VOLUME I: RESEARCH COMPONENT

THE FEASIBILITY OF TRIALLING A PSYCHOLOGICAL PREHABILITATION INTERVENTION FOR SARCOMA PATIENTS: A FEASIBILITY STUDY

By

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Thesis Overview

This thesis consists of two volumes submitted towards the Doctorate in Clinical Psychology.

Volume I consist of three research chapters. The first chapter presents a systematic review of the literature reporting outcomes for people living with a mental illness when diagnosed with cancer. People with comorbid mental illness and cancer were found to have a poor cancer outcome compared to the general population, beginning with the lack of use of cancer screening services and ending with an increased likelihood of cancer mortality. The second chapter is an empirical research study reporting the feasibility of conducting a trial of a psychological prehabilitation intervention for patients diagnosed with sarcoma. Nine participants were recruited and randomised to the control or experimental arm of study, they completed measures before and after their surgery (and intervention for those in the experimental arm). The results highlight that the trial is feasible to conduct, and the measures used were sensitive to the changes that sarcoma patients undergo, however, a number of modifications are suggested to improve the control of a larger study in addition to the success of recruitment. The third chapter consists of two public dissemination documents that offer an overview of the systematic review and empirical paper in a manner that is both brief and accessible for the general public.

Volume II consists of five clinical practice reports. The first report presents the case of Margaery[1], a 51-year old lady living with a diagnosis of schizophrenia presenting with intrusive thoughts. Two formulations are presented: A cognitive behavioural formulation of intrusive thoughts in the context of obsessive-compulsive disorder and a psychodynamic formulation are presented to understand the distress that Margaery experiences. The second report presents a service evaluation of staff members perceptions of the current pathway for clients diagnosed with emotionally unstable personality disorder in a local adult mental health community service. The third report presents the case of Alfred, a 65-year old man being treated in a local older adult inpatient ward, presenting with symptoms of a panic disorder. Alfred's distress is formulated within a cognitive behavioural therapy(CBT) formulation. A CBT intervention, including graded exposure, is then described and analysed using a single case A-B design. The fourth report describes the case of Daisy, a 26-year old

[1] All client's names have been changed to maintain their anonymity.

female diagnosed with a mild learning disability, who presented with difficulties with interpersonal difficulties and health anxieties. A formulation informed by cognitive analytic therapy(CAT) is presented along with a CAT informed intervention. The final report describes the case of Jess, a 13-year old female presenting to a local child and adolescent mental health service with symptoms of generalised anxiety. Three formulations are presented: cognitive behavioural therapy, in addition to a systematic formulation and a psychodynamic formulation, which were used to reformulate the case are presented. The beginning of an anxiety management intervention is described, and the outcomes obtained during the time of intervention.

Acknowledgments

I would like to begin by thanking all the participants who contributed to the empirical paper. These participants largely came with the view of "anything to help others" and I am grateful for them selflessly offering themselves and their time to a study that had no guarantee of having a direct benefit to them. The patients I met were strong and hopeful and this has been inspiring during times when I have been low in these two virtues.

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CHAPTER I

LITERATURE REVIEW

OUTCOMES FOR PATIENTS LIVING WITH A MENTAL ILLNESS WHEN DIAGNOSED WITH CANCER

Abstract

Background: The diagnosis of a cancer has a number of physical and emotional impacts on an individual. NICE (2004) published guidance highlighting the need for the psychological wellbeing of cancer patients in routine practice. However, there is little consensus, within the literature, of how those who have a mental illness pre-existing their cancer are cared for. Research suggests that people with a mental illness experience disparity in care when living with a number of comorbid health conditions.

Aim: The aim of the present review is to collate and systematically evaluate the literature on cancer outcomes in people with a pre-existing mental illness.

Method: Six databases were systematically searched for published empirical research concerning cancer and pre-existing mental illness. Twenty-Eight papers were selected for review upon fulfilling the inclusion and exclusion criteria. Each paper was evaluated for their methodological quality using standardised quality measures.

Results: People living with comorbid mental illness and cancer experience disparities in their care from the beginning of their cancer journey through to the end. People with a pre-existing mental illness were found to be diagnosed later, which is attributable to the lack of detection of cancer symptoms and use of cancer screening services. This resulted in higher cancer related case fatalities, when compared to the general population. Furthermore, in mainstream services, cancer patients are less likely to receive recommended cancer treatments. Exceptions to these findings are found in veteran healthcare settings.

Conclusions: A number of high-power epidemiological papers evidence that cancer outcomes for people with a mental illness is poor. There are limited number of prospective, longitudinal and experiential papers in the present literature. These papers are needed to further understand the identified disparities and to begin to make progress in this area.

1. Introduction

i) The Experience of Cancer

'Cancer' is an umbrella term, for almost 200 different diseases characterised by abnormal cells dividing in an uncontrolled way (Cancer Research UK, N.D). The lifetime prevalence of getting a cancer is 1 in 2 (Cancer Research UK, N.D) and is accountable for 42% of deaths of people under 75 in the UK (Department of Health, 2014).

Previous literature has described the cancer journey for patients (Hayes et al., 2008; Mistry, Wilson, Priestman, Damery & Haque, 2010); the journey is characterised by detection of the cancer via screening or detection of an abnormal physiological symptom, followed by investigations to contribute towards a diagnosis, then medical treatments to address the cancer and finally there is a cancer outcome which may be remission, survivorship (if cancer free for 5 years) or for some, death. For clarity, the journey has been described here as a set on linear events, however, the process can be unfixed to a procedural structure (Schildmeijer, Frykholm, Kneck & Ekstedt, 2019).

Lung, breast, prostate and bowel cancer are the most common forms of cancer in the world; with breast cancer being the most common in females and prostate cancer being the second most common cancer in males (Smittenaar, Petersen, Stewary & Moitt, 2016; Bray et al., 2018). Survival rates for all cancers are improving (Smittenaar et al., 2016) with breast cancer and prostate cancer having relatively good rates of survival, whilst lung cancer and brain tumours have poor rates of survival (Cancer Research UK, N.D). Estimates of cancer incidence highlights that as a consequence of an ageing population and health issues such as obesity both cancer incidence and number of deaths will increase by 2035, however, mortality rates will improve (Mistry, Parkin, Ahmad & Sasieni, 2011; Smittenaar et al., 2016). This reduction in the rate of mortality has been seen since 1993 in breast cancer patients (Smittenaar et al., 2016) with causes for this decrease being attributed to better screening, which leads to cancers being treated before the cancer is classified as stage 4 (McPhail, Johnson, Greenberg, Peake & Rous, 2015).

Cancer patients report an increased incidence of anxiety (Maddineni, Lau & Sangar, 2011; Mitchell et al., 2011; Vehling et al., 2012; Ford, Catt, Chalmers & Fallowfield, 2012), depression (Mitchell et al., 2011; Walker et al., 2012; Ford et al., 2013; Yang et al., 2013), fear of cancer reoccurrence (Simard & Savard, 2009; Puts, Papoutis, Springall & Tourangeau, 2012; Swash, Hulbert-Williams & Bramwell, 2014), post-traumatic stress disorder (Koutrouli, Anagnostopoulos & Potamianos, 2012) and decisional regret (Chambers, Hyde, Ip, Dunn & Gardiner, 2013). In addition to these emotional issues', cancer patients report issues in sexual functioning (Lammerink, De Bock, Pras, Reyners & Mourits, 2012; Krychman, 2012; Moran et al., 2013), cognitive functioning (Koopelmans, Breteler, Boogerd, Seynaeve & Schagen, 2013) and socioeconomic status (Kimman et al., 2012). However, these issues can vary from patient to patient with factors such as age (Howard-Anderson, Ganz, Bower & Stanton, 2012; Hess & Chen, 2014), education level (Kourtrouli et al., 2012; Koch, Jansen, Brenner and Arndt, 2013), income (Jansen, Koch, Brenner & Arndt, 2010; Koutrouli et al., 2012), ethnicity and culture (Koch et al., 2013), number of children (Fiszer, Dolbeault, Sultan & Bredart, 2014) and personality (Crist & Grunfeld, 2013; Sales, Carvalho, McIntyre, Pavlidis & Hyphantis, 2014) being factors that moderate elevated distress in cancer patients.

Thus, it is understood that there are more health implications to consider than just the cancerous cell, with emotional distress now being assessed routinely alongside pulse, respiration, blood pressure, temperature and pain (Bultz & Holland, 2006).

ii) The Psychological Impact of Cancer

Over the 20th Century, advances in medicine meant that the detection, treatment and survival of cancer was increasing and so the view of cancer as a death sentence was beginning to shift (Holland, 2018). With this newly generated optimism around cancer, focus has now been placed on wellbeing whilst living with cancer.

As afore mentioned, there are a large number of emotional and psychological issues that arise for patients during their cancer journey. Owing to the well-understood psychological impact of cancer, NICE have formally acknowledged the expectation that an individual's

psychological wellbeing should be taken into account throughout their cancer journey (NICE, 2004).

The publication of the NICE guidance saw a move towards psychological awareness being embedded into the oncology culture and psychological care being offered by all staff members; Bultz and Holland (2006) describe how emotional distress is now seen as the "sixth vital sign" due to it being routinely assessed by medical staff. Prior to 2004, there was an awareness of the presence of psychological distress (van't Spijker, Trijsburg & Duivenvoorden, 1997), however, interventions for emotional distress were largely seen as the work of clinical psychologists (Rieger, Touyz & Wain, 1998).

iii) Mental Health and Cancer

Whilst the NICE guidelines (2004) have influenced researchers and clinicians to consider the psychological impact of cancer, there has been little acknowledgment for those with psychological health needs preceding their cancer diagnosis.

Research suggest that as much as 50% of people with cancer have experienced a mental health condition in their lifetime and for approximately 30% of cancer patients these mental health conditions have been chronic (Derogatis et al., 1983; Massie, 2004; Akechi et al., 2004; Walker et al., 2012; Krebber et al., 2014; Watts, Prescott, Mason, McLeod & Lewith, 2015; Walker, McGee & Druss, 2015). Individuals with severe mental illness are found to smoke more than the general population (Kelly & McCreadie, 1999), engage in less physical activity (Daumit et al., 2005), have less healthy eating habits (Scott & Happell, 2011) and take medications that have side effects related to cancer (Correll, Detraux, De Lepeleire & De Hert, 2015). Each of these factors can increase someone's vulnerability to cancer.

iv) Current Review

Despite the understanding that factors associated mental health can be associated with cancer risk factors and that having cancer can lead to adverse psychological experiences there is little understanding of the relationship between cancer care and pre-existing mental illness. In their position paper, Howard et al., (2010) proposed the presence of disparities in the use of screening services, receipt of specialist treatments and mortality rates, for people living with

pre-existing mental illness'. This is fitting with the findings from research into health care and cancer (Thornicroft, 2011); including conditions such as cardiac disease (Desai, Rosenheck & Druss, 2002) and diabetes (Sullivan, Han, Moore & Kotria, 2006).

The present review seeks to systematically answer the question "What are the challenges of providing cancer care to individuals with a pre-existing mental health difficulty?".

2. Method

i) Identification of Papers

a. Search Strategy

Electronic searches were conducted on 20th August 2018 using PsychInfo, PsychArticles, Embase and Medline. To identify all relevant papers, to the present question, a broad search strategy was used. Table 1 presents the search terms and strategy used. The researcher identified the terms related to mental health by consulting the Mind website's list of 'types of mental health problems'. (Mind, N.D; accessed on 17th August 2018). A further search was conducted on 3rd September 2018 using Scopus and CINAHL. The phrase 'Pre-existing mental health cancer' was searched on these free text databases.

Table 1. *Search terms and Strategy used on Ovid Databases*

Search terms		
1. Cancer 2. Pre-existing 3. Pre-morbid 4. Longstanding 5. Chronic 6. Pre-existent 7. Persistent 8. Enduring 9. Long-term 10. Mental health 11. Mental illness 12. Mental disorder 13. Psychiatric patient 14. Mental issue 15. Mental difficulties 16. Mental patient 17. Anger 18. Anxiety 19. Panic	20. Bipolar 21. Body dysmorphic disorder 22. BDD 23. Personality disorder 24. BPD 25. Depression 26. Dissociative 27. Eating Disorder 28. Anorexia 29. Bulimia 30. Mania 31. Obsessive compulsive Disorder 32. OCD 33. Paranoia 34. PTSD 35. Stress 36. Post-traumatic stress disorder	37. Post-natal depression 38. Psychosis 39. Schizo* 40. Seasonal affective disorder 41. SAD 42. Self-esteem 43. Self-harm 44. Sleep disorder 45. Suicide* 46. Psychotic
Search Strategy 1 AND (2 or 3 or 4 or 5 or 6 or 7 or 8 or 9) AND		

(10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46)

b. Inclusion and Exclusion Criteria

Table 2 presents the inclusion and exclusion criteria which was used to screen the papers produced by the search.

Table 2. Inclusion/exclusion criteria.

Inclusion/Exclusion criteria	
Included: Study participants who had experience and/or a diagnosis of mental illness prior to their diagnosis of cancer	Exclusion: Study participants who developed mental illness following their diagnosis of cancer
Included: Empirical studies concerning cancer outcomes or experiences; this including diagnosis, treatment, mortality, survival, reactions to cancer, care packages, liaison with health professionals, professional issues and challenges	Exclusion: Empirical studies solely concerned with topics such as the prevalence of mental illness in cancer and vice versa
Included: Empirical studies published in the English language	Exclusion: Empirical studies that were not available in the English language
Included: Papers that concerned mental illnesses defined as a mental illness by the Mind (N.D) website	Excluded: Papers concerned with Dementia and Learning Disabilities, two populations who are seen within mental health services but have an organic aetiology.

c. Database Search Results (PRISMA)

Using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), Figure 1 presents the flow of papers and information found through the different phases of the review. Using the PRISMA method allows for clarity and transparency of the methodological approach (Moher, Liberati, Tetzlaff & Altman, 2009).

A total of twenty-six papers were included in the final review. The search of Ovid databases (PsychInfo, PsychArticles, Medline and Embase) yielded a total of 4,908 citations. After the

removal of duplicates, 2,477 of titles were screened for eligibility. Of these, 2,421 were identified as reviews or irrelevant. Following this the abstracts of the remaining fifty-six papers were screened for inclusion/exclusion criteria. Forty-six were excluded on the basis of this criteria leaving ten papers. The reference sections of the papers found in the search were screened and an additional sixteen papers were identified as appropriate and met the criteria for inclusion.

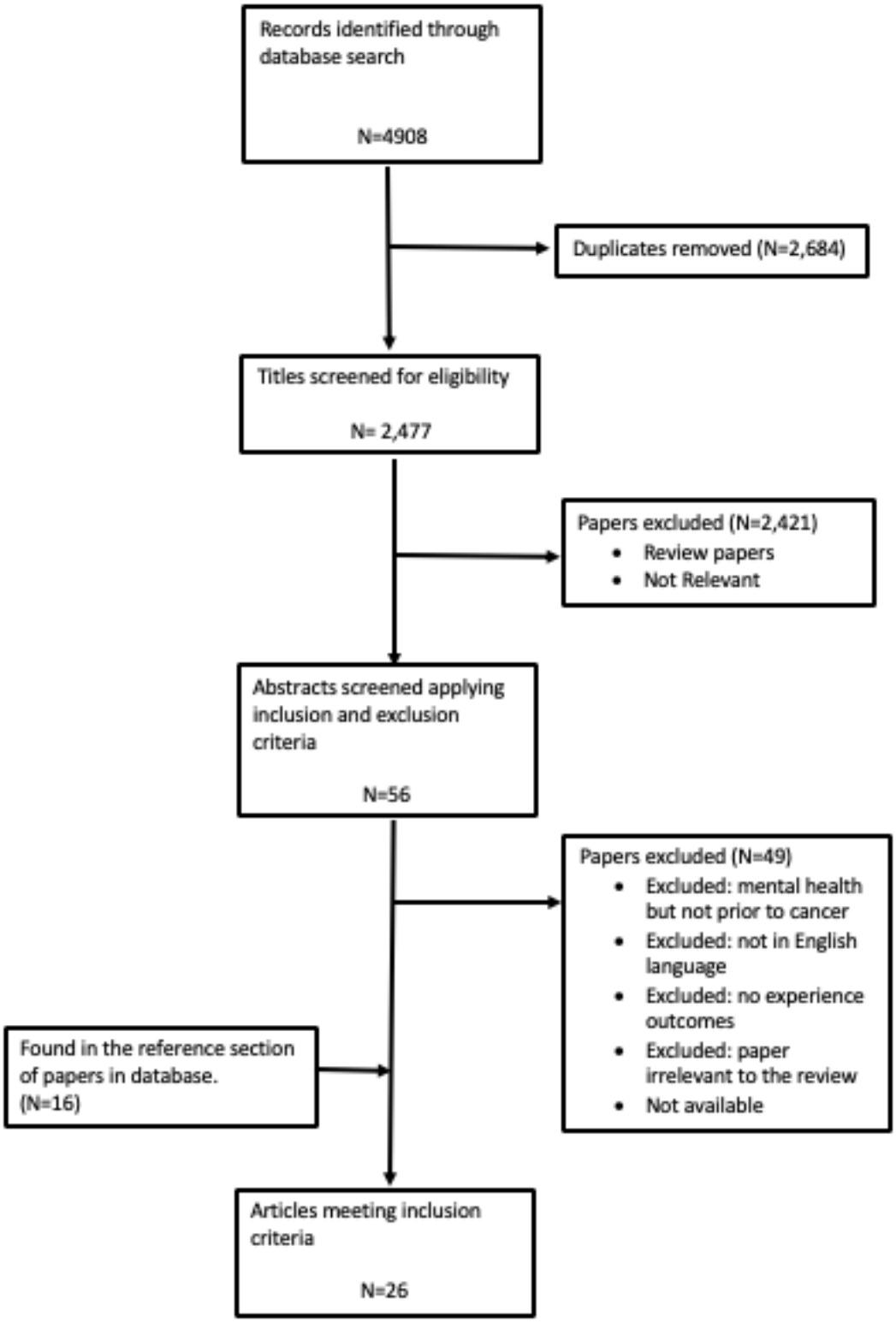

Figure 1. PRISMA flow of information through phases of the review

ii) Quality Review

a. Method of Quality Appraisal

The 'QualSyst' tool developed by Kmet, Cook & Lee (2004) provides a scoring systems for Quantitative research (See Appendix 1 for scoring guidelines). The QualSyst tools were particularly useful for this review as there is not a reliance on papers being randomised control-trials but allows for a variety of both quantitative and qualitative methodology, which was the case with the papers identified. For quantitative papers, quality is defined based on the clarity, transparency, the controls for bias and the presence of an appropriate amount of information. For the qualitative papers quality was defined broadly by the adherence to a defined methodology, transparency and evidence of controlling for biases.

A number of additional quality indicators were included in the rating scale to account for the number of epidemiological studies that were included in the review. The Strengthening The Reporting of Observational Studies in Epidemiology (STROBE; Von Elm et al., 2007) was referred to and a number of the additional items were based on indicators used in this measure.

All studies reviewed and included in this paper were quantitative.

b. Quality Scores of reviewed papers

A summary of the quality ratings for the reviewed studies is presented in Table 3 (please see Appendix 1 for guidance on scoring).

The studies reviewed were clear in their descriptions of the study question or objective, those which were not clear still identified a gap or inadequacy in the research rather than a defined question. Fifteen studies were rated as being flawed in the study design; this was largely due to the high number of retrospective case linkage designs. Whilst this allows for a large sample size it is flawed due to the potential for bias. A prospective epidemiological design, such as the one described by Tran et al. (2008), is an example of a better design. Furthermore, ten studies were found to be missing reports of key participant information, such as age.

For all studies both random allocation and blinding were not applicable. This was also the case for controlling for confounding in the experimental arms, due to studies not dividing

participants into separate conditions. This highlights the absence of any randomised control trials or interventional studies in the reviewed literature.

The outcomes for fourteen studies were perceived to be open to improvement. This again was largely due to the large number of epidemiological studies which relied on retrospective notes. These notes are open to bias and furthermore, some data may be missing, such as data that was not required to be kept in medical records. Furthermore, the use of case notes meant that the studies were limited in the outcomes they were able to use and thus the studies were lacking in their reports of influencing and moderating factors such as socioeconomic status and social support.

However, of the studies reviewed there was consistency in the analytic methods used; most studies used regression and or chi-square to analyse the data, those that were concerned with mortality and/or survival rates often choose to use a survival curve to analyse the data. Results from these analyses were reported in sufficient detail with tables and figures to support the written results, all studies reported at least one effect size for the outcome data. The studies were found to be accurate in their conclusions, based on the results reported. Whilst one would assume due to the large sample sizes in these studies that the results would be generalizable, fourteen studies did not discuss implications for generalising this to the wider population.

Table 3. Quality Rating Summary for reviewed studies

	Shinden et al., 2017	Irwin et al., 2017	Iglay et al., 2017	Ribe et al, 2016	Cunningham et al., 2015	Waida et al., 2015	Musuza et al., 2013	Guan et al., 2013	Kiesley et al., 2012
Provide in the abstract an informative and balanced summary of what was done and what was found	2	2	2	2	2	2	2	2	2
Question/objective sufficiently described?	2	2	2	2	2	2	2	2	2
Design evident and appropriate to answer study question?	1	2	1	2	2	1	1	2	1
Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	2	2	2	2	2	2	2	2	2
For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	0	2	2	2	2	2	2	2	2
Method of subject selection or source of information described and appropriate?	2	2	2	2	2	0	2	2	1
Subject (and comparison, if applicable) described?	1	2	2	0	2	2	0	1	0
Was random allocation described?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Blinding described?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Outcome measures described and robust to misclassification bias? Means of assessment reported?	1	1	2	1	2	1	2	2	1
Sample size appropriate?	1	1	2	2	2	2	2	2	2
Analysis described and appropriate?	2	2	2	2	2	2	2	2	2
Report other analyses done? e.g. analyses of subgroups and interactions, and sensitivity analyses	0	2	2	2	2	2	2	2	2
Estimate of variance reported for the results?	1	2	2	2	2	0	2	2	2
Controlled for confounding	0	2	0	2	2	2	2	1	2
Results reported in sufficient detail	2	2	2	2	2	2	2	2	2
Conclusions supported by results	2	2	2	2	2	2	1	2	2
Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	2	2	2	2	2	2	2	2	2
Discuss the generalisability (external validity) of the study results	0	2	2	2	0	1	0	2	2
Summary Score	21/34 (62%)	32/34 (94%)	31/34 (91%)	31/34 (91%)	32/34 (94%)	28/34 (82%)	28/34 (82%)	32/34 (94%)	29/34 (85%)

Table 3. Quality Rating Summary for reviewed studies

	Batty et al., 2012	Hwang et al., 2012	Baillargeon et al., 2011	Ganzini et al., 2010	Tilbrook et al, 2010	Sharma et al., 2008	Tran et al., 2008	Kiesley et al., 2008	Gathinji et al., 2008
Provide in the abstract an informative and balanced summary of what was done and what was found	2	1	2	2	2	2	2	2	2
Question/objective sufficiently described?	2	1	2	1	2	2	2	2	2
Design evident and appropriate to answer study question?	1	0	1	2	1	1	2	2	1
Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	2	2	2	2	2	2	2	2	2
For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	1	1	2	2	0	0	2	2	2
Method of subject selection or source of information described and appropriate?	2	2	2	2	2	2	2	1	2
Subject (and comparison, if applicable) described?	1	1	2	2	0	0	2	0	2
Was random allocation described?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Blinding described?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Outcome measures described and robust to misclassification bias? Means of assessment reported?	1	1	1	2	0	1	2	1	1
Sample size appropriate?	2	0	2	1	1	1	1	2	2
Analysis described and appropriate?	2	0	2	0	2	0	2	2	2
Report other analyses done? e.g. analyses of subgroups and interactions, and sensitivity analyses	2	0	2	0	2	2	2	2	0
Estimate of variance reported for the results?	2	0	0	1	1	0	2	2	2
Controlled for confounding	2	0	2	0	2	2	2	2	0
Results reported in sufficient detail	2	0	1	0	2	1	2	2	2
Conclusions supported by results	2	1	2	2	2	1	2	2	2
Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	2	2	2	1	2	1	2	2	2
Discuss the generalisability (external validity) of the study results	2	0	2	0	2	0	0	0	0
Summary Score	30/34 (88%)	12/34 (35%)	29/34 (85%)	20/34 (59%)	25/34 (74%)	18/34 (53%)	31/34 (91%)	28/34 (82%)	26/34 (77%)

Table 3. Quality Rating Summary Table for reviewed Studies

	Xiong et al., 2008	O' Rouke et al., 2008	Carney & Jones, 2006,	Brunnault et al., 2006	Alderete, 2006	Inagaki 2006	Goodwin et al., 2004	Stommel et al., 2001
Provide in the abstract an informative and balanced summary of what was done and what was found	2	2	2	2	2	2	2	2
Question/objective sufficiently described?	2	2	2	2	2	1	1	2
Design evident and appropriate to answer study question?	1	1	2	2	2	1	1	2
Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	2	2	2	2	2	2	2	2
For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	2	2	2	2	2	1	2	2
Method of subject selection or source of information described and appropriate?	1	2	2	2	2	1	2	2
Subject (and comparison, if applicable) described?	2	1	2	2	2	2	2	2
Was random allocation described?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Blinding described?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Outcome measures described and robust to misclassification bias? Means of assessment reported?	2	2	2	2	2	0	1	1
Sample size appropriate?	2	0	2	0	2	0	2	2
Analysis described and appropriate?	1	2	2	2	2	0	2	2
Report other analyses done? e.g. analyses of subgroups and interactions, and sensitivity analyses	0	2	2	0	2	0	2	2
Estimate of variance reported for the results?	0	2	2	1	2	0	2	2
Controlled for confounding	0	2	2	0	2	0	2	2
Results reported in sufficient detail	1	2	2	2	2	2	2	2
Conclusions supported by results	2	2	2	2	2	2	2	2
Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	2	2	2	2	2	1	2	0
Discuss the generalisability (external validity) of the study results	2	0	2	0	2	0	0	2
Summary Score	24/34 (71%)	28/34 (82%)	34/34 (100%)	25/34 (74%)	34/34 (100%)	14/34 (41%)	29/34 (85%)	31/34 (91%)

iii) Overview of Studies

a. Methodological designs

Twelve papers are cohort epidemiological papers (for a summary of all papers please see Appendix 2). These epidemiological papers are correlational, in addition to another thirteen studies which are also correlational. These papers focus on the frequency of cancer mortality in participants with a mental illness (N=13), receiving cancer treatment (N=10) or screening (N=4) and issues around diagnosis (N=6).

b. Participant Samples

A total of 3,735,576 participants were included in this review, although it is difficult to ascertain if some participants were duplicated across studies, due to the use of national databases. Of these 125,851 are reported as experiencing comorbid mental illness and cancer. The remaining participants were either used as a comparison or it was unclear what percentage of the sample were participants with a pre-existing mental illness or control.

Participants were recruited via national databases in twelve studies . These being databases for various states in the USA, Europe and Eastern Asia. Fifteen studies recruited directly from healthcare settings.

Mental Health diagnosis

Mental Health was operationalised in a number of different ways. The majority (N=17) through the identification of a diagnostic code (ICD 9/10, N=13; DSM-IV, N=5) in participants medical or health insurance records, nine studies reported contact with psychiatric services as evidence of a mental illness, Six studies reported the use of diagnostic assessments to determine the presence of a mental illness. These diagnostic assessments included the Anxiety Disorders Interview Schedule-IV(Grisham, Brown& Campbell, 2005), Hamilton Rating Scale for Depression (Hamilton, 1960), General Health Questionnaire (version 12; Goldberg & Blackwell, 1970), Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983), Brief Psychiatric Rating Scale (Overall & Gorham, 1962), Positive and

Negative Syndrome Scale (Kay, Fiszbein & Opler, 1987), Centre for Epidemiologic Studies Depression Scale (Devins, 1985), Fresno-Composite Interventional Diagnostic Interview (Aguilar-Gaxiola, Vega, Peifer & Gray, 1995) and the Vrangenlijst Voor Kenmerken Van de Persoonlikheid(Duijsens, Eurelings-Bontekoe, Diekstra & Ouwersloot, 1993).

Twelve of the studies reviewed focused on all types of mental health difficulties or did not specify a target diagnosis. Nine studies specifically cited schizophrenia as a diagnosis of interest, while seven focused on individuals with a diagnosis of depression. In addition to this, three studies specifically named people living with diagnoses of bipolar, anxiety or personality disorder as being of interest.

Type of cancer

The most common cancer focused upon in the studies reviewed was breast cancer (N=11). In addition to this colorectal, bladder, brain cancer, cervical, head and neck, urethral, prostate were studied. Eleven did not specify a specific cancer as the focus of the research. Four studies (Alderete, 2006; Xiong, 2008; Tilbrook, 2010 & Laser et al., 2003) studied the use of screening services by individuals living with a mental illness, thus these participants at the time of the research did not have a diagnosed cancer.

Cancer was operationalised in eighteen of the studies reported by registration on a cancer registry or in patients files, with a corresponding ICD code. Nine studies conceptualised cancer through the use of a cancer service by the participant.

Age

Thirteen of the studies reviewed did not report the age range of inclusion for participation; however, most provided a mean age of those who were included in the studies. Three studies targeted participants who may be referred to as older adults (67+) and a total of 7 studies reported targeting individuals of working age and older, although it was inconsistent at what age this recruitment began.

Gender

The studies reviewed included both male and female participants; Eighteen studies combined research of both genders. Nine studies reported findings from only one gender; seven of these studied the experience of females with breast cancer or being investigated for breast cancer, via a mammography (Lam et al.,2017; Alderete et al., 2006; Iglay et al., 2017; Goodwin et al., 2004; Sharma et al.,2010; Ribe et al., 2016; Carney et al., 2005; Xiong et al., 2008). A further study focused on females receiving cervical cancer screening (Tillbrook et al., 2010) and one study focused on males (Batty et al., 2016).

3. Findings

What are the challenges of providing cancer care to individuals with a pre-existing mental illness?

The present literature found that the challenges of providing cancer care to individuals with a mental illness were providing a timely diagnosis, offering and making accessible the recommended treatment and the increased vulnerability to mortality as a consequence of cancer. These findings pertaining to these three factors will be described.

i) Providing a timely diagnosis

When reviewing Medicare surveillance, epidemiology and end results (SEER) data Baillargean et al., (2011) found that older adults(67 years and older) living with mental illness, for at least 2 years prior to their cancer diagnosis, were more likely to either be diagnosed at an unknown stage of cancer (with a lack of stage being recorded in their medical notes) or during autopsy, when compared with the normal population. The medical reports of fifty-five veterans living with both schizophrenia and breast cancer indicated that these patients had ignored signs of breast cancer, such as a palpable breast mass, nipple retractions and nipple discharge for anytime between six months to nine years, resulting in diagnoses being made when the tumour was categorised as stage III-IV (Hwang et al., 2011) and metastases being present (Kiesley et al., 2013). Iglay et al. (2017) & O'Rouke et al., (2008) supported these findings, reporting in three thousand six hundred and ninety one & six hundred and thirty, respectively, psychiatric patients a delay in excess of 90 days between symptom recognition and breast cancer diagnosis, as reported on the patient's medical records. This was in comparison to delays of 35 days in a breast cancer patient without a mental illness (O'Rouke et al., 2008).

Shinden et al., (2017) reported that individuals with comorbid mental illness and breast cancer were less aware of their cancer symptoms and thus were reliant on family members and care staff to identify symptoms warranting investigation. Even when there was evidence of screening for cancer (breast, cervical, colorectal & prostate) medical records highlighted that individuals with mental illness' were less likely to return for routine screens, thus meaning their screenings were out of date (Xiong et al., 2008).

Lasser et al., (2003) found evidence to contradict this and suggested that there was no difference in mammography rates between women screened positively for mental health difficulties and those who screened negatively for mental health difficulties and Cunningham et al., (2015) found that a diagnosis of depression was not associated with a delay in diagnosis, although a diagnosis of schizophrenia was. Carney and Jones (2005) reported a correlation between the severity of an individual's mental health difficulty and increasing vulnerability for not having received a mammography.

Waidia et al. (2015) also reported no difference between the diagnosis time for veterans with or without mental health difficulties. However, the setting for recruitment was unique, being a veteran health affairs centre where mental health services were integrated with primary care services. They concluded that this offers a good example of how the delay in diagnosis for people living with comorbid mental illness and cancer can be overcome.

ii) Accessing appropriate treatment

Medical data reviews found that patients with a psychiatric diagnoses were less likely than individuals without a psychiatric diagnoses to receive a variety of specialised cancer treatments (Kiesley et al., 2013); these included surgery for patients with oesophageal cancer (O'Rouke et al., 2008) and colon cancer (Baillargeon et al., 2011), adjuvant chemotherapy (Baillargeon et al.,2011; Hwang et al., 2011; Iglay et al., 2017; Shinden et al., 2017), radiotherapy (Bailargeon et al., 2011; Shinden et al., 2017) and postoperative endocrine (Hwang et al., 2011). In those that were offered treatment, Goodwin et al., (2004) found in 1,841 patients records, who were diagnosed with depression (present for at least two years) and breast cancer, that these patients were more likely to be offered inappropriate treatment, when compared to breast cancer patients without a diagnosed mental illness. Furthermore, Shinden et al. (2017) found that in forty-six patients diagnosed with schizophrenia, dementia or intellectual disabilities, more total mastectomies were used to treat breast cancer than in those without such a diagnosis.

The absence of psychiatric information (name of psychiatrist and antipsychotic medication) in patients notes and/or inpatient psychiatric admission, for people with a comorbid mental

illness was correlated with disruptions to cancer treatment (Irwin et al., 2017), as was a poor understanding of the treatment and the presence of negative symptoms (in the context of schizophrenia; Inagaki et al., 2006).

In contrast to this, Ganzini (2010) found that for sixty veterans living with schizophrenia and cancer, their end of life care was either comparable or better than those without a schizophrenia diagnosis. End of life care included being enrolled in a hospice, having an advanced directive, having orders relating to CPR and tube feeding, orders from physicians regarding life sustaining treatment, place of death, being prescribed opiates, and having a cancer biopsy, chemotherapy and surgical treatment for cancer. Waidia et al. (2015) also reported that veterans with mental illness did not appear to have different treatments to those without a mental illness.

iii) Increased incidence of death due to cancer

The literature (N=9) that focuses on patient mortality reported that having a pre-existing mental illness increases a person's risk of dying from their cancer, relative to the general population (Goodwin et al., 2004; Kiesley et al., 2008; Tran et al., 2008; Gathinji et al., 2009; Batty et al., 2012; Guan et al., 2013; Musuuza et al., 2013; Cunningham et al., 2015; Ribe et al., 2016)

Kiseley et al., (2008) collated mental health records and cancer registrations along with records of death. The researchers found an increase in cancer mortality, which they concluded could not be explained by an increase in cancer incidence, as they had found that to the contrary individuals with a mental illness had a decreased incidence of cancer, relative to the general population. More so it was that the risk of death for cancer patients with a pre-existing mental health diagnosis, was higher than the risk that would be expected for just cancer (Stommel et al., 2001); even when accounting for degree of disability, tumour grade and treatment modalities the risk for patients with a mental illness was still markedly increased (Gathanji et al., 2009).

Guan and colleagues (2012) found that in the time following cancer diagnosis, patients with a mental illness (schizophrenia, bipolar and depression) were more likely to die by suicide or

other causes than matched controls without a mental illness . In addition to this, those with pre-existing mental illness who survived the increased vulnerability of death by suicide or other causes were then at an increased risk of dying due to their cancer. Stommel, Given and Given (2001) found that the risk of mortality for patients with pre-existing depression was as great as the risk for individuals with pre-existing physical difficulties.

Explanations for the excess mortality in cancer patients was attributed to the aforementioned factors of disparities in treatment and delays in diagnosis (Jackson et al., 2013; Cunningham et al., 2015) patients with mental illness were reported to die more frequently within a year of their cancer registration (Batty et al., 2012) and for some the diagnosis of cancer was only made during autopsy (Baillargeon et al., 2011). Cunningham et al., (2015) reported that the high burden of physical illness and co-morbidities in cancer patients could explain some of the increases in mortality found.

Of all mental health difficulties studied, Baillargeon and colleagues (2011) reported that individuals living with schizophrenia and dementia were at the greatest risk of mortality due to their cancer diagnosis.

4. Discussion

i) Findings

The present review provides a view into cancer care for individuals with a comorbid mental illness. The literature suggested that the majority of people with a mental illness are less likely than the general population to attend screening services for cancer, which may delay diagnosis and contribute to the excess in case fatalities. Furthermore, the recommended treatments for several cancers were found to not be offered to patients with a mental illness and, if offered, were difficult to carry out. It appeared that there was a positive correlation between disparities in cancer care and severe mental illness. However, exceptions to these findings were found in patients treated in veteran health care settings, where physical and mental health are addressed within the same service.

What are the challenges of providing cancer care for individuals with?

The studies reviewed here largely provide an observation of the correlation between mental illness and disparities in cancer care. This is fitting with the findings that disparities exist in other physical illness' (Desai, Rosenheck & Druss, 2002; Sullivan, Han, Moore & Kotria, 2006). However, only few of the studies included in this review attempt to provide an explanation as to why these disparities occur. Table 5 lists the reasons found in papers for the disparities.

Table 4. A table summarising the reported reasons for disparity in the care of people with comorbid mental illness and cancer.

Study	Disparity in	Reported Reasoning
Inagaki et al., 2006	Treatment	• Patients with negative symptoms, of schizophrenia, find it hard to understand and co-operate with treatment • The disease is advanced and is no longer amenable to first line treatment • Clinicians were unable to give sufficient notice of cancer to patients who went untreated
Carney and Jones, 2006	Use of Screening Services	• Severity of mental illness (particularly women with depression)
Mateen et al., 2008	Treatment	• Presence of COPD or infection • Patient Declined • Patient with "Schizophrenia symptoms" • Disorientation from a lobotomy (earlier in life)
Hwang et al., 2011	Treatment	• Treatment not offered by clinician • Treatment refused by patient • Hostility towards carers • Advanced stage cancer at diagnosis

Baillargeon et al., 2011	Mortality	• Diagnosed later • Less likely to have had surgery, chemotherapy or radiotherapy • Less likely to have had chemotherapy at stage 3
Kiesley et al., 2013	Mortality	• Metastasis more likely to be found at diagnosis • Less specialist treatment
Cunningham et al., 2015	Mortality	• Later stage at diagnosis
Irwin et al., 2017	Treatment	• Not having a documented psychiatrist • Not having documented antipsychotic medication • Psychiatric admission during the time of proposed treatment

The absence of screening was found to be both a disparity in itself and a cause for increases in mortality (Cunningham et al., 2015). Cancer screening is advised as a preventative strategy (Stewart, 2014); the lack of use of screening services and detection of cancer appeared to onset a difficult cancer journey. This is surprising given the knowledge that people with mental illness are in frequent contact with primary care practitioners (Tilbrook et al., 2010), a profession who are fundamental in the early detection of cancer symptoms (Department of Health, 2000). However, Lam et al. (2016) reported that individuals who screen for high persistent distress, often view cancer as "another blow" in life, thus it might be an avoidance of "another blow" that leads those with pre-existing mental illness' to not access screening services.

It appeared that a lack of screening leads to delays or lack of diagnosis and an excess mortality.

Differences in treatments had a more varied aetiology, being found to be attributable to the clinician's opinion of the patient or the patients expressed preferences. It was found that issues such as violence towards staff members (Hwang et al., 2011), difficulty with providing consent (Inigaki et al., 2006) or understanding of cancer (Inagaki et al., 2006) were factors that clinicians reported as being reasons for not offering treatment such as lung surgery and chemotherapy to people with mental illness. Patients were also reported to sometimes refuse treatment (Hwang et al., 2011), which often impacted the treatment they received.

Veterans in the USA receive tailored care where both mental health and physical health are addressed in the same setting, allowing for better integration of physical and mental health (Waidia et al., 2015). However, being a veteran would suggest the presence of a number of unique variables, which may have biased the findings of Ganzini et al. (2010) & Waida et al. (2015), such as the unique impact of combat on the consequent reactions to distress (Larner & Blow, 2011). A randomised control trial would help to understand this further.

ii) Methodological and Conceptual Issues

Due to the methodological and conceptual issues that arose whilst conducting this systematic review, the conclusions are made tentatively.

The literature available, and thus reviewed, consisted largely (N=22) of data retrieved retrospectively from medical reviews, known as a "chart review" (Hess, 2004). This type of study is vulnerable to biases created by information being reported inaccurately within patient records, as well as only select information being reported or accessible to the researchers. Furthermore, the studies reviewed here were unable to control for additional confounding variables. Thus, the present data can only suggest a hypothesis that there are poor outcomes for people with comorbid mental illness and cancer rather than offering an in depth understanding. The use of longitudinal prospective studies, for example where participants with comorbid mental illness and cancer are tracked over a number of years, with data being recorded for a variety of different outcomes, would be a more robust design, that could begin to establish cause and effect. In addition to this, qualitative designs where patients and clinicians were asked about their experiences would add depth to this area of research.

Whilst searching for the papers reviewed, difficulty was encountered when trying to operationalise the search terms. A search of mental health and associated terms alone returned a large number of studies, however, the majority of these concerned mental health difficulties that occurred after a cancer diagnosis. It is reported that eighty percent of papers regarding mental health and cancer are focused on mental health difficulties following cancer (Purushotham, Bains, Lewison, Szmukler & Sullivan, 2012). Thus, the search strategy was altered to add the term "pre-existing", however, this was hard to operationalise. This is potentially evidenced by sixteen of the studies in this review being found through the references section of papers identified in the search.

Furthermore, as a consequence of the difficulty of operationalising the specific target population (cancer patients with pre-existing mental health difficulties) and the small amount of research into this area (Purusotham et al., 2012), a broad question was asked – not limited to any specific part of the cancer journey, experience or a patient demographic. Thus, the present findings are vulnerable to bias by a specific demographic. For example, schizophrenia was the most frequently researched mental illness, within this study. It is understood that individuals living with a diagnosis of schizophrenia are a group exposed to

excess mortality, regardless of cancer (Hayes, Marston, Walters, King & Osborn, 2012) with some evidence reporting this can result in death fifteen years earlier than the general population (Hjorthøj, Stürup, McGrath & Nordentoft, 2017). Furthermore, the present study identified that cancer outcomes were worse for people experiencing more severe mental health difficulties (Bailargeon et al, 2011; Inagarki et al, 2006) such as psychotic and negative symptoms, which are encountered in schizophrenia.

It is understood that mental health does not just affect an individual's cognitive and emotional world, but that there is also a relationship between socioeconomic status (Reiss, 2013; Carter, Barr & Clarke, 2016), race and ethnicity (Rosenfield, 2012), occupation (Fujino et al., 2016) and an array of physical illness'(Scott et al., 2016) . Whilst a few of the studies reviewed did consider and control for such as confounding variables, this was infrequently done. Thus, the current literature lacks in a holistic understanding of the wider systems that may impact or be impacted by a person's mental illness.

Despite some of the discussed flaws in the methodology and conceptualisation of this study, it has still been possible to review and collate the findings of a number of good quality epidemiological studies to identify that cancer outcomes are often very poor for patients living with mental illness, throughout their cancer journey. These high-power studies and the hypotheses that can be generated, provide a good foundation for further research to be conducted in this area.

iii) Clinical Implications

A fundamental finding of this study is that the scant use of screening services and detection of a cancer has a profound impact on case fatality. However, it is understood that patients with mental illness have frequent contact with general practitioners (Tilbrook et al., 2010), which offers an opportunity for general practitioners and other clinicians in contact with individuals with mental illness to encourage the use of screening services and have discussions regarding abnormal bodily symptoms during their contacts with individuals with mental illness.

As well as adapting the current physical health checks, this review highlights the need for an increase in collaborative working across oncology and mental health settings. In studies

where clinicians worked separately there were issues in the clinicians ability to manage the mental health symptoms of patients with mental illness (Irwin et al., 2017) and patients' understanding of cancer. It would be expected that clinicians in mental health settings would be skilled at sharing difficult information with people with a mental illness as well as using strategies to manage challenging behaviour. These skills could be shared with oncology staff, in a collaborative working model. Ganzini et al. (2010) presented findings from a service where physical and mental health staff worked collaboratively. The findings found that veterans with comorbid mental illness and cancer had access to good end of life care, including hospice care and life-sustaining treatment. In the USA this collaborative care for veterans is referred to as a whole health care model (Oliver, 2007). In this model both the physical and mental health of veterans are offered under the same provider; doing so ensures better collaboration between health professionals, leading to better outcomes for people with comorbid mental illness and cancer.

iv) Recommendations and Future Research

To further support the claim for a more holistic healthcare model researchers should look at conducting randomised control trials comparing the differences in stage at diagnosis and mortality rates between individuals cared for in settings that offer a whole health care approach with traditional settings where cancer care and mental health care are separate.

Furthermore, to gain a holistic understanding research needs to be conducted where service users' personal experiences are sought. Currently the literature can provide an account of cancer outcomes for people living with comorbid mental illness and cancer through the lens of the medical reports; thus this is open to biases towards topics that are important to the medical field and so is missing a sense of what mental health patients understand to be important when living with cancer. This kind of information is key to beginning the path towards a co-produced healthcare model, where service users are no longer treated as passive consumers of care, but their voices are empowered and services reflect the true needs of service users (Realpe & Wallace, 2010). Furthermore, co-production is thought to be an influencing factor in supporting self-management in long-term conditions (Wagner, 1998). This research highlights that self-management is a potential issue for this population, due to the difficulties seen in gaining a diagnosis and understanding treatment.

v) Conclusions

There is a drive to improve the quality of life of people with a mental illness (Department of Health and Social Care, 2014), however, this research highlights how the relationship between chronic mental illness and cancer is neglected. We have evidence of the substandard outcomes for people with a mental illness once diagnosed with cancer, ultimately leading to excess fatalities. Whilst the NICE (2004) guidelines have successfully impacted on improvements in the psychological care offered to the cancer population, it appears that outcomes for those with pre-existing psychological issues is an area that is still neglected. Furthermore, the findings here are similar to that of Howarth et al (2010), further evidencing the lack of progress that has been made in almost a decade.

The literature has for over a decade identified that disparities occur from the beginning of the cancer journey to the end and now should begin to use cross sectional and longitudinal studies to add depth to this finding and look for avenues to improve cancer outcomes in patients with mental illness'. Hope is offered by the studies mentioned in the present review that report the successful outcomes for patients when oncology services and psychiatric services collaborate. In addition to this, research should look to empower the voice of this group and their experiences, rather than understand their experience from their medical records following their death.

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CHAPTER II

EMPIRICAL PAPER

THE DEVELOPMENT OF A PSYCHOLOGICAL PREHABILITATION INTERVENTION FOR SARCOMA PATIENTS: A FEASIBILITY STUDY

Abstract

Introduction: Sarcoma is a rare form of cancer that is often misdiagnosed or diagnosed at an advanced stage. Surgery is the recommended first line treatment. Patients diagnosed with sarcoma report anxiety before surgery and a percentage of this patient population are at risk of psychological distress following surgery. The practice of prehabilitation has a growing evidence base for improving surgical outcomes for a range of cancers; however, it is yet to be demonstrated if prehabilitation for Sarcoma is feasible and offers benefit to sarcoma patients. The present study looks to investigate the feasibility of trialling a randomised control trial of psychological prehabilitation for Sarcoma patients.

Method: A controlled pre - post study was designed, following a request from the sarcoma health care team at the local trust, reporting a need for care before surgery. Furthermore, previous research conducted by Tsimopoulou (2015) and Asfaw (2019), identified the need and benefits of prehabilitation in sarcoma patients. A one-hour intervention was created and offered to sarcoma patients, recruited to the study. Participants were randomised to either a control or experimental arm. Participants were asked to complete six questionnaires regarding their emotional and physical wellbeing. Following this, participants in the experimental arm received a psychological intervention with a trainee clinical psychologist prior to their surgery. The intervention was informed by Acceptance and Commitment Therapy and Compassion Focused Therapy. All participants then underwent surgery. Outcome measures were repeated at approximately four weeks after surgery. In addition to the formal outcome measures, the feasibility of the study was assessed in regard to the feasibility of recruitment, follow-up and randomisation, amongst other parameters.

Results: Nine participants took part in the feasibility study. It was feasible and acceptable to randomise participants between conditions; however, participants completed follow up measures within differing timescales. A Cohen's D power calculation identified that for a randomised control trial to have sufficient power, one hundred and sixteen participants would need to be recruited. Finally, reliable change calculations highlighted the appropriateness of the chosen measures as they were found to be sensitive to changes in this population.

Discussion: The study indicated that it would be feasible to implement the psychological intervention as part of a randomised control trial of prehabilitation for sarcoma patients, with a number of modifications to the present design. Modifications include embedding the study within the service to utilise existing resources in order to increase both recruitment the controllability of the study. Furthermore, prehabilitation may only be indicated for a percentage of patients with Sarcoma therefore a pathway approach, where individuals are screened for vulnerabilities to psychological decline following surgery are identified, with other patients receiving treatment as usual.

1. Introduction

i) Background Literature

Sarcoma is a rare cancer which can be broadly divided into three types: soft tissue sarcoma, bone sarcoma and gastrointestinal stromal sarcoma (Sarcoma UK, N.D). In 2015, 5345 people in the UK were diagnosed with sarcoma, making up 1.3% of all cancer diagnosed; 71% of sarcomas diagnosed are of the soft tissue (Sarcoma UK, N.D). Sarcomas will frequently be undetected or misdiagnosed (Smith, Johnson, Grimer & Wilson, 2011), typically being around 10.2 centimetres by the time they are diagnosed (Sarcoma UK, N.D). Once diagnosed treatment is often needed promptly. Surgery is recommended as the primary treatment for sarcoma patients (Grimer, Judson, Peake & Seddon, 2010; Gerrand et al., 2016). Surgery for sarcoma is often palliative in nature and has a poor prognosis (Grimer, Mottard & Briggs, 2010); the tumour can be aggressive and surgery may include limb-salvage/reconstruction (Shehadeh et al., 2013), amputation (Alamanda, Crosby, Archer, Song, Schwartz & Holt, 2012) and the removal of the tumour and its surrounding organs (Gronchi, Bonvalot, Le Casne & Casali, 2009). Following on from surgery, patients have a higher likelihood of physical disability relative to other cancers (Tang et al., 2012), higher levels of pain and a reduction in mobility (Davis, 1999). Thus, the diagnosis and treatment of sarcoma offers a unique challenge to patients. Cheville, Beck, Petersen, Marks and Gamble (2009) report that often it is not the cancer diagnosis that causes psychological distress for patients, but more so the impact of complex treatments, such as surgery.

The period before any surgery is a time of vulnerability for patients due to their physical illness but also the psychological issues that occur as a result of anticipating surgery (Ascari et al., 2013). Whilst awaiting surgery patients report feeling apprehensive (Vagras, Maia & Dantas, 2006), anxious (Fitzsimons, Parahoo, Richardson & Stringer, 2003) and fearful of going under anaesthesia (Ruhaiyem et al., 2016). In addition to this, the preoperative phase has been characterised by individuals beginning to pre-empt the pain they will experience as a result of surgery (Egan, Ready, Neddly & Greer, 1992) and setting unrealistic expectations for their recovery (Phil et al, 2016). For cancer patients in particular, Macmillan Cancer Trust (2013) reports that the preoperative period involves patients worrying about their cancer

growing during the wait or returning after surgery, a decline in self-esteem, financial worries, sexual difficulties and difficulties associated with changing life roles. Potential psychological turmoil that patients experience is reported to be elevated in patients awaiting major and elective surgeries (Vagras et al., 2006), for which sarcoma surgery would be considered one. Research suggests that the experience of these negative states pre-operatively has an impact on post-operative outcomes including pain (Granot, Goldstein & Ferber, 2005) and wound healing (Broadbent, Petrie, Alley & Booth, 2003). A more complicated recovery has been associated with difficulties in the long-term psychological health of patients (Pinto, Faiz, Davis, Almourdaris & Vincent, 2016).

NICE (2004) identifies a number of points throughout the cancer journey during which psychological intervention may be beneficial, of these, intervention before surgery is highlighted. Research too has begun to identify the benefits of intervening between diagnosis and surgery (Cheema et al*.,* 2011). The act of intervening during this period has been coined 'prehabilitation' (Silver, Baima & Mayer, 2013, p.307).

Research into the impact of sarcoma is sparse, possibly due to the rareness of the disease and range of locations that sarcoma can affect (Fletcher et al., 2002), however, associations have been made between sarcomas and the risk of physical, functional and psychosocial difficulties (Pakulis*.* Young & Davis*,,* 2005 & Aksnes et al., 2009). The majority of the research focuses on these risks as a long-term effect of sarcoma rather than exploring the wellbeing of patients during the brief but distressing interim between receiving a diagnosis and awaiting surgery.

In the interim between diagnosis and treatment of sarcoma, clinical levels of anxiety are reported in 29.4% of patients and clinical depression in 22.6% (Paredes et al*.,* 2011). Paredes, Pereria, Simoes & Canavarroo (2012) report that sarcoma patients who are particularly vulnerable to experiencing psychological distress include those living with partners, people who infrequently used humour and those who presented as being in denial of their diagnosis. Typically, living with a partner and having a family would be considered a protective factor against depression (Inaba, Thoits, & Ueno, 2005), however, it is possible that the impact of disability following sarcoma surgery impacts on an individual's role in their family, thus giving rise to feelings of anxiety or depression. Both lack of humour and denial are understood as contributors towards psychological distress. The use of humour has been

associated with protection from compassion fatigue (Perry, 2008 & Moran, 2013) and so the absence of humour may give rise to reduced self-compassion. Self-compassion is positively correlated with physical (Dunne, Sheffield & Chilcot, 2016) and emotional (Zessin, Dickhauser & Garbade, 2015) wellbeing, while patients who engage in denial are reported to be vulnerable to post-traumatic stress responses (Richardson, Morton & Broadbent, 2016). It may be of benefit to offer patients presenting with these social and emotional coping strategies, with psychological support to prevent subsequent psychological distress.

In a review of current psychological prehabilitation offered before surgery to treat cancer Tsimopoulou et al. (2015) reported the following interventions to be in use: relaxation techniques (progressive muscular relaxation, breathing and meditation), guided imagery, problem solving and coping strategies, psychoeducation regarding the planned surgery and psychotherapy. Frequently, psychological prehabilitation interventions are offered for a brief period of time, namely, 1-2, one-hour sessions (Larson, Duberstein, Talbot, Caldwell & Moynihan, 2000; Haase, Scwenk, Hermann & Muller, 2005; Parker et al., 2009; Cohen et al., 2011; Garssen et al., 2013). Benefits of psychological prehabilitation include improvements in immunologic functioning, quality of life, somatic symptoms, psychological outcomes (Tsimopoulou et al., 2015), pain, return to premorbid functioning and discharge from hospital (Powell et al., 2016).

Research into prehabilitation is in its infancy and so traditional psychological interventions, such as stress management (Parker et al., 2009; Garssen et al., 2008; Cohen et al., 2011) have currently been trialled. However, it is possible that new third wave psychological interventions such as acceptance and commitment therapy (ACT; Hayes, 2004) and compassion focused therapy (CFT; Gilbert, 2009) may be beneficial in addressing the unique challenges faced by sarcoma patients.

Acceptance and Commitment Therapy (ACT) is growing in popularity as an intervention in physical health settings, with evidence showing it to be an effective intervention for patients in chronic pain (Dahl, Wilson & Nilsson, 2004; Wicksell, Ahlqvist, Bring, Melin & Olsson, 2008; Thorsell et al., 2011; Wetherell et al., 2011; Burham et al, 2013) diabetes (Gregg, Callaghan, Hayes, Glen-Lawson, 2007; Amsberg, Livheim, Toft, Johansson & Anderbro, 2018) and irritable bowel syndrome (Ferreira, Gillanders, Morris & Eugenicos, 2018). ACT can be summarised into two principles (a) clarifying individuals values and encouraging an

individual to move in the direction of those values and (b) promoting defusion as a way of getting an individual to engage in valued behaviours when feared situations are present (Guiterrez, Luciano, Rodriguez & Fink 2004). For sarcoma patients this offers a promising avenue of prehabilitation due to the acknowledgment that the feared situation is real whilst respecting the values that an individual holds and empowering them to move towards these goals regardless of the feared situation – without intervention it is possible that upcoming surgery and disability following surgery may leave someone with the belief that they cannot continue to live in accordance with their values. ACT has proven to be effective in promoting hope (Montazer, Nemati, Dehghani & Fallah, 2017), quality of life (Chambers et al*.,* 2015), reducing fatigue, improving sleep quality and resilience (Golshani & Pirnia, 2019).

A further third wave therapy may have value. Compassion Focused Therapy (CFT) suggests that when an individual's emotional regulation systems are unbalanced, distress arises (Gilbert, 2009). The emotional regulation systems include the Threat System, which is concerned with protection; the Drive System, which is concerned with obtaining resources; and the Soothing System, which is concerned with managing distress (Gilbert, 2009). Compassionate approaches aim to rebalance the system by activating the Soothing System through the use of compassion, such that people are better able to cope with distress (Gilbert, 2009). For sarcoma patients it is likely that the diagnosis of a potentially life-threatening condition, which requires surgery, and that could leave one with a range of physical impairments would trigger the Threat System and the associated emotions (fear and anxiety) and behavioural repertoires (e.g. fight or flight, avoidance). Thus, it is possible that an intervention aimed at promoting self-compassion may counteract the emotional distress that arises from sarcoma. In support of this hypothesis, Fogarty and colleagues (1999) found that even a brief exposure to a compassionate intervention improved psychological wellbeing in cancer patients. Furthermore, self-compassion is understood to be a protective factor for cancer patients against psychological distress (Pinto-Gouveia et al*.,* 2014).

ii) Aims and Rationale

In order to restore inner balance, under new circumstances and reduce emotional discomfort cancer patients need to be able to adjust to their cancer (Religioni, Czerw & Deptala, 2018). However, the challenges that arises from sarcoma and surgery, in addition to the brief period

of time between diagnosis and surgery make it unlikely that sarcoma patients can engage in the cognitive and behavioural process of adjusting to their.

A series of studies, conducted within the current setting, has looked to identify how with assistance from psychological knowledge patients could be supported during the period between diagnosis of sarcoma and surgery. The first study, a systematic review, looked to answer the question the effectiveness of psychological prehabilitation for cancer patient's (Tsimopoulou et al., 2015). The second study looked to understand, through qualitative methods, the experience of surgery for sarcoma patients and their perceptions of what would have been helpful prior to surgery. The present study looks to investigate how feasible it is to study psychological prehabilitation for sarcoma patients before they receive surgery.

The present study specifically looks to investigate the feasibility of conducting a Randomised Controlled Trial (RCT) in a national centre of cancer excellence, offering soft tissue and gastrointestinal stromal tumour sarcoma patients a one-hour psychological prehabilitation setting informed by ACT, CFT and pre-existing prehabilitation methods. Arain, Campbell, Cooper & Lancaster (2010) defines a feasibility study as one which looks to trial the design of the study, focusing on features such as:

- Standard deviation of the outcome measures, so to allow for estimates of the sample size to be made
- Willingness of participants to be randomised
- Willingness of clinicians to recruit participants
- Number of eligible patients
- Characteristics of the proposed outcome measure
- Follow-up rates, response rates to questionnaires, adherence/compliance rates

With this in mind, the present study looked to explore the various parameters required for successful implementation of an RCT, whilst also exploring the preliminary individual differences between participants.

Whilst the individual differences of participants was of interest a feasibility study does not focus on gaining a large number of participants (Arain *et al.,* 2010). Thus, the present study looked to recruit a small sample of sarcoma patients to test the protocol and acceptability of

2. Method

i. Ethical Approval

Ethical approval was sought and approved by the East Midlands Research Ethics Committee (see Appendix 3) via the Health Research Authority (see Appendix 4). In addition to this, approval was granted by Research and Development from the local teaching hospital trust to conduct this research at the local cancer centre of excellence within a large teaching hospital (see Appendix 5). The study was sponsored by the University of Birmingham (see Appendix 6).

ii. Design

The present study was a feasibility study using a randomised control design. The researcher sought to test the feasibility with regard to several factors: i) recruiting participants with a sarcoma in the time period after diagnosis and before surgery; ii) the feasibility and willingness of participants to be randomised to control and intervention arms iii) the acceptability of the intervention; iv) the sensitivity of the measures to change in this population v) any changes seen between pre and post in participants; v) the follow up rates of recruited participants.

Prior to this study a qualitative study was conducted with a sample of Sarcoma patients (Asfaw, 2019). This study asked participants what their lived experience of the sarcoma surgery was and what people believed would have been beneficial to them before their surgery. It was proposed that this study would inform the design of the present study. However, there were delays in this study meaning that the protocol was designed before the results of the qualitative study had been collected and analysed.

iii. Participant Recruitment

An opportunity sampling strategy was applied; participants were initially approached during their clinic appointment where the diagnosis of sarcoma was being investigated. At this

appointment participants, who met the eligibility criteria to participate (see Appendix 7), were given a verbal introduction to the research by their sarcoma surgeon (see Appendix 7) and provided with an information leaflet to consider their participation in the study (see Appendix 8). At their next clinic appointment, more than 1 week later, patients were asked if they had had chance to consider participating in the research and if they would like to participate. Patients who expressed an interest in participating were then advised that the researcher for the research would need to contact them, to provide more information and instructions relating to their participation, and so they were asked to sign a form consenting to being contacted by the researcher (see Appendix 9).

The surgery team then provided the researcher with the potential participants' names and their email address. This information was shared via a secure NHS email or in person when their researcher visited the hospital site.

The researcher contacted participants via telephone call. Participants were provided with a recap of the study, similar to the introduction that the surgeons had provided. The randomisation procedure was explained(See Appendix 10), and the researcher clarified if the participant had access to the internet, to enable them to complete the questionnaires and sign the online consent form. If participants confirmed they had internet access then they were asked for their email address and then sent a consent form (to sign online; See Appendix 11), a link to the online questionnaire(see Appendix 12 for questionnaires used) and a unique participant code (produced using a random code generator tool). Participants were asked to send back their consent form to the researcher's secure email address.

For participants in the intervention arm, the researcher liaised with the hospital team to identify a time and date that was convenient for the participant to receive the psychological intervention, before surgery. Participants in the intervention arm then received the psychological intervention, in a clinic room next to the general surgery ward at the teaching hospital, in addition to treatment as usual. Participants in the control arm received only treatment as usual. Treatment as usual is defined as clinic appointments to investigate the sarcoma, a preoperative assessment and access to a clinical nurse specialist for support. Four weeks after surgery, all participants were contacted and asked to complete the post-surgery measures (see Appendix 12). In addition to this, the chief investigator kept a reflective diary, documenting the experience of running the study (see Appendix 13).

iv. Sample

Participants were patients with a diagnosed sarcoma who were scheduled to have this sarcoma treated via surgery; with the surgery being performed at a national centre in the local teaching hospital. Eligible participants were patients age eighteen and above, diagnosed with a sarcoma and undergoing surgery, able to provide informed consent, without a known mental health difficulty and with a good comprehension of the English language (see Appendix 7 for full inclusion and exclusion criteria).

In total twelve patients were recruited over a 5-month period, between October 1st 2018 and March 29th 2019. Eight were allocated to the intervention arm of the intervention. Of these eight, five completed the full protocol. Two participants were unable to receive surgery due to poor health, another one opted out of the study before receiving the intervention and declined to give a reason. A total of four participants were allocated to the control arm. All control participants completed the entirety of the study.

v. Data Collection

Before and after their surgery participants were asked to complete six questionnaires. A large number of measures were chosen given the novelty of the research, with their being no research to hypothesis what elements of wellbeing were amenable to change following surgery, in addition to not having data available (at design) from the qualitative study regarding the issues that sarcoma patients found important. Thus, fitting with the remit of a feasibility study, the sensitivity of the measures for this population was an interest point.

The aim of these questionnaires was to gain an understanding of participants' pain and functional status, wellbeing and affective mood in addition to measuring factors hypothesised to act as mediators: adaptation to cancer and self-compassion.

Outcome measures

a. Numeric Pain Rating Scale (NPRS; Hatrick, Kovan & Shapiro, 2003)

It is well recognised that persistent and chronic post-surgical pain is a frequently reported adverse outcome of surgeries for cancer (Macrae, 2001) and NICE (2004) recommend that outcomes for sarcoma care should focus on experiences of pain.

The NRS is an 11-point rating scale where responders are asked to rate the severity of their pain on a scale of 0 to 10; with 0 representing "no pain at all" and 10 representing "the worst pain imaginable". The NPRS reports both good reliability (α=0.95; Alghadir, Anwer, Iqbal & Ahmed, 2018) and validity(α=0.94; Alghadir et al., 2018). Furthermore, it is reported to be an appropriate of measure of pain in cancer (Jensen, 2003) as well as being responsive to difference in pain for both genders (Ferreira-Valente, Pais-Ribeiro & Jensen, 2011).

b. Nottingham Extended Activities of Daily Living Scale (NEADL; Nouri & Lincoln, 1987)

Activities of daily living are of interest following surgery not only because of the correlation with pain (Wildgaard, Ravin, Nikolajsen, Jakobsen, Jensen & Kehlet, 2011) but also due to the changes being indicative of the recovery journey; immediately after surgery activities of daily living are reported to be at a decreased level but in the long term activities of daily living typically increase to levels exceeding those before surgery (Amemiya, et al., 2007).

The NEADL is a 22-item questionnaire that measures participants ability to engage in activities of daily living (including household chores, managing money and being mobile). Participants rate themselves on a four-point scale of how able they are to perform each task, with the ratings ranging from "not at all" to "on your own". The NEADL is widely used both in research and clinical practice as a measure of patient wellbeing. The reliability of the measure has been reported as having good reliability(α=0.96) and validity(α=90) in physical health patients (Nicholl, Lincoln & Playford, 2002; Harwood & Ebrahim, 2002)

c. Compassionate Engagement & Action Scale (Gilbert et al., 2017)

Self-compassion is reported to be a factor that mediates the experience of pain (Wren et al., 2012). Neff (2003) found that individuals who demonstrate self-compassion were more likely to face life challenges by using positive coping strategies and being able to repair their emotional state when necessary.

The Compassionate Engagement & Action Scale (CEAS; Gilbert et al., 2017) is made up of three scales; self-compassion, compassion to others and compassion from others, this study used the self-compassion measure. Participants rate themselves on a scale of 0 (never) to 10 (always) on their motivation and engagement for self-compassion when distressed (8 statements) and their coping when distressed (5 statements). Gilbert et al. (2017) report good validity(α=0.81) and reliability (α=0.88) for this scale.

d. Mini Mental Adjustment to Cancer scale (Mini MAC; Watson et al., 2008)

Mental adjustment to cancer can be described as an individual's cognitive and behavioural reactions to their cancer diagnosis (Grassi et al., 2005). The following five responses have been identified: fighting spirit, anxious preoccupation, fatalism, hopelessness-helplessness and avoidance. A patients' emotional coping response has been identified as important to physical outcomes in cancer patients (NICE, 2004).

The mini-MAC is a 29-item questionnaire where participants rate themselves on a scale of 1 to 4 (1 meaning "definitely does not apply to me", 4 meaning "definitely applies to me") against statements representing the 5 aforementioned responses to cancer. The mini-MAC is a widely used measure of coping in cancer and is able to demonstrate good validity(α=0.78-0.93) and reliability (α= 0.62-0.99) (Pereira & Santos, 2014).

e. Hospital Anxiety and Depression scale (HADS; Zigmond & Snaith, 1983)

Low mood and anxiety are understood as being common responses to cancer (Linden, Vodermaier, MacKenzie & Greig, 2012). The presence and severity of these affective conditions can have an impact on functioning, hospital stay and treatment adherence (Hopwood & Stephens, 2000).

The HADS is a 14-item scale that asks respondents to rate themselves seven statements concerning behaviours related to the presence of anxiety and seven items related to the presence of depression. Responders rate themselves against a set of statements relating to how frequently they felt or behaved like this. The HADS has been frequently used in populations with cancer and is useful in discriminating the presence of these affective

conditions from the symptoms of physical conditions (Bjelland, Dahl & Tangen Haug & Neckelmann, 2002). Bjelland et al (2002) reported good validity and reliability to the scale.

f. Warwick Edinburgh Mental Wellbeing Scale (WEMWBS; Tennant et al., 2007)

NICE (2004) recognise the need to address the emotional health of cancer patients and incorporate this into the care of cancer patients.

The Warwick Edinburgh Mental Wellbeing Scale is a 14-item scale measuring respondents experiences of positive mental wellbeing; it is notable for its focus on positive experiences. Respondents are asked to rate themselves on a five-point scale of how often they experience these attributes of positive mental wellbeing and the scale ranges from 1(none of the time) to 5 (all of the time). Tenant et al. (2007) reported that the scale had good content validity, good test-retest reliability and was highly correlated with other measures of mental wellbeing and had low correlation with measures of general health.

vi. Design of the Intervention

The initial need for an intervention was proposed by surgeons specialising in sarcoma at the teaching hospital; they identified the need for the psychological wellbeing of their patients to be addressed. Tsimopoulou et al. (2015) had previously, as part of their work with the same sarcoma surgery team, conducted a review of psychological rehabilitation before surgery, where seven RCTs of psychological interventions before surgery for cancer were identified, which found that prehabilitation did result in improvements in well-being, however, the literature base was still identified as in its infancy. With this in mind, further work that was specific to sarcoma was needed before psychological prehabilitation could be introduced in this setting for sarcoma patients. An exploratory study was conducted by Asfaw (2019) to describe the experience of sarcoma patients who had undergone surgery and explore what support thought they would have benefited from before. It was identified that patients thought a peer-support system to reduce anxiety and more information regarding the risks of surgery. Furthermore, existing studies of prehabilitation in non-cancer populations undergoing surgery have reported the use of psychoeducation, relaxation, guided imagery, exercise, supportive telephone calls and hypnotic interventions (Arthur, Daniels, McKelvie, Hirsh & Rush, 2000;

Nelson et al., 2013). As such, the intervention offered was a combination of psychoeducation, applied relaxation and therapeutic techniques/interventions informed by acceptance and commitment therapy (ACT; Hayes, 2004) and compassion focused therapy (CFT; Gilbert, 2009).

a. Psychoeducation

The literature regarding prehabilitation frequently reports that psychoeducation, including information on surgery, its side effects and recovery following it, is frequently used as a prehabilitation intervention for cancer and non-cancer patients (Nelson et al., 2013; Paich et al., 2016) to good effect. In particular the results report that psychoeducation provides patients with an opportunity to form a realistic expectation of their recovery journey (Arthur et al., 2000; Paich et al., 2016).

b. Applied Relaxation

The use of applied relaxation techniques for physical health conditions has been incorporated into practice for a number of decades (Baum & Posluszny, 2000). It has been reported that the use of applied relaxation is beneficial in alleviating the effects of cancer treatment and also in recovery following surgery (Astin, Shapiro, Eisenberg & Forys, 2002). Parker et al. (2009) suggested that that stress management (mainly relaxation techniques guided by a psychologist) were effective in improving short- and long-term surgery outcomes, particularly regarding physical health. Progressive muscular relaxation, in particular, is widely used in health settings (Li et al., 2015) and is evidenced as being an effective intervention for cancer patients (Matovina, Birkeland, Zick & Shuman, 2017; Paras-Bravo et al., 2018).

c. Acceptance and Commitment Therapy (ACT; Hayes, 2004)

ACT is a popular psychological intervention in physical health settings and there is a growing evidence base for its use for a range of issues, including coping with cancer (Jiménez , 2012). An ACT intervention can be summarised into two principles (a) clarifying an individuals' values and encouraging an individual to move in the direction of those values and (b) promoting defusion from distress as a way of getting an individual to engage in valued behaviours when feared situations are present (Guiterrez et al., 2004).

Research has found that the concept of psychological flexibility targets the avoidance of negative feelings or thoughts which has been an issue in cancer patients, which in turn increased quality of life, experience of distress and mood issues (Feros, Lane, Ciarrochi & Blackledge, 2013).

d. Compassion Focused Therapy (CFT)

It has been found that compassion is a mediating factor between cancer related symptoms and psychological distress, with those who reported lower levels of compassion having greater emotional difficulties related to their cancer (Przezdziecki et al., 2013). The importance of self-compassion as a protective factor, specific to cancer, was highlighted by Pinto-Gouveia and colleagues (2014) who found stronger correlations between self-compassion and reduced psychological distress when compared to a healthy sample. Even brief exposures to compassionate interventions have proved to be effective for cancer patient's psychological wellbeing (Fogarty, Curbow, Wingard, McDonnell & Somerfield, 1999).

The Use of CFT in cancer populations is yet to be fully understood, however, one may predict that a cancer diagnosis activates the Threat System regarding the threat to one's life.

vii. Intervention

The procedure for the intervention was as follows:

1. Participants were provided with a guided tour around the key areas that they would encounter during their stay for the visit. This included a tour of the intensive care unit and the general surgery ward. For participants unable to do the tour, due to mobility or access to wards a verbal description was provided of the wards.
2. Participant were provided with a space to explore their feelings, thoughts, fears and hopes of both their journey so far, surgery and their upcoming recovery. Within this conversation the concepts of ACT & CFT were introduced and discussed in the context of the conversation.
3. Participants engaged in an ACT activity where they were encouraged to think about their values and how they could continue to work towards these values despite the difficulties that may arise during their recovery (see Appendix 14)

4. Participants were introduced to the “takeaway documents”(see Appendix 15). In particular, participants were given a gift box, and following this the psychologist provided instructions on building a box containing compassionate self-help tools.
5. To end the session, participants were invited to engage in a progressive muscular relaxation exercise (see Appendix 16). This lasted for 10 minutes.

viii. Data Analysis

The data analysis for this study looked to identify whether the study was feasible to conduct. The guidance of outcomes of interest as presented by Arain et al. (2010) was divided into two categories: feasibility of the process and feasibility of offering the content.

To answer the question of the feasibility of the process, observations were made of the descriptive statistics, the participants’ flow through the study and interpretation of the researchers reflective diary was made. Furthermore, sample size was estimated by calculating Cohens d coefficient. To do so, the mean and standard deviation of the post-surgery outcome for both treatment arms on the scale of wellbeing was used.

A reliable change index analysis was conducted to analyse the preliminary individuals outcomes. Jacobson and Traux (1991) proposed that using the normative standard deviation and test-retest score a reliable change index (RCI) can be calculated to understand the change at an individual level. For this study the test-retest reliability was drawn from the existing literature and the standard deviation was derived from this samples pre-surgery scores.

3. Results

i. Descriptive Statistics

Twelve patients consented to participate in the study. Two of these participants were unable to undergo surgery, due to illness and so were not followed up. Another one participant changed their mind before receiving the psychological intervention, and so was also not followed up. For characteristics of the participants who completed the study please see Table 6.

Table 5. Sample Characteristics

	INTERVENTION GROUP (N=8)	**CONTROL GROUP (N=4)**	**ALL GROUP (N=12)**
AGE	61.38(8.04)	60 (8.12)	60.92 (7.72)
GENDER	4 Females	3 Females	7 Females
LOCATION OF SARCOMA			
• **ABDOMEN**	3	2	5
• **PELVIS**	2	1	3
• **GROIN**	3	1	4
LOST TO FOLLOW UP	3	0	3

a. Pain and Functional Outcomes

Table 7 presents that pain and functioning at baseline for both the participants in the control (M=3.25, SD=0.82) and treatment (M=3, SD=4.12) report mild levels of pain (Boonstra et al., 2016), as shown in table 2. Following surgery, the intervention groups mean (M=3.4, SD=2.19) remained in the mild range, whereas the control groups mean (M= 5.5, SD=1.29)

rose to a level that would be deemed moderate (Boonstra et al., 2016). Functioning was observed to reduce between baseline and post intervention for both participants in the control and intervention arms of the study.

b. Affective Mood and Wellbeing Outcomes

Anxiety prior to surgery and intervention (if allocated to the treatment arm) was found to be in the range of clinical concern as described by Zigmond and Snaith (1984) for both the control arm (M= 8.25, SD=4.57) and intervention arm (M=9.8, SD=4.44). Depression prior to surgery and intervention fell within the "normal" range (Zigmond & Snaith, 1984;) as did wellbeing (Stewart-Brown, 2008). Following surgery anxiety decreased in both arms of the study, for the treatment arm the new mean would be classified as "normal" (M=6.2, SD=3.56). Whilst anxiety reduced in the control arm following surgery, the mean score would still be in the range of clinical concern (M=8, SD=3.46). Wellbeing was found to decrease in those in the control arm following surgery but increase in participants in the intervention arm. Consistent with this depression increased in the control arm to a "borderline abnormal" range (M=7.25, SD=2.06) and decreased in the intervention arm.

c. Mediating Factors

Whilst pain, functioning, wellbeing and affective mood symptoms are the primary outcome measures, the study looked to observe the change in potential mediating mechanisms of coping (Mini-MAC) and compassion (CEAS) to gain a better understanding of how the intervention influenced change, if at all. Prior to surgery participants appeared to engage in anxious preoccupation as their primary coping method. Both the control group and the intervention group reported high levels of compassionate engagement(Control M= 32, SD=6.78; Intervention M=25.8, SD=11.69) and action(Control M=40, SD=10.03, Intervention M=39, SD=18.76) prior to surgery. Following surgery, both groups of participants reduced in their use of anxious preoccupation (Control M=16, SD=5.29; Intervention M=21.75 , SD=2.06) as an adaptation method and helplessness hopelessness. Similarly, both groups of participants reduced in their reports of compassionate action (Control M=40, SD=10.03; Intervention M=39, SD=18.76). However, both groups increased in their reports of compassionate engagement (Control M=41.6, SD=16.99; Intervention M=35, SD=7.96).

Table 6. Descriptive Statistics of participants scores both pre and post-surgery

SCALE	GROUP	BASELINE MEAN (SD)	POST-SURGERY MEAN (SD)	CHANGE SCORE BASELINE-POST SURGERY
Numeric pain rating scale	Intervention	3 (4.12)	3.4 (2.19)	-0.4
	Control	3.25 (0.82)	5.5 (1.29)	-2.25
Warwick-Edinburgh mental wellbeing scale	Intervention	48.4(14.19)	52.8 (10.18)	4.4
	Control	50.5 (10.41)	43.25 (5.91)	7.25
NEADL*- MOBILITY	Intervention	21.8 (1.64)	18.6 (3.85)	3.2
	Control	19.5(3.32)	14(4.08)	5.5
NEADL - KITCHEN	Intervention	19.8 (0.48)	17.4 (1.67)	2.4
	Control	20 (0)	17 (2.16)	3
NEADL – DOMESTIC	Intervention	17 (4.47)	12 (5.51)	5
	Control	19 (1.41)	10.5 (2.38)	8.5
NEADL – LEISURE	Intervention	15.4 (2.79)	12.6 (2.61)	2.8
	Control	16.75 (2.22)	13.75 (1.71)	3
Hospital anxiety & depression scale - Anxiety	Intervention	9.8(4.44)	6.2(3.56)	3.6
	Control	8.25(4.57)	8(3.46)	0.25
Hospital anxiety & depression scale-Depression	Intervention	6.4(4.93)	4.8(4.27)	1.6
	Control	5(1.41)	7.25(2.06)	-2.25

Mini-Mac (Helplessness-Hopelessness)**	Intervention	16.6(6.35)	12.6(5.23)	4
	Control	10(1.83)	12.25(3.2)	-2.25
Mini-Mac (Anxious-Preoccupation)	Intervention	23.4(6.62)	16(5.29)	7.4
	Control	24.25(3.95)	21.75(2.06)	2.5
Mini-Mac (Fighting Spirit)	Intervention	11.8(2.86)	10.6(2.41)	1.2
	Control	13 (2.16)	11.75(0.96)	1.25
Mini-Mac (Cognitive Avoidance)	Intervention	11.75(3.5)	12.75(3.4)	-1
	Control	12.4(2.61)	12(3.32)	0.4
Mini-Mac (Fatalism)	Intervention	12.2(1.92)	14.6(2.07)	-2.4
	Control	16.25(1.89)	15(2.71)	1.25
CEAS* - Engagement**	Intervention	25.8(11.69)	41.6(16.99)	-15.8
	Control	32(6.78)	35(7.96)	-3
CEAS - Action	Intervention	39 (18.76)	29(9.57)	10
	Control	40(10.03)	26.75(4.99)	13.25

Note * NEADL- Nottingham Extended Activities of Daily Leisure Scale; **Mini-Mental Adjustment to Cancer Scale;***Compassionate Engagement and Action Scale.

i. Participant Journey

In the 5-month period that recruitment ran, a total of thirty-two patients consented to be contacted by the researcher after having been given introductory information about the research. Figure 2 offers an illustration of their journey through the study. Following a conversation with the researcher, which included an email with details on how to provide informed consent and a link to the questionnaire, twelve participants returned informed consent forms and completed the pre-surgery questionnaires. Participants were randomly allocated (see Appendix 10 for randomisation procedure). A total of three participants dropped out before receiving their surgery, due to poor health meaning they were unable to

undergo surgery (N=2) or "changed mind) (N=1). The remaining 9 participants completed the entirety of the protocol. At follow up four participants completed the questionnaires within the four-week period, the longest wait for follow-up data was eight weeks. Five participants required prompting from their clinical nurse specialist to complete the post-surgery questionnaire.

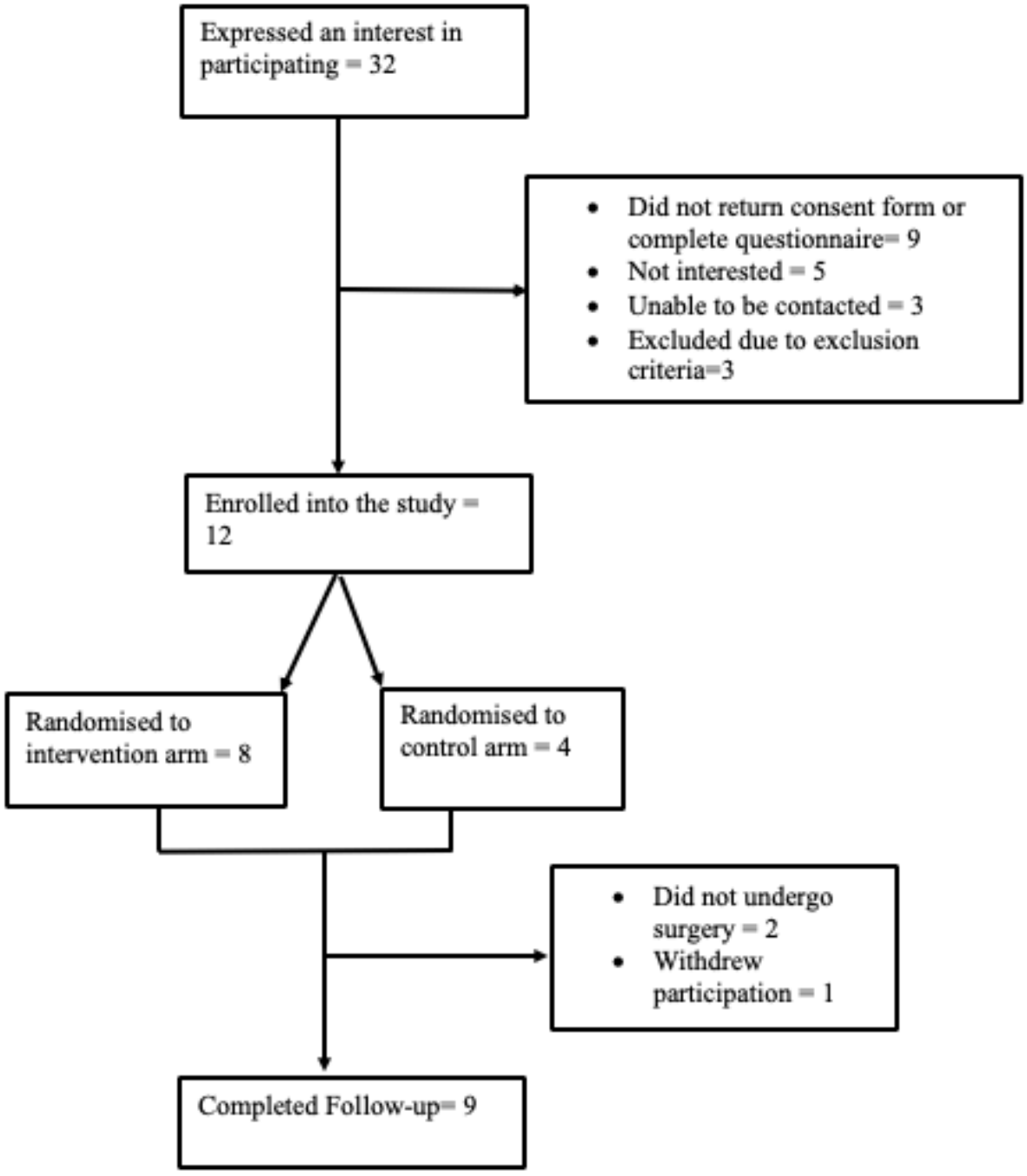


Figure 2. Diagram of the flow of participants through the study

i. Sample Estimates

An *a posteriori* power calculation was performed to inform the number of participants that would be required in a randomised control trial to yield an effect size of .80 at the 95% confidence interval. To conduct this power calculation the mean and standard deviation from both the intervention (M=52.8, SD=10.18) and control group (M=43.25, SD=5.91), post-surgery, measures of wellbeing (WEMWBS) was used. Wellbeing was chosen as the primary outcome due to the well-researched ability of psychological interventions to influence emotional wellbeing in cancer patients.

The Cohens d criterion (D=1.15) posits that to yield an effect size of 0.8 a total of fifty-eight participants would be needed in each condition, one hundred and sixteen participants in total.

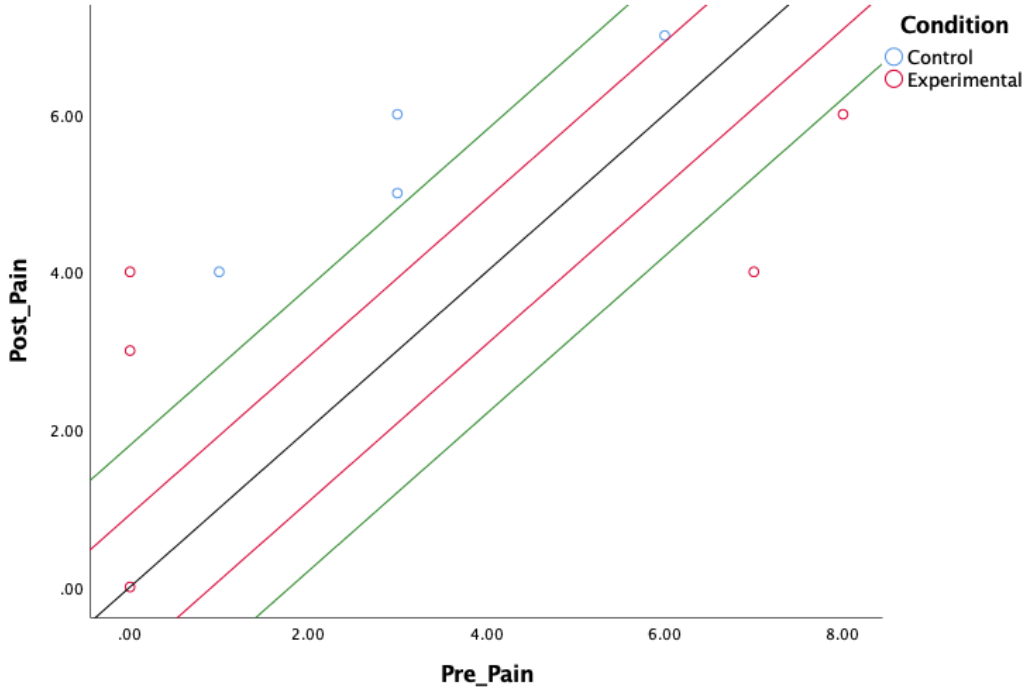
ii. Reliable change analysis

The proportion of participants who were classified as showing considerable change (decline or increase) or no change are described below for each of the four primary outcome measures; pain, functioning, wellbeing and affect (to see individual reliable change scores and scores at each assessment point see Appendix 17).

a. Pain

As can be seen in Figure 3, a total of three control participants and two experimental participants reported an increase in pain that was reliably and clinically significant at the 95% CI (1.80). A further one control participant shows a clinically reliable change (66% CI =0.92). By contrast two participants in the experimental arm reported decrease in pain following surgery which is both clinically and reliably significant (95% CI=1.80).

Figure 3. Scatter plot depicting the reliable change index for self-reports of pain, with a line of no effect, 66th confidence interval and 95th confidence interval.



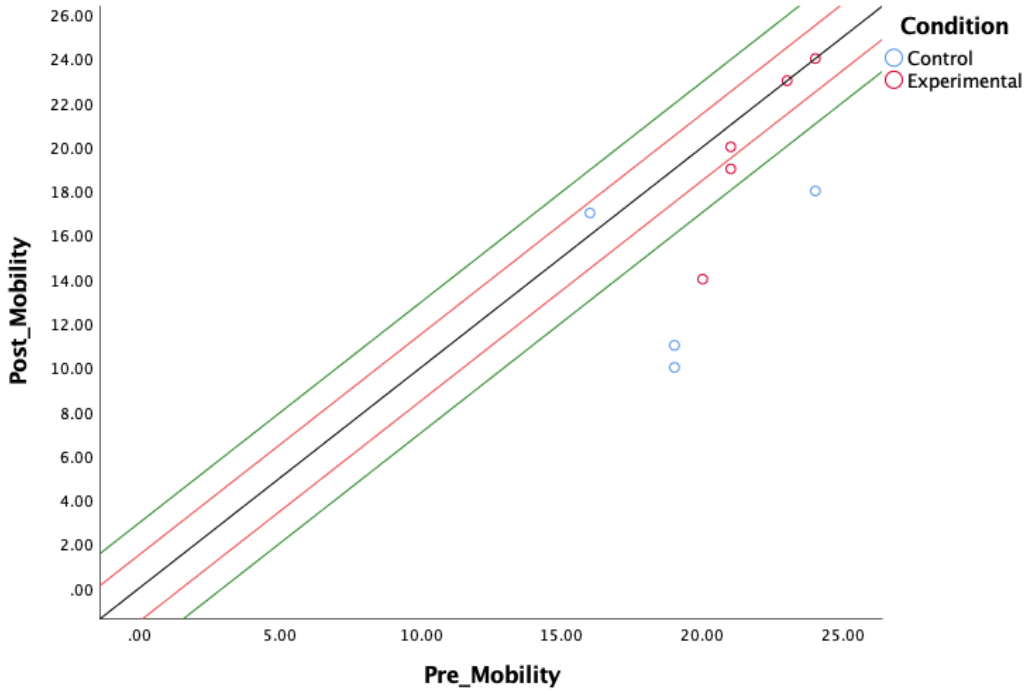
Note. Black line represents the line of no effect, the red line is the 66% confidence interval and represents clinically reliable change and the green line represents the 95% confidence interval and thus scores that are clinically and significantly reliable.

b. Activities of Daily Living

Mobility

Figure 4 depicts that six participants reported a decrease in functional mobility following surgery. Three participants allocated to the control arm and one allocated to the experimental arm reported a clinically and reliably significant reduction in mobility (95% CI =2.96). An additional one participant in the experimental arm reported a clinically reliable reduction in mobility following surgery (66% CI=1.51). Only one participant, allocated to the control arm, reported an increase in mobility following surgery, this change was clinically significant (66% CI=1.51)

Figure 4. Scatter plot depicting the reliable and clinical change reported between pre-surgery and post-surgery on the rating of mobility, with a line of no effect and the bandwidths for the 66^{h} and 95th confidence interval.

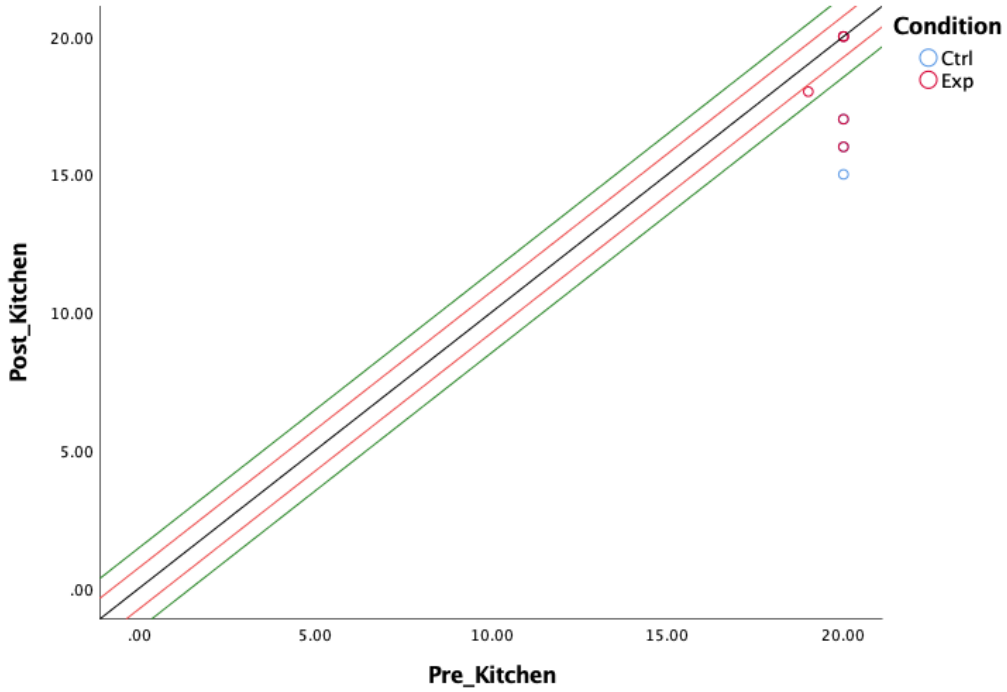


Note. Black line represents the line of no effect, the red line is the 66% confidence interval and represents clinically reliable change and the green line represents the 95% confidence interval and thus scores that are clinically and significantly reliable.

Kitchen

Following surgery, two participants in the experimental arm and one in the intervention arm reported both clinically and significantly reliable decreases (95% CI=1.47), as can be seen in Figure 5. A further one participant reports a change that would be understood as clinically reliable (66% CI-0.75).

Figure 5. A scatterplot of the change scores between pre-surgery and post-surgery, for self-rated kitchen abilities, with a line of no effect and the bandwidths for the 66^{h} and 95th confidence interval.

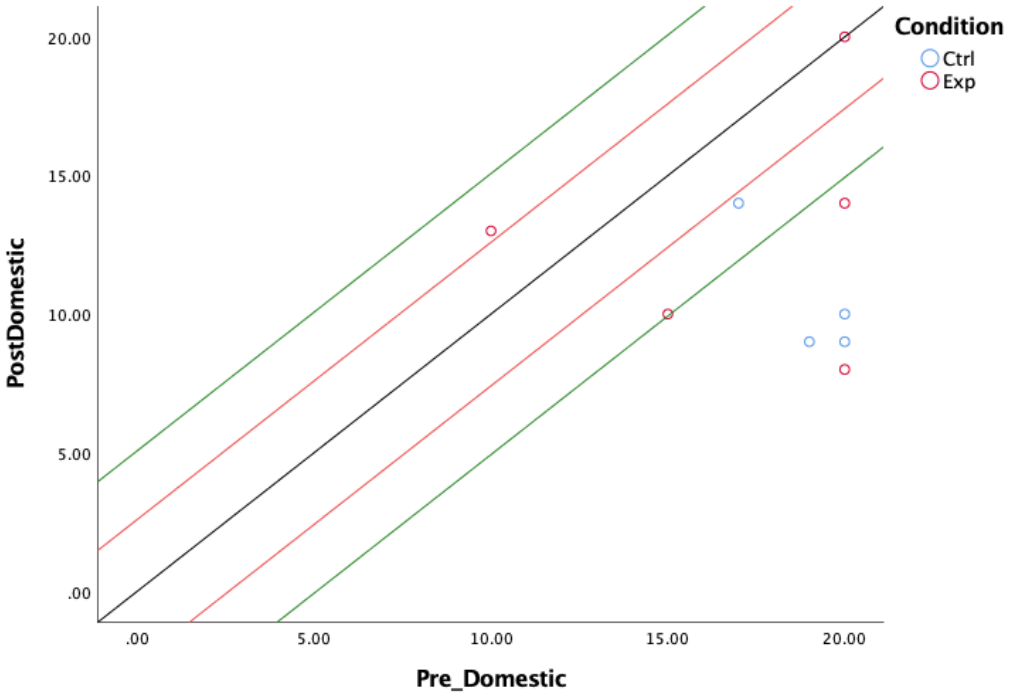


Note. Black line represents the line of no effect, the red line is the 66% confidence interval and represents clinically reliable change and the green line represents the 95% confidence interval and thus scores that are clinically and significantly reliable.

Domestic

As is observed in Figure 6, all participants in the intervention arm reported a decrease in their abilities to engage in domestic abilities. Three of these results can be deemed both clinically and significantly reliable (95% CI=5.07), two participants in the experimental arm also reported a clinically and significantly reliable change too. One control participant and one experimental participant report a clinically reliable reduction (66% CI=2.59). Figure 5 also depicts that one participant in the intervention arm reported a clinically reliable increase in domestic abilities (66% CI=2.59).

Figure 6. A scatterplot of the change scores between pre-surgery and post-surgery, for self-rated domestic abilities, with a line of no effect and the bandwidths for the 66th and 95th confidence interval.

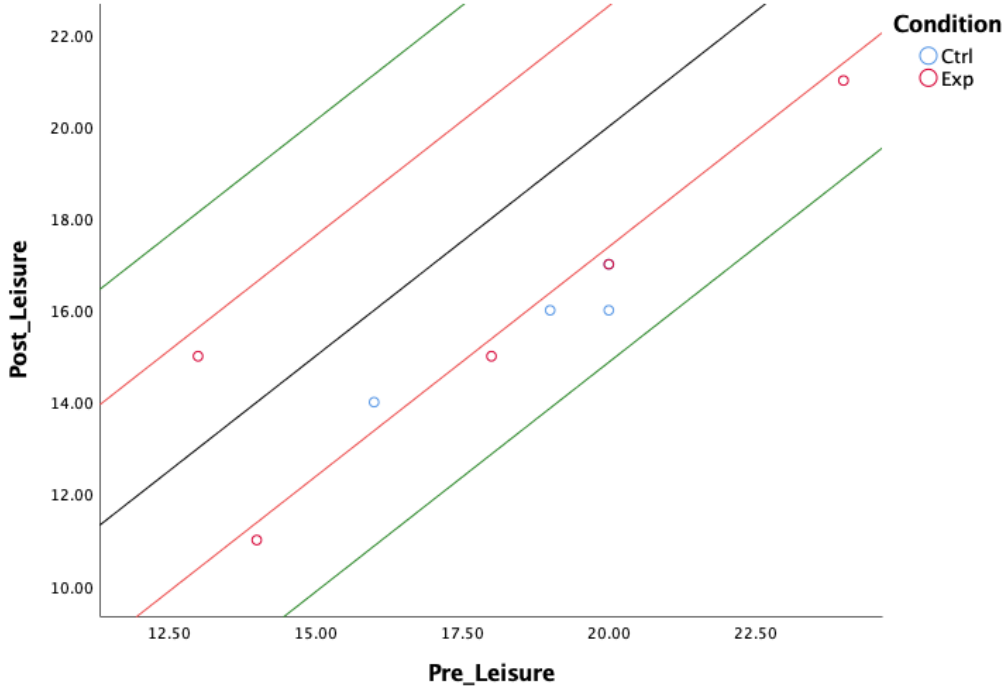


Note. Black line represents the line of no effect, the red line is the 66% confidence interval and represents clinically reliable change and the green line represents the 95% confidence interval and thus scores that are clinically and significantly reliable.

Leisure

All but one participant reported a decrease in leisure activities following surgery, six of these decreases are clinically reliable changes (66% CI =2.62). One experimental arm participant reported an increase in abilities, however, this was not reliably or clinically significant either, as seen in Figure 7.

Figure 7. A scatterplot of the change scores between pre-surgery and post-surgery, for self-rated leisure abilities, with a line of no effect and the bandwidths for the 66^{h} and 95th confidence interval.

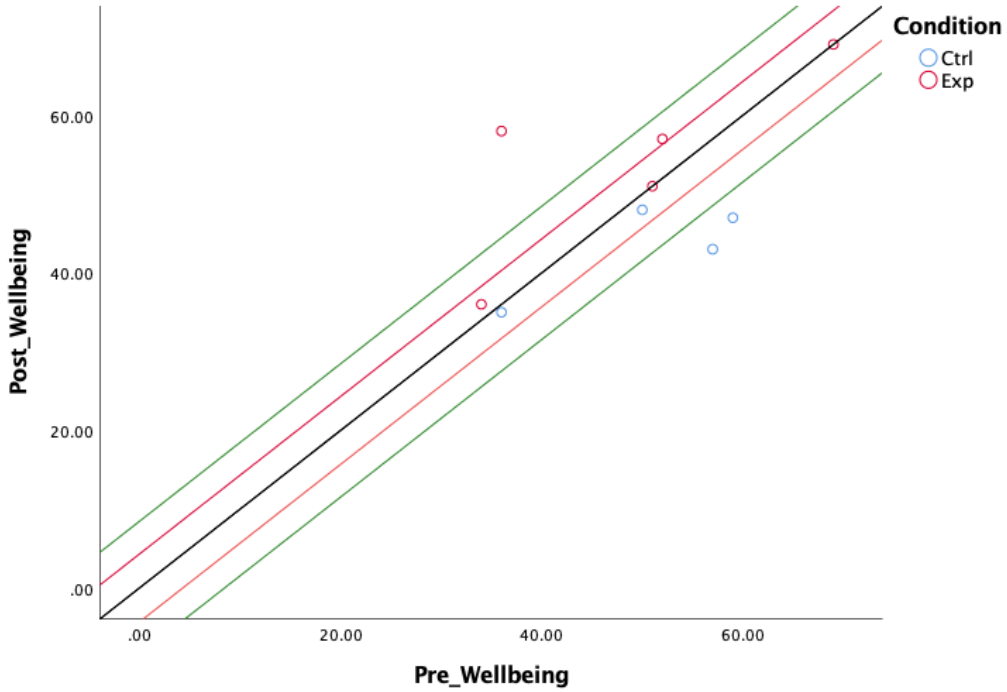


Note. Black line represents the line of no effect, the red line is the 66% confidence interval and represents clinically reliable change and the green line represents the 95% confidence interval and thus scores that are clinically and significantly reliable.

c. Wellbeing

In Figure 8 it can be seen that all four control participants show a decrease in wellbeing following surgery, two of these decrease in wellbeing are clinically and significantly reliable (95% CI=8.46) and the additional two participants reported decreases are clinically reliable (66% CI= 4.31). Participants in the experimental arm, reported increases, with one of these increases being clinically and significantly reliable (95% CI = 8.46) and a further one being deemed a clinically reliable increase in wellbeing (66% CI =4.31).

Figure 8. A scatterplot of the change scores between pre-surgery and post-surgery, for self-rated wellbeing, with a line of no effect and the bandwidths for the 66th and 95th confidence interval.

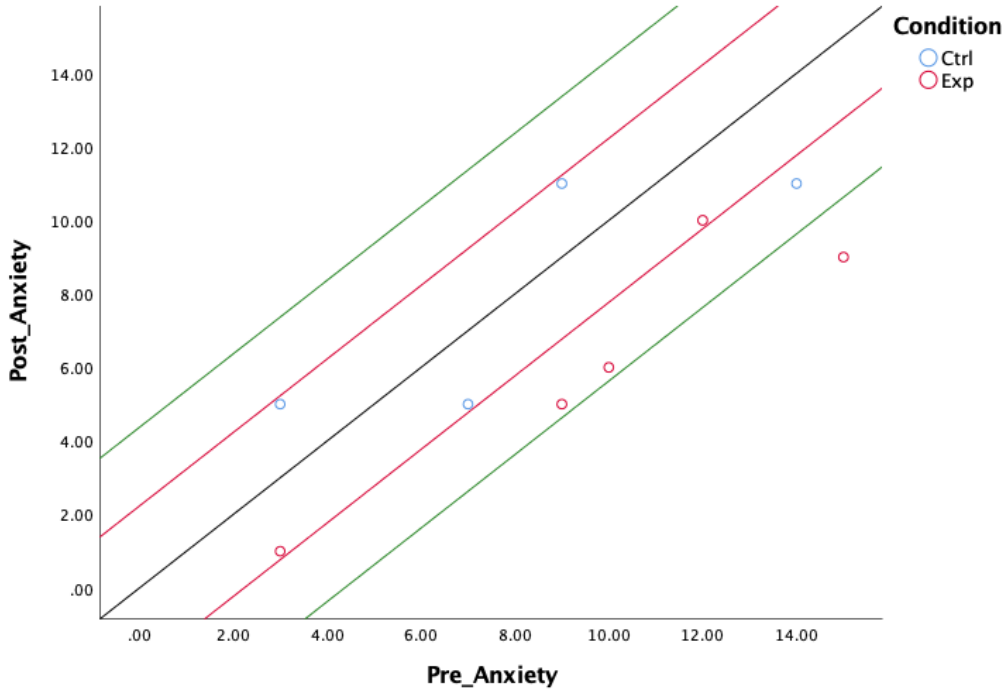


Note. Black line represents the line of no effect, the red line is the 66% confidence interval and represents clinically reliable change and the green line represents the 95% confidence interval and thus scores that are clinically and significantly reliable.

d. Affect

Anxiety was reported decrease to a clinically reliable level following surgery for two experimental participants and one control participants (66% CI=2.23). Furthermore, one participant in the experimental arm reported a clinically and significantly reliable (95% CI = 4.37) reduction in anxiety following surgery. As can be seen in Figure 9, two experimental participants reported increases in anxiety following surgery, these changes were analysed as clinically reliable (66% CI=2.23).

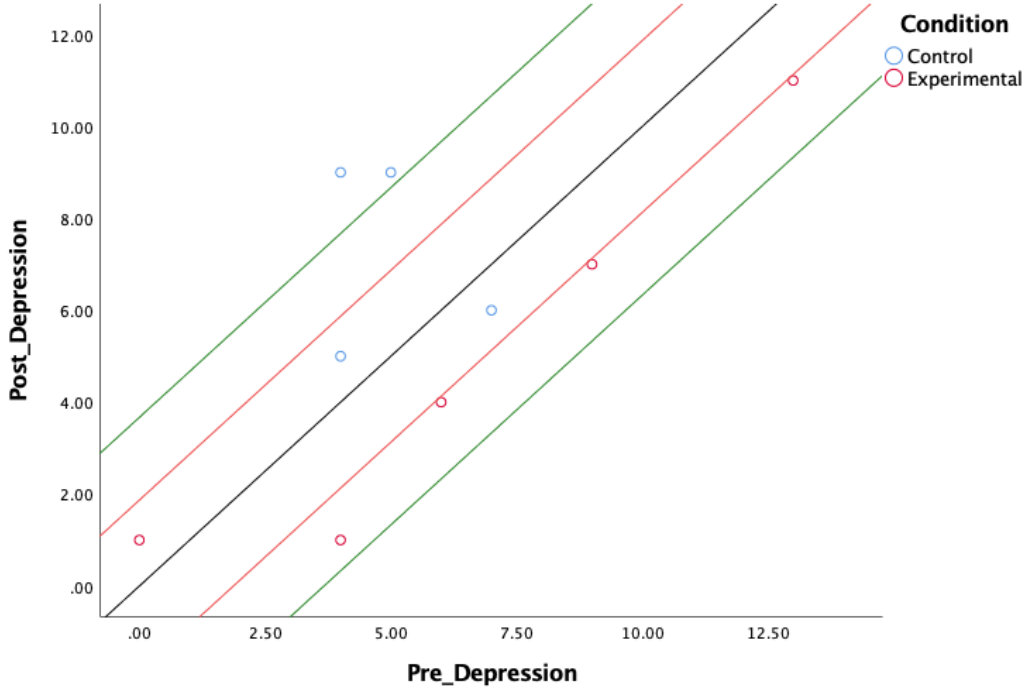
Figure 9. A scatterplot of the change scores between pre-surgery and post-surgery, for self-rated symptoms of anxiety, with a line of no effect and the bandwidths for the 66th and 95th confidence interval.



Note. Black line represents the line of no effect, the red line is the 66% confidence interval and represents clinically reliable change and the green line represents the 95% confidence interval and thus scores that are clinically and significantly reliable.

As can be seen in Figure 10, four out of five participants in the experimental arm reported a reduction in depression following surgery; this reduction was clinically reliable (66% CI=1.87). Furthermore, figure 10 demonstrates that two participants in the control condition reported a clinical and significant reliable increase in symptoms of depression following surgery (95% CI = 3.67).

Figure 10. A scatterplot of the change scores between pre-surgery and post-surgery, for self-rated symptoms of depression, with a line of no effect and the bandwidths for the 66th and 95th confidence interval.



Note. Black line represents the line of no effect, the red line is the 66% confidence interval and represents clinically reliable change and the green line represents the 95% confidence interval and thus scores that are clinically and significantly reliable.

i. Subjective Experience of trialling the research

It was noted during the course of research that reassuring participants that the research would not involve extra travel seemed to be important to them (see reflective diary Entry 1 in Appendix 13). Therefore, scheduling a time to meet them around their existing appointments was key, and flexibility on the part of the researcher supported the implementation of this (e.g. meeting participants at the hospital after late appointments outside of normal working hours).

The researcher observed that a frequent naturally-occurring process prior to surgery was the act of saying goodbye to family members; this was perceived to be an important moment but was often interrupted by the psychological intervention (See reflective diary Entry 2 in

Appendix 13). Consequently, the researcher reflected on how the intervention ran the risk of disrupting an important process of preparing for surgery.

Following surgery, participants reported that the transition home following surgery was another difficult time period (see reflective diary entry 3 in Appendix 13). Participants thought that an additional psychological intervention would be beneficial prior to their return home.

4. Discussion

The present study aimed to investigate the feasibility of running a randomised controlled trial in a UK centre of excellence for cancer, where one psychological intervention session was trialled before surgery for sarcoma patients. The presence of data to analyse and discuss highlights that it is possible to conduct a study of this nature in this setting. However, the results of the present study will be discussed regarding the findings of the feasibility of the research process and then the feasibility of offering the proposed intervention (the content).

i. Feasibility of the process

Of the participants who choose to participate in the present study generally it was found that the study as a whole was acceptable and there were no concerns raised regarding randomisation; a number of participants reported being keen to do "anything to help others" (see diary entry 4 in Appendix 13). Furthermore, participants completed all the measures requested, although at follow-up there were significant delays in the completion of this data, thus compromising the feasibility of the follow-up procedure.

Whilst the completion of measures and lack of objection to randomisation is evidence of acceptability of the protocol to the minority who participated, the overall recruitment of participants was difficult, with an average of 1.8 participants being recruited per month over a five-month period. In total 53% of the people who expressed and interest and were able to be contacted choose not to participate in the study, after having spoken with the researcher. This highlights a potential issue with acceptability for the majority of sarcoma patients approached. Inspection of the recruitment process highlights that participants were introduced to the research during their clinic appointments with the surgeons. It is hypothesized that there may have been a difficulty in processing the research information during the clinic appointment, where important and potentially overwhelming health information is already being discussed (mainly the likelihood of a cancer diagnosis). Interruptions to the emotional and cognitive processing of a cancer diagnosis can have detrimental effects to a participant (Oginska-Bulik & Michalska, 2019), effecting a patients wellbeing but also their ability to provide informed consent for research.

A potential modification to the recruitment strategy would be to establish a role for a research assistant embedded in the hospital team, thus allowing the researcher to support the research to be introduced at a more appropriate time, rather than during their first clinic appointment. This would hopefully lead to an increase in participants. An *a posteriori* power analysis revealed that one hundred and sixteen participants would be needed to provide the study with enough power to find an effect, if one was there to be found. If the same recruitment strategy was used, where 1.8 participants were recruited per month then it would take five years and three months to collect enough participants to conduct the RCT. If modifications to the recruitment strategy were made, it would be hoped that participants could be recruited more successfully and swiftly.

In addition to an appropriate sample size, an RCT is also expected to measure outcomes at a specific time, in order to fulfil the criteria of being controlled (NICE, N.D). In the present study this was not fulfilled due to 55% of participants requiring prompts by the clinical nurse specialist to complete the follow-up measures such that the four weeks follow up period was breached for over half the participants. It is understood that following surgery an individual will often temporarily show heightened distress, but this reduces as time passes (White 2001; Zabora et al. 2001; Moorey & Greer 2002; Carlson et al. 2004; Paredes et al. 2012). Consequently, time is a confounding factor which makes the results difficult to interpret.

Participants did respond to the questionnaires when asked by their clinical nurse specialist (CNS). This offers a direction for increasing the controllability of a future RCT. Harding, Beesley, Holcombe, Fisher and Salmon (2015) found that breast cancer patients reported that the staff member who had supported them the most was their clinical nurse specialist. It is hypothesized that this is the reason why the present participants completed the follow-up questionnaires for the CNS and thus a collaboration with the CNS team would improve the controllability of an RCT.

ii. Feasibility of the content

The measures of pain, functional abilities, wellbeing and affect are shown to be sensitive measures of outcome in this sample of sarcoma patients, as indicated by the clinically and significantly reliable changes observed in both positive and negative directions. This

indicates that each of these primary outcome measures would be appropriate for use in a larger scale study, due to their ability to capture scores that reflect change.

Anxiety, for this sample, is established as an issue of concern prior to surgery in both the control (M=8.25,SD=4.57) and experimental (M=9.8,SD=4.44) participants. Whilst the standard deviations do show a lot of variability, this can be expected in such a small sample size and this is a preliminary indication of levels of anxiety that would traditionally be defined as "borderline abnormal" (Zigmond & Snaith, 1983). It can be seen that 77% of participants reported reduction in anxiety following surgery, three of which can be deemed clinically reliable and another one deemed to be reliable both clinically and statistically significant. The majority of these changes are seen in the intervention arm, which suggests the potential usefulness of contact with a psychologist prior to surgery in addressing a primary emotional concern for this population. With a larger sample size, the variability that is reported in this study could be explored to identify what levels of anxiety look like prior to surgery in this population and how that compares to reports of anxiety that are defined as "abnormal"; this could inform the way in which a future study approaches anxiety.

Whilst anxiety bordered levels of clinical concern, wellbeing and depression scores were not at such elevated levels. Participants in the experimental condition reported a mean score of 5 (SD= 1.41) and control participants reported a mean score of 6.4 (SD=4.93) for symptoms of depression. According to Zigmond and Snaith's (1983) classification, these scores would be deemed "normal". Furthermore, participants' mean scores at baseline (Experimental-M=48.4, SD=14.19; Control -M=50.5, SD=10.41), for wellbeing would be deemed "normal" ("Collect, score, analyse and interpret (S)WEMWBS", N.D). These findings are contrary to the high levels of distress that were assumed by the medical team allied to the research.

This finding does not, however, preclude the need for prehabilitation, as prehabilitation does not solely focus on high levels of distress prior to treatment but has a focus on difficulties that may arise in the future, following treatment, as well as preparing patients for the practicalities of surgery (Silver, Baima & Mayer, 2013). We can see the impact that surgery can have on a vulnerable minority, in the case of Control Participant 2 (See appendix 17 for individual reliable index scores), who at pre-surgery reported relatively robust levels of physical and emotional wellbeing, but then reported a number of clinically and statistically significant reliable changes, suggesting a detrimental effect. It can be tentatively hypothesized that these

changes may be attributable to the reliable increase observed in the Mini-Mac scores for Helpless-Hopeless and Cognitive Avoidance response to cancer, as well as a decrease in the Fighting Spirit and Compassionate Engagement (see Appendix 17 for reliable change index scores for the mini-mac). It can be hypothesised that cognitions around ability to cope with the realities of recovering from surgery and limited self-compassion could create a cycle where distress continues to increase and triggers difficulties in the perception of pain and ability to engage in activities. Such a profile may highlight patients who would find prehabilitation beneficial.

In the interest of ongoing research and clinical work it may be of value to consider how participants' responses to questions may be more indicative of their coping style rather than the dependent variable of the measure. An example of this would be Intervention Participant 1. This participants' post-surgery profile appears perplexing. This participant reported 0 pain (the same as prior to surgery) and reported no difficulties on any of the activities of daily living, which would suggest a good outcome. However, this participant was one of the only participants to be observed as having a clinically and reliably significant decrease in compassionate engagement (with the other participant being Control Participant 2 who is analysed as having experienced a significant decline in wellbeing and did not receive the intervention). This outcome on the compassionate engagement scale is contrary to the aim of the intervention, which would not have predicted a decrease in compassionate engagement. However, Gilbert et al (2017) explains that compassion requires an individual to be aware of their distress and suffering for effective engagement. It is possible that Intervention Participant 2's scores on the pain and NEADL allude to their difficulty in acknowledging distress. This finding highlights a potential participant profile of whom this intervention may not be useful for, in that engagement in their distress, so to bring about wellbeing, is not a method they are motivated to use.

A commonality amongst participants allocated to the intervention and control arms of the study was the reduction in abilities to engage in domestic activities: five participants reported a clinically and significantly reliable change and a further two reported a clinically reliable change. As this was shared by both intervention and control participants it can be assumed that this was an area impacted by surgery, particularly given that surgery is understood to impact on domestic activities (Mosher et al., 2013; Thomas et al., 2015; Poghosyan, Sheldon, Leveille & Cooley, 2015). Thus, a further development of the research may be to adapt the

intervention so to place a higher focus on working towards the values of home life and domestic activities, for which ACT has an evidence base for improving, in the context of pain (Yu, Norton & McCracken, 2017).

iii. Limitations of Research

Whilst the study was successful in randomising participants, and participants were observed to find the randomisation acceptable, blinding was not attempted in the present study. This simply did not seem feasible with a research team made up of one person. However, blinding does have potential benefits such as less likelihood of participants having a biased response to the intervention, investigators/intervention administers are less likely to transfer their inclinations or attitudes to participants and assessors of outcomes are less likely to pay attention to outcomes that support their proposed hypothesis (Schulz & Grimes, 2002). It is possible that any changes observed in the present study can be attributed to the afore-mentioned biases. However, whilst this must be conceded as a limitation of the present research, it still remains difficult to blind participants in such research in an ethically appropriate manner.

A further issue with the control of the present study was that in between the pre and post measures participants received surgery as well as the psychological intervention, this makes the data unclear to determine what is an effect of surgery or the removal of imminent surgery and what is the effect of the intervention. Whilst the control group allows for some assumptions to be made, a better way of controlling for this would be to add in an additional measurement point, before surgery after the intervention has been received. This would allow for changes to be tracked before surgery. It would also help in improving the confidence in asserting that the increase's seen in pain were more so attributable to the process of surgery, rather than an iatrogenic effect of the psychological intervention.

iv. Recommendations

This aim of the present feasibility study has been to inform the design of a randomised control trial. The first of these recommendations would be for a larger study to recruit a research assistant, embedded into the clinical team. It is hoped that this would allow the research to reach the full recruitment potential, as it is hoped that this research assistant

would be able to be available to support clinicians with the introduction of the research and would be able to be more flexible to support participants needs, both in the instance of introducing the research and offering the intervention. Furthermore, this research assistant could look to work alongside the clinical nurse specialists, who have been hypothesized as useful resources, to solve the issues with control that the present study faced.

Additionally, the results of the present research highlight that a common difficulty experienced following surgery was engagement in domestic activities. A following study could look to adapt the intervention to address this need in sarcoma patients. In particular activities focusing on psychological flexibility and the acceptance of pain are proven to be effective on pain related disability, which may explain the psychological disability in this population (Vowles, Witkiewitz, Sowden & Ashworth, 2014). However, any further researcher will need to give careful consideration to the addition of further elements to the intervention, due to the limited time available to offer the intervention.

Finally, as is seen in the researcher's reflective diary, three participants reported an interest in being visited by the intervention administrator for a "top-up" session before they returned home. A randomised control trial could look to employ a repeated measures design where measures are collected at baseline, following the prehabilitation intervention, following surgery and then following the top-up session, to gain an understanding of what is most helpful, whilst providing clarification over the effects of surgery and the effects of the interventions.

In addition to recommendations for future research, the present research has identified some recommendations for clinical practice. In particular, it is seems that such an intervention would be helpful for a small percentage of vulnerable sarcoma patients, however, most participants may not need an intensive intervention, like the one used here, but could still benefit from an ACT and CFT informed care. Thus, it is proposed that in services such as the host of the current research, a screening tool of psychological distress could be used, where patients could be allocated to one of two pathways; those demonstrating risk factors for decline following surgery could be referred for a psychological session, such as the one described in the study. Participants who are not screened as vulnerable could be referred to a pathway where they still receive ACT and CFT informed care, so to maintain their wellbeing, as was seen in this study, but delivered by the traditional clinical team.

v. Reflections

Whilst this piece of research proposes the need for a potentially beneficial intervention, it has to be acknowledged that even to conduct this feasibility study has been difficult. Largely, the difficulties have been in recruiting enough participants. Difficulties in running clinical trials with cancer patients have been identified (Mills et al. 2006), with difficulties including that research can be inconvenient, the research does not feel appropriate for the cancer or is perceived to have no benefits. To my knowledge, in the present study, those who dropped out following providing consent, mainly did so due to poor health preventing them from being able to undergo surgery. One participant reported that they had "changed my mind" and then there were a number of people who expressed an interest but did not return consent forms or complete the questionnaires. Researching in an area of rare cancer means that the loss of a participant or potential participant was disappointing. However, it has been important to be open and aware of this disappointment as a clinician and academic researcher. Taking this approach has ensured that the response received by participants who have dropped out or declined to participate has still embodied the principles of this intervention which are an authentic compassionate and patient-focused approach. It is inevitable in this population that the seriousness of the illness and the overwhelming feelings that can ensue around a diagnosis of sarcoma will impact on the ability to recruit participants, thus it is important that research of this nature is not done in isolation and more so as part of a supportive team; a team who can support the researcher through the difficulties of recruitment so to ensure that any frustrations are not transferred onto a patients experience of sarcoma care or research involvement. Complementary to this, an embedded researcher within the service would mean that the support could be reciprocal with the researcher developing good lines of communication with the clinical team so to become involved in the team and offer support where needed.

vi. Conclusion

A novel piece of piece of research has been presented here, that has not only the potential to be adapted into a randomised control trial but also the ability to be beneficial in ensuring the wellbeing of patients with this rare cancer. The study fulfilled its aims of investigating feasibility and can conclude that a study based on this protocol would be feasible, given a number of adaptions.

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CHAPTER III

PUBLIC DISSEMINATION DOCUMENT

OUTCOMES FOR PATIENTS LIVING WITH A MENTAL ILLNESS WHEN DIAGNOSED WITH CANCER AND THE DEVELOPMENT OF A PSYCHOLOGICAL PREHABILITATION INTERVENTION FOR SARCOMA PATIENTS: A FEASIBILITY STUDY

This chapter provides an accessible summary of a literature review and empirical study carried out by Victoria Caines as part of the qualification of Doctorate in Clinical Psychology from the University of Birmingham.

Literature Review: Outcomes for Patients Living with a Mental Illness when Diagnosed with Cancer

Background

Throughout the cancer journey an individual can experience changes in both their physical and mental health. The psychological impacts of cancer can include anxiety (Maddineni, Lau & Sangar, 2011; Mitchell et al., 2011; Vehling et al., 2012; Ford, Catt, Chalmers & Fallowfield, 2012), depression (Mitchell et al., 2011; Walker et al., 2012; Yang et al., 2013; Ford et al., 2012), fear of cancer reoccurrence (Simard & Savard, 2009; Puts, Papoutis, Springall & Tourangeau, 2012; Swash, Hulbert-Williams & Bramwell, 2014), post-traumatic stress disorder (Koutrouli, Anagnostopoulos & Potamianos, 2012) and regret (Chambers, Hyde, Ip, Dunn & Gardiner, 2013).

NICE (2004) onset changes in the oncology care where the psychological wellbeing was the responsibility of all clinical staff. Consequently, Bultz & Holland (2006) commented on symptoms of anxiety being routinely assessed by nursing staff, along with traditional measures of physical health.

It is reported that as many as 50% of cancer patients have experienced a mental health condition in their life, with 30% of cancer patients having experienced a chronic mental health condition (Krebber et al., 2014; Watts, Prescott, Mason, McLeod & Lewith, 2015; Walker et al., 2015). However, little is understood about cancer outcomes for people living with a mental illness. This literature review looks to systematically review the available literature to understand the outcomes for individuals with a mental illness when diagnosed with cancer.

Method

Six electronic databases were searched for published research regarding cancer in people living with a mental illness. Twenty-eight papers were reviewed. The quality of each paper was evaluated using a standardised tool.

Findings

Cancer is often diagnosed later in individuals with a mental illness. People with mental illness and cancer were less likely to use screening services or detect abnormal bodily symptoms. Furthermore, in some cases cancer was only found following an individual's death. A number of studies highlighted that individuals with mental illness were less likely to receive specialist cancer care. This was sometimes due to the expressed preferences of the patient and at other times was due to a decision made by oncology clinicians. Exceptions to this, were found in veterans with cancer and mental illness. Veterans in these studies were treated in services, in the united states, where cancer and mental health were collaboratively cared for. Ultimately, the low rate of diagnosis and lack of treatment were found to lead to an increase in case fatalities for those with comorbid mental illness and cancer.

Conclusions

People living with a mental illness and cancer experience poorer outcomes than the general population. However, the studies reviewed were mainly retrospective case file reviews. Thus, the link between cancer and mental health could be understood better if research was designed to collect data directly from people living with a mental illness and cancer, in addition to research that did not use historical data, but data collected in the present.

Empirical Paper: The Development of a Psychological Prehabilitation Intervention for Sarcoma Patients: A Feasibility Study

Background

Sarcoma is a cancer that can be found in the soft tissue, bone and gastrointestinal system (Sarcoma UK, N.D). Sarcomas are often misdiagnosed, meaning they are larger by the time that they are diagnosed (Grimer, Judson, Peake & Seddon, 2010) and so treatment is needed urgently. The primary treatment for a sarcoma is surgery (Gerrand et al., 2016; Grimer, Judson, Peake & Seddon, 2010). This surgery can often be aggressive in nature and may require loss of body parts to remove the tumour (Shehadeh et al., 2013).

The period between being diagnosed with a sarcoma and undergoing surgery can lead to depression and anxiety in patients (Paredes et al., 2011). This experience of anxiety and depression before surgery has been found to impact negatively on recovery after surgery (Broadbent, Petrie, Alley & Booth, 2003; Granot, Goldstein & Ferber, 2005).

Prehabilitation, the act of offering a supportive therapy before a treatment, has been found to be beneficial for cancer patients before surgery (Tsimopoulou et al*.,* 2015). Benefits of psychological prehabilitation include improvements in immunologic functioning, quality of life, fatigue, psychological outcomes (Tsimopoulou et al., 2015), pain, return to pre-surgery functioning and discharge from hospital (Powell et al., 2016).

The present study looks to investigate if it is feasible to study the effectiveness of psychological prehabilitation for sarcoma patients, using a randomised controlled design.

Method

Nine people diagnosed with a sarcoma consented to participate in this study and were randomly allocated to either a control condition or an intervention condition. All participants were asked to complete six measures of physical and psychological wellbeing. Following this, the participants in the control condition received treatment as usual followed by their surgery. Those in the intervention arm received treatment as usual in addition to a one-hour

prehabilitation session with a psychologist, followed by their surgery. Four weeks after surgery all participants were asked to complete the same six outcome measures of physical and psychological wellbeing.

Findings

It was found that study participants found the randomisation procedure acceptable. However, there were issues in receiving all the questionnaires back at the same time and so there is a risk that the data received for follow-up is not controlled, for the bias of time.

A calculation was conducted to identify how many participants would need to be recruited in a larger study. The calculation predicted that one hundred and sixteen participants would need to be recruited for a future study to be powerful enough to find any difference between people allocated to the control group and intervention group.

The outcome measures found that anxiety was in the "borderline abnormal" range (Zigmond & Snaith, 1983) but on most other measures participants appeared to be robust. After surgery all participants reported a decline in their ability to engage in domestic activities.

Some participants showed a decline in physical and emotional wellbeing after surgery, whilst some participants reported that their physical and emotional wellbeing had remained the same.

Conclusions

The findings suggest that it is feasible to conduct a study of prehabilitation for sarcoma patients in this setting. The measures used appear to be appropriate as they were able to detect change. However, adaptions need to be made to the design in order to improve the controllability of the study.

We can begin to predict that there is a need for prehabilitation for sarcoma patients, but only for a proportion of patients; the other proportion may not need an intensive psychological intervention but, rather, psychologically informed care to maintain their wellbeing, as was seen in this small sample.

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APPENDICES FOR VOLUME I

Appendices for Literature Review

Appendix 1. – Scoring criteria

	0	1	2
Provide in the abstract an informative and balanced summary of what was done and what was found	Inaccurate or too brief	Some bias	Balanced
Question/objective sufficiently described?	No question	Vague	Clear
Design evident and appropriate to answer study question?	Not appropriate	Flaws in the design such as potential for bias	Answers question, free from bias, collects accurate data
Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	None	Some	All data
For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	No mention	Alluded to	Detailed description
Method of subject selection or source of information described and appropriate?	No	Partial	Detailed
Subject (and comparison, if applicable) described?	Not described	Some description but lacking	Full description, possibly with graphs
Was random allocation described?	Appropriate to use but did not	Mentioned but not described	Described
Blinding described?	Appropriate to use but did not	Mentioned but not described	Described
Outcome measures described and robust to misclassification bias? Means of assessment reported?	Not described	Reliant on biased data (retrospective)	Acknowledged and Validity described
Sample size appropriate?	Under powered	Medium sample	Large sample
Analysis described and appropriate?	No	Partial	Yes
Report other analyses done? eg analyses of subgroups and interactions, and sensitivity analyses	No	Partial	Yes
Estimate of variance reported for the results?	No	Partial	Yes
Controlled for confounding	No	Partial	Yes
Results reported in sufficient detail	Brief	Fair amount of detail	Lots of detail including figures
Conclusions supported by results	Not based on the results	Some unsupported comments	Clear description
Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	No mention of limitations	Limited acknowledgement of other factors	Mention of other factors
Discuss the generalisability (external validity) of the study results	No	Partial	Yes

Appendix 2 – Summary of Reviewed studies

	Country	Description	Aim	Number of Participants (N=with comorbid mental illness & cancer)	Gender	Age (years)	Type of Cancer	Diagnostic Category	Outcome	Summary
Shinden et al., 2017	Japan	A case review of patients with a diagnosis of schizophrenia, dementia or intellectual disability who underwent curative treatment for their breast cancer. Data was then compared	To understand the clinical features,clinico-pathological factors, treatments and outcomes of people with a mental illness and breast cancer.	773 (46)	Not reported	Mental illness – 65 Control - 59	Breast Cancer	Schizophrenia(in addition to dementia and learning disability)	Diagnosis and Treatment	Patients with a mental illness less likely to detect own cancer leading to a later stage at diagnosis. Less patients underwent chemotherapy

		with a control group. Those with mental disorders were found to be less likely to have received postoperative adjuvant chemotherapy.								
Iglay et al., 2017	USA	A retrospective cohort design, reviewing medicare data of women diagnosed with breast cancer between 2005-2007. Finding that comorbid	To compare diagnosis and treatment delays in elderly breast cancer patients with and without pre-existing mental illness	16,636(3961)	All Female	68+	Breast Cancer	Anxiety, Depression, Bipolar, Schizophrenia & "Psychotic Symptoms	Diagnosis Delay and Treatment Disparities	Diagnosis delay found to be in excess of 90 days, treatment delay found to be in excess of 60-90 days

		anxiety an depression is associated with treatment delay in excess of 90 days. Those with a severe mental illness experience a treatment delay in excess of 60 days.								
Irwin et al., 2017	USA	Medical record review of patients treated between 1993-2015, who had diagnoses of breast cancer and schizophre	To characterise disruptions in breast cancer patients with schizophrenia. In addition to identifying modifiable predictors of those disruptions.	95 (95)	98.9% Female	Average Age 58.6	Breast Cancer	Schizophrenia	Treatment Disparities	1 in 5 Patients with a mental illness experience a deviation from cancer treatment guidelines

		nia. The review targeted disruption to guideline concordant care. They found that people with schizophrenia experience at least one disruption. Deviations were associated with recurrence at 5 years. Collaboration with mental health professionals was identified as a potential								

		mediating factor.								
Brunault et al., 2006	France	Cross sectional study completed 7 months after breast cancer diagnosis, where measures of QoL, coping strategies, major depressive disorder, pain severity, tumour severity and treatment received were taken, as well as personality disorder. A regression	To determine what factors were associated with physical, emotional and global QOL in non-metastatic breast cancer patients.	120(120)	All Female	Not reported	Breast Cancer	Depression Personality Disorder	Quality of Life	People with premorbid mental illness have a lower quality of life when living with cancer

		analysis identified that lower QoL scores were associated with individuals pre-morbid psychological characteristics and ability to deal with cancer								
Ribe et al., 2016	Denmark	A population-based cohort study where women with severe mental illness were compared to women without. Finding that	To estimate the all-cause mortality of women with severe mental illness	2700000(1, 106)	All Female	Not reported	Breast Cancer	Severe Mental Illness – Schizophrenia, Schizoaffective disorder, bipolar effective disorder	Mortality	An increase in mortality for women with severe mental illness and cancer

		mortality in women with severe mental illness and breast cancer is markedly increased when compared to women with breast cancer but without severe mental illness.								
Cunningham et al., 2015	New Zealand	Cancer specific survival was compared for recent psychiatric service users and non-users. It was found that	To explore the reasons for worse cancer survival in people with experiences of mental health, including differences by cancer	12,784 (630)	Not clearly reported	18-64	Breast and Colorectal Cancer	Severe Mental Illness	Mortality	Those with severe mental illness are less likely to survive cancer

		the high burden of physical disease and delayed cancer diagnosis in those with psychotic disorders contributes to worse cancer survival.	type and psychiatric diagnoses							
Waida et al., 2015	USA	A retrospective review of patient charts, between 2008-2011. The review focused on stage at diagnosis, comorbid mental illness, treatment received,	To compare stage at diagnosis and timeliness of care of cancers in veterans with and without mental illness.	408 (151)	99% Male	23-84	Urotheral, Colorectal and Head & Neck	Depression	Diagnosis and Treatment Delay	No delays in routine care

		key time intervals and appointments missed. It was found that there was no difference between diagnosis or timeliness of care for those with or without mental illness.								
Musuuza et al., 2013	USA	A cross sectional population study between the years of 2004-2007 using death certificate data. An excess in mortality	To compare patterns of site-specific cancer mortality in people with and without mental illness.	101,689 (1981)	Not reported	1+	All	Mental health service use	Mortality	People with a mental illness and cancer die 10 years earlier than those without a mental illness

		from most cancers was found.								
Kiesley et al., 2012	Australia	A population-based linkage study linking mental health records with cancer registration and death records between 1988 and 2007. It was found that psychiatric patients were more likely to be diagnosed	To assess why psychiatric patients are no more likely than the general population to develop cancer but are more likely to die from it.	135,442(6586)	47.8 Male (psychiatric)	Mean age 64.3	All	All	Mortality, Stage of Diagnosis and Treatment	Cancer incidence lower but mortality is higher. More advanced cancer at diagnosis. Less Likely to receive treatment.

		when cancer was advanced and were less likely to receive specialist treatment.								
Batty et al., 2012	UK & Sweden	A population record linkage finding that survival in cancer was worse for those with a history of psychiatric illness.	To investigate the association between psychiatric disorder and case fatality in males with cancer, living in Sweden.	16,498(1372)	All Male	Not reported	All	Psychiatric hospital admission	Mortality	Worse survival rates for patients with a mental illness
Hwang et al., 2012	USA	The records of patients who had a diagnosis of schizophrenia and went on to develop breast cancer	To describe the outcomes of management in a large population-based sample of schizophrenic veterans who	55(55)	67% Female	Mean age 53	Breast Cancer	Schizophrenia	Treatment	Patients not always offered chemotherapy and not always compliant

		were reviewed. It was found that the cancer was often advanced when diagnosed and patients refuse treatment or are hostile towards staff, which is associated with not receiving cancer treatment.	were offered adjuvant chemotherapy.							
Baillargeon et al., 2011	USA	A retrospective cohort study, linking medicare data.	To evaluate the extent to which pre-existing mental disorders influence	80,670 (20,699)	57.6% Female	67+(46% 75-84)	Colon Cancer	Schizophrenia or Schizoaffective disorder	Diagnosis, Treatment, Mortality	Delays or lack of diagnosis, disparities in the treatment offered,

		Patients with mental illness, particularly dementia and psychosis, had unfavourable diagnosis and treatment outcomes.	diagnosis, treatment, and survival in older adults with colon cancer.							mortality risk increased
Ganzini et al., 2010	USA	A cross-sectional study comparing the notes of veterans with and without schizophrenia, who died of cancer. The note review was focused on hospice enrolment,	To compare the quality of end-of-life care between veterans without and without schizophrenia who died of cancer.	256(60)	93% Male	Mean age 64.4	Multiple	Schizophrenia	Treatment	Veterans received comparable and sometimes better end of life care

		palliative and life sustaining interventions, advanced directive and site of death. Veterans with schizophrenia were found to receive comparable of better end of life care than those without a mental illness.								
Tilbrook et al., 2010	Canada	A retrospective cohort study reviewing the charts of females	To investigate the rates of cervical cancer screening among female	169(51)	All Females	20-69	Pap test (cervical cancer screening)	Psychotic conditions	Screening use	Primary care screening is low for women with

		with and without psychosis. The review focused on the number of pap tests in a 3-year period. It was found that women with psychosis were 5 times less likely to receive PAP screening.	patients with psychosis when compared to those without.							psychotic disorders
Sharma et al., 2008	UK	A retrospective cohort case review of individuals with breast cancer and schizophrenia. Concerned	To investigate the clinic-pathologic presentation, chemotherapeutic tolerance and delivery in women with a pre-existing	90,676(37)	All Female	Mean Age 55 (Range 30-90)	Breast Cancer	Schizophrenia	Diagnosis Treatment	Schizophrenia does not affect treatment delivery

		with treatment delivery and outcomes. It was found that schizophrenia does not affect treatment deliver or outcomes in this population.	diagnosis of schizophrenia							
Tran et al., 2008	France	A prospective cohort study that identified people with a diagnosis of schizophrenia and followed them up after 11 years. It was found	To examine cancer related mortality and predictors.	3470(74)	62.2% Male	Mean 28.4 (Range 18-64)	All	Schizophrenia (hospitalised for less than one year)	Mortality	Women with schizophrenia at a higher risk dying from cancer – not men.

		that there was an increased risk, for those with schizophrenia of death by lung cancer, which was associated with duration of smoking.								
Kiesley et al., 2008	USA	A record linkage of patients in contact with mental health services was linked to cancer registrations and death records. It found that people with a mental illness had	The association between mental illness and cancer incidence, first admission and mortality	247,344 (4690)	Not clearly reported	Not clearly reported	Multiple	Contact with psychiatric services	Mortality	Increased mortality

		an increased incidence of cancer mortality, which was not accounted for by increased incidence of cancer.								
Gathinji et al., 2008	USA	A retrospective review of patients who underwent surgical management of brain astrocytoma. It was found that preoperative depression was linked with decreased	To determine whether patients with a depression diagnosis before surgery experienced decreased survival independent of treatment modality or degree of disability.	1052(49)	59% Male (without depression) 48% Male (with depression)	Average 51	Astrycoma	Depression	Mortality	A reduced risk of survival at 12 & 20 months following high-grade gliomas

		survival, independent of degree of disability, tumor grade or subsequent treatment modalities.								
Xiong et al., 2008	USA	Interviews were conducted with outpatient regarding their use of preventive health services. The interviews found that lifetime screening of cervical cancer was higher than for breast, prostate	To examine the use of screening services by persons with serious mental illness	229(229)	54% Female	Mean age 40.15 (18+)	Breast Colorectal Prostate Cervical	Use of mental health services – schizophrenia, bipolar and major depressive disorder	Screening	Low rates of screening for breast, colorectal and prostate cancer compared to cervical cancer.

		and colorectal cancers.								
O'Rouke et al., 2008	USA	A retrospective cohort study, where charts were reviewed with a focus on psychiatric illness and time to diagnosis. The study found that psychiatric illness was a risk factor for delayed diagnosis and a lower likelihood of receiving surgical therapy.	To determine the impact of co-existing mental illness on time to diagnosis, disease stage and survival in esophagael cancer.	160(52)	99% Male	Mean age 64.6	Esophogal	Mixed	Delays in Diagnosis & Mortality	Depression & Psychiatric illness are risk factors for delayed diagnosis.

Carney & Jones, 2006	USA	A retrospective study of administrative claims data of women with and without a claim for mental illness were reviewed for evidence of receive a screening mammography. Women with a mental illness claim were found to be less likely to have received a mammogra	To measure the influence of type and severity of mental illness of receipt of mammography,	191,356(59,673)	All Female	40-64	Mammography	All	Screening	Severity of mental illness increases the likelihood of not having a mammography.

		phy screening.								
Alderete et al., 2006	USA	Telephone interviews were conducted with women after they received an abnormal mammography result. The interview focused on demographic data, access to health care and depression and anxiety. Depression was a risk factor for an abnormal	To identify the prevalence of depressive symptoms attributable to abnormal mammography examination and the effect of demographic, psychosocial and medical factors on recent onset of depressive symptoms.	911(400)	All Females	Mean age 56.1 (Range 40-80)	Abnormal Mammogram/ Breast Cancer	Depression	Screening	People with depression beforehand are more likely to have depression afterwards

		mammography test.								
Inagaki et al., 2006	Japan	14 Patients treated at a hospital in Japan were divided into two conditions – those who received cancer treatment and those who did not. Factors regarding their cancer and mental health were explored. It was found that people with more severe schizophrenia had more difficulty in	To present the experience of treating schizophrenia patients with cancer, whilst receiving consultation-liaison services. Discussing the medical management of such cases.	14(14)	79% Female	33-75	Multiple	Schizophrenia	Treatment	Increase in mental illness correlated with an increase in difficulties in treatment

		receiving cancer treatment.								
Guan et al., 2013	Netherlands	A retrospective cohort study collating information from the psychiatric case register and death records to predict the risk of cancer death. It found that cancer patients with a psychiatric history are at an increased	To assess if the observed cancer mortality in patients with a psychiatric illness is attributable to another cause of death.	109,202(21,797)	45% Male	Average age 41.1	Multiple	Schizophrenia, Bipolar, Major Depression	Mortality	Cancer patients have an increased risk of dying from cancer in a short period but in the long term their risk of dying from other causes is higher than their risk of dying from cancer

		risk of death from other causes and following this are at an increased risk of cancer related deaths.								
Goodwin et al., 2004	USA	Retrospective data from medical notes and SEER, of women diagnosed with breast cancer, with information on their cancer. Furthermore, a diagnosis of depression	To assess the effect of a prior diagnosis on the diagnosis, treatment and survival of older women with breast cancer.	24,696(1,841)	All Women	67-90	Breast Cancer	Depression	Treatment Mortality	Women with depression less likely to receive definitive treatment and have a higher risk of death.

		was sought. The study found women with depression are at a greater risk of receiving non definitive treatment and worse survival.								
Stommel et al., 2001	USA	Interview data, questionnaires, medical records and death registers were analysed were compared for people with a variety of cancers. They found	To examine the extent to which depression and functional limitations contribute towards mortality of newly diagnosed cancer patients.	871(82)	51.2% Female	Unclear	Breast, Colon, Lung & Prostate	"emotional problems"	Mortality	Emotional problems and physical problems predict survival trajectory; however, this is not a problem for people whose emotional and functional

		that depressive symptoms following cancer did not affect survival, however cancer patients with depressive symptoms before had a greater hazard of dying from their cancer.								problems are a response to cancer rather than a pre-existing issue

Appendices for Empirical Paper

Appendix 3 – East Midlands Research Ethics Committee Approval

Removed from Printed Copy

Appendix 4 – Health Research Authority Approval

Removed from printed copy

Appendix 5 – Approval from trust R&D

R&D Governance Office University Hospitals Birmingham NHS
NHS Foundation Trust

(RPAv45)

Dr Anant Desai
Consultant Surgeon
Queen Elizabeth Hospital Birmingham
Mindelsohn Way
Edgbaston
Birmingham B15 2WB

UHB Research Governance Office
1st Floor, Institute of Translational Medicine
Heritage Building
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Birmingham B15 2TH
Tel. 0121 371 4185

Research Project Authorisation

Project reference:**RRK 6402**

Main Ethics Committee Reference	18/EM/0133
IRAS Project ID	233953

27 September 2018

Dear Mr Desai

Can a pre-operative psychological intervention improve post-operative outcomes in Sarcoma Patients?

Thank you for submitting details of your proposed research project, which I am happy to authorise on behalf of University Hospitals Birmingham; this includes confirmation of Capacity and Capability under the HRA Approval process.

Approval covers the following site(s) only: **Queen Elizabeth Hospital Birmingham**

The following main document versions were reviewed (note this is not a complete list of all documents submitted):

Protocol - version: V4 11/06/18
Participant information sheet (main) - version: V5 06/06/18
Participant consent form (main) - version: V4 06/06/18

Acv1/18

Sponsorship
University of Birmingham has agreed to act as sponsor for this study.

Indemnity arrangements.
Researchers who hold substantive or honorary contracts with University Hospital Birmingham (UHBT) will be covered against claims of negligence by patients of UHBT under the Clinical Negligence Scheme for Trusts (CNST). This scheme does not cover 'no fault' compensation and the Trust is precluded from taking out separate insurance to cover this. Any patient or volunteer taking part in the study is entitled to know that if they suffered injury as a result of participating in the study they would first have to prove negligence in a court of law before they could gain compensation.

If the study involves patients of any other Trust or healthcare organisation, you will need to confirm the indemnity arrangements with that organisation.

R&D Office
Head of R&D Governance: Dr Christopher Counsell
Head of R&D Operations: Joanne Plumb
R&D Office, 1st Floor, ITM, Heritage Building, Queen Elizabeth Hospital Birmingham, Edgbaston Birmingham B15 2WG
Tel: 0121 371 4185 *Fax:*0121 371 4204 *Email:* R&D@uhb.nhs.uk
Website: www.research.uhb.nhs.uk
Projects database: //uhb/userdata/R & D/R&D database/distributed database 2002.mdb

Pharmacy
If your study involves Pharmacy then you must ensure that they are ready to initiate the study before the first patients are recruited.

Medical Devices
Any medical devices used specifically for this study, whether purchased, loaned or borrowed must be registered with the Medical Engineering Department. Equipment must not be used until it has completed formal acceptance testing by Medical Engineering. A calibration and maintenance schedule must be drawn up and agreed with Medical Engineering in accordance with the manufacturer's recommendations. There should be a formal maintenance contract in place if maintenance is to be carried out by external contractors (including the equipment manufacturers). If, at the end of the study, the equipment is transferred or disposed of, details must be sent to Medical Engineering to amend the equipment asset register.

Reporting Adverse Events
If this study involves an intervention in the treatment of patients then you must ensure that any serious adverse events, **regardless of whether you believe the event is related to the research or the intervention**, are reported according to the Trust's policy on reporting research-related adverse events. Please see attached memo. Note that you must also follow any SAE reporting requirements stipulated by the sponsor.

A copy of the Trust policy may be obtained from the R&D office and is also available on the R&D section of the Trust's intranet and internet sites. A copy of a blank SAE form is enclosed, this may be used if it is not possible to report the event through the Trust's online reporting system.

Drugs and Treatment outside the study
Approval for the study to commence cannot be taken to imply approval for the same form of treatment to continue beyond the end of the study, or for patients who are not part of the study. If it is likely that continuing treatment is required at the end of the study, then it is the Principal Investigator's responsibility to ensure that study participants are fully aware of the types of treatment that would be available to them.

Research Governance
You should ensure that you and your research team abide by the Trust policies on research governance. These are available from the R&D Office and on the R&D section of the Trust's intranet and internet sites (www.uhb.nhs.uk/research)

Study Files
You must set up and maintain a study file containing the essential documents needed to facilitate a full audit of the conduct of the study. The minimum requirements for the content and layout of the study file are set out in the enclosed documents. This file may be audited at short notice by the R&D Office, the sponsor, or regulatory authorities.

Delegated Duties Log
You must maintain a list of all those people who have responsibility for delivering any study-related tasks set out in the protocol. The log must list the names of the individuals, their roles and responsibilities, the date they started working on the study, and, if appropriate, the date they finished. Each entry must be signed by the person accepting the responsibilities. Note that anyone who is involved in the direct care of patients must hold a substantive or honorary contract with University Hospitals Birmingham.

PICS and Accrual Records
Research studies are now listed on a separate research tab on the trust's Prescribing, Information and Communication System (PICS). When a participant is consented or recruited into this study you must ensure that this is promptly recorded on PICS. If you have any queries about how to do this please contact the PICS training team (PICSTrainingTeam@uhb.nhs.uk). The consented date and recruitment date may be different if screening procedures are required after consenting to confirm eligibility for a study.

R&D Office
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Website: www.research.uhb.nhs.uk
Projects database: //uhb/userdata/R & D/R&D database/distributed database 2002.mdb

RRK6402

The R&D Governance Office will use anonymised records from PICS to update central recruitment records on the UKCRN Portfolio. From April 2017 this will be the only way of recording recruitment on portfolio studies so it is essential that PICS records are accurate.

You should separately keep accurate records on the study file of recruitment and participation in your study. There should be a record, with dates, of patients approached, consented, screened, recruited, completed, and dropped out as appropriate.

Annual Reports
The R&D Office will request information about progress with the study in 6 months, 12 months and annually thereafter. Approval for this study may be withdrawn if you do not complete and return reports when requested.

Protocol Breaches
Serious protocol breaches must be reported to the R&D office as soon as possible and must be notified to the Chief Investigator and Sponsor immediately you become aware of them. If you are the Chief Investigator you must notify the Ethics Committee within 7 days and, for CTIMP studies, you must notify the MHRA within 7 days. A serious breach is one that is likely to affect to a significant degree the mental or physical integrity of the research participants or the scientific value of the study. A report of a serious breach should identify measures taken to correct the consequences of the breach and measures to prevent future similar breaches (a so-called 'CAPA' log). Minor protocol breaches should be recorded in your study file.

Urgent Safety Measure
If necessary, appropriate urgent safety measure to protect clinical trial subjects from any immediate hazard to their health and safety can be taken immediately without waiting for Ethics Committee, Regulatory Authority or R&D approval. However you must inform the R&D Office, Chief Investigator, Sponsor, Ethics Committee and MHRA, as appropriate, in writing within 3 days.

Protocol Amendments
Trust approval will usually automatically cover minor protocol amendments but you must send details to the R&D office for information. Details of all substantial amendments must be sent to the R&D Office for authorisation together with copies of the ethics approval and/or regulatory approval for the amendments and any revised documentation. The R&D office will acknowledge all amendments. A substantial amendment is defined by NRES (the National Research Ethics Service) and would include any change that could affect the safety, conduct or the resource implications of the study.

Duration
It is expected that the study will begin at University Hospital Birmingham within 12 months of Trust authorisation. If there is a long delay in starting the study, the Trust may consider withdrawing authorisation for the study. Unless explicitly withdrawn, Trust approval lasts for as long as the study has valid ethics committee and regulatory approval.

End of Study
According to information you have provided, this study is expected to end in **June 2019** and the minimum recruitment target is **16**. The R&D Office will request a final report shortly after this date. If the study ends for any reason before this date you must notify the R&D Office. Note that the Chief Investigator for the whole study is required to provide an end of study report to the main research ethics committee and regulatory authorities.

Archiving
For studies designated as a Clinical Trial of an Investigational Medicinal Product (CTIMP), it is a **legal** requirement to retain essential documents for at least **5 years** after the declared end of the study. The sponsor or regulatory authorities may insist on a longer retention period for a particular study. For all other

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types of study there are no statutory requirements but generally accepted good practice guidelines recommend that documents are retained for at least 5 years. Documents must be archived in a way such that they can be readily accessed (24 hours notice) if required for audits or regulatory purposes. The costs of archiving is borne by the Principal or Lead Investigator and should be taken into account when applying for research grants or seeking other forms of funding. For CTIMPs, there must be a named archivist, approved by the sponsor, who is responsible for setting up and controlling the archive.

Health Records Labelling
The Health Records of study subjects are retained according to the Trust's "Health Records Management Policy"; for patients in research studies the retention period is 15 years after the last treatment or consultation related to the study. The Principal Investigator must ensure that all records for patients involved in a study are clearly labelled to ensure that the retention policy can be followed.

Cover for absence
If the Principal Investigator is likely to be absent and out of contact for a prolonged period (> 2 weeks), the PI must either explicitly suspend patient recruitment and patient-related activity in the study, or explicitly delegate the responsibilities of Principal Investigator to a named deputy. The PI must be satisfied that their deputy is sufficiently qualified through education, training and experience to take on the role of PI. These periods of absence and delegation must be recorded in the study file.

Website entry
Basic details of your study will be made available on the Trust's website at
http://www.research.uhb.nhs.uk/trials/RRK6402

70 day target
The Department of Health target has now **removed** the target to recruit the first patient into a trial within 70 days of receipt of a complete application pack. However, the Trust is still required to report recruitment metrics so you should aim to recruit the first patient as soon as possible and at least within 70 days of the date of this letter. .

Guidance Tool
The Trust R&D Office has developed a Powerpoint-based tool summarising some of the regulations relevant to clinical research. This is available at \\uhb\userdata\R & D\R&D Shared Docs\Guide to Responsibilities\Guide to Investigator Responsibilities.ppsx (requires access to the Trust's network)

Dr Christopher Counsell
Head of R&D Governance

Enclosed: Sample study file layout
Incident Reporting & Serious Adverse Event Form

Copies to:
Relevant Service Departments
Division B Manager, Lynn Willetts

R&D Office
Head of R&D Governance: Dr Christopher Counsell
Head of R&D Operations: Joanne Plumb
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Projects database: //uhb/userdata/R & D/R&D database/distributed database 2002.mdb

Incident Reporting

As from October 2010 all clinical incidents occurring at University Hospitals Birmingham should be reported through the online reporting system http://uhbhome/departments/riskmanagement/onlinereporting.aspx . This system now includes a separate section for research related events. For incidents occurring away from UHB relating to patient involved in research studies at UHB, then the paper form attached should be completed and returned to the R&D Office.

Statutory Reporting Requirements

If this study is a clinical trial of a medicine or a device then there are statutory reporting requirements. The Principal Investigator must make an assessment of the seriousness of the incident, its relatedness to the study intervention or any breach of the study protocol, and the expectedness of the event (against known characteristics of the medicine or device). An incident which is serious, related and unexpected is referred to as a SUSAR and must be reported to the Chief Investigator and Sponsor as soon possible. The CI/Sponsor are responsible for reporting SUSARs to the MHRA within 15 days of becoming aware of the event (7 days in the case of events resulting in death). SUSARs must also be reported to the manufacturer of the medicine or device if they are not the sponsor of the study.

Pregnancies

For clinical trials involving medicines (CTIMPs) for which the effect of the IMP on an unborn child is unknown, special care should be taken to avoid pregnancies during the interventional phase of the trial. Advice on appropriate contraception should be provided to potential participants before recruitment into a study. If a female participant, or the female partner of a male participant, becomes pregnant during the interventional phase of a CTIMP, then the pregnancy must be reported to the sponsor as soon as possible. In the case of CTIMPs sponsored by University Hospitals Birmingham, pregnancies must be reported immediately to the R&D Office. Pregnancies must be followed through to term to be able to check for any birth defects that could be attributable to the treatment. Birth defects are classed as serious adverse events and may be reported as a SUSAR depending on their expectedness and relatedness to the intervention.

Serious Adverse Event Form (v2)
(Research drugs, devices and interventions)
University Hospital Birmingham NHS Trust

This form must be completed in the event of a Serious Adverse Event / Incident.
This can be defined as an untoward medical occurrence in a patient during clinical research involving a pharmaceutical product or clinical intervention that: is fatal; is life threatening; results in persistent or significant disability/ incapacity ; requires inpatient hospitalisation or prolongs a current hospitalisation; is a congenital anomaly in offspring; or an event that may jeopardise the patient or may require intervention to prevent one of the outcomes listed above.

(R&D SAE id:_____)

Study Title or Trust RRK Number:

Section A - Details of Subject Affected by Serious Adverse Event

Has the Principal Investigator been informed of this event prior to completion of this form? **Yes** ☐ **No** ☐

Subject Initials:_____ Risk Form Number:_____ Subject Number:_____

Section B - Details of the Serious Adverse Event

Date of Onset:_____ **Time: _____**

Hospital:_____ **Exact Location: _____**

Definition of Serious Adverse Event: (tick the appropriate category for the event)

Death	☐	**Resulted in Disability**	☐	**Congenital abnormality**	☐
Life threatening	☐	**Required Hospitalisation**	☐	**none of above**	☐

Describe Event: (A summary of signs and symptoms (including severity), vital signs, diagnosis, treatment of event, concurrent treatment, other relevant medical history, details of study drug/ device. Please include the time point in the study at which the event occurred.)

Number of additional pages added, if any____

(R&D SAE id:_____) **Risk Form Number:**_____

Section C - Relationship To Study Involvement

1. Was the incident related to the patient's involvement in the study?

Likely ☐ **Possible** ☐ **Unlikely** ☐

2. Is the event related to a break in the study protocol? **Possible** ☐ **Unlikely** ☐

3. If you answered **Possible** to number 2,please give details below

4. Was the event unexpected (i.e. not consistent with available information about the drug, device or intervention)? **Expected** ☐ **Unexpected** ☐

5. Action Taken Regarding Participation In Study:

Temporarily Discontinued **Date:**_____
Decision taken by:_____

Permanently Discontinued **Date:**_____
Decision taken by:_____

Patient Continued In Study (Please Tick Box) ☐

Section D - Outcome Of Serious Adverse Event

Recovered ☐

Event Continuing ☐

Patient Died ☐

If necessary please give additional details below:

Section E - Reporter's Details

(Please Print)

Name:_____ **Title:**_____ **Post:**_____

Department:_____ **Contact Number:** _____

Please attach the completed form to a Trust Incident Report Form and complete sections A (Details Of The Person Affected By The Incident) and D (Details Of The Person Completing The Form). Forward both forms to: The R&D Office, Queen Elizabeth Hospital Birmingham, Edgbaston, Birmingham
Forward one copy of this form to the Principal Investigator and retain one copy in the Study File.

(SFv4)

Study File

It is a requirement of Trust authorisation of a study that the Principal Investigator establishes and maintains a study file. A dedicated member of the study team is responsible for maintaining and updating the file.

Good Clinical Practice guidelines require those documents to be collected in a Study Master File which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

Some sponsors may provide their own study file (also known as an Investigator File, Site File, or Trial Master File) for specific studies. If it is a multicentre study, the sponsor may organise the documents into a central Trial Master File and separate Site Files.

Clinical Trials of Investigational Medicinal Products (CTIMPs) fall within the remit of EU Directive 2005/28/EC (the "GCP Directive") which contains detailed requirements for filing and archiving essential documents. For CTIMPs it is a **legal** requirement to follow the requirements of the GCP Directive. The Trust recommends that as a principle of good research practice, study files for all types of studies are maintained to the standards set out in the GCP Directive.

- The site study file must be kept secure at all times.
- The local Principal Investigator must take care to ensure that only personnel authorised by them can amend the file.
- The file should be available for reference by members of the local study team as needed.
- The file must be available for inspection, with 24 hours notice, by representatives of the Sponsor, the Trust, or regulatory authority.
- The file must be retained after the end of the study (final data collection from the final research subject) for at least 5 years.

Documentation

The following good documentation principles should be followed:

- All documents in the file must be complete, legible, accurate and unambiguous
- Documents should be signed and dated as appropriate (e.g. protocol, letters, records of actions etc.)
- If stored on electronic, optical, magnetic format then suitable controls must be in place to ensure the documents cannot be altered without appropriate authorisation
- There must be an audit trail of modifications to the files
- Important documents must carry version numbers or dates (in particular the protocol, investigator brochure, subject information leaflets, subject consent forms, template case report form/data collection form)
- Version numbers must tally with those approved by regulatory authorities, including the ethics committee
- The current and previous versions of documents should be retained on file
- Previous versions should be clearly marked as no longer current together with the date they were superseded.
- Details of amendments made over the course of the study should be recorded in the appropriate section of the file. If necessary, full copies of previous versions may be retained in a separate file.

R&D Office
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Website: www.research.uhb.nhs.uk
Projects database: //uhb/userdata/R & D/R&D database/distributed database 2002.mdb

There must be sufficient information on file for auditors to be able to recreate the document versions used at each time-point for the study.

- A monitor from the sponsor will usually review the accuracy and completeness of the investigator file before formally closing the study

Storage

- The file must be stored so that records remain legible and can be readily retrieved
- The storage facilities must be secure with appropriate environmental controls and adequate protection from physical damage
- Any change in the location of the documents must be recorded to enable complete tracking

Archiving

- Named individuals approved by the sponsor are responsible for archiving
- Access to the archives must be restricted to the named responsible individuals
- The named individuals must maintain a log of the documents retained in the archive and to track movement of documents into and out of the archive
- The study file can be transferred on to alternate media for archiving but the transfer must be certified for accuracy and completeness
- The sponsor can determine how long the study files and all study data should be retained but it must be for a minimum of 5 years after the last clinical intervention on the last participant in the study
- Documents must not be destroyed until agreed with the sponsor

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Abbreviations

ARSAC	Administration of Radioactive Substances Advisory Committee
CAG	NIHS Confidentiality Advisory Group
CI	Chief Investigator
CRF	Case Record Form
CRO	Contract Research Organisation
CTA	Clinical Trial Agreement or Clinical Trial Authorisation depending on context
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
GMSC	Genetics Modification Safety Committee
GTAC	Gene Therapy Advisory Committee
HFEA	Human Fertilisation and Embryology Authority
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IRMER	Ionising Radiation (Medical Exposure) Regulations
MHRA	Medicines and Healthcare Products Regulatory Authority
NRES	National Research Ethics Service
PI	Principal Investigator
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SUSAR	Suspected Unexpected Serious Adverse Reaction

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Suggested Contents and Layout

Inteventional Study

This layout is applicable for any study that involves an intervention in the care of patients.
(Not all documents may be appropriate for all studies, but where the documents do exist they should be included in this file)

1. R&D Specific		Site File	Sponsor Master File
1.1. Documents			
1.1.1.	PI Agreement	•	
1.1.2.	Clinical Director's agreement	•	
1.1.3.	UHB Sponsor letter	•	
1.1.4.	IRMER Schedule 8 Form	•	
1.1.5.	ARSAC Certificate	•	
1.1.6.	GMSC Risk Report (for gene therapy studies)	•	
1.1.7.	Trust approval letter	•	•
1.1.8.	Other R&D documents (Data Transfer Form, Treatment Continuation Form etc.(	•	
1.1.9.	R&D correspondence	•	
2. GCP Study File			
2.1. Basic documents			
2.1.1.	Investigator Brochure*	•	•
2.1.2.	Protocol (signed by Chief/Principal Investigator)	•	•
2.1.3.	IRAS Application (all sections)	•	•
2.1.4.	Participant Information Sheets & Consent Forms	•	•
2.1.5.	Advertisement for subject recruitment	•	
2.1.6.	Sample letters (e.g. to GP)	•	•
2.1.7.	Randomisation procedures	•	•
2.1.8.	Template Case Report Form or other data collection proformas (if not in protocol)	•	•
2.1.9.	Normal ranges for lab tests	•	•
2.1.10.	Medical/laboratory/technical tests and procedures	•	•
2.2. Approvals			
2.2.1.	Ethics committee approval	•	•
2.2.2.	Health Research Authority (HRA) approval	•	•
2.2.3.	Regulatory (MHRA) authorisationl		
2.2.4.	Funding approval	•	•
2.2.5.	Peer-review reports	•	•
2.2.6.	Other regulatory authority authorisations (GTAC, CAG, HFEA etc.)	•	•

*or Summary of Product Characteristics (SmPC) if the medicinal product is already licensed

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2.3.	**Study Personnel**		
2.3.1.	CVs	•	•
2.3.2.	Delegated duties log & Signature sheet	•	•
2.4.	**Agreements**		
2.4.1.	Financial agreement	•	•
2.4.2.	Insurance statement	•	•
2.4.3.	Sponsorship statement	•	•
2.4.4.	Sponsor-Site agreement/ Clinical Trial Agreement	•	•
2.5.	**Pharmacy***		
2.5.1.	Investigational Medicinal Product(s) characteristics	•	•
2.5.2.	Instructions for handling investigational product	•	•
2.5.3.	Sample of labels attached to medicinal products		•
2.5.4.	Investigational products shipping and distribution records	•	•
2.5.5.	Investigational products accountability record (destruction, return etc.)	•	•
2.5.6.	Decoding procedures for blinded trials	•	•
2.6.	**Amendments**		
2.6.1.	Updates of Investigator Brochure	•	•
2.6.2.	List of protocol amendments	•	•
2.6.3.	Approvals for substantial amendments (ethics, regulatory, R&D)	•	•
2.6.4.	Updates to laboratory normal values/ranges	•	•
2.6.5.	Updates to medical/laboratory/technical tests and procedures	•	•
2.7.	**Correspondence**		
2.8.	**Subject enrollment**		
2.8.1.	Subject screening log	•	
2.8.2.	Subject recruitment log	•	
2.8.3.	Subject identification code	•	
2.8.4.	Signed consent forms (these may be kept separately provided their location is clearly indicated in the master study file)	•	
2.8.5.	Completed CRFs or location of source data	•	
2.8.6.	Record of retained human tissue & fluid samples	•	
2.9.	**Adverse events**		
2.9.1.	Sample SAE form	•	•
2.9.2.	SAE/SUSAR reporting procedures	•	•
2.9.3.	List of Expected Serious Adverse	•	•

* Pharmacy documents may be kept in a separate file held in pharmacy: this should be indicated in the main study file.

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	Reactions		
2.9.4.	Completed SAE forms	•	•
2.9.5.	Notification by Sponsor/Investigator to regulatory authorities of SUSARs	•	•
2.9.6.	Notifications by sponsor to investigators of safety information	•	•
2.10. Monitoring			
2.10.1.	Study initiation report	•	•
2.10.2.	Monitoring/audit log	•	•
2.10.3.	Audit reports	•	•
2.11. Reports			
2.11.1.	Annual reports (to ethics committee, MHRA, R&D …)	•	•
2.11.2.	Final report	•	•
2.11.3.	Publications list	•	•

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Non-Interventional Study

This layout is applicable for any study that does not involve a direct intervention in the care of patients. Including, but not limited to, studies simply involving:

- questionnaires to patients or staff
- collection of human tissue
- analysis of existing data from patient records

Not all documents may be appropriate for all studies, but where the documents do exist they should be included in this file.
*Star indicates a document that must be on file as an absolute minimum.

1 R&D Specific
- 1.1 Documents
  - 1.1.1 PI Agreement*
  - 1.1.2 Clinical Director's agreement*
  - 1.1.3 UHB Sponsor letter
  - 1.1.4 Trust approval*
  - 1.1.5 Other R&D documents
  - 1.1.6 R&D correspondence

2 GCP Study File
- 2.1 Basic documents
  - 2.1.1 Protocol (signed by Chief/Principal Investigator)*
  - 2.1.2 IRAS Application
  - 2.1.3 Participant Information Sheets & Consent Forms*
  - 2.1.4 Questionnaires
  - 2.1.5 Advertisement for subject recruitment
  - 2.1.6 Sample letters (e.g. to GP)
  - 2.1.7 Case Report Form or other data collection proforma (if not in protocol)
- 2.2 Approvals
  - 2.2.1 Ethics committee approvals*
  - 2.2.2 Health Research Authority approval*
  - 2.2.3 Funding approval
  - 2.2.4 Peer-review reports
  - 2.2.5 Regulatory authority authorisations (GTAC, CAG, HFEA etc.)
- 2.3 Study Personnel
  - 2.3.1 CVs*
  - 2.3.2 Delegated duties log & Signature sheet
- 2.4 Agreements
  - 2.4.1 Sponsorship statement
  - 2.4.2 Financial agreement
  - 2.4.3 Sponsor-Site agreement
- 2.5 Amendments
  - 2.5.1 List of protocol amendments*
  - 2.5.2 Approvals for substantial amendments (ethics, regulatory, R&D) *
- 2.6 Correspondence
- 2.7 Subject enrollment
  - 2.7.1 Subject screening and recruitment logs
  - 2.7.2 Signed consent forms (these may be kept separately provided their location is clearly indicated in the master study file)*
  - 2.7.3 Completed CRFs or location of source data
  - 2.7.4 Record of retained human tissue & fluid samples
- 2.8 Monitoring
  - 2.8.1 Monitoring/audit log
  - 2.8.2 Audit reports
- 2.9 Reports
  - 2.9.1 Annual reports (to ethics committee, MHRA, R&D …)

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2.9.2 Final report
2.9.3 Publications list

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Appendix 6 – Sponsorship Approval from University of Birmingham

UNIVERSITY OF BIRMINGHAM

FINANCE OFFICE

Miss Victoria Caines
School of Psychology
University of Birmingham

Monday, 09 April 2018

Dear Miss Caines

Project Title:	Can a pre-operative psychological intervention improve post-operative outcomes in Sarcoma Patients?
Sponsor Reference:	RG_17-154
ERN reference:	ERN_17-1107

Under the requirements of Department of Health Research Governance Framework for Health and Community Care, the University of Birmingham agrees to act as Sponsor for this project. Sponsorship is subject to you obtaining a favourable ethical opinion and NHS R&D management approval where appropriate.

As Chief Investigator, you must ensure that local study recruitment does not commence until all applicable approvals have been obtained. Where a study is or becomes multi-site you are responsible for ensuring that recruitment at external sites does not commence until local approvals have been obtained.

Following receipt of all relevant approvals, you should ensure that any subsequent amendments are notified to the Sponsor, REC and relevant NHS R&D Office(s), and that an annual progress report is submitted to the Sponsor, REC and NHS R&D departments where requested.

Please ensure you are familiar with the University of Birmingham Code of Practice for Research (http://www.birmingham.ac.uk/Documents/university/legal/research.pdf) and any appropriate College or School guidelines.

Finally please contact researchgovernance@contacts.bham.ac.uk should you have any queries.

You may show this letter to external organisations.

Yours sincerely

[redacted]

Dr Sean Jennings
Head of Research Governance and Ethics
Research Support Group

University of Birmingham Edgbaston Birmingham B15 2TT United Kingdom
w: www.finance.bham.ac.uk

Appendix 7 -Eligibility to participate and introductory script for surgeons

Introduction to study script

We are currently involved in a pilot study which I would like to let you know about. We are looking to see if a session with a psychologist, tailored to the needs of someone diagnosed with a sarcoma, would help a patient's surgery outcome and recovery following surgery. Not all involved will receive the session with the psychologist; some would be used as a comparison. Everyone involved would be asked to complete a set of questionnaires before their surgery and after their surgery. Taking part is completely optional and your choice to or not to participate does not affect the care you will receive here at the hospital. Even if you decide you'd like to participate and then you change your mind you are welcome to do so, and again this will not affect the treatment you receive here. Does this sound like something you would be interested in being part of?

Inclusion and Exclusion Criteria

Inclusion	Exclusion
• Sarcoma Diagnosis • Receiving surgery as a treatment for their Sarcoma • Fluent in English • Provide informed consent	• Previous treatment for Cancer • Previous major surgery • Head and Neck Sarcoma • A known enduring or serious mental health difficulty (e.g. a participant who is currently under the care of secondary care mental health services) • Participation in another research study

Appendix 8 – Participant Information Sheet

UNIVERSITY OF BIRMINGHAM

Participant Information Sheet

Information Sheet

Can a psychological intervention before surgery increase positive post operation outcomes in Sarcoma patients?

Chief Investigator
Miss Victoria Caines
School of Psychology, University of Birmingham, Edgbaston, Birmingham, B15 2TT

IRAS Study reference Number: 233953

We would like to invite you to take part in a research study. Before you decide to take part you need to understand why this research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others, including family & friends about the study, if you wish. Ask the researcher if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The study aims to investigate if a psychological intervention before surgery will improve outcomes after surgery, for Sarcoma patients.

This research and the data from it will be used as part of the chief investigator's doctoral thesis for the qualification of Doctorate in Clinical Psychology.

Why have I been invited?

People invited into this study can either be female or male, aged 18 or above, who have been diagnosed with Sarcoma, which is being treated with surgery.

Do I have to take part?

Your participation in this research study is voluntary and you do not have to take part if you do not wish to. We will describe the study and go through this information sheet, which we will then give to you. We will ask you to sign an electronic consent form, to show you have agreed to take part. You are free to withdraw at any time, without a given reason. Whether or not you provide your consent for participation in this research study will have no effect on the care you receive from the University Hospital Birmingham or the Royal Orthopaedic Hospital. Neither will it affect any relationship you have or will have with The University of Birmingham.

What happens to me if I take part?

If you decide to take part in this research study you will be asked to complete a set of questionnaires. These questionnaires will be looking to find out how you cope in general with life's difficulties, what your mood is currently like, how you show yourself care, your level of pain, the activities you get up to daily and your relationship with the diagnosis of cancer. You will then be split into two groups. One group will receive the treatment that they would usually expect to receive and have surgery. The second group will meet with the chief investigator, a trainee clinical psychologist, once. This meeting will take place in between their clinic appointment and before their surgery. During this session the psychologist will have discussions with you and offer support in regards to your upcoming surgery. Finally, after surgery participants in both groups will complete the same set of questionnaires that they completed originally.

What are the possible risks of taking part?

It is possible that you may not find this intervention useful. The researcher team have consulted with previous research to identify pre-operation interventions that other cancer groups have found useful. This has been done in order to minimise the risk of you not finding the intervention useful.

There is a further possibility that you may feel worse after the intervention, due to feeling distressed by discussing the topic of your surgery. In these circumstances we will look to sign post you to your GP, Sarcoma UK support services and or your clinical nurse specialist who can provide you with additional support.

We are also aware that participating in this research will require you to make an additional trip to the Queen Elizabeth Hospital. To avoid unnecessary use of your time travelling we have chosen to ask participants to sign an electronic consent form and to complete their questionnaires online.

As a research team, we are also aware that following your surgery you may be unwell and being contacted to complete the follow up information may not be appropriate. To avoid adding any further distress we will first contact your surgeon to ensure that it is an appropriate time to contact you.

What are the possible benefits from taking part?

For those receiving the session from the psychologist we hope that you will feel better following your surgery than you would if you had not have had the session. For all regardless of whether you receive the session or not your participation will help clinicians understand the support that Sarcoma patients need before their surgery. We hope that the findings will influence the care options for future Sarcoma patients.

What if there is a problem?

If you are unhappy or unsure about anything that happens during the study, please feel free to contact the researchers at any time. They will do their best to listen to and address any concerns you may have. Their contact details are printed below. If you feel unable to do this, or are not satisfied with the response that you receive in reaction to your concerns, the normal NHS complaint procedures apply.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against University of Birmingham but you may have to pay your legal costs.

Will my taking part in the study be kept confidential?

The data collected in this study will be used only for the purpose described in this form, and will be available only to the chief investigator listed on this Information Sheet and other personnel involved in this study at the University of Birmingham. All records related to your involvement in this research study will be stored in a locked filling cabinet, at the Queen Elizabeth Hospital. Data gathered from this study will be maintained for 10 years following the publication of empirical articles or communications describing the results of the study.

Every effort will be taken to protect the names of participants in this study. You will be allocated a participant identification code once you consent to participate. Your identity will not be recorded as part of your data, and will not be revealed in any publication that may result from this study. All information you provide will be kept confidential, except as governed by law.

However, your General Practitioner will be contacted by letter, with your consent, to notify them that you are participating in this research.

What will happen If I don't want to carry on with this study?

You are free to withdraw from the study at any time. Should you choose to withdraw, you will have until the 31st December 2018 to withdraw your data. If you request this, any data collected from you will be located and destroyed. You may make this request, to Victoria Caines (email: at any time prior to the cut-off date of the 31st December 2018. This is as by this date your data will be incorporated into the final write up document and will thus be too difficult to remove.

What will happen if I can't complete the study?

Before contacting you to complete the follow-up questionnaires, I will contact your surgeon to ensure you are well enough to complete the measurements. If for any reason the Surgeon suggest you will not be able to complete the survey your previous data will be stored and analysed to understand participants who did not complete the study. You or an approved advocate for yourself can request for this data to be withdrawn, if the request is made before the 31st December 2018.

What will happen to the results of the research study?

The results will form the basis of a thesis project. In addition we may publish the results in an academic journal.

Who is organising the research?

The research is organised by the School of Psychology, University of Birmingham.

How will my data be managed ?

The University of Birmingham is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Birmingham will keep identifiable information about you 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information https://www.birmingham.ac.uk/university/governance/policies-regs/data-protection.aspx.

For further information and contact details.

Victoria Caines

Email:

Supervised by Dr Ruth Howard (R.A.HOWARD.20@bham.ac.uk) and Dr Andy Fox (A.P.Fox@bham.ac.uk)

Appendix 9 – Consent to be contacted form

University Hospitals Birmingham NHS
NHS Foundation Trust

UNIVERSITY OF BIRMINGHAM

CONSENT TO BE CONTACTED FORM

Can a psychological intervention before surgery increase positive post operation outcomes in Sarcoma patients?

University Hospital Birmingham & Royal Orthopaedic Hospital
Chief Investigator: Victoria Caines

	Please initial boxes	
1. I confirm that I have read the Participant Information Sheet and have had time to consider if I would like to participate in this research project.	☐	
2. I consent to my Surgeon passing on my contact details to Victoria Caines (chief investigator) so that she can call me to discuss how I can consent to participate in the study.	☐	

....
Name Date Signature

Appendix 10 – Randomisation Procedure

The chief investigator wrote down the word intervention eight times and the word control eight times. Following this the numbers one to sixteen were written down on 16 small pieces of paper. The numbers were then pulled out of a hat; the first eight were assigned to the intervention arm and the next set of numbers were assigned to the control arm. The numbers were then placed back into a hat. Once participants returned their consent forms and completed the questionnaire at time one, a number was pulled out of the hat, the chief investigator then consulted the previous record to see if this number was associated with the intervention or control arm. Participants were then made aware by telephone conversation which arm they had been randomised to. For those in the intervention arm the intervention was then scheduled.

Appendix 11 – Consent Form

CONSENT FORM

UNIVERSITY OF BIRMINGHAM

Can a psychological intervention before surgery increase positive post operation outcomes in Sarcoma patients?

University Hospital Birmingham & Royal Orthopaedic Hospital
Chief Investigator: Victoria Caines
IRAS Study Reference Number: 233953

1. I confirm that I have understood the information sheet dated 06.06.2018 (v 5.0) for the above study. I have had the opportunity to consider the information, ask questions and have these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time during the research interview, without giving any reason, without my medical/social care or legal rights being affected. ☐
3. I consent for my General Practitioner (GP) to be notified, in writing, by the researcher, of my intent to participate in this study. ☐
4. I understand that the data collected during this study will be looked at by the researcher and their supervisors (Dr Ruth Howard & Dr Andy Fox) at the University of Birmingham to ensure that the analysis is a fair and reasonable representation of the data. ☐
5. If I share any information that suggests to the researcher that I may be so distressed that I do not want to undergo my surgery then this will be shared with my GP and Surgeons (Mr. Anant Desai & Mr. Max Almond). ☐
6. I understand that the research data may also be viewed by regulatory authorities and the sponsor of this research (the university of Birmingham). Should these authorities look at my data it will be for the purpose of ensuring that the research is being conducted in an ethical manner and to the standard that the researchers agreed with the regulatory authorities. ☐
7. I understand that my questionnaire data will be published in the write-up of the research and any other disseminations of the research study. I will remain anonymous in any write ups; neither my name nor any personally identifiable data will be used. ☐

8. I understand that the information that I provide will be stored on a University of Birmingham computer located at The Queen Elizabeth Hospital Birmingham. All access to my information will be protected using password encryption. This computer will use a university of Birmingham server and will be back up daily. ☐

9. I agree to take part in the above study. ☐

Participant Identification Number:.....

Please initial boxes

.....	.....	.....
Name of participant	Date	Electronic Signature
.....	.....	.....
Name of researcher	Date	Electronic Signature

Appendix 12 – Outcome Measures

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Appendix 13 – Reflective Diary Extracts

Diary Extract 1

All the people I spoke with were really keen to participate and the conversations lasted less than 10 minutes. The part of the conversation that took the longest was reassuring participants about the timing of the intervention – despite having reassured them early in the conversation that the intervention would be tagged onto a date when they were already at the hospital. Those who I spoke to mainly wanted to reiterate that they could not have another journey due to the distance that they were travelling. I got the overwhelming sense that the distance that people were travelling was a burden. After being reassured that the intervention would be offered on the same day all participants were happy to receive further information. However, it has now dawned on me that on the surface it appears that it would be beneficial to meet on the same day as a preoperative appointment, but actually this has the potential to become overwhelming. I can most certainly imagine that for myself this would be overwhelming. As part of my duty of care towards the people who may participate this is something I should take into account, as this intervention should make people feel cared for rather than adding another distressing appointment to attend.

Diary Extract 2

I arrived on the ward and looked amongst the beds for X name. Once I found X's name I noticed a lady sat on the bed with a man to the side, I presumed this to be her partner. For a moment I thought about leaving and giving them some time. But with it already being 5:30pm I could not leave it till much later to offer the intervention. So, I decided to introduce myself and check if X and the man needed 5 minutes. X and her husband (as I had now discovered) said they were fine, although X looked nervous. They then began to exchange items for X's husband to take with him, with X saying, "I can't take them to surgery with me". It dawned on me that this was the last time they would see each other before X underwent surgery. They then kissed each other goodbye. I did an awkward half turn. X's husband then left. For myself this was one of the top 10 most awkward situations I have encountered as a psychologist. I can't imagine how it must have felt for X. What this highlighted to me was the importance of the timing of when this intervention was offered – whilst I am not sure what the literature says my instincts would tell me that a goodbye with family is a natural process which is just if not so more important than a psychological intervention.

Diary Extract 3

Generally, X commented on how the service at the hospital had been exemplary and she had been happy to be able to leave within less than a week. X did add that she had expected to see me before she left, to prepare her to go home. I wasn't sure what to say. I didn't feel as though I needed to apologise as I had not offered to do this, but I also wanted to understand the need more. X went on to explain that for her going home was quite scary because she was expected to get back to "normal life" when she did not feel normal. I said we would consider this when developing the research.

Diary 4

Of all the people I spoke with today, I think at least one quarter made a statement to the effect of “anything to help others” when rationalising why they wanted to participate. This made me think of the drive behind cancer and how it puts an onus on each of us to do our bit to “beat” cancer. I have thought about how this fit with the descriptions we use of cancer “survive” “beat” “battling” and how this often gives us a sense of control. I wonder if for those who I spoke with today if thinking about how they can beat cancer as a whole for others gave them a sense of control maybe in a time when they were feeling less in control about their own individual battle with cancer.

Appendix 14 – Acceptance and Commitment Therapy Activity

Values

Our values reflect what we find meaningful in life. They are what you care about, deep down, and what you consider to be important. Everybody's values are different, and they can change over time. They reflect how we want to engage with the world, with the people around us, and with ourselves.

Values are different from goals. Put crudely, goals can be *achieved* whereas values are more like directions that we want to head in. For example we might have the value of *being a good parent* which may require a lifetimes's effort, and the specific achievable goal of *getting our children to school on time*. Or we might have the goal of *going for a jog* while placing value upon our *physical health*.

The domains below are valued by some people. There might be values you think are important, and others that don't matter so much to you. There are no 'right' answers. Read the descriptions and think about what makes for a meaningful life that you could value.

Family	*What kind of relationships do you want to have with your family? What sort of brother / sister / mother / father / aunt / uncle / neice / nephew do you want to be? How do you want to be in those relationships?*
Marriage / Couple / Intimacy	*What kind of husband / wife / partner do you want to be? What kind of relationship do you want to be a part of? What sort of partnership do you want to build? What kind of person do you want to be in a relationship?*
Parenting	*What sort of parent do you want to be? What qualities do you want your children to see in you? What kind of relationships do you want to build with them?*
Friendships / Social life	*What sort of friend do you want to be? What friendships is it important to cultivate? How would you like to act towards your friends? What kind of social life matters to you?*
Career / Employment	*What kind of work is valuable to you? What qualities do you want to bring as an employee? What kind of work relationships would you like to build? What kind of work matters to you?*
Education / Personal growth & development	*How would you like to grow as a person? What kind of skills would you like to develop? What matters to you about education and learning? What would you like to know more about?*
Recreation / Fun / Leisure	*How would you like to enjoy yourself? What relaxes you? When are you most playful?*
Spirituality	*What kind of relationship do you want with God / nature / the Earth?*
Citizenship / Environment / Community	*What kind of environment do you want to be a part of? How do you want to contribute to your community? What kind of citizen would you like to be?*
Health / Physical wellbeing	*What kind of values do you have regarding your physical wellbeing? How important to you is your health? How do you want to look after yourself?*

Participant Take Away Documentation 8, v.1.0 dated 18.04.2018

The Willingness and Action Plan

My goal is to (be specific):

The values underlying my goal are:

The actions I will take to achieve that goal are (be specific):

The thoughts/memories, feelings, sensations, urges I'm willing to make room for (in order to achieve this goal):-

• Thoughts/memories:

• Feelings:

• Sensations:

• Urges:

• It would be useful to remind myself that:

• If necessary, I can break this goal down into smaller steps, such as:

• The smallest, easiest step I can begin with is:

• The time, day and date that I will take that first step, is:

Appendix 15 – Participant Documents to take away

Life is like a Cake

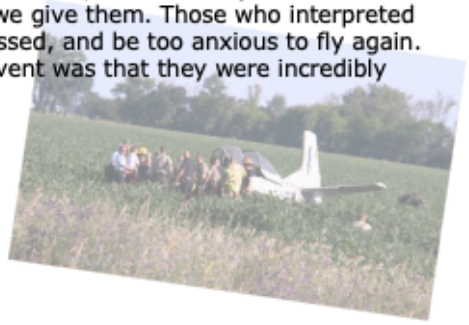
Many ingredients can go into a cake, but the finished cake is down to what we do with those ingredients. We all have different life situations, but we can choose what we do with those ingredients. Some people have many fantastic ingredients, but the cake is not the best. Others have few ingredients, or less desirable ingredients, but are great cooks and make wonderful cakes.

Participant Take Away documentation 9, v.1.0 dated 18.04.2018

The Plane Crash

Not so long ago, a plane landed seemingly miraculously on the River Hudson. All 155 people came out alive. What did those 155 people feel as they stood on dry land and realised what they'd been through? Would they all have had the same reaction? Absolutely not! Many would have felt very distressed and

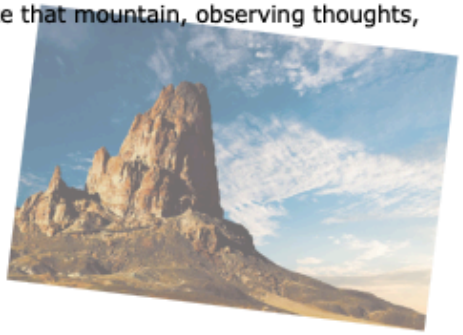
upset – they nearly died, and they might decide never to fly again as it's clearly too dangerous. Others might been overwhelming relief and happiness at having survived. Some might decide to live life to the full as a result of their experience, and be determined to fly even more. There could be 155 different reactions. Same event, different responses. It's not the event which causes our emotions, it's the meaning we give them. Those who interpreted the event as terrifyingly dangerous may feel very distressed, and be too anxious to fly again. Others will feel ecstatic as the meaning they gave the event was that they were incredibly lucky to survive.



Participant take away documentation 11, v.1.0 dated 18.04.2018

The Mountain

Whatever the weather, or whatever happens on the surface of the mountain – the mountain stands firm, strong, grounded, permanent. We can be like that mountain, observing thoughts, feelings, sensations, knowing inner stillness.

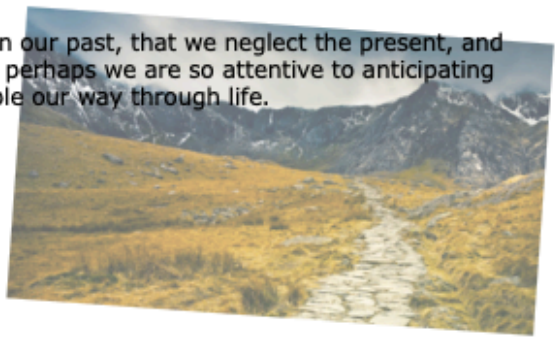


The Walk of Life

When we are walking along the footpath, we tend to look just ahead of us most of the time, with occasional glances behind us and far ahead. We look behind as we need to know of anything approaching from behind or to see where we have come from, and look far ahead to make sure we are heading in the right direction to get to where we want to go. Most of the time though, we need to know where we are putting our feet.

If we were constantly looking behind us, then we would be walking into obstacles or tripping over. If we were constantly focused on the far distance, we would slip and trip over obstacles beneath us.

So it is with life. Sometimes we are so focused on our past, that we neglect the present, and wonder why we keep falling flat on our faces. Or perhaps we are so attentive to anticipating dangers up ahead, that again, we trip and stumble our way through life.




Touch
Blanket
Tangle Therapy
Small embroidery kit
Teddy bear/soft toy
Silk scarf
Taste
Chocolate
Crackers
Coffee
Biscuits
Flapjack
Juice/carton/can
MAKE YOUR OWN
Comfort Kit
TOUCH TASTE SOUND SMELL SIGHT
Sight
Gameboy
Book
Inspirational quote card
Photograph album
Colouring book & pencils
Smell
Scented candle
Room Spray
Pot pourri
Coffee beans
Vanilla pod
Sound
MP3 player (get some podcasts or your favourite mix)
Singing bowl
Rain stick
Bells
DAB radio

- - - SELF-CARE KIT - - -

What can you put in your self-care kit that makes you feel safe, uplifted, and cared for? Use your senses as a guide.

Sight	
Smell	
Touch	
Taste	
Sound	
Spirit	
Other	

Appendix 16 – Progressive Muscular Relaxation Script

Progressive Muscle Relaxation Script

Progressive muscle relaxation is an exercise that relaxes your mind and body by progressively tensing and relaxation muscle groups throughout your entire body. You will tense each muscle group vigorously, but without straining, and then suddenly release the tension and feel the muscle relax. You will tense each muscle for about 5 seconds. If you have any pain or discomfort at any of the targeted muscle groups feel free to omit that step. Throughout this exercise you may visualize the muscles tensing and a wave of relaxation flowing over them as you release that tension. It is important that you keep breathing throughout the exercise. Now let's begin.

Begin by finding a comfortable position either sitting or lying down in a location where you will not be interrupted.

Allow your attention to focus only on your body. If you begin to notice your mind wandering, bring it back to the muscle you are working on.

Take a deep breath through your abdomen, hold for a few second, and exhale slowly. Again, as you breathe notice your stomach rising and your lungs filling with air.

As you exhale, imagine the tension in your body being released and flowing out of your body. And again inhale and exhale. Feel your body already relaxing.

As you go through each step, remember to keep breathing .

Now let's begin. Tighten the muscles in your forehead by raising your eyebrows as high as you can. Hold for about five seconds. And abruptly release feeling that tension fall away.

Pause for about 10 seconds.
Now smile widely, feeling your mouth and cheeks tense. Hold for about 5 seconds, and release,

appreciating the softness in your face. Pause for about 10 seconds.

Next, tighten your eye muscles by squinting your eyelids tightly shut. Hold for about 5 seconds, and release.

Pause for about 10 seconds.

Gently pull your head back as if to look at the ceiling. Hold for about 5 seconds, and release, feeling the tension melting away.

Pause for about 10 seconds.
Now feel the weight of your relaxed head and neck sink.

Breath in...and out. In...and out.
Let go of all the stress In...and out.

Now, tightly, but without straining, clench your fists and hold this position until I say stop. Hold for about 5 seconds, and release.

Pause for about 10 seconds.
Now, flex your biceps. Feel that build up of tension. You may even visualize that muscle tightening. Hold

for about 5 seconds, and release, enjoying that feeling of limpness. Breath in...and out.

Now tighten your triceps by extending your arms out and locking your elbows. Hold for about 5 seconds, and release.

Pause for about 10 seconds.
Now lift your shoulders up as if they could touch your ears. Hold for about 5 seconds, and quickly

release, feeling their heaviness. Pause for about 10 seconds.

Tense your upper back by pulling your shoulders back trying to make your shoulder blades touch. Hold for about 5 seconds, and release.

Pause for about 10 seconds.

Tighten your chest by taking a deep breath in, hold for about 5 seconds, and exhale, blowing out all the tension.

Now tighten the muscles in your stomach by sucking in. Hold for about 5 seconds, and release.
Pause for about 10 seconds.

Gently arch your lower back. Hold for about 5 seconds, relax. Pause for about 10 seconds.

Feel the limpness in your upper body letting go of the tension and stress, hold for about 5 seconds, and relax.

Tighten your buttocks. Hold for about 5 seconds..., release, imagine your hips falling loose. Pause for about 10 seconds.

Tighten your thighs by pressing your knees together, as if you were holding a penny between them. Hold for about 5 seconds...and release.

Pause for about 10 seconds.
Now flex your feet, pulling your toes towards you and feeling the tension in your calves. Hold for about

5 seconds, and relax, feel the weight of your legs sinking down. Pause for about 10 seconds.

Curl your toes under tensing your feet. Hold for about 5 seconds, release. Pause for about 10 seconds.

Now imagine a wave of relaxation slowly spreading through your body beginning at your head and going all the way down to your feet.

Feel the weight of your relaxed body. Breathe in...and out...in...out....in...out.

Appendix 17. Reliable Change Scores for Each Measure

Pain

Groups	Participant	Reliable Change	Significance
Pain: Pre-Surgery to Post-Surgery			
Intervention	Int1	0	1
	Int2	4.35	0.00**
	Int3	-2.17	0.02*
	Int4	3.26	0.001**
	Int5	3.26	0.001**
Control	Ctrl1	1.09	0.28
	Ctrl2	2.17	0.03*
	Ctrl3	3.26	0.001**
	Ctrl4	3.26	0.001**

Nottingham Extended Activities of Daily Living Scale

Group	Participant	Subtest	Reliable Change Index	Significance
Activities of Daily Living: Pre-Surgery to Post-Surgery				
Intervention	Int1	Mobility	0	1
		Kitchen	0	1
		Domestic	0	1
		Leisure	-1.15	0.25
	Int2	Mobility	-3.87	0.00**
		Kitchen	-4	0.00**
		Domestic	-2.32	0.02
		Leisure	-1.15	0.25
	Int3	Mobility	-1.32	0.19
		Kitchen	-1.33	0.18
		Domestic	-1.93	0.05

		Leisure	-1.15	0.25
	Int4	Mobility	-0.76	0.45
		Kitchen	-5.33	0.00**
		Domestic	-4.64	0.00**
		Leisure	-1.15	0.25
	Int5	Mobility	0	1
		Kitchen	0	1
		Domestic	1.16	0.25
		Leisure	0.76	0.45
Control	Ctrl1	Mobility	0.66	0.51
		Kitchen	-6.66	0.00**
		Domestic	-3.87	0.00**
		Leisure	-1.15	0.25
	Ctrl2	Mobility	-5.29	0.00**
		Kitchen	-5.33	0.00**
		Domestic	-4.25	0.00**
		Leisure	-1.15	0.25
	Ctrl 3	Mobility	-5.95	0.00**
		Kitchen	-4	0.00**
		Domestic	-1.16	0.25
		Leisure	-0.76	0.45
	Ctrl 4	Mobility	-3.97	0.00**
		Kitchen	0	1
		Domestic	-3.87	0.00*
		Leisure	-1.53	0.13

Warwick Edinburgh Mental Wellbeing Scale

Group	Participant	Reliable Change	Significance
Wellbeing: Pre-Surgery to Post-Surgery			
Intervention	Int1	0	1
	Int2	1.16	0.25
	Int3	0.46	0.64
	Int4	0	1
	Int5	5.10	0.00**
Control	Ctrl1	-0.46	0.64
	Ctrl2	-3.42	0.00**
	Ctrl3	-0.23	0.82
	Ctrl 4	2.78	0.01**

Hospital Anxiety and Depression Scale

Group	**Participant**	**Subtest**	**Reliable change**	**Significance**
Affective Mood: Pre-Surgery to Post-Surgery				
Intervention	Int1	Anxiety	-1.81	0.07
		Depression	-1.61	0.11
	Int2	Anxiety	-2.56	0.01**
		Depression	-0.98	0.33
	Int3	Anxiety	-0.84	0.4
		Depression	-0.89	0.37
	Int4	Anxiety	-0.90	0.37
		Depression	0.53	0.59
	Int5	Anxiety	-1.79	0.07
		Depression	-1.07	0.29
Control	Ctrl1	Anxiety	-1.2	0.23
		Depression	0.45	0.65
	Ctrl2	Anxiety	0.97	0.33
		Depression	2.48	0.01**

	Ctrl3	Anxiety	-0.85	0.39
		Depression	1.96	0.05
	Ctrl4	Anxiety	0.90	0.37
		Depression	-0.53	0.59

Mini-Mental Adjustment to Cancer Scale

Group	***Participant***	***Subscale***	***Reliable change***	***Significance***
Coping Styles: Pre-Surgery to Post-Surgery				
Intervention	Int1	Helpless-Hopeless	-2.67	0.00**
		Anxious Preoccupation	-6.36	0.00**
		Fighting Spirit	0	1
		Cognitive Avoidance	0.82	0.41
		Fatalism	0.73	0.46
	Int2	Helpless-Hopeless	-10.67	0.00**
		Anxious Preoccupation	-6.36	0.00**
		Fighting Spirit	-1.61	0.11
		Cognitive Avoidance	0	1
		Fatalism	1.1	0.27
	Int3	Helpless-Hopeless	-4	0.00**
		Anxious Preoccupation	-3.82	0.00**
		Fighting Spirit	1.61	0.11
		Cognitive Avoidance	0	1
		Fatalism	0	1
	Int4	Helpless-Hopeless	0.00	1
		Anxious Preoccupation	-2.54	0.01**
		Fighting Spirit	-9.69	0.00**
		Cognitive Avoidance	-1.64	0.10
		Fatalism	1.10	0.27
	Int5	Helpless-Hopeless	-9.34	0.00**
		Anxious Preoccupation	-5.39	0.00**
		Fighting Spirit	3.23	0.00**

		Cognitive Avoidance	0.82	0.41
		Fatalism	-0.73	0.46
Control	Ctrl1	Helpless-Hopeless	0	1
		Anxious Preoccupation	-3.18	0.00*
		Fighting Spirit	-3.23	0.00**
		Cognitive Avoidance	-1.64	0.1
		Fatalism	-0.37	0.71
	Ctrl2	Helpless-Hopeless	9.34	0.00
		Anxious Preoccupation	0.64	0.53
		Fighting Spirit	-4.84	0.00**
		Cognitive Avoidance	2.47	0.01**
		Fatalism	-0.73	0.46
	Ctrl3	Helpless-Hopeless	5.34	0.00
		Anxious Preoccupation	0.64	0.53
		Fighting Spirit	-1.61	0.11
		Cognitive Avoidance	0	1
		Fatalism	0	1
	Ctrl4	Helpless-Hopeless	-2.67	0.01**
		Anxious Preoccupation	-4.45	0.00**
		Fighting Spirit	-3.23	0.00**
		Cognitive Avoidance	2.47	0.01**
		Fatalism	0	1

Compassionate Engagement and Action Scale – Self-Compassion

Group	***Participant***	***Subtest***	***Reliable Change***	***Significance***
Self-Compassion: Pre-Surgery to Post-Surgery				
Intervention	Int1	Engagement	-2.64	0.01**
		Action	-0.35	0.73
	Int2	Engagement	0.88	0.38
		Action	0.35	0.73
	Int3	Engagement	0.22	0.83
		Action	0.17	0.86

	Int4	Engagement	1.60	0.11
		Action	0	1
	Int5	Engagement	3.08	0.00**
		Action	2.59	0.01**
Control	Ctrl1	Engagement	0.66	0.51
		Action	-0.52	0.60
	Ctrl2	Engagement	-2.64	0.01**
		Action	-1.73	0.08
	Ctrl3	Engagement	0.22	0.83
		Action	-0.86	0.39
	Ctrl4	Engagement	-1.32	0.19
		Action	0.52	0.60