, thus the values reported here are the chair stand times for those who were able to complete them at each.
[c]For these outcomes a related measures signed rank test was used and medians (IQRs) reported as differences were not symmetrical upon visual inspection of a histogram.
[d]For Oxford Score, higher score equals lower self-reported impact of the joint on one's physical function.

Significant differences were found in the intervention group for the SPPB Total Score, which was equivalent to an increase in mean score of 0.71 (95% CI, 0.068 to 1.360) points, $t(20)=2.306$, $p=0.032$, which exceeds the 0.54 cut-off for the minimum clinically significant increase (table F.4.) (Perera *et al.*, 2006). An effect size of $d=0.503$ (Cohen's *d*, mean difference divided by standard deviation) was calculated, indicating a medium effect within the intervention group. In the usual care group, there

was a non-significant increase of 0.38 (95% CI, -1.63 to 0.88) points, *t*(8)=-0.704, *p*=0.504 in overall SPPB score (figure F.1.). This increase in total score in the intervention group was mainly due to improvements in chair rise stand time, whereby median time decreased by 5.14 seconds (IQR, -9.70 to -0.48s, *z* = -2.405, *p*=0.013), resulting in an increase of 1 point in the median chair stand score (IQR 0.00 to 1.00, *z* = 2.486, *p*=0.013). The usual care group also improved in chair rise time by -3.19s (95% CI, -8.73, 2.36), *t*(6)=-1.407, *p*=0.209, but this was not statistically significant.

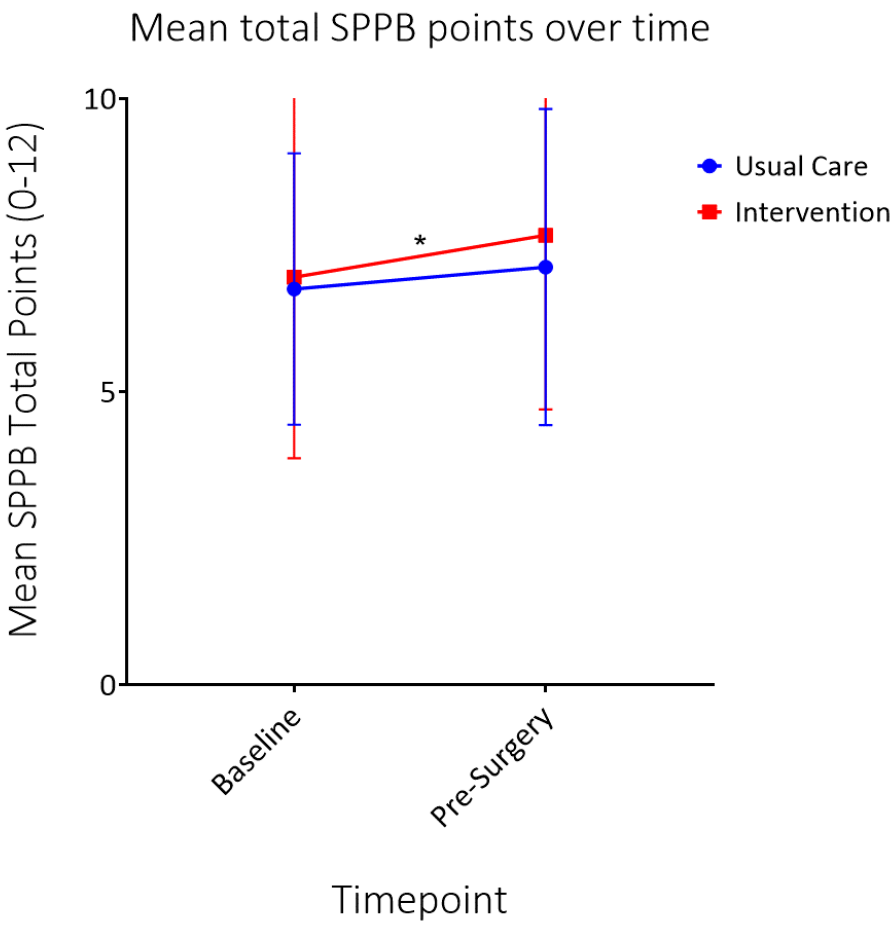


Figure F.1. Mean SPPB total points at baseline and pre-surgery stratified by group. Error bars are standard deviation.

F.1.4. Psychological variables

Table F.5. Within-group assessment of changes in basic psychological needs (SDT) variables.

Outcomes	Intervention Group			Usual Care Group		
	Baseline (n=21)	Pre-Surgery (n=21)	*p*-value	Baseline (n=9)	Pre-Surgery (n=9)	*p*-value
Basic Psychological Needs – Autonomy (0-7)	6.29 (1.50)[c]	6.14 (1.43)[c]	0.481[c]	4.89 (1.12) [a]	5.18 (1.32)[a]	0.314[a]
Basic Psychological Needs – Competence (0-7)	4.64 (1.13)[a]	4.67 (0.96)[a]	0.105[a]	4.13 (1.18)[a]	4.13 (1.16)[a]	0.767[a]
Basic Psychological Needs – Relatedness (0-7)	6.25 (1.00)[c]	6.25 (0.94)[c]	0.238[c]	6.00 (1.01)[c]	5.75 (0.94)[c]	1.00[c]

Note: Values are shown only where both baseline and pre-surgery data are present.
[a]For these outcomes paired t-tests were used as data were normally distributed and means are shown; the unmarked values indicate that Wilcoxon Signed Rank nonparametric tests were used and the values are median plus inter-quartile range.
[c]For these outcomes a related measures Sign rank test was used and medians (IQRs) reported as differences were not symmetrical upon visual inspection of a histogram.

For the psychological variables, higher scores indicate more positive psychological states. There were no significant differences within groups for the Basic Psychological Needs of autonomy, competence, nor relatedness (table F.5.).

F.1.5. Quality of life and activities of daily living

Table F.6. Within-group comparisons of changes in quality of life and activities of daily living data.

Outcomes	Intervention Group			Usual Care Group		
	Baseline (n=21)	Pre-Surgery (n=21)	*p*-value	Baseline (n=9)	Pre-Surgery (n=9)	*p*-value
EQ-5D-5L Mobility (0-5)	1.86 (1.01)[a]	2.90 (1.00)[a]	0.002**[a]	1.67 (1.12)[a]	3.22 (0.67)[a]	0.015*[a]
EQ-5D-5L Self-Care (0-5)	2.00 (2.00)[c]	1.00 (2.00)[c]	0.289[c]	2.89 (1.17)[a]	1.89 (0.93)[a]	0.081[a]
EQ-5D-5L Usual Activities (0-5)	3.00 (1.50)	3.00 (1.50)	0.057	3.44 (1.13)[a]	3.11 (0.78)[a]	0.438[a]
EQ-5D-5L Pain (0-5)	2.00 (1.30)[a]	3.33 (0.91)[a]	0.001**[a]	2.11 (1.27)[a]	3.33 (1.00)[a]	0.065[a]
EQ-5D-5L Anxiety (0-5)	3.14 (1.24)[a]	1.38 (0.59)[a]	<0.001**[a]	3.00 (2.00)[c]	2.00 (2.00)[c]	0.070[c]
EQ-Visual Analogue Scale (0-100)	67.57 (21.14)[a]	72.86 (17.36)[a]	0.388[a]	65.00 (27.50)[c]	55.00 (22.50)[c]	1.000[c]
	Baseline (n=21)	Pre-Surgery (n=21)	*p*-value	Baseline (n=8)	Pre-Surgery (n=8)	*p*-value
Katz Activities of Daily Living (0-6)	6.00 (1.00)	6.00 (1.00)	1.00	5.00 (1.50)[c]	5.50 (1.00)[c]	0.625[c]

[a]For these outcomes paired t-tests were used as data were normally distributed and means are shown; the unmarked values indicate that Wilcoxon Signed Rank nonparametric tests were used and the values are median plus inter-quartile range.
[c]For these outcomes a related measures signed rank test was used and medians (IQRs) reported as differences were not symmetrical upon visual inspection of a histogram.
** Indicates p<0.05.*
*** Indicates p<0.005*

For EQ-5D-5L scores, higher scores indicate greater problems in daily life. The EQ-5D scores showed several statistically significant within-group differences in both the intervention and usual care groups (table F.6.). Both intervention and usual care groups reported a statistically significant increase of in mean mobility scores of 1.05 (95% CI, 0.43, 1.66) points, $t(20)=3.532$, $p=0.002$, and 1.56 (95% CI, 0.40, 2.72) points, $t(8)=3.092$, $p=0.015$ respectively, from baseline to pre-surgery, from 1 points to 3 points, which is equivalent to moving from “no problems in walking about” to “moderate problems in walking about”. This was also reflected by increases in pain score, particularly in the intervention group, wherein the mean increased by 1.33 (95% CI, 0.58, 2.09), $t(20)=3.696$, $p=0.001$ from a mean of 2 (“some pain or discomfort”) to over 3 points (“moderate pain or discomfort”). However, both groups had a mean of 3.33 points at the pre-surgical timepoint. It was also found that anxiety statistically significantly decreased in the intervention group by -1.76 (95% CI -2.34, -1.19) points, $t(20)=-6.402$,

p<0.001. The usual care group also trended towards a decrease in median anxiety score by 1 point (z = -1.833, *p*=0.067) (figure F.2.).

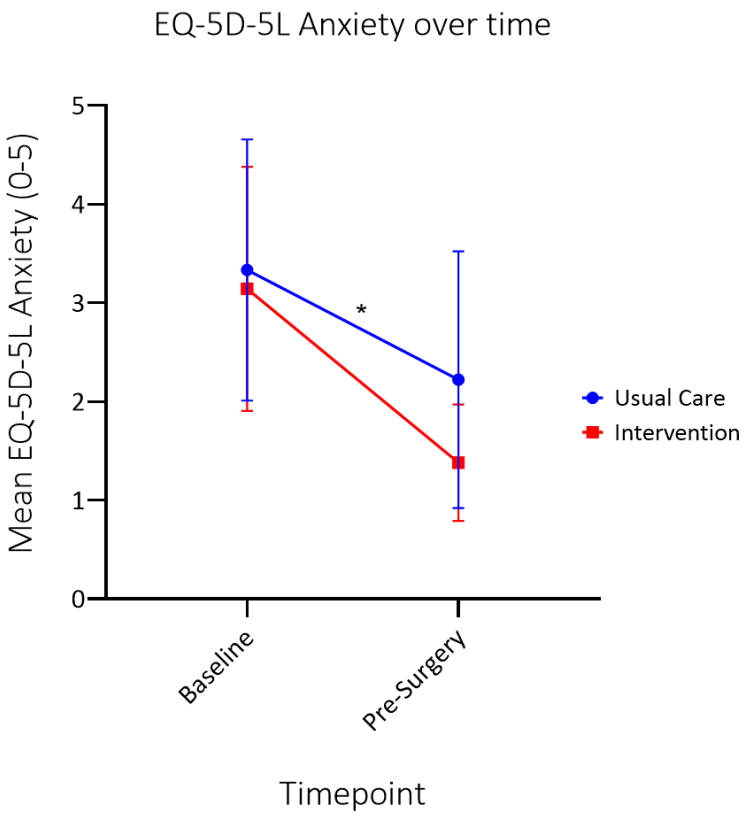


Figure F.2. EQ-5D-5L Anxiety score at baseline and pre-surgery stratified by group. Error bars are standard deviation.

F.1.6. Cardiometabolic and hormonal biomarkers

Table F.7. Within-group comparisons of cardiometabolic and hormonal biomarkers.

Outcomes	Intervention Group			Usual Care Group		
	Baseline (n=14)	Pre-Surgery (n=14)	*p*-value	Baseline (n=6)	Pre-Surgery (n=6)	*p*-value
Triglycerides (mmol.l^{-1})	1.30 (0.65)[c]	1.00 (0.75)[c]	0.549[c]	1.20 (0.32)[a]	1.37 (0.44)[a]	0.195[a]
Cholesterol (mmol.l^{-1})	4.36 (0.91)[a]	4.29 (0.92)[a]	0.655[a]	4.60 (2.48)	4.30 (1.33)	0.273
Low-density lipoprotein (mmol.l^{-1})	2.31 (0.75)[a]	2.25 (0.77)[a]	0.541[a]	2.77 (1.35)[a]	2.28 (0.79)[a]	0.210[a]
High-density lipoprotein (mmol.l^{-1})	1.39 (0.36)[a]	1.47 (0.39)[a]	0.180[a]	1.47 (0.64)[c]	1.41 (0.79)[c]	1.000[c]
	Baseline (n=13)	Pre-Surgery (n=13)	P-Value	Baseline (n=4)	Pre-Surgery (n=4)	P-Value
Cortisol (mmol.l^{-1})	334.39 (131.23)[a]	374.62 (77.08)[a]	0.269[a]	315.00 (22.52)[a]	526.00 (239.90)[a]	0.295[a]
	Baseline (n=13)	Pre-Surgery (n=13)	*p*-value	Baseline (n=3)	Pre-Surgery (n=3)	*p*-value
DHAS (mmol.l^{-1})	1.36 (0.77)[a]	1.30 (0.72)[a]	0.519[a]	1.71 (1.18)[a]	1.71 (1.07)[a]	0.990[a]
	Baseline (n=16)	Pre-Surgery (n=16)	*p*-value	Baseline (n=5)	Pre-Surgery (n=5)	*p*-value
HbA1C (mmol.l^{-1})	39.13 (8.57)[a]	39.44 (8.40)[a]	0.401[a]	39.4 (1.82)[a]	39.4 (1.14)[a]	1.000[a]

[a]For these outcomes paired t-tests were used as data were normally distributed and means are shown; but the unmarked values indicate that Wilcoxon Signed Rank nonparametric tests were used and the values are median plus inter-quartile range.

[c]For these outcomes a related measures sign rank test was used and medians (IQRs) reported as differences were not symmetrical upon visual inspection of a histogram.

No statistically significant differences were present in any of the groups with respect to the blood measures (table F.7.).

F.2. Baseline (T1) to Post-Surgery (T3) ANOVAs

F.2.1. SPPB - physical function

There was no statistically significant interaction between the group and time for total SPPB score, $F(2, 30) = 0.51$, $p = 0.951$, partial $\eta^2 = 0.003$. However, the main effect of time showed a statistically significant difference in mean SPPB total score across the different time points, $F(2, 30) = 10.955$, $p < .001$, partial $\eta^2 = 0.422$. The main effect of group showed no statistically significant difference in SPPB score between intervention groups, $F(1, 15) = 0.981$, $p = 0.338$, partial $\eta^2 = 0.061$.

F.2.2. ActivPal3 sedentary time (min.d^{-1})

There was no statistically significant interaction between the group and time for sedentary time, F(2, 20) = 0.992, p = 0.388, partial η2 = 0.090. There was also no significant main effect of time for sedentary time, F(2, 20) = 0.724, p = 0.497, partial η2 = 0.068. The main effect of group showed that there was no statistically significant difference in mean sedentary time between study groups $F(1, 10) = 0.000$, p = 0.998, partial $\eta^2 = 0.000$. However, there was a non-significant reduction in mean sedentary time of -66.02 (95% CI, -180.50, 48.46) min.d^{-1} in those who were retained for all three timepoints, which is equivalent to a medium-large effect size of 0.667 (Hedge's g).

F.2.3. Upright time (min.d^{-1})

There was no statistically significant interaction between group and time for upright time, F(2, 20) = 0.396, p = 0.678, partial η2 = 0.038. There was also no significant main effect of time for upright time, F(2, 20) = 1.246, p = 0.309, partial η2 = 0.111. The main effect of group showed that there was no statistically significant difference in mean upright time between study groups $F(1, 10) = 0.109$, p = 0.748, partial $\eta^2 = 0.011$.

F.2.4. Mean steps per day

Although the means suggest that those in the intervention group did manage to increase their mean steps per day and that this continued at the post-surgery stage, the group x time interaction was not significant, F(2, 20) = 0.800, p = 0.463, partial η2 = 0.074. There was also no significant effect of time for steps per day, F(2, 20) = 1.045, p = 0.370, partial η2 = 0.095. The main effect of group showed that there was no statistically significant difference in mean steps per day between study groups $F(1, 10)$ = 0.174, p = 0.686, partial $\eta^2 = 0.017$.

F.2.5. BPNS autonomy (0-7)

Data were not normally distributed for all within-groups timepoints, as baseline intervention data were not-normal, as indicated by a Shapiro-Wilk test (p=0.029). However, all other timepoints and groups

were normally distributed (Shapiro-Wilk test p>0.05), and as ANOVAs are considered robust to small violations of normality, a two-way mixed ANOVA was performed (Schmider *et al*., 2010).

There was a statistically significant interaction between the group and time for BPNS Autonomy, F(2, 30) = 0.800, p = 0.024, partial η2 = 0.220. There was also a significant effect of time for Autonomy, F(2, 30) = 4.131, p = 0.026, partial η2 = 0.216. The main effect of group showed that there was a statistically significant difference in Autonomy between study groups $F(1, 15) = 17.234$, p = 0.001, partial η^2 = 0.535.

F.2.6. EQ-5D-5L anxiety

Data were not normally distributed for all within-groups timepoints, as pre-surgery intervention data were non-normal, as indicated by a Shapiro-Wilk test (p<0.001), as well as post-surgery data in both groups (p=0.006 for usual care and 0.030 for intervention). Attempts were made to apply a reflect and inverse transformation, but it was not possible to achieve a normal distribution. As such, the two-way mixed ANOVA was still attempted, as it is robust to violations of normality. However, the test was not completed due to violating Box's test for equality of covariance matrices. Figure F.3. depicts the means over time.

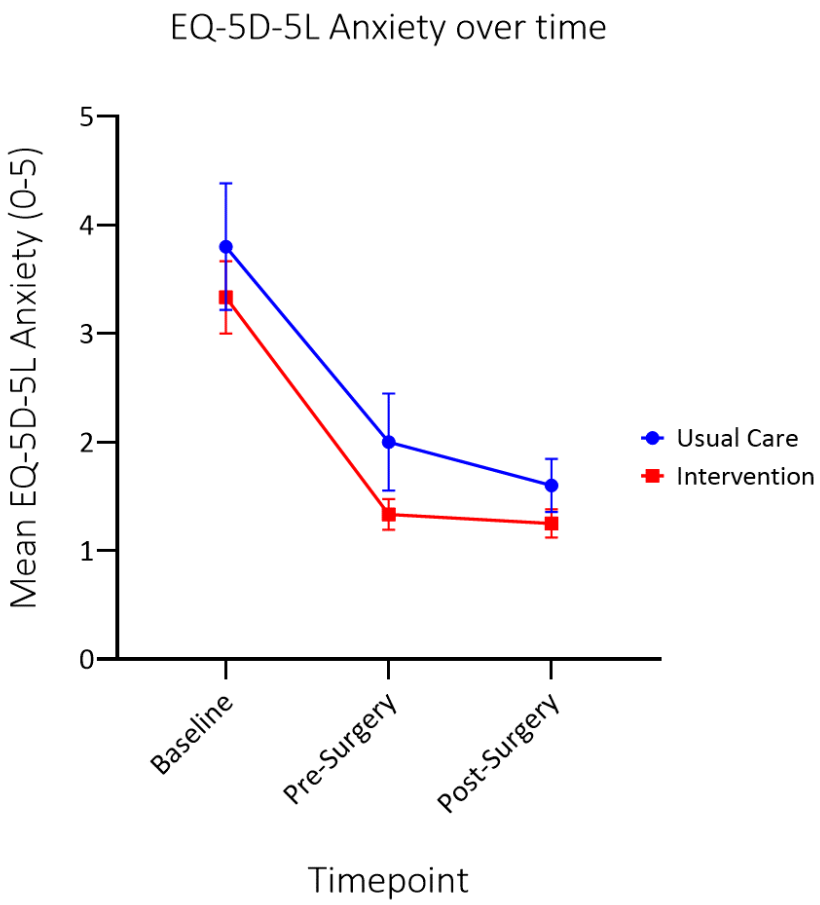


Figure F.3. Mean EQ-5D-5L Anxiety score over all three timepoints stratified by group. Higher score is higher anxiety. Error bars are standard error of the mean.

F.2.7. Oxford joint score

Normality tests indicated that data at all timepoints were normal as indicated by a Shapiro-Wilk test ($p>0.05$), with the exception of the usual care pre-surgery timepoint ($p=0.003$). As the test is robust to violations of normality, the ANOVA was continued.

There was no statistically significant interaction between the group and time for Oxford Score, $F(2, 30) = 0.961$, $p = 0.394$, partial $\eta 2 = 0.060$. There was, however, a significant main effect of time for Oxford Score, $F(2, 30) = 39.171$, $p < 0.001$, partial $\eta 2 = 0.723$. The main effect of group showed that there no statistically significant difference in Oxford Score between study groups $F(1, 15) = 1.722$, $p = 0.209$, partial $\eta^2 = 0.103$ (table 17).

F.3. Summary

Significant within-groups differences were identified from baseline to pre-surgery within the intervention group for SPPB, equivalent to 0.71 pts (p=0.032), a clinically significant increase. For EQ-5D-5L, mean mobility and pain scores increased significantly within the intervention group by about 1pt each, indicating greater problems with pain and mobility (both p=0.001). Anxiety score also significantly decreased by about 2pts (p<0.001). Mobility score in the usual care group also significantly increased by about 1.5 pts (p=0.015), indicating they had more issues with mobility over time as well. Sedentary time decreased, whilst upright time, and steps/day increased in the intervention group – the intended directionality of effects, whilst the inverse was true in the usual care group. These were not statistically significant. No statistically significant between-group differences were identified either from baseline to pre-surgery with independent T tests in 30 participants, nor from baseline to post-surgery in 17 participants with 2x3 ANOVAs.

F.3. Analysis of missing data and feasibility of data collection

F.3.1. Baseline

Data collected from questionnaires and physical measurements at baseline were complete in both the 24 individuals in the Intervention group, and the 11 in the usual care group, indicating a high degree of feasibility for this type of data.

F.3.1.1. Blood sampling

There were issues concerning blood sample collection, which meant that completeness for certain measures ranged from 81.8% (9) in the usual care group for red blood cell concentration, to 77.7% (7) for cortisol concentration. This discrepancy in number between measures was primarily due to issues with analysis at the University Hospitals Birmingham Clinical Laboratory Services (UHB CLS), whereby results of certain analyses were not returned to the researcher, without reason being given, causing missing data for certain biomarkers. However, the missing 2 cases in the usual care group were due to

inability to find a vein by the primary researcher. As phlebotomy was conducted in people's homes, it was not possible to have another member of the study team to take the sample, so three attempts were made and then attempts were ceased. In the intervention group, there was a similar discrepancy; with 95.8% (23) of values being present for vitamin D, but only 91.6% (22) present for cholesterol, LDL, and others. This was also due to issues with analysis, most often due to results not being returned to the research team or an insufficient sample remaining after the initial analyses.

F.3.1.2. ActivPal measurements

ActivPal measurements were also not complete, with 90.9% (10) of usable (defined as >2 valid days of recording) data present in the usual care group, and 91.7% present in the intervention group. In the usual care group, the n=1 missing case was due to data corruption, and in the intervention group, the missing cases were due to one data corruption, and one drop out/non-return of the device.

F.3.2. Pre-surgery (visit 4)

The majority of data were feasible to collect, with few missing data present in the n=21 (Intervention) and n=9 (usual care) individuals that reached this time point. One pre-surgical meeting in the usual care group had to be cut short due to a participant's health issues, which led to missing data (n=1) for SPPB, WHR, weight, BMI, IPAQ, blood measures, and Oxford joint score. However, other questionnaire-based data were recovered via a follow-up phone call.

F.3.2.1. Blood sampling

The most missing data, again, were due to issues with blood sampling. The usual care group had 77.8% (7) of data present for cholesterol, LDL, triglycerides, etc., however, only 55.5% (5) of data was present for cortisol, for example. This discrepancy was again due to analysis issues at UHB CLS. However, it was also not possible to gain blood samples from 2 participants.

In the intervention group, blood sample data was present in some level of completeness for 81.0% (17) of participants. This again varied from 17 cases for red blood cell count, but only 15 for cortisol. The

discrepancy within subjects was again due to analytical issues, however, the missing 4 participants were due to insufficient time to ask the participant to fast (1), difficulty in blood draw (2), and refusal (1).

F.3.2.2. ActivPal measurements

Only 66.7% (6) participants in the usual care group and 95.2% (20) of those in the intervention group provided sufficient ActivPal data for analysis pre-surgery. It was difficult to acquire all data at this timepoint as measurements had to occur during the week preceding surgery (in those who had surgery), and if data were corrupted or lost power too quickly, then measurements could not be re-attempted. Data were missing in the usual care group due to non-return of ActivPal (1), data corruption (1), and battery failure (1). In the intervention group, one was missing due to insufficient time to record (1).

F.3.3. Post-surgery (visit 5)

All data for physical measures (weight, SPPB, etc.) and questionnaires (EQ-5D-5L, MOST, etc.) were present for the 5 individuals in the usual care group and the same applied for the 12 individuals in the intervention group.

F.3.3.1. ActivPal measurements

Data were present for all 5 individuals in the usual care group, but only 66.7% (8) of the intervention group. This is due to incorrect wear (1), data corruption (2), and battery failure (1).

F.4. Summary of analysis of missing data and feasibility of data collection

It was feasible to collect all the data for this intervention, however, battery power, lack of time for sufficient measurement, and other technology issues affected ActivPal data completeness, and a lack of backup personnel and analytical issues affected blood measure completeness.

Appendix G. Full analysis of interview with research nurse

G.1. Interview findings

Headings indicate the themes being discussed, and bold text indicates the subtheme. Themes and subthemes are depicted in figure 30.

What were the problems that arose during recruitment? (Practicality)

Several problems with recruitment were identified. Not all problems presented here were directly related to recruitment, but also to study processes in general. These included: problems related to understaffing, inaccurate expectations, IT problems, problems relating to phone calls, time management, and problems with surgery scheduling.

Problems relating to understaffing. As the second RN assigned to the project had an unforeseen leave of absence, this led to a significant burden on the primary RN and an increase in their workload. The RN mentioned that this led to increased burden, as sending out PIS' *"would take like a whole day"*, and if the other RN was present, then *"we could have done it a bit differently"*. However, they did not report that this impacted recruitment, just made it more difficult, as *"we've definitely picked up everyone that we could have picked up, everyone's had the opportunity"*.

Inaccurate expectations. At the site initiation visit, the researcher was informed that it was very likely that the target of 45 participants over one year would be achieved. This was based on the number of eligible patients likely to be listed for surgery in the period. However, the RN reported that *"there weren't as many responses as I thought to come back"*.

IT problems. The RN initially had problems accessing surgery dates directly, which negatively impacted recruitment up until 04.05.2018, when the issue was resolved. The RN reported that: "*initially I couldn't do it myself on the IT system, so I was having to email the secretaries to send me their updated theatre lists, which obviously wasn't as live as if I could just do it every day, if you know what they*

mean, and some of them were reluctant in sending it, or just not sending it. So that was a delay at the start, but when I was able to get access it was sorted."

Problems relating to phone calls. Two issues were reported with the phone calls, firstly, that *"they probably weren't done the week after if you know what I mean, just because of workload and other stuff in the office or whatever…"*. Additionally, the RN reported that there were wrong numbers in the patient records, and that many didn't answer. This meant that the RN *"did manage to speak to quite a few, but yeah, not all of them, really"*.

Problems with time management. The RN reported throughout that it was a time-intensive process to do the recruitment tasks, both the phone calls and sending out PIS'. In relation to the study, they mentioned that when they were busy, *"you could say [the study] was pushed to the side if you know what I mean – but it wasn't delayed"*.

Problems with surgery scheduling. Towards the end of the study, and over the summer 2018 period, there were lulls in recruitment. The RN reported that the problem times were *"Christmas! Christmas! And, weirdly, summer, because of all the holidays that people have – both patients and – so they start to on the waiting list you can see that they can't have their surgery between here and here, so it gets delayed and stuff by the patients"*. Evidently, one of the reasons for these delays were holidays. However, the RN also mentioned that there were problems with the surgical theatres over the Christmas period: "*theatre 10 has got some kind of problem, and as such they've opened up an outdoor thing, some kind of Vanguard unit. Could that have affected [scheduling]? Yes. Whether it did? I don't know."*

How could recruitment have been improved?

The RN identified a few areas for improvement, these included improving recruitment processes, improved integration with the healthcare sector, lengthened recruitment times, and giving RNs a better understanding of study processes.

Improving recruitment processes. The RN suggested that we could improve the uptake rate by approaching participants face-to-face, to *"see a few patients in the hospital and tie it in with the initial clinic day, almost have a stand with posters or something, and just say if this would be something you'd be interested in once they were listed for theatre and we know you've got a date"*. The RN believed that simply sending the PIS was too passive and that it *"would have been better if we were able to see them physically rather than it just being sent out"*. Likewise, the PIS material was too long and needed to be cut down. According to the RN, based on phone calls they had experienced, *"some of [the patients] just didn't want to know just because of the amount they were being sent"*, which could have affected the uptake rate more. A further perspective resulting from the phone calls was that the participants would have preferred to talk to the researcher, as the researcher was better informed regarding the study processes and *"could say [I am] the one who would directly come out to see them"*.

Prolonged recruitment times could mean more patients could have been followed-up due to long surgery delays. The RN suggested that although we *"need a time limit when you're trying to recruit these patients, but if you had two years, then you wouldn't have had [so many issues]"*.

Integration with the healthcare team. When asked about integrating the research team with hospital processes more, the RN thought that *"if you could have better access at whatever hospital you were at, just so if you could even remotely access the system and stuff, yeah, that would be good"*. Direct access to surgery lists by the researcher could streamline research processes but may present ethical issues.

Better understanding of study processes. The RN reported that "*it could have been quite good to have seen a visit, maybe, it just might have been useful to see what it fully entailed, as you understand it quite a bit better then, rather than saying 'I think this is going to happen', and you know*". As over 99% of study visits were scheduled at home, it wasn't possible to coordinate one with the research nurses, but this would have enabled them to explain the study on the phone to participants more effectively.

How would such a study scale to another research site or a definitive trial?

The RN reported that expanding the study to another research site would likely come across the same issues with respect to surgery scheduling, as they *"assume it would be the same, as they all have the same 18-week wait or something"*. Furthermore, they responded affirmatively to the question of whether other hospitals "would all suffer from the same bed shortages".

What were the positive aspects of the design of the INTEREST feasibility study?

The RN thought that the approach to recruitment, although flawed in some ways, was beneficial in others, as outlined further below.

Coverage. Although not everyone wanted to take part, *"we were capturing the right patients that were supposedly going to be seen"*.

Communication. With respect to communication between the RN and the research team, the RN thought it was good. Although having direct access by researchers to surgery lists would make processes more fluid, the RN thought that *"the communication [between RN and researcher] was the most information you could have had"*.

Flexibility. The RN was also happy about the flexibility that the recruitment processes offered, as they could send out PIS' and make calls around their other commitments.

Burden. The RN was of the opinion that the study did improve uptake rate as *"[the researcher] definitely picked up more people because of going to their houses"*, which reduced participant burden.

G.2. Summary

The primary roadblocks affecting practicality that were perceived by the RN were problems with operating theatres and the length of participant-facing documents. Recruitment could be improved by reducing the length of these documents, increasing the recruitment period and overall study length, and by affording the RNs a better understanding of activities within study visits. For adaptation, the

RN does not foresee any issues with scaling to other research sites, other than that the same caveats found here are likely to remain. Lastly, for the category of satisfaction, they found that the recruitment processes in INTEREST were positive since it managed to reach all eligible patients, and the visits in participants' homes likely improved uptake rate due to reducing burden.

Appendix H. Coding of action plans and environmental modifications

H.1. Goals formulated by participants

In total, 22 participants allocated to the intervention group formulated 6 goals and 3 modifications each, comprising 132 goals and 66 modifications. The goals and environmental modifications fitted into three broad themes: modifying the physical environment, modifying movement patterns, and modifying the social environment (figure H.1.). Within modifying the environment, there were several common subthemes, namely: changing seating arrangements, using exercise equipment, modifying clothing, using reminders in the environment, and removing objects from around chairs. The theme of movement patterns was much broader, and encompassed goals around reducing many seated behaviours. These behaviours included TV viewing, computer/tablet/gaming device usage, drinking, eating and cooking, hobbies, reading, social activities, toileting, transport, and sitting in general. Within these themes were sub-themes for whether goals focused on breaking up sitting bouts, increasing standing, increasing sit-to-stand transitions, or increasing walking. Certain activities like TV viewing also contained goals that focused on reducing the incidence of that activity. Social modifications comprised of social reminders, encouragement, and co-opting tasks from others.

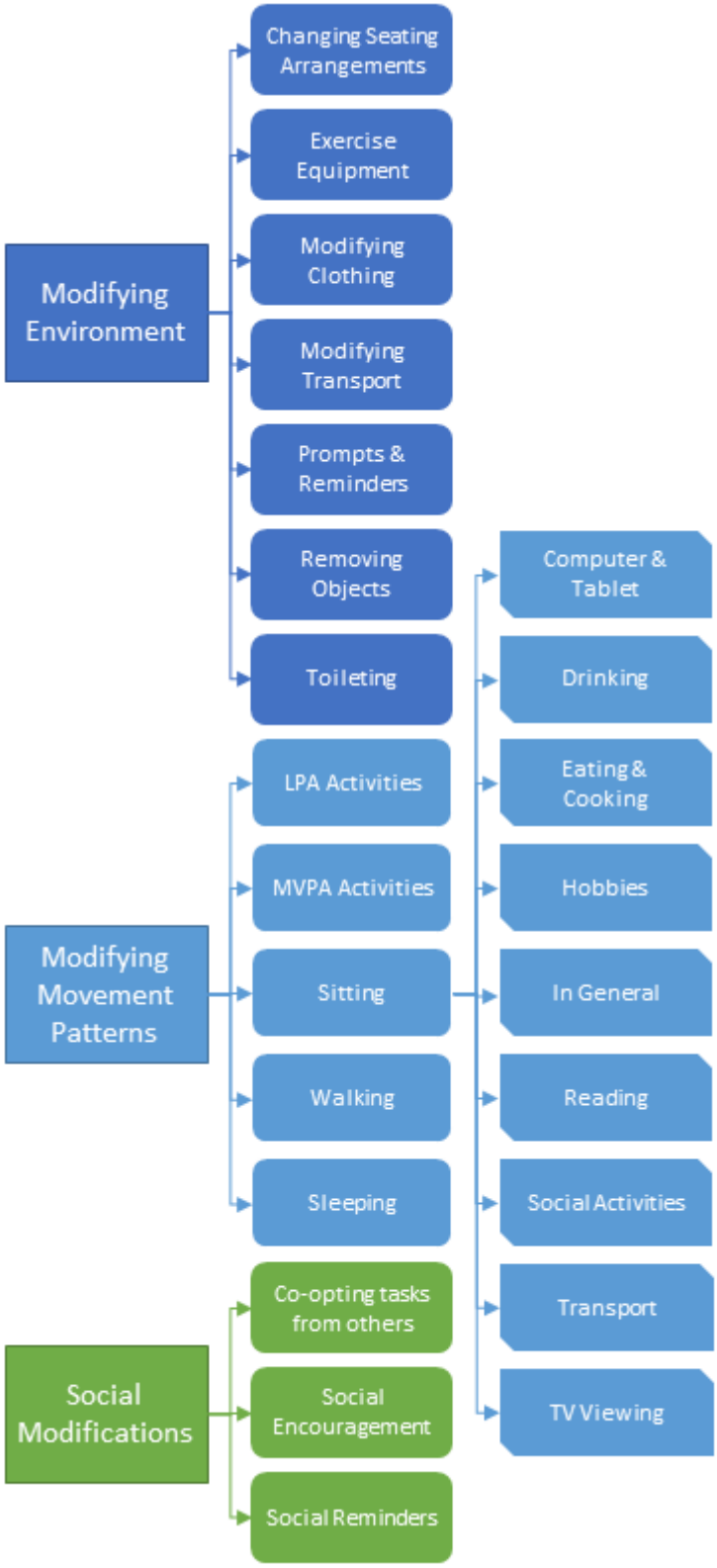


Figure H.1. Higher-order coding categories for behavioural targets of goals.

Most of the goals related to sitting, with 71 goals relating to seated behaviours. After sitting, walking was assigned 44 codes, and LPA activities 11 codes. Within the theme of sitting, the most popular targeted behaviours were TV viewing (27 goals), eating and cooking (17), reading (10), and using the computer or tablet (9). For walking, there was a relatively equal division between adding walks at various times of day (23) and modifying step targets (21). Goals relating to LPA activities primarily focused on increasing gardening (5) and household chores (5).

With respect to modifying the physical environment, the top themes were modifying clothing (e.g. wearing pedometer) (24), removing objects from vicinity of chairs (16), setting up environmental prompts (10), and modifying transportation (6). Social modifications encompassed co-opting tasks from others (3), social encouragement (2), and social reminders (2).

Overall, this coding of goals provided a comprehensive overview of the kinds of behaviours in which the participants were engaged, which were targeted to reduce their sedentariness.

Appendix I: Application of Theory Coding Scheme

Item	Description	Yes/No/Don't know	Location in thesis
1. Theory/model of behaviour mentioned	Models/theories that specify relations among variables, in order to explain or predict behaviour (e.g., TPB, SCT, HBM) are mentioned, even if the intervention is not based on this theory.	Yes	Section 3.6
2. Targeted construct mentioned as predictor of behaviour	('Targeted' construct refers to a psychological construct that the study intervention is hypothesised to change). Evidence that the psychological construct relates to (correlates/predicts/causes) behaviour should be presented within the introduction or method (rather than the Discussion).	Yes	Section 3.6
3. Intervention based on single theory	The intervention is based on a single theory (rather than a combination of theories or theory + predictors).	Yes	Section 3.6
4. Theory/ predictors used to select recipients for the intervention	Participants were screened/selected based on achieving a particular score/level on a theory-relevant construct/predictor.	No	n/a
5. Theory/ predictors used to select/develop intervention techniques	The intervention is explicitly based on a theory or predictor or combination of theories or predictors.	Yes	Section 3.6-3.7
6. Theory/ predictors used to tailor intervention techniques to recipients	The intervention differs for different sub-groups that vary on a psychological construct (e.g., stage of change) or predictor at baseline.	No	The intervention was "personalised" to participants, but this was generally based on physical characteristics and not psychological.
7. All intervention techniques are explicitly linked to at least one theory-relevant construct/predictor	Each intervention technique is explicitly linked to at least one theory-relevant construct/predictor.	Yes	Section 3.6

8. At least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct/ predictor	At least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct/ predictor.	N/A	N/A (see item 7)
9. Group of techniques are linked to a group of constructs/ predictors	A cluster of techniques is linked to a cluster of constructs/ predictors.	Yes	Section 3.6
10. All theory-relevant constructs/predictors are explicitly linked to at least one intervention technique	Every theoretical construct within a stated theory, or every stated predictor (see item 5), is linked to at least one intervention technique.	Yes	Section 3.6
11. At least one, but not all, of the theory relevant constructs/predictors are explicitly linked to at least one intervention technique	At least one, but not all, of the theoretical constructs within a stated theory or at least one, but not all, of the stated predictors (see item 5) are linked to at least one intervention technique.	N/A	N/A (see item 10)
12. Theory-relevant constructs/ predictors are measured	a) At least one construct of theory (or predictor) mentioned in relation to the intervention is measured POST-INTERVENTION. b) At least one construct of theory (or predictor) mentioned in relation to the intervention is measured PRE AND POST-INTERVENTION.	Yes Yes	Section 3.6 (BPNS), section 3.10.4.4.
13. Quality of Measures	a) All of the measures of theory relevant constructs/predictors had some evidence for their reliability b) At least one, but not all, of the measures of theory relevant constructs/predictors had some evidence for their reliability	Yes Yes Yes	BPN in General Scale (Gagne, 2003).

	c) All of the measures of theory relevant constructs/predictors have been previously validated d) At least one, but not all, of the measures of theory relevant constructs/predictors have been previously validated e) The behaviour measure had some evidence for its reliability f) The behaviour measure has been previously validated.	Yes Yes Yes	Yes (ActivPal3), section 3.11.1.).
14. Randomization of participants to condition	a) Do the authors claim randomization? b) Is a method of random allocation to condition described (e.g., random number generator; coin toss) c) Was the success of randomization tested? d) Was the randomization successful (or baseline differences between intervention and control group statistically controlled)?	Yes Yes No No	Section 3.10.2. Section 3.10.2. This type of analysis would not be relevant at this stage of the intervention's development (within a small feasibility study) Meaningful baseline differences were present in Autonomy and other variables due to small sample size.
15. Changes in measured theory-relevant constructs/predictor	The intervention leads to sig.change in at least one theory-relevant construct/predictor (vs. control group) in favour of the intervention.	No	This type of analysis would not be relevant at this stage of the intervention's development (within a small feasibility study)

16. Mediational analysis of construct/s / predictors	In addition to 14, do the following effects emerge?: a) Mediator predicts DV? (or change in mediator leads to change in DV) b) Mediator predicts DV (when controlling for IV)? c) Intervention does not predict DV (when controlling for mediator)? d) Mediated effect statistically significant?	No, mediation analysis not performed No No No	These types of analysis would not be relevant at this stage of the intervention's development (within a small feasibility study)
17. Results discussed in relation to theory	Results are discussed in terms of the theoretical basis of the intervention.	No	Analyses based on theory integration were not possible. Although future steps towards better integration were discussed, it was not a priority for the current test of this intervention.
18. Appropriate support for theory	Support for the theory is based on appropriate mediation OR refutation of the theory is based on obtaining appropriate null effects (i.e. changing behaviour without changing the theory-relevant constructs).	No	As it was a feasibility study, it was not intended to definitively refute/support the theoretical framework.
19. Results used to refine theory	The authors attempt to refine the theory upon which the intervention was based by either: a) adding or removing constructs to the theory, or b) specifying that the interrelationships between the theoretical constructs should be changed and spelling out which relationships should be changed.	No	Not enough data to make definitive conclusions about the theoretical integration.