Changing behaviour: Role of theories and techniques in increasing physical activity in non-specific low back pain patients

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Abstract

Non-specific low back pain (NSLBP) causes more global disability than any other condition. NSLBP is a recurrent and chronic condition affecting individuals of all ages, costing billions of pounds in the United Kingdom (UK). Physical activity is recommended in National and International guidelines as a self-management strategy for patients with NSLBP. However, the effectiveness of using physical activity as a self-management strategy for patients with NSLBP is still debated in the literature. The use of behaviour change theories and behaviour change techniques (BCTs) in the development of physical activity interventions in NSLBP research has not been investigated.

This thesis had a distinct aim with five key objectives. The aim of this thesis was to explore "how" physical activity intervention should be designed, developed, and delivered to NSLBP patients. The first objective was to scope the literature of non-prescribed, unsupervised physical activity interventions for NSLBP patients. The second objective was to investigate the content of non-prescribed, unsupervised physical activity interventions for NSLBP patients, and to evaluate the use of behaviour change theories and BCTs in the interventions. The third objective was to test the validity of wearing an accelerometer around the waist, using a belt, to measure physical activity levels in humans. The fourth objective was to systematically design and develop four physical activity interventions using a relevant and valid behaviour change model and to select the BCTs to aid behaviour change, and increase the physical activity levels of a NSLBP population. Finally, the last objective was to perform a randomised mixed methods feasibility-pilot trial in a student-led osteopathy clinic, using the knowledge and resources gained from the previous objectives to deliver four non-prescribed physical activity interventions to NSLBP patients.

Methods: Objective 1 was met by conducting an initial scoping review to assess the breadth and depth of the literature of non-prescribed, unsupervised physical activity interventions for NSLBP patients. To meet objective 2, a systematic review was conducted to analyse the content of non-prescribed, unsupervised physical activity interventions used to increase physical activity levels in NSLBP patients. The results of this study informed the two proceeding accelerometer pilot trials and the randomised feasibility-pilot trial. The two pilot trials were performed to evaluate the validity of mounting an accelerometer around the

waist on a belt, compared to the 'gold standard' of attaching the accelerometer directly to the skin. This trial aimed to validate the wearing method (belt method) and test the reliability of a set of instructions to be used by the participants in the feasibility-pilot trial (objective 3). Objective 4 was completed by using the Behaviour Change Wheel (BCW), incorporating the relevant BCTs to aid behaviour change and increase the physical activity levels of a NSLBP population, to design four physical activity interventions. A randomised, mixed-methods feasibility-pilot trial was performed to evaluate the acceptability, viability, and credibility of the trial protocol and the four interventions, designed using the BCW, for the NSLBP patients (objective 5). The acceptability, viability, and credibility of the trial protocol for the clinicians at the University College of Osteopathy (UCO) student-led clinic was also evaluated.

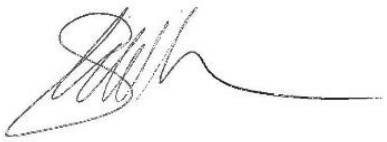
Results: The systematic review demonstrated that the use of non-prescribed, unsupervised interventions normally takes the form of "advice to be active", as the minimal intervention in the control group. All the interventions in the included trials did not appear to be informed by behaviour change theories, used few BCTs and do not use an objective measure for physical activity. The two pilot trials showed no significant differences between the two mounting methods of the accelerometer and demonstrated that the instructions were reliable in guiding participants to wear the belt method in the correct place (spinal level L4-L5). The feasibility-pilot trial indicated that more in-depth planning of the trial is warranted if it is to be used in the UCO student-led clinic due to 1) poor patient participant recruitment, 2) the nature of the clinic and 3) the acceptability of the term "NSLBP" amongst the clinicians, whom all used variations in definitions for NSLBP. The use of the BCT "feedback on behaviour", in two of the interventions, was identified as the most useful component for the NSLBP patients in encouraging them to increase their activity levels.

Conclusion: The work presented in this thesis has identified three novel and valuable findings which will advance NSLBP and physical activity research. This thesis identified 1) a method to comfortably wear an objective measure to monitor physical activity over several weeks, 2) has demonstrated that future NSLBP research should investigate the use of BCTs in interventions to increase physical activity, particularly the BCT "feedback on behaviour" and 3) the acceptability, confusion and different understandings of the term NSLBP between clinicians. The different understandings of this term hampered the recruitment of NSLBP

patients in the feasibility-pilot trial. Qualitative research in this field is sparse but required. Future qualitative studies need to investigate the thoughts and perceptions of practitioners and clinicians about the term NSLBP to create standardised terminology which is acceptable to practitioners and clinicians, and which can be used in future trials.

Declaration

I declare that the work presented in this thesis is the original work of the author unless stated. This work has been solely submitted for the degree of Doctor of Philosophy at London Southbank University.



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12th October 2020

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Glossary: List of abbreviations

%	percent
£	pounds
+	plus
↑	increase
↓	decrease
–	minus
^{18}O	Heavy oxygen
^{2}H	Heavy hydrogen
ADMR	Average daily metabolic rate
APEASE	Affordability, practicability, effectiveness/cost-effectiveness, acceptability, side-effects/safety and equity
AS	Ascending stairs
BCT	Behaviour change technique
BCTTv1	Behaviour change technique taxonomy version one
BCW	Behaviour Change Wheel
BM	Body mass
BMI	Body mass index
BMR	Basal metabolic rate
BPAQ	Baecke physical activity questionnaire
BW	Body weight
CD	Compact disc
CDSMP	Chronic disease self-management programme

CI	Confidence interval
CLBP	Chronic low back pain
CMC	Clinically meaningful change
CNSLBP	Chronic non-specific low back pain
CO_2	Carbon dioxide
COM-B	Capability, opportunity, motivation – behaviour system
COPD	Chronic obstructive pulmonary disease
COS	Core outcome set
DIY	Do it yourself
DLW	Doubly labelled water
DS	Descending stairs
EE	Energy expenditure
FAQ	Frequently asked questions
FPQ	Fear of pain questionnaire
FQPA	Freiburger Questionnaire on Physical Activity
FR	Fast running
FW	Fast walking
GP	General practitioner
GPAQ	General physical activity questionnaire
GPPAQ	General Practise Physical Activity Questionnaire
HCP	Health care professional
HDL	High density lipoprotein
HPA	Hypothalamic pituitary gland

HR	Heart rate
HRQoL	Health-related quality of life
ID	Identification
IP	Internet protocol
IPA	Interpretive Phenomenological Analysis
IPAQ	International physical activity questionnaire
Kg	Kilograms
LBP	Low back pain
LSBU	London South Bank University
MANOVA	Multivariate analysis of variance
MBHPAQ	Modified Baecke habitual physical activity questionnaire
MCID	Minimal clinically important difference
MET	Metabolic equivalent
mm	millimetre
MMR	Mixed Methods Research
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NPRS	Numeric pain rating scale
NR	Normal running
NRS	Numeric rating scale
NSLBP	Non-specific low back pain
NW	Normal walking

ODI	Oswestry Disability Index
OHS	Occupational health setting
OMT	Orthopaedic manual therapy
PAEE	Physical activity energy expenditure
PAI	Physical activity index
PAL	Physical activity level
PAR-Q	Physical activity recall questionnaire
PC	Personal computer
PICO	Participant, Interventions, Comparison, Outcomes
ppm	parts per million
QALY	Quality-adjusted life year
QoL	Quality of life
RCT	Randomised controlled trial
RMDQ	Roland Morris disability questionnaire
RMR	Resting metabolic rate
RPAQ	Recent physical activity questionnaire
SAS	School of Applied Science
SD	Standard deviation
SF-36	Short form health survey questionnaire
SPSS	Statistical package for social science
SR	Slow running
SW	Slow walking
TDEE	Total daily energy expenditure

TDF	Theoretical Domains Framework
TEE	Total energy expenditure
TIDieR	Template for intervention description and replication
TPM	Theory of Planned Behaviour
TTM	Transtheoretical Model
TTO	Time-trade off
UCO	University College of Osteopathy
UK	United Kingdom
USA	United States of America
USB	Universal serial bus
VAS	Visual analogue scale
vs	versus
WHOQoL-BREF	World Health Organization quality of life brief version

Preface

The research presented in this thesis is based on my passion, as a Sports Therapist and Rehabilitator, for treating patients with non-specific low back pain (NSLBP). As a competitive trampoline and double-mini trampoline gymnast, low back pain, caused via an injury, was something I suffered with in my early teenage years which threatened my sporting career. And the haunting question for me was why? Why does this happen and what can be done about it? So, I embarked on a career to help treat and rehabilitate people hampered by injury and LBP (non-specific or otherwise). I spent my undergraduate and postgraduate studies at the University of Kent trying to figure out why this condition manifested itself in individuals in the hope that I could find the "guilty tissue" (by tissue I mean muscle, ligament, tendon or nerve supply) for causing the pain and therefore treat the individual accordingly. Throughout those studies I realised that perhaps the answer does not begin with how and why the condition starts (as NSLBP is multifactorial and muscular tissues rarely work in isolation), but effort should be focused on developing interventions to help patients who suffer with NSLBP. As a sports woman, I never stopped moving and have been active my whole life. It concerned me to learn that the majority of patients with NSLBP avoid activity through the ideology that activity is bad and harmful for the spine. Physical activity and its contribution to good health and quality of life (QoL) is well known. Physical activity is reported to have beneficial effects on most musculoskeletal conditions, not excluding LBP (Olaya-Contreras *et al.*, 2015). Activity provided me with an outlet, a social life away from the pressures of School and University, lifted my mood and made my body and mind feel strong. People suffering with NSLBP who avoid movement and activity are often reported to be withdrawn, sometimes depressed, socially isolated and feel their body is weak. As the modern world progresses, with technology and advanced transport systems replacing the amount of activity individuals engage in, the majority of individuals lead a sedentary lifestyle. However, the human body is designed to move with major systems: skeletal, muscular, metabolic, digestive, circulatory and endocrine, all requiring stimulation from regular physical activity to develop and function properly. The National Institute of Clinical Excellence (NICE) recommend advising NSLBP patients to be physically active (National Institute for Health and Care Excellence, 2016). But how do you make a population, who are reported to have an intolerance or fear of physical activity more active? You are essentially

asking individuals to change their behaviour and thoughts and feelings towards a particular entity. Just think of how many times you have said to yourself you will start eating healthy or go on a diet, to only revert to your old habits within a couple of weeks. Behaviour change is complex and behaviour change interventions require careful consideration and planning.

The work presented in this thesis is an exploration of how physical activity interventions in NSLBP research should be designed, developed and delivered to promote behaviour change and increase physical activity in a NSLBP population. By identifying "how" interventions should be designed and delivered to a NSLBP population, tools to help break down the barriers NSLBP patients exhibit towards physical activity can be developed to advance the field. Future research relating to increasing the physical activity levels of NSLBP patients will benefit from understanding the "how" and will be able to use the work presented for the optimal performance of future clinical trials. The interventions of interest in this thesis are non-prescribed and unsupervised. The rationale was to design non-prescribed, unsupervised interventions which could be easily incorporated as part of normal routine in a healthcare clinic or GP centre. Non-prescribed interventions were the focus as it is known that interventions which can fit into an individual's daily life and routine, may be more sustainable and aid the process of behaviour change. Prescribing specific interventions (i.e., yoga) may not be sustainable if 1) the individual has no interest in yoga and 2) if the individual perceives they cannot or do not want to fit yoga into their daily routine.

Programme aims

The aim of this programme of research was to explore "how" physical activity interventions should be designed, developed, and delivered to promote behaviour change and increase the physical activity levels of NSLBP patients. Refer to page xxxvii for a flowchart, detailing how the different studies relate to each other and contribute to the aim of this thesis.

To fulfil this exploration, this programme of research had several objectives:

1) Scope the current literature on non-prescribed, unsupervised physical activity interventions for patients with NSLBP
2) To highlight the gaps and areas of improvement by evaluating the content of current interventions to inform the feasibility-pilot trial including the outcome measures used
3) Research and identify a valid, non-intrusive objective measure for physical activity
4) Identify a framework or model for behaviour change to design and develop the delivery of the interventions used in the feasibility-pilot trial
5) Run a feasibility-pilot trial in a University, educational outpatient osteopathy clinic to test the feasibility and acceptability of the objective measure and the interventions designed to increase physical activity levels in patients with NSLBP.

Structure of thesis

Chapter 1

This chapter presents an introductory overview to the global burden of non-specific low back pain (NSLBP) and the rationale for using physical activity as a self-management intervention for NSLBP patients. The chapter briefly reports the current physical activity and exercise interventions in the NSLBP literature. This chapter concludes with an outline of the purpose and direction of this thesis.

Chapter 2

This chapter presents the results of an initial scoping exercise to determine the breadth of the literature surrounding NSLBP and non-prescribed, unsupervised physical activity interventions. This chapter describes the aim of the review, the rationale behind why the review was necessary and how it enhances the knowledge of the current literature. This chapter also describes the systematic review protocol and displays the results of the systematic review.

Chapter 3

This chapter discusses the measures used to monitor and collect physical activity data in the general literature and in NSLBP research. The rationale for using accelerometers in the feasibility-pilot trial is provided. The justification for two exploratory (pilot) trials – validation trials for a mounting method for the accelerometers - is reported. The chapter concludes with the results and discussion of the two exploratory trial

Chapter 4

This chapter describes the development of the four interventions used in the feasibility-pilot trial and specifies the intervention components. The interventions were systematically developed using the Behaviour Change Wheel (BCW). This chapter also describes the importance of utilising behaviour change theories, frameworks and models when designing complex healthcare interventions aiming to change behaviour in accordance with the Medical Research Council (MRC) guidelines. Different frameworks and models are discussed and the rationale for using the BCW is provided.

Chapter 5

The aim of this chapter is to provide the rationale and justification for using a mixed methods feasibility study design for the main trial of this thesis. This chapter explains the appropriateness of this methodological approach in line with the purposes of this thesis. The chapter also addresses and provides the rationale and justification for the type of qualitative methods selected.

Chapter 6

This chapter presents the methodology of the mixed-methods feasibility-pilot trial. The feasibility-pilot trial was a pragmatic four-armed RCT conducted in the UCO student-led osteopathy clinic. A mixed methods approach was adopted to ascertain feasibility of the trial protocol, for the patient and clinician participants, and acceptability of the methods employed, including the acceptability and credibility of the interventions and measurement tools used (questionnaires, accelerometer). A previous chapter (*chapter 4)* outlined how the interventions described in this trial, for the patient participants, were designed and

developed using the BCW model, according to previous literature advocating the use of the theoretical frameworks and models in intervention development. *Chapter 5* presented the rationale for adopting a mixed-methods approach for this trial.

Chapter 7

This chapter is divided into three sections. The first section evaluates the results of the mixed methods feasibility-pilot trial for the patient participants. The second section provides a process evaluation, answering the sub-questions of this thesis, about the trial procedure, interventions, the accelerometer and the other measurement tools used for the patient participants. The final section provides a process evaluation relating to the sub-questions surrounding the acceptability of the interventions used and the acceptability and feasibility of the trial procedure for the clinicians at the UCO outpatient clinic.

Chapter 8

This chapter outlines and discusses the main findings of this thesis and highlights the importance of the application of these findings to the current literature and clinical practice. Future research recommendations are also provided.

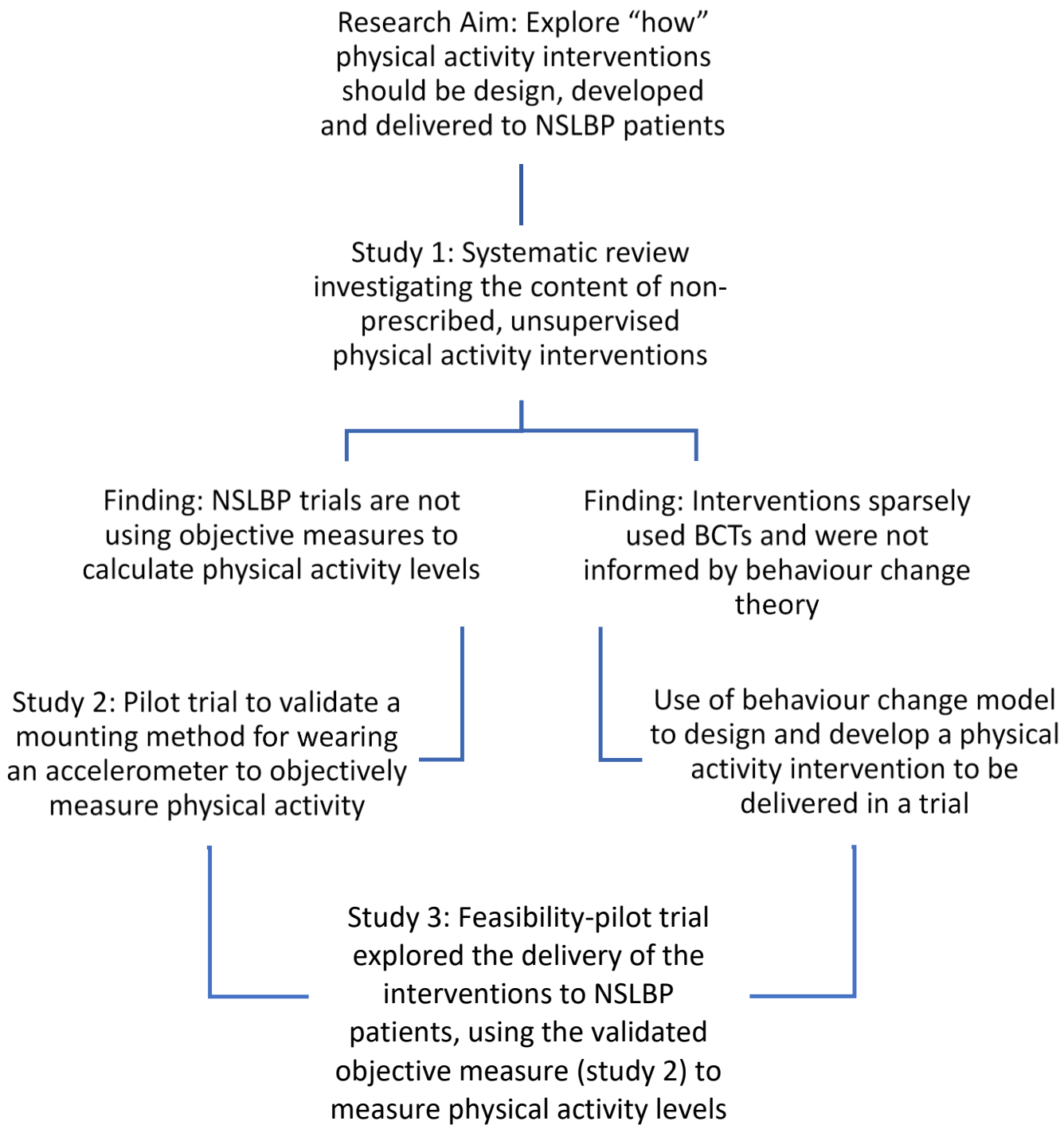

Figure 0.1: Flowchart depicting how each of the studies presented in this thesis relate to each other and achieve the overall aim of this programme of work

Acknowledgements

"Challenges are what make life interesting, overcoming them is what makes life meaningful"

Joshua J. Marine

I would like to thank my supervisors for supporting me throughout this journey. It has been a rocky road at various points throughout this thesis and I cannot thank my supervisors enough for keeping me on track. To *Professor Raymond Lee,* I thank you for accepting me as a candidate for a PhD and starting me off on this journey. To *Professor Ian Albery,* I cannot find enough words to express how grateful I am to have had you as my Director of Studies. You have helped me grow not just as an academic, but also as a person. You listened when I needed someone to hear me, and always went above and beyond in your advice and help to get me moving forward. I feel so very fortunate to have been one of your PhD students. If there was ever somebody to challenge my knowledge, develop me as an academic and turn every seed into a flower it was you *Dr Eleni Vangeli*. Your invaluable input in my thesis has made all the difference. I started out having "all the gear and no idea" about systematic reviews and behaviour change. Without you, the key areas of this thesis were not possible, and I would not have enhanced my understanding, knowledge, or appreciation of behaviour change theories, frameworks or techniques and how to apply them. Thank you to *Dr Jin Luo* for your brilliance in biomechanics and making every concept of collecting and analysing data seem so easy. Your easy-going, clear thinking nature was inspiring, and I hope I can channel some of that in the future when a problem arises.

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xxx

1 Chapter 1 – Low Back Pain

This chapter presents an introductory overview to the global burden of non-specific low back pain (NSLBP) and the rationale for using physical activity as a self-management intervention for NSLBP patients. The chapter briefly reports the current physical activity and exercise interventions in the NSLBP literature. This chapter concludes with an outline of the purpose and direction of this thesis.

1.1 The burden of low back pain

NSLBP is one of the most prevalent patient complaints in the general population, with a lifetime prevalence of up to 75-84 percent (%) (Hoy, March, *et al.*, 2010; Hoy *et al.*, 2012). NSLBP is defined as back pain which has no identifiable pathology (Krismer and van Tulder, 2007). It is estimated that around 90% of all patient complaints of back pain are non-specific (Koes, van Tulder and Thomas, 2006) with only 5-10 % of cases having an identifiable source (Cedraschi *et al.*, 1999; Krismer and van Tulder, 2007). This condition is reported to be recurrent (i.e., after an episode of NSLBP, patients are likely to have more episodes of pain (Stanton *et al.*, 2008)) and chronic (persisting for a long time) (Hoy et al., 2010; Hoy et al., 2012; Koes, van Tulder, & Thomas, 2006; Van Der Windt & Dunn, 2013). NSLBP affects people of all ages (Balagué *et al.*, 2012) in high-, middle- and low-income countries (Hartvigsen *et al.*, 2018). It is reported that over three quarters of individuals with NSLBP will suffer a recurrence of their back pain within a year of their first episode (Heliovaara *et al.*, 1989). It has been recently demonstrated that NSLBP causes more global disability than any other condition (Hoy *et al.*, 2014; Hartvigsen *et al.*, 2018) resulting in high costs to society (Staal *et al.*, 2003).

Over the decades the cost of NSLBP has been substantially increasing. In 1993, the cost of NSLBP on the National Health Service (NHS) was estimated at approximately 480 million pounds (£) and was reported to affect around sixteen and a half million people (Campbell and Muncer, 2005). A study published in the year 2000 estimated the cost of NSLBP in the United Kingdom (UK) on the NHS was around £251 million per annum (Maniadakis & Gray, 2000). In 2012, NSLBP in the UK cost approximately £12.3 billion, of which £1.6 billion came

from informal care, £1.6 billion from direct healthcare costs and £9.1 billion through production loss due to absences from work (Whitehurst *et al.*, 2012). The costs of NSLBP exceed the amount of money spent on other conditions such as coronary artery disease, and eclipses the cost of rheumatoid disease, stroke, diabetes and respiratory infection (Stoll, 1982). NSLBP is also becoming more prevalent throughout the years, with a one-year prevalence increase of 12.7% during a 10-year period between 1987-8 and 1997-8 (Palmer *et al.*, 2000). The increase in the cost of NSLBP on the NHS from 2000 to 2012 in conjunction with the increasing prevalence of the condition suggests that the economic burden of NSLBP on the NHS will only increase over time. This burden on the economy can be reduced if NSLBP can be more effectively managed.

A potential reason for the increasing prevalence, and subsequent rising costs of NSLBP, is an increased reporting of the condition. Cultural changes have been identified as a reason for the increases in reporting of NSLBP (Palmer *et al.*, 2000). Patient perceptions and awareness of the signs and symptoms of minor back injuries are growing and so is the readiness of patients to report their pain to a healthcare professional (Palmer *et al.*, 2000). Despite the increased awareness of the condition, there are still only a few recommendations on how to effectively manage NSLBP (Van Der Windt and Dunn, 2013). There is also speculation surrounding the aetiology (cause) of the condition (Van Der Windt and Dunn, 2013).

1.2 Classification and aetiology of non-specific low back pain

A problematic issue surrounding NSLBP is the lack of a definitive definition – vast differences in opinion exist between medical professionals and clinicians on the definition, aetiology and nature of NSLBP (Skelton *et al.*, 1995; Campbell and Muncer, 2005; van Middelkoop *et al.*, 2011; Van Der Windt and Dunn, 2013). There is some controversy in the literature surrounding a definition for NSLBP. Some researchers define NSLBP as pain between the 12th rib and inferior gluteal folds (Hartvigsen *et al.*, 2018) which occurs with or without radiating leg pain (Krismer and van Tulder, 2007). NSLBP is also defined in the literature as pain within the lumbosacral region of the back, thighs and buttocks, which is 'mechanical' in nature; varying in time and with physical activity (Deyo *et al.*, 1998; Campbell and Muncer, 2005). There are also different variations in the definition for recurrent NSLBP (Stanton *et*

al., 2010). Von Korff (1994) defined recurrent LBP as "back pain present on less than half the days in a twelve-month period, occurring in multiple episodes over the year". Other authors of trials have defined recurrent LBP as patients experiencing pain "at least ten times" (Mikkelsson *et al.*, 2006) or pain which occurs twice during a week, over a period of six months (Feuerstein, Carter and Papciak, 1987).

There is also controversy in the literature in which area of the back classes as the lower back (Hoy, Brooks, *et al.*, 2010) and what constitutes as an episode of NSLBP (de Vet *et al.*, 2002). The current literature also does not distinguish between the persistence of an original episode of NSLBP and a flare-up or recurrence of an original episode (i.e., if the original episode of NSLBP has been recovered from and the pain is coming from a new episode or if the pain is a flare-up or recurrence of the original episode of NSLBP) (Stanton *et al.*, 2010). Previously, NSLBP has been classified by how long the pain has been present – acute (pain less than six weeks), sub-acute (pain between six weeks and three months) and chronic (pain present beyond three months) (Cedraschi *et al.*, 1999; Campbell and Muncer, 2005; Koes, van Tulder and Thomas, 2006; Krismer and van Tulder, 2007; Hoy, Brooks, *et al.*, 2010; Van Der Windt and Dunn, 2013). However, there is controversy with classifying NSLBP this way, as it suggests the nature of NSLBP runs a linear course, which is stable rather than interchangeable and unpredictable (Cedraschi *et al.*, 1999).

NSLBP is reported to be multifactorial (involving several factors) in nature (Balagué, Dudler and Nordin, 2003). There have been many risk factors proposed to lead to the onset and development of NSLBP. NSLBP, although defined to have an unknown cause or caused by an unknown pathology (Foster *et al.*, 2018; Hartvigsen *et al.*, 2018), the pain is often attributed to various lifestyle choices, occupation and psychological influences (see table 1.1). A review by Deyo and Weinstein (2001) reported that the structures of the vertebrae, such as the intervertebral discs (Aoki *et al.*, 2012), and mechanisms like neuropathic pain or muscle atrophy (Hodges and Richardson, 1996) have been mainly focussed on in order to understand the pathophysiological mechanisms which lead to NSLBP. Some of the specific causes of NSLBP include degenerative conditions, inflammatory conditions, referred pain, psychogenic pain, metabolic bone disease, trauma, congenital disorders and infective and neoplastic causes (Krismer and van Tulder, 2007; Balagué *et al.*, 2012; Hartvigsen *et al.*, 2018). NSLBP can have negative impacts on how an individual perceives their quality of life

(QoL) (Punnett *et al.*, 2005; Ricci *et al.*, 2006; Alsufiany *et al.*, 2020). In a study by Vilar Furtado et al. (2014) a correlation was identified between the presence of NSLBP and negative reporting on aspects of life quality (body pain, vitality, social functioning and general health). These negative aspects on health-related quality of life (HRQoL) include reduced functioning, depression, and physical inactivity.

Another risk factor for NSLBP is physical inactivity (sedentary behaviour) (Citko *et al.*, 2018). Over recent decades, the amount of physical activity we engage in has reduced and many are leading a sedentary lifestyle (Sitthipornvorakul, Janwantanakul and Lohsoonthorn, 2015). The developments of new technologies have taken over the amount of labour required to carry out everyday tasks in the workplace and around the house. Throughout time, with the introduction of cars, the need to walk or cycle to destinations has been drastically reduced, and with the attraction of television, computers and electronic devices, such as iPhones and iPads, the way people spend their leisure time, especially children has changed (Kotecki, 2013). According to Public Health England, physical activity levels in the UK have been decreasing since the 1960s. Adults are 20% less active today, than they were in the 1960s (Public Health England). It is reported that 40% of NSLBP patients will reported a permanent reduction in physical activity levels (Heliovaara *et al.*, 1989).

Table 1.1.: Risk factors for NSLBP associated with individual, psychological and occupational influences. Adapted from Hartvigsen et al. (2018), Vilar Furtado et al. (2014), Krismer and van Tulder (2007) and Xu et al. (1997).

Risk factors			
Individual and lifestyle influences	Age	Physical fitness	Sedentary
	Gender	Obesity	Occupation
	Smoking	Muscular strength of back muscles	High levels of pain and disability
	Education		
Psychological influences	Stress	Pain perception	
	Distress	Mood/emotions	
	Anxiety	Depression	
Occupational influences	Heavy lifting throughout the day	Whole body vibrations	Control
	Bending and twisting		Job dissatisfaction

There is some evidence for a theoretical U-shaped relationship between physical activity and NSLBP, indicating that moderate physical activity has a beneficial effect on NSLBP (see figure 1.1) (Heneweer, Vanhees and Picavet, 2009; Olaya-Contreras *et al.*, 2015). There are only a few studies that have described the association between levels of physical activity and NSLBP (Heneweer, Vanhees and Picavet, 2009; Hendrick *et al.*, 2011; Lin *et al.*, 2011).

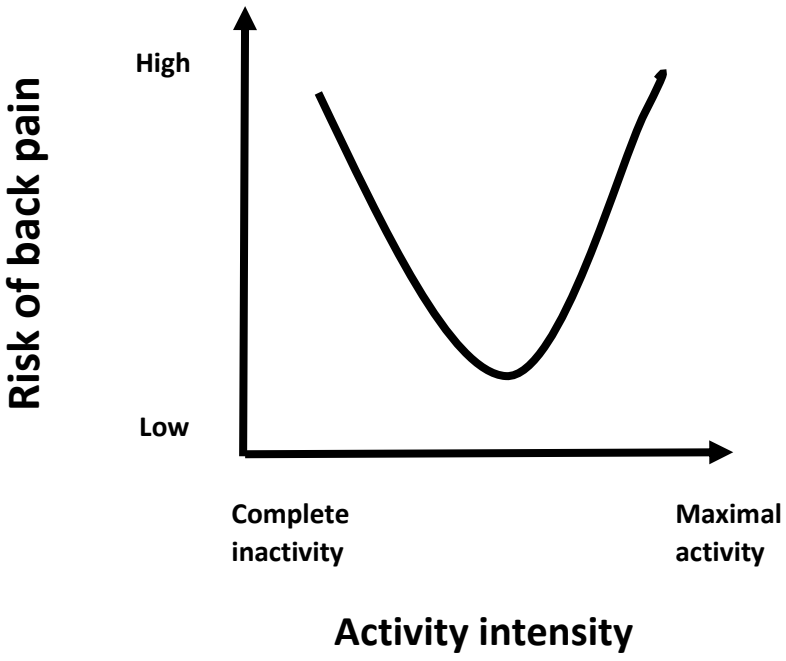


Figure 1.1: U-shaped relationship between NSLBP and amount of physical activity. Adapted from (Heneweer, Vanhees and Picavet, 2009).

1.2.1 Psychological aspects of NSLBP

According to the biopsychosocial model (Waddell, 1992) LBP is a condition which interacts not just with physical the aspects of an individual, but also the psychological and social aspects of an individual. Perceptions on the nature and seriousness of NSLBP inherently play a vital role in how patients react to their pain. Throughout the development of NSLBP and during the progression of persistent pain and disability, psychological factors play a crucial role (Linton, 2000; Pincus *et al.*, 2006; Iles, Davidson and Taylor, 2008; Ramond *et al.*, 2011; Darlow *et al.*, 2015). Poor prognosis of the condition forms negative assumptions about the back (e.g., patients believing there is a problem with the vertebrae, such as being cracked) which can in turn lead to heighten the perceived threat that is often associated with NSLBP (Darlow *et al.*, 2015). Key psychological factors include fear avoidance beliefs, catastrophisation, emotional distress, expectations of outcome of their pain (i.e., the back will never heal) and depression (Darlow *et al.*, 2015). NSBLP has been reported, in a qualitative study, to impact a patient's sense of self (Smith and Osborn, 2007).

Biopsychological perspectives on NSLBP are increasing in the literature with the psychological factors induced by NSLBP being recognised as fundamental in both the assessment of the condition (Waddell and Burton, 2001; Main and George, 2011) and the subsequent treatment and management for patients (Burton *et al.*, 2006; Chou *et al.*, 2007; Eland, 2013; Baird and Sheffield, 2016; Foster *et al.*, 2018).

In order to help patients to self-manage their NSLBP, the reasons behind these psychological factors needs to be understood to ensure they are addressed effectively (Vlaeyen and Crombez, 1999; Iles *et al.*, 2009; Jeffrey and Foster, 2012; Geraghty *et al.*, 2015).

1.3 Clinical management of NSLBP

Clinical guidelines are evidence informed and provide guidance for clinicians or other medical healthcare professionals on the best care for their patients. The current guidelines released by the National Institute for Health and Care Excellence (NICE) recommend that patients with NSLBP should self-manage their pain by remaining physically active (National Institute for Health and Care Excellence, 2016). Current clinical practice now focusses on pain reduction and more activity participation (Krismer and van Tulder, 2007). As such, physical activity has become a core component of self-management programmes (May, 2010; Geraghty *et al.*, 2015; National Institute for Health and Care Excellence, 2016). National and international guidelines (Michaleff *et al.*, 2014; National Institute for Health and Care Excellence, 2016; Qaseem *et al.*, 2017; Stochkendahl *et al.*, 2018) also recommend utilising the biopsychosocial model in the assessment of a patient's NSLBP (Foster *et al.*, 2018).

Pain reduction and activity participation are considered the most important factors in the prevention or early management of NSLBP (Krismer and van Tulder, 2007) and are the most consistent amongst international guidelines (Foster *et al.*, 2018). NSLBP patients should be provided with education about the nature of NSLBP, reassurance there is not a serious underlying problem with the back and encouraged to maintain activity levels (Foster *et al.*, 2018). Health interventions for NSLBP should include the core outcome set (COS) which include pain intensity, HRQoL and physical functioning (Chiarotto *et al.*, 2015). At present the interventions used to promote prevention of NSLBP (i.e., work-place ergonomics, back

belts, education, no-lift policies etc.) do not have a strong evidence base (Foster *et al.*, 2018).

1.3.1 Outcome measures

Generic self-reported and disease-specific health instruments, such as questionnaires or rating scales, are commonly utilised in longitudinal observational studies and clinical trials (Jordan *et al.*, 2006). The COS recommends which domains of NSLBP should be included in clinical trials investigating effectiveness or efficacy of interventions for NSLBP (Chiarotto *et al.*, 2015). The COS have been updated three times. A standardised measurement set were initially produced in 1998 consisting of a brief 6-item set for usual care (GP consultations) and an expanded set for research purposes (Deyo *et al.*, 1998).

These standardised measures were updated in 2015 to just four domains – pain intensity, physical functioning, number of deaths and HRQoL (Chiarotto *et al.*, 2015). These domains were updated again in 2018 and the current domains in the COS are pain intensity, physical functioning and HRQoL (Chiarotto *et al.*, 2018). There are no clear objective biomarkers for back pain, thus the self-reported pain, disability and HRQoL questionnaires are the only tools available for researchers to measure the impact NSLBP is having on an individual. When trying to subjectively measure NSLBP there are four clinically important domains which directly relate to NSLBP (Ostelo and de Vet, 2005). These are: pain intensity, NSLBP related disability, patient satisfaction with treatment outcome and work disability (Ostelo and de Vet, 2005). There are a variety of questionnaires and scales in the literature, which were designed to measure each of the four domains related to NSLBP. Some of the most commonly used questionnaires and scales to assess NSLBP include:

- Roland Morris Disability Questionnaire (RMDQ) (Roland and Fairbank, 2001)
- Oswestry Disability Index (ODI) (Fairbank *et al.*, 1980)
- Visual analogue scale (VAS) (Ogon *et al.*, 1996)
- Numeric pain rating scale (NPRS) (Childs, Piva and Fritz, 2005)

1.4 Low back pain and fear avoidance behaviours

The terms fear and anxiety are often used to describe the psychological burden of NSLBP on patients. Fear and anxiety are terms frequently used interchangeably when trying to explain behaviours towards pain, yet they have distinctly different meanings. Fear is defined as an emotional reaction to an identifiable, specific and immediate threat (Leeuw *et al.*, 2007). Fear instigates defensive behaviour, which may protect the individual from perceived harm, associated with the inherent flight or fight response (Leeuw *et al.*, 2007). Fear is composed of three components; interpretation of the stimulus (how an individual perceives the current situation and determines if there is a level of threat), increased sympathetic arousal (increases in heart rate (HR) or dilation of pupils), and defensive behaviour (avoiding the situation). Anxiety is described as a future-orientated affective state, with the source of threat being more elusive with no clear, direct focus. The components of anxiety are similar to those of fear, but they are less intense. Hypervigilance (increased awareness) is one of the main components of anxiety. The subtle difference in both terms is that anxiety provokes avoidance behaviours whereas fear induces preventative behaviours.

The fear avoidance model refers to the avoidance of activities or movement due to fear (Vlaeyen and Linton, 2000). Fear avoidance behaviours have been suggested to be one of the central mechanisms for the development of chronic NSLBP (Vlaeyen and Linton, 2000). Patients suffering with NSLBP are described to demonstrate behaviours of intolerance for physical activity (Verbunt *et al.*, 2001) and are reported to have lower levels of physical activity (van der Velde and Mierau, 2000; Smeets *et al.*, 2006; Ryan *et al.*, 2009) or altered levels of activity (Griffin, Harmon and Kennedy, 2012), compared to a population who do not suffer with NSLBP (Verbunt *et al.*, 2001).

Vlaeyen and Linton (2000) proposed a cognitive behavioural model of chronic NSLBP (CNSLBP) which has become widely known as the fear-avoidance model (see figure 1.2). Vlaeyen's fear avoidance model demonstrates the psychological processes and behaviours of those with NSLBP in relation to engaging in physical activity. The fear avoidance model has been used to explain a decrease in physical activity levels or general movement in individuals experiencing chronic pain (Lethem *et al.*, 1983). According to Vlaeyen's fear-avoidance model subgroups of individuals with CNSLBP are fearful of engaging in or

increasing their physical activity levels through fear of increasing or exacerbating their pain or perhaps fear of (re)injury (Lethem *et al.*, 1983; Philips, 1987; Vlaeyen and Linton, 2000; Leeuw *et al.*, 2007; Ryan *et al.*, 2009).

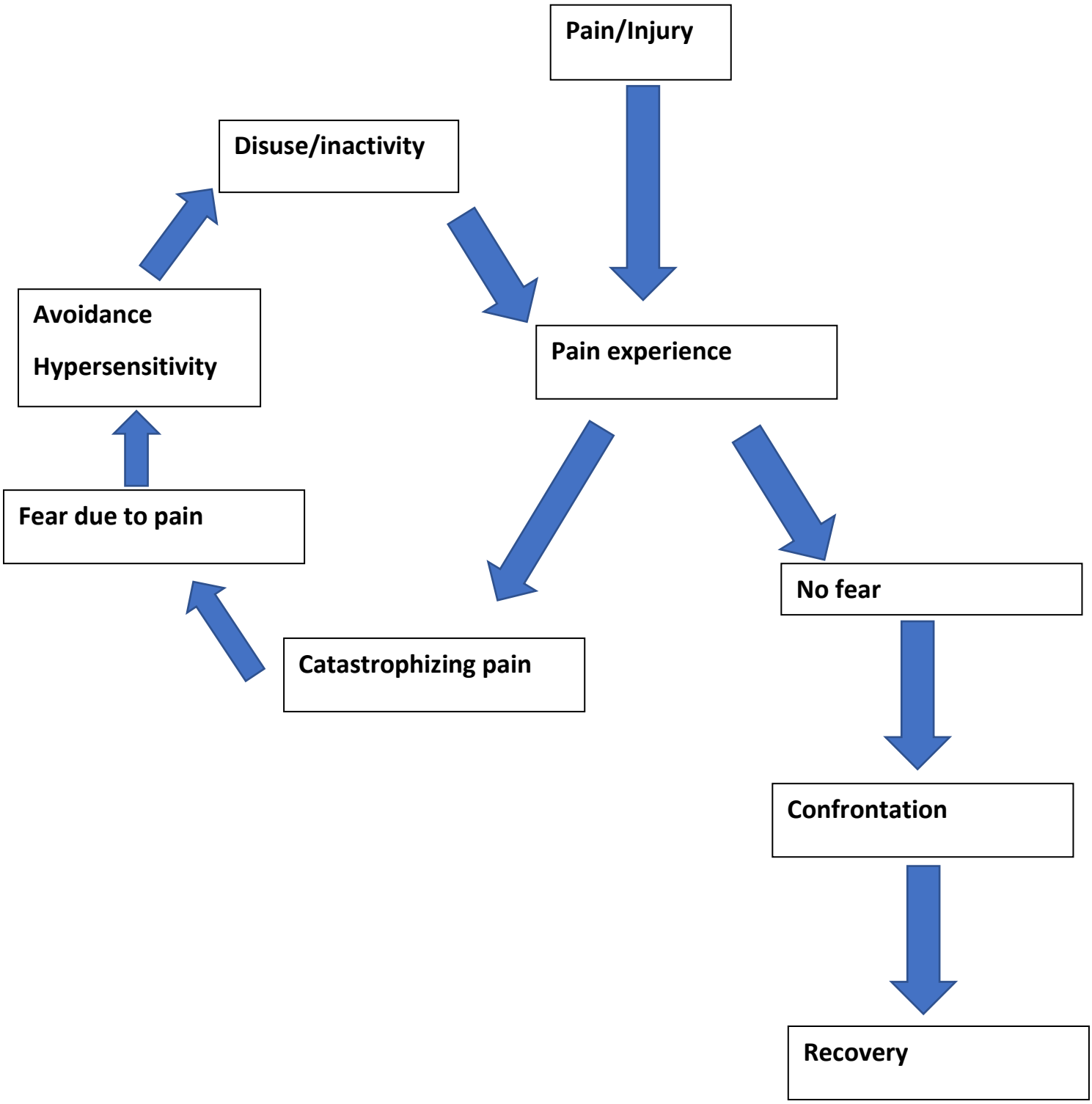


Figure 1.2: The fear avoidance model. Adapted from Vlaeyen and Linton (2000).

There is some controversy in the literature surrounding the idea of a NSLBP population displaying fear avoidance behaviours when it comes to physical activity (i.e., the belief that NSLBP patients do not demonstrate fear of activity). The avoidance-endurance model suggests that there are a sub-group of patients who ignore their pain and continue to be active despite their pain (Hasenbring, Hallner and Klasen, 2001). The claim that patients suffering with NSLBP have reduced physical activity levels compared to otherwise healthy individuals is also disputed in the literature.

Only a few studies, which have objective measures to calculate activity levels, have compared the activity levels of NSLBP patients against the activity levels of healthy controls (Ryan *et al.*, 2009). Some studies have shown no difference in the activity levels between healthy controls and CNSLBP patients (Spenkelink *et al.*, 2002; Weering, 2007). A systematic review focussing on the activity levels between healthy controls and NSLBP patients also discovered no conclusive evidence to suggest that CNSLBP patients are less active than healthy controls (Griffin, Harmon and Kennedy, 2012). No differences in energy expenditure (EE) were reported between people with CNSLBP and otherwise healthy controls in another study (Verbunt *et al.*, 2001). This means that the healthy controls and CNSLBP patients spent similar amounts of energy in a day on activity, after adjusting for average daily metabolic rate (ADMR) and resting metabolic rate (RMR). Other studies demonstrated that CNSLBP patients spent more time lying down during the day and evening, walking at a slower cadence and spend less time standing in the evening than their matched controls (Spenkelink *et al.*, 2002; van den Berg-Emons *et al.*, 2007). Similarly, Ryan et al. (2009) suggested that patients with NSLBP engaged in lower levels of physical activity and had an altered pattern of physical activity compared to matched healthy controls. The altered pattern of physical activity was attributed to CNSLBP patients walking at a slower cadence than the healthy, age-matched controls. The CNSLBP patients also took fewer steps in the evening.

The evidence surrounding NSLBP patients having reduced amounts of physical activity than matched healthy controls is not consistent with other evidence surrounding NSLBP patients and the fear avoidance model. However, there is a lot of heterogeneity amongst the studies aiming to measure physical activity levels in NSLBP versus (vs) healthy control population. The studies varied in the methods used to measure physical activity and NSLBP, and in what

the authors of the study were to measure - i.e., activity or EE. Different measures for physical activity will give contrasting results for levels of activity. Physical activity and EE are very different constructs (Hills, Mokhtar and Byrne, 2014). EE is a way of measuring activity intensity (Murphy, 2009) which takes into account a variety of confounding factors, such as the basal metabolic rate (BMR) of an individual. Using accelerometers to measure physical activity will provide different results to EE as accelerometers detect acceleration and can quantify time spent in activities which vary in intensity (Hills, Mokhtar and Byrne, 2014). No one measure can directly capture all aspects of physical activity in free-living conditions (Hills, Mokhtar and Byrne, 2014). There is a lot of heterogeneity between the studies in the methods used to quantify physical activity, which could explain the controversy in the literature.

The measures for pain used in the studies varied. Only three studies (Verbunt *et al.*, 2001; Ryan *et al.*, 2009; Smeets, van Geel and Verbunt, 2009) included a form of pain measurement (VAS 100 millimetre (mm) or pain diaries). However, the reported pain intensities did not appear to be significantly high – mean values and standard deviation (SD) reported at 31 ± 18 (Ryan *et al.*, 2009), 33.7 ± 27.2 (Verbunt *et al.*, 2001) and 49 ± 24.7 (Smeets, van Geel and Verbunt, 2009). These studies may not have found difference in activity levels because their population was not in enough pain to inhibit the amount of physical activity they engage in. These studies also did not include a measure for pain-related fear, such as the fear of pain questionnaire (FPQ). The participants in the studies may have had low amounts pain-related fear which therefore did not hamper their activity levels. Alternatively, the participants recruited may have been the type of patients which carry on with their activities despite their pain as stipulated by the avoidance-endurance model. These are potential reasons why the results of these studies did not find a difference between the healthy controls and NSLBP patients. Without a measure for pain-related fear, it is hard to determine the severity or impact NSLBP is having on a patient. By quantifying pain-related fear, future research could develop a scale to identify patients who may need more support from interventions designed to increase activity levels and identify patients who may not need as much support because they are not fearful of pain which may arise from movement.

Another possibility for the equivocal results between studies is the fact that many people are now leading a sedentary lifestyle (Sitthipornvorakul, Janwantanakul and Lohsoonthorn, 2015). The data released by Public Health England on the activity levels of adults in society nowadays supports this suggestion. Therefore, the possibility that NSLBP patients are being as active as their healthy counterparts could be simply down to the healthy counterparts leading a more sedentary lifestyle. With no studies providing baseline measures of physical activity before data collection it is also hard to determine if the physical activity data collected during the main trial provides an accurate representation of how active the groups are. Another limitation of these studies comes from a lack of adequate controlling. All of the studies mentioned above controlled for age and gender, but did not take work status into account, even though work status has been demonstrated to impact on physical activity (Sallis and Haskell, 1985; Philippaerts and Lefevre, 1998).

This amount of heterogeneity makes it hard to compare the results of one study with the results of another study. When designing interventions to manage NSLBP, fear avoidance behaviours should be taken into consideration. Such behaviour towards activity is a leading cause of disuse, which has been identified in the literature as engaging in a reduced amount of physical activity in day-to-day life (Verbunt *et al.*, 2003). By individuals reducing the amount of activity they engage in has the ability to maintain or worsen the condition (Verbunt *et al.*, 2003) and could lead to physical deconditioning (deterioration of cardiac and skeletal muscle).

1.5 Physical activity for musculoskeletal health and NSLBP

Physical activity is a vital component of leading a healthy lifestyle (Macera, Hootman and Sniezek, 2003). It is recommended that an individual engages in at least one hundred and fifty minutes of moderate physical activity a week (Tremblay *et al.*, 2011; World Health Organization, 2016). Physical activity and exercise are commonly used together, but the two words have different meanings. Physical activity has been defined, in the literature, as any form of bodily movement which involves EE and is produced via the skeletal muscles (Caspersen, Powell and Christenson, 1985). This includes any activity undertaking when playing, working, doing housework, travelling, and participating in recreational pursuits.

Examples of these activities are: gardening, cycling, climbing stairs, shopping, dancing, walking, and lifting. Exercise is defined as a 'subset' of the umbrella term "physical exercise", which is mostly structured, repetitive and planned (Melzer, Kayser and Pichard, 2004; Marley *et al.*, 2014). Refer to figure 1.3 for physical activity and the domains which come under this umbrella term. Table 1.2 provides the definition of the different words which are associated with physical activity.

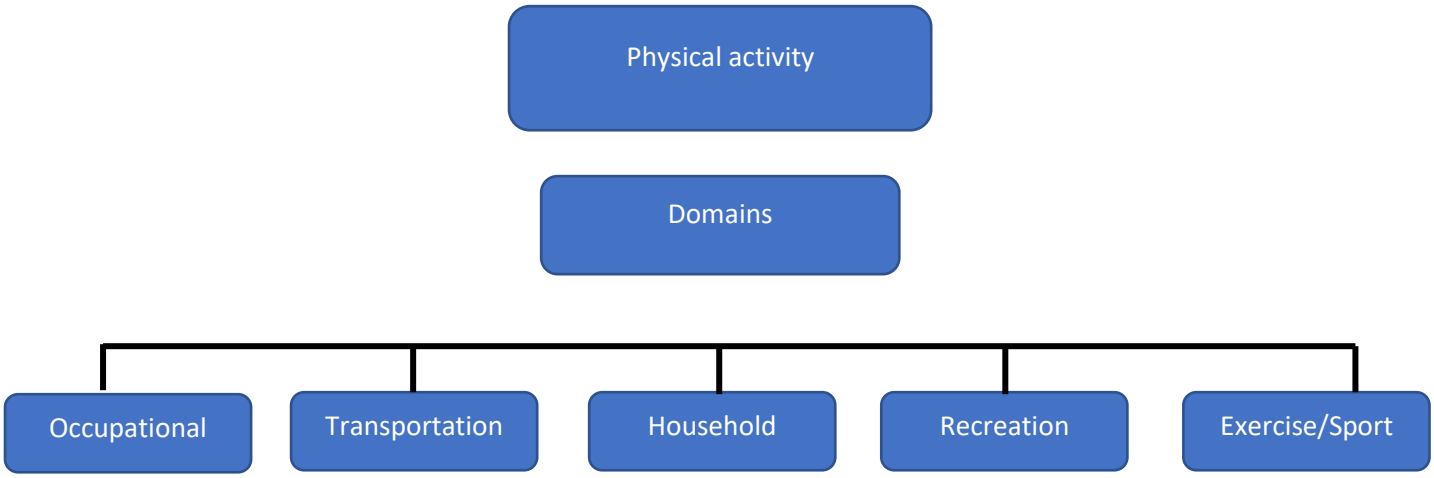


Figure 1.3: The domains of physical activity and the energy expenditure (EE) for each activity as presented from low to high EE

The idea that being physically active leads to multiple health benefits and longevity has been recognised for some time (Melzer, Kayser and Pichard, 2004). Physical activity is linked to enhanced health and reduced risk of all-cause mortality such as cardiovascular disease, hypertension, obesity, osteoporosis, sarcopenia, cognitive disorders (such as Alzheimer's or dementia (Laurin *et al.*, 2001; Jedrziewski, Lee and Trojanowski, 2007)), type 2 diabetes and some forms of cancer (Melzer, Kayser and Pichard, 2004). It has been shown that engaging in regular physical activity can lead to as much as a 30% reduction in all-cause mortality rates (Melzer, Kayser and Pichard, 2004).

Table 1.2: Terms and definitions of the different subsets used to describe physical activity. Adapted from Melzer et al., 2004.

Term	***Definition/description***
Physical activity	Any bodily movement, resulting in EE, produced by skeletal muscles
Leisure time physical activity	Activity an individual participates in during their free time. This type of activity is often based on the individual's personal interests and preferences
Occupational physical activity	Any type of physical activity which is linked to an individual's job - usually occurs during a typical workday (eight-hour period)
Exercise	A subset of physical activity that is planned, structured, and repetitive. Exercise normally has a predetermined goal such as improving physical fitness.
Aerobic exercise	Exercise involving large muscle groups during dynamic activities. This type of activity usually results in an increase in HR and EE
Anaerobic exercise	High intensity exercise, over a short period of time. A lot of the energy provided comes from glycolysis and stored phosphocreatine
Resistance exercise	Exercise to increase muscular strength, endurance and power by using a variety of resistances (i.e., weights) - usually repeated for a predetermined number of times in a single set (group) of exercise. Numbers of sets increase or decrease depending on the goal and often have rest intervals
Physical fitness	Characteristics which are either health or skill-related such as physical endurance, flexibility, muscular strength, and body composition

Recent systematic reviews on physical activity (Warburton, Gledhill and Quinney, 2001a, 2001b) have reported that functional independence, glucose homeostasis, mobility, bone health, overall QoL and psychological well-being are associated with an enhanced musculoskeletal health (Warburton, Nicol and Bredin, 2006). Physical activity can elicit health benefits in people who were previously sedentary (Warburton, Nicol and Bredin, 2006). Physical activity aids the development of strong muscles, tendons and ligaments, thicker and denser bones, and healthy joints. Aerobic fitness does not need to change in order for improvements in health status to occur as a result of increasing physical activity levels (Warburton et al., 2006).

There are several biological mechanisms responsible for the reduction in chronic disease and disability with routine physical activity (Warburton, Nicol and Bredin, 2006). Physical activity can produce beneficial effects on the body on a local (within muscle or bone structures), structural (the musculoskeletal system) and psychological platforms.

Physical activity has demonstrated an effect on:

- improving body composition (Seidell *et al.*, 1991; Warburton, Gledhill and Quinney, 2001b, 2001a; Maiorana *et al.*, 2003)
- reducing blood pressure, improving glucose homeostasis and insulin sensitivity, enhancing lipid lipoprotein profiles (Halle *et al.*, 1996; Berg *et al.*, 1997; Warburton, Gledhill and Quinney, 2001b, 2001a)
- increasing high-density lipoprotein (HDL) cholesterol levels and improving autonomic tone (Adamopoulos *et al.*, 1992; Tiukinhoy, Beohar and Hsie, 2003),
- reducing systemic inflammation (Adamopoulos *et al.*, 2001)
- decreasing blood coagulation (Rauramaa *et al.*, 1986; National Institutes of Health, 1996)
- augment cardiac function (Warburton *et al.*, 2004)
- enhancing endothelial function (Hambrecht, Gielen, *et al.*, 2000; McGavock *et al.*, 2004)
- improving coronary blood flow (Hambrecht, Wolf, *et al.*, 2000; Warburton, Nicol and Bredin, 2006).

Routine physical activity can improve musculoskeletal fitness (Warburton, Nicol and Bredin, 2006). Increasing evidence shows that enhanced musculoskeletal fitness is linked to improvements in overall health status, disability and chronic diseases (Warburton, Nicol and Bredin, 2006).

Due to the wide range of health benefits, physical activity is commonly advised and prescribed in rehabilitation programmes (Ribaud *et al.*, 2013) and is claimed to be a vital part of rehabilitation programmes for patients with NSLBP (Schaller and Froboese, 2014). The majority of the guidelines relating to NSLBP refer to the importance of regular physical activity and exercise in the prevention and management of the condition (Burton *et al.*, 2006; Chou *et al.*, 2007; Savigny *et al.*, 2009; National Institute for Health and Care Excellence, 2016). Physical activity can be beneficial for NSLBP in several ways. NSLBP is sometimes associated with an increase in inflammation in the affected area, potentially in some of the tissues of the lower back (Langevin *et al.*, 2009). Moderate exercise/bouts of physical activity generate an anti-inflammatory response on the body, due to the production and release of Myokines. This has been demonstrated to decrease the levels of inflammatory markers in the body in randomised controlled trials (RCTs) (Warburton et al., 2006). It has also been suggested that physical activity increases blood flow to the back (Benjamin, 2014; Gordon and Bloxham, 2016). This is important as increased blood flow to the back is reported to aid the healing process of the soft tissues (Benjamin, 2014; Gordon and Bloxham, 2016; Gopez, 2017).

Physical activity is considered to be a contributor to bone development and in strengthening the connective tissues of the musculoskeletal system (Melzer, Kayser and Pichard, 2004). It is well documented that if some muscular structures of the spine or connective tissues (such as transverse abdominis or multifidus) are weak in a person, then the person is at risk of suffering from NSLBP (Panjabi, 2003; Moseley and Hodges, 2005; Demoulin *et al.*, 2007; Ferreira *et al.*, 2007; Hodges *et al.*, 2009).Therefore, strengthening of these connective tissues and structures, through regular physical activity and exercise, may be beneficial in reliving an individual's NSLBP pain or disability. A negative process termed physical deconditioning or disuse syndrome (figure 1.4) could exacerbate pain in NSLPB patients if they avoid activity due to their pain levels. Physical deconditioning is defined as a reduction in physical fitness which can lead to a deconditioning of musculoskeletal strength,

cardiovascular endurance and neuromuscular coordination (Mayer and Gatchel, 1988). Deconditioning of the musculoskeletal system can cause muscular weakening or atrophy, bone mineral density reduction (a precursor to osteopenia and osteoporosis) and loss of motor control (Verbunt, 2003). Worsening of musculoskeletal fitness, through physical deconditioning, can lead to a rapid decline in the capacity to perform basic activities of daily living such as climbing the stairs, or getting out of a chair (Warburton, Nicol and Bredin, 2006) (see figure 1.5).

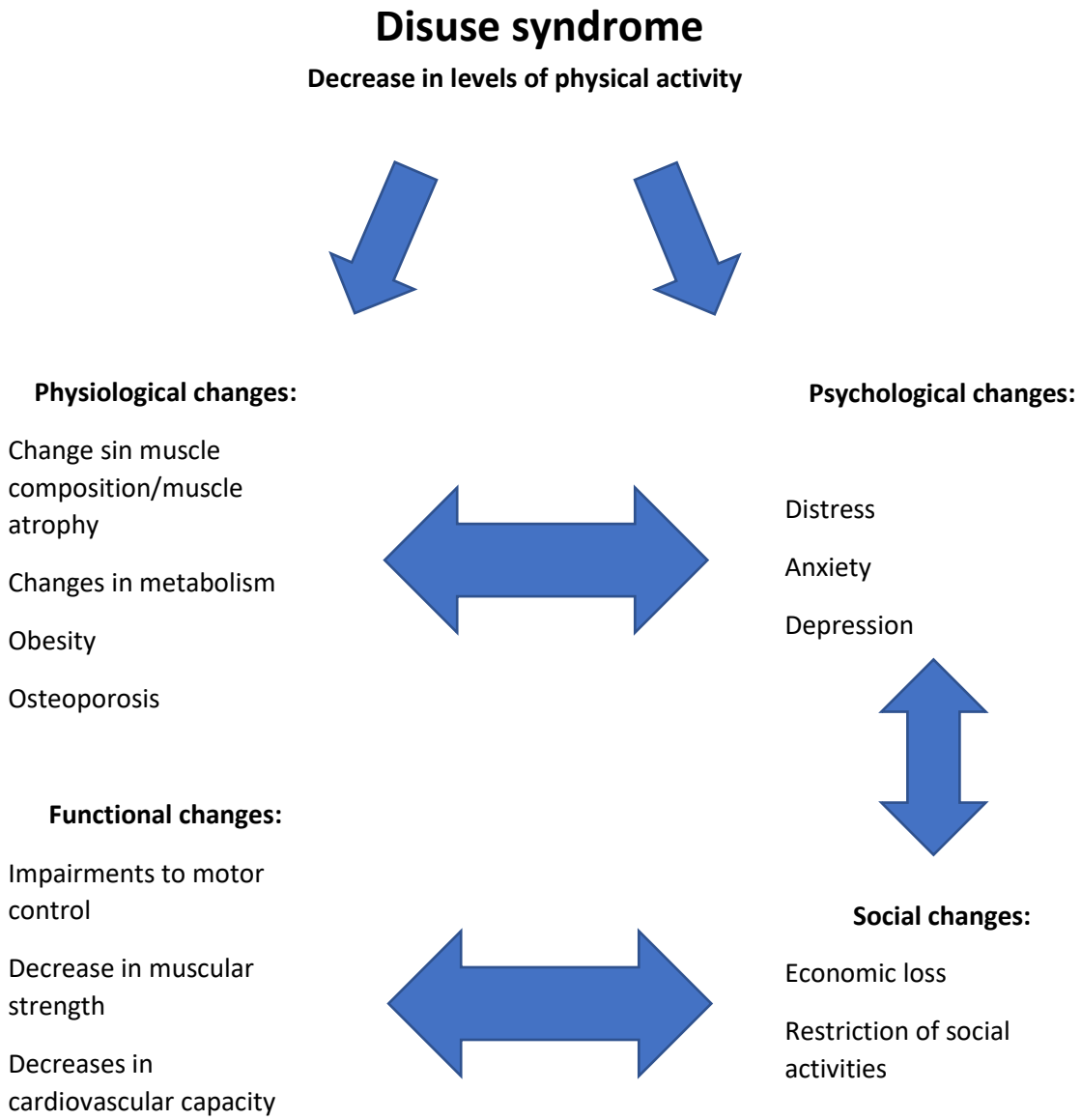


Figure 1.4: Disuse syndrome: consequences of long-term inactivity for individuals (Verbunt *et al.*, 2003).

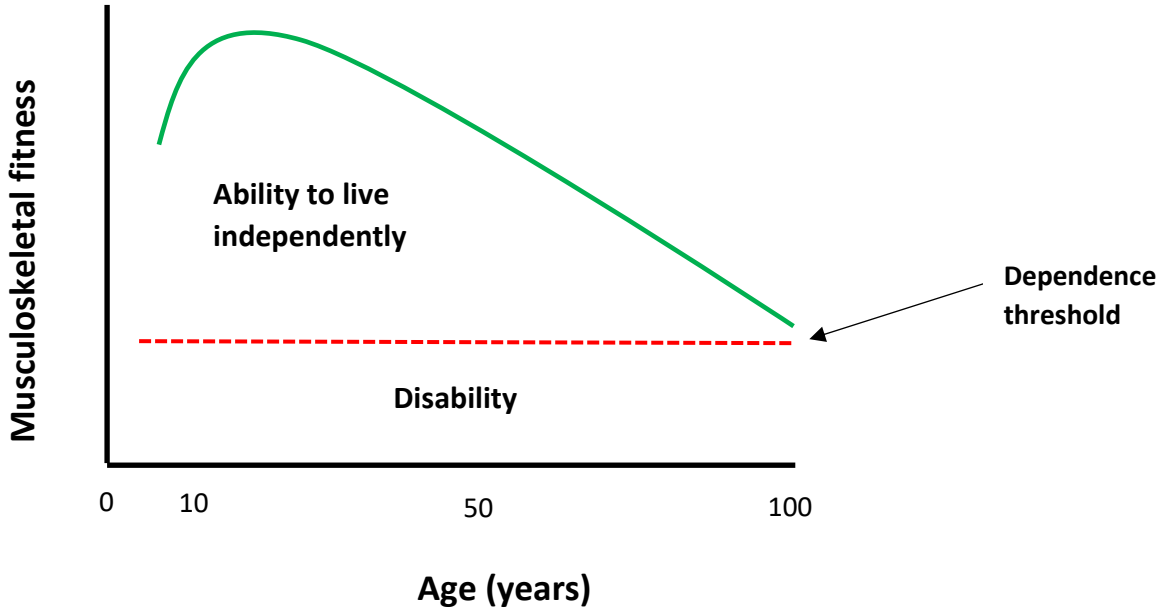


Figure 1.5: Theoretical relationship between musculoskeletal fitness and independent living. Adapted from (Warburton, Nicol and Bredin, 2006).

Physical activity is also linked to elevations in mood rates and increased psychological well-being (Guszkowska, 2004). NSLBP patients can become depressed, anxious or distressed – demonstrated extensively in various studies (Taylor, Sallis and Needle, 1985; Fox, 1999; Verbunt *et al.*, 2003). However, engaging in regular physical activity can improve mental well-being and QoL in NSLBP patients (Fox, 1999; Verbunt *et al.*, 2003). There is evidence that physical activity can improve psychological well-being by reducing stress, depression and anxiety (Guszkowska, 2004; Taylor et al., 1985; Tomporowski, 2003; Verbunt et al., 2003; Warburton et al., 2006). This is due to the influence physical activity has on the hypothalamic-pituitary-adrenal (HPA) axis, which affects the physiologic reactivity to stress (Guszkowska, 2004; Sharma, Madaan and Petty, 2006; Ströhle, 2009). Regular physical activity can affect HRQoL. HRQoL is directly related to functional status and the ability to maintain independence (Macera, Hootman and Sniezek, 2003). It seems that physical activity improves HRQoL by enhancing psychological well-being (positive relationships with

others, personal growth etc.) and improving physical functioning in individuals with poor health (Macera, Hootman and Sniezek, 2003).

1.6 Physical activity and exercise interventions for the management of non-specific low back pain

Physical activity and exercise interventions are prominent interventions in NSLBP research. These types of interventions are recommended within the guidelines set by NICE to encourage NSLBP patients to self-manage their back pain by engaging in regular physical activity (National Institute for Health and Care Excellence, 2016). There is a difference between these two types of intervention. Exercise interventions are traditionally structured and premediated (planned prior to trial commencement) and physical activity interventions focus on increasing activity as part of a participant's daily routine (Dunn *et al.*, 1999). Exercise interventions have been a primary focus in the research for NSLBP. Table 1.3 demonstrates the different types of exercise interventions which have been investigated in NSLBP research. Physical activity interventions have been focused on less by researchers, with only a few trials published (Taylor, Evans and Goldie, 2003; McDonough *et al.*, 2010; Hurley *et al.*, 2015; Milosavljevic *et al.*, 2015; Olaya-Contreras *et al.*, 2015).

Table 1.3: Research which has investigated the use of exercise interventions for NSLBP management.

Type of exercise	Authors
Pilates	Rydeard, Leger and Smith (2006); Donzelli *et al.* (2006); Gladwell *et al.* (2006); Sorosky, Stilp and Akuthota (2008); La Touche, Escalante and Linares (2008); da Fonseca, Magini and de Freitas (2009); Posadzki, Lizis and Hagner-Derengowska (2011); Quinn, Barry and Barry (2011); Pereira *et al.* (2012); Wajswelner, Metcalf and Bennell (2012); Aladro-Gonzalvo *et al.* (2013); da Luz *et al.* (2014); Cruz-Diaz *et al.* (2015(; Natour *et al.* (2015); Yamato *et al.* (2015(; Cruz-Diaz *et al.* (2017); de Oliveira *et al.* (2016); Kofotolis *et al.* 2016); Oksuz and Unal (2017)
Yoga	Williams *et al.* (2005); Tekur *et al.* (2008); Posadzki and Ernst (2011); Tilbrook *et al.* (2011); Cramer *et al.* (2013); Saragiotto, Yamato and Maher (2015); Wieland *et al.* (2017)
Low-to-moderate intensity aerobic exercise	Chan, Mok and Yeung (2011); Shnayderman and Katz-Leurer (2013)
High intensity aerobic exercise	Chatzitheodorou *et al.* (2007); Chatzitheodorou, Mavromoustakos and Milioti (2008)
Core stabilisation and muscular strength exercises	Hodges and Richardson (1996); Suni *et al.* (2006); Hall *et al.* (2009); Aluko, DeSouza and Peacock (2013); Inani and Selkar (2013); Kim *et al.* (2013)

Type of exercise	**Authors**
Stretching/flexibility programmes	Kuukkanen and Mälkiä (1998); Gladwell *et al.* (2006); Masharawi and Nadaf (2013); Yang, He and Zhou (2018)
Exercise therapy*	Abenhaim *et al.* (2000) and Hayden, van Tulder and Tomlinson (2005)
Movement coaching	Schaller *et al.* (2016)

*Exercise therapy is defined as "a series of specific movements with the aim of training or developing the body by a routine practice or as physical training to promote good physical health" (van Middelkoop *et al.*, 2011)

Several systematic reviews and meta-analyses (Hayden *et al.*, 2005; Hayden, van Tulder and Tomlinson, 2005; Lim *et al.*, 2011; Posadzki and Ernst, 2011; Posadzki, Lizis and Hagner-Derengowska, 2011; Searle *et al.*, 2015; Gordon and Bloxham, 2016; Wewege, Booth and Parmenter, 2018; Owen *et al.*, 2019) have been conducted to investigate which exercise interventions are the most effective in reducing pain and disability levels in the self-management of NSLBP. However, the most effective form of exercise intervention for the treatment and management of NSLBP is still unknown (Hayden, van Tulder and Tomlinson, 2005; Kolber and Beekhuizen, 2007; Foster *et al.*, 2018).

Exercise interventions may not be demonstrating effectiveness due to the prescribed nature of the exercise. If the prescribed exercise is not of interest to the patient or does not fit into the patient's daily routine, the exercise may not be sustainable and could result in poor patient adherence in the trial. Adherence to the interventions in NSLBP trials is reported to be low (Hanney, Kolber and Beekhuizen, 2009; Marley *et al.*, 2014; Milosavljevic *et al.*, 2015). Non-prescribed, unsupervised physical activity interventions may be more sustainable as the patient will be able to choose an activity they enjoy doing and which can fit into their daily routine. This in turn could increase adherence in trials. It has been reported that physical activity interventions which are able to fit into an individual's routine can lead to uptake and sustainability of the behaviour (Ogilvie *et al.*, 2007; Yang *et al.*, 2010).

During a literature search for this thesis, no systematic review or meta-analyses could be found for the effectiveness of physical activity interventions on NSLBP, aside from the reviews investigating the effectiveness of the "advice to stay active" on NSLBP (Waddell, Feder and Lewis, 1997; Liddle, Gracey and Baxter, 2007). It is unclear if there are any non-prescribed, unsupervised physical activity interventions in the literature. Similarly, it is unclear if the content of physical activity interventions has been systematically evaluated in the literature. If it is unclear what components of interventions work and which components do not, NSLBP research does not have a clear direction on how to advance either pre-existing or new physical activity interventions to maximise effectiveness. This highlights potential gaps in physical activity interventions in NSLBP research and demands further exploration.

1.7 Conclusion

NSLBP presents a global economic burden and affects the physical, psychological, and social aspects of an individual. Physical activity has been suggested to be beneficial for patients with NSLBP and is recommended by national and international guidelines. However, there is still no consensus on which physical activity or exercise interventions are beneficial to NSLBP patients in terms of reducing pain and disability levels, increasing HRQoL and increasing the physical activity levels of this population. The psychological aspects of NSLBP are starting to be investigated in NSLBP research, but it is also unclear if authors of trials are considering these psychological aspects during the design of trial protocol and interventions. It is also unclear if the content of physical activity or exercise interventions have been evaluated. The field cannot be advanced if there is no clear direction on how future physical activity interventions need to be delivered to NSLBP patients to help in the self-management of the condition and positively affect the COS (pain, pain-related disability and HRQoL) for NSLBP patients.

1.8 Chapter summary

- The terms “physical activity interventions” and “exercise interventions” are used interchangeably in the literature, yet the content of these types of interventions are distinctly different
- The effectiveness of physical activity or exercise interventions for NSLBP patients in reducing pain and disability scores is disputed in the literature, with no consensus on which type of interventions are most effective for NSLBP patients
- There are gaps in the current research using physical activity interventions in a NSLBP population
- The majority of physical activity interventions are supervised, prescribed, and directed by the researchers of the trial.
- Non-prescribed and unsupervised interventions may be more sustainable and appealing for a NSLBP population due to the multifactorial and subjective nature of the condition

The next chapter:

The next chapter conveys the systematic review which evaluated the content of non-prescribed and unsupervised physical activity interventions in NSLBP research.

Direction of the thesis:

This thesis examines the current research of interventions used to promote and increase physical activity levels in NSLBP patients, and evaluates the content of these interventions (e.g., intervention development, use of psychological models and tools). The validity and reliability of a mounting method of an objective measure for physical activity was investigated to inform the main trial of this thesis *(Chapter 3)*. This thesis reports on a four-armed, randomised feasibility-pilot trial, which used four interventions, conducted in an educational osteopathy clinic (*Chapter 7)*. The interventions used in this trial have been developed and informed by behaviour change techniques, as reported in *Chapter 4*. The aim of this trial was to assess feasibility using a mixed methods research paradigm (*Chapters 5 and 6).*

2 Chapter 2 – Evaluation of the content of physical activity interventions for non-specific low back pain patients: a systematic review

2.1 Chapter introduction

This chapter presents the results of an initial scoping exercise to determine the breadth of the literature surrounding NSLBP and non-prescribed, unsupervised physical activity interventions. This chapter describes the aim of the review, the rationale behind why the review was necessary and how it enhances the knowledge of the current literature. This chapter also describes the systematic review protocol and displays the results of the systematic review.

2.2 Introduction

Physical activity interventions for NSLBP patients are becoming prominent in NSLBP research. The NICE guidelines recommend patients with NSLBP should be encouraged to be active despite their pain (National Institute for Health and Care Excellence, 2016). There is no clear consensus on how to get the NSLBP population more active. Knowledge about the effectiveness of physical activity interventions in increasing physical activity levels of NSLBP patients is limited. Conflicting results are often published (i.e., some results show effectiveness, others do not) and this problem needs to be addressed to allow for the design of effective and efficient interventions to increase activity behaviours for patients in the self-management of NSLBP. Adherence to physical activity interventions in NSLBP patients is low (Hanney, Kolber and Beekhuizen, 2009; Ryan *et al.*, 2009; McDonough *et al.*, 2010; Lonsdale *et al.*, 2012; Marley *et al.*, 2014; Milosavljevic *et al.*, 2015).

For physical activity interventions to provide a beneficial effect for NSLBP patients, they need to be able to change an individual's behaviour towards physical activity and lead to the adoption of activity. Interventions aimed at trying to change a person's attitude/behaviour towards a particular entity should be informed by behaviour change theories and health

models (Michie et al. 2011; Cane et al. 2012; Michie et al. 2011). The NICE guidelines have suggested that establishing the behaviour change techniques (BCTs) and behaviour change theories designed to encourage and sustain physical activity in pain management needs to be a research priority (National Institute for Health and Care Excellence, 2014, 2016). Behaviour change theories and BCTs should be incorporated into any type of intervention aiming to change behaviour (Michie, van Stralen and West, 2011). Evidence suggests that the interventions which are designed using behaviour change theories and BCTs are more effective than the interventions which are not (Michie, van Stralen and West, 2011). Health care interventions are reported to often be theoretically underdeveloped (Michie, Ashford, *et al.*, 2011; Michie *et al.*, 2013). The descriptive nature of some interventions is insufficient, in terms of the intervention content and delivery (Michie *et al.*, 2009; Michie, Abraham, *et al.*, 2011; Hoffmann *et al.*, 2014). Details of any BCTs and theories employed to encourage participant adherence to the intervention are also absent (Michie, Abraham, *et al.*, 2011). Previous systematic reviews have not examined or evaluated the use of BCTs or behaviour change theories in the intervention design and have not differentiated between studies that do and do not use BCTs or theories. These tools can aid participant adherence to an intervention and could enhance the sustainability of the new behaviour.

Previous systematic reviews (Hayden *et al.*, 2005; Hayden, van Tulder and Tomlinson, 2005; Lim *et al.*, 2011; Posadzki and Ernst, 2011; Posadzki, Lizis and Hagner-Derengowska, 2011; Gordon and Bloxham, 2016) have investigated the effect of a premediated exercise or pain management programme(s). Previous physical activity trials (Taylor, Evans and Goldie, 2003; McDonough *et al.*, 2010; Hurley *et al.*, 2015; Milosavljevic *et al.*, 2015) have focused on premediated mode of physical activity, predominately walking. There is a common limitation with premediated physical activity and exercise interventions. These activities or exercises may not be what the participants may necessarily engage in or have a desire to engage in. Adherence to premediated physical activity and exercise interventions may therefore be low. Non-prescribed interventions may demonstrate better effects on NSLBP as the participant can choose an activity that appeals to them and thus may encourage them to be more adherent with the intervention. Non-prescribed, unsupervised physical activity interventions have not yet been evaluated in the current literature. The content of

non-prescribed, unsupervised physical activity interventions has also not been evaluated in the literature.

There is a need for a systematic review and meta-analysis to synthesize the RCTs which have 1) used non-prescribed and unsupervised interventions to increase physical activity levels in NSLBP patients and 2) used appropriate BCTs and behaviour change theories in the interventions. The behaviour change theories and BCTs which support the intervention(s) were identified and evaluated where possible.

2.3 Initial scoping

Following recommendations of Armstrong *et al.* (2011), prior to conducting the systematic review, an initial scoping review was conducted to identify the breadth of the literature of NSLBP and physical activity interventions, to determine the appropriate framework for the review (i.e., in characterising the targeted population, intervention, comparators and outcomes (PICO)) and in determining the probable capacity of the systematic review. The scoping review was conducted in order to develop and pilot the search strategies and eligibility criteria to gain a general scope of the literature.

The search strategies (appendix A) were applied to the following databases: MEDLINE, PubMed, CINHAL, ScienceDirect, ISI Web of Science, APA PsycNET (psycARTICLES and psycINFO), Cochrane Library, and SPORTDiscus. Each database was searched for studies published from inception to December 2018. Grey and unpublished literature was searched for using the SIGLE database for grey literature.

2.3.1 Scoping results

The results of the brief scoping review of the literature demonstrated that the search strategies and eligibility criteria were not appropriate. There was a lot of difficulty in identifying interventions which used non-prescribed activity interventions as the main intervention in RCTs. The eligibility criteria stipulated that trials were excluded if the non-prescribed interventions were not the focus of the RCT (i.e., these interventions could not

be used in a control group). After applying the eligibility criteria to all the studies retrieved, there were no studies which were relevant for the review. Therefore, the protocol used in the scoping review demanded rigorous refinement. This ensured the systematic review had a better purpose and direction which would lead to a more informative and purposeful review.

Refinements in the protocol

A refinement in the search terms was required as there were a lot of studies retrieved which had no relevance to the main topic of the review (i.e., studies about pregnancy and surgery). The refinements in the search terms were completed by changing the Boolean operators used and by adding in search terms to include relevant articles which may appear under different keywords relating to specific therapies, such as physiotherapy or chiropody and rehabilitation.

Two databases (ScienceDirect and ISI Web of Science) were removed from the search strategy and another database was included (PEDro). ScienceDirect was excluded because the database provides coverage of the Physical Sciences and Engineering, Life Science, Health Sciences and Social Sciences and Humanities. ISI Web of Science was excluded as a database as it mainly covers Science, Social Sciences, and Arts and Humanities. These databases would not have provided articles which were relevant to the aim of the systematic review. The database PEDro was included because PEDro is a Physiotherapy Evidence Database. The reviewers decided more appropriate and relevant articles could be sourced in this database.

The initial eligibility criteria were refined. The initial exclusion criteria were restrictive in what interventions could be included in the review. Any trials using muscle-specific exercise-based interventions or site-specific rehabilitative exercises interventions were to be excluded regardless if a non-prescribed intervention was also present. Moreover, the non-prescribed interventions were required to be the main intervention of the trial. As such, any trials using non-prescribed activity as a control group were excluded. This led to no trials being eligible during the initial scoping. Refinement of the exclusion criteria allowed for

trials using non-prescribed interventions in the control group to be included in the systematic review.

2.4 Systematic Review

2.4.1 Aim of this review

The aim of this systematic review was to assess the content of non-prescribed physical activity interventions used in NSLBP research. A descriptive account of the interventions, in the included trials, is provided, including an appraisal of the behaviour change theories or BCTs which were present in the interventions, when applicable.

There were two additional aims of this review: 1) to assess which interventions demonstrated effectiveness of non-prescribed physical activity interventions on reducing pain, pain-related disability, and increasing HRQoL and physical activity in patients with NSLBP, and 2) to evaluate the different methods studies were using to measure the amount of physical activity the participants engaged in, how they measured compliance and the validity of these measures in the literature.

2.5 Methodology

2.5.1 Search methods for study identification

A detailed search strategy to identify potential studies for inclusion was used for each of the electronic databases selected for this review (appendix B).

2.5.2 Electronic databases

The databases searched were: MEDLINE, SPORTDiscus, APA PsycNET, PubMed, PEDro, CINAHL and the Cochrane Library. Each database was searched for articles published from inception to January 2019. Grey and unpublished literature was searched for using the SIGLE database for grey literature.

Definition of "non-prescribed" and "unsupervised" physical activity interventions

General advice to stay active from either a researcher or health care professional(s) (HCPs) or advice to continue to engage in activities of daily living/physical activity at first contact. This advice does not specify which type of activity the patient should do (non-prescribed) and leaves it up to the patient to decide how they wish to be physically active or more physically active. Whatever activity the patient decides to do is not supervised by a HCP or exercise specialist (i.e., no-one is present to ensure the patient is doing the activity). This is exclusive of wellbeing programmes, social programmes, and social prescribing.

Definition of "prescribed" physical activity interventions

Prescribed interventions were defined as specific physical activities provided to the participants by either a researcher or HCP. These activities may or may not be supervised (i.e., someone watching the participant engage in the activity). Prescribed physical activity refers to any activity which is planned, structured and/or repetitive. This type of activity includes patient handouts of exercises, dedicated programmes, and chronic disease self-management programmes (CDSMP).

2.6 Eligibility criteria

2.6.1 Inclusion criteria

Studies which met the following inclusion criteria were used in this review.

1. Published English language RCTs, using a physical activity-based intervention for patients with NSLBP. Physical activity was defined as - "any bodily movement produced by the skeletal muscles requiring energy expenditure" (Caspersen, Powell and Christenson, 1985).
2. Studies using non-prescribed, unsupervised interventions aimed at promoting physical activity. This means that if the intervention advised the participants to be

more active, the participants need to have chosen the way they increased their physical activity levels. This type of intervention may be in the control group.

3. Outcome measures (objective or subjective) which provided a measure for at least one of the following: pain, pain-related disability and HRQoL. Increases in physical activity were assessed if the study included a measure for this.
4. Adults (≥18 years of age) with NSLBP.

2.6.2 Exclusion criteria

The following exclusion criteria were applied.

1. Studies where participants in the trial were either perioperative or postoperative. Trials including participants with specific back pathology including trauma and fracture, recent history of spinal surgery, diagnosis of nerve root pain, spinal cord, or cauda equina compression, spinal stenosis, osteoporosis, cancer, infection, fibromyalgia, or systemic inflammatory disorders were excluded.
2. Mixed populations of back and spinal conditions with multiple pain locations were excluded.
3. Media campaigns or community-wide trials.
4. Studies which were not written in the English language or had not been translated into English were not included.

2.7 Outcomes

The primary outcomes of concern to this review were pain intensity and pain-related disability. For inclusion trials needed to provide a measure for pain recorded on standardised scales such as the visual analogue scale (VAS) (Collins, Moore and McQuay, 1997), numeric rating scale (NRS) (Turk, Rudy and Sorkin, 1993), questionnaires like the McGill Pain questionnaire (Melzack, 1975) or pain diaries. Pain-related disability needs to be measured using standardised scales or questionnaires such as the Roland Morris

questionnaire (RMDQ) (Roland and Fairbank, 2001), Oswestry Disability Index [ODI] (Fairbank *et al.*, 1980) or VAS for perceived disability (Boonstra *et al.*, 2008).
The secondary outcome of interest to this review was QoL (also reported as HRQoL). The additional outcome of interest was physical activity. The measures used, in included trials, to quantify physical activity were checked in the literature for validity and reliability. Included trials needed to provide a measure of HRQoL using validated tools such as the short-form 36 (SF-36) (Ware and Sherbourne, 1992), EuroQoL (EuroQoL Group, 1990), or similarly validated indexes. Physical activity was required to be measured either objectively or subjectively. Objective measures of physical activity include sensors such as pedometers, accelerometers etc. Subjective measures are predominately self-reported through the use of questionnaires such as the Baecke habitual physical activity questionnaire (BPAQ) (Baecke, Burema and Frijters, 1982), international physical activity questionnaire (IPAQ) (Lee *et al.*, 2011), activity diaries or logs. It was anticipated that most of the studies would not provide a measure for physical activity or have measurements for compliance in being more active.

2.8 Data collection and synthesis

2.8.1 Study selection

All the studies identified by the database search were screened by the first reviewer (SW). 50% (n= 1,512) of the titles were independently screened by two other reviewers (EV and JL). A PRISMA flow diagram (figure 2.1) demonstrates the articles included and eliminated at each stage of the screening process and provides reasons for the excluded articles at the full-text screening stage.

Uncertainty and disagreements regarding the inclusion of a study, at full text (n=5) were discussed between the two reviewers (SW and JL). On discussion, it was agreed not to include three of the papers (due to not meeting the inclusion criteria). The authors of the other two articles were contacted for further information to determine eligibility. Where full-text articles were not available for viewing, they were purchased from the British Library.

2.9 Data extraction and quality assessment

Data from the selected studies was extracted separately by two independent reviewers (SW and EV). A modified Cochrane data extraction form was used to extract the outcome measures (pre- and post-intervention scores for pain, pain-related disability and HRQoL) used in the eligible studies (see appendix C). Where applicable, confidence intervals (CI) and mean differences between groups were extracted. Any measures for physical activity were also extracted and described using the modified Cochrane data extraction form, if this information was present in the article. Methodologic quality of the eligible studies was assessed by two independent reviewers (SW and EV), using the Cochrane risk of bias tool.

Intervention content was extracted using the template for intervention description and replication (TIDieR) checklist (appendix D) to evaluate the description of the interventions used in the included trials. The TIDieR checklist was applied to each of the ten interventions used in the included trials. If it was unclear if an intervention met any of the items on the checklist, the item was not recorded as "met" (i.e., if counselling was given to the participants of an intervention, specific details of what was included in the counselling session needed to be described either in-text or provided as a supplementary material). To extract the BCTs and behaviour change theories a customised table was created and used (appendix E). The BCTs were coded in each of the interventions using the BCT Taxonomy, version one (BCTTv1) (Michie *et al.*, 2013). BCTs were only coded when there was clear evidence that the BCT was present – i.e., the BCT "goal setting" was not coded if the description of the intervention group just stated that exercises were completed. Specific details to show the goal set (i.e., exercise was to be completed once a day) were required.

2.9.1 Missing data

When there was data missing, the original authors of the article were contacted via email in an attempt to acquire the required data. Unreported data from the included studies (i.e., content of the materials used) which were relevant to the aims of this review, was handled by contacting the original authors to retrieve the missing information. This action was

completed for two of the papers which met the inclusion criteria of the review (Schaller and Froboese, 2014; Schaller *et al.*, 2016). The authors of these studies did not reply. These papers were only critically appraised as part of the narrative (Schaller and Froboese, 2014; Schaller *et al.*, 2016).

2.10 Results

2.10.1 Search results

From the initial search in seven databases yielding 75, 344 hits and after initial filters were applied 2, 092 titles and 788 abstracts were excluded as they did not meet the eligibility criteria. The most common reasons for exclusion were articles about NSLBP relating to pregnancy, spinal surgery or the trials did not include non-prescribed interventions. The search for unpublished and grey literature did not provide any articles which met the eligibility criteria. After full text screening of the remaining articles, four articles were included in the systematic review.

The characteristics and key findings of each study were summarised, condensed, and are presented in a summary table (table 2.1). The extracted variables included the author(s) and year; sample size; country and setting; interventions; timespan; outcomes assessed; authors' results; and the conclusion. The BCTs used in the interventions are described in the results section. A meta-analysis could not be conducted due to the small sample size of articles retrieved after the complete screening process and due to the lack of homogeneity in outcome measures between the studies.

The results of the systematic review identified several areas of weakness in the literature. Interventions were poorly described and were not developed using any behaviour change theories. The included articles did not provide any measure for physical activity and the included trials did not provide measurements for all the COS of NSLBP. Clinical significance of increases in outcomes measures was not discussed or reported and elements of performance bias was noted between the groups in included trials.

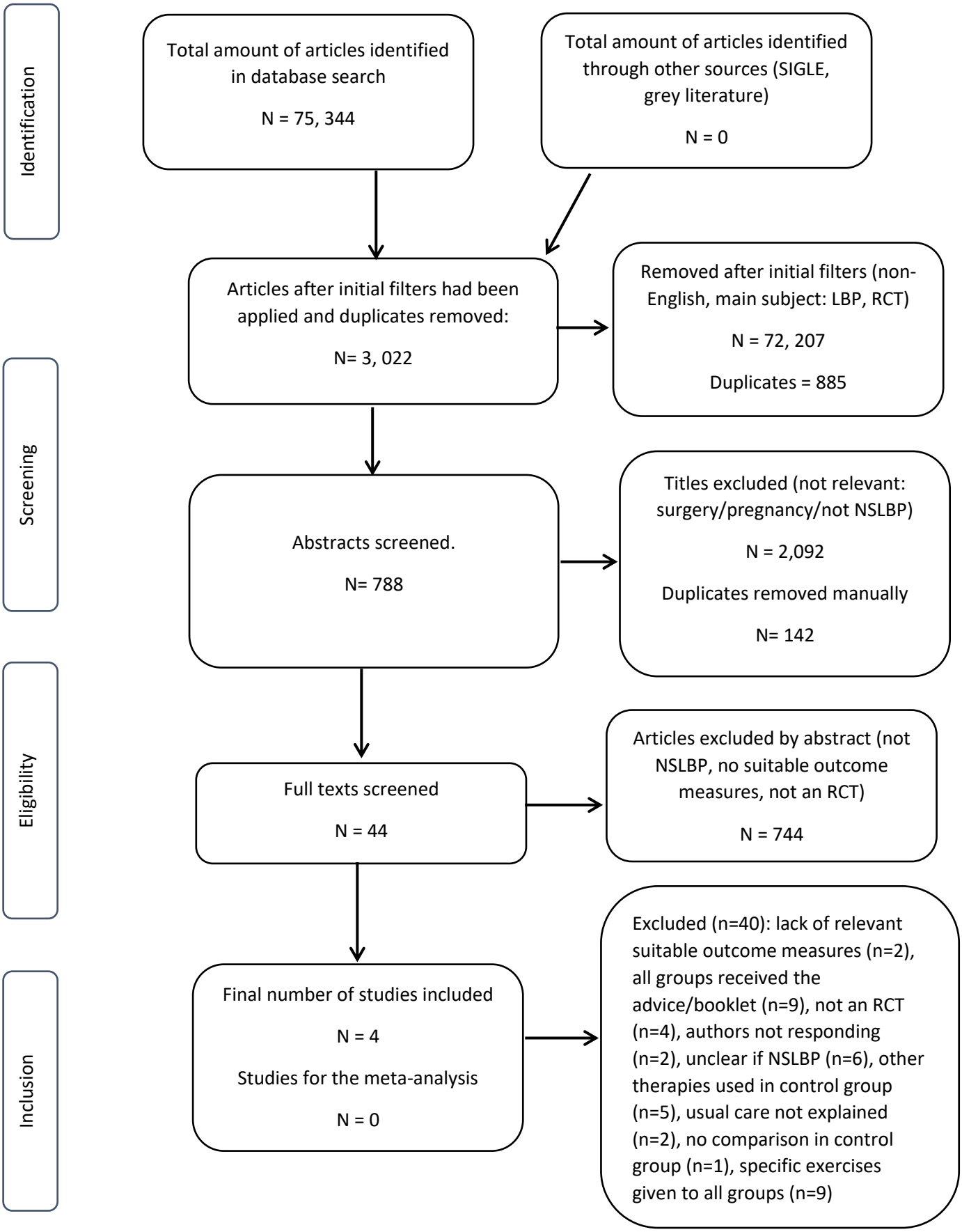


Figure 2.1: PRISMA flow diagram of screening phase

Table 2.1: Key characteristics of the included articles

Self-management of NSLBP using non-prescribed, unsupervised physical activity

Patients or population: NSLBP patients between 18-65 years

Setting: Outpatient clinics, hospitals, private practise

Intervention: Non-prescribed, unsupervised physical activity

Authors/year	Title	Sample	Location and setting	Intervention/Control	Outcomes	Results and Conclusion
Rozenberg *et al.* (2002)	Bed rest or normal activity for patients with acute low back pain	281	France, private practice	4 days of bed rest vs continuing normal activity	VAS, Efiel index	Results were reported as CI. Day 6 or 7 normal activity group (pain: 23.99 ±1.70) bed rest (pain: 28.05 ±1.74) CI: 90%, -8.06 to – 0.04. Disability for normal activity group (6.34 ±0.41) and bed rest (7.37 ±0.41) CI: 99% -2.55 to 0.50. **Conclusion:** Bed rest was demonstrated to be equivalent to continuing with normal physical activity
Rydeard, Leger and Smith (2006)	Pilates-Based Therapeutic Exercise: Effect on Subjects With Non-Specific Chronic Low Back Pain and Functional Disability: An RCT	39	Hong Kong, Private and public physician, and physiotherapy centres	4-week programme of Pilates vs usual care	NRS, RMDQ	Pilates-based exercise was reported to significantly decrease pain (p = 0.002) and disability (p = 0.023) compared to usual care. **Conclusion:** Pilates-based approach was more efficacious than usual care.

Authors/year	Title	Sample	Location and setting	Intervention/Control	Outcomes	Results and Conclusion
Aboagye *et al.* (2015)	Cost-effectiveness of early interventions for non-specific low back pain: A randomised controlled study investigating medical yoga, exercise therapy and self-care advice	159	Occupational health services (OHS) in Sweden's Stockholm County	6-week programme of medical yoga vs 6-week programme of exercise therapy vs self-care advice	ED-5Q	Medical yoga practiced more than twice a week, significantly increased HRQoL compared to self-care (p = 0.031). Medical yoga practiced less than twice a week did not significantly increase HRQoL compared with exercise therapy (p = 0.177) and self-care advice (p = 0.073). Medical yoga did not significantly increase HRQoL compared to exercise therapy when practiced more than twice a week (p = 0.574). **Conclusion:** six weeks of uninterrupted medical yoga is a cost-effective intervention for NSLBP patients, when adhered to.
Paatelma *et al.* (2008)	Orthopaedic manual therapy (OMT), McKenzie method or advice only for low back pain in working adults: A randomized controlled trial with one-year follow-up	134	Finland, in four occupational health care centres	Manual therapy vs McKenzie method vs advice only 3-7 treatments in the manual therapy or McKenzie method (mean 6 visits)	RMDQ, VAS	McKenzie method significantly decreased pain (p = 0.009) and disability (p = 0.003) at 6-months follow-up and disability at the 12-month follow-up (p = 0.028) compared to the advice-only group. No significant differences between OMT and usual care at the 6 month and 12-month follow-up for pain and disability scores (OMT disability score p = 0.068). **Conclusion:** OMT and McKenzie method was only slightly more effective than one session of advice-only and assessment.

2.11 Intervention descriptions

The TIDieR checklist (Hoffmann *et al.*, 2014) was used to evaluate the description of the interventions used in the included trials. The TIDieR checklist was designed to ensure sufficient intervention description was included in research articles (Hoffmann *et al.*, 2014).

None of the included trials met all 12-items on the checklist. The descriptions of the interventions in the included trial were scored against the 12-item checklist as either "included", "unclear" or "not included". The key items on the checklist for this review were the rationale or theory (for the included interventions) materials (booklets, exercise sheets etc.) used in the interventions, the procedures/processes used in the interventions, who provided the interventions (GPs, physiotherapists etc.) and intervention fidelity (i.e., was the intervention delivered as intended and adhered to).

Rozenberg *et al.* (2002) met 67% of the checklist criteria for the description of the two interventions used in the trial. Aboagye *et al.* (2015) only met 32% of the criteria on the TIDieR checklist across all the intervention groups. The description of the medical yoga group met only 16% of the checklist, whilst both the exercise therapy and self-care group met just 8% of the checklist criteria. Two of the trials (Paatelma *et al.*, 2008; Aboagye *et al.*, 2015) did not fully describe the materials (information) used in the interventions. For example, Paatelma *et al.* (2008) referred to an "educational component" but there was no description of what this educational component was or what is entailed. If the component is too complex to describe fully in the article, it is recommended the materials are presented as an appendix (Hoffmann *et al.*, 2014). Some of the included trials described the procedures and processes in full for some interventions and not for others (Rydeard, Leger and Smith, 2006; Paatelma *et al.*, 2008; Aboagye *et al.*, 2015). For example, Rydeard, Leger and Smith (2006) fully explained the apparatus and exercises used in the Pilates group, including frequency and duration of the exercises, but did not fully explain the procedure for the control group. Rozenberg *et al.* (2002) was the only author to provide information on who delivered the interventions. Similarly, only Rozenberg *et al.* (2002) included a detailed description of how well the interventions were adhered to by the participants - e.g., the bed rest protocol was followed by 75% of the participants randomised to that group. Percentages and mean scores were used to illustrate the adherence rates. Some trials

(Rydeard, Leger and Smith, 2006; Aboagye *et al.*, 2015) included a brief description of how the intervention adherence was being measured, but there was no description or evidence of how well the intervention(s) was adhered to. Paatelma *et al.* (2008) provided no description of how intervention adherence was measured, if it was measured.

2.12 Theoretical underpinnings and behaviour change techniques

Ten interventions were used in the four trials. The included articles were searched for the use of any theory (behaviour change or otherwise) underpinning the use of the interventions selected. There was no evidence or description of any behaviour change theories used in the interventions in the included trials. The interventions used in the trials were based on the rationale, results and scientific theories of previous research – i.e., the use of Pilates-based exercises was based on previous research indicating Pilates can assist in reconditioning altered neuromuscular control mechanisms linked to LBP (Rydeard, Leger and Smith, 2006). However, some BCTs were coded in the interventions (see table 2.2).

Table 2.2 Behaviour change theories and BCTs coded from the descriptions of the interventions used in the included trials

Trial	Intervention/Control		BCTs coded	Behaviour change theory
Rozenberg *et al.*, 2002	Intervention:	Bed rest	Instructions on how to perform behaviour Pharmacological support Goal setting Self-monitoring of behaviour	None described
	Control:	Continue with normal activity	Instructions on how to perform behaviour Pharmacological support Goal setting Self-monitoring of behaviour	
Rydeard, Leger and Smith, 2006	Intervention:	Pilates-based therapeutic exercise	Instructions on how to perform behaviour Behavioural practice/rehearsal Demonstration of behaviour Generalisation of target behaviour Self-monitoring of behaviour Goal setting Action planning	None described
	Control	Continue with normal activity	None coded	

Trial	Intervention/Control		BCTs coded	Behaviour change theory
Aboagye *et al.*, 2015	Intervention 1	Medical yoga	Instructions on how to perform the behaviour Behavioural practice/rehearsal Generalisation of target behaviour Goal setting	None described
	Intervention 2	Exercise therapy	Instructions on how to perform the behaviour Behavioural practice/rehearsal Generalisation of target behaviour Goal setting	
	Control	Self-care advice	Information about health consequences Pharmacological support Credible source Behaviour substitution	
Paatelma *et al.*, 2008	Intervention 1	OMT	Instructions on how to perform the behaviour Behavioural practice/rehearsal Generalisation of target behaviour Demonstration of behaviour Goal setting Action planning	None described

Trial	Intervention/Control		BCTs coded	Behaviour change theory
Paatelma *et al.*, 2008	Intervention 2	McKenzie method	Credible source Instructions on how to perform the behaviour Goal setting Action planning	
	Control	Advice only	Information about health consequences Pharmacological support Credible source Behaviour substitution	

The most BCTs coded in a single intervention was seven; for one intervention no BCTs were coded. Two of the included trials used *The Back Book* (Burton *et al.*, 1999) as an educational booklet for the control groups (Paatelma *et al.*, 2008; Aboagye *et al.*, 2015). *The Back Book* uses the BCTs of "information about health consequences", "credible source", "behaviour substitution", and "pharmacological support". The most commonly coded BCTs in the interventions were: "instructions on how to perform the behaviour" and "goal setting", coded from seven interventions (70%). Two other commonly used BCTs were coded in 40% of the interventions: "behavioural practice/rehearsal" and "generalisation of target behaviour".

Some BCTs could not be coded as it was unclear in the description of the intervention if the BCT was present. For example, Paatelma *et al.* (2008) describes that the control group received counselling with a physiotherapist and were given medication advice. The BCT "pharmacological support" could not be coded as it was unclear if the physiotherapist was suggesting medication to control pain to facilitate the desired behaviour. In one of the trials (Aboagye *et al.*, 2015) it was unclear if the BCT "action planning" could be coded in the two interventions due to the absence of detailed descriptions of the interventions.

2.13 Quality appraisal

Risk of bias in the included studies was assessed using the Cochrane risk of bias tool (Higgins *et al.*, 2011). A summary of the results is presented in table 2.3.

Table 2.3: Risk of bias

	Low	Unclear	High
	+	?	—

	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective outcome reporting	Other bias
Rozenberg *et al.* (2002)	+	+	?	?	—	?	+
Rydeard, Leger and Smith (2006)	+	+	?	+	?	+	—
Aboagye *et al.* (2015)	+	+	+	?	?	+	—
Paatelma *et al.* (2008)	+	+	?	?	+	+	—

Overall, the risk of bias of the included studies was judged as unclear. This judgement has been made due to the participants not being blinded to the intervention groups and other bias detected which could have had an effect on the outcomes of the trials.

Random sequence and allocation generation was met in all the included studies. Blinding of participants and personnel occurred in just one of the included trials. This was judged as unclear as it is not known if insufficient blinding of the participants to the trial conditions resulted in changes in behavioural outcomes (i.e., engagement with the intervention conditions) (Higgins *et al.*, 2011). Also, 80% of the included trials were unclear if the outcome assessor was blinded to the intervention conditions. Incomplete outcome data was noted in one of the trials, where reasons for missing participants were not given, despite using an intention-to-treat analysis.

Other bias (performance bias) was noted in 80% of the included trials. Performance bias was identified due to the intervention groups receiving more attention than the control group (Higgins *et al.*, 2011). In 75% of the included trials the participants in the intervention groups received constant contact with either the physiotherapists, exercise therapists, GPs, or researchers throughout the entirety of the trial. This included set classes or training (for the interventions) the participants were required to attend or the number of sessions with a

healthcare consultant the participants received. The control groups received the minimalist amount of support. These control groups received their instructions at the start of the trial (to maintain activity or to be active) and did not receive any more contact throughout the duration of the trial. For example in Paatelma *et al.* (2008) the advice-only group received one session with a physiotherapist, whereas the other two intervention groups (OMT and McKenzie Method) received a maximum of seven treatments throughout the trial.

2.14 Discussion

This systematic review is the first to investigate the use of non-prescribed, unsupervised physical activity interventions in NSLBP research and the first to apply the BCTTv1 to the interventions used in the included trials in NSLBP research.

Despite an extensive literature search only four articles were included for evaluation in this review. It was noted throughout the screening process that non-prescribed, unsupervised interventions to increase physical activity, are generally delivered in the form of advice to be active in RCTs. None of the trials included in this review used non-prescribed, unsupervised interventions which were different from providing advice to be active or using an educational booklet to facilitate the message of keep active.

Some of the trials (n = 6) were excluded at the full-text screening stage due to inconsistencies in the terminology used to describe the type of LBP the trial was investigating. For example, Hahne *et al.* (2017) was excluded due to reporting the trial was investigating "non-compensable" LBP. However, it is not clear what "non-compensable" LBP is as the term is not used in the literature and no definition of this type of LBP was provided in the paper. Lack of consistency in terminology confuses the landscape of NSLBP research and limits the interpretations of research in this area.

Intervention content and description

The TIDieR checklist (Hoffmann *et al.*, 2014) was used to evaluate the quality of the descriptions of the interventions present in the included trials of this review. Poor intervention description does not allow the interventions to be replicated or allow

researchers to advance the findings of the research (Hoffmann *et al.*, 2014). The key areas of interest for this review were how the authors of the included trials described the rationale and/or theory for the interventions, materials, procedures/processes, intervention provider and fidelity/adherence assessments used in the interventions. Description quality between the interventions varied within and between the trials. For example, the description of the OMT intervention group in Paatelma *et al.* (2008) met 41% of the TIDieR checklist for the OMT intervention group, yet the other intervention groups (McKenzie Method and advice-only) met just 16% and 25% of the TIDieR checklist respectively. In the trial conducted by Rydeard, Leger and Smith (2006) the Pilates-based intervention met 50% of the checklist, whereas the control group (continue with normal activity) only met 16% of the checklist. Only one of trials (Rozenberg *et al.*, 2002) met at least 67% of the TIDieR checklist for both of the interventions used in the trial.

The main areas where the trials were not meeting the TIDieR criteria were in the description of the materials used in the interventions, the processes and procedures of the interventions and the fidelity/adherence of the interventions. Some of the interventions were unclear in the description for some of the items of the checklist. For example, Aboagye *et al.* (2015) recruited participants from OHS in Sweden, but specific details of where the interventions were provided were not reported. Moreover, one of the intervention conditions in this trial was a 6-week course of medical-yoga. Specific details on the yoga session duration, programme content (what types of movements were used in the Kundalini-based programme) and content of the materials (what was on compact disc (CD) provided to participants) were not reported. These unreported details resulted in three of the 12-item checklist not being recorded as "met" and were instead recorded as "not included".

Adherence to the intervention conditions (number of patients who followed the intervention protocol) was not monitored for 80% of the interventions in this review. One of the trials (Paatelma *et al.*, 2008) did not provide any details on how adherence to the intervention was planned to be measured and did not provide any adherence rates for any of the interventions used in the trials. Two of the trials (Rydeard, Leger and Smith, 2006; Aboagye *et al.*, 2015) very briefly mentioned how adherence to the interventions was collected (i.e., through text messages and diary logs) but did not provide any description or

results of how many participants adhered to the intervention condition. Adherence rates was only reported in both intervention groups in Rozenberg *et al.* (2002). Adherence rates need to be reported to inform researchers which interventions were acceptable to NSLBP patients.

These inconsistencies in intervention description make it hard to distinguish between the effect of the content on the outcome measures of interest. Poor quality descriptions also do not enable researchers to advance future interventions if the content of previous interventions is unknown or unclear. The poor descriptions caused clarity issues over the presence of some BCTs. Some BCTs were not coded in the interventions due to insufficient evidence that the BCT was present in the intervention. The BCT "demonstration of behaviour" could not be coded in one intervention as it was unclear if the participants received a demonstration of the behaviour. According to the BCTTv1 "demonstration of behaviour" can only be coded if the participants received an observable sample of the performance of the behaviour, directly or indirectly (Michie, Atkins and West, 2014). BCTs were only coded when there was clear evidence in the intervention description that the BCT was present as indicated by Michie, Atkins and West (2014) .

Behaviour change theories

There was no evidence that the interventions, in the included trials, were developed using behaviour change theories. The Medical Research Council (MRC) guidelines recommend health-care interventions are developed using relevant theory (Craig *et al.*, 2008). There was also no information present on how the authors developed their interventions. The results of this review reinforce the statement that the effect of a behavioural change strategy has not been investigated with regards to influencing a NSLBP population to be physically active (Broonen *et al.*, 2011). The rationale on why a certain exercise programme or exercise may benefit NSLBP patients was included in the introductions of the included trials. For example, Rydeard, Leger and Smith (2006) provided a justification of why Pilates-based therapeutic exercise would benefit a patient with NSLBP, using the theory of neuromuscular control. However, there was no theory used to justify the control group intervention which was usual care (consultation with a GP or other specialist) (Rydeard, Leger and Smith, 2006).

BCTs coded in the interventions

BCTs have been reported to aid the facilitation of certain types of behaviour, including behaviour towards physical activity (Michie, Atkins and West, 2014, p. 147). Previous trials have reported significant intervention effects when using BCTs to increase physical activity (Kriska *et al.*, 1986; Calfas *et al.*, 1996; Halbert *et al.*, 2000; Baker *et al.*, 2008; Butler *et al.*, 2009; Hemmingsson *et al.*, 2009; Pal *et al.*, 2009).

Ten BCTs were coded across ten interventions in the included trials. The most BCTs coded for a single intervention was seven, with zero BCTs coded in one intervention. The most common amount of BCTs coded in an intervention was four, which occurred in 60% of the interventions. The most frequently coded BCTs in the interventions evaluated in this review were "instructions on how to perform the behaviour" and "goal setting". These BCTs were coded for 70% of the interventions. As a meta-analysis was not appropriate for this review due to the small sample size and heterogeneity between the outcome measures, the association between the amount of BCTs present per intervention and the intervention effect could not be calculated.

The BCTs coded in the trials of this review are not similar to the BCTs reported in other systematic reviews of physical activity interventions for other conditions (Bird *et al.*, 2013). Bird *et al.* (2013) demonstrated significant effects for twenty-one different interventions, across eighteen articles, for increasing walking and cycling levels in adults. The BCTs in Bird *et al.* (2013) were coded using the 26-item taxonomy (Abraham and Michie, 2008). The maximum amount of BCTs coded in an intervention was twelve and the minimum amount of BCTs coded in an intervention was one (Bird *et al.*, 2013). The most commonly used BCTs in these interventions were "prompt self-monitoring of behaviour" (asking the person to monitor and record their behaviour), and "prompt intention formation" (encourage patient to set a general goal or to decide to act) (Abraham and Michie, 2008; Bird *et al.*, 2013). These BCTs were coded in thirteen (68%) of the interventions. These BCTs were not similar to the BCTs coded in this review and the interventions in this review had less BCTs present. It has been reported that increasing the amount of BCTs present in an intervention is associated with positive intervention effects (Samdal *et al.*, 2017). This has been shown in other trials (Lara *et al.*, 2014; Bishop *et al.*, 2015). This may have limited the intervention

effect in the trials of this review, especially in the interventions where only three or zero BCTs were coded.

BCTs used in other interventions

Greaves *et al.* (2011) who conducted a systematic review of reviews demonstrated which BCTs were associated with effectiveness in increasing levels of physical activity in adults with type 2 diabetes. These BCTs were coded using the 26-item taxonomy (Abraham and Michie, 2008). The most commonly coded for encouraging physical activity levels were "prompting practice" (rehearsing the desired behaviour so it is performed in the context needed), "prompting self-monitoring of behaviour", "goal setting" (agree a specific goal which to achieve the desired behaviour) and "individual tailoring" (adapting the content of the intervention or counselling session for the individual to achieve the desired behaviour) (Abraham and Michie, 2008; Greaves *et al.*, 2011). Similarly, a systematic review by Samdal *et al.* (2017) provided evidence of positive intervention effects for the use of the BCTs "goal-setting (behaviour)" and "self-monitoring of behaviour" in physical activity and healthy eating interventions for obese and overweight adults.

The BCT "goal setting" is the only similar common BCT coded in the interventions evaluated in this review compared the BCTs coded in interventions evaluated in previous systematic review (Greaves *et al.*, 2011; Samdal *et al.*, 2017). Out of the seven interventions in this review coded with the BCT "goal-setting", three of the interventions demonstrated statistically significant effects on outcome measures. Two interventions in Rozenberg *et al.* (2002) on which inferential statistics were not completed, demonstrated positive results on pain and disability scores. However, this association, between BCT and intervention effectiveness, could not be explored due to the inability to perform a meta-analysis.

Outcome measures

In 1998, Deyo *et al.* created a six-item standardised set of outcome measures. These outcome measures were provided to be used in clinical trials for NSLBP to provide precise measurements (Deyo *et al.*, 1998). The set of outcomes were "pain symptoms", "function", "well-being", "disability", "disability (social role)" and "satisfaction with care". This

standarised set of outcome measures were updated in 2015 (Chiarotto *et al.*, 2015) and in 2018 (Chiarotto *et al.*, 2018). Four core outcome domains were identified (Chiarotto *et al.*, 2015). The updated core outcome domains for NSLBP are "pain", "physical functioning", "HRQoL" and "number of deaths" (Chiarotto *et al.*, 2015). The trials included in this review were completed before 2015 and before the updated core set of outcome measures. However, the included trials did not include 50% of the standardised set of outcome measures provided by Deyo *et al.* (1998). Three trials (Rozenberg *et al.*, 2002; Rydeard, Leger and Smith, 2006; Paatelma *et al.*, 2008) only provided measures for pain and disability. One trial (Aboagye *et al.*, 2015) only incorporated a measure for HRQoL which encompassed the "well-being" outcome. NSLBP is considered to be a condition which interacts with physical, psychological and social aspects of an individual's life as reported in the biopsychosocial model (Waddell, 1992). Trials should use the core outcomes for NSLBP as a minimum to account for the multiple effects NSLBP has on an individual. Whilst an intervention might not demonstrate postive effects on pain scores the intervention might have been beneficial in increasing participants HRQoL. However, without a measures to encapsulate the biopsychosocial model for NSLBP these positive effects of interventions will be missed.

Measures for physical activity

Moreover, physical activity was not measured, objectively or subjectively, in the included trials for this review. All the included trials incorporated the use of a control group which received a minimal intervention – advice to be active or to continue with their normal routine. Effectiveness of physical activity, exercise or advice to be active cannot be accurately reported if it is unknown how much physical activity the participants engaged in, especially when adherence is reported to be low in NSLBP trials (Hanney, Kolber and Beekhuizen, 2009; Marley *et al.*, 2014; Milosavljevic *et al.*, 2015). Previous trials investigating the effect of an exercise on spinal muscle strength (Takemasa, Yamamoto and Tani, 1995; Smith *et al.*, 2011; Kendall *et al.*, 2015; Helmhout *et al.*, 2017) and hip muscle strength in relation to NSLBP (Alsufiany *et al.*, 2020) have included an objective method of measuring increases in strength. Without a measure for activity the effect of physical

activity on outcomes cannot be evaluated in-depth. All the trials reported the control group were advised to "be active" and "continue with their daily routine" (Rozenberg *et al.*, 2002; Rydeard, Leger and Smith, 2006; Paatelma *et al.*, 2008; Aboagye *et al.*, 2015).

However, the absence of objective measures for physical activity make it impossible to determine what the participants usually did. For instance, some of the participants might have been active before the trial and continued being active throughout the trial. Some participants might have been leading a sedentary lifestyle. All the recruited participants in the control group could have been inactive prior to the trial. Therefore, adherence to the intervention protocol, or conclusions on how effective the "advice to be active" and the continuation of a "normal routine" cannot be determined without a measure, objective or subjective, for physical activity. Physical activity measurements need to be consistently measured to inform research and HCPs on the effectiveness of interventions in getting a NSLBP population more active.

Reporting physical activity measurements will enable researchers to 1) determine participant adherence to the physical activity interventions, 2) determine if the content of the interventions was adequate enough to promote physical activity and, 3) allow future researchers to evaluate the effectiveness of the interventions in increasing physical activity. If authors of trials also accurately describe the interventions, inform the interventions with BCTs and measure physical activity then future research can build upon previous physical activity interventions and evaluate which BCTs have been most commonly used in interventions that did increase the physical activity of NSLBP patients.

Statistical and clinical significance

Out of the ten interventions used across the included trials, six of these interventions were prescribed to the participants. 50% of the prescribed interventions in the trials demonstrated statistical significance of effect on the outcome measure(s) (refer to table 2.1). None of the non-prescribed interventions demonstrated statistically significant effects on the outcome measure(s). Statistical significance may not have been demonstrated for pain measures in Rydeard, Leger and Smith (2006) due to the amount of pain the recruited participants were in. The control group (non-prescribed) reported higher ratings of pain on

the NRS (pre-trial:30.4 (±4.2) than the Pilates-based exercise group (pre-trial: 23.0 (±17.7). The difference between the groups in terms of pain severity could be responsible for the intervention effect reported in control group.

Clinical significance was not reported for any of the interventions, in the included trials, even when the results were statistically significant. Clinically significant data are related to the magnitude of the observed effect size and if it is big enough to influence changes in a clinical setting (Skelly, 2011). Clinical significance is an important concept and should reported to determine efficacy in an intervention (Skelly, 2011). Clinical significance cannot be inferred from statistical significance (Younger, Mccue and Mackey, 2009) and statistical significance does not show a treatment's strength (Younger, Mccue and Mackey, 2009).

Clinical significance in the non-prescribed interventions

Clinical significance was noted in 75% of the non-prescribed interventions. The advice-only group in Paatelma *et al.* (2008) demonstrated a median change of 20 points on the VAS from the baseline measurement to the first follow-up and a median change of 8 points from disability scores on the RMDQ. In the trial by Rozenberg *et al.* (2002) the normal activity group demonstrated an overall change in pain score with a mean difference of 38.31 points (VAS) and a mean difference of 6.26 in disability scores (Eifel index) from the baseline measurement to day 6 or 7 post-intervention. The non-prescribed intervention (advice to continue normal activity) demonstrated a clinically significant result in HRQoL when practiced less than twice a week at the 6-week follow-up (Aboagye *et al.*, 2015).

Clinical significance in the prescribed interventions

83% of the prescribed interventions demonstrated clinical significance in outcome measures at the first follow-up post-intervention. The results in Rydeard, Leger and Smith (2006) showed clinically significant results in post-test adjusted mean pain scores for the Pilates-based therapeutic exercise group, with a change of 4.7 points post-intervention. No clinically significant results for change in disability were recorded. Clinically significant changes in HRQoL (EQ-5D) were recorded at 6 weeks post-intervention for medical yoga and exercise therapy when practiced more than twice a week (Aboagye *et al.*, 2015). Clinical

significance in HRQoL scores were also recorded for the exercise therapy group when the exercise therapy was practiced less than twice per week. Clinically significant results for the bed rest group were noted in Rozenberg *et al.* (2002) with mean changes of 5.73 points (disability) and 35.15 (VAS) points at day 6 or 7 post-intervention. Clinical significance in pain scores (VAS) and disability scores (RMDQ) in both the OMT (VAS, median change of 17 points; RMDQ, change of 7 points) and McKenzie method group (VAS, median change of 22 points; RMDQ, median change of 8 points) were shown in Paatelma *et al.* (2008) at the first follow-up (3 months) post-intervention.

Authors of trials should report clinical significance irrespective of statistical significance. By reporting clinical significance researchers can identify interventions which demonstrated positive effects on outcome measures and advance those interventions in future trials. This would only be viable if authors accurately report the content of the interventions used. The ability to identify common elements of interventions which had statistical significance and the common elements of interventions which had clinical significance, can result in the development of effective interventions. This would not only benefit future research, but also benefit clinicians when deciding what interventions should be used with NSLBP patients.

Risk of bias

Performance bias was identified in all the trials included in this review. The performance bias was detected due to discrepancies in contact-time, between the intervention group(s) and control group (the non-prescribed intervention). These control groups were the minimal intervention group. The control groups appeared to be a non-priority as the participants did not receive the same amount of attention as those included in the main interventions. For example, the participants in the main intervention groups were kept in contact with throughout the trial duration, on a weekly basis as a minimum. These participants were followed up at specific time-points and received more than one contact session with the HCP or researcher. Participants in the control groups were given the intervention (advice to be active) at the start of the trial during an initial consultation with the HCP or researcher. These control groups did not receive any more contact or follow-up from either the trial

researchers or HCPs throughout the duration of the trial. Less contact with the HCP is a performance bias because the difference in levels of care or contact a participant receives can cause differences in the performance of the groups in the trial. Contact with the HCPs reinforces the message or intervention of the group. For example, the participants in the manual therapy group and the McKenzie method group in Paatelma *et al.* (2008) received between three and seven treatments whereas the participants in the advice group received their advice during their initial consultation. Inevitably, better results would be expected in the groups which received more attention.

Behaviour change is complex and advising a patient to be active at one time-point may not be sufficient to cause changes to their normal physical activity routine. Changing behaviour requires powerful psychological, environmental or social influences to be overcome (Michie, Atkins and West, 2014). Due to the demand for the desired behaviour (physical activity) to be practiced, physical activity interventions are reported to be more intensive than other interventions (Greaves *et al.*, 2011). Other trials have reported contact time of weekly sessions, lasting sixty minutes is required to achieve the desired behaviour for behavioural interventions (Shaw *et al.*, 2005) and physical activity interventions lasting between three to twelve months require contact of three to five sessions a week, with a session duration of forty-five minutes to show a positive effect (Shaw *et al.*, 2006). “Advice to be active” is a minimal physical activity intervention and therefore requires more contact time with the participants, than was given to this intervention group in the included trials, to facilitate the desired behaviour.

2.15 Future research recommendations

This systematic review highlighted that non-prescribed, unsupervised interventions are sparsely used in NSLBP research and when they are, they come in the form of “advice to be active” in control groups. Future physical activity interventions should investigate the use of non-prescribed, unsupervised physical activity interventions. These non-prescribed interventions allow the patient to choose the way they wish to be active, which fits in with their lifestyle. Physical activity interventions which can easily be integrated into participant’s

daily lives has been suggested to increase the up-take and sustainability of the behaviour (Ogilvie *et al.*, 2007; Yang *et al.*, 2010).

This systematic review confirms previous statements about the poor descriptive nature of intervention content and delivery (Michie *et al.*, 2009; Michie, Abraham, *et al.*, 2011; Hoffmann *et al.*, 2014). Future interventions need to provide thorough and detailed descriptions of intervention content and develop these interventions with appropriate theory to achieve behaviour change. Details of the specific techniques involved to facilitate behaviour change is also warranted. The absence of intervention description and detail limits future intervention development to improve effectiveness and does not enable the intervention to be reproduced (Michie, Abraham, *et al.*, 2011; Hoffmann *et al.*, 2014). None of the included trials used behaviour change theories in the design of the intervention. Future interventions need to incorporate behaviour change theory and BCTs in the intervention development, and accurately report this. The effectiveness of physical activity interventions can be enhanced through the application of behaviour change strategies and interventions should be developed with relevant theory (Craig *et al.*, 2008) and BCTs to facilitate the desired behaviour.

Increasing physical activity levels is a desired behaviour of NSLBP patients and therefore behaviour change theories should be considered during the design of physical activity interventions (Marley *et al.*, 2014). Future interventions should also incorporate an objective measure for physical activity to 1) demonstrate if the interventions were adhered to and 2) if the intervention had the desired effect (i.e., did the intervention manage to increase the physical activity levels of the recipients).

This systematic review is the first to evaluate the content of physical activity interventions. Future systematic reviews and meta-analyses need to investigate which BCTs are present in other physical activity interventions, as it is currently unclear what BCTs have been used in previous interventions. This would enable the identification of the BCTs which are present in interventions that have demonstrated a positive effect and can be used in the development of future interventions. Additionally, this would also identify any common BCTs used in interventions which had high adherence rates by the participants who received them. This would enhance future physical activity interventions in NSLBP research and would advance the field as it would allow researchers and intervention developers to build on the previous

interventions after reviewing the content of interventions. This would allow for the identification of what components of the interventions worked and what components need refining or changing to improve effectiveness and adherence rates.

2.16 Conclusion

This systematic review highlighted that non-prescribed, unsupervised physical activity interventions are under-researched in NSLBP literature and not used as the main interventions in RCTs. The main aim of this review, and the additional aims, were answered as the results of this review provided the following information: (i) the content of interventions are not designed using behaviour change theory - there is evidence of some BCTs in the interventions, yet it is not clear if the interventions were specifically designed to incorporate the BCTs, (ii) the description of the intervention(s) content is lacking detail, which makes it difficult to replicate the intervention and assess whether there are any BCTs in the undescribed elements, (iii) clinical significance of non-prescribed interventions demonstrating reductions in pain and pain-related disability, or increases in HRQoL, was not commented on in the trials, and (iv) the included trials did not objectively, or subjectively, measure the amount of physical activity the participants were engaging in.

The results of this systematic review provided this thesis with the necessary information to design and develop the methods of the feasibility-pilot trial. An objective measure for physical activity needs to be researched and chosen to monitor the physical activity levels of the participants in the feasibility-pilot trial. The results of this review also reinforced the demand to design and develop physical activity interventions with relevant behaviour change theory and BCTS to facilitate the desired behaviour of the participants in the feasibility-pilot trial.

2.17 Chapter summary

- Non-prescribed, unsupervised physical activity interventions are commonly used as a minimalistic intervention, in the control group in trials

- The interventions used in the trials included in this systematic review did not appear to be informed by any behaviour change theories and incorporated a few (maximum of five) BCTs
- Physical activity was not being measured objectively in any of the trials included in this review
- Future interventions need to include an objective measure for physical activity to determine the effectiveness of the interventions in increasing physical activity in NSLBP patients
- Non-prescribed, unsupervised physical activity interventions need to be developed using behaviour change theories and BCTs to enhance effectiveness and achieve the desired behaviour.

3 Chapter 3: Evaluation of methods to mount an accelerometer for the assessment of physical activity

3.1 Chapter introduction

This chapter discusses the measures used to monitor and collect physical activity data in the general literature and in NSLBP research. The rationale for using accelerometers in the feasibility-pilot trial is provided. The justification for two exploratory (pilot) trials – validation trials for a mounting method for the accelerometers - is reported. The chapter concludes with the results and discussion of the two exploratory trials.

3.2 Introduction

Research has highlighted the benefits of daily physical activity and the negatives of a sedentary lifestyle on physical and mental well-being (Blair *et al.*, 1985; Craig *et al.*, 2003; Macfarlane *et al.*, 2006; Reilly *et al.*, 2008). Health-care professionals and various national and international guidelines (World Health Organization, 2015; National Institute for Health and Care Excellence, 2016) recommend physical activity to maintain good health, in the prevention and management of NSLBP and in preventing chronic diseases such as diabetes mellitus and cardiovascular disease (Melzer, Kayser and Pichard, 2004). Physical activity is the umbrella term used to describe movement, which includes non-sport activities and sport activities. As such, physical activity is defined as "any bodily movement produced by skeletal muscles requiring energy expenditure" (Caspersen, Powell and Christenson, 1985). Exercise and sport are subsets of the term "physical activity" in which the activities are structured, repetitive and planned, with specific goals in mind – e.g., maintaining or improving physical fitness (Caspersen, Powell and Christenson, 1985). Non-sport activities are performed as part of daily living, in occupational, household and leisure-time domains, including transportation and personal care. Examples of these activities include housework, gardening, cleaning, climbing stairs, walking to and from work and running for the bus or train.

Physical activity is a multidimensional entity, with no single method of measurement able to capture and account for the domains of the activity of interest and all of the subcomponents of physical activity (Warren *et al.*, 2010). Therefore, assessing physical activity is riddled with difficulties. Techniques and methods of estimating habitual physical activity are validated using calorimetry (Westerterp, 2013).

There are a variety of techniques and methods to evaluate physical activity, which range from behavioural observation and self-report to motion sensors (Westerterp, 2013). These methods are often categorised as subjective and/or objective measures. Subjective measures include questionnaires, activity diaries and interviews. Subjective measures are easy and cost effective, yet the ability to gain accurate information is limited due to the results being open to interpretation and based on memory recall (Sallis and Saelens, 2000; Althubaiti, 2016). Memory recall often provides the problem of over- and underestimation of events (i.e., individuals may feel they did more activity than what they actually did) (Gendreau, Hufford and Stone, 2003). Objective measures can provide information on the physical activity levels of a patient by quantifying movement. Effective measurement of physical activity levels or free-living conditions are required in the surveillance and assessment of public health campaigns or to determine the effectiveness of interventions aiming to increase physical activity levels.

3.3 Measuring physical activity

Physical activity is measured by calculating total daily energy expenditure (TDEE) over a twenty-four-hour period divided by basal metabolic rate (BMR). Figure 3.1 highlights the components of TDEE and measurements for these components. Measuring EE alone does not provide as estimation of physical activity levels. The terms EE and physical activity are often used interchangeably, yet each term has different meanings (Hills, Mokhtar and Byrne, 2014). It is vital to differentiate between the two concepts of EE and physical activity. EE can be defined as the act of using energy to perform several physical processes, which include homeostasis maintenance, thermogenesis, growth and performing physical activity (von Loeffelholz and Birkenfeld, 2000; Hills, Mokhtar and Byrne, 2014). Physical activity energy expenditure (PAEE) is determined by body size and body movement due to the

complex relationship between physical activity and body weight (Westerterp, 2013). Adjustments in differences in body size is required when assessing physical activity against energy expenditure (Westerterp, 2013). See table 3.1 for brief a summary of the methods used to measure physical activity, their validity, and what kind of research they would be most applicable in.

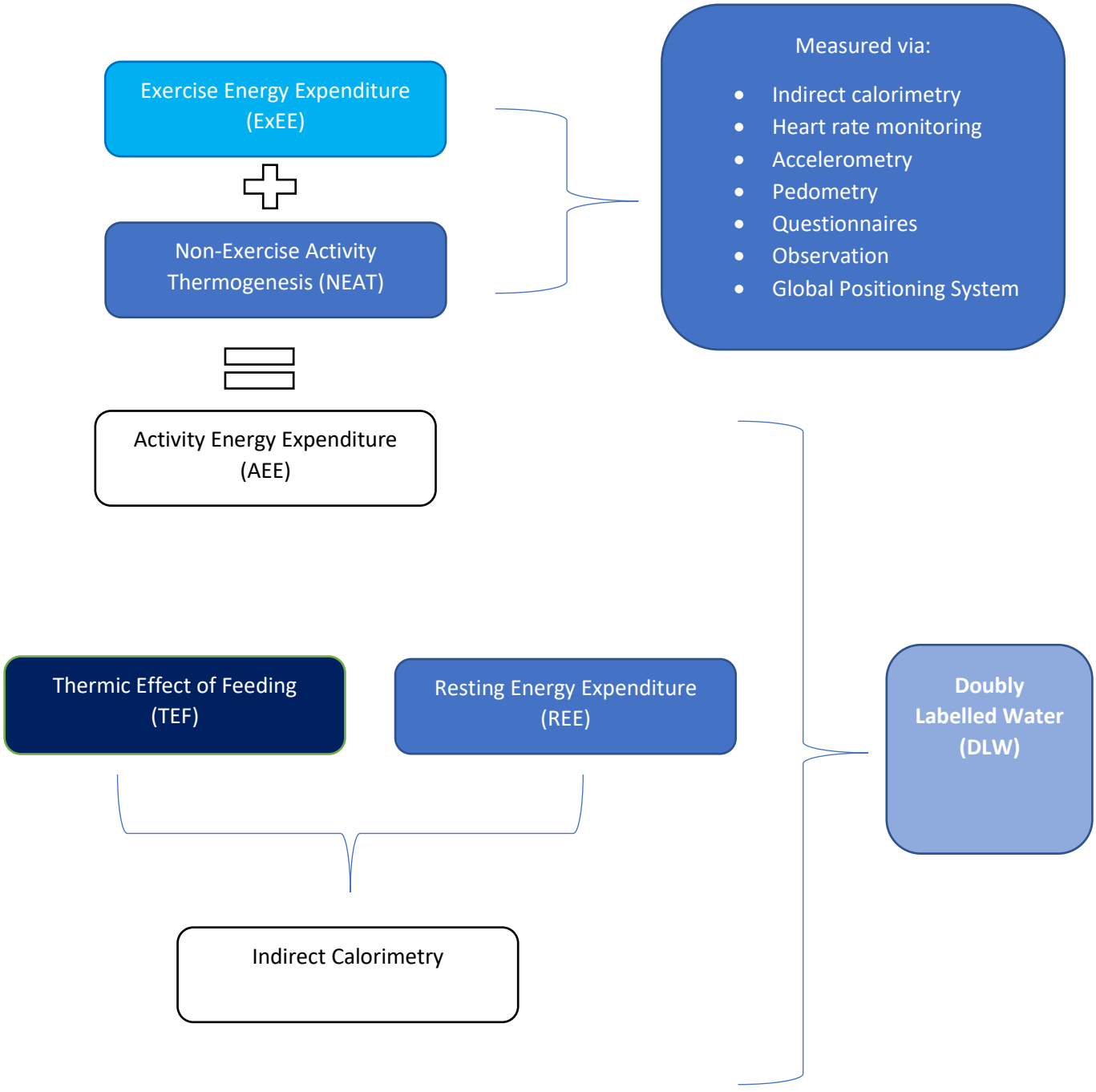


Figure 3.1: Total daily energy expenditure components and their subsequent measurement approaches. Taken and adapted from Hills et al. (2014).

Table 3.1: *Summary of methods used to measure physical activity. Taken and adapted from Warren et al. (2010).*

Method	**Measure**	**Primary outcome (1), secondary outcome (2)**	**Validity for assessing primary outcomes and EE**	**Study examples and other resources**	**Where to use in research – appropriate research aim**
Doubly labelled water	Carbon dioxide (CO_2) production	Total energy expenditure	(1) Valid	Suitable for all populations Expensive Moderate burden for respondent	Accurate measure of total energy expenditure. Does not provide information on the frequency, duration, or intensity of physical activity.
Accelerometry	Acceleration of the body or body segments in one or more directions.	(1) acceleration (2) estimates of duration, frequency, and intensity of body movement	(1) Valid Valid for a group level for free-living PAEE estimates.	Suitable for all populations Software packages have improved making data analysis easier Cheap monitors	Objective measure of overall physical activity, time spent in the activities, with varying intensities. Gives an indicator of frequency and duration of the activities

Method	Measure	Primary outcome (1), secondary outcome (2)	Validity for assessing primary outcomes and EE	Study examples and other resources	Where to use in research – appropriate research aim
Heart rate monitoring	Heart rate i.e., beats per minute	(1) Heart rate; duration and frequency of moderate and vigorous physical activity and vigorous physical activity. (2) PAEE can be estimated using regression equations taken from group or individual calibration	(1) Valid, Valid in group settings for estimating the energy expenditure for activities of a higher intensity. Is improved by individual calibration	Suitable for all populations Easy to obtain data and analyse data Relatively cheap Burden of non-respondents emerging for short wearing times. Could be problematic over longer periods.	Objective measure of PAEE and time spent in different intensities. Provides insight into the duration and frequency of these activities.

Method	Measure	Primary outcome (1), secondary outcome (2)	Validity for assessing primary outcomes and EE	Study examples and other resources	Where to use in research – appropriate research aim
Combined heart rate and accelerometer devices	Heart rate and acceleration of the body	(1) Acceleration and heart rate. Duration, frequency, and intensity of physical activity. PAEE	(1) Valid. Valid in estimating PAEE for a group setting. The validity for this tool at an individual level emerging.	Suitable for all populations Software packages have improved making data analysis easier Respondent burden is low	Objective measure of the time spent in activities of a variety of intensities. Evidence does suggest it is a suitable method to measure PAEE. Index for the duration and frequency of activities.
Pedometry	Step count	Number of steps taken	(1) Valid Not a valid tool to estimate energy expenditure during free living.	Suitable for all populations Quick and easy data collection and analysis Cheap Respondent burden is low	Suitable to measure steps taken during walking

Method	Measure	Primary outcome (1), secondary outcome (2)	Validity for assessing primary outcomes and EE	Study examples and other resources	Where to use in research – appropriate research aim
Direct observation	Activity categorisation	(1) Time spent in the activities (varying in intensity) and number of bouts of activity. (2) Estimates of energy expenditure using MET values	(1) Valid to estimate PAEE	Expensive. Typically used in paediatric studies. No burden to respondent. Software programs available for the ease of data collection and recording.	Detailed qualitative and quantitative information on physical activity performed for a specific time frame.
Self-report	Time put aside to different domains of activity. Time spent in the different types of activities.	(1) Time spent in activities of varying intensity and the number of bouts of exercise. (2) EE estimated by imputing METs to the reported activities and the specified durations.	(1) Valid. Varies in validity for being able to categorise individuals into groups and for the ranking of the individuals. (2) Not a valid tool for estimating EE at an individual level.	Suitable for all populations. Burden for responders low. Cheap. Easy to collect and analyse data.	Surveillance tool. Some of these tools provide qualitative information (types of activities). Provides information on frequency, duration and intensity of the activities and the domain(s) of the activities.

3.4 Physical activity measurements in NSLBP research

As research in NSLBP is moving towards advising patients to be physically active, it is vital that physical activity is being monitored effectively in interventions. The cost of monitoring and assessing physical activity is related to its accuracy. As discussed above, objective measures are considered to be the best tool to measure physical activity levels, in conjunction with some self-report measures. However, the methods used in NSLBP literature to assess physical activity are inconsistent (see table 3.2).

Most LBP studies looking at promoting and increasing physical activity rely on subjective tools - most commonly questionnaires. Some studies do not even provide a measure for physical activity, as indicated in *Chapter 2,* which leaves some uncertainty about how effective the intervention was in increasing the physical activity levels of the participants.

There is no systematic or narrative review on which methods are best used to monitor physical activity levels in a NSLBP population. Similarly, there are no published trials which have appraised and synthesised the effectiveness of different physical activity measurement modalities. The trials presented in table 3.2 are either observational, cross-sectional, or trial protocols and have either evaluated the relationship between LBP and physical activity or assessed the effects of an exercise or predetermined physical activity intervention on outcome measures. These trials were all excluded from the systematic review presented in *Chapter 2* for these reasons as they were not relevant to the aim of the review.

Table 3.2: Trials in LBP research which aim at increasing physical activity levels in a LBP population.

Authors (year)	Sample size	Age	Type of study	Length of study	Location	Physical activity measure	Aim	Outcome
Hendrick *et al.*, 2009 **Protocol**	120 (aimed)	18-65	Observational (longitudinal)	12 months	New Zealand	Accelerometer, activity recall questionnaire, Baecke Questionnaire (BPAQ)	Provide a predictive relationship between change in physical activity and functional recovery in LBP	Not applicable
Jacob, Baras, Zeev, & Epstein, 2004	2,000	22-70	Cross-sectional	12 months	Israel	Baecke Questionnaire (BPAQ)	Evaluate relationship between physical activity and LBP	Indirect association between LBP and sports physical activities, direct association between LBP and physical load in workplace.
Malmivaara & Aro, 1995	186	18-65	RCT	12 weeks	Finland Occupational health care setting,	Questionnaire (not specified)	Differences in recovery rate	Maintaining ordinary activities lead to a faster recovery

Authors (year)	Sample size	Age	Type of study	Length of study	Location	Physical activity measure	Aim	Outcome
McDonough *et al*., 2010 **Protocol**	50 (aimed)	18+	Single blinded feasibility trial	8 weeks	Ireland	ActivPAL, Graded pedometer driven walking programme	Test feasibility of the trial	Not applicable
Milosavljevic *et al.,* 2015 **Protocol**	200 (aimed)	18+	Fully powered single-blinded RCT	12 weeks	Canada	Yamax DigiWalker Pedometer driven walking programme IPAQ short form	Investigate the effect of walking as a sustainable mean of physical activity to improve disability in CLBP	Not applicable
Ryan *et al.,* 2009	15 with CLBP, 15 with no LBP	18-65	Cross-sectional observational	1 week	Scotland Physiotherapy outpatient clinic	ActivPAL (accelerometry over 7 days – reported 6 different outputs)	Differences in physical activity between groups – altered patterns of activity	People with CLBP walk at a slower cadence and have decreased activity levels over average 24-hour day

Authors (year)	Sample size	Age	Type of study	Length of study	Location	Physical activity measure	Aim	Outcome
Schaller *et al.* (2015)	412	18-65	Single-blinded RCT,	6 months	Germany In-patient medical centre	General physical activity questionnaire (GPAQ). METs score - multiplying the minutes for each domain by their associated METs	**Primary:** Increasing physical activity after inpatient rehabilitation	Not significant in total activity, workplace, leisure activity, pain, or transport. Physical activity decreased during follow-up
Sitthipornvorakul, Janwantanakul, & Lohsoonthorn, 2015	387	20-45	Prospective cohort	12 months	Bangkok	Pedometer Self-administered questionnaire	Examine the causal relationship between daily walking steps and 1-year incidence of LBP	Not significant
Taylor, Evans, & Goldie, 2003	16	Not specified	Controlled trial	1 day	Australia	Treadmill – walking	Strategies used to change from self-selected pace to fast walking Effect of a period of fast treadmill walking on LBP	10 min. walking at a self-selected pace decreases pain and acute LBP patients use different strategies to walk faster

Authors (year)	Sample size	Age	Type of study	Length of study	Location	Physical activity measure	Aim	Outcome
Van Weering *et al*., 2008	40	18-65	Cross-sectional	7 days	Holland	Accelerometry over 7 days self-constructed activity diary	Insight into daily physical activity patterns of CLBP patients compared to controls	Not significant between controls
Verbunt *et al.*, 2001	13 with CLBP, 13 no CLBP	18-60	Cross-sectional	2 weeks	Holland	Accelerometry over 14 days, DLW	Physical activity in daily life between LBP patients and controls	Not significant, mean activity levels between the LBP patients and controls did not differ
Leonhardt *et al.* (2008)	1,378 patients with NSLBP	18-65	Cluster randomised controlled trial (3 arms)	1 year	Germany	Freiburger Questionnaire on Physical Activity *(*FQPA)	Effectiveness of transtheoretical model (TTM) on physical activity levels using self-efficacy	No effect of the TTM counselling on physical activity levels
Lunde *et al.* (2015)	420	Not specified. SD = 17.5 ± 1.2 years	Prospective cohort	6.5 years	Oslo, Norway	Self-report on 1 question	Association between physical activity and LBP	Unclear. No predictive relationship can be ascertained. No recommendations on how much activity is protective against LBP

Authors (year)	Sample size	Age	Type of study	Length of study	Location	Physical activity measure	Aim	Outcome
Hurwitz, Morgenstern and Chiao (2005)	610 NSLBP	18-70+	RCT	18 months	America	Self-reported physical activity questionnaire	Estimate effects of several outcomes of recreational physical activity among LBP patients	LBP patients should refrain from specific back exercises and focus on non-specific recreational activities to reduce pain and improve psychological health
Kuukkanen and Mälkiä (1996)	57 CLBP patients, 47 at 5-year follow-up	22-50	Controlled study	3 months	Finland	Structured questionnaire Recall	Investigate the effectiveness of home exercise on disabling NSLBP	Overall physical activity did not increase. Not significant
Bousema *et al.* (2007)	124, (106 completed study)	18-60	Longitudinal cohort study	1 year	Holland	RT3 Triaxial accelerometer – over 7 days repeated twice	Evaluate the development of disuse and physical deconditioning in patients with LBP. Investigate which factors may predict a change on PAL over 1 year	Disuse and physical deconditioning empirical evidence is lacking

Authors (year)	Sample size	Age	Type of study	Length of study	Location	Physical activity measure	Aim	Outcome
Hendrick *et al.* (2013)	101	18-65	Prospective cohort study	3 months	New Zealand GP surgery (n=16), physiotherapy clinic (n=77), newspaper advertisement (n=8)	RT3 accelerometer, Daily diary	To see if LBP patients change their physical levels over a 3-month period and if activity levels (and any changes in these) are predictors of disability at 3 months from an episode of LBP	Changes in physical activity from baseline to 3 months was not a predictor of disability or changes in disability

3.5 Measuring physical activity in the feasibility-pilot trial

The feasibility-pilot trial was designed to encompass a subjective (self-report) and an objective (motion senor) measure to quantify the physical activity levels of the recruited participants.

3.5.1 Self-report measure in the feasibility-pilot trial

Self-report measures have continued to be one of the most widely used tools for the quantification of physical activity (Sallis and Saelens, 2000) and have been used in previous physical activity trials in NSLBP research. Self-report measures can be defined as interviewer-administered (i.e., over the telephone or face-to-face) (Warren *et al.*, 2010) or self-administered recall questionnaires (Florindo and Latorre, 2003), activity diaries or logs and proxy reports (usually used to assess young children) (Sallis and Saelens, 2000).

The self-report measure used in the feasibility-pilot trial was the General Practice Physical Activity Questionnaire (GPPAQ). Questionnaires are the most commonly used method to assess physical activity (Castillo-Retamal and Hinckson, 2011) and are dependent on the recall ability of the participant (Godberg, Becker and Brigham, 2017). Questionnaires are the easiest and cheapest (Ishikawa-Takata *et al.*, 2008; Besson *et al.*, 2010) method to collect physical activity data in a short amount of time, even with a large sample size (Warren *et al.*, 2010). The GGPAQ is a validated screening tool commonly used in routine general practice (Heron *et al.*, 2014). This questionnaire is a simple tool which provides a four level physical activity index (PAI) by asking eight questions (Heron *et al.*, 2014). The PAI can help practitioners decide when to offer interventions aimed at increasing activity. Other validated questionnaires used extensively in the literature and in previous LBP research (see table 3.2) such as the International Physical Activity Questionnaire (IPAQ) (Craig *et al.*, 2003; Rachele *et al.*, 2012), Modified Baecke Habitual Physical Activity Questionnaire (MBHPAQ) (Baecke, Burema and Frijters, 1982) and Recent Physical Activity Questionnaire (RPAQ) (Besson *et al.*, 2010) were not appropriate for the purposes of the feasibility-pilot trial. The purpose of the physical activity questionnaire in the feasibility-pilot trial was get an idea of the type of physical activity the participants were engaging in, prior to the trial. The

questionnaire also needed to be easily administered as part of normal practice for HCPs. The IPAQ and RPAQ are time-consuming (a minimum of fifteen minutes to administer is needed (Maddison *et al.*, 2007)) and require in-depth answers (e.g., identifying how much time in minutes/hours they spent doing a certain activity). This would be erroneous for the participants to complete. The questionnaire for the feasibility-pilot trial needed to be able to be administered quickly as it would in normal clinical practice. The MBHPAQ was not used as the GGPAQ has been recommended in NICE guidelines (Jelley and Lake, 2013).

Other measures for self-reported physical activity were considered for use in the trial but were not appropriate or practical for the design and aims of the trial. Activity diaries have been used in the evaluation of physical activity for some decades (Bratteby *et al.*, 1997). However, the accuracy of this measure is very reliant on the co-operation of the participants and for ease of use, the recording has to be fairly simple for the participant (Bratteby *et al.*, 1997). Activity diaries and logs are hampered by participant response rates and to what extent the participant complies with the instructions given (Sallis and Saelens, 2000). This could result in inaccurate information being recorded and would not benefit the results of the feasibility-pilot trial. Direct observation uses an independent observer monitor to record the physical activity (Sleap and Warburton, 1996; McKenzie *et al.*, 2000). This measurement method is often used when the activity being observed is confined to a small space (i.e., a classroom) (McKenzie, 1991; Sleap and Warburton, 1996; Sallis *et al.*, 2003). The context in which the trial was completed in (i.e., a clinic setting, with the participants engaging in more activity during their daily routine) was not relevant for this type of measurement.

Therefore, the use of a questionnaire (GGPAQ) was incorporated into the measures for physical activity in the feasibility-pilot trial. However, there are several disadvantages with using questionnaires to quantify physical activity levels such as the inability to accurately measure light and moderate activity (Jacobs *et al.*, 1993). Questionnaires can be swayed by external factors such as social desirability, age, seasonal variation and the intricacy of the questionnaire (Baranowski *et al.*, 1984; Klesges *et al.*, 1990; Uitenbroek, 1993; Durante and Ainsworth, 1996; Vanhees *et al.*, 2005). Questionnaires are unable to be completed in 'real time' which means data can therefore be susceptible to memory bias as well as participant reactivity – the anomaly of behaviour change due to an awareness of being observed (Lindamer *et al.*, 2008; Ling, Masters and McManus, 2011; Hardy *et al.*, 2013).To overcome

these disadvantages with using the questionnaire, and to see if the interventions were successful in increasing the physical activity levels of the NSLBP patients, an objective measure was incorporated in the feasibility-pilot trial.

3.6 Objective measure for the feasibility-pilot trial

The results of the systematic review demonstrated that physical activity interventions should use an objective measure for monitoring physical activity to help determine the effective of the intervention. A review of the literature on objective measures for physical activity was conducted to choose the most appropriate measurement which met the requirements of the feasibility-pilot trial and were applicable in the context of the trial.

Use of the other objective measures, such as pedometers and accelerometers can offer a possible solution to some of the problems which come with collecting self-reported data (Troiano *et al.*, 2008). A highly accurate method for measuring EE is doubly labelled water (DLW), but this is also the most expensive and bothersome method (Florindo and Latorre, 2003; Warren *et al.*, 2010). The DLW method is considered the 'gold standard' for assessing the validation of other methods to measure physical activity (Melanson and Freedson, 1996). DLW method is typically used to quantify and assess total energy expenditure (TEE) (Schoeller and Van Santen, 1982; Hills, Mokhtar and Byrne, 2014; Godberg, Becker and Brigham, 2017; Westerterp, 2017). This method provides researchers with precise and accurate information on carbon dioxide (CO_2) production (Hallal *et al.*, 2013). The DLW method involves participants consuming water which has the hydrogen and oxygen elements partly or completely replaced (i.e., labelled) with heavy hydrogen (^2H), also known as deuterium, and heavy oxygen (^{18}O) (Westerterp, 2017). Participants receive a measured amount of the DLW to increase the body water for ^{18}O of 2000 parts per million (ppm) with at least 180ppm (Westerterp, 2017). Body water is also increased for ^2H of 150ppm with 120ppm (Westerterp, 2017). The difference in washout kinetics (usually urine, salvia or blood) between the two isotopes is measured, as a function of CO_2 (Hills, Mokhtar and Byrne, 2014; Westerterp, 2017). The samples are analysed for ^2H and ^{18}O using isotope ratio mass spectrometry (Westerterp, 2017). These measurements occur at the start and end of the observation period, commonly 1-3 weeks (Westerterp, 2017). This method is not

practical for use in the feasibility-pilot trial as it is expensive, exhibits a high participant burden and is time-consuming (Melanson and Freedson, 1996; Westerterp, 2009), and is not generally feasible for use in large trials/studies (Ejima *et al.*, 2020). This method also does not provide information on daily physical activity (Neilson *et al.*, 2008) and therefore would not meet the requirements of the trial in measuring daily physical activity levels of participants.

Heart rate (HR) monitoring can provide a physiological estimation of EE and physical activity (Sirard and Pate, 2001). HR monitoring is reported to be a valid measurement of EE in controlled settings (Eston, Rowlands and Ingledew, 1998; Trost *et al.*, 1998) and in free-living contexts (Mulberg *et al.*, 1992; Ekelund *et al.*, 2001) in young people (Corder *et al.*, 2005). HR monitors are versatile, cheap, non-invasive, and convenient (Sirard and Pate, 2001). Minute-by-minute HR monitoring allows for real-time detailed information on the intensity (Hills, Mokhtar and Byrne, 2014), frequency and duration of free-living physical activity (Schutz, Weinsier and Hunter, 2001). HR monitoring in an inconspicuous (can be worn on the wrist or around the chest), low-effort way for measuring physical activity in periods of time up to one month (Welk and Corbin, 1995; Sirard and Pate, 2001; Pahkala *et al.*, 2006). HR monitoring is able to capture EE during activities which do not involve vertical trunk displacement. However, HR monitoring was not an appropriate measure to meet the aim and outcomes of the feasibility-pilot trial. The objective measure needed to suitable for individuals of all ages and activity levels. Discrepancies occur in HR monitoring data especially at very high or low intensities (Freedson and Miller, 2000; Sirard and Pate, 2001; Terbizan, Dolezal and Albano, 2002; Macfarlane *et al.*, 2006; Pahkala *et al.*, 2006). These discrepancies are due to EE and HR not having a linear relationship, at low intensity and rest (activity is confounded by other variables like caffeine, body position and stress) or high intensity (Livingstone, 1997). Gender, fitness levels, muscle mass, body composition and age also have an effect on this linear relationship and therefore, reduce the accuracy of this method (Trost, 2001). The interventions in the feasibility-pilot trial were designed to increase the amount of the daily physical activity of the NSLBP patient participants, who were in an age range of 18-75, had varying body masses and different fitness levels.

Pedometers are the most commonly used objective tools in physical activity/free living research as they are easy to administer, cost effective, and good for measuring short

durations of physical activity – a factor which is often overlooked by self-report measures (Godberg, Becker and Brigham, 2017). Pedometers measure the number of steps performed during running and walking activities for the period of time that they are worn (Lonsdale *et al.*, 2012). Pedometers are also often used as a motivational tool to help encourage inactive and sedentary people to adopt a more physical lifestyle (Hills, Mokhtar and Byrne, 2014). Pedometers are generally worn on the wrist, but may also be attached to other anatomical sites, such as the lower back, or worn around the waistband (Crouter, Churilla and Bassett, 2006; Crouter, Clowers and Bassett, 2006). However, there are limitations with using pedometers in a NSLBP population. Despite the wide use of pedometers, the literature has identified several shortcomings of this method in terms of accuracy. The majority of pedometers do not take into account leg length and height of the user (i.e., less steps required to cover the same distance of a person with a smaller leg length) (Hills, Mokhtar and Byrne, 2014). This would make it seem like the individual is not as active as they could be due to taking less steps in a day. Pedometers are less accurate at measuring the number of steps taken if the participant is walking at a slow speed (<60m/min) (Abel *et al.*, 2011). This can make them inappropriate use in an adult population (Hills, Mokhtar and Byrne, 2014) or in a population where a condition may be present that inhibits the speed they walk at. NSLBP patients have been described to walk at a slower cadence than their otherwise healthy counterparts (Ryan *et al.*, 2009). The NSLBP population is also described to utilise different strategies in order to walk faster compared to a population without NSLBP (Taylor, Evans and Goldie, 2003). Acute NSLBP patients are reported to increase the frontal plane movements of the pelvis and stride length to a greater extent (Taylor, Evans and Goldie, 2003). Therefore, the use of pedometers would not have been practical for measuring the activity levels of NSLBP patients. Pedometers would have also not been practical to use as they also have significantly less data storage capacity than other objective methods like accelerometers (Freedson and Miller, 2000). The different activities of daily living are complex in nature which further makes the applicability of pedometers to accurately estimate and assess free-living activities limited (Plasqui and Westerterp, 2007). The measurement in the trial also needed to provide a more in-depth assessment of the physical activity levels of the participants beyond the number of steps the participants completed in a day. Pedometers are fairly limited when measuring physical activity levels in participants as they only measure step count in time unlike accelerometers which provide information

on activity intensity, duration and frequency (Freedson and Miller, 2000; Trost *et al.*, 2002; Warren *et al.*, 2010; Lonsdale *et al.*, 2012; Aparicio-Ugarriza *et al.*, 2015).

Accelerometers have gained popularity in research and are one of the most commonly used objective measures for recording daily physical activity (Lee *et al.*, 2017), and demonstrate improvements over self-report methodologies (Kohl, Fulton and Caspersen, 2000; Trost, 2001; Dencker and Andersen, 2011). The results of a systematic review demonstrated that 57% of the article included used accelerometers to measure physical activity levels in a population with cardiometabolic conditions (Hodkinson *et al.*, 2019). Accelerometers have been used in previous LBP trials (Verbunt *et al.*, 2001; Bousema *et al.*, 2007; Hendrick *et al.*, 2009, 2013; Ryan *et al.*, 2009; van Weering *et al.*, 2009) and in a trial investigating the responsiveness of disability measures with physical activity measures for CNSLBP patients (Morelhão *et al.*, 2018). Other trials have used accelerometers to measure the physical activity of patients of other conditions, such as chronic obstructive pulmonary disorder (COPD) (Teylan *et al.*, 2019) and lung disease (Mesquita *et al.*, 2017).

Accelerometers are motion sensors which can detect the acceleration of the body and provide an objective measure of physical activity (Innerd *et al.*, 2015). Accelerometers are described to be non-intrusive with the ability to monitor activities throughout a day or over periods of time (Chahal, Lee and Luo, 2014) long enough to account and represent normal daily life (Deyo *et al.*, 1998; Lonsdale *et al.*, 2012; Mannini *et al.*, 2013). Acceleration can be defined as the rate of change in velocity over a given period of time (Ridgers and Fairclough, 2011). Accelerometers contain piezoelectric transmitters which are stressed by acceleration forces (Hills, Mokhtar and Byrne, 2014). Accelerometers measure the acceleration of the body in one (vertical), two (vertical and medio-lateral) or three orthogonal planes (vertical, medio-lateral and anterior-posterior) and register this acceleration in 'real time', otherwise known as counts per unit of time (also referred to as an epoch) (Bassett and Chen, 2005; Rachele *et al.*, 2012; Arnardottir *et al.*, 2013; Mannini *et al.*, 2013; Hills, Mokhtar and Byrne, 2014). Accelerometers allow researchers to estimate EE, movement and activity patterns, and sedentary behaviour in free-living situations (Sirard *et al.*, 2011). Estimation of intensity and duration of movement is also enabled by accelerometry and the relationship between energy costs and accelerometer counts enables physical activity to be classified by intensity (Oliver *et al.*, 2007; van Cauwenberghe *et al.*, 2011). Accelerometers have become a

favourable tool of estimating physical activity as they are practical, objective, accurate, non-invasive and reliable in quantifying volume and intensity of physical activity with minimal discomfort to the participant using/wearing the accelerometer (Westerterp, 2009).

Accelerometers provide continuous acceleration data, which enables measures of physical activity to be drawn from published and validated algorithms (Welk and Corbin, 1995; Castillo-Retamal and Hinckson, 2011). Kelley et al. (2014) developed an algorithm for accelerometers to derive loading intensity from activities of daily living using the magnitude and frequency of the signals of the accelerometers (Chahal, Lee and Luo, 2014). It is reported that the algorithm is able to differentiate between the loading intensities of different physical activities of daily living (Chahal, Lee and Luo, 2014).

For these reasons, accelerometers were decided to be the most appropriate objective measure for the context and aim of the feasibility-pilot trial. Accelerometers are worn by attaching the device to the hip, the lower back, wrist (Vanhelst *et al.*, 2012; Urbanek *et al.*, 2017; Full *et al.*, 2018), thigh (Arvidsson, Fridolfsson and Börjesson, 2019) or ankle (Kinder *et al.*, 2012). The attachment sites of the accelerometer are thought to be irrelevant, however the most preferable place to attach the accelerometer is at the hip or lower back (Warren *et al.*, 2010). The attachment methods of the accelerometers to the lumbar spine posed an implication for data collection in the feasibility-pilot trial. The lumbar spine (L4-L5) was chosen as the attachment site as this site is reported to represent the actual acceleration of the lower trunk when walking (Moe-Nilssen, 1998). This attachment site also has lower levels of transverse plane rotation during movement (Kavanagh and Menz, 2008).

3.7 Research implications for using an accelerometer

Accelerometers, in research settings, have generally been attached to the human body using double-sided, hypoallergenic sticky tape in previous trials (Brayne *et al.*, 2018) and in previous back pain trials (Wong, Lee and Yeung, 2009). Bone mounted accelerometers are considered the “gold standard”, but there are ethical issues with this approach (Wong, Lee and Yeung, 2009). Double-sided tape is often used as it is the closest alternative to mounting the accelerometer to bone (Wong, Lee and Yeung, 2009) and has the lowest frequency response (Hanley, 2017). This means the tape does not interfere with the data

collected by the accelerometer and promotes transmissibility (Endevco, 2010). The feasibility-pilot trial required participants to wear the accelerometer daily over a period of 6 weeks. Using double-sided hypoallergenic sticky tape to mount the accelerometer could be detrimental to the trial and to the participants. The participant's skin may become tender, irritated, and sore with the daily reapplication of the double-sided sticky tape. Additionally, perspiration could result in the accelerometer, mounted via the use of tape, falling off. From a research point of view, this task may become monotonous, and the participant can easily forget to attach the accelerometer to the spine. Additionally, if the participant's skin does become tender, due to the constant reapplication of the sticky tape, then participants may not be compliant with wearing the accelerometer daily. Therefore, it was necessary to investigate other methods of mounting an accelerometer to the spine to collect physical activity data which would not be taxing for the recruited participants and would not interfere with data collection. Current published research articles have focussed on the validity and reliability of different models of accelerometers to collect physical activity data (Aadland and Ylvisåker, 2015; Lee *et al.*, 2017) or have compared the data collected via an accelerometer with another method of collecting physical activity data, such as oxygen consumption (Kelly *et al.*, 2013). Other studies have looked at the most optimal site on the body to attach the accelerometers in order to measure physical activity (Boerema *et al.*, 2014; Nightingale *et al.*, 2015). There are no validation studies for wearing an accelerometer on a strap (belt) with the device enclosed in a case. To the authors knowledge there is no published research article to compare the two different methods (tape method vs the belt method) of wearing the RX3 accelerometers at the same site (lumbar spine). Therefore, there is a gap in the literature and the need for a trial to validate the use of a belt as a mounting method for an accelerometer. This led to the development of two pilot trials to assess the validity and reliability of mounting accelerometers enclosed in a latex-free pouch, around the waist on a latex-free belt. The tape method was used for comparison during data collection.

3.8 Comparison of two different methods of attaching accelerometers to the human body for the measurement of physical activity

3.9 Aim of this trial

The aim of this trial was to validate the wearing method of an accelerometer, mounted on a latex-free belt (ActiGraph) enclosed in a pouch. This trial is divided into two parts. Trial 1 investigated the difference between the tape method versus the belt method when worn simultaneously at the same location (lumber spine, spinal level L4-L5). Trial 2 investigated whether a set of instructions were reliable and could guide participants in correctly positioning and wearing the belt method. Differences in positioning was also assessed and evaluated in this trial. These trials informed the feasibility-pilot trial on the best mounting method for wearing the accelerometer.

3.10 Pilot trial 1

3.10.1 Trial design

The trial was a repeated measures-controlled trial. Pilot trial 1 was approved by the London South Bank University (LSBU) Ethics Committee (Ref: School of Applied Science (SAS)1711).

3.10.2 Eligibility criteria

To be eligible for this study participants had to be:

- Over the age of 18
- Free of musculoskeletal injury or disability
- Be physically able to complete the set physical activities

3.10.3 Participants

The participants in this trial were drawn from an opportunistic sample of people known to the primary researcher, consisting of family, friends, and supervisors.

3.10.4 Anthropometric measurements

The participant's height was measured without shoes to the nearest 0.1 centimetre (cm) using a stadiometer (Seca 799). Body mass (BM) was measured in kilograms (Kg) (Seca 799), in everyday clothing. A clothing allowance of 0.5kg was provided. Body mass index was calculated using the equation: weight (kg) / height squared (m^2).

3.10.5 Sample size

Ten healthy adults aged between 18 and 65 years old (age = 31.8, SD = ±10.75; height = 172.82cm, SD = ±11.91, weight =76.11kg, SD= ± 16.41; BMI = 25.34, SD = ±4.83) volunteered to participate. Participants were recruited by providing them with a participant information sheet (appendix F). Participants provided written formal consent (appendix G) and completed a physical activity readiness questionnaire (PAR-Q) (appendix H) to ensure it was safe to proceed with the exercise activities. A customised demographic questionnaire (appendix I) was completed prior to beginning the trial to collect data on participants' age, weight, and height. Participants received a debriefing sheet (appendix J) after the trial had finished.

3.10.6 Accelerometers

Three-axis accelerometers (23 x 32.5 x 7.6 (mm); AX3 logging sensor, Axivity Ltd, UK) were used to measure physical activity. The accelerometers were set up with a sampling frequency of 50Hz, with a magnitude range of ±16g using AX3 GUI (The Open Movement Software, Newcastle University, UK). Previous work suggests that a sampling rate of 20 Hz is a reasonable standard for recording human activities (Khan *et al.*, 2016). This derives from the Shannon-Nyquist theorem. The Shannon-Nyquist theorem indicates that for a successful

(i.e., loss-less reconstruction of a particular signal) the data needs to be sampled with at least twice its highest frequency (Khan *et al.*, 2016). As voluntary human movements are not assumed to typically exceed 10 Hz, Shannon-Nyquist stated that >20 Hz would be reasonable when recording accelerometer data using wearable sensing platforms (Khan *et al.*, 2016).

The participants were required to wear 2 accelerometers simultaneously in trial 1 using both the tape method and the belt method– see figure 3.5. Participants were advised that both accelerometers should be taken off when they were doing any aquatic activities, including showering.

3.10.7 Accelerometer mounting method

Tape method

The tape method involved mounting the accelerometer to the patient's lumber spine (L4-L5 level) using double sided hypoallergenic sticky tape (see figure 3.2).

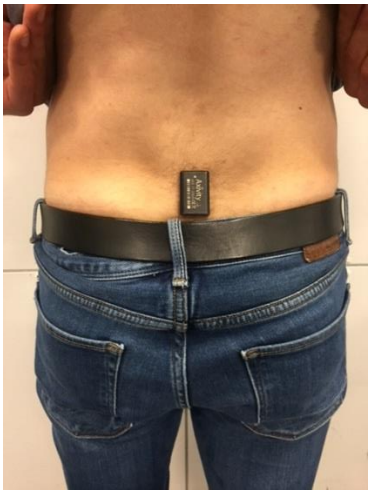


Figure 3.2: Tape method of mounting the accelerometer to the spinal level L4-L5 using double-sided hypoallergenic sticky tape

Belt method

The belt method involved mounting an accelerometer inside a latex-free pouch (ActiGraph, United States of America (USA), using double-sided sticky tape (see figure 3.3), and

mounting the pouch on a latex-free elastic belt (ActiGraph, USA). The belt was worn around the participant's waist, to a snug fit, around the lumbar spine (L4-L5 level) (see figure 3.4).

Figure 3.4: accelerometer taped in the pouch

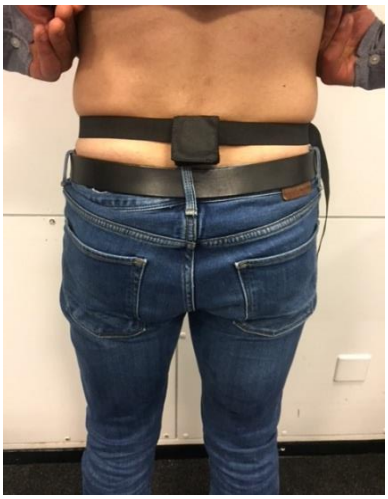


Figure 3.3: the belt worn around the waist at the L4-L5 spinal level

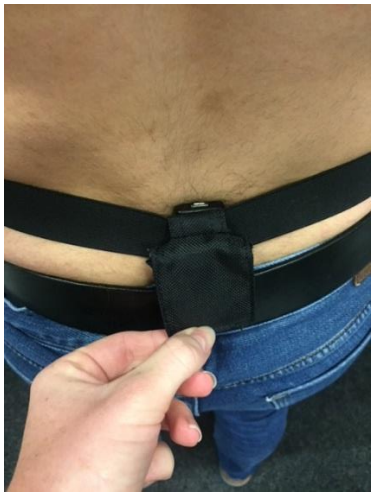


Figure 3.5: How the participants wore both acceleormeters simultaneously.

3.10.8 Testing protocol

Day 1 – controlled activities

On the first day participants were required to provide informed consent and to have their height and weight measured. The researcher applied the two mounting methods for the accelerometer to the participants. The participants wore the accelerometers simultaneously during the controlled activities. The participants completed eight controlled activities of slow, normal, and fast walking, slow, normal, and fast running and descending and ascending four flights of stairs. The walking and running measurements were performed on a treadmill. Each of these activities lasted approximately thirty seconds. The speed set on the treadmill for each domain were as follows: slow walking (3.4km/h), normal walking (4km/h), fast walking (5km/h), slow running (6km/h), normal running (6.5km/h), and fast running (8km/h). Descending and ascending the stairs were self-paced by the participant. These speeds were chosen to allow all the participants to comfortably complete the activities without the activities being too strenuous and to include participants with low fitness levels. After completing each of the controlled activities, the participant was required to wait for a period of one minute before progressing onto the next controlled activity (e.g., normal walking). This was performed to ensure that all the activities could be distinguished on both sets of accelerometer data.

Day 2 – Free living activities monitoring

This day of testing included wearing both mounting methods with the accelerometers for a whole day. The participants were asked to wear the accelerometers exactly how they wore them during the controlled activities. The researcher visually demonstrated and verbally instructed how to correctly apply both wearing methods at the spinal level of L4-L5. The researcher asked the participant to practise this in the laboratory and checked for understanding, until the participants were confident that they could correctly apply both methods by themselves, during the controlled activity testing.

The belt and pouch containing the second accelerometer were worn over the top of the accelerometer at L4-L5. Participants were instructed to wear the accelerometers (using both

the tape and belt method) during their waking hours. Participants were asked to record the time they removed the accelerometers at the end of the day, or at any point in the day where they took off the accelerometers. A set of instructions were designed, with pictures, to guide the participants on how to properly wear both the accelerometer and the belt, and how to locate the spinal level of L4-L5 (see appendix K) should they have required extra guidance.

3.10.9 Data analysis

Statistical analyses were carried out using IBM Statistical Package for Social Science (SPSS) version 21 for windows (SPSS, Chicago, IL). The level of significance was set at $p < 0.05$.

Accelerometer data analysis and MATLAB algorithm

The accelerometer data was downloaded using AX3 GUI [V1.0.0.30] (the Open Movement software) and then analysed using a customised MATLAB script. The customised script calculated the resultant acceleration, which was then filtered using a Butterworth bandpass filter (0.1 to 6Hz) in order to remove the static gravitational acceleration and noise. The computed acceleration data for twelve hours during a day (8am to 8pm) were divided into 8640 consecutive segments with a length of five seconds (s) each. Fast Fourier transformation was completed at each segment in order to ascertain the Fourier series in each frequency domain. The loading intensity, normalised to body weight (BW), of the activities were calculated at each segment. Every one of the 8640 segments (12-hour long segments) were then categorised according to the segments loading intensity into one of the following: very light activity (less than 5 BW/s), light activity (5-10 BW/s), moderate activity (10-15 BW/s), or vigorous activity (over 15 BW/s). More details can be found in the previous publication (Chahal, Lee and Luo, 2014).

Controlled activities data analysis

To examine the effects of accelerometer positioning on loading intensity during the controlled exercises a repeated-measures multivariate analysis of variance (MANOVA) was used. Loading intensity of each controlled activity was used as the dependent variables and accelerometer mounting position (tape method and belt method) was used as a between-groups factor.

Whole day data analysis

To examine the effects of accelerometer positioning on registered loading intensity in very light, light, and moderate exercise across twelve-hours of monitoring, a MANOVA was conducted using loading dose (BW) as dependent variables and accelerometer mounting method as a between groups factor.

3.11 Results

3.11.1 Controlled activity data

Initial analyses showed that the core assumptions for MANOVA were met. No multivariate outliers were found using the critical chi squared value at 0.001 (Mahalanobis Distance = 2.026 – 11.616). Equality of covariance matrices were met (Box's M = 31.5, F (21,1191.6) = .95, p = 0.53). There were no consistent patterns of multicollinearity (Pearson's r = .2 to .88). Linearity was met and was evaluated using scatter plots.

Results showed no significant multivariate effect for accelerometer mounting method (Wilks' Lambda = .034, F (9, 1) = 3.18, p = .411, $p\eta^2$ = .97). There were no differences in loading intensity during controlled exercises between the belt and tape wearing positions (figure 3.6). See table 3.3 for the means and standard deviation for the loading intensity during the controlled exercise.

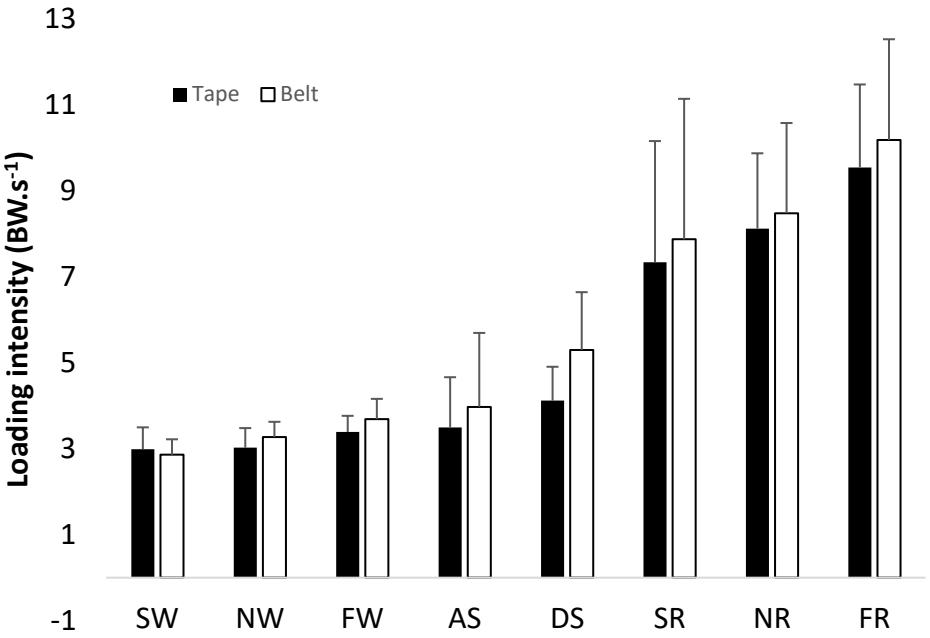


Figure 3.6: Loading intensities of the belt method (belt) and tape method (tape), with error bars for SD, during slow walking, (SW), normal walking (NW), fast walking (FW), slow running (SR), normal running (NR), fast running (FR), ascending stairs (AS) and descending stairs (DS).

Table 3.3: Means and standard deviation for the loading intensity of the 8 controlled exercises.

Controlled Activity	**Wearing position**	**Loading intensity (BW/s) Mean ± SD**
Slow walking	Belt	2.85 (±.36)
	Tape	2.99 (±.51)
Normal walking	Belt	3.3 (±.35)
	Tape	3.0 (±.46)
Fast walking	Belt	3.69 (±.47)
	Tape	3.4 (±.38)
Slow running	Belt	7.9 (±3.3)
	Tape	7.3 (±2.8)
Normal running	Belt	8.5 (±2.1)
	Tape	8.1 (±1.8)

Controlled Activity	Wearing position	Loading intensity (BW/s) Mean ± SD
Fast running	Belt	10.2 (±2.3)
	Tape	9.5 (±1.9)
Descending stairs	Belt	5.3 (±1.3)
	Tape	4.2 (±1.0)
Ascending stairs	Belt	3.7 (±1.2)
	Tape	3.6 (±1.3)

3.11.2 Whole day data

Initial analyses showed that the core assumptions for MANOVA were met. No multivariate outliers were found using the critical chi squared value at 0.001 (Mahalanobis Distance = 1.627 – 18.011). There was also no consistent pattern of multicollinearity (Pearson's r = .24 to 92). Equality of covariance matrices were met (Box's M = 329.96, F (45,1064.39) = 3.19, p < 0.001). Linearity was met and was evaluated using scatter plots.

No significant multivariate effect was shown between the belt and back mounting method of the accelerometer for the whole day data analysis (Wilks' Lambda = .0.84, F (9,1) = 1.2, p = .61, $p\eta^2$ = .92). There was no difference in time spent in physical activity and loading intensity between the belt and tape wearing positions during a whole day measurement (see table 3.4). None of the participants recorded any vigorous activity.

Table 3.4: Means and standard deviation for the dose of activity the participants completed in each category (very light, light and moderate activity) for the whole day analysis, measured in dose (BW).

Category of activity	Wearing position	Dose (BW) Mean ± SD
Very light		
	Belt	13,921.3 (±5,989.7)
	Tape	14,074.6 (±6,128.4)
Light		
	Belt	765.4 (±1,021.4)
	Tape	649.3 (±772.9)
Moderate		
	Belt	125.7 (±339.7)
	Tape	171.2 (±369.7)

3.12 Pilot Trial 2

Several limitations were identified in pilot trial 1, specifically the fact that both mounting methods of the accelerometer were worn simultaneously during the controlled activities and whole day measurements, and the instructions for guiding the participants to correctly wear the accelerometer had not been tested for reliability. These instructions were to be used in the feasibility-pilot trial and so reliability needed to be checked. The researchers were worried that the application of both mounting methods simultaneously may have caused interference with the data collected (i.e., the accelerometers may have been impacting on one another and inhibiting the amount of natural free movement which would be present when wearing just one mounting method). Pilot trial 2 is a refinement of the testing protocol used in pilot trial 1. This trial was approved by the LSBU Ethics Committee (Ref: SAS1810).

3.12.1 Sample size

Ten healthy adults (5 male and 5 female) aged between 18 and 65 years old (age = 37.7 SD = ±15.98; height = 171.8 SD = ±11.91; weight = 81.2 SD = SD ±10.1; BMI = 27.6 SD = ±3.7) volunteered to participate in the trial. An updated participant information sheet (appendix L) was provided to participants to account for the refinements made to this trial. Informed consent was provided using a consent form specific to this pilot trial (appendix M). Height and weight of the participant were measured, using the same demographic questionnaire (appendix I) from pilot trial 1.

3.12.2 Testing Protocol

This protocol required testing of the participants on two occasions, one week apart. Informed consent was provided. Height and weight of the participant were measured. The participants were required to read a set of instructions on how to apply the belt around their waist (appendix K). As they understood from the instructions, the participants attached the belt around their waist without any interference from the researcher. To check for reliability of the instructions, the position of the belt was checked, and the researcher noted

if the belt was in the correct position. No formal measurement was taken. The researcher did not inform the participant if the belt was positioned correctly. The testing protocol of the controlled activities from trial 1 was then implemented with the participant. The participant removed the belt after all the controlled activities were complete and the researcher mounted a new accelerometer in the correct position (L4-L5) directly to the participant's skin, using double sided, hypoallergenic sticky tape. The testing protocol from trial 1 for the controlled exercises were repeated.

On the second visit, the participants repeated the protocol the same as they did on their first visit. The researcher did not inform the participant if they applied the belt method in the correct position until after all the testing protocols and data collection was complete. At the end of the trial, the participants were provided with a debriefing sheet (appendix N).

3.12.3 Data analysis

The same statistical tests were completed as the ones outlined in *3.10.10 Data Analysis* for the controlled activities. The only difference is the type of MANOVA which was used. For this trial a one-way repeated measures, within-subjects MANOVA was used with loading intensity measures for each of the controlled activities as dependent variables and the trial week (visit 1 and visit 2) and the wearing position of the accelerometer (tape method and belt method) as independent variables.

3.12.4 Results

Controlled activity data across both days

Initial analyses showed that the core assumptions for a one-way repeated measures MANOVA were met. Mahalanobis Distance identified no multivariate outliers. There was no consistent pattern of multicollinearity (Pearson's r = -.25 to .87). Linearity was met and was evaluated using scatter plots.

Results showed no significant multivariate effect for accelerometer wearing condition (Wilks' Lambda = .35, F (7, 3) = .79, p = .64, $p\eta^2$ = .65). There were no differences in loading

intensity during controlled exercises between belt and tape wearing positions across both days of testing. Figure 3.7 and figure 3.8 demonstrate the loading intensities of the belt and tape method across the controlled exercises, during visit one and visit two respectively.

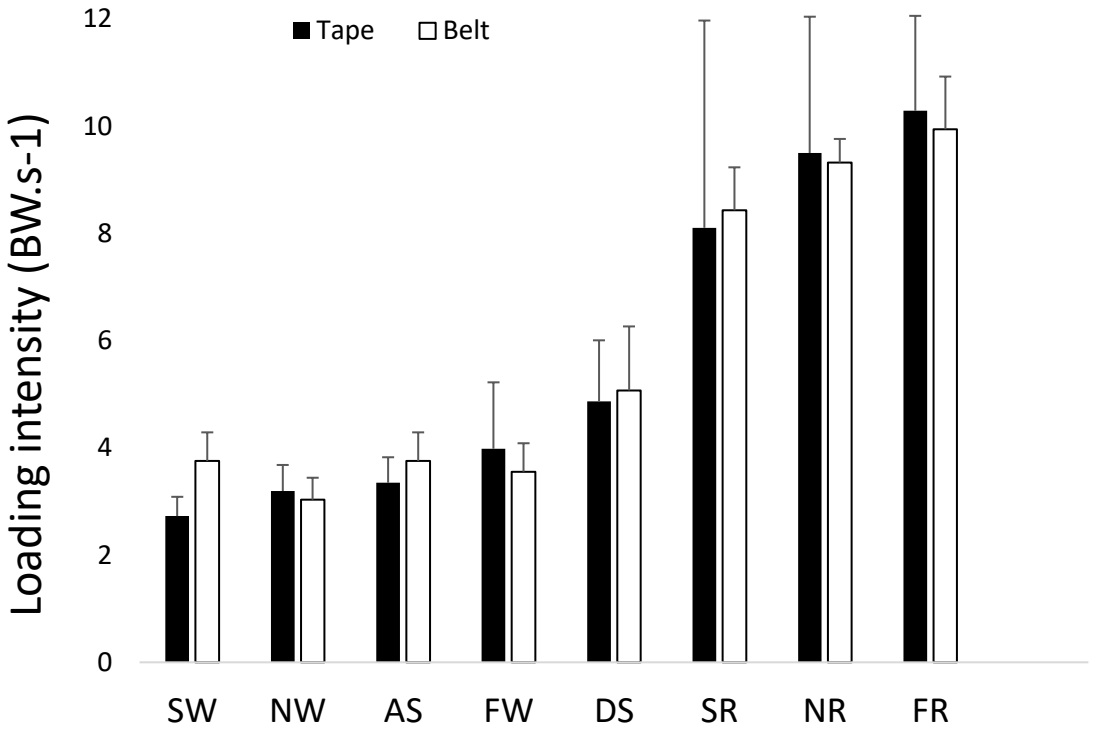


Figure 3.7: Visit 1 - Loading intensities of the belt method (belt) and tape method (tape), with error bars for SD, during SW, NW, FW, SR, NR, FR, AS and DS.

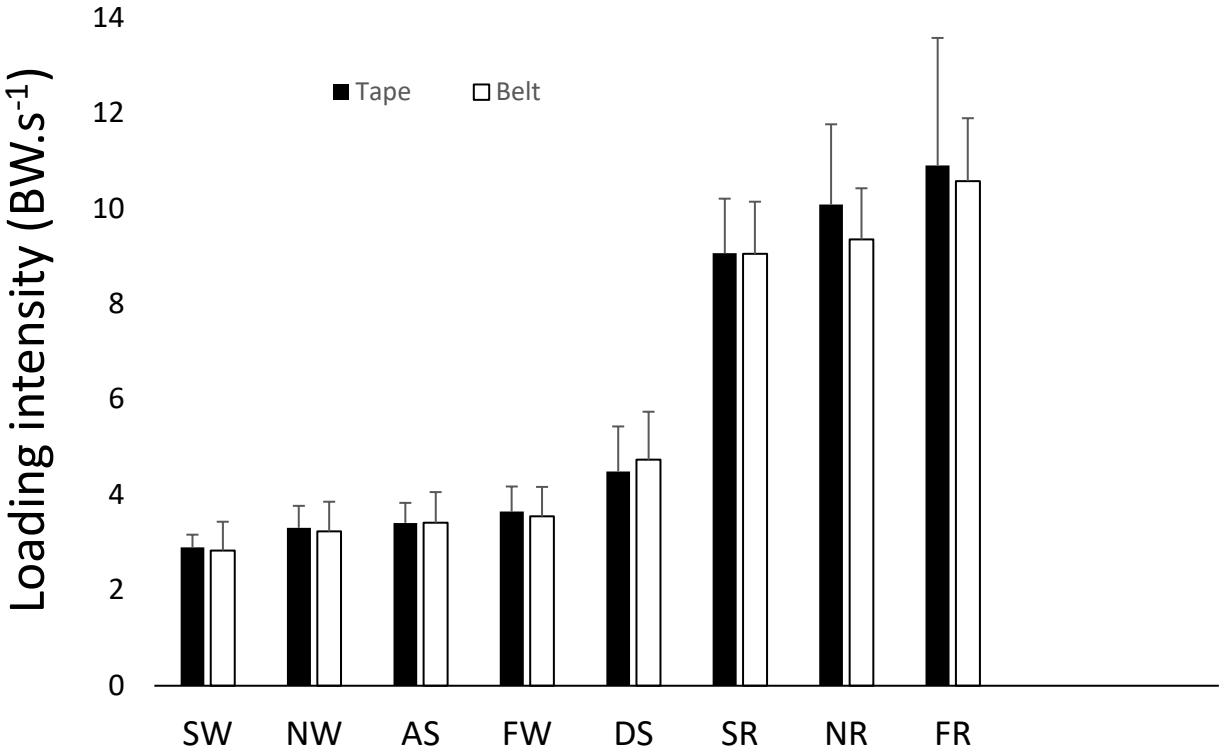


Figure 3.8: Visit 2 - Loading intensities of the belt method (belt) and tape method (tape), with error bars for SD, during SW, NW, FW, SR, NR, FR, AS and DS.

3.12.5 Reliability of the instructions

Results showed that 80% of the participants correctly positioned the belt around their waist on their first visit with the researcher. 90% of participants correctly positioned the belt around their waist on their second visit with the researcher. The participants who did not position the accelerometer correctly placed the accelerometer within 1.5cm of the correct spinal level, with the accelerometer positioned either lateral of L4-L5 (i.e., on the erector spinae muscles) or superior to L4-L5 (i.e., more at the spinal level of L1-L2).

3.13 Discussion

These trials demonstrate that the belt method is a reliable and valid method of capturing data in free-living conditions. The set of instructions designed and used in this trial have been shown to be reliable in guiding the participants to wear the belt at the correct spinal level. There were no significant differences between the tape method and the belt method

of mounting accelerometers during free-living conditions and controlled exercise, in either of the trials.

These trials are similar to previous research, whereby differences in data collection in different accelerometer models, at the same anatomical site, have been investigated (Bouten *et al.*, 1997; John, Tyo and Bassett, 2010; Lee *et al.*, 2017). There were no reported significant differences between the different accelerometer models in their ability to monitor and collect physical activity data when attached to the same anatomical site. A similar trial (Montoye *et al.*, 2016) investigated different anatomical mounting sites for accelerometers, comparing the accuracy of the data collected by the accelerometers at each site for physical activity and sedentary behaviour. A waist-worn accelerometer (ActiGraph), mounted on the non-dominant hip was tested for validity against an accelerometer worn around the ankle, just above the ipsilateral lateral malleolus (Motl *et al.*, 2010). The results of this trial demonstrated that the waist-worn accelerometer was able to collect intra- and inter-person variation in walking (Motl *et al.*, 2010).

These trials found similar findings to that of Chahal, Lee, & Luo (2014). Chahal, Lee, & Luo (2014) discovered that very little time was spent on moderate and vigorous activity, with over half of the participant sample not recording any vigorous activity data. This is comparable to another study which demonstrates that an acceleration magnitude greater than 3.1 gravitational force (g) (moderate levels of activity) is rare when recording activities of daily living (Deere *et al.*, 2012). For studies only requiring measurement of activities of daily living, this is not a problem.

However, the results of the two pilot trials differ to those reported by Kelley, Hopkinson, Strike, Luo, & Lee, (2014) whom looked at the loading dose of physical activity on bone. The same customised MATLAB script was used to analyse the loading intensity and loading dose of the controlled exercises and the whole day physical activity data collected via an RX3 Axivity accelerometer. However, different loading intensities for the controlled activities of walking and running were reported in this trial compared the study by Kelley *et al.* (2014). There is a possible reason to explain these differences. Kelley *et al.* (2014) asked their participants to complete the eight controlled activities in the natural environment, at a self-selected pace. In these trials the pace for the eight activities was pre-determined for the participants in a laboratory. This could account for the differences in loading intensity for

the controlled activities between the two trials. The walking and running speeds used in this trial may have underestimated the actual pace humans walk and run at in everyday life. This would account for the lower loading intensities reported. Moreover, as the paces were set, there would be no real variability in the data recorded, aside from stride length. This would also provide an explanation for the lower loading intensities reported.

The only real cause of concern for the researchers was the fact that both methods (tape and belt method) were worn simultaneously by the participants. Unintentional inference in data collection between the accelerometers in either method may have occurred due to the accelerometers being pressed snugly against the participant's lumbar spine. The result of this may have inhibited the natural movement of the accelerometers in either method, whereas the natural movement may be greater when applying each method singularly to the participant. The researchers considered this as another reason why the loading intensities produced in pilot trial 1 was lower than those reported by Kelley *et al.* (2014). This led to the design of trial 2 using a slightly different methodology. Trial 2 was designed purposefully to assess any differences in data collection between the tape method and the belt method when applied singularly to the participants throughout the controlled activities. Trial 2 did not assess differences in whole day data collection as the variability in the amount of activity a participant engages in from day-to-day could not be accounted for. The loading intensities in trial 2 were also consistently depicting lower loading intensities for the controlled activities. This reinforces the suggestion that the reason for this was due to the pre-determined paces used and how they may have been underestimated. Trial 2 was also designed to test the reliability of a set of instructions, instructing the participant how to correctly apply the belt method themselves, without interference from the researcher. These sets of instructions were designed to be able to be used as part of the feasibility-pilot trial methodology. As demonstrated in the results more than half of the sample size were able to correctly position the belt. When participants did not correctly apply the belt, displacement of the belt was within 1.5cm (lateral or superior) of the correct spinal level. However, this did not impact on the results of the trial as no significant differences between the mounting methods were found. This highlights that even if the participants do slightly misposition the belt, the belt method is still a valid mounting method compared with the tape method. Therefore, the set of instructions were demonstrated to be reliable. Trial 2

reinforces the results from trial 1, that there are no significant differences between the tape method and the belt method in capturing data in free-living conditions.

These trials have several strengths. Firstly, these studies assessed the data collected when both methods were simultaneously and singularly applied to the participant. A set of instructions have been appraised for reliability and the results indicate the instructions are reliable in guiding the participant to correctly apply the belt method, by themselves and can therefore be used in the feasibility-pilot trial of this thesis. The results also provided a more participant-friendly, convenient, and easy to apply wearing method (belt method) of using accelerometers in order to collect data during free-living conditions. This method can be used over extended periods of time, with little discomfort and stress to the participant. Finally, the results highlight that the belt method is comparable to the 'gold standard' of applying accelerometers using double-sided adhesives stuck to the skin.

There are several limitations in these trials. None of the participants recorded any vigorous activity and only a few managed to record some moderate activity during the whole day assessment. The validity of the belt method during vigorous activity could not be assessed and evaluated as a result of this. As previously mentioned and demonstrated by another study (Chahal, Lee and Luo, 2014), recording a magnitude over 3.1g is scarce when measuring activities of daily living (Deere *et al.*, 2012). The sample size is small but was enough for the purpose and objectives of this trial.

3.13.1 Clinical implications and future research

The results of these trials would benefit future studies where data collection is consistently required over a long period of time (e.g., several weeks). It was reported by the participants in trial 1 that the accelerometer attached to the lumbar spine with double-sided hypoallergenic sticky tape often became lose, and in some instances the accelerometer fell off, due to human sweat and prolonged movement. This would be unideal and interfere with the integrity of the data collected in a trial and possibly make the participant uncompliant, if the participant was 1) to keep on having to re-apply the accelerometer to their lumbar spine and 2) if the accelerometer was to be lost after falling off the lumbar

spine. The belt method would address these issues as there is minimal chance of the accelerometer being lost and the belt is quick and easy to apply. Finally, prolonged taping of the accelerometer to the lumbar spine would cause some skin irritation. The belt method allows for skin irritation to be minimised. Future studies should look at the differences in data collection using alternative mounting methods during vigorous activity to fill in this gap in the literature.

3.14 Conclusion

These two small pilot trials demonstrated that the belt mounting method of an accelerometer around the lumbar spine is a reliable and valid method to assess daily physical activity. This method is as good as the 'gold standard' of mounting the accelerometer to the lumbar spine via double-sided hypoallergenic sticky tape. These trials provide researchers with an alternative method of mounting the accelerometer for monitoring and collecting physical activity data, especially for studies designed to monitor activity daily over a long period of time. These trials validated the methods used in the feasibility-pilot trial of this thesis.

3.15 Chapter summary

- There are a variety of methods, subjective and objective, for the measurement of daily free-living conditions
- It is important to select the appropriate measurement for physical activity which reflects the aims and outcomes of the proposed work
- Mounting an accelerometer on a belt, in a pouch, around a participant's waist is a reliable and valid method for wearing an accelerometer

4 Chapter 4 – Interventions: development, justification, and underpinning theory

4.1 Chapter introduction

This chapter describes the development of the four interventions used in the feasibility-pilot trial and specifies the intervention components. The interventions were systematically developed using the Behaviour Change Wheel (BCW). This chapter also describes the importance of utilising behaviour change theories, frameworks and models when designing complex healthcare interventions aiming to change behaviour in accordance with the Medical Research Council (MRC) guidelines. Different frameworks and models are discussed and the rationale for using the BCW is provided.

4.2 Introduction

Self-management of NSLBP has been recognised to decrease the burden of this condition on healthcare resources (Oliveira *et al.*, 2012; National Institute for Health and Care Excellence, 2016). Self-management interventions are poorly defined and described in the literature which presents a challenge to understanding their effectiveness (Oliveira *et al.*, 2012). Current NICE guidelines recommend NSLBP patients are encouraged to self-manage their pain by engaging in regular physical activity (National Institute for Health and Care Excellence, 2016).

The authors of a review reported that NSLBP self-management interventions are sparsely developed using theory (Mansell, Hall and Toomey, 2016). A review of BCTs and theories in group-based self-management interventions for persistent LBP demonstrated that only three of the twenty-two included studies were indexed as “theory informed” (Keogh *et al.*, 2015). It has been acknowledged that a lack of theoretical rationale is a vital impediment in developing effective interventions (Craig *et al.*, 2008; Michie *et al.*, 2008; Prestwich, Webb and Conner, 2015). This lack of theoretical rationale could provide an explanation for some of the heterogeneity surrounding the effectiveness of interventions for the self-

management of NSLBP (Mansell, Hall and Toomey, 2016). Theoretically underpinning an intervention enables researchers and clinicians to understand how and why the intervention had an impact on the outcomes (or no impact). This information equips researchers with the ability to focus on the mechanisms of change, allowing such interventions to be tested and enhanced (Michie *et al.*, 2008; Painter *et al.*, 2008).

The intervention development stage of complex intervention trials is often overlooked, and the important processes and decision-making of intervention development are seldom reported (Hoddinott, 2015). Until recently, researchers have not been interested in the publication of the intervention development studies (Hoddinott, 2015). Improving the design of complex interventions is as important as their evaluation when aiming to improve the effectiveness of such interventions (Wight *et al.*, 2015).

Therefore, the purpose of this chapter is to document how the interventions used in the feasibility-pilot trial of this thesis were developed with an explanation and specification of the underpinning BCTs applied.

4.3 Developing complex interventions – frameworks and theories

Behaviour change is a key concept in improving healthcare and associated health outcomes (Cane, O'Connor and Michie, 2012). Designing effective interventions to change behaviour is a challenging and complex process (Jenkins *et al.*, 2018). Trying to change behaviour is not easy, but it is more effective if the interventions are designed using evidence-based principles of behaviour change (Cane, O'Connor and Michie, 2012). There is evidence to suggest that interventions designed to change behaviour informed by theory are more effective than the interventions that are not informed by theory (Cane, O'Connor and Michie, 2012). BCTs are reported to be important when designing healthcare interventions as most health care interventions are theoretically underdeveloped (Michie, Ashford, *et al.*, 2011; Michie *et al.*, 2013).

In a LBP population, there may be some avoidance behaviours towards activity, such as fear avoidance (Lethem *et al.*, 1983; Vlaeyen and Linton, 2000) or fear of movement/re-injury

(Vlaeyen, Kole-Snijders, Rotteveel, *et al.*, 1995), which need to be addressed and changed if the intervention is going to be effective in its purpose (i.e., increasing physical activity). NICE have stated that establishing the optimal types of BCTs, designed to encourage and sustain physical activity, needs to be a research priority (National Institute for Health and Care Excellence, 2014).

There are a variety of theories which can be incorporated in an intervention to bridge the intention-behaviour gap and increase physical activity in a NSLBP population These theories include Bandura's theory of self-efficacy (Bandura, 1977) (as part of the social cognitive theory), the Theory of Planned Behaviour (TPB) (Ajzen, 1985) and the Protection Motivation Theory (Rogers, 1975). The intention-behaviour gap is the gap between forming an intention (e.g., wanting to be active) and what the resultant behaviour is (e.g., the individual carried out their intention to be active) (Sniehotta, Scholz and Schwarzer, 2005).

Several process models, such as the Behaviour Change Wheel (BCW) (Michie, van Stralen and West, 2011), the Health Belief model (Rosenstock, 1974), Transtheoretical Model (TTM) (Prochaska and Velicer, 1997) and Theoretical Domains Framework (TDF) (French *et al.*, 2012) have been developed to aid the development of interventions to expedite behaviour change (Hodder *et al.*, 2016; Jenkins *et al.*, 2018). However, the majority of theories and models have a degree of construct overlap, and it is not always clear which model or theory is best utilised.

In order to bring about a change in behaviour, interventions need to embody elements of:

- Needs/behaviour analysis
- Appropriate techniques
- Strategies to implement the techniques
- Evaluate the developed intervention (Bartholomew, Parcel and Kok, 1998; Michie *et al.*, 2008; Craig *et al.*, 2008)

Pilot testing of the developed intervention is necessary to improve the delivery of the intervention in a clinical setting (Jenkins *et al.*, 2018).

There are already existing frameworks and guidance for the development of complex interventions (Wight *et al.*, 2015). These include: Intervention mapping (Bartholomew,

Parcel and Kok, 1998), MINDSPACE (The Institute for Government, 2010), Conceptual framework for planning intervention-related research (de Zoysa *et al.*, 1998), PRECEDE-PROCEED model (Green, Kreuter and Green, 2005), and the framework for design and evaluation of complex interventions to improve health (MRC, 2008). The MRC guidelines for complex interventions provide a step-by-step process guide on how complex interventions should be developed, tested and evaluated (Craig *et al.*, 2008). Four key process were identified as integral components of developing complex interventions (see figure 4.1).

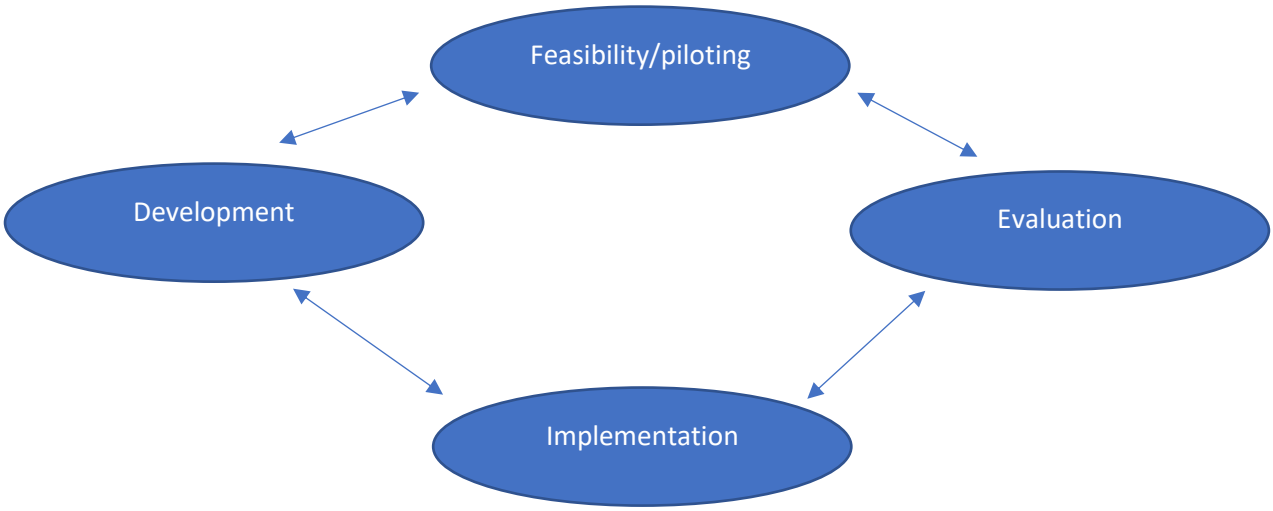


Figure 4.1: *The key elements of developing and evaluating complex interventions as defined by the MRC. Adapted from* Craig *et al.* (2008).

These four key processes, and the steps involved with each process are outlined below.

Development:

1. Analysing the current evidence base
2. Establishing/developing relevant theory
3. Shaping the process and outcomes

Feasibility/piloting:

1. Trialling the procedures
2. Estimating the recruitment and retention rates

3. Determining/calculating a sample size

Evaluation:

1. Evaluating effectiveness
2. Understand the change process
3. Appraise cost-effectiveness

Implementation:

1. Present findings
2. Observation and audit
3. Follow-up (long-term)
4.

4.4 Developing complex interventions – which theory, model or framework is best?

The decision on which relevant behavior change theory to adopt for an intervention is challenging, particularly because there are a large number of theories to select from, with concepts which are either the same or have overlapping constructs (Michie *et al.*, 2005). In the published evaluations of interventions, there is a skewedness towards a small number of theories which are prominent in the topic area (Painter *et al.*, 2008). There is rarely an analysis of the behaviour problem to guide the choice of theories. This suggests that interventions, which are theoretically underpinned, use "commonsense models of behaviour" or a "common" theory - i.e., a theory is used because it has been used previously, rather than used because it is the most appropriate for the purpose of the intervention (Michie, van Stralen and West, 2011). This approach limits the benefit of the intervention having a theoretical underpinning (Michie, van Stralen and West, 2011). The current behaviour change theories and models do not account for the full range of potential influences on behaviour, even in the instance that two or more theories, or models, are

utilized (Michie, van Stralen and West, 2011). For example, the Theory of Planned Behaviour and the Health Belief Model are unable to account for the some of the behavioral influences, such as impulsivity, habit, emotional processing or self-control (West and Brown, 2013).

There are a variety of behaviour change frameworks available for researchers to classify behaviour change interventions. However, these existing frameworks, after an informal analysis by Michie, van Stralen, & West (2011), were deemed to be not "comprehensive" and were "conceptually" incoherent. An example of this is the MINDSPACE framework (The Institute for Government, 2010). The informal analysis completed Michie, van Stralen, & West (2011) suggested that the framework did not cover all the vital intervention types, and only recognises two systems of human behaviour which can be influenced – reflective and automatic – with a focus on the latter.

The Theoretical Domains Framework (TDF) was developed to address the plethora of the different and overlapping behaviour change theories, and provide some guidance on to choose between the many theories (Michie *et al.*, 2005; Cane, O'Connor and Michie, 2012; Davis *et al.*, 2015). The TDF, informed by 128 explanatory constructs (components of theories) from 33 theories (sorted into 12 domains), was developed by psychologists and implementation researchers (Michie *et al.*, 2005), and is a framework of theoretical domains which account for, and explain, the barriers and facilitators of behaviour for any specific scenario (Cane, O'Connor and Michie, 2012; Davis *et al.*, 2015). One of the problems with using the TDF is that is does not consider the relationship(s) between the constructs and the theoretical domains - i.e., it does not specify the effect one domain or construct may have on each other. Therefore, the TDF provides a "theoretical lens through which to view the cognitive, affective, social and environmental influences on behaviour" (Atkins *et al.*, 2017).

When aiming to change behaviour, it is important for researchers to be able to identify the type(s) of intervention which are likely to be effective. Therefore, it is vital that researchers are able to systematically select these interventions, whilst having the full range of options highlighted (Michie, van Stralen and West, 2011). This can only be achieved if there is a system which addresses all the types of interventions possible, characterising the

interventions alongside a system which connects the behaviour target, target population and context where the intervention will be delivered (Michie, van Stralen and West, 2011) .

The challenge in selecting a relevant behaviour change theory becomes harder because, until now with the BCW, and partially with the TDF, there has been a lack of guidance on which theory to select (Michie, van Stralen and West, 2011) based on the purpose of the intervention or desired behaviour the intervention aims to promote.

The BCW is a model of behaviour providing a systematic way of characterising the interventions, alongside a system linking the target behaviour with the target population and context. The BCW allows for interventions to be developed using a step-by-step process to guide researchers or intervention developers in designing effective interventions for a specific behavioral target. The BCW with the COM-B analysis acknowledges that behaviour is part "of an interacting system" involving the components of "capability", "opportunity", "motivation" and "behaviour" (Michie, Atkins and West, 2014). The COM-B analysis and the BCW allows for the behavioral problem to be addressed more broadly as it encompasses for problems relating to "capability and opportunity" (Michie, Atkins and West, 2014). The BCW, with COM-B analysis, highlights which components of behaviour need to change to achieve the desired behaviour, and links these components to the relevant intervention functions, which are most likely to be effective to achieve the desired behaviour. These intervention functions are linked to the most effective policy categories (if the intervention is trying to influence policies), and once this is complete the researchers are provided with a 'menu' of which BCTs can be incorporated and are most effective based on the intervention components, functions and policy categories identified. Finally, the BCW highlights the different modes of delivery the intervention can take, based on the goal of the intervention.

The BCW is the first model to provide researchers and intervention developers with the tools and guidance to design robust behaviour change interventions. The simple, practical and all-encompassing nature of the model led to extensive up-take in the fields of interventions, policy and academia (Michie, Atkins and Gainforth, 2016). The simplistic, step-by-step nature of the model also allows researchers and intervention developers to evaluate past interventions, which can help identify why the intervention did not achieve the desired goal, if necessary (Michie, Atkins and Gainforth, 2016).

4.4.1.1 The Behaviour Change Wheel

The interventions to be used in the feasibility-pilot trial were developed using the BCW. The BCW was constructed as the result of a consensus study by over 30 researchers in health psychology and implementation sciences (van Aerde, 2015). Michie and colleagues complied different theoretical models (Mansell, Hall and Toomey, 2016) with the aim of applying theory towards changing behaviour, through an array of interacting behaviour change frameworks (Mansell, Hall and Toomey, 2016). These frameworks include the capability, opportunity and motivation – behaviour (COM-B system), the Theoretical Domains Framework (TDF) and the BCT taxonomy (Michie, van Stralen and West, 2011; Cane, O'Connor and Michie, 2012; Michie *et al.*, 2013). The result was one framework (the BCW) which encapsulates and combines all the relevant components of other frameworks to allow for a comprehensive and systematic approach to designing interventions for behaviour change (Michie, Atkins and West, 2014, p. 17). The BCW is comprised of 3 concentric circles (see figure 4.2) (van Aerde, 2015).

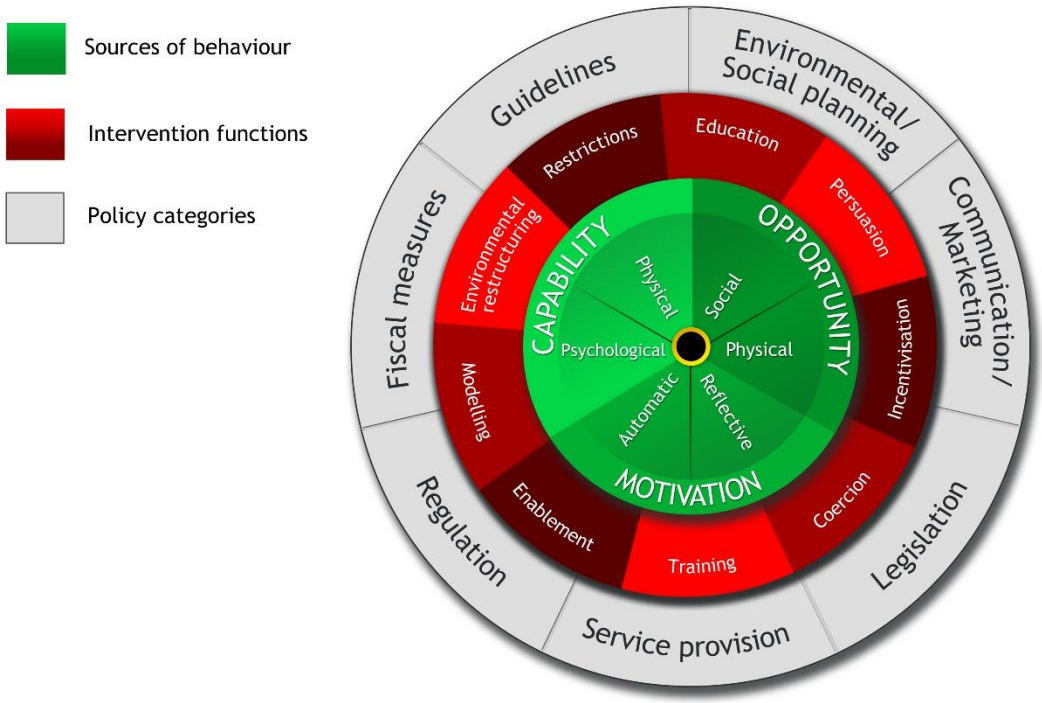


Figure 4.2: The Behaviour Change Wheel (Michie, van Stralen and West, 2011).

The inner circle (presented in green) depicts the sources of behaviour which cause and maintain it and/or prohibit it from changing (van Aerde, 2015). This inner circle is also referred to as the COM-B system. The inner circle allows the user to specify the target behaviour and then identify what needs to change in order to reach the target behaviour (van Aerde, 2015). When the target behaviour has been identified, the BCW provides a variety of choices of nine evidence-based interventions (van Aerde, 2015).

The intervention functions are highlighted in the middle circle and the outer circle is constructed of the categories of policy that need to be taken into consideration when designing an intervention to support the delivery of the functions of the intervention (van Aerde, 2015). The policy categories highlight the types of decision that are needed to be made by relevant authorities to support and achieve the intervention that has been deemed to be effective.

4.4.1.2 The COM-B model of behaviour

This behaviour system demonstrates the sources of behaviour (the green circle in figure 4.2) in the BCW. In this 'behaviour system' capability, motivation and opportunity all interact in order to generate behaviour, which in turn influences these components (Michie, 2011) as shown in figure 4.3. The single- and double-headed arrows in figure 4.3 demonstrate the potential influence between the components in the system (Michie, van Stralen and West, 2011).

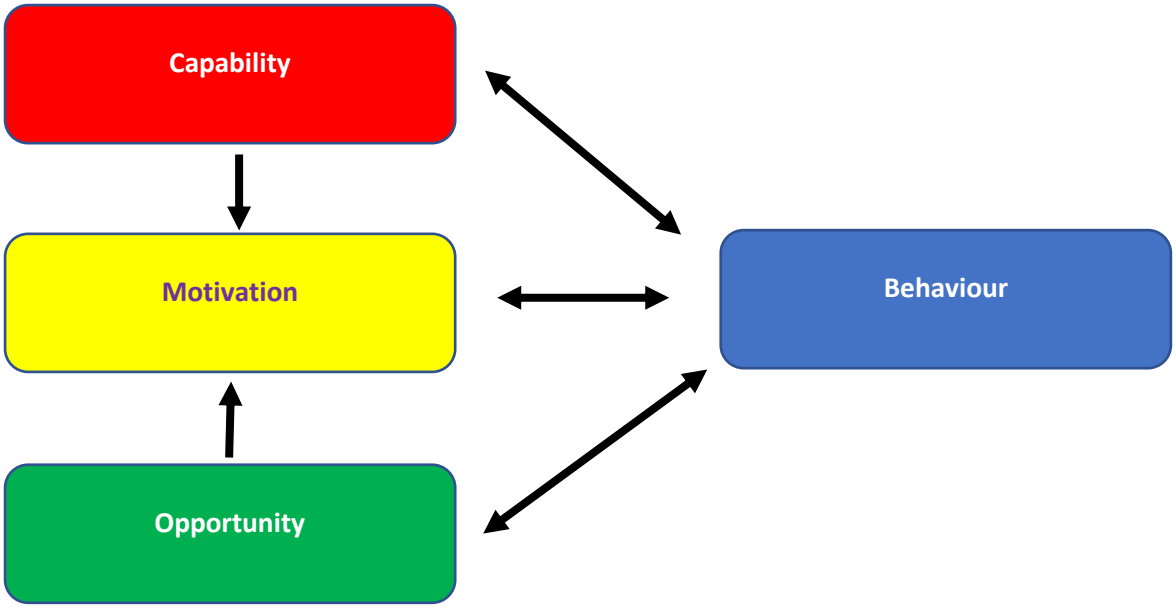


Figure 4.3: The COM-B behaviour system. Adapted from (Michie, van Stralen and West, 2011)

Capability is defined as an individual's physical capacity and psychological capacity to engage in the activity concerned (Michie, 2011; Michie, van Stralen and West, 2011). This includes having the necessary knowledge and skills (Michie, 2011) to engage in the activity concerned.

Motivation (reflective and automatic mechanisms) is defined as all the brain processes which direct and energise behaviour, not limited to just goals and conscious-decision-making (Michie, van Stralen and West, 2011). Analytical decision making, emotional responding and habitual processes are included in this term (Michie, van Stralen and West, 2011).

Opportunity is defined as the factors which lie outside of the individual that make or prompt behaviour (Michie, 2011).

The COM-B system can also provide a basis for designing interventions, focussing on changing behaviour even though it is a model of behaviour (Michie, 2011). It allows the user to specify the target behaviour (i.e., the desired behaviour – in this thesis it is physical activity) and then identify what needs to change in order to enable the target behaviour to occur (van Aerde, 2015).

4.5 Intervention design

The BCW outlines three crucial stages, comprised of eight steps to designing and developing complex interventions. These steps were utilised for the design and development of the four interventions used in the feasibility-pilot trial.

4.6 Stage 1

4.6.1 Step 1: Understand the behaviour of the population

The first step in designing complex theory informed interventions, as stipulated by the BCW, is to understand the behaviour of the population trying to be changed and identify the problem behaviour. For the development of the interventions, the behavioural problem has been identified as a lack of activity in NSLBP patients.

4.6.2 Step 2: Identify the target behaviour

As indicated by previous research and national guidelines, the target behaviour for the NSLBP population is increasing normal physical activity levels (see table 4.1).

Table 4.1: Identification of the target behaviour

What behaviour?	Increasing daily physical activity levels as outlined by the NICE guidelines
Where does the behaviour occur?	This behaviour needs to occur anywhere in the patient's daily life. E.g., this could be at home, in the gym or on their way to work.
Who needs to perform the behaviour?	NSLBP patients

4.6.3 Step 3: Specify the target behaviour

The target behaviour of increasing physical activity levels in a NSLBP population was selected. This behaviour was broken down in more specific details, including what the target behaviour is and the specifics of how to achieve the target behaviour in the target population. Table 4.2 outlines the specifics of the target behaviour for increasing physical activity in NSLBP patients. The specifics of who, what, where, when, how often and with whom the NSLBP population are going to increase their physical activity levels.

Table 4.2: Components of achieving the target behaviour

Target behaviour:	**Increasing physical activity levels**
Who needs to complete the target behaviour?	NSLBP patients
What do they need to do differently to achieve the desired change?	Increase their levels of physical activity
When do they need to do it?	Daily
Where do they need to do it?	Anywhere they wish. Outside in the park, garden, gym facilities. Wherever they feel comfortable.
How often do they need to do it?	Guidelines suggest daily physical activity for a minimum of 30 minutes a day is acceptable (Tremblay *et al.*, 2011; World Health Organization, 2015)
With whom do they need to do it	They can do it by themselves or with a group of friends

4.6.4 Step 4: Identify what needs to change

The COM-B self-evaluation questionnaire was used to identify what needs to change for the desired behaviour (NSLBP patients increasing their activity levels) to occur. This questionnaire provided an understanding of the barriers that NSLBP patients could face when trying to be more physically active which would prevent the desired behaviour from occurring.

For the purposes of the interventions to be used in the feasibility-pilot, the primary researcher identified the areas which may need to change to make NSLBP patients more active, based on the suggestions and findings of the current literature and clinical experiences of the primary researcher. The qualitative data presented in Darlow *et al.*, (2015, 2016) was adapted and used to create a needs analysis diagram (see figure 4.4) to identify which areas of the COM-B self-evaluation questionnaire needed to change to allow the desired behaviour to occur. The qualitative data was based on participant's attitudes towards being physically active whilst experiencing NSLBP (Darlow *et al.*, 2015, 2016). These areas for change are highlighted in green on the COM-B self-evaluation questionnaire (see table 4.3).

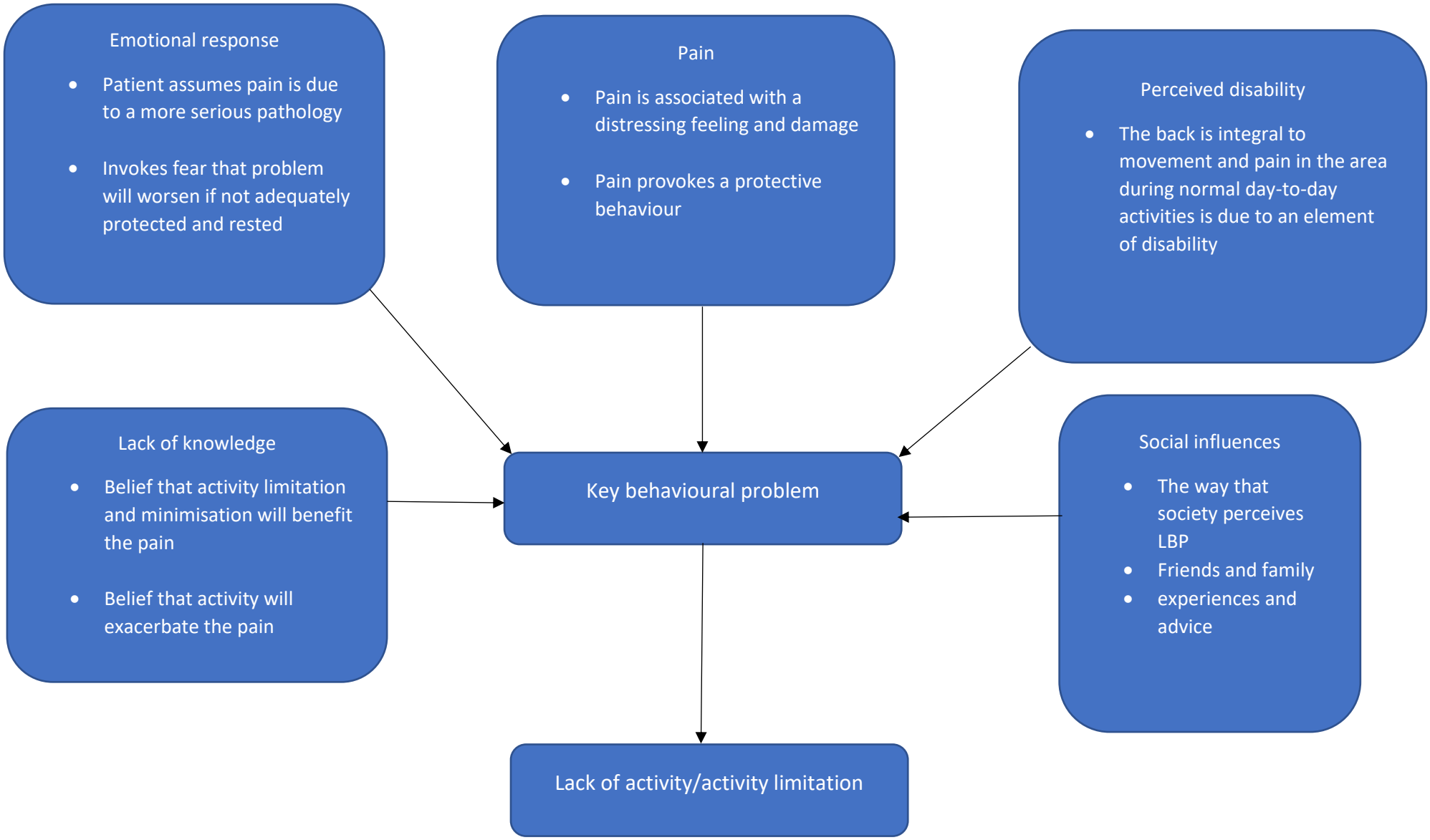


Figure 4.4: Needs analysis depicting key behavioural problems which limit physical activity in patients with NSLBP. Adapted from the qualitative data presented in Darlow *et al.* (2015, 2016).

Table 4.3: COM-B self-evaluation questionnaire

Capability

Know more about why it was important	have a better understanding of the benefits of being physically active
Know more about how to do it	Have a better understanding of effective ways of doing more physical activity
Have better physical skills	Not applicable for the context of the trial
Have better mental skills	Not applicable for the context of the trial
Have more physical strength	Not applicable for the context of the trial
Have more mental strength	Develop a stronger resilience against not doing physical activity
Overcome physical limitations	Not applicable for the context of the trial
Overcome mental obstacles	Reduce negative feelings associated with being physically active
Have more physical stamina	Not applicable for the context of the trial
Have more mental stamina	Not applicable for the context of the trial

Opportunity

Have more time to do it	Finding time in the day to be more active
Have more money	Not applicable for the context of the trial
Have the necessary materials	Not applicable for the context of the trial
Have it more easily accessible	Not applicable for the context of the trial
Have more people around them doing it	Not applicable for the context of the trial
Have more triggers to prompt them	Not applicable for the context of the trial
Have more support from others	Not applicable for the context of the trial

Motivation

Feel that they want to do it enough	Feel more of a sense of pleasure or satisfaction from being physically active

Feel that they need to do it enough	Care more about the negative consequences of not being physically active
Believe that it would be a good thing to do	Understand the benefits and have a stronger sense that people with NSLBP should be physically active
Develop better plans for doing it	Create weekly plans for when they will add more activity to their daily life
Develop a habit for doing it	Get into a pattern of being physically active without having to think

The parts of the COM-B self-evaluation questionnaire (highlighted in green) indicate specific areas of the COM-B system which are needed to encourage NSLBP patients (target population) to become more physically active (target behaviour).

The highlighted areas have been linked to the specific components of the COM-B system in table 4.4. Table 4.4 demonstrates the specific COM-B components and how they relate to the desired behaviour (what needs to happen with these components to achieve the desired behaviour) and if a change in these components is needed. The areas where change was indicated in the COM-B questionnaire, based on the findings presented in (Darlow *et al.*, 2015, 2016) and clinical experiences of the primary researcher, resulted in a behaviour diagnosis. The behavioural diagnosis is presented at the bottom of table 4.4.

Table 4.4: Specific components of the COM-B system, identifying areas where change is needed in order for the target behaviour (increase in activity levels) for NSLBP patients.

COM-B components	What needs to happen for the target behaviour to occur?	Is there a need for change?
Physical capability	Having the strength to be more active	No change needed. Physical activity involves normal day-to-day movement in a person's routine. Everyone can be more active.
Psychological capability	Understanding what physical activity is required	Change needed. People can confuse specific exercise with general physical activity.
	Understanding the health benefits of being physically active when experiencing NSLBP.	Change needed. Patient might believe activity could damage their back

COM-B components	What needs to happen for the target behaviour to occur?	Is there a need for change?
Physical opportunity	Having the facilities to be more active	No change needed. Increase in activity could just involve more walking/running. An activity the patient enjoys doing.
	Having more time to be active	No change needed. Everyone has time to include more activity in their day such as taking the stairs at work instead of the lift
Social opportunity	Access to GP/HCP and receiving advice to be active	No change needed. Activity should always be advised as part of NICE guidelines and good practice.
Reflective motivation	Intending to be more active – feel that they want to and need to be more active	Change needed. The intention may not be there due to a belief that physical activity could provoke pain

COM-B components	What needs to happen for the target behaviour to occur?	Is there a need for change?
Automatic motivation	Feeling anticipated pain relief at the prospect of engaging in physical activity	Change needed. Most NSLBP patients do not perceive physical activity to benefit their pain and worry it may worsen their pain.

Behavioural diagnosis: Psychological capability, reflective motivation and automatic motivation need to change for the target behaviour to occur.

4.7 Stage 2: Identify intervention options

4.7.1 Step 5: Identify intervention functions

Table 4.4 concluded with a behavioural diagnosis of the COM-B components which need to be changed to get NSLBP patients to increase their activity levels. The behavioural diagnosis identified changes in NSLBP patient's psychological capability, social opportunity, reflective motivation, and automatic motivation were required to help them achieve an increase in physical activity levels. This allowed for appropriate intervention functions to be selected for the identified COM-B components. Using the matrix of links between COM-B and intervention functions (see figure 4.5) potential intervention functions were identified, based on the behavioural diagnosis. The shaded segments on figure 4.5 show which intervention functions can be used for certain COM-B components. For the development of the interventions for the feasibility-pilot trial only the COM-B components highlighted in the behavioural diagnosis were linked to the appropriate potential intervention functions highlighted on the matrix of links.

COM-B components	Intervention function								
	Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
Physical capability					■				■
Psychological capability	■				■				■
Physical opportunity					■	■	■		■
Social opportunity						■	■	■	■
Automatic motivation		■	■	■	■	■		■	■
Reflective motivation	■	■	■	■					

Figure 4.5: Matrix of links between COM-B and intervention function (Michie, Atkins and West, 2014).

Table 4.5 presents the potential intervention functions for the intervention development based on the COM-B components identified as needing change in table 4.3.

Table 4.5: The COM-B components identified in the behaviour diagnosis, barriers to achieving the desired behaviour for NSLBP patients and what intervention functions can be used to overcome the barriers

COM-B components	**Barrier**	**Intervention Function**
Psychological capability	Knowledge of being physically active with NSLBP	Education
Reflective motivation	Belief about consequences of being physically active with NSLBP (i.e., activity provokes pain and causes more damage to back/spine)	Education Persuasion
	Beliefs about capability to be physically active with NSLBP	Education Persuasion
	Intending to be more active – making conscious decisions to be active even when experiencing pain related to their NSLBP	Education Persuasion Incentivisation Coercion
	Having the confidence to be physically active when experiencing pain related to their NSLBP	Education Persuasion
Automatic motivation	Emotion – fear and anxiety arising at the idea of being active when experiencing pain related to their NSLBP	Persuasion Incentivisation Coercion Modelling Enablement

Once the potential intervention functions were identified the affordability, practicability, effectiveness/cost-effectiveness, acceptability, side-effects/safety, and equity (APEASE)

criteria was applied. The intervention functions which met the APEASE criteria were used going forward in the intervention development (see table 4.6).

Table 4.6: APEASE criteria applied for the identified potential intervention functions

Intervention functions	**Does the intervention function meet the APEASE criteria?**
Education	Yes.
Persuasion	Yes.
Incentivisation	Not practicable. This behaviour needs to be sustainable, and incentives would be a confounding variable against how effective the intervention really is at changing the undesired behaviour.
Coercion	Not acceptable to patients. This is not good practice and is unethical.
Modelling	Not practicable. There is currently no example of this behaviour to show patients for them to aspire to or imitate.
Enablement	Yes.
Selected intervention functions:	Education, persuasion, and enablement

Step 6 of the BCW relates to identifying policy categories. However, the feasibility-trial is not trying to influence policy or policy holders and so therefore step 6 not applicable or relevant for the development of this intervention.

4.8 Stage 3: Identify content and implementation options

4.8.1 Step 7: Identify BCTs

The penultimate stage of the BCW in guiding the design of interventions is to select appropriate BCTs for the content of the intervention. BCTs are used and defined as "an active component of an intervention designed to change behaviour" (Michie, Atkins and West, 2014, p. 145).

Table 4.7 presents the most frequently used BCTs for the selected intervention functions and COM-B components for the interventions used in the feasibility-pilot trial. Table 4.7 also includes the APEASE criteria and demonstrates if the BCTs are relevant and practical in the context of increasing physical activity levels in a NSLBP population. The BCTs which met the APEASE criteria are presented at the bottom of the table. The BCTTv1 was examined to highlight other BCTs which could be used in the context of the feasibility-pilot trial in addition to the BCTs presented in the table.

Table 4.7 APEASE criteria applied to the suggested BCTs for the relevant identified intervention functions and COM-B components

Intervention function	COM-B component	Most frequently used BCTs	Does the BCT meet the APEASE criteria in the context of getting NSLBP patients more active?
Education	Psychological capability Reflective motivation	Information about social and environmental consequences	Not relevant in this context
		Information about health consequences	Yes
		Feedback on behaviour	Yes
		Feedback on outcome(s) of the behaviour	Not practicable in this context
		Prompts/cues	Unlikely to be effective in this context
		Self-monitoring of behaviour	Unlikely to be practicable in this context
Persuasion	Automatic motivation Reflective motivation	Credible source	Yes
		Information about social and environmental consequences	Not relevant in this context
		Information about health consequences	Yes
		Feedback on behaviour	Yes
		Verbal persuasion about capability	Yes
		Feedback on outcome(s) of the behaviour	Not practicable in this context

Intervention function	COM-B component	Most frequently used BCTs	Does the BCT meet the APEASE criteria in the context of getting NSLBP patients more active?
Enablement	Automatic motivation	Social support (unspecified)	Not practicable in this context
		Social support (practical)	Not practicable in this context
		Goal setting (behaviour)	Yes
		Goal setting (outcome)	Not practicable in this context
		Adding objects to the environment	Not practicable in this context
		Problem solving	Yes
		Action planning	Yes
		Self-monitoring of behaviour	Unlikely to be effective in this context
		Restructuring the physical environment	Not practicable in this context
		Review behaviour goal(s)	Yes
		Review outcome goal(s)	Not practicable in this context

BCTs selected:
Feedback on behaviour
Information about health consequences
Credible source
Verbal persuasion about capability
Goal setting (behaviour)
Action planning
Problem solving
Review behaviour goal(s)

The BCTs selected met the APEASE criteria and could be delivered in the context in which the feasibility-pilot trial was conducted in. To this list the following less frequently used BCTs were added as they met the APEASE criteria for the context of the trial. These BCTs were “discrepancy between current behaviour and goal”, “commitment” and “monitoring of behaviour without feedback”.

4.8.2 Step 8: Identify mode of delivery

The BCTs which met the APEASE criteria for the trial were: feedback on behaviour, information about health consequences; credible source; verbal persuasion about capability; action planning; problem solving; goal setting (behaviour); review behaviour goal(s); commitment; discrepancy between current behaviour and goal(s) and monitoring of behaviour without feedback .

The mode of delivery for the interventions to increase physical activity in NSLBP patients was face-to-face on an individual basis. This mode of delivery was the most appropriate for the trial as it met the APEASE criteria.

4.9 The interventions for the feasibility-pilot trial

Eleven BCTs were identified during step 7 as potential strategies to design the interventions for the feasibility-pilot trial. Due to wanting to explore the acceptability of these BCTs to NSLBP patients, how different combinations of BCTs effect physical activity levels and to explore different intensities of interventions (i.e., small interventions like advice compared to interventions with more materials and resources provided), the intervention was split into four levels (small interventions). Each of the four groups were created, utilising different strategies and BCTs to deliver each of the interventions.

Table 4.8 explains the intervention strategies for each intervention and how it links in with the intervention functions, COM-B components and selected BCTs identified in the previous steps of the BCW.

Table 4.8: Intervention strategies for the four groups and how they relate to the interventions functions, COM-B components and BCT(s)

Intervention	Intervention strategy	Intervention function	COM-B component	BCT(s)
Group 1 [α] Advice and education	Education This intervention will be delivered on a sheet of paper highlighting the benefits of keeping active with NSLBP and the disadvantages to not being active with NSLBP. The information on the sheet came from *the Back Book*, Arthritis UK, and the NICE guidelines. This was highlighted to the patients on the sheet.	Education, Enablement Education	Psychological capability Reflective motivation	Information about health consequences Credible source
	Advice: The primary researcher will reinforce the message of "keep active" to the patients. The primary researcher will reinforce the benefits of being active and that the patient can be more active, at every meeting with the patients	Persuasion, Enablement Persuasion Enablement, Education	Reflective motivation Automatic motivation Reflective motivation Psychological capability	Credible source Verbal persuasion about capability

Group 2 Advice and education + feedback on activity levels	Feedback on behaviour: The feedback on activity levels will be delivered, weekly, by the primary researcher after downloading the data from the accelerometer on how active the patient was that week. The primary researcher would give feedback on if the patient managed to increase, or decrease, their activity levels that week after the previous session. The feedback will give the patient details of their activity in four domains: very light, light, moderate and vigorous.	Education Persuasion Enablement	Psychological capability Automatic motivation Reflective motivation	Feedback on behaviour
	Advice and education	See above	See above	See above
Group 3 [α] Advice and education + implementation intentions	Implementation intentions: The implementation intentions were delivered on a structured sheet giving participants the chance to write down their thoughts on opportunities in their daily life to increase activity, obstacles they feel will be preventing them from becoming more active, ways to	Enablement	Reflective motivation	Action planning Goal setting (behaviour) Problem solving Commitment

	overcome these obstacles and their thoughts on the benefits of being physically active. The last activity on the sheet is a set of statements, where the participants are required to fill in the blanks about how, when and where they will aim to become more physically active.			
	Advice and education	See above	See above	See above
Group 4 Advice and education + feedback on activity levels + implementation intentions	Combination of all interventions* The primary researcher will give the participants feedback on their activity levels and ask the participants to review their feedback against their goals. The primary researcher will point out if the activity levels fell short or met the goals set by the participants.	Enablement Education Persuasion Enablement	Automatic motivation Reflective motivation Psychological capability Automatic motivation Reflective motivation	Review behaviour goal(s) Discrepancy between current behaviour and goal
	Advice and education	See above	See above	See above
	Feedback on behaviour	See above	See above	See above
	Implementation intentions	See above	See above	See above

*In group 4 the participants received all the interventions (advice and education, feedback on behaviour and implementation intentions). However, due to receiving all the interventions, and associated BCTs, there are two extra BCTs which are unique to this group.

α All the participants are required to wear an accelerometer daily to collect data on activity levels. However, an additional BCT "monitoring of behaviour without feedback" is present in groups 1 and 3, due to these groups not receiving any feedback on their behaviour but were still having their activity levels monitored. This BCT is just the result of the strategy to monitor the participants physical activity levels and was not part of the strategy for behaviour change in the intervention design.

4.10 Intervention content and summary

All the interventions were delivered face-to-face to the NSLBP patients by the primary researcher once a week (over a period of five weeks), at the UCO outpatient osteopathy clinic. Fidelity (event at which the intervention(s) were delivered as intended) was to be evaluated post-trial. There is an overlap in the BCTs in groups one to three as the interventions used in these groups all incorporated advice and education. All the BCTs used in groups one to three are present in group four, with two additional BCTs unique to this group.

Differences in BCTs present in the four groups

Each participant was required to wear an accelerometer every day during waking hours to collect data on their physical activity levels. The BCT of "monitoring of behaviour without feedback" was only present in groups one and three and was not present in groups two and four. Groups one and three received no feedback on their activity levels. Groups two and four were the only groups to receive feedback on their activity behaviour as collected by the accelerometer. Therefore, use of the accelerometer in groups one and three was only to monitor if the patients changed their behaviour and were more physically active after receiving the interventions used in these groups.

Despite groups two and four both receiving "feedback on behaviour" the BCT of "goal setting (behaviour)" is not present in group two as the patients in this group were only advised to "increase your (their) activity levels this week". This advice is only a suggestion and does not set a goal for the participants as it is not specific (i.e. indicating by how much the participants need to increase their activity by). Therefore, the lack of specificity means that this advice does not meet the definition of the BCT "goal setting" according to the BCTTv1 (Michie, Atkins and West, 2014). The definition of this BCT according to the BCTTv1 is to "set or agree a goal defined in terms of the behaviour to be achieved" (Michie, Atkins and West, 2014) – e.g., walk 10,000 steps per day. "Goal setting" is only present in group four. The BCT "goal setting" is present in group four due to the patients being prompted to

set themselves the weekly goal of when, how, and on how many days they will try to be more active.

Similarly, the BCT "discrepancy between current behaviour and goal" was only present in group four due to the researcher providing feedback to the participants and pointing out if they met their goal(s) for the week.

Group 1: Advice and Education

Advice was verbally given to the NSLBP patients on being active. The advice provided was "continue to be active and try to increase your activity levels, however you would like to do this. You can increase your physical activity levels as it is good for your back and will not cause harm to your back". The BCTs in the advice element of this intervention were "persuasion about capability" (verbal communication that having back pain does not prevent oneself from being active and the individual can be active despite their back pain), "information on health consequences" (providing information on the health consequences of being physically active for back pain) and "credible source" (verbal communication by the primary researcher (who is also a HCP) in favour of the behaviour (increase activity levels)).

The education sheet was delivered on a leaflet (print media). The education sheet mimicked the verbal advice and provided more information pertaining to the consequences of not being active with NSLBP, the benefits of being active with NSLBP, and educated the patients on the nature of NSLBP. The BCTs in the education element of this intervention are "information about health consequences" and "credible source".

Group 2: Feedback on activity levels plus advice and education

The feedback on activity levels were delivered verbally to the patients during their individual sessions with the primary researcher. This feedback gave the patient an overview on how much activity they completed over the week in percentages. Percentages for increases or decreases in very light, light, moderate and vigorous domains were given.

The BCTs used in the advice and education intervention were also used in this intervention.

Group 3: Implementation Intentions plus advice and education

Implementation intentions are reported to be powerful tools for health education programmes and have already been demonstrated to promote exercise participation in elderly populations (Milne, Orbell and Sheeran, 2002; Hall *et al.*, 2012, 2014; Bélanger-Gravel, Godin and Amireault, 2013). The effect of a behavioural change strategy (implementation intentions) has not been investigated in regards to getting a NSLBP population physically active (Broonen *et al.*, 2011). The implementation intentions were delivered to the NSLBP patients using print media: a leaflet. The implementation intention sheet invited the NSLBP patients to explore the obstacles and barriers they may experience when trying to be more active and the benefits of being more active. A plan at the end of the sheet encouraged patients to fill in how, when and where they will be more active.

For example:

I will commit to __[*walking to the shops]*_____ for __[*3 times a week]*_____ on__[*Mondays, Fridays, and Saturdays]*_____.

The BCTs described in group one are present in this group. The BCTs used in this intervention are “goal setting” and “action planning” (planning to be physically active on a particular day for a set number of times a week), “commitment” (patients affirm “I will” and “I will commit to” statement, as shown in the example above) and “problem solving” (asking the patient to identify barriers and obstacles to being active and ways to overcome these barriers/obstacles).

Group 4: Combination of all interventions

All the interventions (advice and education, feedback on activity levels and the implementation intentions) were used simultaneously in this intervention. The interventions were delivered to the patients as described above. The content of the interventions did not change and the same BCTs, as described above and in table 4.8, were used. The additional BCTs used in this intervention were “review behaviour goal(s)” (evaluate if the person

carried out the set goals by examining if their activity levels increased) and “discrepancy between current behaviour and goal” (the researcher would indicate to the participant if they had increased or decreased their activity).

4.11 Chapter summary

- Behaviour change is important and needs to be considered when designing and developing healthcare interventions
- The BCW is a framework which encompasses and combines the relevant components of other behaviour change frameworks, allowing for a comprehensive and systematic approach to designing interventions for behaviour change
- The BCW was used to design an intervention, to be used in the feasibility-pilot trial, to encourage NSLBP patients to be more active
- This intervention was split to create four interventions once the key components for behaviour change had been identified.

5 Chapter 5 – Methodological approach

5.1 Chapter introduction

The aim of this chapter is to provide the rationale and justification for using a mixed methods feasibility study design for the main trial of this thesis. This chapter explains the appropriateness of this methodological approach in line with the purposes of this thesis. The chapter also addresses and provides the rationale and justification for the type of qualitative methods selected.

To fulfil the aim of this chapter, several objectives were set:

- To research and identify evidence for conducting feasibility trials and to distinguish between feasibility trials and pilot trials
- Research mixed-method trial designs and identify the advantages of using a mixed-method approach in health care research
- Justify how the aim of the intended feasibility-pilot trial can be met using a mixed-methods approach
- Present the quantitative and qualitative methods to be used, as part of the mixed-methods approach, for the feasibility-pilot trial.

5.2 Feasibility trials: An overview

A feasibility study is not a pilot study, yet these terms are used interchangeably. A feasibility study design is commonly used when there is not enough evidence to indicate that a full-scale RCT can be performed. They are designed to provide the foundation for the larger planned intervention study (Tickle-Degnen *et al.*, 2013). There are three subgroups in which feasibility studies have been divided into: randomised pilot studies, non-randomised pilot studies and feasibility studies (that are not pilot studies) (Eldridge, Lancaster, *et al.*, 2016). A pilot study is a study with the aim of determining the initial data for the primary outcome

measure to enable a power calculation to be performed (Lancaster, Dodd and Williamson, 2004).

RCTs are both timely and costly; major funding bodies such as the UK MRC will require evidence that the RCT is viable and valuable before allocating large amounts of money into the execution of an RCT (Lancaster, Dodd and Williamson, 2004). Feasibility and pilot studies are primarily used to appraise the application of the prospective intervention study and to diminish any threats that should arise concerning the validity of the study (Tickle-Degnen *et al.*, 2013). The MRC recommend that when developing and evaluating complex interventions the RCT design should be tested using pilot studies to test the procedures for acceptability, provide an estimation in recruitment and retention rates and to conclude the sample size(s) needed in the main trial(s) (Craig *et al.*, 2008). Feasibility studies should not measure intervention effectiveness and null hypothesis significance testing is not appropriate for this type of study if the sample size is not powered properly (Eldridge, Chan, *et al.*, 2016; Eldridge, Lancaster, *et al.*, 2016). The statistical tests to determine intervention effectiveness should only occur in the main study (Tickle-Degnen *et al.*, 2013). Feasibility analyses are mainly descriptive and centre on confidence interval estimations and not inferential testing (Lancaster, Dodd and Williamson, 2004; Moore and Carter, 2011; Leon, Davis and Kraemer, 2012; Lancaster, 2015).

Feasibility studies are helpful and are paramount in research, as conducting a full-scale complex intervention RCT without checking if the methodology is viable, can lead to unforeseen and difficult circumstances revolving around the design of the RCT, recruitment problems or the acceptability of the interventions being used (Vogel and Draper-Rodi, 2017).

5.3 Feasibility trial justification

The research presented in this thesis follows the design of a randomised pilot study, one of the subgroups of feasibility studies. The research in this thesis is not an outright pilot study as the intended aim of the research is to determine feasibility and not to establish a power calculation. Assessment of the primary outcome has not been conducted. The research presented in this thesis revolves around four interventions, developed by the researchers.

These interventions were developed based on the findings of a systematic review (see *chapter 2*), where gaps in the current physical activity interventions for NSLBP patients were identified.

In the context for the trial presented in this thesis, it was unknown if running a full-scale RCT was feasible and practical in the University College of Osteopathy (UCO) student-led outpatient clinic. A variety of unknown factors compounded the need to conduct a feasibility-pilot trial. The unknown factors were: 1) feasibility of recruiting student and tutor osteopaths (clinicians), 2) the acceptability of the trial protocol for the clinicians to recruit NSLBP patients, 3) general feasibility of recruiting NSLBP patients in the UCO clinic, 4) the acceptability, usability and adherence of the patient participants to wearing an accelerometer for six consecutive weeks, 5) the acceptability of the interventions to the patient and clinician participants and, 6) it was not possible to carry out a sample size calculation for statistical power. To assess feasibility and acceptability of the trial, quantitative and qualitative data was collected.

Therefore, for these reasons it was decided to carry out a mixed methods feasibility-pilot trial to assess the feasibility of the recruitment procedure, feasibility, acceptability and usability of the measurement tools and the acceptability and credibility of the interventions for a larger scale RCT.

5.4 Mixed methods introduction

Mixed methods research (MMR) was initially conceptualised in 1989 by Greene, Caracelli and Graham (Mckim, 2017). MMR is the type of research which combines the use of quantitative and qualitative research approaches (Creswell and Plano Clark, 2007; van Griensven, 2016). There are three basic core designs of MMR: the convergent design, explanatory sequential design and exploratory sequential design (Creswell and Plano Clark, 2007). There are also four prominent types of complex mixed methods designs: mixed methods experimental (or intervention), mixed methods case study, mixed methods participatory-social justice and mixed methods program evaluation (Creswell and Plano

Clark, 2007). These designs are usually seen in MMR where the study is large (multiple research phases, over a period of several years), involving multi-investigators, have substantial funding and where the methods used are more complex (using mixed methods core designs in different phases of the study) (Creswell and Plano Clark, 2007). There are many more complex MMR designs and new designs emerge all of the time (Creswell and Plano Clark, 2007).

Health and health care are complex areas of research and cannot always be fully investigated using a single method approach (Morgan, 1998; van Griensven, Moore and Hall, 2014). The purpose of combining both research approaches is to gain depth and breadth of understanding and for corroboration (Creswell and Plano Clark, 2007). The weaknesses of using a single research method approach are reduced when adopting a mixed methods approach (Creswell and Plano Clark, 2007). A more in-depth analysis of the research subject is possible using MMR and gives the piece of research more scope (Greene, 2007; Johnson, Onwuegbuzie and Turner, 2007; van Griensven, Moore and Hall, 2014).

5.5 Mixed methods justification

A mixed methods design was used in the feasibility-pilot trial of this thesis to collect quantitative and qualitative data to answer the research sub-questions and aims of the trial. These sub-questions and aims related to the feasibility, acceptability and credibility of the trial procedure and equipment, and the feasibility of conducting a full-scale RCT in the future.

The feasibility-pilot trial of this thesis uses one of the core designs of MMR: an explanatory sequential design (Creswell and Plano Clark, 2007). In this design of MMR, the data collection methods occur in two stages: the quantitative strand occurs first followed by the qualitative strand (Creswell and Plano Clark, 2007). The qualitative strand proceeds the quantitative strand in this design of MMR for several reasons, dependant on the goal of the trial (Creswell and Plano Clark, 2007). The qualitative strand can be used as an attempt to explain the results, outlier results or unexpected results (significant or insignificant) of the quantitative phase (Morse, 1991; Bradley *et al.*, 2009; Morgan, 2014). This design of MMR

research can also be used to explain the mechanisms behind the quantitative results (i.e., why they happened, and can they be explained) (Creswell and Plano Clark, 2007). Both the quantitative and qualitative strands were designed simultaneously (like in the convergent design) but implemented at different stages (explanatory sequential design) for the feasibility-pilot trial presented in this thesis (See figure 5.1 for the mixed methods design).

The reason for designing the quantitative and qualitative elements simultaneously was purely focussed on the study being a feasibility-pilot trial. The aim of the trial was not to distinguish and explain the quantitative results per say, as the results are descriptive. The qualitative strand was used to provide an insight and understanding of how the methodological procedures were for the patient and clinician participants, but also as an explanatory element for determining the overall feasibility of the study (i.e., can the research be done, and be conducted effectively and efficiently in the UCO clinic).

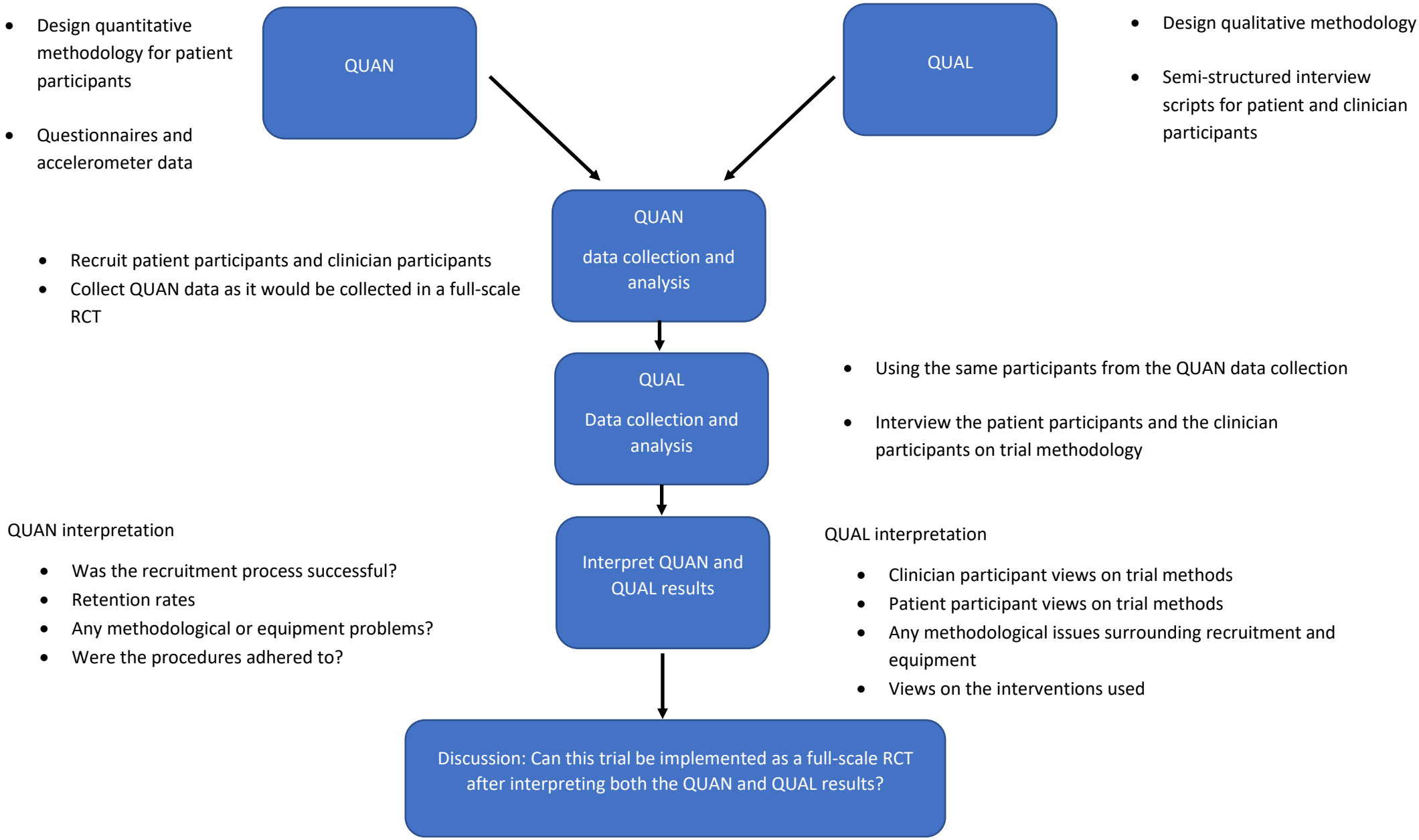


Figure 5.1: Flowchart of the mixed methods explanatory sequential design for the feasibility-pilot trial.

5.6 Feasibility quantitative and qualitative methods

5.6.1 Quantitative methods

The quantitative methods used for the patient participants in this study were a series of self-report questionnaires for pain, pain-related disability, HRQoL and physical activity. An objective measure for monitoring and recording the patient participants physical activity levels on a weekly basis was also used. The objective measure was discussed in more detail in chapter 3. The patient participant's physical activity levels were monitored and recorded using an AX3 Axivity accelerometer. For the purposes of this study, the patient participants were asked to wear the accelerometer around their waist, using a latex-free belt and pouch (ActiGraph). A set of instructions were customised to help the participant locate the correct spinal segment and position to wear the accelerometer. Recruitment and retention rates were recorded throughout as these were key elements to assessing feasibility of the trial (Craig *et al.*, 2008).

5.6.2 Qualitative methods

A qualitative approach was used in the feasibility-pilot trial to collect the views of all the participants recruited in the trial. The researchers were interested in what the participant's thoughts and feelings were towards the trial procedure - the equipment used, the recruitment process, timescales (of the trial, interventions and wearing of the accelerometer), and the credibility and acceptability of the interventions amongst the patient and clinician participants. The qualitative data was collected in the form of semi-structured interviews. The six-step alternative method approach to verbatim transcription of interview data outlined by Halcomb and Davidson (2006) was used. Analysis of interview data normally relies on adequate transcription of the interview content. Verbatim transcription is the most common and widely used method to analyse interviews. Full verbatim transcription was not used in this trial, as the alternative approach used does not require the verbatim transcription of the interview data (Halcomb and Davidson, 2006). Steps 4 and 5 in the Halcomb and Davidson (2006) approach require a content analysis. A conventional content analysis (Hsieh and Shannon, 2005) was used for these steps. This type

of analysis involved the counting and comparisons of the keywords and content of the interview data. The level of analysis required in the trial did not demand the benefits of transcription or any in-depth analyses as the aim of the interviews was to see what was being said (from a patient and clinician point-of-view) and what factors of the trial were identified as good or needed modifying. This method is discussed in more detail in *Chapter 6*.

5.7 Chapter summary

- The MRC recommends that complex interventions should be tested in pilot trials before conducting a full-scale RCT
- Mixed methods research was chosen for the trial design of the feasibility-pilot trial as health care is a complex area to investigate, requiring more than a single method approach
- Due to the number of unknown variables surrounding the proposed RCT, it is vital to test the feasibility of the trial protocol and pilot the interventions designed in *Chapter 4,* to test acceptability using a mixed methods approach

6 Chapter 6: Feasibility-pilot trial methodology

6.1 Chapter introduction

This chapter presents the methodology of the mixed-methods feasibility-pilot trial. The feasibility-pilot trial was a pragmatic four-armed RCT conducted in the UCO student-led osteopathy clinic. A mixed methods approach was adopted to ascertain feasibility of the trial protocol for the patient and clinician participants, and acceptability of the methods employed, including the acceptability and credibility of the interventions and measurement tools used (i.e., questionnaires, accelerometer). A previous chapter (*chapter 4)* outlined how the interventions described in this trial, for the patient participants, were designed and developed using the BCW model, according to previous literature advocating the use of the theoretical frameworks and models in intervention development. *Chapter 5* presented the rationale for adopting a mixed-methods approach for this trial.

The mixed methods used in this trial followed the explanatory sequential design (discussed in *chapter 5*), in which the quantitative strand (recruitment and retention rates, outcomes etc.) was followed by a qualitative strand (semi-structured interviews to explore the views of the participants on the trial methodology) (Creswell and Plano Clark, 2007).

6.2 Aim of chapter

The aim of this chapter is to present the methodology used in the randomised mixed-methods, feasibility-pilot trial.

6.3 Aims of feasibility-pilot trial

The overall aim of the feasibility-pilot trial was to conduct a pragmatic RCT to investigate the acceptability, credibility, and validity of the physical activity interventions to increase physical activity levels in adults with NSLBP.

To fulfil this aim, four sub-questions of the trial were posed:

1. What is the acceptability, usability, and feasibility of the accelerometers to measure physical activity in people with NSLBP?

2. What is the acceptability and credibility of a physical activity intervention amongst the NSLBP patient and clinician participants?

3. What is the feasibility and acceptability of the trial procedure for the patient and clinician participants?

4. What is the feasibility and acceptability of the questionnaires for the patient participants?

To answer the sub-questions of the trial, in order to fulfil the aim of this trial, several objectives relating to the patient participants and clinical participants were set.

6.3.1 Objectives for the patient participants

- To assess the feasibility and acceptability of four interventions to increase physical activity levels in NSLBP patients at the UCO clinic.

- To assess the usability of the accelerometer to measure physical activity.

- To assess changes in physical activity, pain, pain-related disability and HRQoL scores

- To assess the response rate, actual numbers recruited, follow-up response rate and drop-out rates for each intervention.

6.3.2 Objectives for the clinician participants

- To evaluate the feasibility of the trial protocol specifically for the clinicians to gain a perspective of how they found integrating the trial in the day-to-day clinic processes

- To evaluate the acceptability of using physical activity as an intervention as part of a normal treatment plan

6.4 Justification for research

The results of the systematic review presented in this thesis highlighted gaps in NSLBP research when using physical activity interventions as self-management tools for NSLBP patients. Trials are yet to investigate the use of non-prescribed, unsupervised physical activity interventions for increasing activity levels in a NSLBP population. The results of the systematic review also indicated that physical activity interventions (prescribed and non-prescribed) are not designed and developed using behaviour change theories and only incorporated a few BCTs. A range of behaviour change theories and BCTs need to be incorporated to address and account for habit, self-control, impulsivity, emotional processing and associative learning (Michie, van Stralen and West, 2011). The effect of a behavioural change strategy has not been investigated with regards to influencing an NSLBP population to be physically active (Broonen *et al.*, 2011). Therefore, the benefit of physical activity for NSLBP patients cannot be demonstrated without a trial using interventions encompassing BCTs for behaviour change. This trial aimed to address these gaps in the research. This study focused on delivering advice and education, verbal feedback, and implementation intentions as interventions to increase NSLBP patient's physical activity levels. These interventions were delivered separately to three groups, with a fourth group receiving all the interventions.

6.5 Ethics

This research study was approved by the LSBU Ethics Panel (Ref: SAS1812) and the UCO Research Ethics Committee (Outcome: Approved).

6.6 Trial overview

Osteopathic students and tutors were initially recruited and were asked to identify NSLBP patients who were eligible to participate in the trial. Due to data protection and patient confidentiality, this was the only viable method to identify eligible NSLBP patient participants. Patient participants, presenting with a first-time or a new episode of NSLBP, and osteopath students and tutors (referred to as clinicians in this trial) from UCO were recruited to assess feasibility. The identified eligible NSLBP patients received a recruitment pack for the trial, which was handed out by the student osteopaths who consented to the trial. Patients were asked to contact the primary researcher if they wanted to enrol on the trial. The patient participants who consented to take part in the trial completed questionnaires (pain (NRS), disability (RMDQ), HRQoL (EQ-5D-5L) and physical activity (GPPAQ)) at various time points (baseline, week 5 and at 6-week follow-up post-trial) and wore the accelerometer for one week to collect baseline measurements for physical activity. Participants were then randomised to one of four groups, receiving the interventions designed in *Chapter 4*, and continued to wear the accelerometer for a period of five weeks. Randomisation was achieved using an online random number generator (www.random.org). The patient participants met with the researcher on a weekly basis for the researcher to download the accelerometer data for that week and have the interventions reinforced – depending on what group the patient was randomised to. Pain scores were also collected weekly. The patient participants received osteopath treatment as normal throughout the trial.

Both the clinician and the patient participants were invited to attend an interview at the end of the trial. The interview data was used to answer the four sub-questions of the trial. This trial assessed the appropriateness of the protocol and methods used through quantitative and qualitative methods (i.e., measuring drop-out rates and interviewing the participants for user feedback) to inform the feasibility of running a full-scale RCT. Figure 6.1 presents a simplified diagram of the trial procedure for the clinician and patient participants.

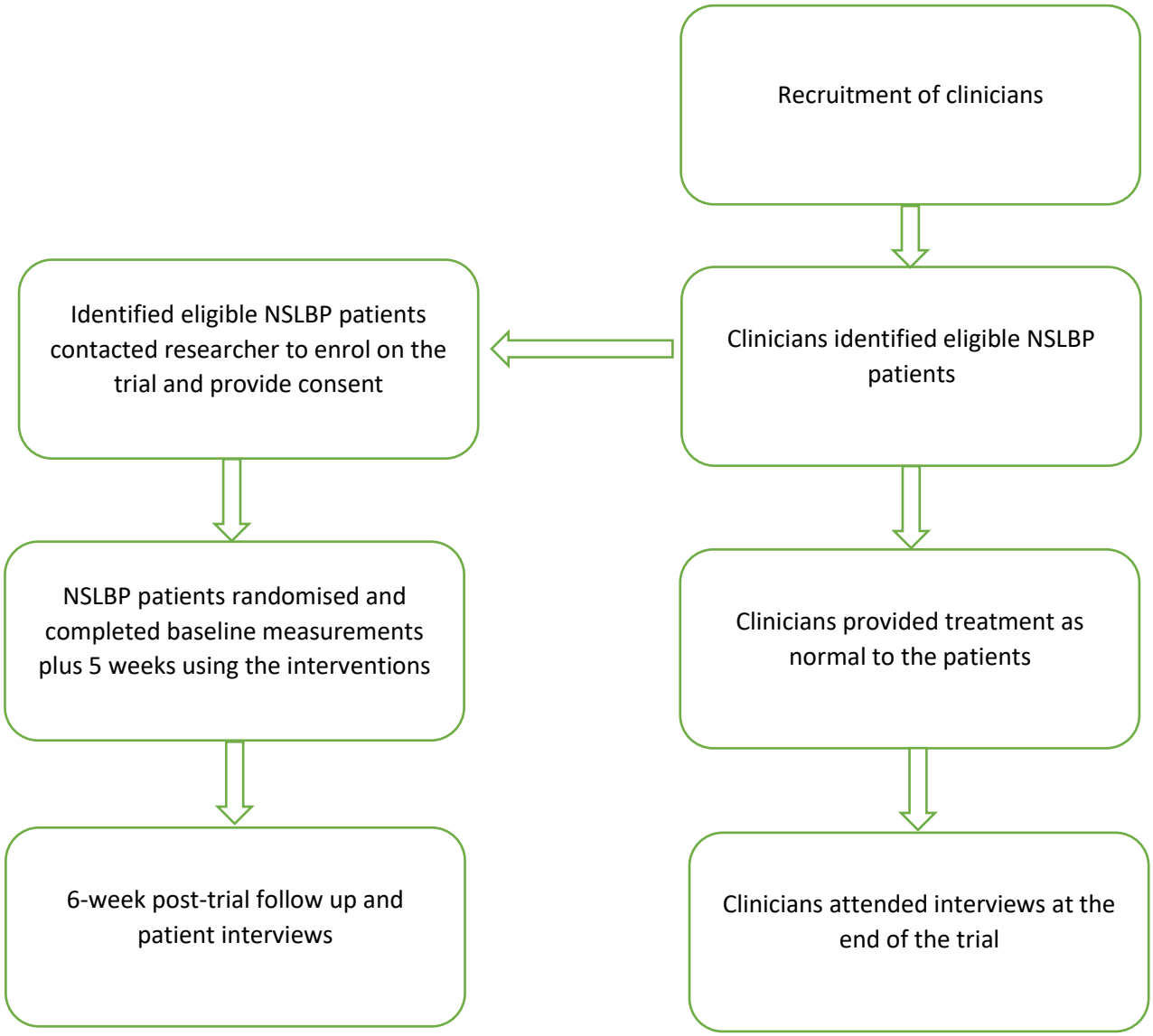


Figure 6.1: Flow diagram of the trial for the patient and clinician participants

6.7 Methodology

6.7.1 Trial design

This trial was a feasibility-pilot trial of a pragmatic RCT using the mixed methods explanatory sequential design.

6.7.2 Outcome measures for the patient participants

Semi-structured interviews were used to assess 1) the feasibility and acceptability of the four physical activity interventions, 2) the usability and acceptability of wearing the accelerometer and 3) the feasibility of the trial protocol.

Feasibility of the trial protocol was also measured by evaluating recruitment and retention rates (drop-out rates), time taken to complete the questionnaires and adherence to the trial protocol (i.e., did the participants return for their weekly appointment with the researcher, did the participants complete all necessary paperwork for the interventions each week and did the participants wear the accelerometer every day).

Recruitment rates were assessed by monitoring how many participants were identified as eligible and received a patient recruitment pack versus how many patients got in touch with the primary researcher to enrol on the trial. Retention and follow-up rates were assessed by recording how many participants dropped out of the trial and how many participants responded to the 6-week follow-up and interview invitation.

This trial used the recommended core outcome measurements for NSLBP (Chiarotto *et al.*, 2018). The outcome measurements of this trial used to assess changes in physical activity, pain, pain-related disability and HRQoL scores were: physical activity using the GGPAQ (appendix Z) and accelerometer data, pain using the NRS (appendix AA), pain-related disability using the RMDQ (appendix CC), and HRQoL using the EQ-5D-5L questionnaire (appendix BB). Changes in physical activity from the data collected by the accelerometer was assessed by comparing the total average dose of activity from the previous week of the trial for very light, light, moderate and vigorous activity (e.g., week 1 dose compared to baseline dose, week 2 dose compared to week 1 dose). A change in two points for pain (Salaffi *et al.*, 2004) and a change of two on RMDQ was assessed as a clinically meaningful change (CMC), based on the NICE guidelines for assessing clinical importance (National Institute for Health and Care Excellence, 2016). The health states of the participants as recorded on the HRQoL questionnaire were mapped to the health state value sets for England (Devlin *et al.*, 2017) to obtain a utility index value. A minimal clinically meaningful change (MCID) in utility index value has been identified as change of 0.03 (National Institute for Health and Care Excellence, 2016). It is reported that a MCID for the EQ-5D-5L overall

health VAS scores is 0.07 for cancer patients (Simon, Neary and Cella, 2007). It is not known if this MCID translates to patients with NSLBP as the is currently no indication of a MCID or CMC in overall health VAS scores for NSLBP patients. Therefore, the MCID as indicated by the NICE guidelines was used in this trial.

This trial did not use the time-trade off method (TTO) (Dolan, 1997) to gain a utility index value for the EQ-5D-5L. The TTO method (Dolan, 1997) involves interviewing each participant and asking them statements to determine quality-adjust life-year (QALY). These statements reflect the length of time (in terms of life expectancy) the respondent would be prepared to trade-off (give up) to live in full health rather than live in a sub-perfect health state (Attema *et al.*, 2013; Devlin *et al.*, 2017). Perfect health has a utility value of 1 and death has a utility value of 0 (Devlin *et al.*, 2017; EuroQol Research Foundation, 2019; Wang *et al.*, 2020). The TTO method is most commonly used in cost-utility analyses (Arnesen and Norheim, 2003) or economic evaluations of interventions (EuroQol Research Foundation, 2019) . The purpose of the feasibility-pilot trial was not to conduct a cost-analysis of interventions for NSLBP and therefore the trial did not require the use of the TTO method to obtain QALY.

6.7.3 Outcomes for the clinician participants

Semi-structured interviews were used to assess the feasibility of implementing the trial protocol in the clinic and the acceptability of using physical activity as an intervention.

6.7.4 Recruitment

The recruitment process for this feasibility trial occurred in 2 phases. Phase 1 included recruiting the student and tutor osteopaths in the UCO clinic. Phase 2 included recruiting the eligible NSLBP patient participants from the UCO clinic. Posters (appendix O) were put up around the UCO clinic reception, thirty-six treatment rooms and five team rooms advertising the trial to generate interest from potential participants, patients, or osteopaths (who had yet to consent to the trial).

6.7.5 Recruitment packs

Recruitment packs were available for the patient and clinician participants.

The patient participant recruitment packs contained a cover letter to the patient, explaining why they have been given a recruitment pack and what the recruitment pack contains (appendix P), a participant information sheet (appendix Q), a consent form (appendix R), a frequently asked questions (FAQ) sheet on the accelerometers (i.e., what accelerometers are, how they will be used in the trial and how the participants will be asked to use them (appendix S)), and a sheet containing the contact details needed to express an interest in the trial (appendix T). The set of instructions on how to wear the accelerometer (appendix K), trialled in pilot 2 in *Chapter 3,* was included in the recruitment pack.

The clinician recruitment packs contained a clinician participant information sheet (appendix U), and consent form (appendix V), a FAQ for the clinicians about the trial (i.e., what is required of the clinicians in the trial and what they should do if they have a problem (appendix W)) and a patient identification (ID) form (appendix X). The patient ID form was completed after a patient recruitment pack was handed out to inform the researcher how many patients received a pack in order to monitor recruitment rates (i.e., identify eligibility to consent ratios).

Both sets of recruitment packs were placed in the five osteopath team rooms in folders with big labels to help the clinicians select the relevant pack.

6.7.5.1 Eligibility criteria for patient participants

The inclusion criteria for the participants were patients presenting for treatment at the UCO clinic with a first episode or reoccurrence of NSLBP. NSLBP is an occurrence of LBP which often cannot be identified to a specific pathology (Krismer and van Tulder, 2007; Tesarz *et al.*, 2011; Balagué *et al.*, 2012). This term included people with pain between the lower ribs and the gluteal folds of the buttocks. This also included commonly made diagnoses that osteopaths may use as a working hypothesis to inform their treatment. For example, facet joint or lumbar muscular or ligamentous pain, and presentations that may include elements of osteoarthritic change in the spine or suspected minor discal injury without neuropathic

leg pain. Participants were required to be able to read and understand English and return a signed consent form.

Participants were excluded from participating in this trial if they had a clinical diagnosis of back related neuropathy including those with neurological deficits suggesting nerve root compression, spinal deformity (scoliosis, kyphosis, spinal stenosis), previous surgery for back pain, such as lumbar spinal fusion, rheumatoid arthritis, cauda equina syndrome or spinal cord compression, cardiorespiratory/pulmonary health issues, pregnancy, or had NSLBP rating less than a 10mm (or 1cm) on the NRS. A pain rating of less than 1 on the NRS suggests the pain is insignificant or "no pain" is present (Krebs, Carey and Weinberger, 2007). If the participants had any of the conditions listed above, they were excluded on the grounds that their pain is caused by a specific condition (therefore, it is not non-specific). Pregnancy was excluded as there is a tendency for pregnant woman to experience LBP due to the hormonal release of the enzyme "relaxin" which causes the ligaments of the spine to 'loosen', causing instability and pain (Katonis *et al.*, 2011).

6.7.5.2 Criteria for osteopathic students and tutors

Currently a student or tutor at UCO who returned a signed consent form.

6.7.6 Sample size calculation

Based on the recommendations for feasibility trials from Teare et al. (2014), Browne (1995), and Lancaster, Dodd and Williamson (2004) the aim of this trial was to recruit a minimum sample size of 60 patient participants (15 per group). Ideally, it was agreed that it was desirable to recruit 100 patient participants (25 per group), but this was dependent on the success of the recruitment strategy. In terms of osteopathic student and tutor recruitment, the aim was to recruit a minimum of 30 student osteopaths and 15 clinic tutor osteopaths.

6.7.7 Participants

The participants of this study were NSLBP patients (n=5) and osteopath students (n=30) and the clinic tutors (n=15). Consent forms were signed and returned to the primary researcher before the trial began (for the clinician participants) and before any data was collected (for the patient participants.

6.7.8 Confidentiality

To maintain participant confidentiality all personal names and references were anonymised and coded. This was explained to the participants on the consent forms for the patient and clinician participants.

6.7.9 Location

Data collection and recruitment occurred at the UCO outpatient clinic in Southwark (London).

6.8 Research Protocol

6.8.1 Baseline measurements

Baseline measurements were conducted by the researcher, once a participant had been identified as eligible for the trial and after the participant agreed to participate by signing a consent form. The participants height (in cm using a stadiometer (Seca 799)) and weight (in kg) were measured, as well as their waist-to-hip ratio (using a tape measure). These measurements were recorded onto a customised demographic questionnaire (appendix Y). The status (first time occurrence or recurrent) of the patient's NSLBP was also recorded on this questionnaire.

These measurements took place in a research/interview room at the UCO clinic. Participants completed the GPPAQ, NRS for pain scores, RMDQ and EQ-5D-5L for HRQoL. The

participants were provided with an accelerometer in a latex-free pouch attached to a latex-free belt to wear over a period of 7 days to measure their current activity levels. The primary researcher checked the participants understood how to correctly wear the accelerometer by asking the participants to read the instructions and apply the belt accordingly. This also allowed to researcher to answer any questions the participants had about wearing the belt.

6.8.2 Allocation process

After recording baseline data for physical activity levels, the participants were randomly allocated to one of either of the four groups using an online random number generator (www.random.org).

6.8.3 Protocol

After the baseline measurements and group allocation procedures all the participants continued to wear the accelerometers for the remaining 5 weeks of the study, following the protocol outlined for the group they were randomised into (see below). Participants were asked to wear the sensors during waking hours except when the participant was showering or sleeping. The participants were given a universal serial bus (USB) cable and/or plug charger for the accelerometer to charge the accelerometer during sleeping hours. This ensured the accelerometer was fully charged during their waking hours when data collection was taking place and to minimise loss of physical activity data. Participants were asked to return to the clinic weekly to visit the researcher, even if the patient did not have an osteopathic treatment booked. During the weekly visits the participants in all the groups had their accelerometer data downloaded onto a password protected computer. The researcher erased the "used" accelerometer of its data, once the data had been downloaded, as accelerometers typically have a storage capacity of 1 week. During their weekly visit, the participant's NRS score for pain was obtained and they were asked if they have received any advice from their osteopath about physical activity. They were asked if they were seeking care outside of osteopathy to manage their pain. The answers were

noted. The participants then had the intervention they received reinforced by the primary researcher. The protocol for each intervention group is outlined below.

6.8.3.1 Interventions

All the groups received the mandatory advice to stay active as per the NICE guidelines (National Institute for Health and Care Excellence, 2016). All the patient participants were asked to wear an accelerometer daily, during waking hours, and received usual osteopathic care (as required) for 5 weeks. For details on how these interventions were designed and developed, including behaviour change content, refer to *Chapter 4.*

6.8.3.2 Group 1 (Advice and education group)

Advice may have been given by the student osteopaths as per normal practice and guideline recommendations (National Institute for Health and Care Excellence, 2016). Advice was provided to the participants in group 1 by the researcher. This advice was "continue to be active and try to increase your activity levels, however you would like to do this. You can increase your physical activity levels as it is good for your back and will not cause harm to your back".

Participants in group one also received an education sheet (appendix DD), informing them about the benefits of being physically active despite their NSLBP. This education sheet was based on information from T*he Back Book* (Burton *et al.*, 1999), NHS website for LBP (NHS, 2020) and Arthritis UK (Arthritis Research UK, 2014).

6.8.3.3 Group 2 (Feedback on activity levels)

The researcher provided the participant with weekly feedback on their activity levels from the data collected by the accelerometer. The researcher took the accelerometer from the participant and handed them an unused accelerometer to wear for the following week. The researcher downloaded the data from the "used" accelerometer onto a password protected computer using the Open Movement Software [V1.0.0.36]. Once the raw data had been downloaded, the researcher using a customised MATLAB script in order to retrieve the

amount of activity the participant had engaged in on a day-by-day basis (refer to *Chapter 3, section 3.10.10* for more details). This data was then imported into a password protected Excel spreadsheet where weekly average activity (in dose) were calculated and percentage increases in the activity (from the previous week) were determined. The researcher proceeded to email the participant with this information as part of their feedback. Encouragement to be more physically active was given to the participant at this point in time (appendix EE) even if the participant had increased their activity levels from the previous week. They were also given the same education sheet and advice provided to the participants in group one.

6.8.3.4 Group 3 (Implementation intention)

Participants in this group completed the implementation intentions sheet (appendix FF) weekly, when they returned to the UCO clinic for their appointment with the primary researcher. The implementation intentions sheet encouraged the participants to identify barriers and obstacles to physical activity, ways to overcome these barriers and set a weekly action plan (on how they planned to be more active). The primary researcher was present during these sessions to aid or prompt the participants when required to help the patient participants complete the form in case they struggled or had any questions or concerns. They were also given the advice to be more active and the education sheet on physical activity and NSLBP. Participants in this group did not receive any feedback on their activity levels.

6.8.3.5 Group 4 (Education, feedback, and implementation intentions)

The participants who were randomised into this group received a combination of the interventions the other three groups received. They received the same education sheet and advice, completed the implementation intention sheet, and received feedback on their activity levels. This feedback also included informing the participants in this group if they had met their goals, by reviewing the goals with the participants (did they complete the goals) and intentions to be active (accelerometer data collected compared to the goals and intentions recorded on the implementation intentions sheet).

6.8.3.6 Week 5

At the end of the 5 weeks (after the baseline measurement), the participant returned their accelerometer to the researcher and completed the RMDQ, EQ-5D-5L, GPPAQ and the NRS. All the data from the accelerometers and self-reported measures (pain, pain-related disability and HRQoL) were analysed. A letter was sent to participants requesting the return of the accelerometer (appendix II), if they dropped out of the trial before their weekly appointment with the researcher.

6.8.4 Follow-up

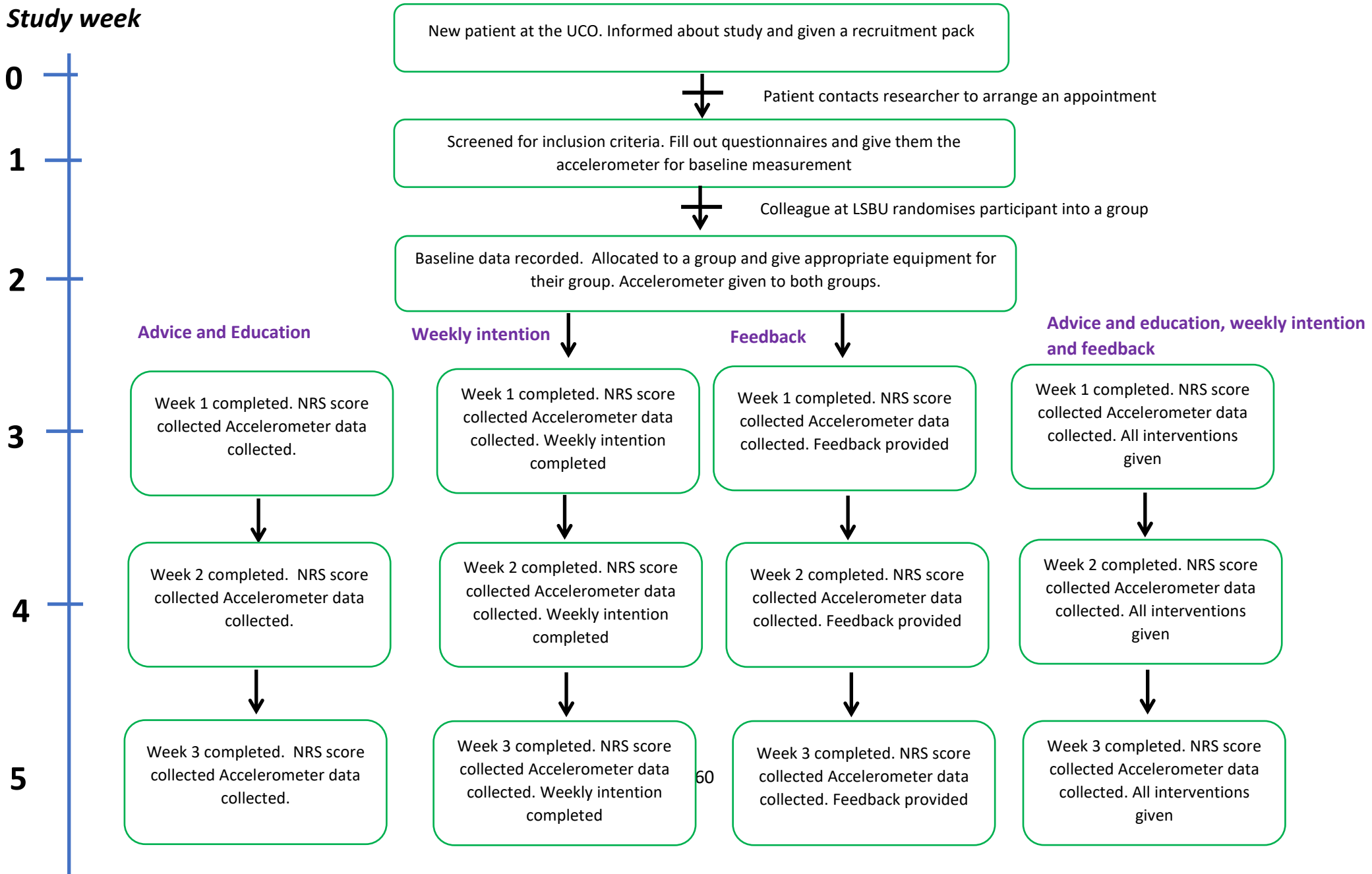
Patient participants were sent the same questionnaires (RMDQ, EQ-5D-5L, NRS and GPPAQ) at the 6-week follow up post-trial by either email (appendix HH), telephone (script in appendix JJ) or in person at UCO when the participant came in for their post-trial interview. If a participant did not reply within 1 week, they were resent the email again. If a participant did not respond after this, then they were no longer pursued and were marked as having dropped out of the trial (n=1). The follow-up data for the relevant participant was recorded as missing.

6.8.5 Interviews

After the trial the patient and clinician participants were invited to attend a semi-structured interview, individually, lasting between thirty to sixty minutes. These interviews were conducted in the UCO clinic, in a meeting room. The option of a voice-over-internet protocol (IP) interview, through the use of Skype or Google talk etc., or a telephone interview was also available to all of the participants. Consent to attend this interview was obtained on the patient and clinician consent form. Information about the interview was also included in the patient and clinician participant information sheets.

The questions in the semi-structured interviews for the patient participant (appendix KK) focussed on how the participant found the trial procedure, measurement tools, wearing the accelerometer, and the intervention group they were assigned to. The questions for the clinician interviews (appendix LL) were designed to gather information on how the clinician

felt about the trial running alongside their osteopathic treatment (i.e., was it acceptable, was it burdensome) and how the clinicians perceive physical activity interventions for NSLBP. Care was taken to avoid asking potentially leading or loaded questions. For example, where clarification or elaboration was required from the participant simple probing techniques were used. For example, if the participants referred to “pain”, the word was reflected back as a question (e.g., “pain?”) to prompt the respondent into providing more information. All interviews were audio recorded but were not transcribed verbatim – see *6.9.2 Qualitative data analysis* for further details. After the interviews had been completed, the participants (patient and clinician) were provided with a trial debriefing sheet (appendix GG). A flow diagram of the entire trial protocol for the patient participants is shown in figure 6.2.


Study week
0
1
2
3
4
5
New patient at the UCO. Informed about study and given a recruitment pack
Patient contacts researcher to arrange an appointment
Screened for inclusion criteria. Fill out questionnaires and give them the accelerometer for baseline measurement
Colleague at LSBU randomises participant into a group
Baseline data recorded. Allocated to a group and give appropriate equipment for their group. Accelerometer given to both groups.
Advice and Education
Weekly intention
Feedback
Advice and education, weekly intention and feedback
Week 1 completed. NRS score collected Accelerometer data collected.
Week 1 completed. NRS score collected Accelerometer data collected. Weekly intention completed
Week 1 completed. NRS score collected Accelerometer data collected. Feedback provided
Week 1 completed. NRS score collected Accelerometer data collected. All interventions given
Week 2 completed. NRS score collected Accelerometer data collected.
Week 2 completed. NRS score collected Accelerometer data collected. Weekly intention completed
Week 2 completed. NRS score collected Accelerometer data collected. Feedback provided
Week 2 completed. NRS score collected Accelerometer data collected. All interventions given
Week 3 completed. NRS score collected Accelerometer data collected.
Week 3 completed. NRS score collected Accelerometer data collected. Weekly intention completed
Week 3 completed. NRS score collected Accelerometer data collected. Feedback provided
Week 3 completed. NRS score collected Accelerometer data collected. All interventions given

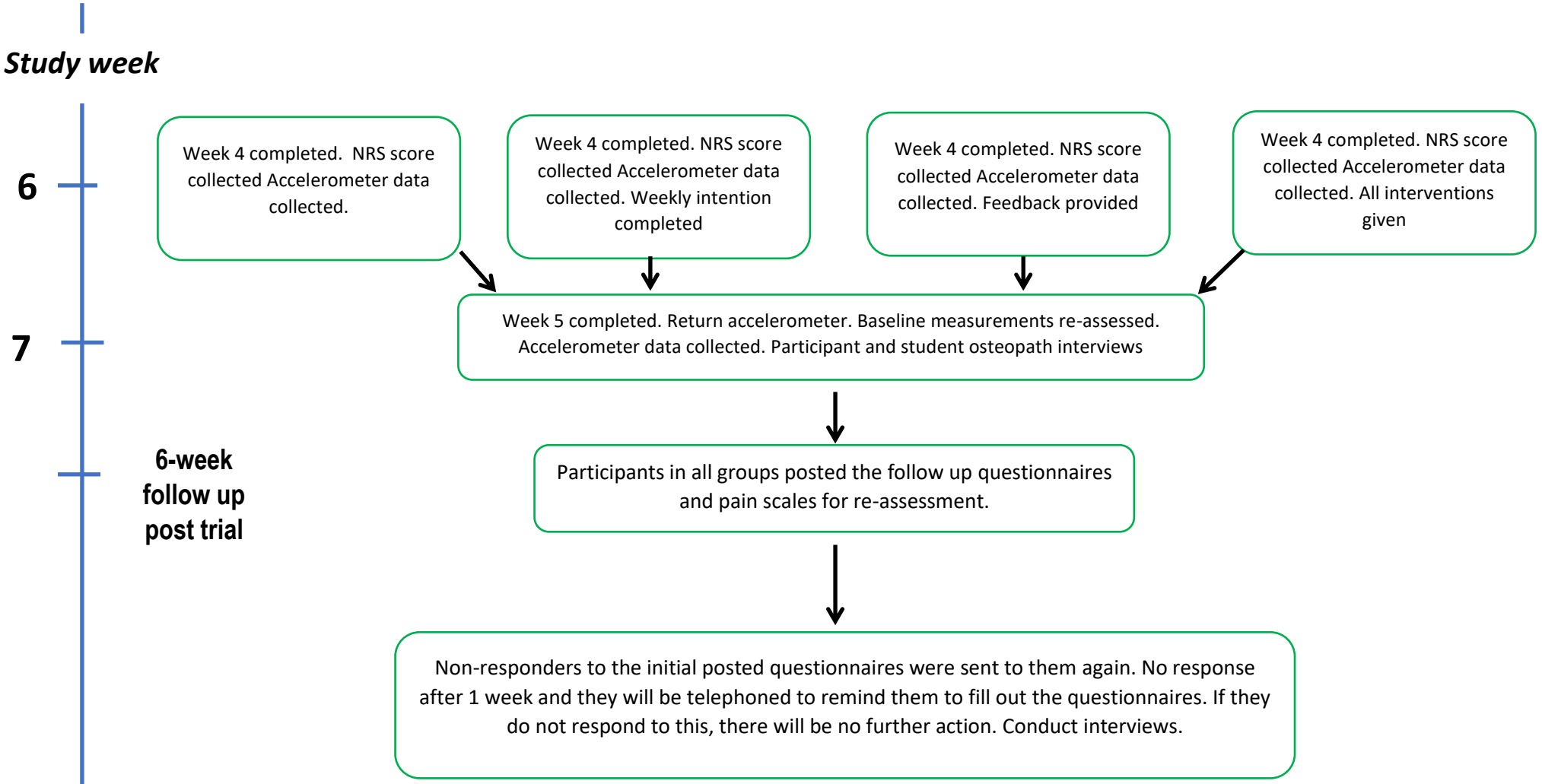


Figure 6.2: Flow diagram of the trial protocol for the patient participants

6.9 Data analysis

A mixed methods design was used to collect quantitative and qualitative data in order to address the research questions and aims relating to the acceptability and credibility of the trial procedure and equipment used, and the feasibility of conducting a full-scale RCT in the future. MMR is recommended as it is not always possible to investigate the complex nature of health and healthcare through the use of one approach (Morgan, 1998; van Griensven, Moore and Hall, 2014). *Chapter 5* provides the background of MMR and the rationale behind using MMR for this feasibility pilot trial.

6.9.1 Quantitative data analysis

According to Lancaster, Dodd, and Williamson (2004) the analysis of any type of pilot study should be descriptive or focus on CI. The planned analyses for this trial were descriptive, with a focus on means and CI (set at 95%). However, due to an inadequate sample size (total of n=5 patient participants), means and CI could not be calculated. Medians and interquartile ranges could also not be calculated or used and comparative testing between the groups could also not be performed. Therefore, only a descriptive analysis of the results is provided. Data was analysed at the end of the trial once all the data had been collected. The level of missing data and number of participant withdrawals (during the trial, follow-up, or both) from each group have been reported. Missing data, i.e., a participant withdraws from the study, was collected up to the point of withdrawal and were included in the descriptive analysis. One participant did not complete the follow-up questionnaires and pain scales. They did not respond to the emails for the follow-up appointment (6-week follow up post-trial) or for the interview.

The data from the accelerometers were analysed using the protocol set out by Chahal *et al*. (2014). The data from the sensors was exported onto MSR software (MSR 4.16) and then onto a customised MATLAB script for further analysis (Chahal, Lee and Luo, 2014). The resultant acceleration was computed and then filtered using a Butterworth bandpass filter (0.1- 6 Hz) – this removed the static gravitational acceleration and noise (Chahal, Lee and Luo, 2014). The resultant acceleration was divided into 7200 (12 hour long) consecutive

segments. The loading dose of physical activity level was calculated (Chahal, Lee and Luo, 2014). Refer to *Chapter 3,* section *3.10.10* for further details.

The key issues identified by Avery *et al.* (2017) for developing and creating progression criteria for RCTs, after a pilot trial, were used to inform the feasibility of this trial. The criteria which would suggest a full-scale RCT is feasible are as follows:

- Trial recruitment – Recruiting at least twelve NSLBP patients per month over a 5-month period to meet the pre-determined recruitment goal of 60 patients. Recruiting at least five student osteopaths and five clinic tutors within the first month of running this trial was required to aid the recruitment process.

- Protocol adherence – those participants recruited followed the trial protocol as it was set out, with the NSLBP patients receiving and adhering to the intervention they were allocated to, and with the clinicians identifying patients who met the eligibility criteria (NSLBP). An adherence rate of at least 70% to the trial protocol by the patients, and clinicians was deemed adequate.

- Outcome data – Of the recruited patient participants at least 75% should provide completed data at the pre-determined measurement time-points.

6.9.2 Qualitative data analysis

Qualitative data was analysed using an alternative approach to verbatim transcription (Halcomb and Davidson, 2006). This method offers a rigorous and alternative approach to transcription and arguably a more appropriate approach for the descriptive analysis that also had the added benefit of being more cost-effective. A key strength of this method is the emphasis on process of direct engagement of two researchers with the original interview data via audio-recordings rather than a text copy (i.e., transcription) that may contain errors and lose details of emphasis and tone. Verbatim transcription is a necessary step for most types of in-depth qualitative analysis (e.g., Interpretive Phenomenological Analysis (IPA), Grounded Theory, Discourse Analysis, Thematic Analysis). The reason for not transcribing the interview data verbatim was that the analysis conducted in this trial was predominately descriptive rather than interpretative. The level of analysis for the interview data in this trial

did not demand the benefits of transcription where in-depth analyses or linguistic structures are being explored. The primary focus of these interviews was to gain a descriptive account of the participant's experience of taking part in the feasibility-pilot trial.

This six-step method for analysing interview data suggested by Halcomb and Davidson (2006) has been used in previous health and behavioural studies (Adejuyigbe *et al.*, 2015; Graham, Alderson and Stokes, 2015; Strachan *et al.*, 2015) including a doctoral study carried out at UCO (Draper-Rodi, 2016). This 6-step method included:

1. *Audio taping whilst taking field notes.* This was completed using dictaphones.

2. *Reflective journaling post interview.* This was used to expand and comment on the field notes and to record initial key impressions and content raised in the interview.

3. *Listening to and reviewing the audio recordings along with further revision of the field notes and reflective journal*. This process enhanced the accuracy of the researcher's notation and reflection of the interview.

4. *Preliminary analysis*. A content analytic approach was used. Initial codes, and subsequent categories were identified from the finalised field notes and reflective journal. Themes were constructed from the categories. This type of analysis involved the counting and comparisons of categories, keywords, and thematic content.

5. *Secondary content analysis.* The preliminary analysis was reviewed by a second researcher (supervisor). Selected audio recordings of interviews were listened to alongside the first researcher's preliminary analysis to explore the trustworthiness of the initial analysis and to assure the quality of the thematic analysis. Amendments to codes, categories and themes were made through discussion.

6. *Thematic review.* The secondary content analysis was reviewed by the research team to agree and confirm the established themes and illustrative quotes to evidence the content of the thematic analysis.

Steps 4 and 5 were completed using a conventional content analysis (Hsieh and Shannon, 2005) to describe this data. This type of analysis involves the counting and comparisons of keywords and content, which is the aim of steps 4 and 5 as outlined by Halcomb and

Davidson (2006). Key themes from each section of the interviews (step 6) were noted and summarised. Anonymised quotes were used to illustrate the descriptive accounts of the themes and a summary of the analysis was provided. In line with the realist approach, the purpose of the interviews, and the data subsequently collected, was not to establish any deeper meaning beyond what the participant said or to provide an explanation for patterns which arose from the data.

This analysis was independently carried out by two researchers providing an audit trail, supporting the trustworthiness of the analysis, and providing an approach to support the validity of the themes identified. Both researchers had a copy of the interview field notes which were reviewed and enhanced alongside listening to the audio interviews. Only the researcher and supervisory team had access to the interview field notes and audio data, which was kept behind a locked door in a draw requiring a combination code. Digital copies of the notes and audio data were stored on a password protected computer.

6.10 Chapter summary

- This chapter details the mixed methods methodology used in the feasibility-pilot trial
- This trial aimed to answer the main question surrounding the feasibility and acceptability of the trial, and trial components, in an educational, student-led University clinic.
- *Chapter 7* reports the results of the feasibility-pilot trial
- The discussion of this thesis is presented in *Chapter 8*

7 Chapter 7 – Evaluation of the mixed methods feasibility trial results

7.1 Chapter introduction

This chapter is divided into three sections. The first section evaluates the results of the mixed methods feasibility-pilot trial for the patient participants. The second section provides a process evaluation, answering the sub-questions of this thesis, about the trial procedure, interventions, the accelerometer, and the other measurement tools used for the patient participants. The final section provides a process evaluation relating to the sub-questions surrounding the acceptability of the interventions used and the acceptability and feasibility of the trial procedure for the clinicians at the UCO outpatient clinic.

The sub-questions of this thesis are:

1. What is the acceptability, usability, and feasibility of the accelerometers to measure physical activity in people with NSLBP?

2. What is the acceptability and credibility of a physical activity intervention for people with low back pain amongst the patient and clinician participants?

3. What is the feasibility and acceptability of the trial procedure for the patient and clinician participants?

4. What is the feasibility and acceptability of the questionnaires for the patient participants?

7.2 Feasibility-pilot trial: Patient participants

The aim of this trial was to recruit NSLBP patients from the UCO clinic and randomise them into one of four intervention groups. The intervention groups were designed using various BCTs to encourage these patients to be more physically active (refer to Chapter 4 for more details on the intervention development). Potential participants were identified by the clinicians (student and tutor osteopaths). The recruited patient participants were involved in a pilot of the trial and were asked to attend an interview at the end of the trial. The interviews were designed to assess the acceptability and credibility of the trial protocol, the use of the accelerometer, the physical activity interventions and the questionnaires used in the trial.

Five healthy participants (4 male and 1 female), with recurrent NSLBP, aged between 18 and 75 years old (age = 44.6, SD =± 22.2, height =176.2, SD =± 8.8, weight = 75.6, SD =± 9.0, BMI = 24.3, SD =± 1.8 and waist-to-hip ratio = .8982, SD =± 0.6) were recruited and randomly assigned to an intervention group. Two participants were assigned to the implementation intentions group (group 3) and one to each of the other groups (i.e., advice and education (group 1), feedback (group 2), and all the interventions (group 4)). One participant was excluded from the trial, as they did not meet the eligibility criteria for NSLBP. Their LBP was caused by a herniated disc, diagnosed with imaging, which is not a "non-specific" pathology.

Due to the small number of participants recruited to the trial it was not possible to conduct CI. A detailed description of the characteristics of each participant and their data across the trial is provided. A qualitative analysis highlights what the patient participants thought of the interventions they received and which BCT was identified to be the most acceptable to them. Cross-comparisons between the amount of physical activity the participant completed with their scores for pain and disability have been included.

7.3 Results of the raw data

All the patients (n=5) were presenting with recurring NSLBP. Two of the participants were retired (P01 and P02), one of the participants worked night shifts in a supermarket (P03) and the remaining two participants were students (P04 and P05).

7.3.1 Physical activity levels

7.3.1.1 Baseline measurements

During the baseline measurements, participants P01, P02 and P05 appeared to do very similar amounts of very light physical activity, despite the differences in occupation and age. Two of the participants were retired (P01 and P02) and did very similar amounts of light activity and did not engage in any moderate or vigorous amounts of physical activity. P03 and P04 did similar amounts of very light activity, but P04 engaged in more light activity, which was on par with the amount P05 did. P03, P04 and P05 all managed to do some moderate activity, with P04 doing the most, followed by P03 and P05 respectively. P04 was the only participant to record any amount of vigorous activity. P03 worked a night shift pattern, so daily amounts of physical activity were always changing. Very light, light, moderate and vigorous activity dosages are calculated by the MATLAB algorithm used in this trial (see *chapter 3: 3.10.9 Data analysis* for details).

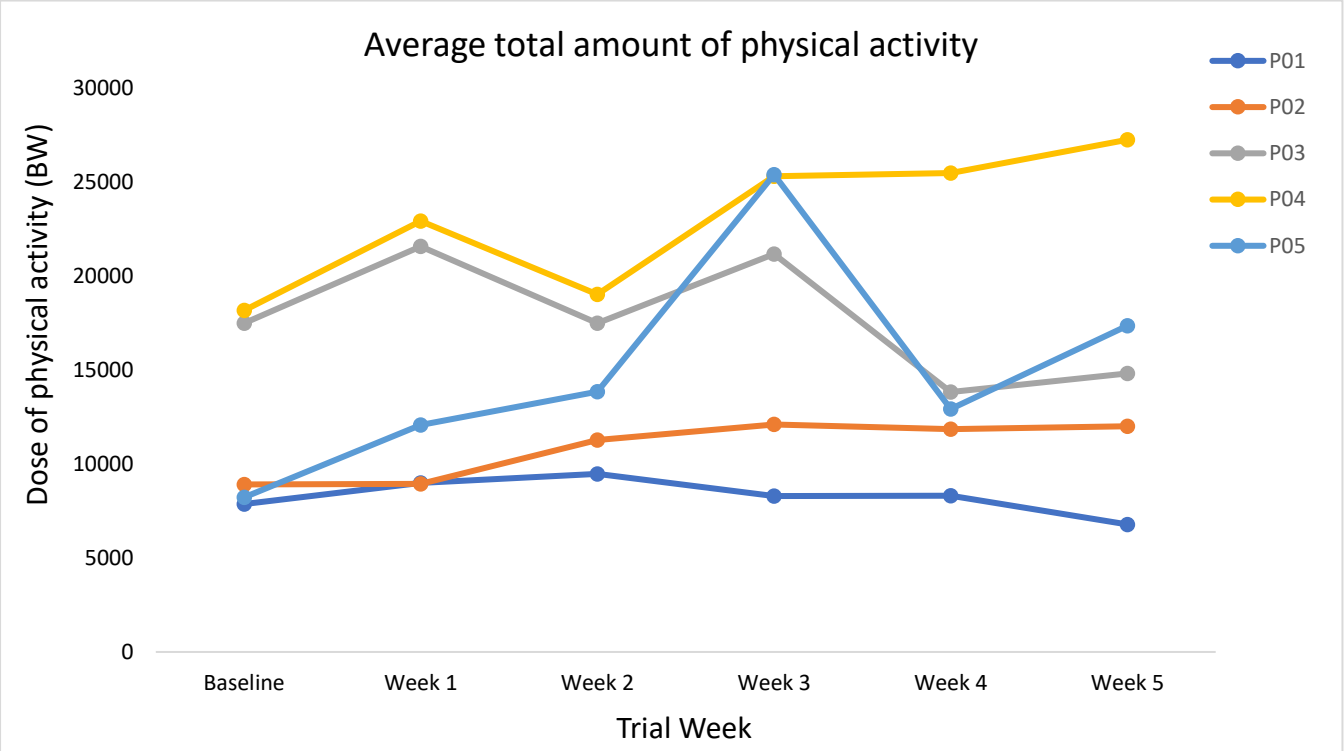


Figure 7.1: Average total amount of physical activity recorded by the participants from baseline to week 5.

Four of the participants managed to increase their physical activity levels from their baseline measurements throughout the trial (see figure 7.1). One participant (P01) demonstrated an initial increase in physical activity levels up until week 2 of the trial. Hereafter, this participant gradually engaged in less physical activity for the final three weeks of the trial. P02 started to increase the amount of activity they were engaging in, but by week 3 they seemed to plateau. Four of the participants (P01, P02, P03 and P05) were able to increase their activity levels weekly, up to week 3. However, hereafter they decrease were shown in the amount of activity they were doing (i.e., physical activity levels decreased in week 4 and 5). Only one participant (P04) managed to maintain and increase their activity levels past week 3. Trial fatigue could be a potential reason for the decrease in activity levels noted in the other participants.

Changes in the participants physical activity levels, on an individual basis throughout the duration of the trial, are presented below. This is presented in a series of graphs, highlighting changes in very light, light, moderate and vigorous activity. The graphs have been truncated to make the data easier to read. The activity levels of the participants are individually narrated throughout the next section. The differences between the activity dose for very light, light, moderate and vigorous activity recorded from one week to the next is reported. The reported percentage increases are relative to baseline. Increases in activity percent (%) are doted by the symbol (↑) and decreases in activity % are denoted by the symbol (↓). Increases in dose are denoted by (+) and decreases in dose are denoted by (-).

7.3.2 Group 1

The participant (P05) in this group received weekly advice and education to be physically active, despite their NSLBP. P05 gradually increased the total amount of physical activity they engaged in throughout the duration of the trial.

Figure 7.2 shows the average levels of physical activity for very light, light, moderate and vigorous activity for P05 throughout the duration of the trial. Despite being one of the youngest participants on the trial, P05 did not regularly complete any vigorous physical activity. During the baseline measurements P05 recorded the following doses: 8057 BW of

very light activity, 156 BW of light activity and 8 BW of moderate activity. No dose for vigorous activity was recorded.

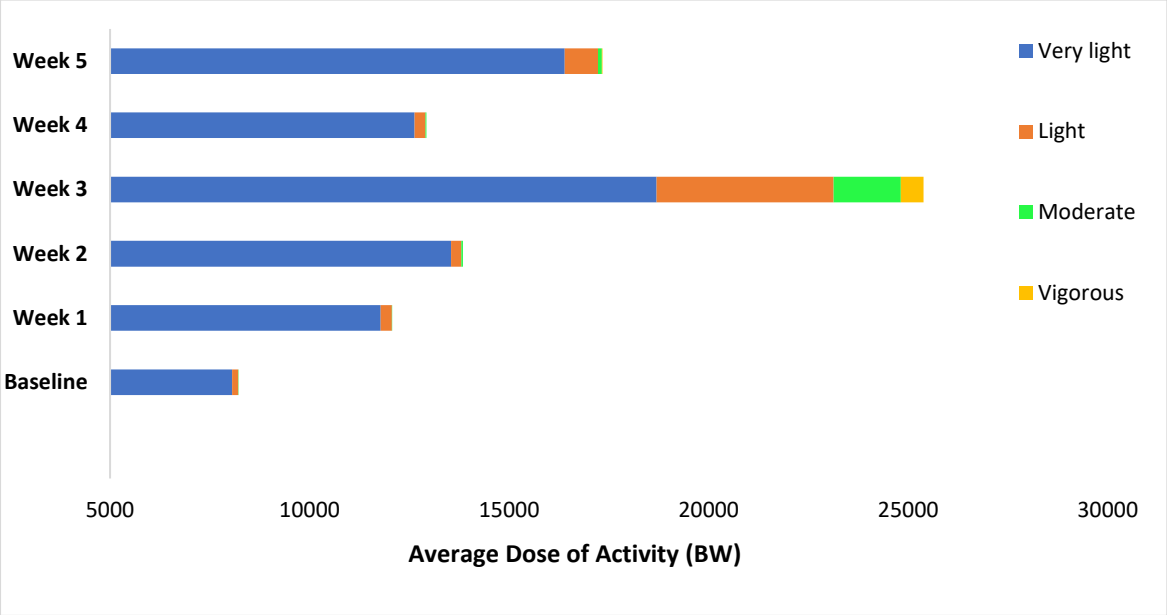


Figure 7.2: Changes in intensity of activity throughout the trial for P05. The graph has been truncated and starts at 5000 BW.

P05 increased their physical activity levels during week 1 from their baseline measurements as indicated in figure 7.2. The dose for very light activity increased by 3,725 BW (↑ of 46% from the baseline measurement). An increase in light activity (dose: +122 BW) was recorded indicating a 78% ↑ in activity from the baseline measurement. An increase (dose: +2 BW (+26% from baseline)) of moderate activity was engaged in. No vigorous activity was completed in week 1 by P05.

Throughout week 2, P05 engaged in more very light activity (dose: +1,767 BW, ↑ of 68% relative to baseline) and more moderate activity (dose: +29 BW) compared to the previous week. A slight decrease in light activity was noticed (dose: –21 BW) compared to the dose of light activity recorded in week 1. This was still an increase of 65% from the baseline measurements. No vigorous activity was recorded in week 2. During week 3, P05 recorded the highest amounts of physical activity in comparison to the amount recorded during the other weeks on the trial as indicated by figures 7.1 (average overall change in activity) and 7.2 (weekly changes in activity). Increases in very light (dose: +5,149 BW, ↑ of 132% from

baseline), light (dose: +4,174 BW, ↑ of 2735% from baseline) and moderate activity (dose: +1,648 BW, ↑ of 20895% from baseline) were recorded. Vigorous activity was completed in week 3 (dose: +571 BW, ↑ of 100% from baseline).

These increases were not maintained in week 4. Whilst engaging in more physical activity than their baseline measurements, reductions in very light activity (dose: -6,066 BW, ↑ of 57% from baseline), light activity (dose: –4,162 BW, ↑ of 73% from baseline) and moderate activity was recorded (dose: –554 BW, ↑ of 207% from baseline) compared to the previous week. No vigorous activity was completed by P05 in week 4. P05 engaged in more very light (dose: +3,762 BW, ↑ of 103% from baseline), light (dose: +563 BW, ↑ of 433% from baseline), moderate (dose: +69 BW, 1070% from baseline) and vigorous activity (dose: 22 BW) compared to the previous week.

7.3.3 Group 2

The participant (P03) in this group received weekly feedback on their activity levels. During the baseline measurements, P03 mentioned being on high doses of pain killers for her NSLBP. Figure 7.3 shows the increase in physical activity levels for very light, light, moderate and vigorous activity for P03 throughout the duration of the trial. During the baseline measurements, P03 recorded doses of 17,354 BW in very light activity, 108 BW of light activity, and 17 BW of moderate activity. No vigorous activity was recorded during the baseline measurements.

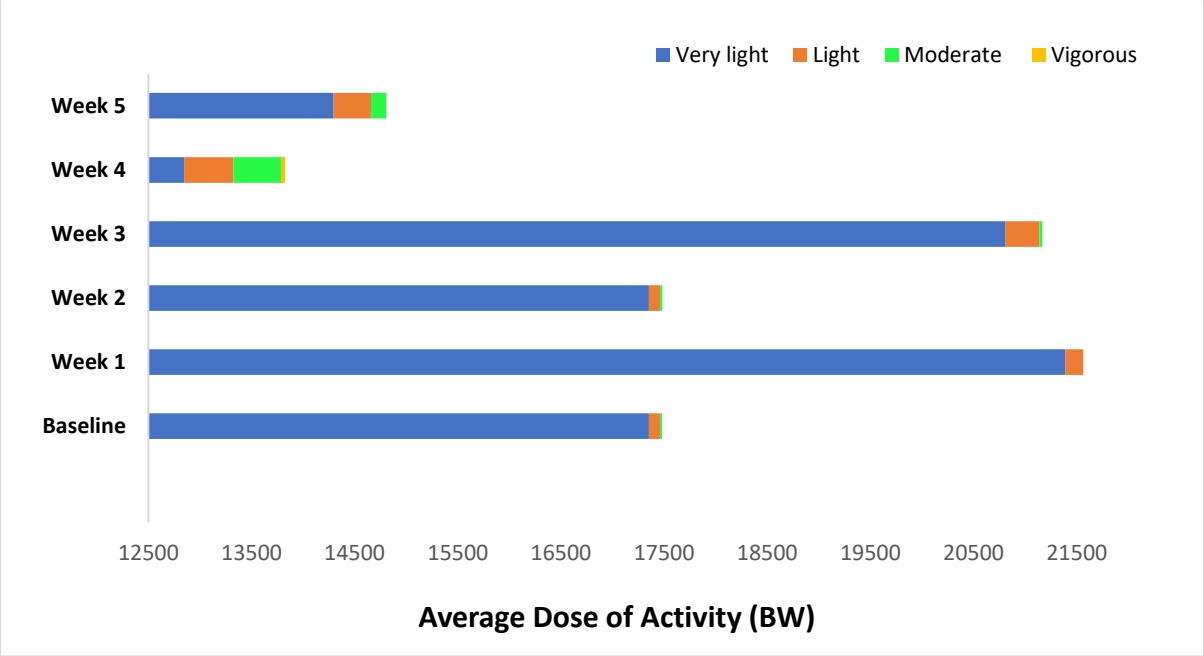


Figure 7.3: Changes in intensity of activity throughout the trial for P03. The graph has been truncated to 12500 BW.

P03 increased their activity levels in week 1 for very light (dose: +4,036 BW, ↑ of 23% from baseline) and light activity (dose: +67 BW, ↑ of 62%) from their baseline measurements as shown in figure 7.3. In week 1, P03 engaged in more very light activity than they did throughout the rest of the trial. No moderate or vigorous activity was completed during week 1.

A reduction in total amount of physical activity (see figures 7.1 and 7.3) occurred during week 2. Reductions in very light (dose: –4,036 BW) and light activity (dose: –67 BW) were seen. However, the reductions recorded demonstrated a 0% change in very light and light activity from the baseline measurements. An increase in moderate activity (dose: +21 BW, ↑ of 17% from baseline) was shown in week 2. This increase could be due to P03 trying to engage in more moderate activity as per their feedback from the previous week.

After receiving feedback on their activity levels from week 2, P03 increased the total amount of physical activity they engaged in during week 3. Increases in doses for very light (dose: +3,453 BW, ↑ of 20% relative to baseline) light (dose: +224 BW, ↑ of 208% relative to baseline) and moderate activity (dose: +7788 BW, ↑ of 43286% relative to baseline) were recorded. No vigorous activity was recorded in week 3.

Vigorous activity was recorded during week 4 (dose: +36 BW). Week 4 was the only week during the trial in which P03 engaged in vigorous activity. Increases in light activity (dose: +148 BW, ↑ of 345% from baseline) were recorded. However, reductions in very light activity (dose: –7,962 BW ↓ of 26% from baseline) and moderate activity (dose: –7347 BW, ↑ of 2468% from baseline) were recorded.

During the last week of the trial (week 5), P03 decreased in the total average doses of activity they completed. Decreases in light activity (dose: –114 BW, ↑ of 239% from baseline) and moderate activity (dose: –314 BW, ↑ of 723% from baseline) was recorded in week 5 compared to week 4. An increase in very light activity (dose: +1,449 BW) was recorded but this was a reduction of 18% from the baseline measurements. The total amount of activity dose completed in week 5 was, again, lower than the total amount of activity dose recorded during the baseline measurements.

7.3.4 Group 3

The two participants in this group (P01 and P02) received the implementation intentions. The participants in this group were both retired. Figures 7.4 (P01) and 7.5 (P02) shows the increase in physical activity levels for very light, light, moderate and vigorous activity throughout the duration of the trial for the participants in this group.

During the baseline measurements, P01 recorded doses of 7827 BW of very light activity and 44 BW of light activity. No doses of moderate or vigorous activity were recorded by P01 during the baseline measurement. P02 recorded baseline measurement doses of 8849 BW of very light activity and 59 BW of light activity. Similar to P01, P02 did not record any moderate or vigorous activity. P02 did not record any vigorous physical activity throughout the duration of the trial.

During week 1, both participants managed to increase the amount of activity they performed. P01 was able to complete a higher dose of very light activity during week 1 from their baseline measurement (dose: +1,026 BW, ↑ of 13% from baseline). P01 also increased the amount of light activity (dose: +67 BW, ↑ of 153% from baseline). A dose of moderate activity (dose: 26 BW, ↑ of 100% from baseline) was also recorded for P01. No vigorous

activity was completed by P01. Small increases were seen in P02 for very light (dose: +27 BW, 0% change from baseline) and light activity (dose: +9 BW, ↑ of 15% from baseline) during week 1. No moderate or vigorous activity was recorded by P02 in week 1 (figure 7.5).

Both participants increased in the total amount of physical activity completed in week 2 as shown in figures 7.1, 7.4 (P01) and 7.5 (P02). Week 2 was the week P01 increased the total amount of physical activity they engaged in. An increased amount of very light activity (dose: +519 BW, ↑ of 20% from baseline) was recorded. However, a reduction in light activity (dose: –22 BW, ↑ of 102% from baseline) was recorded. P01 engaged in moderate activity during week 2 (dose: 9 BW, ↑ of 100% from baseline).

Despite increasing levels of very light activity in week 2 (dose: +2375 BW, ↑ of 27% from baseline), P02 decreased the amount of light activity (dose: –52 BW, ↓ of 73% from baseline) they engaged in.

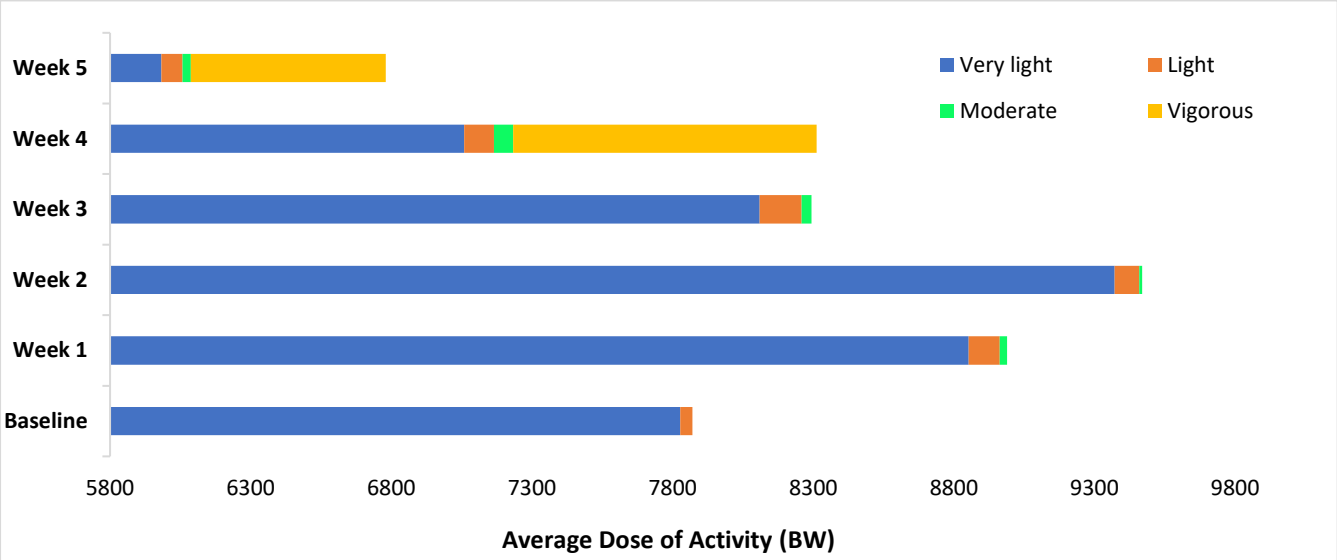


Figure 7.4: Changes in intensity of activity throughout the trial for P01. The graph has been truncated at 5800 BW

During week 3, P02 increased the total amount of physical activity completed (see figure 7.5). An increase of very light activity (dose: + 689 BW, ↑ of 35% from baseline) and an increase in light activity (dose: +125 BW, ↑ of 138% from baseline) were recorded. P02 recorded a small dose of moderate activity (dose: 17 BW, ↑ of 100% from baseline) for the

first time during the trial (week 3). P01 demonstrated a decrease in total physical activity levels for week 3. A reduction in very light activity (dose: –1262 BW, ↑ of 4% from baseline) was recorded. However, increases in light (dose: +61 BW, ↑ of 242% from baseline) and moderate (dose: +26 BW, ↑ of 100% from baseline) activity were recorded in week 3 for P01.

P02 did not sustain the increased levels of physical activity into week 4. P02 decreased the amount of moderate activity (dose: 0 BW) they engaged in. Decreases in dose of very light (dose: –195 BW, ↑ of 33% from baseline) and light activity (dose: –37 BW, ↑ of 76% from baseline) were also recorded by P02. P01 recorded vigorous activity (dose: 1079 BW) in week 4, which is an ↑ of 100% relative to the baseline measurements for this participant. Slight reductions in doses of very light (dose: –1050 BW, ↓ 10% from baseline) and light activity (dose: –44 BW, ↑ of 141% from baseline) were recorded for P01 in week 4. An increase in moderate activity (dose: +32 BW) and vigorous activity (dose: 1080 BW) was recorded for P01.

During the last week of the trial (week 5), the dose of very light activity completed by P02 was +175 BW more than the previous week (↑ of 35% compared to baseline). A reduction in light activity (dose: –18 BW, ↑ of 44% from baseline) was recorded in week 5 for P02. P01 decreased the total amount of physical activity they engaged in this week, as reflected in figure 7.4. The total dose amount was lower than the baseline measurements for P01 for total average physical activity levels (figure 7.1). Decreases in very light (dose: –6984 BW, ↓ of 99% from baseline) and light activity (dose: –76 BW, ↓ of 34% from baseline) were recorded for P01 in week 5. However, increases in moderate activity (dose: +626 BW) was recorded during the final week (week 5) for P01 (see figure 7.4). No vigorous activity was completed in week 5 by P01.

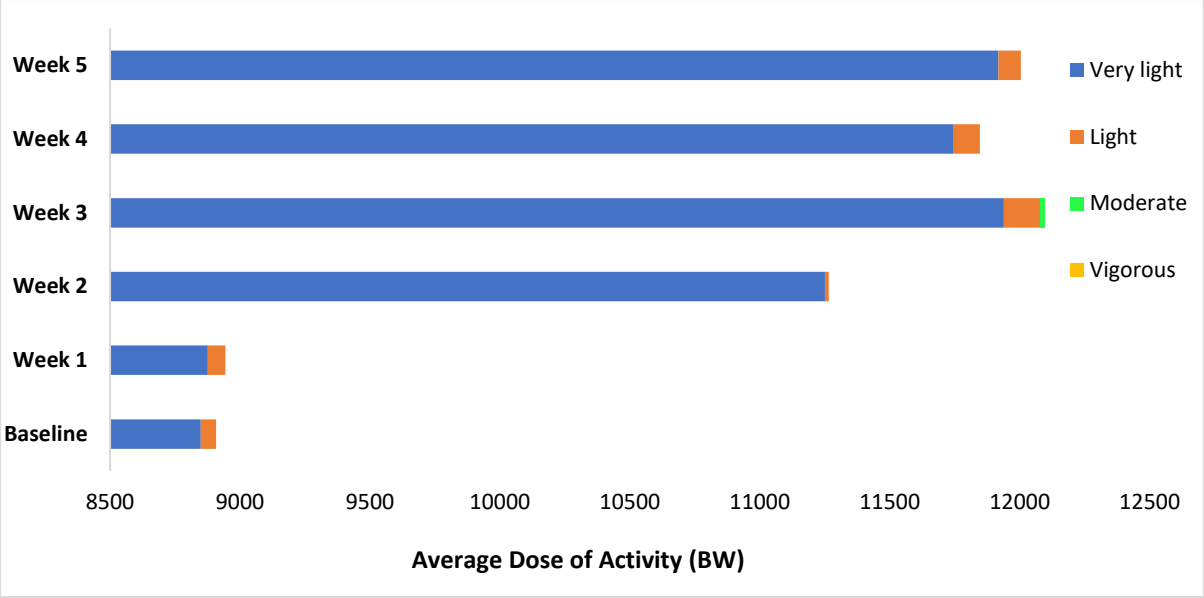


Figure 7.5: Changes in intensity of activity throughout the trial for P02. The graph has been truncated at 8500 BW.

From week 3 to week 5, P02 managed to maintain their levels of very light activity, with the dose fluctuating by small amounts (week 3 dose: 11939 BW, week 4 dose: 11744 BW, week 5 dose: 11919 BW). This level of consistency, for very light activity levels, was not matched by any other participant on the trial, throughout the duration of the trial.

7.3.5 Group 4

The participant (P04) in this group received all the interventions: advice and education, feedback, and the implementation intentions. Figure 7.6 demonstrates the change in physical activity levels for very light, light, moderate and vigorous physical activity for P04 throughout the weeks of the trial. The graph has been truncated at 13000 BW. P04 was the only participant to record doses of vigorous activity during the baseline measurements and was also the only participant to record doses of vigorous activity in every week of the trial.

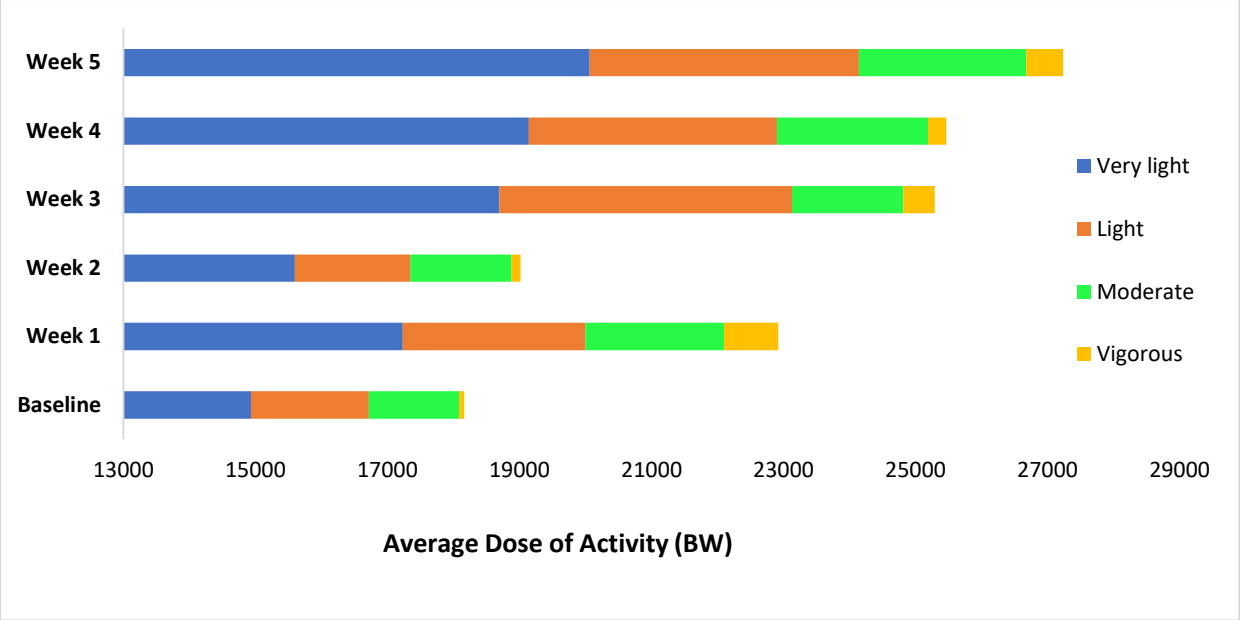


Figure 7.6: Changes in intensity of activity throughout the trial for P04

P04 managed to increase their activity levels for very light (dose: +2,301 BW, ↑ of 15% from baseline), light (dose: + 983 BW, ↑ of 55% from baseline), moderate (dose: +734 BW, ↑ of 54% from baseline) and vigorous activity (dose: +738 BW, ↑ of 941% from baseline) from their baseline levels during week 1 as shown in figure 7.6. P04 recorded the highest dose of vigorous activity (dose: 816 BW) out of all the participants throughout the trial, during week 1. These increases in physical activity were not sustained during week 2. Reductions in doses for very light (dose: –1633 BW, ↑ of 4% from baseline), light (dose: –1023 BW, ↓ of 2% from baseline), moderate (dose: –567 BW, ↑ of 12% from baseline) and vigorous activity (dose: –679 BW, ↑ of 76% from baseline) were recorded.

P04 increased the levels of activity during week 3. It was noted that P05 and P04 completed almost the exact same total amount of activity this week, with the only difference being P04 recorded a higher dose of vigorous activity. The rest of the dose amounts of activity were the same for both participants. Increases in very light (dose: +3099 BW, ↑ of 25% from baseline), light (dose: +2683 BW, ↑ of 148% from baseline), moderate (dose: +155 BW, ↑ of 24% from baseline) and vigorous (dose: +337 BW, ↑ of 506% from baseline) were recorded for P04 during week 3.

P04 maintained these levels of activity throughout week 4 and increased the dose amount of total physical activity during this week. Very light activity (dose: +443 BW, ↑ of 28% from

baseline) increased during week 4. A reduced dose of light activity was seen (dose: –671 BW, ↑ of 110%), but an increased dose of moderate activity (dose: +604 BW, ↑ of 68%) was also shown in week 4 for P04. The reduction in light activity could be due to the increase in moderate activity dose throughout week 4. A decrease in vigorous activity (dose: –198 BW) was recorded, but this value was still an increase of 253% compared to the baseline measurements.

These increases in physical activity doses were increased upon again during week 5. During week 5, P04 completed the most total average amount of physical activity (in dose) from their baseline measure (see figure 7.1 and figure 7.6). P04 recorded the highest dose of moderate activity (dose: +244 BW, ↑ of 86% from baseline) during week 5. Week 5 was also the week P04 recorded the highest dose of very light activity (dose: +925 BW, ↑ of 34% from baseline). Increases in light activity (dose: +318 BW, ↑ of 128% from baseline) and vigorous activity (dose: +282 BW, ↑ of 102% from baseline) were recorded. Apart from week 2, this was the only participant to consistently increase their activity levels week on week throughout the duration of the trial.

7.3.6 Overall physical activity change

Overall changes in physical activity levels were calculated by averaging the dose of total activity (the doses recorded for very light, light, moderate and vigorous activity) for each week of the trial. Percentage change was calculated by comparing the average dose of activity recorded during weeks one to five of the trial for each participant, to the total average dose recorded by each participant during the baseline measurements. Figure 7.7 shows the overall average physical activity change (in dose) for each of the participants.

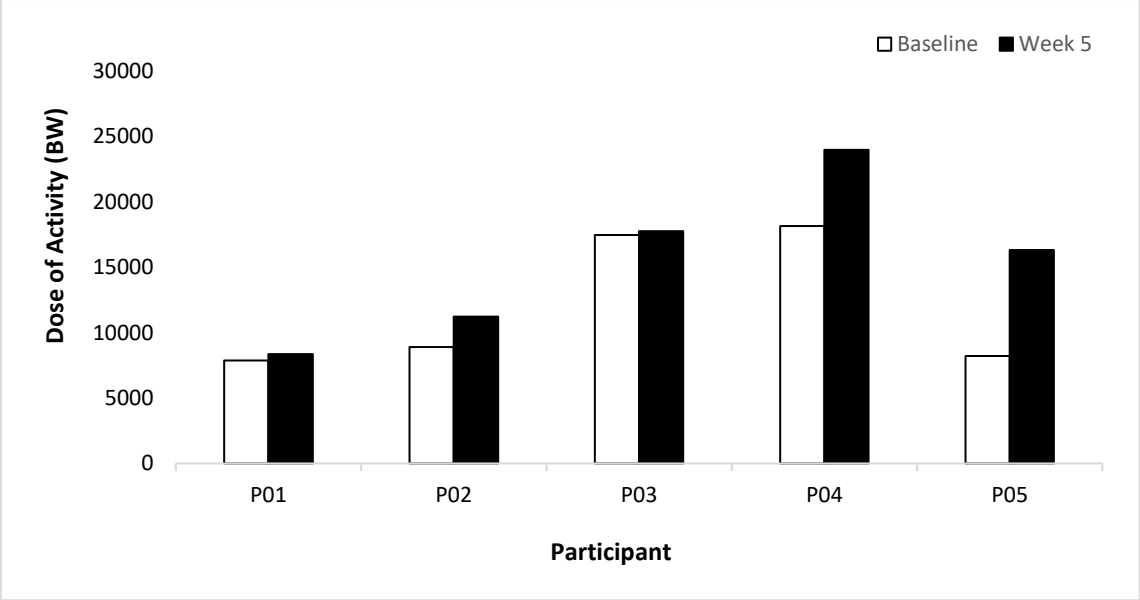


Figure 7.7: Overall changes in average dose of physical activity levels from the baseline measurement to week 5.

As shown in figure 7.7, P04 recorded the highest average dose (dose: 5825 BW) of physical activity compared to any other participant week 5. P04 recorded an overall change in average physical activity dose of 32% relative to the baseline measurement. However, P05 showed the highest overall change in average dose of physical activity (dose: 8093 BW) at week 5. P05 demonstrated an overall average physical activity dose increase of 98% compared to their baseline measurements. P03 demonstrated the least change in average overall dose of physical activity (dose: 17768 BW), with a 2% increase compared to the baseline measurement. Despite being the oldest on the trial, P02 demonstrated more changes in average overall dose of physical activity (dose:11231 BW) than P01 (dose: 8369 BW) and P03. P02 increased their overall average dose of activity by 26% relative to the baseline measurements. P01 demonstrated a 6% increase in overall average activity dose compared to their baseline measurement. The youngest participants increased their activity levels the most throughout the trial.

Given the small sample sizes in each intervention group it was not possible to undertake inferential analysis with respect to exercise intensity change. A larger cohort in each of the intervention groups would have allowed any significant increases in physical activity levels from baseline measurements to be calculated. However, there needs to be an indication of a CMC in physical activity levels, in the literature, to further show effectiveness.

7.3.7 Pain levels

Pain levels were assessed using the NRS scale and were completed when the participant attended their weekly appointment with the primary researcher. The scale ranged from zero (no pain) to ten (worst pain imaginable) (Hawker *et al.*, 2011).

7.3.7.1 Baseline Measurements

All the participants recorded their pain as a four or lower out of ten. One participant rated their pain as a six out of ten. Pain rated four or below correlates to mild pain (Jensen, 2011). Scores between five and six indicate the participant is complaining of moderate pain levels (Jensen, 2011). Figure 7.8 depicts the pain scores recorded for each of the participants throughout the duration of the trial from baseline to follow-up measurements. P01 dropped out after week 5 (at the 6-week follow-up measurement) so there is no score for this participant on the graph at this timepoint.

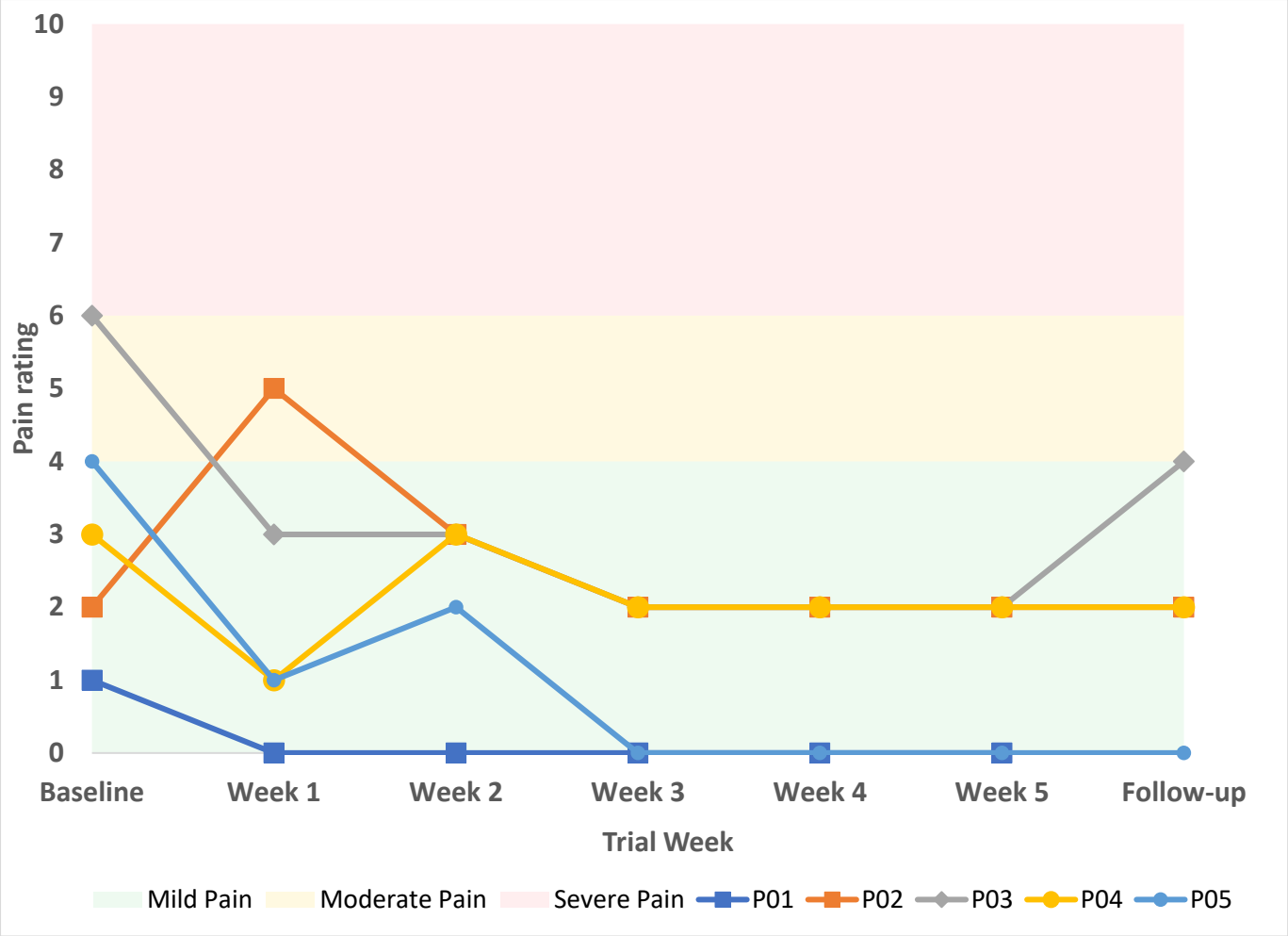


Figure 7.8: Subjectively reported pain experienced (NRS score) from baseline to week 5 and then 6-week follow up post trial for each participant.

7.3.7.2 Weekly pain

P01 was the only participant to record very mild pain at baseline and was the only participant to record a zero (indicating no pain) throughout the remainder of the trial (up to week 5). This participant did not attend their follow-up appointment and therefore no pain measurement could be obtained.

Figure 7.8 highlights the fluctuating nature of NSLBP. For example, P04 initially recorded a decrease in pain levels from baseline to week 1 (three out of ten to one out of ten). However, when recording pain for week 2, the pain levels had increased back to the baseline measurement score of three out of ten. This fluctuation in pain levels can be seen in some of the other participants as well.

Two of the participants (P03, P05) recorded CMC in pain scores throughout the duration of the trial. A CMC on the NRS scale is reported to be the difference of minus two points (Salaffi *et al.*, 2004; National Institute for Health and Care Excellence, 2016). P03 reported a decrease in pain from six to two out of ten by the end of the trial at week 5. P05 recorded a decrease in pain from four to zero out of ten by the end of trial at week 5. Whilst it is possible that the pain scores are related to the changes in physical activity for the participants, no inferential analysis could be undertaken due to the small sample size.

7.3.8 Pain-related disability

Pain-related disability was measured using the RMDQ 24-item questionnaire at three timepoints: baseline, week 5 and follow-up. High scores on the RMDQ relate to high levels of pain-related disability (Doualla *et al.*, 2019)

7.3.8.1 Baseline measurements

All the patient participants in this trial reported very low ratings of pain-related disability (≤6), which suggests the pain-related disability does not impact much of the participants day-to-day life. Figure 7.9 shows the changes in RMDQ score for each of the participants at the three measurement timepoints. P01 does not show any data for the follow-up measurement as they were considered to have dropped-out of the trial after not responding to the email for the follow-up measurements. No data is present on the graphs for P02 at week 5 and P05 at week 5 and the follow-up. This is due to both participants recording a score of 0 on the RMDQ at those data collection points.

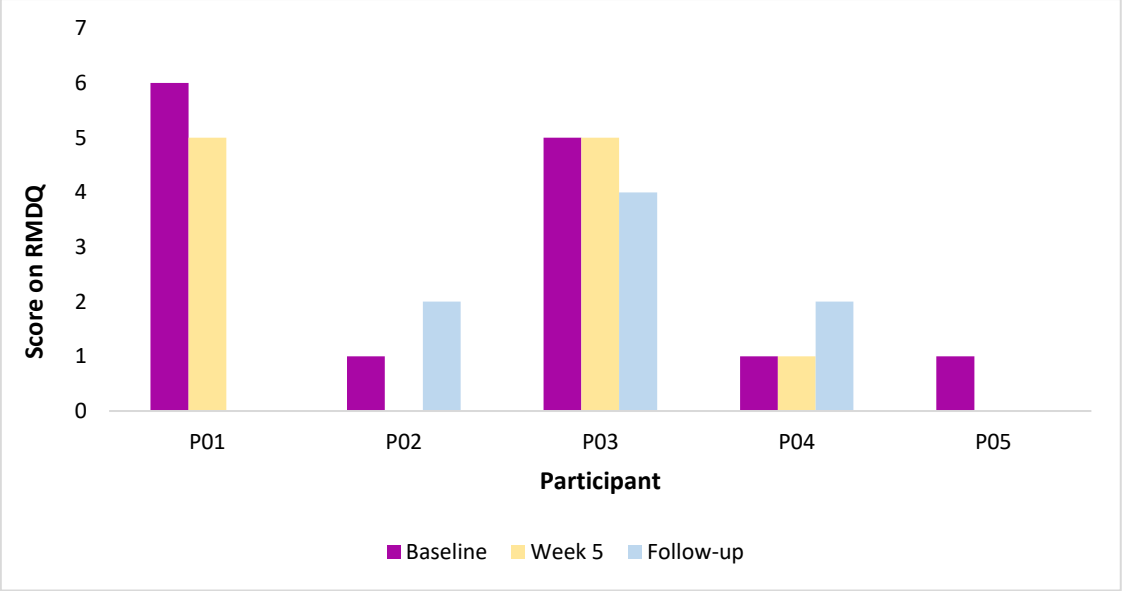


Figure 7.9: RMDQ scores from baseline, week 5 and at the 6-week follow-up post trial measurements

No CMC were shown in the scores for the RMDQ between baseline and week 5 or from the baseline to the 6-week follow-up measurements by any of the participants. A CMC for the RMDQ is a change of 2 points (National Institute for Health and Care Excellence, 2016). Only two participants reported a one-point increase in disability from their baseline measurements and their measurement during the follow-up. Despite reporting lower levels of pain, and a CMC in pain scores, P03 only reported a change of one point at their follow-up and no change at the week 5 measurement for their pain-related disability.

Whilst it is possible that the RMDQ scores are related to the changes in physical activity for the participants, no inferential analysis could be undertaken due to the small sample size.

7.3.9 Health-related Quality of Life

HRQoL was measured using the EuroQol EQ-5D-5L questionnaire at three timepoints: baseline, week 5 and at 6-week follow up post trial. The EQ-5D-5L generates a health state for the responder using the five responses (no-, slight-, moderate-, severe- and extreme problems) to five statements in each of the five categories (mobility, self-care, usual activity, pain/discomfort and anxiety) pertaining to QoL (EuroQol Research Foundation, 2019). Each response is scored with a 1-digit number, one to five, to indicate the level of impact – no

problems equals one, slight problems is scored as two, moderate problems equals three, severe problems is a score of four and extreme problem is scored as a five. For example, the health state of a responder recording no problems with any of the five categories will have a health state score of 1-1-1-1-1. This means they have no problems with their mobility, ability to care for themselves, can carry out their usual activities, have no pain or discomfort and are not suffering with anxiety. Similarly, the responder could have a health state of 5-4-3-2-1, indicating they have extreme problems with mobility, severe problems with caring for themselves, moderate problems completing usual activities, slight pain or discomfort and no problems with anxiety. At the end of the questionnaire, the participants rated their overall health on the VAS. VAS on the EQ-5D-5L ranges from 0 (worst possible health) to 100 (best possible health).

The health states were mapped to the EQ-5D-5L value set for England (Devlin *et al.*, 2017) to get an estimated single utility index value (see table 7.1). The minimal clinically important difference (MCID) for the health states utility index is reported to be a change of 0.03 (National Institute for Health and Care Excellence, 2016).

7.3.9.1 Baseline measurements

Table 7.1 shows the health state of each participant at each of the measurement timepoints of the trial and the utility index value associated with the health state recorded. Figure 7.10 presents the scores for overall health, scored on VAS, at baseline, week 5 and the follow-up for each of the participants.

The only participant who recorded moderate problems with their usual activities was P01 whilst P03 was the only participant who reported moderate problems with pain and discomfort due to their NSLBP. P01 (health state: 2-1-3-2-1) also reported slight problems with mobility and pain and discomfort, and no problems with the ability to care for themselves or anxiety. P02 also reported slight problems with mobility and pain and discomfort, with no problems in the ability to care from themselves. Moderate problems were recorded for P02 with pain and discomfort (health state: 2-1-2-3-2). This is the same as the health state recorded by P03 (2-1-2-3-2). No problems with mobility, self-care, or

anxiety were reported by P04 (health state: 1-1-2-2-1). Only slight problems in carrying out usual activities and pain and discomfort were recorded for P04. P05 recorded a health state of 1-1-1-2-1 for the baseline measurements meaning this participant was “fairly healthy” (EuroQol Research Foundation, 2019). Only slight problems with pain and discomfort were recorded for P05.

Table 7.1: Health states for the participants recorded at the baseline, week 5 and 6-week follow-up measurement timepoints

Participant ID	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety	Health state	Utility index
P01							
Baseline	2	1	3	2	1	2-1-3-2-1	0.811
Week 5	2	1	2	2	1	2-1-2-2-1	0.829
Follow-up				Dropped out			
P02							
Baseline	2	1	2	2	1	2-1-2-2-1	0.829
Week 5	2	1	1	2	1	2-1-1-2-1	0.887
Follow-up	1	1	1	2	1	1-1-1-2-1	0.937
P03							
Baseline	2	1	2	3	2	2-1-2-3-2	0.73
Week 5	2	1	2	3	2	2-1-2-3-2	0.73
Follow-up	2	1	2	2	1	2-1-2-2-1	0.829
P04							
Baseline	1	1	2	2	1	1-1-2-2-1	0.887
Week 5	1	1	1	2	1	1-1-1-2-1	0.937
Follow-up	1	1	1	2	1	1-1-1-2-1	0.937

Participant ID	Mobility	Self-care	Usual activities	Pain/discomfort	Anxiety	Health state	Utility index
P05							
Baseline	1	1	1	2	1	1-1-1-2-1	0.937
Week 5	1	1	1	1	1	1-1-1-1-1	1
Follow-up	1	1	1	2	1	1-1-1-2-1	0.937

A score of:

1 = no problems, 2 = slight problems, 3 = moderate problems, 4 = severe problems, 5 = extreme problems

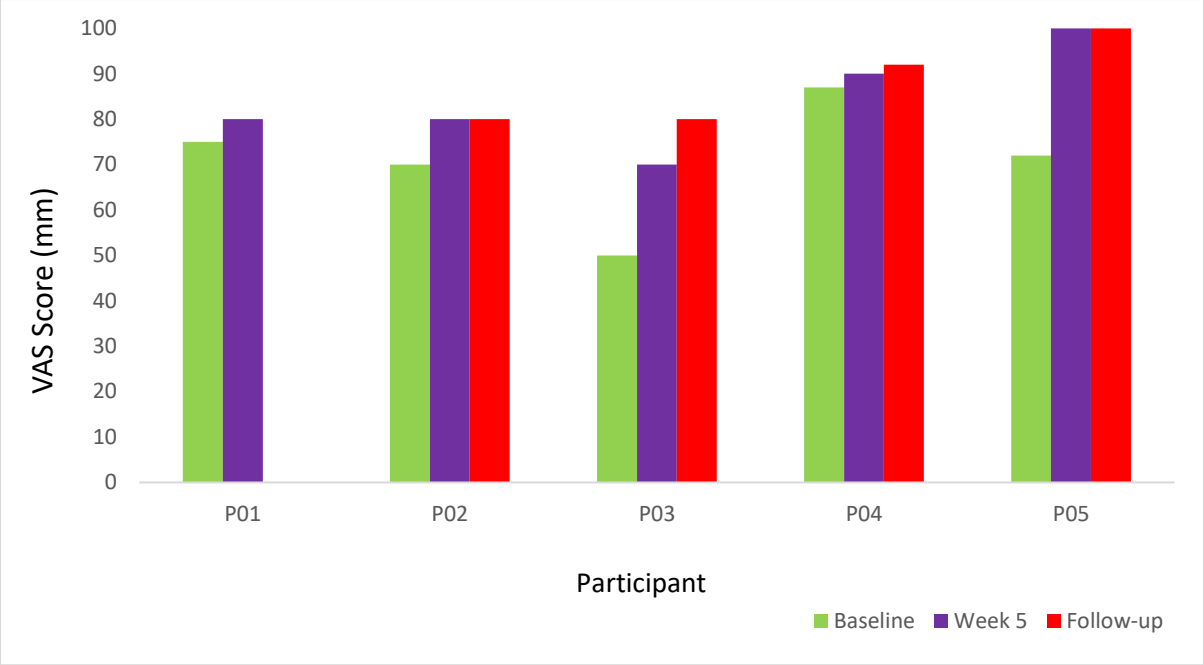


Figure 7.10: Results of the EQ-5D-5L for overall health using VAS

A score of one hundred out of one hundred on the EQ-5D-5L VAS indicates the "best possible health ever" (EuroQol Research Foundation, 2019). P01 and P02 (both retired) recorded similar overall health scores on VAS of seventy-five and seventy out of one hundred respectively (see figure 7.10). P03 recorded the lowest overall health score of fifty out of one hundred on VAS. P04 recorded the highest overall health score on VAS which was eighty-seven out of one hundred. P05 recorded an overall health score of seventy-two out of one hundred on VAS, similar to P01 and P02. Unlike the VAS for pain scores, the EQ-5D-5L VAS does not provided indicators of how to interpret the scores. For example, on the VAS for pain a score of moderate pain is between 45-74mm (Hawker *et al.*, 2011). However, there is no indication that a score of seventy out of one hundred relates to the responder feeling as if they are in "good" health.

7.3.9.2 Week 5 and the 6-week follow-up post-trial measurements

Changes in health state can be found by referring back to table 7.1 and changes in VAS scores can be found by referring back to figure 7.10.

No changes were recorded for mobility, self-care, pain/discomfort, and anxiety for P01. The changes recorded were in usual activity for P01, decreasing from moderate problems to slight problems. The change in the utility index value for P01 from baseline to the week 5 measurement improved, but this improvement was not a MCID. This participant dropped out after week 5 and therefore did not record any more measurements.

The health state recorded by P02 at the 6-week follow-up also indicated they were "fairly healthy" (EuroQol Research Foundation, 2019). Improvements in usual activities was recorded for this participant, as they recorded slight problems with completing their usual activities at the baseline measurement, but at the week 5 and 6-week follow-up this had improved to P02 having no problems completing their usual activities. An increase in overall health on VAS was recorded for P02 at the week 5 measurement from their baseline measure of seventy out of one hundred to eighty out of one hundred. This change was maintained at the 6-week follow-up measurement. A MCID in HRQoL was noted for this participant at the week 5 and 6-week follow-up, for changes in utility index value of 0.05 and 0.058 respectively.

The health state recorded for P03 at week 5 had not changed from the baseline measurement (2-1-2-3-2). This also indicated no change in the utility index value at the week 5 measurement. However, this participant recorded a better score on the VAS for their health from fifty out of one hundred to seventy out of one hundred. An improvement in both health state (2-1-2-2-1) and overall health on VAS (eighty out of one hundred) was recorded for P03 at the 6-week follow-up post-trial. The improvement in health state recorded at the 6-week follow-up post-trial demonstrated an improvement in pain and discomfort, which was initially recorded as causing moderate problems (baseline and week 5) to only having slight problems with pain and discomfort. P03 recorded a MCID at 6-week follow-up for utility index value with a change of 0.099.

The week 5 and follow-up health states recorded for P04 (week 5 and follow-up: 1-1-1-2-1) and P05 (week 5: 1-1-1-1-1; follow-up 1-1-1-2-1) indicated that these participants are "fairly healthy" (EuroQol Research Foundation, 2019). P04 recorded an improvement in their ability to carry out usual activities in week 5 and week 6 (no problems compared to baseline measurement of slight problems). P04 demonstrated increases in their overall health on VAS from their baseline measurement (eighty-seven out of one hundred) to ninety and

ninety-two out of one hundred at the week 5 and 6-week follow-up measurements respectively. A MCID in utility index value was recorded at week 5 from the baseline measurement (change of 0.05) which was maintained at the 6-week follow-up for P04.

P05 demonstrated increases in their VAS score for their overall health from their baseline measurements, recording their health as one hundred out of one hundred (best health possible) at the week 5 measurement and the 6-week follow-up post-trial. P05 recorded a change in utility index value from 0.937 to 1 (which is a score for best possible health). A value of 1 is obtained through the participant recording no problems in any of the five dimensions on the EQ-5D-5L (Devlin *et al.*, 2017). This change was not maintained at the 6-week follow-up, but the value recorded at the 6-week follow-up equalled the utility index recorded during the baseline measurements. The change in utility index value at the 6-week follow-up was due to P05 recording "slight problems" with pain/discomfort. This increase in pain/discomfort score fits in with the fluctuating nature of NSLBP (i.e., some days there is no pain and on other days there are). Therefore, the quality of life of this participant was not negatively affected during the trial. P05 was the participant who increased their physical activity the most throughout the trial (overall change of 98% from baseline).

Due to the small sample size, inferential statistics could not be conducted to compare groups or calculate mean values for the health states nor could CMC in overall health VAS scores be calculated. It was noted that the participants who did increase their overall average activity levels throughout the trial demonstrated the MCID in utility scores at the 6-week follow-up. It was also noted that the increase in activity levels did not have a negative effect on the participants QoL (i.e., their health state, VAS score and utility value did not worsen). The inability to conduct inferential statistics also resulted in the inability to calculate if the increased HRQoL health states and utility values were related to the increase in physical activity levels.

7.3.10 Self-administered Physical Activity Questionnaire

7.3.10.1 Measurements for physical activity

The GGPAQ was used as a subjective measure of physical activity. This questionnaire was given to the participants for completion at the baseline, week 5 and 6-week follow-up measurements. The first set of questions are designed to find out how much activity is involved with the responder's work/employment. Two of the participants (P01 and P02) are retired, P03 works in a supermarket as a shelf stacker, which included spending most of the time at work standing or walking, but not requiring intense physical effort. Two participants (P04 and P05) were university students and felt their work was involved with definite physical effort including handling heavy objects and use of tools.

The second set of questions are designed to find out how many hours, in the past week, the responder spent doing: physical exercise (swimming, aerobics, tennis, gym, workout etc.), cycling, walking, housework/childcare and do-it-yourself (DIY)/gardening. The responder was asked to tick a box for: none (no hours), some but less than one hour, 1 hour but less than three hours, and three or more hours. Only one of the participants engaged in walking for less than one hour a week.

None of the participants demonstrated changes in the amount of time they spent doing DIY/gardening, cycling, or doing housework/childcare during any of the measurement timepoints (see table 7.2). Only one participant (P04) demonstrated a change in their physical exercise baseline measurement going from some physical exercise less than an hour duration to more than one hour but less than three hours in duration at week 5. This change was maintained at the 6-week follow-up post-trial. Only one participant (P01) showed a negative change in their walking baseline measurement going from more than one hour but less than three hours in duration to engaging in some walking but less than an hour duration at week 5. The rest of the participants demonstrated no change in their activity habits from the baseline measurements to week 5 or the 6-week follow-up post-trial. This partially reflects the data collected by the accelerometer for overall average changes in physical activity (refer to figure 7.7 in section *7.3.6 Overall physical activity change*).

Minimal overall average changes in activity levels were seen in participants P01, P02 and P03. P04 and P05 demonstrated changes of 32% and 98% from their objective baseline measurements respectively. It is probable that P05 engaged in more walking than their baseline measurements, as the GGPAQ is ambiguous in defining physical activity which exceeds more than three hours. P05 may have been doing exactly three hours of walking at their baseline measurement but at the week 5 and week 6 follow-up this participant may have been engaging in five hours of walking. P04 engaged in more physical exercise than their baseline measurements (as recorded on the GGPAQ) and this could be the reason behind their increase of 32% in physical activity levels.

Table 7.2: Measurements for each participant on the GGPAQ at baseline, week 5 and the 6-week follow-up post-trial.

Participant code	Physical exercise	Cycling	Walking	Housework/childcare	DIY/Gardening
P01					
Baseline	Some but <1 hour	None	>1 hour but <3 hours	None	3 hours or more
Week 5	Some but <1 hour	None	Some but <1 hour	None	Some but <1 hour
Follow-up			Dropped out		
P02					
Baseline	None	None	3 hours or more	None	3 hours or more
Week 5	None	None	3 hours or more	None	Some but <1 hour
Follow-up	None	None	3 hours or more	None	Some but <1 hour
P03					
Baseline	Some but <1 hour	None	>1 hour but <3 hours	Some but <1 hour	None
Week 5	Some but <1 hour	None	>1 hour but <3 hours	Some but <1 hour	None
Follow-up	Some but <1 hour	None	>1 hour but <3 hours	Some but <1 hour	None

Participant code	Physical exercise	Cycling	Walking	Housework/childcare	DIY/Gardening
P04					
Baseline	Some but <1 hour	None	3 hours or more	None	None
Week 5	>1 hour but <3 hours	None	3 hours or more	None	None
Follow-up	>1 hour but <3 hours	None	3 hours or more	None	None
P05					
Baseline	>1 hour but <3 hours	None	3 hours or more	None	None
Week 5	>1 hour but <3 hours	None	3 hours or more	None	None
Follow-up	>1 hour but <3 hours	None	3 hours or more	None	None

7.4 Process Evaluation

Four patient participants attended a semi-structured individual interview lasting between thirty and sixty minutes. One participant did not respond to the initial email sent about the follow-up measurements or interview invitation. Two more emails were sent to the participant about the follow-up measurements and interview, but the participant did not respond and so were counted as a drop out at this stage (6-week follow up post-trial). The purpose of the interviews was to address the sub-questions of this thesis relating to the acceptability of the trial procedure, the interventions used, the accelerometer and the other measurement tools (i.e., questionnaires). Anonymised quotes, from the patient participants, have been used to illustrate the points raised during the interview. Themes arising from the interview data are also presented.

7.4.1 Trial procedure

The mixed methods feasibility-pilot trial was designed to answer the sub-questions of this thesis. By answering the sub-questions, a conclusion and decision on running the trial as a full RCT could be decided. The sub-questions related to the acceptability, usability and feasibility of the accelerometers for the patient participants; the acceptability and credibility of the physical activity interventions for the patient and clinician participants; the feasibility and acceptability of the trial procedure; and the feasibility and acceptability of the questionnaire measurement tools.

This section provides an evaluation of the feasibility of the trial protocol including assessments on the recruitment processes, retention rates, data collection, data analysis and the acceptability and use of the outcome measures, including the acceptability of using the accelerometer to collect physical activity data.

7.4.2 Recruitment

A total of forty-six participant information packs were handed out to potential eligible patient participants by the UCO student osteopaths between July 2018 to December 2018.

The number of information packs handed out was recorded by counting the amount of completed participant ID forms (due to be completed each time a pack was handed out to a potential eligible patient) by the students. Two of the potential participants were osteopath students working at the UCO clinic, who were also receiving treatment at the clinic for their NSLBP and were keen to participate. Three external patients responded to the researcher after receiving the trial information packs and one patient contacted the researcher after seeing one of the recruitment posters. The participant, who responded after seeing the poster, was excluded on the grounds of having specific LBP (disc herniation which had been confirmed by imaging). Therefore, only three external patients participated in the trial.

Trial uptake was measured by dividing the number of patients consenting to the trial (n=5) by the total amount of patient participant information packs handed out (n=46). Trial uptake by the patients was only 10%. Four participants completed the trial, the 6-week follow-up and attended the interview phase (i.e., retention rate 80%). One participant only completed the trial up to week 5 and was considered to have dropped out when no response was obtained following three email attempts by the researcher.

7.4.2.1 Recruitment Strategy

The recruitment strategy for this trial relied on the student osteopaths identifying suitable NSLBP patients and required the student's tutor to agree that the patient was eligible for the trial. Once this agreement was met the students were required to provide the eligible patient with a participant information pack. If the patient accepted the information pack, the student was required to complete a recruitment ID form (write patient's name, age and sex on form and provide their- and their tutors signature to show agreed eligibility of patient) to inform the researcher how many patients were given a pack, in order to calculate study uptake percentages. Posters advertising the study were displayed in all thirty-six clinic treatment rooms, five student-osteopath team rooms and in the main reception of the clinic. The team rooms are solely for the student and tutor osteopaths and is where students discuss their patients with the tutors in terms of patient presentation and treatment options. Four recruitment folders were placed in each of the team rooms with patient information packs, clinician information packs, blank recruitment ID forms and a

folder for the completed recruitment ID forms. The researcher emptied the completed ID forms folder at the end of each day.

7.4.2.2 Problems

The recruitment strategy had several problems. Problems with the recruitment strategy relating to the clinicians is discussed in section *7.6.2 Recruitment,* sub-section *7.6.2.2. Problems.* The posters in the team rooms were to remind the clinicians about the trial and were originally placed on a notice board. Throughout the duration of the trial, the notice boards were becoming cluttered and the posters, in some rooms, had been taken down or covered up by other documents. The poster in the main reception were moved around and put in a less conspicuous place. The poster was originally put in a prime position on the big notice board in the main reception which meant the patients would see it immediately on arrival into the clinic and could be viewed whilst they were waiting for their appointment. Throughout the trial, the poster was moved behind a support pillar, hidden from the main reception as the clinic staff put other information on the notice boards. It was also noted that there was more than one research poster in each of the team and treatment rooms. The implications of this have been discussed in section *7.6.2. Recruitment,* sub-section *7.6.2.5. Research in the clinic.* The problems with the posters could have potentially hampered trial recruitment due to the potential patient participants being unaware the trial was being conducted.

Also, having the patient and clinician recruitment packs in the team rooms created another problem. The clinician recruitment packs were placed in the team rooms to allow the clinicians to refresh their memories of the trial procedure and in case they required any more information about the trial they may have forgotten. However, sometimes the clinician recruitment packs were observed to be placed in the folder for the patient information packs. As such, this may have resulted in some patients being given the wrong recruitment pack. The researcher observed that the clinicians were also confused by which packs they needed to hand out, and which forms they needed to complete despite this being explained to them. Poor paper management by the clinicians also resulted in the recruitment folders becoming cluttered with osteopath consultation forms or blank bits of

paper. These issues may have hampered the number of patients who were handed out the correct recruitment packs.

7.4.2.3 Solutions

In order to make the current patient recruitment strategy feasible to conduct a full scale RCT, the problems observed need to be addressed with some refinements to make sure maximal uptake of the study is possible. On reflection, having the four recruitment folders in each of the clinic rooms may have been too much and caused confusion amongst the clinicians on which forms they needed to hand out and which ones they needed to complete. The research team need to work more closely with the clinic staff regarding the poster placement. An agreement with the clinic about the placement of the posters needs to be made to ensure none of the posters for the trial are moved throughout the duration of the trial.

7.4.3 Acceptability of the questionnaires

Participants completed the NRS, RMDQ, GGPAQ and the EQ-5D-5L. These were completed at baseline, week five, and the 6-week follow up post-trial. Completion of the questionnaires took less than ten minutes. Two themes emerged from the patient interview data about the feasibility and acceptability of the questionnaires.

7.4.3.1 Theme: The questionnaires were clear, easy to understand but repetitive and boring

All the participants, who attended the interviews thought the questionnaires were clear and easy to understand.

"Very easy [to understand]*…questionnaire was a bit bland…same repetitive thing each week…but some of questions were a bit odd." [P02, retired]*

"They were clear, easy to answer." [P03, supermarket worker]

"Really clear, really easy" [P05, student]

P02 commented particularly on NRS for pain referring to it as the "*same repetitive thing each week*". The participants were required to complete the NRS at baseline, weekly throughout the 5-week duration of the trial and 6-week follow up post-trial. Participants were instructed to rate their pain from 0 (no pain) to 10 (worst pain imaginable) over the past 24 hours.

7.4.3.2 Theme: Pain cannot be measured using the questionnaires as it does not fully represent the participant's pain

Whilst the pain scale and questionnaires were easy to use the participants commented that they did not think the NRS gave a complete representation of the pain they experienced over a week. Some of the patients found it confusing when trying to rate their pain on the NRS.

" [The questionnaires were] *Based over a week and my problem has been going on over 30 years…most [of the questions] were based on how you were [feeling] today. Wasn't appropriate to me. I have an old problem – would be better for someone if it was a new problem. Don't think it's aimed at people who have had back pain over a period of time. [NRS]…form asked on the present pain rating…needs to be more accommodating for rest of week. Could ask generally do you think its improved or got worse. 24 hours…seems bit arbitrary…. doesn't relate to what my pain has been throughout the week". [P04, student]*

"[The pain] *comes and goes. Difficult to put on a form how it's been today…pointless…needs to be over a week. Some days feel brilliant but tomorrow may feel like rubbish, can't get comfortable" [P02, retired]*.

"Unsure if it was on the day or if a weeks' worth" [P03, supermarket worker]

These comments highlight that the participants felt that the pain rating scale did not account for the day-to-day fluctuations of pain they experienced and therefore provided an inaccurate account of the nature and course of their NSLBP. This fluctuation in pain was

attributed by one participant as the reason they engaged in less physical activity some weeks.

"I was doing the same thing every week anyway unless the pain was really bad" [P02, retired].

All the questionnaires used in this trial, except for the GGPAQ, instructed the responder to complete the questions based on how they were feeling on the day they completed the questionnaires.

7.4.3.3 Problems

Whilst the general feedback about the clarity of the questionnaires was positive, the patients highlighted elements of confusion they faced when completing the questionnaires. The confusions related to the instructions on the questionnaires asking the patients to complete the sheet based on how they were feeling on that day. These comments indicated a universal problem with the pain, pain-related disability and HRQoL questionnaires. The questionnaires used in this trial were based on how the participant was feeling on the day they complete the questionnaires. The true nature and day-to-day fluctuations could not be accounted for. If the questionnaires were completed on a day when the participant felt their back pain was worse, the score recorded on the questionnaire could provide incorrect results, especially in trials evaluating the effectiveness of an intervention. For example, an intervention may be a beneficial in reducing pain-related disability or increasing HRQoL in NSLBP patients. However, if the participant completed the follow-up questionnaires when the back pain was more significant than either the previous day or week, the participant would report negatively (i.e., report more pain-related disability or a bad score for HRQoL. The fluctuating nature of NSLBP needs to be considered when selecting questionnaires to record outcome measurements for NSLBP patients. This trial aimed to account for the fluctuating nature of NSLBP by collecting pain data every week. However, it was apparent that the participants still felt the answers they were providing did not truly represent how their NSLBP had been throughout the week. This suggests that the development of questionnaires to allow participants to provide a weekly analysis of their pain and pain-

related disability may improve acceptability of the questionnaires and enable a closer reflection of patient experience. When the participants asked what they would change about the trial, some of the participants felt the questionnaires should be changed, with the researcher asking them questions about their pain in person.

"More 1:1 questions rather than filling out a form…get a deeper idea of what's happened during that week. Rather researcher asks questions…more of a variety" [P02, retired].

7.4.3.4 Solutions

These measurement tools need addressing, in terms of how frequent the measurement is recorded, in this trial and future trials. NSLBP is reported as and often referred to as a recurring pain (Van Der Windt and Dunn, 2013) which often fluctuates (Dunn, Jordan and Croft, 2006). The use of a linear scale to collect data on pain levels over a 24-hour period may not provide an accurate representation on the nature of a person's NSLBP as NSLBP is not a linear condition. A daily pain diary would have been more effective and efficient in providing the day-to-day fluctuations of pain the participants experienced throughout the week.

There are other validated questionnaires which could be used in a refinement of the trial. The Oswestry Low Back Disability Questionnaire (ODI) (Roland and Morris, 1983) asks patients to record their answers based on their condition, and not how they are feeling on the day the questionnaire is completed. The ODI has also been reported to be a more sensitive measure for detecting changes in NSLBP patients (Davidson and Keating, 2002). The McGill Low Back Pain Questionnaire (Melzack, 1975) invites the responder to circle words to describe their pain (i.e., flickering or burning). The inclusion of this questionnaire could be used to evaluate the effect of physical activity on sensations of pain and if it can reduce a "burning" pain to just an "aching" pain. Alternatively, a set of more one-to-one questions could be developed, as suggested by the participants, to get a deeper idea of the participant's pain and pain-related disability.

The EQ-5D-5L (HRQoL) is also completed based on how the responder feels on the day they receive the questionnaire. The SF-36 questionnaire (Ware, Davies and Donald, 1978) also follows this format. However, the World Health Organization QoL brief version (WHOQoL-BREF) is a HRQoL questionnaire with questions based on the previous four weeks of the responder's life (World Health Organization, 2004). This questionnaire focuses on four QoL domains – physical health, psychological health, social relationships and environment (World Health Organization, 2004). This is a validated questionnaire and could be used as an alternative to the EQ-5D-5L.

7.4.4 Acceptability of the accelerometer

After the baseline measurements (one week in duration) were recorded for physical activity using a 23 x 32.5 x 7.6 (mm) accelerometer, the participants were required to wear the accelerometer every day for five weeks, during their waking hours. The accelerometer was worn around the waist on a belt. On a weekly basis the participants returned to the UCO clinic to have their activity data downloaded. Two of the questions asked in the semi-structured interviews related to how the participants found wearing the accelerometer every day for six weeks (baseline measurement included). Three themes emerged from the interview data relating to the feasibility, usability, and acceptability of wearing the accelerometer for a prolonged period of time.

The first theme was that the method of wearing the accelerometer around the waist was acceptable to the participants. The second theme concerned the comfortability of wearing the accelerometer daily and the final theme was around forgetting to wear the accelerometer on some occasions.

7.4.4.1 Theme: The accelerometer mounted on a belt was an acceptable method to the participants to wear an accelerometer daily over a period of time

The research team were concerned that the belt may have been too burdensome to continuously wear over six weeks and would therefore not be feasible in a long-term RCT. However, the patient participants did not seem to find the belt a problem.

"Get used to it quite quickly and get into a routine quite quickly…at first it's a bit weird. Thinking bloody hell got 6 weeks of this but after few days didn't know it was there. [wearing the accelerometer] *if necessary for the study it could be longer…thought 6 weeks was fine" [P04, student]*

"Excess bit of belt – sorted it out with hair bobble…always checking in correct place. Not a worry [positioning it]*. No hassle…forgot it was on sometimes…Didn't realise the* [trial] *weeks had passed, didn't notice the time" [P03, supermarket worker]*

"I don't know – just got to get on with it really, you forget about the accelerometer and didn't really notice it when driving. It was odd to start with but after a couple of days you get used to it quite quickly" [P05, student]

These comments suggest that it is feasible to wear the accelerometer continuously for a period of time as the participants "*got used to it quite quickly"* and *"forgot it was on sometimes".* Wearing the accelerometer was described as "*no hassle"* which further indicated this method was an appropriate way to continuously measure physical activity levels and could be used in a larger RCT.

7.4.4.2 Theme: Wearing the accelerometer was uncomfortable at times

Whilst the participants did not find wearing the accelerometer unacceptable and too burdensome, some of the participants did find wearing the accelerometer uncomfortable at times.

"Yoga…laying on floor, bit uncomfortable…had to take it off. No hassle…forgot it was on sometimes" [P03, supermarket worker]

"Little bit uncomfortable at times, especially in a hard chair. Notice it's there all the time…pushing into the spine quite a lot. Plus wearing a men's belt, the accelerometer belt gets in the way…feels awkward…FitBit type thing would have been better…less intrusive and could monitor sleep like is the pain waking you up? Get used to it. Just mainly when sitting" [P02, retired]

7.4.4.3 Theme: Forgetting to wear the accelerometer

Some of the participants commented that they sometimes forgot to wear the accelerometer.

"Sometimes I forgot [to wear the accelerometer" *but quickly remembered…you get into a routine, only forgot about 3 times" [P04, student]*

"Some days I forgot to wear the accelerometer but realised and put it on" [P05, student].

"Very rarely did I forget [to wear the accelerometer], *but I quickly remembered" [P03, supermarket worker]*

Whilst the participants "*quickly remembered*" to wear the accelerometer after initially forgetting, data on their activity levels would have been lost. This data could have affected the primary researcher's communications when either providing feedback or pointing out if the participant met their goal (i.e., lost data would have resulted in less activity data being collected, and may have impacted the weekly outputs of activity on which the feedback was based on in groups 2 and 4). This problem would have also obscured the physical activity data collected by the other intervention groups too despite not receiving feedback. In a trial with a bigger sample size, and with the ability to run inferential statistics, these losses in data could affect the overall result of the trial and provide inaccurate information on the effectiveness of the interventions. To mitigate this (forgetting to wear the accelerometer), another BCT ("prompts and cues") could have been used. The BCT of prompts and cues is defined as introducing "environmental stimulus with the purpose of prompting or cueing the behaviour" (Michie, Atkins and West, 2014). This could be implemented in a future trial by prompting the participants to set daily alerts on their smartphone to remind them to

wear the accelerometer. An alert or reminder could also be used to remind the participants to charge the accelerometer before they go to bed. In the instance that the participant does not own a smartphone, this BCT can be implemented by advising the participants to leave a note, either on the bathroom or by their housekeys, reminding them to wear the accelerometer.

7.4.5 The interventions

All the participants, by the end of week 5, had increased their activity levels from the baseline measurements. It was not possible to determine the effectiveness of the interventions (to demonstrate proof of concept) due to the small sample size. All the interventions were delivered as intended (immediately during the appointment with the researcher), but small adjustments were needed when providing the feedback on the patient participants activity levels. The mobile personal computer (PC) was not powerful enough to download the accelerometer data. This was done at LSBU on a laboratory computer and the participants had their feedback emailed to them. The feedback provided was exactly as it is outlined on appendix EE.

7.4.5.1 Exploring BCTs and the challenges to implement them

Each of the physical activity interventions incorporated several BCTs. As all the interventions incorporated advice and education there is an overlap in the BCTs in groups one to three. Table 4.8 explains how the BCTs were used in the trial and section *4.9 Intervention content and summary"* provides an explanation of the BCTs in each group.

The advice and education intervention (group 1) was designed using four BCTs. The BCTs used in the education part of the intervention were "information on health consequences" and "credible source" and the BCTs used in the advice part of this intervention were "credible source", and "verbal persuasion about capability". The final BCT was "monitoring of behaviour without feedback" and this was achieved by asking the patients to wear an

accelerometer daily to monitor and record their physical activity levels. The participants in this group did not receive feedback on their behaviour.

These BCTs are present in all the intervention groups, except for the BCT “monitoring of behaviour without feedback”. The BCT “monitoring of behaviour without feedback” is only present in group one and three as these groups did not receive any feedback on their physical activity levels as collected by the accelerometer.

The feedback on activity levels intervention (group 2) received the BCT “feedback on behaviour”, plus the BCTs used in group 1 (the advice and education intervention). Group 3 received the BCTs of “action planning” and “problem solving”, in addition the BCTs in group 1. Group 4 used a combination of all BCTs used in groups one to three, with the addition of two extra BCTs. These extra BCTs were “review behaviour goal(s)” and “discrepancy between current behaviour and goal”. These BCTs could only be implemented when the participants received their activity level feedback (BCT: feedback on behaviour), and the implementation intentions sheet (BCTs: action planning; problem solving; goal setting, commitment), to see if the goals/intentions they had set for the week had been completed. If the participant did not seem to meet their goals, indicated by how much physical activity was recorded on the accelerometer, the participants were informed they did not meet their weekly goal (BCT: discrepancy between current behaviour and goal) by the researcher. Table 7.3 shows the BCTs which were used in each intervention group. The interviews with patient participants were examined to identify perceptions shared by the patients relating to BCTs.

Table 7.3: List of the BCTs used in each intervention group

Intervention group	BCT used in the interventions
Group 1 – Advice and Education	Credible source Information on health consequences Verbal persuasion about capability Monitoring of behaviour without feedback
Group 2 – Advice and Education Feedback on activity levels	Credible source Information on health consequences Verbal persuasion about capability Feedback on behaviour
Group 3 – Advice and Education Implementation intentions	Credible source Information on health consequences Verbal persuasion about capability Action planning Problem solving Commitment Goal setting Monitoring of behaviour without feedback
Group 4 – Advice and Education Feedback on activity levels Implementation intentions	Credible source Information on health consequences Verbal persuasion about capability Feedback on behaviour Goal setting Action planning Problem solving Commitment Review behaviour goal(s) Discrepancy between current behaviour and goal(s)

7.4.5.2 BCTs received by all the groups

All the participants (n=5) received advice (BCT: credible source; verbal persuasion about capability) and education on being active with NSLBP (BCT: Information on health consequences; credible source). In this section the acceptability of the BCTs used across all the groups is reported.

The acceptability of the education information sheet (BCTs: information about health consequences and credible source) amongst the patient participants was mixed (i.e., some positive comments and some negative comments). Whilst all the participants agreed this type of information was good and informative, the information provided was also perceived to be obvious and common sense.

"Giving that sort of information would be beneficial to people who didn't know about this sort of thing [being active with NSLBP]" [P04, student].

"I can't remember it now. I don't know who it was aimed at…it was so obvious. Obvious things…perhaps there are people who need to be prompted as to what is obvious. [my pain is long term] don't have to be reminded…seems aimed at a child rather than an adult. Common sense [already knew this information]. It's like telling me if you don't look both ways when crossing the road, you might get run over" [P02, retired].

"I was already doing yoga and swimming [through advice from the osteopath]. Always knew sitting around wasn't good for you – its common sense" [P03, supermarket worker].

The information sheet aimed to provide reassurance and encouragement that the participants could be more active despite their NSLBP. Only one participant mentioned that the information sheet gave them some reassurance.

"I learnt that I could be more active. It was reassuring and prompting" [P03, supermarket worker]

The other participants may not have found this information sheet as useful or reassuring and felt they did not learn anything because they already knew about the benefits of being physically active. This was indicated in previous quotes where the information sheet was deemed "*obvious*" and "*common sense*".

Receiving advice to stay active [BCT: credible source) was only mentioned in two of the interviews and the BCT of verbal persuasion about capability was only mentioned in one of the interviews. Whilst receiving advice-to-be active was acceptable to the participants, this information was pointed out to have already been delivered prior to the trial by other HCPs. Advice to be active from the HCPs appeared to be the advice the participants remembered the most and most often referred to.

"GP and physiotherapists in the past have always told me to stay active. They always encouraged me to do some sort of activity" [P03, supermarket worker]

"Physiotherapist gave me a leaflet on exercises and movements to do for my back" [P02, retired]

This could again account for why some of the participants did not find the education sheet on being active with NSLBP useful (i.e., the benefits of activity had been provided to them previously).

The use of the accelerometer was to record physical activity data for all the participants to determine which intervention (in terms of content) was more successful in increasing physical activity levels. The use of the accelerometer enabled feedback to be provided on physical activity levels for the participants in group 2 and 4.

It was anticipated that the participants on the trial may inadvertently increase their physical activity levels on the basis they were aware their activity levels were being tracked. However, only one participant mentioned reacting to wearing the accelerometer during the interview process.

"Made me go out and become more active. I felt lazy with the accelerometer on" [P05, student]

This was the only example of the BCT: monitoring of behaviour without feedback prompting a participant, who was not receiving feedback on their levels of activity, to be more active. This quote suggests that wearing the accelerometer played a role in the reason why this participant became more active. Previous research has reported objective measures, such as an accelerometer, can provoke reactivity in participants (Bravata *et al.*, 2007; Silfee *et al.*, 2018; Hur *et al.*, 2019).

7.4.5.3 BCT used in groups 2 and 4

The BCT used in group 2 was "feedback on behaviour" which was additional to the BCTs used in group 1. This BCT ("feedback on behaviour") is also shared by group 4. One of the themes in the interview data demonstrated that feedback on activity levels was the most helpful and motivating intervention, for the participants when increasing their activity levels. This theme also demonstrates the acceptability of the use of the activity feedback in an intervention.

7.4.5.4 Theme: Feedback on activity levels was motivating and the most useful BCT

Both participants who received feedback on their activity levels identified this to be the most useful BCT of the intervention they received and found that it led to a personal competition to increase their activity levels and a sense of achievement. This included the participant who received all BCTs in Group 4.

"Probably the feedback. Gave me a sense of achievement, competition, drive to be more active…Definitely encouraged me to do more. Felt excited, like oh I've done this. I felt like I'd done something by getting that objective feedback. I really liked the feedback and would want more feedback and more detailed feedback…maybe like more of a breakdown…number of minutes you were doing this or doing that" [P04, student]

"Was more motivating…prompt I need to be more active...rather than I will get the bus there I will walk there…through the study I made sure I walked there. A little bit [of trying to top the week before]. *I found it surprising, I wasn't aware I was doing that much" [P03, supermarket worker]*

P04 continuously increased their activity levels every week of the trial. The motivation P04 felt when receiving the feedback on activity levels could have been the reason this participant increased their activity levels every week of the trial. Due to the small sample size of patient participants the link between increases in activity levels and which BCTs the participants received could not be investigated further. Whilst reporting that the feedback on activity levels was motivating, P03 only managed to increase their overall average physical activity levels by 2% compared to their baseline measurements. This could suggest that intrinsic motivators (competition with oneself) could be targeted in some NSLBP patients to help them increase their activity levels.

7.4.5.5 BCTs received by groups 3 and 4

In addition to receiving the BCTs used in group 1, group 3 received the additional BCTs of "action planning", "goal setting", "commitment" and "problem solving". All these BCTs were shared with group 4. The BCTs of "action planning" and "problem solving" were delivered in the form of implementation intentions. The implementation intention sheets asked participants to identify ways in which they could be more active (BCT: action planning), the benefits of being active, obstacles they may face in being active and how they could overcome these obstacles (BCT: problem solving). The final task was for participants to complete a plan on how, when and where they would be more active completing affirming statements to demonstrate intention (BCTs: action planning, goal setting and commitment).

7.4.5.6 Theme: The implementation intention sheet was not received positively by participants, particularly the tasks of action planning and goal setting

The implementation sheet was not acceptable to the patient participants in the trial. The primary researcher observed reluctance, annoyance and negative comments expressed by all participants, who received the form, each time they completed the form. This was also reflected in the interviews with participants indicating they found the sheet to be a tedious and repetitive task or one that was not appropriate for their situation.

"I only followed what I would normally do. I do what I do already which I find beneficial and on a day-to-day basis depending how one is feeling. [Weekly plan] not aimed at people who have had chronic back pain and who have done something about it. Not beneficial or appropriate" [P02, retired]

"I mean I filled it out….I do think it was not filled out properly…didn't fill it out to the level it needed to be….got repetitive… I was going through the motions. Maybe if I had more of a routine…actually writing it down…makes you think what is stopping me doing it and when I am going to be able to add stuff. I could see it being helpful, but I wouldn't keep to it. Only thing I wasn't clear about was if we had to choose different ones [activities and obstacles] *each week. In the end it just became repetitive – bane of my life and that dastardly bottom task. Some of the stuff is irrelevant" [P04, student]*

The statement by P04 - "*only thing I wasn't clear about was if we had to choose different ones [activities] each week"* – indicated that some of the tasks on implementation intention sheet needed more clarification. The BCTs linked to the identified tasks as not being clear were "action planning", "goal setting" and "problem solving". The instructions on the implementation sheet needed a bit more clarity and provide more direction on what was required of the participants when completing the tasks – i.e., if the participant's needed to choose different activities to engage in each week, if they had to choose different obstacles

and ways to overcome the obstacles, or if they could stick to goals they had set on a previous week.

The BCTs "action planning", "commitment" and "goal setting" were not useful to one of the participants who received these BCTs as one participant mentioned not having the intent to follow the plan they had written down. The way the "commitment" BCT was implemented was not acceptable to the participants as one of the participants referred to it as *"that dastardly bottom task!"* (P04, student).

"I changed some of it…was thinking more about filling out the sheet than what I actually planned to do the next week. My weeks change all the time." [P04, student]

The other participant who received these BCTs did not think the plan *"was aimed at people who have had chronic pain and who have done something about it"* (P02, retired). The only positive remark about the implementation intentions was that it did help trigger memory and gave one participant an insight into the different ways they could be more active indicating that the problem solving BCT may be useful.

"In one sense it was good as it forced me to think outside the box in ways I could become active. It did help a little bit to think how I can add activity into my routine…I do run more to the station. Little bit helped me to keep to it...triggered memory" [P04, student]

This comment indicates that the implementation intentions acted more as a trigger to engage in more physical activity, rather than help the participant to plan when and how they will next be physically active. The method used to implement these BCTs was not acceptable to the participants who received them. In future, the instructions on this type of sheet should be clearer and easier to understand to help participants review their weekly plans for physical activity. Refinements to some of the tasks on the sheet, particularly the last task where the "action planning", "commitment" and "goal setting" BCTs were used, is required to make this intervention more appealing to the recipients.

7.4.5.7 BCTs received in group 4

The participant in this group received all the BCTs used in groups one to three, except the BCT "monitoring of behaviour without feedback" as the "feedback on behaviour" BCT was a condition in this group.

An additional two BCTs were present in this group – "review behaviour goal(s)" and "discrepancy between current behaviour and goal". The participant perceptions relating to the BCTs used in groups one to three have been explored in previous sections. The perception of the participant on the additional BCTs for group 4 is explored in this section. This section also explores the intensity of the interventions – i.e., if the participant felt that receiving all the interventions was manageable or too overwhelming to be provided with every week.

> *"It was about right* [comparing the feedback on activity levels with what activity they completed]. *There was one time I did not think I'd done that much* [activity plan was not followed] *and it was more than I had thought…I changed some of it as my weeks change all the time". [P04, student]*

This statement by P04 indicates that whilst sometimes reviewing the activity plan resulted in some unexpected feedback (more activity being completed compared to what was written in the implementation intention sheet) the plan was not always followed. The plan changed at the last minute due to the participant's weekly schedule. This further indicated that the BCTs also used in this group "action planning" and "goal setting" were not useful for this participant or the other participant who received them in group 3. Therefore, it made it hard for this participant to review their behaviour goals and adjust their plan according to the feedback they received as they did not intend to follow to the plan – *"I was thinking more about filling out the sheet than what I actually planned to do the next week".*

As there was only one participant randomised into this group the benefit or acceptability of the BCTs "review behaviour goal(s)" and "discrepancy between current behaviour and goal" could not be explored fully. There was only one instance in the trial where this participant did not increase their activity levels of the previous week. However, the impact of pointing out when this participant did not meet their goal ("discrepancy between current behaviour

and goal") was not mentioned in the interview, but as the feedback on their activity was found to be "*motivating*" and "*definitely encouraged me to do more*", this BCT (discrepancy between current behaviour and goal) could have been motivating for the participant on the one week when they did not increase their activity levels (i.e., encouraged them to do more).

Whilst the BCTs were not unacceptable to the participant, it also cannot be determined if the BCTs were acceptable for the participant. The participant did not stick to their plan and therefore could not review if the intentions they had written down contributed to their activity levels for the week. A bigger cohort in this group was required to explore the use of these BCTs in an intervention in more depth.

"It didn't take that long to do it all. Wasn't a lot of work really. It was fine [not too much work]. It was quite manageable". [P04, student]

This statement indicates that the intensity of this group due to receiving all the BCTs and the additional BCTs was not perceived to be problematic by the participant, and therefore acceptable.

7.4.5.8 Challenges in BCT implementation

The method of delivering the BCT on "information about health consequences" was acceptable to the participants. The participants may not have found it useful for themselves, as they indicated they already knew about the benefits of being physically active with NSLBP, but it may be useful to others who do not know about it.

Giving weekly advice on being active to the participants was provided by the researcher and should have been provided by the osteopaths as part of normal practice as a component of the strategy to implement the BCT: credible source. The comments made by the participants suggest that advice to be active, as used in this trial, needs to be validated by someone they deem as a more credible source, such as a GP or physiotherapist. These types of HCPs were not included in this trial.

"I've gone back to sheet given by the physiotherapist …[I have been] given different exercises since I've been here [at UCO clinic]…they [exercises provided by physiotherapist] *make up for the information sheet [education sheet]." [P02, retired]*

Alternatively, this participant may have just found the exercise sheet given to them by a physiotherapist more beneficial for their NSLBP than the education sheet provided in this trial.

In order to provide feedback on behaviour an objective measure and data synthesis is required. Whilst the accelerometer wearing method was acceptable to the participants, adherence to wearing the accelerometer was required to facilitate the feedback. Some of the participants did comment on sometimes forgetting to wear the accelerometer.

The task used to implement the BCTs of "action planning", "problem solving" and "commitment" were not acceptable to the participants and was viewed as repetitive or inappropriate. The challenge in implementing these types of BCTs are due to the limited formats they can take to make them appealing to complete The two participants who received the implementation intention sheet commented that the sheet was *"inappropriate"* (P02, retired) and *"repetitive"* (P04, student) to fill out. The participants were just *"going through the motions"* (P04, student). Completing the sheet weekly was the *"bane of my life [specific reference to the "I will commit to… I will… task]"* (P04, student) and the sheet was completed without the intent to complete what was written down - *"was thinking more about filling out the sheet than what I actually planned to do the next week"* (P04, student). This intervention also was confusing for some of the participants who were not clear on *"if we had to choose different ones* [activities and obstacles] *each week"* (P04, student). As the implementation intention sheet was not appealing or acceptable to the participants it may have resulted in participants merely writing down plans that they do not actually intend to commit to. Ways to make implementing these types of BCTs more appealing are needed.

7.5 Feasibility trial: Clinician participants

The aim of the trial was to recruit student and tutor osteopaths (the clinicians) to identify eligible NSLBP patients and provide the eligible NSLBP patients with a recruitment pack. At the end of the trial the clinicians were asked to attend an interview. The purpose of the interview was to answer the sub-questions of the trial and assess the feasibility, acceptability and credibility of the trial procedure and the acceptability of the physical activity interventions for the clinicians.

A total of ten osteopath tutors and six osteopath students (n=16) attended the semi-structured interviews. Initially, a total of twenty students and five tutors were emailed with an invitation to attend an interview. Only one student and two tutors responded to the initial email. The remaining interviewees, whom all provided consent to the trial and interview, were asked in person by the primary researcher, if they were willing to take part.

7.6 Process Evaluation

7.6.1 Trial procedure

This section answers the two sub-questions: 1) what is the acceptability and credibility of a physical activity intervention for people with NSLBP amongst the clinicians? and 2), what is the feasibility and acceptability of the trial procedure for the patient and clinician participants? Anonymised quotes, from the clinician participants, are used to illustrate the points raised during the semi-structured interviews.

7.6.2 Recruitment

A total of fifteen osteopath tutors and thirty osteopath students provided consent to participate in the trial. 170 clinician information packs were handed out to student and tutor osteopaths. Trial uptake was calculated separately for the student and tutor osteopaths by dividing the number of students (n=30) and tutors (n=15) consenting to the trial by the total

amount of information packs handed out (n=170). The trial uptake by the student osteopaths was 18% and 9% for the clinic tutors.

7.6.2.1 Recruitment strategy

The recruitment strategy for the clinicians was to engage the clinicians and gain their interest in the trial by telling them about the trial aims in terms of what the trial was about, what was expected of them should they wish to participate and what the patients would be doing. Any questions they had were answered in full. The primary researcher held daily talks about the study to the clinicians in the clinic team rooms, for one week in July. These talks occurred during the summer block of clinic. The student osteopaths were asked to hand out a patient recruitment pack to any patients they believed had NSLBP. Clinic tutors were asked to sign a form to say they agreed the patient's back pain was from NSLBP. The clinic tutors needed to sign the form before the student could hand out a recruitment pack to the patient.

Using the students as the main facilitators for the recruitment strategy was the only viable method of recruitment for the trial. Due to data protection laws and patient confidentiality, the primary researcher was not allowed to get in contact with the participants or come into contact with potential participants until they had contacted the researcher expressing an interest in the study.

7.6.3 Problems

Several problems with the recruitment strategy were highlighted by the clinicians in the semi-structured interviews. These problems circulated the nature of the clinic, the timing of the trial (i.e., when the trial began), research in the clinic and using the students as the primary recruiters of NSLBP patients in the trial.

7.6.3.1 Nature of the clinic

The UCO clinic is a student-led, educational osteopathy clinic. Students are required to complete one thousand clinical hours in the clinic in order to complete their degree. When discussing the use of the clinic as a recruitment site for the trial with the clinicians in the semi-structured interviews, two themes emerged from the data surrounding the nature of the clinic. These two themes were clinic chaos and remembering the trial during normal clinical procedures.

7.6.3.2 Theme: Clinic chaos

The clinic was portrayed as a very busy environment where students and tutors have high demands placed on them with trial recruitment additional to this and secondary to the other demands.

"Busy, fluid environment – different staff and students throughout the week. Difficult to maintain engagement and consistency. Students have so many demands on their time, depending on time of year. Really hard environment to recruit – consistency issues. I would choose to do it [the trial] *elsewhere" [OST_3, tutor]*

"Chaotic nature of clinic makes things difficult. Complex patients. Complex situation" [OST_6, student]

"It's very busy here, we have a lot going on – exams, not a lot of wiggle room. We don't know how many patients are coming in, and not sure how many staff are coming in" [OST_9, tutor]

"Changed examination system. More [exams] *and* [they] *starts earlier. They have a lot to think about and this was one more added thing to think about. Some would have* [taken the trial] *on board easily and others may not have thought they could cope with it. I don't know if there is an easier way. [You are] at the behest of the system. This clinic may have*

hampered the study somewhat because you have student practitioners, and they have their own pressures" [OST_4, tutor]

"Clinic is very pressurised" [OST_5, tutor]

It could have been easy to integrate, but we got thrown in at the deep end with clinic. We had all of that [clinic pressure] to focus on plus this [the trial]. This was an added thing on a long list of what we needed to do" [OST_5, student]

A key issue in this student-led educational clinic was levels of staff consistency. Staff consistency related to the number of tutors and students present in the clinic on a daily basis. As mentioned above, and mentioned again in quotes in the following section, it seems there were consistency issues with the number of tutors in clinic at any one point and how many might be coming in – "*we don't know how many staff are coming in"* [OST_9, tutor]. These consistency issues would have inhibited the recruitment of the patient participants, and therefore interrupted the trial procedure. Due to the nature of the clinic, if some tutors are off sick or have scheduled time off, the remaining tutors are required to pick up extra students and supervise them as well as the other students they normally supervise. It was noted that there were never 'spare' tutors available who could step in and help when these issues occurred. This was a common occurrence in the clinic and increased the pressure on the clinicians – "*clinic is very pressurised"* (OST_5, tutor), "*It's very busy here, we have a lot going on"* (OST_9, tutor) and the "*chaotic nature of clinic makes things difficult"* (OST_6, student).

Events like these (clinician consistency issues and increased number of exams) added to the chaotic nature of this clinic and as such resulted in the trial taking a further back seat in the minds of the clinicians, as time to discuss patient eligibility for the trial was not available – *"this was an added thing on a long list of what we needed to do"* (OST_5, student). From this perspective, the trial procedure is not feasible to run as an RCT in this clinic, unless refinements can be made.

It was observed that the tutors were also required to examine the student's practical exams in the clinic, during a clinic session (morning and afternoon). As mentioned, the students

now undertake more exams throughout the year, from what was originally two practical exams to now four practical exams – *"changed examination system". More* [exams] *and* [they] *starts earlier* (OST_4, tutor). The tutors were timetabled to examine the exam as part of their clinic routine – adding to the shortage of tutors in team rooms. With more practical exams to prepare for and facilitate, the trial becomes less and less important for the clinicians, as it is another job added onto their list – "*they* [the clinicians] *have a lot to think about and this* [the trial] *was one more added thing to think about"* (OST_4, tutor).

7.6.3.3 Theme: Remembering the trial during normal clinical procedures

Due to the chaotic nature all the clinicians recommended that for a trial to be successful in the clinic, constant repetition is key to ensure the on-going trial is remembered.

"People have poor memories here – memory jogging on a weekly basis" [OST_6, tutor]

"Busy, chaotic clinical setting. Constant repetition and reminding. Easy to forget….Briefing was useful, but we needed it again - constantly. This was extra to what I would normally be doing. Constant reminders are needed due to the other pressures in clinic" [OST_3, tutor]

"If there was an issue [with remembering], it would have been because there wasn't enough of you [researchers] around at one time. Easy to forget in cut and thrust of clinic" [OST_7, tutor]

This information highlighted that the original briefing sessions, held for one week in July, were not enough to help the clinicians integrate the trial into their normal clinical routine – "*easy to forget….Briefing was useful, but we needed it again – constantly. This was extra to what I would normally be doing"* (OST_3, tutor). The chaotic nature of the clinic and other pressures in the clinic increased these issues with remembering the trial was ongoing and the need for the clinicians to recruit for the trial – "*busy, chaotic clinical setting. Constant*

repetition and reminding. Constant reminders are needed due to the other pressures in clinic" (OST_3, tutor). It was also highlighted that more than one researcher needed to be present in the clinic team rooms to help the clinicians to remember to recruit for the trial – "*it would have been there wasn't enough of you [researchers] around at one time"* (OST_7, tutor). There was only one researcher to facilitate the five team rooms in the clinic every day.

7.6.3.4 Timing of the trial

The trial started in July 2018. At the time of trial commencement, the primary researcher was unaware of the implications of starting the trial in July. The clinicians were briefed about the trial in researcher-led meetings, at the clinic for one week in July. The timing of the trial occurred during a lot of changes in the clinic setting. July is part of the summer block in the clinic. During summer block the students are on a rota ('blocks' of students) of working in the clinic for one month. Once their 'block' is complete, the students then do not return to the clinic until the academic term begins in September. A lot of the tutoring staff were absent due to taking annual leave, and the students were in a chaotic cross-over period during clinic. The cross-over period in the clinic (June, July and August) is when (i) second year students are starting to integrate into the clinic, as they are due to start working in the clinic from September, (ii) current third year students are encouraged to manage their own patient list and become autonomous clinicians (iii) fourth year students are in their final year and are completing their own research project for their dissertation. The fourth-year students were unable to be recruited due to them graduating in July and leaving the clinic. During this period some of the students were also away on holiday or on a student exchange programme in Australia. There were also a lot of Australian exchange osteopaths who could not be recruited for the trial.

"It's chaos in the clinic – a lot of people weren't there when the original talk was given. Students not there consistently, tutors not there consistently – term times, holidays" [OST_6, student]

"I met you in a hap-hazard way. I was new to the clinic and wasn't around for the talk you gave. I started after summer block" [OST_2, tutor]

"At the time of the trial, we were in summer block. For us, 2nd year students are going into their 3rd year and panicking about the clinic experience. It was burdensome at the time. When we got used to clinic and the process of clinic, this [the trial] became easier to implement. But then people had forgotten about it. The timing could have been better. At this time of year [January] it would improve the number of people willing to take part and doing it" [OST_4, student]

"I missed the initial intro. I came [to the clinic] a bit later. But once I met you and found out what you were doing it was easier" [OST_10, tutor]

[What would you change?] "Timing. You started your trial a few weeks into the summer block – we already had a lot of new patients" [OST_3, student]

"I wasn't here when you did the initial presentation – I was on holiday. Always a bit difficult [depends on time of year]. Primary focus is on exams – won't be concentrating on promoting this. Summer blocks are very difficult they [the students] *don't want to be there. Pretty chaotic 3 months. Timing was maybe a bit too early. So many staff were off when you gave that presentation" [OST_9, tutor]*

This qualitative data also highlighted that some of the clinic tutors were new staff members of the clinic and did not start working in the clinic until the academic term began – "*I met you in a hap-hazard way. I was new to the clinic and wasn't around for the talk you gave. I started after summer block"* [OST_2, tutor]. The pre-registration Masters students had also not started their degree programme and were absent during the summer block when the trial was introduced to the clinic. These students did not start their degree, or working in the

clinic, until September. These students missed the initial briefing about the trial in July and therefore were unaware the trial was even being conducted. This would have resulted in eligible NSLBP patients not receiving information about the trial and therefore impacted on the number of patients recruited to the trial.

"It was my first term in clinic [MSc pre-registration]. It was overwhelming. I've never been an observer here, so it was straight into the deep end. I was trying to get my head around clinic and open my patient list. I wasn't even aware the trial was going on until I got speaking to you in the team room. I started in September" [OST_5, student]

The qualitative data demonstrated that starting the trial in July during the summer block was ineffective (due to many staff and students not being the clinic) and hampered the success of the trial (i.e., in recruitment).

7.6.3.5 Research in the clinic

Posters were used to recruit patient participants. Another problem, potentially hampering recruitment, was the amount of research posters already mounted on the walls in the treatment rooms and clinic reception. These posters were all advertising different back pain trials. In each of the clinic rooms there were approximately four additional posters, advertising to recruit patients with NSLBP. This is a competing conflict for any trial.

"There are other research posters around – six in this room. Patients get fatigued. Focus should be on one study" [OST_1, tutor]

"Overwhelmed with the amount of research projects there are at UCO. Effort per project gets diluted. We have internal research projects ongoing. We need more focussed projects" [OST_2, tutor]

"There are a lot of studies going on at one time" [OST_10, tutor]

Not only does the number of posters confuse students (i.e., which trial to help recruit for), it can confuse patients. The students also have their own research projects to organise and conduct. This is a problem because it may have been a conflict of interest for the students to recruit for the feasibility-pilot trial because they also needed to recruit patients for their own trial, as part of their dissertation, to complete their university degree.

"There is the weight of competing for information…students doing final years projects…posters on the walls [different projects]" [OST_6, tutor]

"UCO students are trying to do their own study" [OST_6, student]

This would have hampered the trial recruitment strategy due to competition of other research trials also taking place in the clinic. Potential participants may have been lost to the other competing trials.

7.6.3.6 Using the students

Using the students as the primary recruiters for the trial was ineffective and hampered patient recruitment. It was observed that some of the students felt uncomfortable with approaching patients about a research trial. Some clinic tutors were of the impression that using the students as the primary recruiters for the trial was too overwhelming for some of them.

"Students juggle so much. Tutors juggle a lot of patients. Difficult in this setting. Private practise would be better" [OST_1, tutor]

"Students already under a lot of pressure with assessments and assignments. Here's another pressure [the trial]" [OST_4, tutor]

"Focus is on next assignment and next assessment. Always a back seat. Conflict with clinicians – patients come first. Not enough focus on this. Another layer of stress. Another chore" [OST_3, tutor]

"Students already frantic with their own stuff" [OST_2, tutor]

"Some students totally disinterested – so much else going on their plate…time pressures of pending assignments. Back-to-back patient lists" [OST_8, tutor]

"Depends on the students…some are confident...some are really struggling [small minority]. People forget and are so engrossed where they are with their studies and their patients" [OST_6, tutor]

These quotes suggested that the pressures of the clinic, of constant exams and assessments contributed to some of the students being "*totally disinterested"* in the trial due to their own pressures (i.e., "*back-to-back patient lists"* (OST_8, tutor).

The nature of the clinic (pressurised, constant exams, inconsistency in the number of clinicians in the clinic daily and competing interests for patients in trials) hampered the recruitment of patients for this trial. It was suggested by one of the tutors that private practice might be a better option to recruit patients for a trial due to the nature of the clinic and the number of responsibilities the clinicians are juggling – "*students juggle so much. Tutors juggle a lot of patients. Difficult in this setting. Private practise would be better"* (OST_1, tutor).

7.6.4 Adherence to recruitment protocol

Additional to the nature of the clinic, problems with the clinicians adhering to the recruitment protocol inhibited the trial. These problems surrounded the differing conceptualisations of the definition for NSLBP amongst the clinicians. This was another theme identified in the interview data. This theme related to the feasibility and acceptability of the trial procedure amongst the clinician participants.

7.6.4.1 Theme: Different conceptualisations and definitions for NSLBP

This trial used the following definition for NSLBP: an occurrence of LBP which often cannot be identified as a specific pathology (Krismer and van Tulder, 2007; Tesarz *et al.*, 2011; Balagué *et al.*, 2012). It included those people with pain between the lower ribs and the gluteal folds of the buttocks. This also included commonly made diagnoses that osteopaths may use as a working hypothesis to inform their treatment. For example, facet joint or lumbar muscular or ligamentous pain, and presentations that may include elements of osteoarthritic change in the spine or suspected minor discal injury without neuropathic leg pain. This definition was outlined in the clinician information sheet and FAQ sheet for the clinicians. During the interview process it was apparent that all the clinicians used different definitions for NSLBP and interpreted the presentation of this condition differently too. When asked to provide their definition of NSLBP, most of the clinician's responses seemed confused and demonstrated a lack of clarity.

"[unsure herself] Back pain that doesn't have any pathological association. Can't specify any particular definite tissue causing the pain, not neurological in nature. I wouldn't put a timeframe on it. I think you can have NSLBP which is acute and/or chronic or sub-acute – depends on info you get when you take the history…if you can't specify something to it then it would have to go down as…oh God do I really mean that…ok the only pathological thing which could make it not NSLBP is pregnancy" [OST_7, tutor]

It depends. My mind changes like the wind. Some days it's just a back pain and others you need to be more specific on it. In my day you had to be able to diagnose between a facet, a

disc, a muscle but nowadays it comes and goes as to whether we say this is a non-specific LBP because of a restricted thoracic spine. Pathology has to be nailed for safety reasons. I'd work above and below the area, on any restrictions…would be comfortable classing that as NSLBP" [OST_9, tutor]

"Massive term – loads of testing, can't pin a certain disc or facet. Trial and error treatments. NSLBP comes after a few trial and errors and no specific cause found. Centrally sensitised. Can't be aggravated in tests. Nature of way we are taught – very pinned on finding a diagnosis. Diagnosis approach. Rarely diagnose on first session. Massive umbrella term. For example, facet irritation with muscle spasm causing NSLBP picture. What do I treat and prioritise? Use term when other options have been exhausted" [OST_5, student]

"It is category of back pain – not a diagnosis – no underlying disease, neurology and pathology – no systematic nature, mechanical in nature. We have a lot in that mechanical category but a lot cross over with some radiation and neurology so then they are outside of the criteria – transient type symptoms like that" [OST_8, tutor]

"No pathology. Facet joint irritation, muscular strains, ligament strains – considered as mechanical NSLBP. If they are systematically well, no evidence of infection, inflammation, neoplasm…bent over this morning, now have back pain…well you could say it's a muscle strain, but tissues rarely work independently, and nerve supplies are shared. Research shows it is hard to differentiate between structures...they work together….that would be NSLBP mechanical" [OST_4, tutor]

"NSLBP: term has evolved. Osteopaths always thought that something that correlates to a specific cause that can create a generalisation of a back pain that comes from not a particular source. Generalised aching that cannot be fully contributed by one source, but it's important to know what those factors are though. Some of those non-specific may be from a tissue causing element which has a chronic factor or chronic timescale which has altered it a little bit. There is specificity and a non-specific diagnosis…you can see why it's confusing. Us

as osteopaths we think there is specificity in that and if you know other factors in that that aren't life-threatening – harmless back pain. We still get students to dig from the ground up. If the pain can be reproduced there is an element of specificity – therefore it is not non-specific. Our fear is when we teach something like that, they use an umbrella and not look any further. You arrive there once you've checked everything" [OST_5, tutor]

"Category describes things that don't fit the normal pattern….something you can't say has a specific cause. Very generalised. No clear radiculopathies. Guidelines blanket for things you aren't sure about…safely. Facet joint irritation does not always come under the term NSLBP" [OST_10, tutor]

The differing opinions on what constitutes as NSLBP between the clinicians resulted in non-adherence to the recruitment protocol of the trial. Clinicians appeared to forget about the definition they were asked to use in the trial. If an eligible patient did not fit the definition for NSLBP used by a certain tutor, then this patient was not provided with a patient participant recruitment pack. It seems their default understanding and definition of NSLBP was the one that prevailed and as such, more potential patients could have been missed (not recruited).

7.6.4.2 Theme: Disparity amongst tutors over the term NSLBP

The term NSLBP was suggested to not be acceptable to some clinicians, especially the tutors. This discrepancy led to problems such as tutor-student disagreements over the eligibility of some patients.

"Disagreement with tutors over signing the patient to the study [due to] *disagreements over the meaning of NSLBP." [OST_1, student]*

"Some students are afraid to make the diagnosis of NSLBP in case it doesn't meet with the tutor's approval – it's a medical term not an osteopathic term. Tutors can be old school and wanting a tissue causing symptom. Research showing no pathology, no referred pain, no tumour, no infection, no inflammation – it is NSLBP. NSLBP goes against their training. Students can be fearful of tutor disapproval. As osteopaths we used to employ the structural model for pain in the past – research shows that anything that isn't pathological is non-specific. It's a term used when interreacting with the medical profession. Term used between professions – common uses that common professions understand….if you mention L4-L5 facet irritation a doctor may go 'what'. Mechanical specific low back pain speaks to them in a language they understand better. It is tutor dependent – some like a specific cause/prefers a diagnosis and others may be ok with the term NSLBP. Student feels under pressure" [OST_4, tutor]

"Depends on which tutor you are with. Some tutors will say "yeah that's NSLBP" and another tutor will turn around and say, "no you need to be more specific, there is no such thing as NSLBP, we want you to say if it is a facet irritation or disc-related". So, then you may think this is NSLBP, but then you need to confine to something like facet. So, this is now a facet irritation, so now it's not NSLBP, so what is NSLBP? Everyone perceives NSLBP in different ways - some believe in it, and some don't" [OST_5, student]

"[laughs] this phase goes in and out of osteopathic language more times than I change socks. One time it's acceptable the other it's not. Right now, it is not. [according to some of my colleagues today] it is not good enough to refer in an exam as something as NSLBP." [OST_9, tutor]

Tutors needed to agree with the students over the identification of eligible NSLBP patients. Tutors were required to provide their signature on the patient ID form and to allow the students to hand out the patient recruitment packs to the eligible NSLBP patients. The disparity between the acceptability of NSLBP would have resulted in some patients not being provided with an information pack about the trial.

7.6.4.3 Theme: Different timescales used by clinicians before identifying NSLBP

Another variation in the use of the term of NSLBP was regarding a timescale for categorising NSLBP. Some clinicians believed that NSLBP is a chronic condition (present for more than six months), whilst other clinicians seemed ok with using the term NSLBP for acute (present less than six weeks) and sub-acute presentations (present between six weeks and 6 months).

"We were trained when we needed to be specific [about cause of pain]. There is a lot of misunderstanding and misinformation about NSLBP. It's more for chronic/persistent pain, with no specific aggravating and alleviating symptoms. Cannot clinically justify a specific cause. There's too much divided opinion" [OST_1, tutor]

"I don't use a timescale for NSLBP – if it's mechanical in origin and not specific to locate" [OST_1, student]

"It is non-specific in more chronic pictures. Has to be non-life threatening and non-progressive" [OST_5, tutor]

"Oh, that's easy - Anything that has got no red flags or radiculopathy. [timescale] first consultation…I have a very good picture with most of my patients at that stage. At this point of my career, I'm confident with that term and what's excluded" [OST_6, tutor]

"I don't think it matters how long they have had the pain…idea if they have had it for a while there is some central sensation rather than mechanical. We don't have many in the acute stage." [OST_8, tutor]

This variation in timescales for NSLBP would also have hampered the recruitment process of the trial. For example, a patient with sub-acute NSLBP could have been eligible to participant in the trial. However, if the clinician responsible for the identifying eligible patients believed NSLBP needs to have a more chronic picture (pain past months) then this would have resulted in eligible patients not being identified and invited to partake in the trial.

The range of definitions, and acceptability of the term NSLBP demonstrated a confused landscape when conceptualising NSLBP. The definitions that clinicians are using and committed to using for this condition vary and mirrors the different definitions within NSLBP literature (Campbell and Muncer, 2005; van Middelkoop *et al.*, 2011; Van Der Windt and Dunn, 2013). The vastly differing opinions and training the clinicians have had around the term NSLBP will have inevitably hampered recruitment of the patients – eligible patients may have not provided with a recruitment pack and therefore missed.

7.6.5 Solutions

The current method of recruiting patient participants using the students and tutors was not feasible, due to problems with adherence to the trial protocol and the nature of the clinic as a student-led educational-clinic. There are several solutions to improve the recruitment strategy which could make the trial feasible in this setting.

7.6.5.1 Leadership: Helping the students prepare

Some of the students who were involved in the trial did not find the trial burdensome but did state that it was difficult to remember the trial was ongoing. Some of the tutors believed that the trial could have been easy to integrate in the clinic if remembered.

"Easy to integrate if remembered" [OST_1, student]

"If integrated it should work flawlessly" [OST_5, tutor]

"I think it could have been really easy to integrate" [OST_5, student]

In a future refinement of the trial, it would serve the researcher to work more closely with students to ensure patient recruitment packs were handed out and to witness each presentation of the patients (students presenting their patient case to their tutor) to ensure eligible patients are identified and provided with packs. To facilitate, this a larger research team would be beneficial. Having a researcher in each of the five team rooms would enable the researchers to sit in on each of the student presentations about their patients. This would also help students manage the disparity between the tutor's views on NSLBP (i.e., if the tutor does not agree the patient has NSLBP the researcher could reiterate that the patient is eligible under the trial definition for the condition).

Another solution would be to organise regular meetings, at the start of the day and after lunch (as the students change rota at midday during term time) with the clinicians in the team rooms, to remind them about the trial.

"Remind us – easy to forget. In a situation with a team point full of students (different years, groups, knowledge base, anxieties) a lot is going on so it's easy to forget" [OST_5, tutor]

"Just keep badgering us" [OST_ 6, tutor]

In these meetings, the students can also go through their patient list and identify any patients which are/may be suitable for the trial. To ensure they do not forget to hand out a recruitment pack, the students could prepare and place a recruitment pack in their patient's folder. This would be a more structured approach to ensure the clinicians remember about the trial and was recommended by some of the tutors.

"Target the clinic planning session. Come round in the briefing sessions" [OST_8, tutor]

7.6.5.2 Timing and communication

One of the issues hampering recruitment was the timing of the trial starting in the clinic. To avoid the problems surrounding summer block, and to make the trial more integrable for the clinicians, a future trial would need to be introduced in January. By starting the trial during this month, the students should be operating smoothly with the day-to-day operations of the clinic and would potentially not find recruiting for the trial overwhelming or like they had been put *"straight into the deep end"*. Kavanagh, Kearns and Mcgarry (2015) conducted a qualitative trial in Irish healthcare student-led clinics and reported that students initially found working in the clinics as a "big learning curve" and that the students felt they needed more support at the start of their clinic experience. This evidence mimics the experience reported by some of the students in the UCO clinic when they initially started in the clinic. Therefore, starting a future trial in January may be easier for the students to integrate the trial into their normal day-to-day clinic routine. All the students (part-time and MSc pre-registration) would have started working in the clinic by January and the students not so familiar with clinic (students transitioning into the clinic for the first time) would have had six months experience of the clinic. Clinic tutors are less likely to be on holiday and new clinic tutors should have had time to also get used to the processes in the clinic.

The issue of some of the students and tutors having missed the initial researcher-led meetings could be solved by emailing all clinic staff, informing them about the trial, a few weeks before the trial is due to start. This would ensure all clinic staff received information about the trial, and what is required of them, prior to trial commencement. Weekly emails could also be sent to reinforce the trial and remind clinicians what is expected of them. This was suggested by some of the clinic tutors.

"Email us beforehand, informing everyone. Email would have been better at setting the tone – 2 weeks prior to starting [the trial]. The [recruitment] packs arrived before I did. Email us with weekly targets – keep motivation and interest" [OST_1, tutor]

If a trial is going to be conducted in the clinic in the future, the issue of the amount of research the clinic advertises could be a problem. This could be a problem for all the

advertised research in the UCO clinic. An agreement could be made between the research team and the clinic management about accommodating just one trial running at a time at the clinic to mitigate this problem. How viable this is and if it meets the direction the clinic wants to take is currently unknown. If it is not viable, the other solutions recommended could help clinicians focus more on this trial.

7.6.5.3 Training

Training the clinicians on what is required of them in the trial procedure can aid the recruitment process. Training the students on how to approach potential patients could reduce some of the anxieties the students faced with approaching their patients about the trial. Operationalising the term NSLBP for the students and tutors may reduce the disparity between the individuals so 1) there are no disagreements between the students and tutors over patient eligibility and 2) there is a clear definition of NSLBP and what type of patients the term encompasses. To aid the operationalisation of the term, the clinicians could be provided with a checklist. The checklist would outline and remind the clinicians what the criteria for a NSLBP patient is as defined in the trial. If the potential patient meets the criteria outlined on the checklist, the patient can be handed out a trial recruitment pack. This would reduce the risk of potential participants not being recruited for the trial. Additionally, it could be written in the trial consent form, for the clinicians, that agreeing to participate in the trial means they will adhere to the operationalisation of the term NSLBP as stipulated in the trial. These methods would reduce clinicians using their default understanding of the term NSLBP and mitigate the differences in acceptability of the term amongst the clinicians.

7.6.6 Acceptability of the physical activity interventions

All the clinicians agreed that providing patients with advice to be active was and always should be incorporated into treatment plans. The interventions used in the trial were acceptable to the clinicians. However, differing understandings of the term physical activity between the clinicians was noted and was another theme which came from the interview data.

7.6.6.1 Theme: Motion is lotion

All the clinicians who were interviewed agreed that physical activity was key for the self-management of NSLBP. This was captured in the phrase used by several participants 'motion is lotion'.

"Essential – motion is lotion. It's important – you never are still…your body is constantly moving on a cellular level, regenerating with movement and vibration" [OST_5, tutor]

"Hugely [beneficial]. It's not rocket science. It improves mood, it distracts you, helps you to build or retain muscle mass, good for mineral density, keeping weight down, calorie burning, modelling behaviour to younger generation…list goes on" [OST_7, tutor]

"I've thought that for 25 years…I'm totally on board. I've spent 25 years trying to get people moving, despite their pain and that is it good for them. It's taken too long to get into guidelines" [OST_7, tutor]

"Getting them moving can have a much wider effect – giving them confidence – demonstrating they can actually do some movement. Tend to become emotionally and socially isolated. Back pain is an excuse not to do stuff "I can't do that as my back pain might hurt". Takes away confidence. Movement gets people back in touch with their body" [OST_3, tutor]

"The relationship between chronic pain and depression makes exercise important" [OST_6, student]

"It's really important. I'm very careful what I say, the language I use. We don't talk about damage. Language is important…could say [to patients] *"even though you may feel some pain when you move it's important you do move". It gives them confidence, shows them that day on day they can do more...good monitoring, practitioner managing expectations…pain*

will still be there, but you will feel easier if you carry on. Reduces fear and avoidance of activity, empowering, confidence. Affirms what practitioners has said. Gives the right idea" [OST_4, tutor]

The consensus was that the clinicians valued the use of physical activity and exercise for patients with NSLBP. The positive effects of physical activity on the biopsychosocial model for LBP was reported – "*gives them confidence, reduces fear avoidance of activity"* (OST_4, tutor) and *"improves mood"* (OST_7, tutor) as patients often *"tend to become emotionally and socially isolated"* (OST, 3, tutor). These comments reinforce that physical activity is beneficial for NSLBP patients and should be incorporated as part of normal clinical practice to help address the multidimensional nature of the condition.

7.6.6.2 Theme: Too much activity is bad for back pain

Some of the clinicians commented on the negative impact physical activity can have on patients but were sometimes referring to physical activity as specific exercise.

"Physical activity can have a negative impact – doing exercise wrong, doing it too much." [OST_3, tutor]

"Depends on the activity. Not overloading the tissues. Nothing strenuous …walking mid distance and not long distance – could increase pain in that area. From a personal experience it [physical activity] *increases pain and rest is needed. Need right amount of load and duration. Still agree moderate amounts of activity are good. [OST_3_student]*

"Patients don't always listen – they do more reps of the exercise or not quite the way it was taught" [OST_5, tutor]

"Once or twice [physical activity had a negative impact] *but due to the type of activity they were doing or how aggressively they were doing it" [OST_10, tutor]*

"Others [patients] *can over-do it and it affects the treatments". [OST_4, student]*

These comments suggest that physical activity, as a treatment option, should be used carefully due to some patients "*doing too much"* or not doing the exercise "*the way it was taught".* The idea that doing too much activity can negatively impact on treatment for NSLBP mimics the 'U-shaped' relationship between NSLBP and physical activity (refer to *Chapter 1,* figure 1.1) as suggested by Heneweer, Vanhees and Picavet (2009) as "*moderate amounts are good*".

7.6.6.3 Theme: Different interpretations of the term 'physical activity'

However, different interpretations of the term 'physical activity' was noted during the interview process. Physical activity is defined as "any bodily movement" (Caspersen, Powell and Christenson, 1985) with exercise being a subset of the umbrella term physical activity. Exercise is a subset of physical activity that is planned, structured, and repetitive and has a final or an intermediate objective being the improvement or maintenance of physical fitness (Caspersen, Powell and Christenson, 1985). These two terms were used interchangeably by the clinicians. One of the tutors found the trial using the term 'physical activity' misleading as they believed it was about "specific exercise".

"I found the term physical activity misleading [on the information sheet]*. It should have said everyday day-to-day activity rather than perhaps it being about specific exercise. Perhaps we need to change the message a bit and get people to see that everyday physical activity is valid and get them to build on that platform. Rather than starting the campaign with exercise." [OST_7, tutor]*

This statement demonstrated a lack of understanding that physical activity is just about getting to body moving which includes day-to-day activities and does not specifically mean exercise. Other statements reinforced how interchangeably the terms 'physical activity' and 'exercise' are used by clinicians.

"I don't prescribe exercises or give a sheet of exercises. The activity must be easy to do and acceptable for their lifestyle" [OST_9, tutor]

"I advise patients to be as gently active as possible and try and do normal things" [OST_4, tutor]

The question asked to the clinicians was around using physical activity as part of a treatment programme. However, it was commonly referred to that incorporating physical activity in a treatment plan spoke to the clinicians in terms of prescribing certain stretching and strengthening exercises.

"Think about what you are prescribing – exercise. Constantly tweaking what you do" [OST_3, tutor]

"Mobility is great but what about strength and stability. [way I try to teach] look at the strength building concept [when you stop using something it atrophies] ….explain to people and they see what you are trying to do they understand the importance of it. [talks about prescribing stretches and specific exercises]. [physical component] we must [as clinicians] take the fear away from it [feeling muscles working during exercises]" [OST_6, tutor]

"I prescribe prescriptive exercises and stretch with every single client that comes to me" [OST_1, student]

"Rehab and exercise are a huge part. Students have been talking more about after-care and which exercises to use. They are using software to create exercises" [OST_5, tutor]

"I have a personal trainer background. I'm always prescribing exercises" [OST_4, student]

"Keeping active is so important. Manual therapy alone – the benefits are short lived. Stretching exercises and other exercises give better results. I've always given exercise alongside my treatment" [OST_5, student]

Whilst specific exercises and stretches are still modes of physical activity, it seems that clinicians may have misinterpreted the recommendations of the NICE guidelines. Guidelines suggest practitioners should advise and encourage patients to continue normal activities and promote physical activity. This appears to have been interpreted by clinicians as meaning to prescribe exercises. The recommendation of guidelines speaks to the clinicians and practitioners in terms of specific exercises, prescribed, supervised activities (such as yoga) or strengthening and stretching exercises as shown in the quotes from the clinicians. If a patient has no interest in strengthening or stretching exercises or going to yoga classes, then they will not adhere to the advice and the behaviour (being more active) will not be sustainable. This is a potential reason why previous attempts at increasing physical activity in this population have been unsuccessful. As previously mentioned, physical activity which fits into an individual's lifestyle and normal routine is reported more likely to be sustainable (Ogilvie *et al.*, 2007; Yang *et al.*, 2010).

Physical activity can refer to walking more, using the stairs instead of the lift, playing with your children/grandchildren, do some gardening etc. The key message practitioners and researchers provide to patients should be "keep moving" and suggesting simple day-to-day activities. This feasibility-pilot trial attempted to portray this key message rather than prescribe certain exercises or activity, like walking, to the recruited patients. However, it seems this key message should be emphasised clearer in clinical guidelines, with clear definitions for what constitutes as physical activity and exercise. The concept that increasing the physical activity levels of NSLBP patients can be achieved by encouraging them to do more household activities, use active transport (walking/cycling) or do more occupational activities (Sallis *et al.*, 2009) need to be standardised and incorporated in clinical guidelines. This will help researchers and clinicians to 1) accurately label the types of intervention they are investigating or implementing (physical activity or exercise) and 2) help clinicians

identify other means of getting their patients more active, without the need to prescribe exercises. In turn, this could make patients more active and improve outcomes for this population.

7.7 Conclusion

Running a full-scale RCT in the UCO outpatient clinic is currently not feasible based on the criteria outlined in *Chapter 6* which would suggest the trial was feasible to conduct as an RCT. Whilst the tools and measures used with the patient participants were acceptable and feasible to implement, the current recruitment strategy was ineffective and needs detailed refinement. Solutions to the issues raised and observed in the clinic, relating to the recruitment process have been explored. Alternatively, to these solutions, choosing another clinic or another healthcare setting to implement the trial may be more feasible, considering the nature of this clinic. However, the issue of defining NSLBP, with a definition that is acceptable to clinicians, would still be a problem and therefore requires addressing.

7.8 Chapter summary

- The mixed methods feasibility-pilot trial protocol needs refining in order for the trial to be feasible as an RCT
- Due to the small sample size (n=5) confidence intervals could not be calculated, and interferential statistics were not applied
- The qualitative data highlighted several areas where improvements and refinements are needed, in both the trial protocol and future research
- Due to the detailed changes which need to be applied, it would be logical to re-pilot the trial, in a clinical setting, to ensure it is more successful in clinician adherence to the tirl protocol and patient participant recruitment, before time and money are invested in a future RCT

8 Chapter 8 – Discussion

8.1 Introduction

This thesis set out to explore how physical activity interventions in NSLBP research need to be designed, developed, and delivered to promote behaviour change and increase the physical activity levels of NSLBP patients. By identifying the key ingredients required in physical activity interventions and the most favourable way of delivering the interventions, future research can use the work presented in this thesis to equip and enhance the effectiveness of future physical activity interventions to enable the optimal performance of clinical trials.

This thesis initially outlined the global burden of NSLBP and the impact NSLBP has on an individual's life and physical activity levels. NSLBP patients are reported to have reduced and altered levels of physical activity (Ryan *et al.*, 2009), due to activity-avoidant behaviours (Lethem *et al.*, 1983; Vlaeyen, Kole-Snijders, Boeren, *et al.*, 1995). This can result in physical deconditioning in NSLBP patients (Verbunt *et al.*, 2003; Bousema *et al.*, 2007; Duque, Parra and Duvallet, 2009; Steele, Bruce-Low and Smith, 2014).

The rationale for physical activity in self-management programmes for NSLBP was discussed and a brief overview of the physical activity interventions used for the self-management of NSLBP in the literature was provided in *Chapter 1*. However, the effectiveness of physical activity interventions for NSLBP is yet to be determined, with trials providing equivocal results. Using behaviour change strategies in a NSLBP population has yet to be investigated (Broonen *et al.*, 2011)The rationale for the use of non-prescribed, unsupervised physical activity interventions was stated in *Chapter 1* and reinforced throughout this thesis. To explore how physical activity interventions should be designed, developed, and delivered in trials, several questions were posed:

1) What is the behaviour change content of non-prescribed physical activity interventions used in RCTs in NSLBP research?
2) Have previous physical activity interventions been developed using behaviour change theories, frameworks or BCTs?

3) Is wearing an accelerometer on a belt, inside a pouch, a valid method to collect physical activity data on a daily basis?
4) What BCTs should be included in interventions to increase physical activity levels in NSLBP patients?
5) What is the feasibility of running an RCT in the UCO outpatient clinic?
6) How acceptable were the physical activity interventions for the NSLBP patients?
7) How acceptable was the feasibility-pilot trial for the UCO osteopaths?

To address these questions, a systematic review was undertaken to identify the gaps in physical activity interventions in NSLBP research (questions 1 and 2). Once the gaps were identified, two pilot trials (pilot trial 1 and pilot trial 2) (question 3) were conducted and a feasibility-pilot trial (questions 5 and 6) was designed and performed. Question 3 was answered by conducting two pilot trials - the second pilot trial was performed as a refinement of the limitations found in pilot trial 1. Question 4 was answered through reviewing different behaviour change frameworks, models, and guidance to select the most appropriate model to use for the development of the physical activity interventions used in the feasibility-pilot trial.

8.2 Novel findings of the programme of work

This programme of work has produced three valuable and novel findings which will advance research in NSLBP and physical activity. These findings are 1) a method to comfortably wear an objective measure to monitor physical activity over several weeks, 2) the BCT “feedback on behaviour” was the most useful part of the non-prescribed physical activity interventions, designed using the BCW, and 3) the disparity, confusion and acceptability of the term “NSLBP” amongst clinicians.

These findings contribute to research and practice in various ways. The validated accelerometer belt mounting method allows researchers to measure physical activity in a cheap, non-intrusive way over a period of time, rather than relying on more expensive methods of measurement or using pedometers, which only capture one aspect of physical

activity (i.e., number of steps taken). The finding relating to the BCT "feedback on behaviour" provides researchers 1) with an indication of which BCTs are acceptable and most useful for people receiving physical activity interventions, 2) evidence that systematically designing behaviour change interventions using the BCW does have positive outcomes, and 3) allows clinicians to incorporate the use of BCTs in their current practice to aid the attainment of goals they set their patients. This BCT has not been previously investigated in NSLBP research. The final finding relating to the acceptability of the term "NSLBP" amongst clinicians highlights that standardised terminology, which is acceptable to clinicians and practitioners, is required to make research in this field more robust and to align standards of best practice, in accordance with the NICE guidelines, with treatment recommendations for patients with NSLBP.

Throughout this thesis, when answering the questions posed above, several additional insights and findings were identified. These additional insights and findings led to the development of further questions which shaped the direction of this thesis. These insights and findings are highlighted and discussed alongside the question where the additional information was identified. These additional findings presented in this thesis also enhance the previous research and literature on the use of physical activity interventions for the self-management of NSLBP and provide recommendations for future research.

8.3 Thesis results

1) What is the content of non-prescribed physical activity interventions used in RCTs in NSLBP research?

The initial idea for this thesis was to explore the impact of a low-cost intervention, which could be used immediately in a clinical setting, to encourage NSLBP patients to increase their physical activity levels. The use of non-prescribed and unsupervised interventions were of interest based on the rationale that if the patient chooses the activity they want to engage in and which fits into their daily routine, the activity, and subsequently behaviour, may be more sustainable and increase adherence in trials. Adherence in NSLBP trials is reported to be low (Hanney, Kolber and Beekhuizen, 2009; Marley *et al.*, 2014; Milosavljevic *et al.*, 2015).

The systematic review presented in *chapter 2* investigated the previous non-prescribed physical activity interventions used in NSLBP research. This systematic review is the first to 1) investigate and identify the use of non-prescribed, unsupervised physical activity interventions for NSLBP patients and 2) identify the use of behaviour change theories and BCTs as incorporated in the interventions. The main aim of the systematic review was to identify trials using non-prescribed, unsupervised physical activity interventions for NSLBP patients and evaluate the content of these interventions. The nature and quality of these non-prescribed interventions in increasing physical activity levels in patients with NSLBP was completed by evaluating the use of behaviour change theories, frameworks and BCTs in the interventions.

Results of the evaluation process of the included trials demonstrated that non-prescribed, unsupervised activity was given to the participants in the form of “advice-to-be-active” or advice to the participants to continue with their normal routine and was used in the control group of the included trials in the review. It was noted in the screening process that the content of other non-prescribed interventions included the use of *The Back Book,* designed by Burton *et al.* (1999). *The Back Book* is an educational booklet often given to NSLBP patients which provides them with information on how to self-manage their NSLBP, including advice to maintain activity levels. The use of the “advice to be active” is a minimal

intervention and performance bias was detected in the trials. There were inconsistencies in the amount of support the intervention group(s) were receiving compared to the control group (i.e., the intervention groups received multiple follow-ups or clinic sessions and the control group received advice to be active at the start of the trial, with no follow-up sessions). This is important as adherence to the interventions could have been affected by the level of contact each intervention group received and therefore would have had an impact on the overall effectiveness of each intervention.

The content of the non-prescribed, unsupervised physical activity interventions was hard to distinguish, as was the content of the prescribed activity interventions, due to insufficient intervention descriptions. The TIDieR checklist (Hoffmann *et al.*, 2014) was used to evaluate the quality of the descriptions of the interventions used in the included trials. Descriptions in the content and delivery of health-care interventions has previously been reported to be poor (Michie *et al.*, 2009; Michie, Abraham, *et al.*, 2011; Hoffmann *et al.*, 2014). The TIDieR checklist was created in 2014, which is after 75% of the trials included in the review were conducted. However, this does not have much influence on how well described the interventions in the trials were, as the oldest trial, conducted in 2002, met most of the TIDieR checklist compared to newer trials. The purpose of applying the checklist to the trials was to evaluate how well described the interventions were to 1) help identify the content of the interventions in the trial (i.e., what was in them, how were they delivered to participants etc.) and 2) to inform the design and reporting of the interventions used in the feasibility-pilot trial for this thesis.

The quality of the descriptions of the interventions in the included trials were poor. Only one trial (Rozenberg *et al.*, 2002) met at least 67% of the checklist for the descriptions of both interventions used in the trial. None of the included trials included a description of the materials used in the trial and did not supply the materials as an appendix or supplementary material. For example the participants in the medical yoga group described in Aboagye *et al.* (2015) were provided with a CD which was reported to contain written instructions. However, it is unclear what instructions the participants were provided with. Discrepancies between the quality and details of intervention description also varied within and between the trials. For example, one of the interventions in Paatelma *et al.* (2008) met 41% of the checklist whilst the other two interventions only met 16% and 25% of the checklist. This

level of difference between the intervention description does not allow for the interventions to be replicated (Hoffmann *et al.*, 2014) and further obscures the ability to evaluate the content of the intervention and identify the key components of the intervention. This is vital because if researchers are transparent in reporting the interventions used and what components (materials, behaviour change theories etc.) were used in each intervention, the design and content of future interventions can be enhanced. Future interventions could utilise the components of previous interventions, which demonstrated some effectiveness in outcomes for NSLBP patients, and combine with different components to design and develop better, more efficient interventions. Future research should accurately describe the rationale or theory behind the inclusion of the interventions, content (including materials and specific details of the intervention processes), intervention provider (including mode of delivery) and to provide an assessment of fidelity of the intervention(s).

2) **Have previous physical activity interventions for NSLBP patients been developed using behaviour change theories, frameworks or BCTs?**

Theory-based interventions are more likely to be effective and the MRC recommends interventions are designed and based on theory (Craig *et al.*, 2008). Improving physical activity levels, in any population, requires behaviour change (Marley *et al.*, 2014). In a NSLBP population, with some patients described to have fear-avoidant or activity-avoidant behaviours (Lethem *et al.*, 1983; Vlaeyen, Kole-Snijders, Boeren, *et al.*, 1995), behaviour change is essential. Trials aiming to increase physical activity in NSLBP patients, which is essentially a desired behaviour, should be incorporating behaviour change theories, frameworks and BCTs in the development of interventions.

The results of the systematic review demonstrated that none of the interventions (n = 10) were developed or informed with either behaviour change theories, a behaviour change model or framework. This finding reinforces the statement that interventions are often theoretically underdeveloped (Michie, Ashford, *et al.*, 2011; Michie *et al.*, 2013). Despite the poor quality of intervention description, some BCTs were able to be coded in some of the

interventions of the trial included in the systematic review. The maximum amount of BCTs coded in one intervention, using the BCTTv1, was seven. Zero BCTs were coded in one of the interventions. 60% of the interventions were coded with four BCTs. Evidence from systematic reviews on other clinical populations (Greaves *et al.*, 2011; Bird *et al.*, 2013) indicated that the interventions aimed at increasing physical activity levels showed statistically significant effects when using a variety of BCTs more than the interventions which only used a few. The systematic review conducted by Bird *et al.* (2013) focused on the BCTs used in interventions to promote cycling and walking in adults. 85% of the interventions analysed demonstrated statistical significance and had evidence of using up to twelve BCTs (Bird *et al.*, 2013). The results of the review indicated that the majority of interventions, using a variety of BCTs, showed a significant effect on increasing walking and cycling outcomes (Bird *et al.*, 2013). Samdal *et al.* (2017) reported that positive intervention effects were associated with an increased amount of BCTs in the interventions. This evidence has also been demonstrated in other trials (Lara *et al.*, 2014; Bishop *et al.*, 2015).

However, the insufficient description of the interventions resulted in some BCTs unable to be coded in some of the interventions. For example, the lack of description about the written instructions provided to the participants in Aboagye *et al.* (2015) made it difficult to determine if the BCT "demonstration of the behaviour" could be coded. Unless there is explicit evidence that a BCT has been used, the BCT cannot be coded. This reinforces the importance of authors providing full, detailed descriptions of the interventions used. Therefore, it was difficult to determine the 'true' extent of the amount of BCTs used in each intervention. This has implications when deciding which BCTs have been used in interventions that have or have not been effective. The ability to identify which BCTs have been used effective interventions provides an indication of the BCTs to consider incorporating in future interventions. This has the potential to allow researchers and intervention developers to design robust behaviour change interventions.

Implications for the thesis and wider research community

The systematic review highlighted a lack of theoretical underpinning in the interventions and poor quality of intervention description in physical activity interventions in NSLBP

research. Based on this result the physical activity interventions used in the feasibility-pilot trial were designed and developed using the BCW (Michie, Atkins and West, 2014) and incorporated the use of BCTs across four different interventions.

The results of the systematic review also demonstrated that none of the included trials used an objective or subjective measure for physical activity. The effectiveness of physical activity interventions, in increasing activity in NSLBP patients, cannot be examined if the activity levels of the participants are not quantitively measured pre- and post-trial. To more closely examine the effectiveness of an intervention designed to increase physical activity levels, an objective measure to monitor and detect changes in activity levels, in real-time, is needed. This finding resulted in the development of two pilot trials to assess the reliability and validity of using accelerometers to record physical activity. These pilot trials allowed the feasibility-pilot trial to include a valid and reliable objective measure to monitor the participant's physical activity levels.

The systematic review highlighted the complex landscape of NSLBP research and lack of behaviour change content in previous physical activity interventions. The identified lack of theory-informed physical activity interventions and the absence of an objective measure of physical activity provides direction for future NSLBP research. Interventions aimed at other populations, as shown in three previous systematic reviews (Greaves *et al.*, 2011; Bird *et al.*, 2013; Samdal *et al.*, 2017), have used BCTs to enhance the effectiveness of the physical activity interventions and have used objective measures to validate the effect of the interventions at increasing physical activity levels in other clinical populations. Objective measurements in physical activity interventions have previously been under-examined and unused in NSLBP research.

3) Is wearing an accelerometer on a belt, inside a pouch, a valid method to collect physical activity data on a daily basis?

In the systematic review a lack of objective measures to monitor and record the daily physical activity levels of the participants was identified. The two pilot trials (pilot trial 1 and 2) aimed to test the validity and reliability of an objective measure in recording daily

physical activity levels. Accelerometers were decided to be the most cost-effective and accessible tool for use in the feasibility-pilot trial. The results of these two pilot trials indicated that mounting an accelerometer around the waist, on a belt, at the spinal level L4-L5, was valid and reliable at collecting physical activity data.

The pilot trials were designed to assess differences in data collection between an accelerometer mounted to the spine (spinal level L4-L5), using double-sided hypoallergenic sticky tape (tape method) and an accelerometer worn around the waist on a latex-free belt, in a latex-free pouch (ActiGraph) (belt method). Both of the pilot trials found no significant differences between the data collected by the accelerometers using either mounting method. This indicated the belt method was reliable and valid to collect physical activity data. The tape method is also known as a skin mounting method. Skin mounted accelerometers are the closest researchers can get to mimicking the 'gold standard' method of bone mounted accelerometers (Wong, Lee and Yeung, 2009). Skin mounted accelerometers (mounted using double-sided hypoallergenic sticky tape) offers researchers the lowest frequency response (Hanley, 2017), meaning the tape does not interfere with the free-living (physical activity(data collected. The belt method, as shown in the two pilot trials, can distinguish between the different intensities of different types of activities to a comparable level to the skin mounted accelerometers. There were no previous trials or evidence to suggest wearing an accelerometer, mounted with a belt, was comparable to the skin mounted method.

Two pilot trials were conducted as the second pilot trial was designed as a refinement of the first trial to address the limitation identified, which may have interfered with the validity of the results obtained. In the first pilot trial, the two different accelerometer mounting methods were worn simultaneously. This meant the accelerometers were mounted on top of each other and could have interfered with data collection – i.e., belt may have been pushing on the accelerometer directly mounted to the skin and limited the amount of free movement the accelerometer might collect. This interference could have skewed the results of the trial giving false-positive results.

In the second pilot trial, the accelerometers were worn separately over a series of controlled activities. The second pilot trial confirmed the findings of the first pilot trial. This indicated the belt method was reliable and valid to collect physical activity data. However,

the two methods of mounting accelerometers to the body could not be tested separately in a non-laboratory-based environment (i.e., over a whole day) in the second pilot trial. Human nature is unpredictable, as are the demands of regular day-to-day activities. It would be most unlikely that the participants could accurately replicate exactly every bit of movement and activity over two days, in the attempt to allow the accelerometers to the collect the same data when worn separately. As no significant differences were noticed in the first pilot trial between the two accelerometers during a 12-hour day, and the second pilot trial confirmed that there are no differences between the two accelerometer mounting methods when worn separately in a laboratory-based environment, the evidence suggested wearing the belt method singularly in a non-laboratory-based environment would also produce no significant differences. Future research should investigate the different methods of mounting an accelerometer to the human body in a non-laboratory-based environment.

Implications for the thesis and wider research community

These novel findings contribute to the literature and wider research community by providing a validated method which can be used in studies investigating physical activity over a period of time in the future. It was previously unknown if using a belt as a mounting method for capturing accelerometer data was valid.

The feasibility-pilot trial required an objective measure which could be comfortably worn over a period of 6 weeks, every day during waking hours. These two pilot trials provided the feasibility-pilot trial with a valuable method to wear an accelerometer, which is not only comfortable to wear for a prolonged length of time to monitor activity levels, but also a method which provides the same type of evidence as a previously validated method (skin mounted accelerometers). These two pilots also provided the feasibility-pilot trial with a customised set of instructions to help participants find the correct spinal level of L4-L5, so they could mount the accelerometers on their own. The results of the second pilot trial, illustrated the set of instructions were reliable and amenable for the requirements of the feasibility-pilot trial. The feasibility-pilot trial required participants to wear the accelerometer daily over a period of 6 weeks (including the baseline measurement). The

value of testing the instructions for reliability demonstrated that individuals could use the accelerometer and correctly position it at the required spinal level.

The beneficial effects of physical activity on NSLBP cannot be reported, if the activity levels of the participants in the trials is not monitored. The ability to quantify the physical activity levels of the NSLBP patients recruited in the feasibility-pilot trial enabled the content of each intervention to be evaluated (i.e., which intervention seemed to increase the physical activity levels of each participant, allowing for a comparison between the groups).

4) Which BCTs should be included in interventions to increase physical activity levels in NSLBP patients?

As demonstrated in the systematic review, previous physical activity interventions have not used behaviour change theories or frameworks to design the interventions used in NSLBP trials. The MRC guidance was updated to include identifying and developing theory when designing complex healthcare interventions (Craig *et al.*, 2008). Behaviour change interventions present a set of co-ordinated activities (such as goal-setting, identifying the advantages and disadvantages of the behaviour, identifying barriers towards the behaviour) which have been designed to change the specific patterns of the undesired behaviour (i.e., physical inactivity) (Michie, van Stralen and West, 2011). Interventions for increasing physical activity levels need to have elements for behaviour change (Marley *et al.*, 2014) and interventions, aimed at trying to change the normal day-to-day routine of humans, need to be systematically designed and developed. Previous trials have reported significant intervention effects when using BCTs to increase activity (Kriska *et al.*, 1986; Calfas *et al.*, 1996; Halbert *et al.*, 2000; Baker *et al.*, 2008; Butler *et al.*, 2009; Hemmingsson *et al.*, 2009; Pal *et al.*, 2009). The model chosen to design the interventions was the Behaviour Change Wheel (BCW) (Michie, Atkins and West, 2014). The BCW was selected as the most appropriate model as it was constructed using an array of interacting behaviour change frameworks (Mansell, Hall and Toomey, 2016) and provides a taxonomy of BCTs (Michie *et al.*, 2013; Michie, Atkins and West, 2014).

Eleven different BCTs were incorporated across the four interventions. These BCTs were: "feedback on behaviour", "information about health consequences", "credible source", "verbal persuasion about capability", "goal setting (behaviour)", "action planning", "problem solving", "review behaviour goal(s)", "discrepancy between current behaviour and goal", "commitment" and "monitoring of behaviour without feedback". The BCTs selected met the APEASE criteria, were suitable for inclusion based on the components and intervention functions identified, which were recognised as needed changing in the behavioural diagnosis, and could be delivered in the context in which the feasibility-pilot trial was conducted in.

The four interventions used in the feasibility-pilot trial were designed as one intervention, before being split into four interventions ,after identifying the mode of delivery and appropriate BCTs for the intervention functions (education, persuasion, and enablement), and COM-B components (psychological capability, reflective motivation and automatic motivation). The rationale for splitting the intervention into four distinct interventions across four groups of participants, using different strategies (table 5.10), was 1) to try and distinguish between which BCTs were acceptable for the NSLBP patients, 2) to explore how different combinations of BCTs and different intensities of the interventions (i.e., interventions providing a small amount of materials compared to interventions where more materials and resources are provided) were received by the participants, and 3) which BCTs appeared to aid the patients in increasing their activity levels.

A limitation of the designed interventions was identified after the feasibility-pilot trial had been conducted. Step 4 of the BCW requires the identification of what needs to change to enable the NSLBP patients to engage in the desired behaviour – increase activity levels). The BCW does this through the use of the COM-B self-evaluation questionnaire to identify which COM-B components need to be targeted to achieve the desired behaviour. The questionnaire should be administered to the patients but due to time constraints, the primary researcher completed the questionnaire using qualitative information in the literature regarding why NSLBP patients feel activity can harm their back (Darlow *et al.*, 2015, 2016) and based on the experience of the researcher as a healthcare professional. After the feasibility-pilot trial ended, it was apparent that the COM-B self-evaluation questionnaire should have been completed by NSLBP patients, by running a mini-trial, based

on the qualitative data provided by the patient participants in the trial. If the COM-B questionnaire had been completed by NSLBP patients more or different intervention functions, COM-B components and BCTs could have been identified and could have been further incorporated into the interventions used in the feasibility-pilot trial.

The systematic review highlighted three key areas where there are gaps in NSLBP research: 1) the lack of non-prescribed, unsupervised physical activity interventions in NSLBP research, 2) the lack of an objective measure to quantify physical activity levels and 3) the lack of theoretically based interventions to increase physical activity levels in a NSLBP population. These identified key areas all informed the content of the interventions used in the feasibility-pilot trial. An objective measure was required to measure physical activity. The two accelerometer pilot trials were conducted to identify the best method on how to wear an accelerometer to provide accurate data on physical activity levels with the ability to distinguish between the intensities of different types of activity. As previous activity interventions had not been theoretically developed, the BCW was used to design and develop the content of the interventions to be used in the feasibility-pilot trial.

5) How acceptable were the physical activity interventions for the NSLBP patients?

The feasibility-pilot trial adopted a mixed-methods approach, using semi-structured interviews for the patient participants at the 6-week follow-up posttrial. The interviews were designed to explore the acceptability of the content of the interventions used in the trial. The evaluation of the interventions was enhanced as the BCTs, which the participants identified as useful, were compared to the overall changes in physical activity (i.e., if a participant did not find the content of their interventions useful it may have been reflected in the data collected for physical activity (e.g., a reduction in physical activity)).

The BCT of “feedback on behaviour” was the most acceptable BCT used in two of the interventions in the trial. Participants received this BCT on a weekly basis in the form of quantitative information on percentage changes in activity levels from the previous week. This BCT was used in group 2. Participants in group 2 received four BCTs (feedback on behaviour; information on health consequences, credible source, and verbal persuasion

about capability). This BCT was also used in group 4, whereby the participant received all of the BCTs used in groups 1 to 3, and also received the additional BCTs of "review behaviour goal(s)" and "discrepancy between behaviour and goal(s)". This feasibility-pilot trial is the first trial, in NSLBP research, to provide the participants with feedback on their activity levels. Previous NSLBP trials, aimed at increasing activity levels, have not provided the trial participants with any type of feedback on their activity levels. Instead research previously has focused on activity patterns (Ryan *et al.*, 2009) or specific exercise programmes (Gutknecht *et al.*, 2015; Hügli *et al.*, 2015; Saner *et al.*, 2015; Bae *et al.*, 2018). The participants who received the BCT "feedback on behaviour" reported they were more motivated to increase their activity levels week-on-week. It is unclear, due to the small sample size, if the participants receiving the feedback on behaviour BCT had the most effect in increasing activity levels as interferential statistics could not be completed.

This finding is similar to the results of other trials which incorporated feedback in the interventions designed to increase physical activity in obese participants (Hemmingsson *et al.*, 2009; Pal *et al.*, 2009), cardiac patients (Halbert *et al.*, 2000; Baker *et al.*, 2008; Butler *et al.*, 2009), the elderly (Kriska *et al.*, 1986) and the general population (Calfas *et al.*, 1996). These trials incorporated "feedback on behaviour", in conjunction with other BCTs, and demonstrated statistical significance in increasing walking and cycling activities in the participants. The results presented in a systematic review (Samdal *et al.*, 2017) reported a positive association between using the BCT "feedback on outcome of behaviour" in increasing activity levels of overweight and obese adults.

However, the BCTs of "action planning", "commitment" and "problem solving" used in the implementation intentions (group 3) did not appear to be perceived as personally useful by the participants who received them. The implementation intentions were designed as a series of tasks, asking the participants to complete a weekly plan with affirming statements (BCT: "commitment") for incorporating activity into their routine (BCT "action planning") by identifying when, where and how they would add more activity into their routine (BCT "goal setting), and to identify obstacles preventing them from being physically active and then identifying ways to overcome these obstacles (BCT "problem solving"). Implementation intentions are reported to be powerful tools for health education programmes and have already been demonstrated to promote exercise participation in elderly populations (Milne,

Orbell and Sheeran, 2002; Hall *et al.*, 2012, 2014; Bélanger-Gravel, Godin and Amireault, 2013). The implementation intentions were used in groups 3 and 4. The participant in group 4 received all the BCTs used in group 3, and also received the additional BCTS of "review behaviour goal(s)" and "discrepancy between behaviour and goal(s)".

The benefit of the implementation intentions were not understood by the participants, and they indicated they just filled out the action planning and commitment task just to complete it, rather than use the task to help them plan when they can incorporate physical activity into their routine for the next week. Whilst one of the participants (randomised to group 4) increased their activity levels every week of the trial, they reported not actually using or following the action plan they created. The other participant (randomised to group 3) did not manage to increase their activity levels week on week and maintained their activity levels from their baseline measurements (overall change in activity of 2% from the baseline measurements). Interferential analysis could not be completed to see if the no change in activity levels and COM-B component were related due to small sample size of the trial.

Two of the participants reported, in the semi-structured interviews, that they occasionally forgot to wear the accelerometer for a couple of hours in the mornings. The BCT of "prompts and cues" could have been integrated into this trial. This BCT could have been used by asking the participants to set a reminder in their phones to wear the accelerometer or by advising the participants to leave sticky notes in the bathroom or by their house keys to remind them to wear the accelerometer. This would facilitate the trial by introducing environmental stimulus to prompting or cueing the behaviour (Michie, Atkins and West, 2014). Whilst the participants forgetting to sometimes wear the accelerometer did not affect the outcome of the trial, future trials would benefit from using this BCT, or a similar one depending on the context of the trial, to reduce the potential for participants to forget to adhere to elements of the trial protocol.

Additional finding

The feasibility-pilot trial highlighted that there is a lack of clinically meaningful change (CMC) for physical activity levels in research.

CMC for a change in physical activity levels

National and international guidelines recommend adults engage in at least 150 minutes of moderate levels of physical activity a week to receive the widely-report benefits of regular physical activity (e.g., reduced risk of chronic disease, including NSLBP, weight control, improved mental health and mood etc.) (Tremblay *et al.*, 2011; World Health Organization, 2016). Physical inactivity is a global problem and focus has turned to developing and testing interventions to promote and increase physical activity in individuals leading a sedentary lifestyle (Dunn, Andersen and Jakicic, 1998; Kahn *et al.*, 2002). However, currently a CMC (or minimal clinically important change (MCID)) for physical activity levels, measured objectively or subjectively does not exist (Demeyer *et al.*, 2016; Hur *et al.*, 2019; Teylan *et al.*, 2019). Therefore, the extent of these interventions in reducing sedentary behaviour and encouraging physical activity cannot be evaluated in-depth.

Defining a threshold, CMC or MCID in physical activity levels would allow trials to evaluate whether or not their intervention had the desired effect of increasing physical activity levels. This would facilitate the evaluation of the content of health-care interventions in identifying interventions which do increase activity and which interventions do not (i.e., what is incorporated in interventions which have worked). Both subjective and objective measures can provide indicators of MCID and CMC in activity levels. Both types of data would be able to provide physical activity data for identifying a MCID or CMC, but sensitively is higher in objective measures as objective measures allow for the continuous recording of free-living conditions (Yang and Hsu, 2010; Silfee *et al.*, 2018), due to the complex behaviour of physical activity (Silfee *et al.*, 2018). Subjective measures cannot collect data on the lighter activities of the physical activity spectrum – i.e., household jobs, gardening or family care) (Tudor-Locke and Myers, 2001; Prince *et al.*, 2008). Subjective outcome measures, such as questionnaires, also have the pitfall of recall bias (Althubaiti, 2016). Human memory recall is subject to error and bias (Gendreau, Hufford and Stone, 2003) and subjective measures have the problem of the different ways individuals can interpret the question and influence the answers they provide. This difference in interpretation was observed in the feasibility-pilot trial. Some of the participants were unsure what box to tick on the GGPAQ when answering how much physical activity was involved with their occupation. Participants also can under- and over-estimate the amount of physical activity they engage in. The size of

effect would also be bigger in objective measures than subjective measures and provide more accurate indications of CMC in activity levels.

One trial (Hur *et al.*, 2019) aimed to find an estimate for a MCID in physical activity using the IPAQ and a waist mounted accelerometer for people with fibrotic interstitial lung disease. The suggested threshold, derived from the distribution-based results of the trial population, was reported to be unrealistic – the threshold calculated for a MCID ranged from 104 minutes per week to 242 minutes per week (Hur *et al.*, 2019) and would not able to be completed in individuals with lung disease. This threshold exceeds current guidelines of 150 minutes of moderate to vigorous physical activity per week (Tremblay *et al.*, 2011; World Health Organization, 2016). The trial conducted by Chahal, Lee and Luo (2014) aimed to investigate the association between loading dose of physical activity on muscle strength and bone density in woman. The results indicated that increased bone density was associated with a loading dose of moderate to vigorous activity, whilst increased muscle strength was associated with loading doses of light, moderate and vigorous physical activity (Chahal, Lee and Luo, 2014). However, it is not clear if this is clinically meaningful. Identifying thresholds of improvement in physical activity levels may be more applicable than trying to calculate a CMC or MCID in activity levels due to the complex nature of physical activity.

Previous research has suggested that researchers and clinicians should also be looking to target sedentary behaviour and look at data indicating reductions in sedentary behaviour (Mesquita *et al.*, 2017). Mesquita *et al.* (2017) suggested increases in light activity is a potential strategy to reduce the time spent sedentary. Increasing light activities is more achievable for patients with COPD rather than aiming to increase their moderate to vigorous activity levels (Mesquita *et al.*, 2017). This finding is similar to results of some of the NSLBP patients recruited in the trial. Changes in moderate and vigorous activity were not witnessed in 60% of the participants. However, changes in very light and light activity were recorded throughout the trial. Perhaps increasing very light and light activities is easier for patients with NSLBP. If the feasibility-pilot trial had the benefit of a much bigger sample size, differences in changes between sedentary behaviour (i.e., very light and light activity) could have been investigated using inferential statistics. The relationship between the pain, disability and HRQoL scores of the participants and the type of activity the participants engaged in could also have been analysed in more depth.

Future NSLBP trials should incorporate an objective measure for physical activity. Any use of objective measures needs to be consistently reported, including detailed data collection and evaluation methods. Trials could investigate the different patterns in activity levels of NSLBP patients, which would help identify groups of patients who would benefit from receiving minimal physical activity interventions, such as the intervention provided to group 1 in the feasibility-pilot trial, compared to those patients who may require a different intervention approach (i.e., more focus on a behavioural approach, like groups 2, 3 and 4 of the feasibility-pilot trial). Data on beneficial amounts or doses of physical activity for NSLBP patients can also be obtained. Interventions aimed at increasing physical activity levels can be accurately assessed for effectiveness in increasing activity levels and not just evaluated based on the effect the intervention had on NSLBP outcomes. Accurate adherence rates to the interventions can also be produced. These recommendations would advance the field of physical activity interventions for NSLBP patients by enabling researchers and clinicians to understand the extent of effect physical activity interventions have on NSLBP.

6) How acceptable was the feasibility-pilot trial for the UCO osteopaths?

The feasibility-pilot trial was acceptable to the clinicians at the UCO clinic. All the clinicians agreed that the trial should be "*easy to integrate"* if remembered by the clinicians. However, the semi-structured interview data produced two main findings which would suggest some aspects of the trial was not acceptable to the clinicians. These two main findings related to 1) the acceptability of the term NSBLP amongst the osteopath clinicians, and 2) misinterpretations of the term's physical activity and exercise amongst the clinicians.

Acceptability of the term 'NSLBP'

NSLBP refers to pain in lower back which has no identifiable cause or pathology (Balagué *et al.*, 2012). It was already known that there are discrepancies in definition for NSLBP between clinicians and researchers (Van Der Windt and Dunn, 2013). These discrepancies have all surrounded the differing symptoms of NSLBP – for example, some definitions include the buttocks or pain radiating down the legs, whilst others do not. Whilst this

discrepancy was witnessed in the trial, a different discrepancy emerged as a theme from the qualitative data. This discrepancy for NSLBP was not just about the symptoms, but more so the acceptability of the term between the clinicians. Some of the senior clinicians in the UCO clinic accept the term NSLBP and are happy to use it in practice and as a diagnosis – "[at this] *point of my career, I'm confident with that term and what's excluded."* Other clinicians do not accept this term and will not use it in practice, as the term was reported to be "*vague*" and "*unsafe*". Other osteopaths differed in the types of diagnoses they would include in the umbrella term 'NSLBP'. This discrepancy is important for trials implemented in a clinical setting, using clinicians to recruit eligible patients. If there are multiple definitions for what NSLBP is and the term is not 'acceptable' to some of the clinicians, recruitment for the trial will be hampered. This was observed in the feasibility-pilot trial presented in this thesis. Some of the osteopath students were not met with a senior clinician's approval over identifying some patients as having NSLBP – *"some students are afraid to make the diagnosis of NSLBP in case it doesn't meet with the tutor's approval"*. This led to some of the eligible NSLBP patients not being provided with a recruitment pack during their consultation. This differing acceptability of the term NSLBP amongst clinicians is a novel finding and one which has not yet been highlighted or discussed in the literature.

Clarity in use of the term NSLBP is required. Qualitative research is needed to further unpack the issues around NSLBP for clinicians. A general consensus study is needed to determine what is and is not acceptable to clinicians around the term "NSLBP". Reasons for acceptability can be explored. The results of the consensus study, and a suggested definition for NSLBP could be tested in a trial to examine acceptability amongst clinicians and practitioners.

Confusion in the use of the terms physical activity and exercise

The qualitative data derived from the feasibility-pilot trial highlighted the different interpretations of the word 'physical activity' individuals have. Physical activity is defined as "any bodily movement" (Caspersen, Powell and Christenson, 1985). Exercise is a subset of physical activity that is planned, structured, and repetitive and has a final or an intermediate objective, such as the improvement or maintenance of physical fitness (Caspersen, Powell and Christenson, 1985). These terms were used interchangeably by the clinicians. All the

clinicians agreed that physical activity was beneficial for patients with NSLBP but spoke of incorporating physical activity into treatment plans by prescribing specific exercises. This finding reflects the current NSLBP literature on physical activity interventions whereby interventions are often called physical activity interventions when the intervention itself is exercise based (planned, repetitive and structured). Physical activity interventions aim to increase the amount of physical activity in an individual's daily routine (Dunn *et al.*, 1999). Finding physical activities which can be incorporated as part of an individual's daily routine has been suggested to increase the potential for the maintenance of the behaviour (being active) over time (Ogilvie *et al.*, 2007; Bird *et al.*, 2013).

The terms 'physical activity' and 'exercise' needed to be conceptualised in the trial, with guidance and recommendations on what physical activity is. The definition for physical activity operationalised in the participant information sheets for the clinicians seemed to lack clarity as one senior clinician reported to have found the use of the word 'physical activity' "*misleading"* because it should have said "*everyday day-to-day activity rather than perhaps it being about specific exercise"*. There is no indication in the participant information sheets that the trial was about specific exercise. Extra training for the clinicians in what the term physical activity was defined as in the feasibility-pilot trial was required. It is important to minimise the interchangeability of these terms as potential participants may not have been recruited due to the different interpretations of the term 'physical activity'. For example, if some of the eligible patients received the participant information pack and perceived physical activity as being prescribed specific exercise, it may have not been appealing to them and put them off registering an interest in the trial. Similarly, if an eligible patient asked their treating osteopath what was involved in the trial, the osteopath may have misinterpreted the word 'physical activity' and suggested the trial was about specific exercise. Eligible patients may not have been recruited due to this reason, which is another potential reason behind the small sample size recruited. As a future recommendation there is a need to further define the term physical activity and define the subsets of physical activity which fall under this umbrella (i.e., exercise, household, recreation etc.) (refer to figure 1.3). These definitions need to be easy to adhere to (for recruitment purposes in trials) and acceptable to practitioners and researchers to ensure they are used appropriately

in future trials and in guidelines. Qualitative research can be conducted to work around the ontology of these types of terms and to identify recommendations from various practitioners and clinicians to create standardised and unified terminology for what "physical activity" is and for what "exercise" is, especially when using these terms with NSLBP patients.

7) What is the feasibility of running an RCT in the UCO outpatient clinic?

A feasibility-pilot trial of a pragmatic RCT was performed to investigate the feasibility and acceptability of the trial protocol and the acceptability and credibility of the four interventions designed to increase physical activity in adults with NSLBP. Feasibility was assessed through the use of semi-structured interviews with patient participants and the clinicians in the UCO clinic who consented to participate in the trial.

Based on the recommendations provided by Avery *et al.* (2017) to create criteria for determining feasibility (*see Chapter 6),* the results of the trial indicated that conducting the trial as a full RCT using the current protocol at the UCO outpatient osteopathy clinic was not feasible. The trial design was not appropriate for the context/setting in which the trial was implemented and therefore was not feasible. Multiple problems were identified during the semi-structured interviews, relating to the context of the chosen clinic and the trial design. The timing of the trial (when the trial was introduced into the clinic) was identified as 'the wrong time of year to introduce a trial' by the clinicians in the semi-structured interviews

Timing of the trial

One of the problems highlighted in the interview process was the time of the year the trial began. The trial began in the summer (July 2018) which was described by the students and tutors as a "*chaotic"* time of year. During the summer months (June, July, and August), the second-year students are starting to integrate into the clinic to prepare them for officially working in the clinic when they start their third year in September. The third-year students are preparing to move into their final (fourth year) and the fourth-year students are finishing off their compulsory clinic hours to complete their degree. The clinic tutors are not

always present in clinic as this is also their holiday period. New clinic tutors do not start in the clinic until September, and the Masters students do not start their degree until September. This is known as the "cross-over" period in the clinic. The trial was introduced to the clinic staff and students in researcher-led meetings, in July 2018, informing the clinicians of the trial and what their involvement in the trial would be should they consent to participate in the trial. Some of the tutors and students were not present when the researcher held these meetings and missed the introduction of the trial and did not know about the trial until much later. Some of the UCO students found clinic life "*overwhelming*". The trial was "*another added pressure*" for the students. It has previously been reported in a qualitative trial that students in an Irish student-led clinic found their clinic experience as "a big learning curve" and required more support getting used to the clinical process, especially during the first few months of them starting in the clinic (Kavanagh, Kearns and Mcgarry, 2015). The clinicians were required to identify eligible NSLBP patients (due to data protection and patient confidentiality), and these disruptions would have impacted the recruitment process of the trial and is a reason why the trial recruited only five patient participants.

Several solutions were identified to overcome these issues. One solution was to start the trial later, possibly in January when 1) all new staff have started working in the clinic, 2) the undergraduate students have had time to get used to the processes in clinic and 3) the Masters student have also started their clinic experience and would also have had enough time to get used to clinic life. Another solution would be for the researcher to be more "hands on" and help prepare the students by identifying potential eligible patients during the planning sessions held at the start of the day, when the students review the patients they have coming in. A recruitment pack (containing all the information the patient needs to know about the trial, including consent form and participant information sheet) could be placed in the eligible patient file for the student to hand out during the patient's appointment. Another solution would be to hold weekly meetings about the trial with all the tutors and students to ensure any "late arrivals" to the clinic know about the trial and what is required of them should they consent to the trial. This would also remind the clinicians of the trial as it emerged from the qualitative data that one of the difficulties in running a trial in the clinic was ensuring the clinicians remembered about the on-going trial.

Nature of student-led clinics

The nature of the UCO clinic was detrimental to the operation of the trial. The clinic was an educational student-led clinic and was described by the clinicians as "*chaotic*". Student-led clinics are also referred to as "student-assisted clinics" or "student run clinics" (Frakes *et al.*, 2011). Student-led clinics, also termed student-run clinics, rely on the students to take responsibility for the day-to-day operational running and management of the clinic (Frakes *et al.*, 2011). Previous research has identified several challenges in student-led clinics (Frakes *et al.*, 2011; Howell, Wittman and Bundy, 2012; Black, Palombaro and Dole, 2013; Kavanagh, Kearns and Mcgarry, 2015).

Organisational issues such as the high patient caseloads for the students to manage (number of patients they treat in a day), and time-pressured appointment slots contributed to lowered levels of student adherence with the patient recruitment protocol. These issues were raised in the qualitative interviews with the clinicians (student and tutor osteopaths) where the clinic was described as "*pressured*" and "*chaotic*" with students "*frantic*" with the day-to-day running of the clinic – *"It* [the trial] *could have been easy to integrate, but we got thrown in at the deep end with clinic. We had all of that* [clinic pressure] *to focus on plus* this [the trial]. *This was an added thing on a long list of what we needed to do".* Some of the UCO students described their experience of the clinic like been put "*straight into the deep end*", especially as the onus is on the student to manage their own patient caseloads. One of the osteopath tutors commented that the students are often under pressure due to having "*back-to-back"* patients. High patient case-loads has previously been identified as a problem in three Irish student-led clinics (Kavanagh, Kearns and Mcgarry, 2015) and would have contributed further to the UCO students feeling "overwhelmed" in the clinic, which would have evitability contributed to the low recruitment rates of the feasibility-pilot trial. Inconsistencies in staff levels (number of clinic tutors present in the clinic on a single day) was frequently mentioned by the clinicians as a problem adding to the chaotic nature of the clinic.

This is not a problem with the UCO clinic alone, as organisational problems with student-led clinics, including staffing issues has been previously reported (Kavanagh, Kearns and Mcgarry, 2015). Inconsistency issues with poor clinician attendance to the clinic on a daily

basis were also highlighted in the qualitative data –"*different staff and students throughout the week"* and the clinicians *"never know how many staff are coming in"*. A review of student-led clinics conducted by Kavanagh, Kearns and Mcgarry (2015) highlights how "time-intensive" these student-led clinics are, with organisational issues and high student case-loads being witnessed across three different clinics. Poor attendance issues were also witnessed in these clinics (Kavanagh, Kearns and Mcgarry, 2015) indicating a potential universal problem with student-led clinics. This was observed in the UCO clinic, with students having back-to-back patients and lack of staff added to the chaos in ensuring all appointments kept to time. This made it difficult for some of the senior clinicians to remember to identify eligible NSLBP patients, as the priority was supervising the students properly to ensure the patients received good-quality care and treatment. Inadequate staff disrupts the clinic (Kavanagh, Kearns and Mcgarry, 2015) and the UCO clinicians reported they often needed to rush to make sure all the students were appropriately supervised. This chaotic, pressurised nature of the clinic, especially for the students was reported to be the reason some of the clinicians would "*choose to do it* [the trial] *elsewhere*".

This chaotic nature of student-led clinics needs to be overcome to run a successful RCT. Strategies to help tackle some of the challenges of student-led clinics include providing training (in the recruitment protocol) for the staff and students to make identifying NSLBP patients more autonomous, communicating regularly with the clinicians to ensure the on-going trial is not forgotten in the time-intensive, chaotic nature of the clinic, and by using the planning sessions in the morning and afternoon to help students identify the NSLBP patients before the clinic appointments begin.

This evidence would suggest that student-led clinics are not ideal to conduct RCTs in, unless rigorous methods to overcome these issues can be implemented. Alternatively, private clinics or NHS clinics could be used. However, different types of clinics all have different ways of working and the current protocol for this trial may not be applicable in another clinical setting, without refinements. For trials in an NHS setting external funding would be required to cover the costs of running the trial (i.e., production of relevant materials). The trial would also need to be registered on the European Clinical Trials Database or the International Standard Randomised Controlled Trial Number Register (UK).

Implications for the thesis and wider research community

The findings from this trial provides novel information on non-prescribed physical activity interventions (developed using theoretically based BCTs) for the self-management of NSLBP. This trial is the first to incorporate a wide range of interventions using eleven BCTs to promote and increase physical activity levels in a NSLBP population. The next phase of this research would be to refine the protocol of the feasibility-pilot trial and either re-run it in the UCO student-led clinic, using strategies to overcome the nature of student-led clinics as reported in Kavanagh, Kearns and Mcgarry (2015), or to test the trial protocol in a different private practice clinic. A limitation of this study is the small sample size. The sample size was derived as a result of the recruitment protocol and the non-adherence to the recruitment protocol by some of the clinicians. If a larger sample size had been recruited, it would be expected that interferential statistics could be run to assess effectiveness of the interventions, in increasing physical activity levels, and provide a more in-depth detailed analysis of which BCTs were the most effective. This would have facilitated the NSLBP research community and provided more robust future research recommendations for the development of physical activity interventions for NSLBP patients.

Another limitation of the feasibility-pilot trial was the inability to provide the patient participants, in the groups which received feedback on their activity levels, with instant feedback. Instant feedback on activity levels has not yet been investigated in a NSLBP population. However, the effect of instant feedback to university students has been investigated in previous trials (Narciss and Huth, 2006; Denton *et al.*, 2008; Draper, 2009; Jordan and Mitchell, 2009). Narciss and Huth (2006) reported that instant or prompt feedback is beneficial for motivation and achievement. Initially, feedback was supposed to be delivered face-to-face to the patient participants by the primary researcher. However, the facilities at the UCO clinic did not have a laboratory-based computer on which the accelerometer data could be downloaded. Therefore, the primary researcher used a mobile PC to use the Open Movement Software [V1.0.0.36] to download and analyse the accelerometer data. The data was supposed to be downloaded whilst the patient participants received their osteopathic treatment, which always took place before the patient's meeting with the primary researcher. However, the mobile PC had slow processing units which could not cope with the amount of physical activity data collected by the

accelerometer over a seven-day week and could not download all of the data in time for the patient's appointment with the researcher. As an alternative, the patient participants, who were due to receive instant feedback, had to wait a maximum of twenty-four hours before receiving their feedback on their activity levels via email. The primary researcher took the accelerometer with the data (a new accelerometer was provided to the participants weekly as per the original protocol) to a laboratory-based computer to download and analyse the data. Once the data was analysed the primary researcher, with the patient participant's consent, emailed the relevant feedback to the respective participant. The verbal feedback which was planned to be given to the participants was delivered using the same content as outlined in appendix EE but was delivered in written format via email. This may have affected the impact of the feedback provided to the patients – i.e., as opposed to written feedback, verbal feedback has been suggested to have a significant impact on the receiver's feedback perceptions, increase motivation and increase self-efficacy (Agricola, Prins and Sluijsmans, 2019).

This programme of work has provided the research community with three valuable findings. These findings are 1) the acceptability of feedback on physical activity levels for NSLBP patients (use of the BCT "feedback on behaviour"), 2) the identification of a mounting method to wear an objective measure which can be used in future trials and 3) the confusion between clinicians over the term NSLBP. This confusion can be explored in greater depth in qualitative research, in which research is sparse. Future qualitative research, using practitioners and clinicians, could provide a consensus on a clear definition for the term NSLBP and the conditions and patient presentations which come under this term so that the term is 1) used more consistently in trials moving forward and 2) is agreeable to use in practice for clinicians and practitioners.

8.4 Conclusion

The research presented in this thesis was undertaken to explore how behaviour change interventions for physical activity should be designed and developed, and the optimal way to deliver these interventions to a NSLBP population. The work presented in this thesis has identified three key areas and novel findings which will advance future NSLBP and physical activity research: 1) "feedback on behaviour" was considered to be the most useful BCT incorporated in the physical activity interventions, 2) the differing understandings and acceptability of the term NSLBP by clinicians and 3) the identification of a method to comfortably wear an objective measure for physical activity over a period of time.

Physical activity interventions should be designed and developed using a model for behaviour change and BCTs to enhance effectiveness and patient compliance to the intervention. At present, the interventions designed in this thesis are the first physical activity interventions for NSLBP patients to be designed using a behaviour change model (the BCW) and BCTs. The BCW was identified in this thesis as the most optimal and systematic model to use to design and develop robust interventions for behaviour change, which has been widely used in the fields of academia, policy, and intervention development. Whilst effectiveness of the interventions designed in this work could not be distinguished, qualitative data from the participants provided valuable evaluations of the interventions and the way they were delivered. The BCT "feedback on behaviour" was considered to be the most useful part of the physical activity interventions given to the NSLBP patient participants in the feasibility-pilot trial, to encourage them to increase their levels of physical activity. The delivery of some of the BCTs in the interventions was not optimal or acceptable to the patient participants in the feasibility-pilot trial. Delivering the BCTS "problem solving", "commitment" and "action planning" in paper-format every week of the trial was not acceptable to the patient participants in the trial. Refinement of the modes of delivery for some of the BCTs used in the interventions is needed to maintain and increase participant compliance with the intervention. The results of the feasibility-pilot trial also indicate that it is pertinent to pilot newly designed interventions to ensure they are deliverable in the context in which they are required.

8.4.1 Future research and practical recommendations

Future physical activity interventions for NSLBP patients need to be designed and developed using appropriate behaviour change strategies. The effect of the BCT "feedback on behaviour" should be further investigated to see if this BCT is associated with increasing physical activity levels in NSLBP patients. Additionally, future research needs to investigate the use of BCTs in clinical practice (i.e., do clinicians use any BCTs when routinely advising patients to be active).

The literature presents too many differing definitions for the term NSLBP amongst clinicians, and the acceptability of this term varies between clinicians. Therefore, there is a need for standardised terminology for "NSLBP" to be implemented in future trials. There is a need for a clear universal definition for NSLBP and what constitutes as NSLBP, (including the types of diagnosis clinicians may make and the clinical presentations included in this umbrella term), that is acceptable to practitioners/clinicians). At present, some clinicians also do not agree with the term NSLBP, due to the idea that it is an unsafe, vague term. There also needs to be an agreement of what the terms are in the trials. Clinical trials which rely on the judgement of clinicians to identify eligible NSLBP patients for the trial, will inevitably struggle for recruitment due to this discrepancy. If some of the clinicians recruited in the trial do not agree with the term NSLBP or do not identify patients as having NSLBP, then adherence to the trial protocol by the clinicians becomes a problem. This would obscure the recruitment of patients in trials. Qualitative research in the field is sparse and the findings of this thesis has highlighted the need for this type of research. Qualitative research should focus on the acceptability of the term NSLBP amongst clinicians to produce a standardised term of NSLBP with a definition that is acceptable to and will be used by clinicians moving forward.

Finally, research investigating the effects of physical activity for the self-management of NSLBP needs to incorporate the use of objective measures to measure physical activity. Physical activity is often subjectively measured which can be over- and under-estimated between individuals. The use of an objective measure for physical activity was validated in this thesis, and therefore the gap between participant perception (of how active they were) and how much activity the participant engaged in can be bridged. Future research should incorporate objective measures such as accelerometers to provide valid data to inform best

practice. Guidelines for what constitutes as a clinically minimal change (CMC) in physical activity levels needs to be developed. Determining the effectiveness of physical activity interventions is challenging if there is no indication of a CMC in physical activity levels.

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10 Appendices

Appendix A. Search terms for initial scoping review

MEDLINE	("Low Back Pain"[Mesh] OR "Back Pain, Low" OR "Back Pains, Low" OR "Low Back Pain" OR "Low Back Pains" OR "Pain, Low Back" OR "Pains, Low Back" OR "Lumbago" OR "Lower Back Pain" OR "Back Pain, Lower" OR "Back Pains, Lower" OR "Lower Back Pains" OR "Pain, Lower Back" OR "Pains, Lower Back" OR "Low Back Ache" OR "Ache, Low Back" OR "Aches, Low Back" OR "Back Ache, Low" OR "Back Aches, Low" OR "Low Back Aches" OR "Low Backache" OR "Backache, Low" OR "Backaches, Low" OR "Low Backaches" OR "Low Back Pain, recurrent" OR "Recurrent Low Back Pain" OR "Low Back Pain, Postural" OR "Postural Low Back Pain" OR "Low Back Pain, Mechanical" OR "Mechanical Low Back pain" OR "Low Back Pain, Posterior Compartment") AND ("Activities of Daily Living"[Mesh] OR "Exercise Therapy"[Mesh] OR "ADL" OR "Activities, Daily Living" OR "Physical Activity" OR "Activity, Daily Living" OR "Daily Living Activity" OR "Living Activities, Daily" OR "Exercise"[Mesh] OR "Exercises" OR "Exercise, Physical" OR "Exercises, Physical" OR "Physical Exercise" OR "Physical Exercises" OR "Exercise, Aerobic" OR "Aerobic Exercises" OR "Exercises, Aerobic" OR "Aerobic Exercise") AND Intervention*
PubMed	("Low Back Pain"[Mesh] OR "Back Pain, Low" OR "Back Pains, Low" OR "Low Back Pain" OR "Low Back Pains" OR "Pain, Low Back" OR "Pains, Low Back" OR "Lumbago" OR "Lower Back Pain" OR "Back Pain, Lower" OR "Back Pains, Lower" OR "Lower Back Pains" OR "Pain, Lower Back" OR "Pains, Lower Back" OR "Low Back Ache" OR "Ache, Low Back" OR "Aches, Low Back" OR "Back Ache, Low" OR "Back Aches, Low" OR "Low Back Aches" OR "Low Backache" OR "Backache, Low" OR "Backaches, Low" OR "Low Backaches" OR "Low Back Pain, recurrent" OR "Recurrent Low Back Pain" OR "Low Back Pain, Postural" OR "Postural Low Back Pain" OR "Low Back Pain, Mechanical" OR "Mechanical Low Back pain" OR "Low Back Pain, Posterior Compartment") AND ("Activities of Daily Living"[Mesh] OR "Exercise Therapy"[Mesh] OR "ADL" OR "Activities, Daily Living" OR "Physical Activity" OR "Activity, Daily Living" OR "Daily Living Activity" OR "Living Activities, Daily" OR "Exercise"[Mesh] OR "Exercises" OR "Exercise, Physical" OR "Exercises, Physical" OR "Physical Exercise" OR "Physical Exercises" OR "Exercise, Aerobic" OR "Aerobic Exercises" OR "Exercises, Aerobic" OR "Aerobic Exercise") AND Intervention*
Cochrane Library	#1 MeSH descriptor: [Low Back Pain] this term only #2 MeSH descriptor: [Activities of Daily Living] 2 tree(s) all trees exploded #1 AND #2

SPORTDiscus	("BACKACHE" OR "BACKACHE -- Exercise therapy" OR "BACKACHE -- Treatment" OR "Low back pain" OR "Back Pain, Low" OR "Back Pains, Low" OR "Low Back Pain" OR "Low Back Pains" OR "Pain, Low Back" OR "Pains, Low Back" OR "Lumbago" OR "Lower Back Pain" OR "Back Pain, Lower" OR "Back Pains, Lower" OR "Lower Back Pains" OR "Pain, Lower Back" OR "Pains, Lower Back" OR "Low Back Ache" OR "Ache, Low Back" OR "Aches, Low Back" OR "Back Ache, Low" OR "Back Aches, Low" OR "Low Back Aches" OR "Low Backache" OR "Backache, Low" OR "Backaches, Low" OR "Low Backaches" OR "Low Back Pain, recurrent" OR "Recurrent Low Back Pain" OR "Low Back Pain, Postural" OR "Postural Low Back Pain" OR "Low Back Pain, Mechanical" OR "Mechanical Low Back pain" OR "Low Back Pain, Posterior Compartment") AND "PHYSICAL activity" "Activities of Daily Living" OR "ADL" OR "Activities, Daily Living" OR "Activity, Daily Living" OR "Daily Living Activity" OR "Living Activities, Daily" OR ("EXERCISE" OR "Exercise" OR "Exercises" OR "Exercise, Physical" OR "Exercises, Physical" OR "Physical Exercise" OR "Physical Exercises" OR "Exercise, Aerobic" OR "Aerobic Exercises" OR "Exercises, Aerobic" OR "Aerobic Exercise") AND (DE "Intervention")
PyschINFO	(Back Pain OR Low Back Pain OR Back Pain, Low OR Back Pains, Low OR Low Back Pains OR Pain, Low Back OR Pains, Low Back OR Lumbago OR Lower Back Pain OR Back Pain, Lower OR Back Pains, Lower OR Lower Back Pains OR Pain, Lower Back OR Pains, Lower Back OR Low Back Ache OR Ache, Low Back OR Aches, Low Back OR Back Ache, Low OR Back Aches, Low OR Low Back Aches OR Low Backache OR "Backache, Low OR Backaches, Low OR Low Backaches OR Low Back Pain, recurrent OR Recurrent Low Back Pain OR Low Back Pain, Postural OR Postural Low Back Pain OR Low Back Pain, Mechanical OR Mechanical Low Back pain OR Low Back Pain, Posterior Compartment) AND (Physical Activity OR Activities of Daily Living OR ADL OR Activities, Daily Living OR Activity, Daily Living OR Daily Living Activity OR Living Activity, Daily OR (Exercise OR Exercises OR Exercise, Physical OR Exercises, Physical OR Physical Exercise OR Physical Exercises OR Exercise, Aerobic OR Aerobic Exercises OR Exercises, Aerobic OR Aerobic Exercise) AND (Intervention)
PyschARTICLES	(DE "Back Pain" OR "Low Back Pain" OR "Back Pain, Low" OR "Back Pains, Low" OR "Low Back Pains" OR "Pain, Low Back" OR "Pains, Low Back" OR "Lumbago" OR "Lower Back Pain" OR "Back Pain, Lower" OR "Back Pains, Lower" OR "Lower Back Pains" OR "Pain, Lower Back" OR "Pains, Lower Back" OR "Low Back Ache" OR "Ache, Low Back" OR "Aches, Low Back" OR "Back Ache, Low" OR "Back Aches, Low" OR "Low Back Aches" OR "Low Backache" OR "Backache, Low" OR "Backaches, Low" OR "Low Backaches" OR "Low Back Pain, recurrent" OR "Recurrent Low Back Pain" OR "Low Back Pain, Postural" OR "Postural Low Back Pain" OR "Low Back Pain, Mechanical" OR "Mechanical Low Back pain" OR "Low Back Pain, Posterior Compartment") AND (DE "Physical Activity" OR "Activities

	of Daily Living" OR "ADL" OR "Activities, Daily Living" OR "Activity, Daily Living" OR "Daily Living Activity" OR "Living Activity, Daily" OR “Physical Activity”) OR (DE “Exercise” OR "Exercises" OR "Exercise, Physical" OR "Exercises, Physical" OR "Physical Exercise" OR "Physical Exercises" OR "Exercise, Aerobic" OR "Aerobic Exercises" OR "Exercises, Aerobic" OR "Aerobic Exercise") AND (DE “Intervention”)
ScienceDirect	Intervention* AND ("Activities of Daily Living" OR "ADL" OR "Exercise" OR "Exercises" OR "Daily Living Activity") AND ("Low Back Pain" OR "Lower Back Pain" OR "Lower Back Pains" OR "Low Back Pains" OR "Low Back Ache" OR "Low Back Aches" OR "Low Backache" OR "Low Backaches" OR "Lumbago")
CINHAL	(MH "Low Back Pain" OR "Back Pain, Low” OR “Back Pains, Low” OR “Low Back Pain” OR “Low Back Pains” OR “Pain, Low Back” OR “Pains, Low Back” OR “Lumbago” OR “Lower Back Pain” OR “Back Pain, Lower” OR “Back Pains, Lower” OR “Lower Back Pains” OR “Pain, Lower Back” OR “Pains, Lower Back” OR “Low Back Ache” OR “Ache, Low Back” OR “Aches, Low Back” OR “Back Ache, Low” OR “Back Aches, Low” OR “Low Back Aches” OR “Low Backache” OR “Backache, Low” OR “Backaches, Low” OR “Low Backaches” OR “Low Back Pain, recurrent” OR “Recurrent Low Back Pain” OR “Low Back Pain, Postural” OR “Postural Low Back Pain” OR “Low Back Pain, Mechanical” OR “Mechanical Low Back pain” OR “Low Back Pain, Posterior Compartment”) AND (MH "Activities of Daily Living") OR (MH "Human Activities" OR “ Activities, Daily Living" OR "Activity, Daily Living" OR "Daily Living Activity" OR "Living Activities, Daily" OR "Exercise" OR "Exercises" OR "Exercise, Physical" OR "Exercises, Physical" OR "Physical Exercise" OR "Physical Exercises" OR "Exercise, Aerobic" OR "Aerobic Exercises" OR "Exercises, Aerobic" OR "Aerobic Exercise") AND (“Intervention”)
ISI Web of Science	("Low Back Pain" OR "Back Pain, Low” OR “Back Pains, Low” OR “Low Back Pain” OR “Low Back Pains” OR “Pain, Low Back” OR “Pains, Low Back” OR “Lumbago” OR “Lower Back Pain” OR “Back Pain, Lower” OR “Back Pains, Lower” OR “Lower Back Pains” OR “Pain, Lower Back” OR “Pains, Lower Back” OR “Low Back Ache” OR “Ache, Low Back” OR “Aches, Low Back” OR “Back Ache, Low” OR “Back Aches, Low” OR “Low Back Aches” OR “Low Backache” OR “Backache, Low” OR “Backaches, Low” OR “Low Backaches” OR “Low Back Pain, recurrent” OR “Recurrent Low Back Pain” OR “Low Back Pain, Postural” OR “Postural Low Back Pain” OR “Low Back Pain, Mechanical” OR “Mechanical Low Back pain” OR “Low Back Pain, Posterior Compartment”) AND ("Activities of Daily Living" OR "ADL" OR "Activities, Daily Living" OR "Activity, Daily Living" OR "Daily Living Activity" OR "Living Activity, Daily" OR "Exercise" OR "Exercises" OR “Exercise therapy” OR "Exercise, Physical" OR "Exercises, Physical" OR "Physical Exercise" OR "Physical Exercises" OR "Exercise, Aerobic" OR "Aerobic Exercises" OR "Exercises, Aerobic" OR "Aerobic Exercise") AND Intervention

Appendix B. Systematic review search terms

Pubmed	((((((((((((((((((((((((((((low back pain[MeSH Terms]) OR Back Pain, Low[MeSH Terms]) OR Low Back Pains[MeSH Terms]) OR Back Pains, Low[MeSH Terms]) OR Pain, Low Back[MeSH Terms]) OR Pains, Low Back[MeSH Terms]) OR Lumbago[MeSH Terms]) OR Lower Back Pain[MeSH Terms]) OR Back Pain, Lower[MeSH Terms]) OR Lower Back Pains[MeSH Terms]) OR Pain, Lower Back[MeSH Terms]) OR Pains, Lower Back[MeSH Terms]) OR Low Back Ache[MeSH Terms]) OR Ache, Low Back[MeSH Terms]) OR Aches, Low Back[MeSH Terms]) OR Back Ache, Low[MeSH Terms]) OR Back Aches, Low[MeSH Terms]) OR Low Back Aches[MeSH Terms]) OR Low Backache[MeSH Terms]) OR Backache, Low[MeSH Terms]) OR Backaches, Low[MeSH Terms]) OR Low Backaches[MeSH Terms]) OR Low Back Pain, recurrent[MeSH Terms]) OR Recurrent Low Back Pain[MeSH Terms]) OR Low Back Pain, Postural[MeSH Terms]) OR Postural Low Back Pain[MeSH Terms]) OR Low Back Pain, Mechanical[MeSH Terms]) OR Mechanical Low Back pain[MeSH Terms])) AND ((((((((((((((((physical activity[MeSH Terms]) OR Activities of Daily Living[MeSH Terms]) OR Activities, Daily Living[MeSH Terms]) OR Physical Activity[MeSH Terms]) OR Activity, Daily Living[MeSH Terms]) OR Daily Living Activity[MeSH Terms]) OR Living Activities, Daily[MeSH Terms]) OR Exercise[MeSH Terms]) OR Exercise, Physical[MeSH Terms]) OR Exercises[MeSH Terms]) OR Exercises, Physical[MeSH Terms]) OR Physical Exercise[MeSH Terms]) OR Physical Exercises[MeSH Terms]) OR Exercise, Aerobic[MeSH Terms]) OR Exercises, Aerobic[MeSH Terms]) OR Aerobic Exercise[MeSH Terms]) OR Aerobic Exercise[MeSH Terms])))) AND ((((((((((((((physical therapy[MeSH Terms]) OR Modalities, Physical Therapy[MeSH Terms]) OR Modality, Physical Therapy[MeSH Terms]) OR Physical Therapy Modality) OR Physiotherapy [MeSH Terms]) OR Techniques, Physical Therapy[MeSH Terms]) OR Neurological Physiotherapy[MeSH Terms]) OR Physiotherapy, Neurological[MeSH Terms]) OR Neurophysiotherapy[MeSH Terms])) OR ((((((((((((((((((((((((((((((manual therapy[MeSH Terms]) OR Manipulations, Musculoskeletal[MeSH Terms]) OR Manual Therapy) OR Manual Therapy[MeSH Terms]) OR Therapies, Manual[MeSH Terms]) OR Therapy, Manual[MeSH Terms]) OR Manipulation Therapy[MeSH Terms]) OR Manipulation Therapies[MeSH Terms]) OR Therapies, Manipulation[MeSH Terms]) OR Manipulative Therapies[MeSH Terms]) OR Manipulative Therapy[MeSH Terms]) OR Therapies, Manipulative[MeSH Terms]) OR Therapy, Manipulative[MeSH Terms]) OR Therapy, Manipulation[MeSH Terms]) OR Chiropractic Manipulation[MeSH Terms]) OR Spinal Adjustment[MeSH Terms]) OR Spinal Adjustment, Chiropractic[MeSH Terms]) OR Adjustment, Chiropractic Spinal[MeSH Terms]) OR Adjustments, Chiropractic Spinal[MeSH Terms]) OR Chiropractic Spinal Adjustment[MeSH Terms]) OR Chiropractic Spinal Adjustments[MeSH Terms]) OR Spinal Adjustments, Chiropractic[MeSH Terms]) AND Chiropractic Adjustment[MeSH Terms]) OR Osteopathic manipulation[MeSH Terms]) OR Osteopathic Manipulative Treatment[MeSH Terms]) OR Osteopathic Manipulative Treatments[MeSH Terms]) OR Treatment, Osteopathic Manipulative[MeSH Terms]) OR Treatments, Osteopathic Manipulative[MeSH Terms])) OR ((((((((((((((Rehabilitation[MeSH Terms]) OR habilitation[MeSH Terms]) OR Exercise therapy[MeSH Terms]) OR Remedial Exercise[MeSH Terms]) OR Exercise, Remedial[MeSH Terms]) OR Exercises, Remedial[MeSH Terms]) OR Remedial Exercises[MeSH Terms]) OR Therapy, Exercise[MeSH Terms]) OR Exercise Therapies[MeSH Terms]) OR Therapies, Exercise[MeSH Terms]) OR Exercise, Rehabilitation[MeSH

	Terms]) OR Exercises, Rehabilitation[MeSH Terms]) OR Rehabilitation Exercises[MeSH Terms]) OR ((education[MeSH Terms]) OR feedback[MeSH Terms]))))
Cochrane	#1 MeSH descriptor: [Low Back Pain] explode all trees #2 MeSH descriptor: [Exercise] explode all trees #3 MeSH descriptor: [Musculoskeletal Manipulations] explode all trees #4 MeSH descriptor: [Physical Therapy Modalities] explode all trees #5 MeSH descriptor: [Rehabilitation] explode all trees #6 MeSH descriptor: [Education] explode all trees # 1 AND #2 OR #6 AND #3 AND #4 AND #5
MEDLINE (via EBSCO)	(MH "Low Back Pain") AND (MH "Exercise+") OR (MH "Education") AND (MH "Musculoskeletal Manipulations") OR (MH "Physical Therapy Modalities") OR (MH "Rehabilitation") OR (MH "Exercise Therapy") AND (MH "Clinical Trial")
PsychINFO	low back pain AND (physical activity or exercise) AND (manual therapy or mobilization or manipulation or massage or osteopathy or osteopathic)
PEDro	“Abstract and title: low back pain” AND "Therapy: stretching, mobilisation, manipulation, massage" “Abstract and title: low back pain” AND “Therapy: behaviour modification” “Abstract and title: low back pain” AND “Therapy: education” “Abstract and title: low back pain” AND “Therapy: strength training” “Abstract and title: low back pain” AND “Health promotion”
CINHAL	(MH "Low Back Pain") AND (MH "Exercise+") OR (MH "Education") AND (MH "Musculoskeletal Manipulations") OR (MH "Physical Therapy Modalities") OR (MH "Rehabilitation") OR (MH "Exercise Therapy")

Data collection form

Intervention review – RCTs only

This form can be used as a guide for developing your own data extraction form. Sections can be expanded and added, and irrelevant sections can be removed. It is difficult to design a single form that meets the needs of all reviews, so it is important to consider carefully the information you need to collect and design your form accordingly. Information included on this form should be comprehensive and may be used in the text of your review, 'Characteristics of included studies' table, risk of bias assessment, and statistical analysis.

Notes on using a data extraction form:

- Be consistent in the order and style you use to describe the information for each report.
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.

Review title or ID	
Study ID *(surname of first author and year first full report of study was published e.g., Smith 2001)*	
Report ID	
Report ID of other reports of this study	
Notes	

General Information

Date form completed *(dd/mm/yyyy)*	
Name/ID of person extracting data	
Reference citation	

Study author contact details	
Publication type *(e.g., full report, abstract, letter)*	
Notes:	

Study eligibility

Study Characteristics	Eligibility criteria *(Insert inclusion criteria for each characteristic as defined in the Protocol)*	Eligibility criteria met? Yes No Unclear	Location in text or source *(pg & ¶/fig/table/other)*
Type of study	Protocol	☐ ☐ ☐	
	Randomised Controlled Trial	☐ ☐ ☐	
	Quasi-randomised Controlled Trial	☐ ☐ ☐	
Participants	Adults (≥18 years of age) who are suffering with NSLBP.	☐ ☐ ☐	
Types of intervention	Studies using self-prescribed, unsupervised, and self-directed interventions aimed at promoting physical activity. This means that if the intervention advised the participants to be more active, the participants need to have chosen the way they increase their physical activity levels. This type of intervention may be in the control group.	☐ ☐ ☐	
Types of comparison	Comparing a self-directed, non-prescribed physical activity intervention against any other method of treatment (e.g., physiotherapy, manual therapy, exercise programmes etc.)	☐ ☐ ☐	

Types of outcome measures	(Objective or subjective) which provide a measure for at least one of the following: pain, pain-related disability, and health-related quality of life. Increases in physical activity will be assessed if the study includes a measure for this.	☐ ☐ ☐	
INCLUDE ☐		EXCLUDE ☐	
Reason for exclusion			
Notes:			

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

Characteristics of included studies

Methods

	Descriptions as stated in report/paper		**Location in text or source** *(pg & ¶/fig/table/other)*
Aim of study *(e.g., efficacy, equivalence, pragmatic)*			
Design*(e.g., parallel, crossover, non-RCT)*			
Unit of allocation *(by individuals, cluster/ groups or body parts)*			
Start date			
End date			
Duration of participation *(from recruitment to last follow-up)*			
Ethical approval needed/ obtained for study	☐ Yes ☐ No ☐ Unclear		
Notes:			

Participants

	Description *Include comparative information for each intervention or comparison group if available*	Location in text or source *(pg & ¶/fig/table/other)*
Population description *(from which study participants are drawn)*		
Setting *(including location and social context)*		
Inclusion criteria		
Exclusion criteria		
Method of recruitment of participants *(e.g., phone, mail, clinic patients)*		
Informed consent obtained	☐ Yes ☐ No ☐ Unclear	
Total no. randomised *(or total pop. at start of study for NRCTs)*		
Clusters *(if applicable, no., type, no. people per cluster)*		
Baseline imbalances		
Withdrawals and exclusions *(if not provided below by outcome)*		
Age		
Sex		

Race/Ethnicity		
Severity of illness		
Co-morbidities		
Other relevant socio-demographics		
Subgroups measured		
Subgroups reported		
Notes:		

Intervention groups

Copy and paste table for each intervention and comparison group

Intervention Group 1

	Description as stated in report/paper	Location in text or source *(pg & ¶/fig/table/other)*
Group name		
No. randomised to group *(specify whether no. people or clusters)*		
Theoretical basis *(include key references)*		
Description *(include sufficient detail for replication, e.g., content, dose, components)*		
Duration of treatment period		
Timing *(e.g., frequency, duration of each episode)*		
Delivery *(e.g., mechanism, medium, intensity, fidelity)*		
Providers *(e.g., no., profession, training, ethnicity etc. if relevant)*		
Co-interventions		
Economic information *(i.e., intervention cost, changes in other costs as result of intervention)*		

Resource requirements *(e.g., staff numbers, cold chain, equipment)*		
Integrity of delivery		
Compliance		
Notes:		

Outcomes

Copy and paste table for each outcome.

Outcome 1

	Description as stated in report/paper	Location in text or source *(pg & ¶/fig/table/other)*
Outcome name		
Time points measured *(specify whether from start or end of intervention)*		
Time points reported		
Outcome definition *(with diagnostic criteria if relevant)*		
Person measuring/ reporting		
Unit of measurement *(if relevant)*		

Scales: upper and lower limits *(indicate whether high or low score is good)*			
Is outcome/tool validated?	☐ Yes ☐ No ☐ Unclear		
Imputation of missing data *(e.g., assumptions made for ITT analysis)*			
Assumed risk estimate *(e.g., baseline or population risk noted in Background)*			
Power *(e.g., power & sample size calculation, level of power achieved)*			
Notes:			

Other

Study funding sources *(including role of funders)*		
Possible conflicts of interest *(for study authors)*		
Notes:		

Risk of Bias assessment

See Chapter 8 of the Cochrane Handbook. Additional domains may be added for non-randomised studies.

Domain	Risk of bias Low High Unclear	Support for judgement *(include direct quotes where available with explanatory comments)*	Location in text or source *(pg & ¶/fig/table/other)*
Random sequence generation *(selection bias)*	☐ ☐ ☐		
Allocation concealment *(selection bias)*	☐ ☐ ☐		
Blinding of participants and personnel *(performance bias)*	☐ ☐ ☐	Outcome group: All/	
(if separate judgement by outcome(s) required)	☐ ☐ ☐	Outcome group:	
Blinding of outcome assessment *(detection bias)*	☐ ☐ ☐	Outcome group: All/	
(if separate judgement by outcome(s) required)	☐ ☐ ☐	Outcome group:	
Incomplete outcome data *(attrition bias)*	☐ ☐ ☐	Outcome group: All/	
(if separate judgement by outcome(s) required)	☐ ☐ ☐	Outcome group:	

Selective outcome reporting? *(reporting bias)*	☐ ☐ ☐		
Other bias	☐ ☐ ☐		
Notes:			

Data and analysis

Continuous outcome

	Description as stated in report/paper						Location in text or source *(pg & ¶/fig/table/other)*
Comparison							
Outcome							
Subgroup							
Time point *(specify from start or end of intervention)*							
Post-intervention or change from baseline?							
Results	Intervention			Comparison			
	Mean	SD *(or other variance, specify)*	No. participants	Mean	SD *(or other variance, specify)*	No. participants	
Any other results reported *(e.g., mean difference, CI, P value)*							
No. missing participants							

Reasons missing			
No. participants moved from other group			
Reasons moved			
Unit of analysis *(individuals, cluster/ groups or body parts)*			
Statistical methods used and appropriateness of these *(e.g., adjustment for correlation)*			
Reanalysis required? *(specify)*	☐ Yes ☐ No ☐ Unclear		
Reanalysis possible?	☐ Yes ☐ No ☐ Unclear		
Reanalysed results			
Notes:			

Continuous outcome

	Description as stated in report/paper	Location in text or source *(pg & ¶/fig/table/other)*
Comparison		
Outcome		
Subgroup		

Time point *(specify from start or end of intervention)*							
Post-intervention or change from baseline?							
Results	Intervention			Comparison			
	Mean	SD *(or other variance, specify)*	No. participants	Mean	SD *(or other variance, specify)*	No. participants	
Any other results reported *(e.g., mean difference, CI, P value)*							
No. missing participants							
Reasons missing							
No. participants moved from other group							
Reasons moved							
Unit of analysis *(individuals, cluster/ groups or body parts)*							
Statistical methods used and appropriateness of these *(e.g., adjustment for correlation)*							

Reanalysis required? *(specify)*	☐ Yes ☐ No ☐ Unclear		
Reanalysis possible?	☐ Yes ☐ No ☐ Unclear		
Reanalysed results			
Notes:			

Other information

	Description as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
Key conclusions of study authors		
References to other relevant studies		
Correspondence required for further study information *(from whom, what and when)*		
Notes:		

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	_____	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	_____	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g., online appendix, URL).	_____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_____	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g., psychologist, nursing assistant), describe their expertise, background and any specific training given.	_____	_____
	HOW		

6.	Describe the modes of delivery (e.g., face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	_____	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	_____	_____
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	_____	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	_____	_____
	MODIFICATIONS		
10.ǂ	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	_____	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	_____	_____
12.ǂ	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	_____	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

ǂ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Appendix E: Behaviour change theory and behaviour change technique extraction table

Authors	Intervention	Behaviour change theory used? Yes/No	Behaviour change technique observed? Yes/No

How the table was completed:

Authors – study authors and the citation for the study

Intervention – Description of the intervention including purpose, design and timing of the intervention

Behaviour change theory used? Yes/No – Only filled in if the authors state a specific theory was used. If a theory was not stated in the text but a theory was implied to have been used to design the intervention, then this was filled out with "not stated".

Behaviour change technique observed? Yes/No – BCT coded in the article. Information on the coded BCT (what the BCT was and how it was used in the intervention). Information on the frequency and timing of the BCT was noted.

London South Bank University
EST 1892

Participant Information Sheet

Study title: Comparison of two different methods of attaching accelerometers to the human body for the measurement of physical activity.

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

Purpose of the study:

The purpose of this study is to compare two different methods of attaching accelerometers to the human body in order to collect physical activity data. Research has already demonstrated that by taping an accelerometer to a participant's lower back using double-sided hypoallergenic sticky tape; physical activity data can be adequately captured. There is currently no research or guidance on how effective measuring physical activity is when putting the accelerometer in a pouch and wearing it around the waist using a belt. We aim to run a validation experiment testing the wearing of an accelerometer in a pouch, attached to a belt, against the already established wearing position of an accelerometer attached to the lower back using double sided hypoallergenic sticky tape. This will assess differences in the accelerometer's ability to measure physical activity when it is not directly stuck to the participant's lower back.

Why have I been asked to participate?

You have been asked to participate in this study because:

- *You are over the age of 18*
- *Engage in regular physical activity.*

We aim to recruit 10 people in this study (5 male, 5 female). It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason and without any consequences to you. Whether you decide to take part or not will not affect your established relationship with the primary researcher in any way. Should you agree to take part and then wish to withdraw, please contact the primary researcher by using one of the options listed in the contact section of this information sheet. Please note it will not be possible to withdraw after all of the data analysis has been completed and the manuscript has been sent for publication.

What is involved?

You will need to meet with the researcher on 2 separate occasions. You will be asked to travel to meet the researcher at either London South Bank University sports lab (103 Borough Road, SE1 0AA) or Dartfordians Rugby Club gym (Memorial ground, Bourne Road, Bexley, DA5 1LW). Meetings with the researcher will occur at an agreeable time and date, at the location which is suitable and convenient to you.

On the first occasion, you will be asked to meet with the researcher to have your height and weight measured and provide consent to participate in this study. The researcher will then tape 1 accelerometer to your lower back, using hypoallergenic double-sided sticky tape and also ask you to wear a belt and pouch containing another accelerometer underneath your clothes. If you have notable hair growth on your lower back, then this will need to be shaved before the accelerometer is taped to your back to ensure the tape sticks to the skin. The researcher will wear gloves, wash the area to be shaved with disinfectant wipes and use a disposable razor to remove the hair. Once the hair has been removed the researcher will again wash the skin with disinfectant wipes. This may provide a small stinging sensation, but this will dissipate quickly. Please note that the researcher is female.

The researcher will then ask you to engage in the following activities:

Slow walking	Slow running
Normal walking	Normal running
Fast walking	Fast running
Ascending stairs, descending stairs	

Each of these activities will last around 30 seconds.

The researcher will then give you a new belt and pouch, double sided hypoallergenic sticky tape and 2 accelerometers. You will be asked to wear 1 accelerometer, attached to your lower back with the double-sided sticky tape, and wear the other accelerometer on the belt in the pouch, for one whole day, during your waking hours. We ask that you wear both accelerometers from the moment you wake and start moving around until you are ready to go to sleep. We would like you to do this to investigate the differences in physical activity data collection, from either accelerometer, throughout a normal day. The accelerometer is waterproof so it can be worn in the shower.

The next day you will be asked to meet with the researcher again to return the accelerometers, belt and pouch, at a time and place convenient for you.

If you would like to participate in this study, then please contact the primary researcher using one of the options listed in the contact section of this information sheet.

Possible risks/disadvantages to participation

It is not anticipated that you will be at any disadvantage or suffer any risk from this study. You would be giving up some of your time to meet the researcher and partake in the testing. You will also need to wear the accelerometer attached to your lower back with double sided hypoallergenic sticky tape and the accelerometer in the pouch with the belt throughout 1 typical working day. *The sticky tape/latex free belt may cause some skin irritation and/or redness. If you have sensitive skin or eczema, please consider whether or not you are still happy to participate in this study.*

You will not receive any reimbursement for time or travel if you decide to take part in this research.

Possible benefits/advantages to participation

It is not anticipated that you will personally gain any benefit or advantage by partaking in this research project. On a larger scale your participation could lead to new knowledge in the field of accelerometry and physical activity data collection.

Data collection and confidentiality

All the information collected about you and other participants will be kept strictly confidential (subject to legal limitations). Data generated by the study must be retained in accordance with the University's Code of Practice. All data generated in the course of the research must be kept securely in paper or electronic form for a period of 10 years after the completion of a research project.

All information received from you will be handled in a confidential manner and stored in a locked filing cabinet and on a password protected computer in an environment locked when not occupied. Only the researcher and supervisors of this project will have direct access to the information. Your privacy and anonymity will be ensured by coding any reference to yourself. This information will be held until January 2027 and then destroyed.

What will happen to the results of this study?

The results of the study will be used to inform a larger study which will be undertaken by the primary researcher later on this year. We also aim to disseminate this information to a wider population at conferences, seminars etc. and to publish the results of this study in an academic journal. If you wish to obtain a copy of the published research, then please leave your email at the bottom of the consent form and the primary researcher can send you a copy once the manuscript has been approved.

Who is organising and funding the research?

This research is being conducted as part of a funded PhD research degree at the London Southbank University within the Human Sciences Department of the School of Applied Sciences and is in collaboration with The British School of Osteopathy.

Study approval:

This study has been reviewed and approved by the London Southbank University ethics committee.

Contact details:

For further information or if you have any questions you wish to ask, please do not hesitate to contact Sarah using the details below.

Primary Researcher:
Sarah Williamson
Email: willis75@lsbu.ac.uk
Telephone: 020 7815 7937

Academic supervisor for the project:
Professor Ian Albery
Email: alberyip@lsbu.ac.uk
Telephone: 020 7815 5856

Academic Co-Supervisor for the project:
Mr Steven Vogel
Email: s.vogel@bso.ac.uk
Telephone: 0207 089 5331

Academic Co-Supervisor for the project:
Dr Jin Luo
Email: luoj4@lsbu.ac.uk
Telephone: 020 7815 7941

On behalf of myself and my research team, I thank you for taking the time to read this information sheet.

Appendix G. Consent form (accelerometer pilot 1)

Research Project Consent Form

Full title of Project: Comparison of two different methods of attaching accelerometers to the human body for the measurement of physical activity

Ethics approval registration Number:

Participant ID:

Name:

Researcher Position: Primary researcher

Contact details of Researcher: Email: willis75@lsbu.ac.uk Telephone: 020 7815 7937

Taking part (please tick the box that applies)	Yes	No
I confirm that I have read and understood the information sheet/project brief and/or the student has explained the above study. I have had the opportunity to ask questions.	☐	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without providing a reason.	☐	☐
I agree to take part in the above study.	☐	☐

Use of my information (please tick the box that applies)	Yes	No
I understand my personal details such as phone number and address will not be revealed to people outside the project.	☐	☐
I agree for the data I provide to be stored (after it has been anonymised) in a specialist data centre and I understand it may be used for future research.	☐	☐
I wish to receive a copy of the published research once the manuscript has been approved. Email:		

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

Project contact details for further information:

Project Supervisor/ Head of Division name: Professor Ian Albery

Phone: 020 7815 5856
Email address: alberyip@lsbu.ac.uk

Physical Activity Readiness Questionnaire (PAR-Q)

Many health benefits are associated with regular exercise, and the completion of PAR-Q is a sensible first step to take if you are planning to increase the amount of physical activity in your life.

For most people physical activity should not pose any problem or hazard. PAR-Q is designed to identify the small number of adults for whom physical activity might be inappropriate or those who should have medical advice concerning the type of activity most suitable for them. Common sense is the best guide in answering these few questions.

1. Has your doctor ever said that you have a bone or joint problems, such as arthritis that has been aggravated by exercise or might be made worse with exercise? YES / NO
2. Do you have high blood pressure? YES / NO
3. Do you have low blood pressure? YES / NO
4. Do you have Diabetes Mellitus or any other metabolic disease? YES / NO
5. Has your doctor ever said you have raised cholesterol (serum level above 6.2mmol/L)? YES / NO
6. Has your doctor ever said that you have a heart condition arid that you should only do physical activity recommended by a doctor? YES / NO
7. Have you ever felt pain in your chest when you do physical exercise? YES / NO
8. Is your doctor currently prescribing you drugs or medication? YES / NO
9. Have you ever suffered from unusual shortness of breath at rest or with mild exertion? YES / NO
10. Is there any history of Coronary Heart Disease in your family? YES / NO
11. Do you often feel faint, have spells of severe dizziness or have lost consciousness? YES / NO
12. Do you currently drink more than the average amount of alcohol per week (21 units for men and 14 units for women)? YES / NO
13. Do you currently smoke? YES / NO
14. Do you NOT currently exercise on a regular basis (at least 3 times a week) and/or work in a job that is physically demanding? YES / NO
15. Are you, or is there any possibility that you might be pregnant? YES / NO
16. Do you know of any other reason why you should not participate in a physical activity programme? YES / NO

If you answered YES to any of the questions above, please give details:

If you answered YES to one or more questions: If you have not recently done so, consult with your doctor by telephone or in person before increasing your physical activity and/or taking a fitness appraisal. Tell your doctor what questions you answered 'yes' to on PAR-Q or present your PAR-Q copy. After medical evaluation, seek advice from your doctor as to your suitability for:

I. Unrestricted physical activity starting off easily and progressing gradually, and
II. Restricted or supervised activity to meet your specific needs, at least on an initial basis

Please turn over, complete the form and sign

October 2009

If you answered NO to all questions: If you answered PAR-Q accurately, you have reasonable assurance of your present suitability for:

I. A graduated
exercise
programme II. A
fitness appraisal

Assumption of Risk

I hereby state that I have read, understood and answered honestly the questions above. I also state that I wish to participate in activities, which may include aerobic exercise, resistance exercise and stretching. I realise that my participation in these activities involves the risk of injury and even the possibility of death. Furthermore, I hereby confirm that I am voluntarily engaging in an acceptable level of exercise, which has been recommended to me.

Clients Name:

Clients Signature:

Date:

Trainers Name:

Trainers Signature:

Date:

Research project:

Comparison of two different methods of attaching accelerometers to the human body for the measurement of physical activity

Demographics

Participant code :……

Name ……

Date of Birth ……. Age …….

Height……. Weight…….

Occupation……

Appendix J. Debriefing sheet

This study was an investigation into two different methods used to collect physical activity data in human subjects. *Research has already demonstrated that by taping an accelerometer to a participant's lower back using double-sided hypoallergenic sticky tape; physical activity data can be adequately captured. There is currently no research or guidance on how effective measuring physical activity is when putting the accelerometer in a pouch and wearing it around the waist using a belt. We aimed to run a validation experiment testing the wearing of an accelerometer in a pouch, attached to a belt, against the already established wearing position of an accelerometer attached to the lower back using double sided hypoallergenic sticky tape. This would have demonstrated if there is a significant difference in the accelerometer's ability to measure physical activity when it is not directly stuck to the participant's lower back.*

We anticipate there will not be a significant difference in data collection between the 2 different methods in wearing the accelerometer. If this demonstrated in the results of this study, then the participants in the feasibility-pilot trial for the primary researchers PhD degree will wear the accelerometer in belt and pouch.

Please remember that all the information collected about you and other participants will be kept strictly confidential (subject to legal limitations). Data generated by the study must be retained in accordance with the University's Code of Practice. All data generated in the course of the research must be kept securely in paper or electronic form for a period of 10 years after the completion of a research project. All information received from you will be handled in a confidential manner and stored in a locked filing cabinet and on a password protected computer in an environment locked when not occupied. Only the researcher and supervisors of this project will have direct access to the information. Your privacy and anonymity will be ensured by coding any reference to yourself. This information will be held until January 2028 and then destroyed.

Y*ou are still free to withdraw at any time and without giving a reason and without any consequences to you. Whether you decide to withdraw will not affect your established relationship with the primary researcher in any way. Should you agree to take part and then wish to withdraw, please contact the primary researcher on the email address below. Please note it will not be possible to withdraw after all of the data analysis has been completed and the manuscript has been sent for publication.*

Please contact the primary researcher (Sarah Williamson) at the following email address willis75@lsbu.ac.uk if you have any further questions. If you have any questions you would like to contact the supervisory team with, please see below for their contact details.

Academic supervisor for the project:
Professor Ian Albery
Email: alberyip@lsbu.ac.uk
Telephone: 020 7815 5856

Academic Co-Supervisor for the project:

Mr Steven Vogel
Email: s.vogel@uco.ac.uk
Telephone: 0207 089 5331

Academic Co-Supervisor for the project:
Dr Jin Luo
Email: luoj4@lsbu.ac.uk
Telephone: 020 7815 7941

Thank you again for your participant and co-operation in this study!

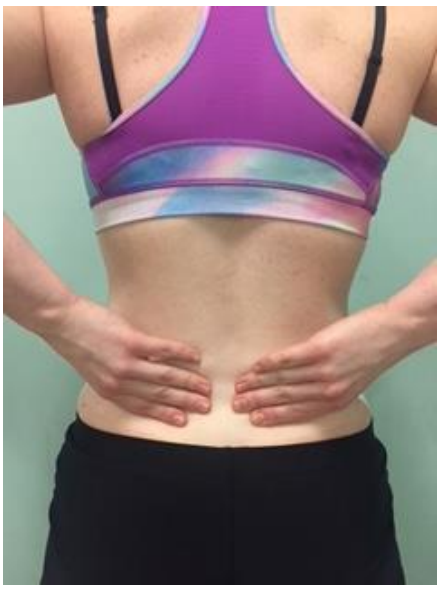
Appendix K: Instructions on how to wear the accelerometer belt

Study title: Comparison of two different methods of attaching accelerometers to the human body for the measurement of physical activity – Part 2

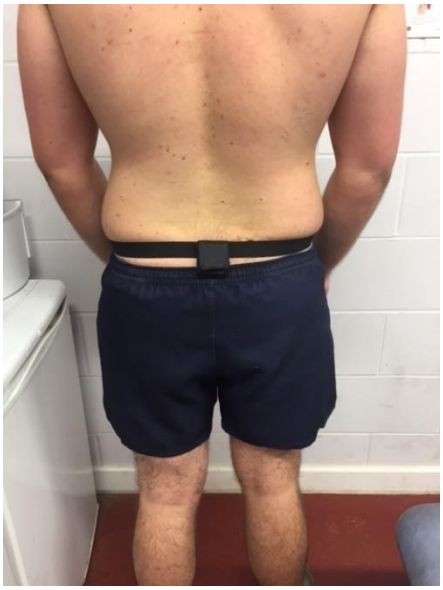
Thank you for volunteering to participate in this study. Your time and effort into this study are greatly appreciated by the primary researcher and research team.

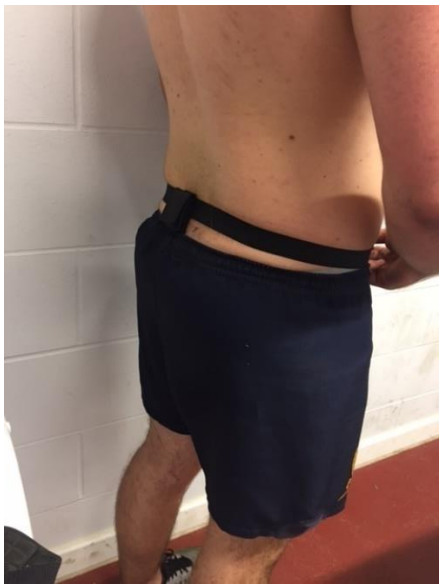
Below are a set of instructions on how to the belt should be worn. There are pictures for further guidance. You do not need to worry about attaching the accelerometer inside the pouch. The primary researcher has done this for you so all you need to do is fasten the belt around your waist. If you have any questions, please do not hesitate to contact the primary researcher using the contact information at the bottom of this sheet.

1. Feel your lower back for the dimples of your pelvis or feel at your sides for your hips bones. Once you have located your hip bones follow the curve your hip round to your lower back until you locate the bony prominence (feels like flat bone) next to your lower spine (just above your buttocks).



2. Once you have found the bony prominence join your hands together on top of the spine, please place the belt around your waist, with the pouch coming to rest on your lower back.





3. *Ensure the belt is fastened for a snug fit and is worn on the lower part of your hip.*

Contact details:

Primary Researcher:
Sarah Williamson
Email: willis75@lsbu.ac.uk
Telephone: 020 7815 7937

Academic supervisor for the project:
Professor Ian Albery
Email: alberyip@lsbu.ac.uk
Telephone: 020 7815 5856

Academic Co-Supervisor for the project:
Mr Steven Vogel
Email: s.vogel@uco.ac.uk
Telephone: 0207 089 5331

Academic Co-Supervisor for the project:
Dr Jin Luo
Email: luoj4@lsbu.ac.uk
Telephone: 020 7815 7941

London South Bank University
EST 1892

Participant Information Sheet

Study title: Comparison of two different methods of attaching accelerometers to the human body for the measurement of physical activity – Part 2.

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

Purpose of the study:

The purpose of this study is to compare two different methods of attaching accelerometers to the human body in order to collect physical activity data. Research has already demonstrated that by taping an accelerometer to a participant's lower back using double-sided hypoallergenic sticky tape; physical activity data can be adequately captured. There is currently no research or guidance on how effective measuring physical activity is when putting the accelerometer in a pouch and wearing it around the waist using a belt. We aim to run a validation experiment testing the wearing of an accelerometer in a pouch, attached to a belt, against the already established wearing position of an accelerometer attached to the lower back using double sided hypoallergenic sticky tape. This will assess differences in the accelerometer's ability to measure physical activity when it is not directly stuck to the participant's lower back. We also wish to see if there is a difference between the data collected when an accelerometer is placed in a different position.

Why have I been asked to participate?

You have been asked to participate in this study because:

- *You are over the age of 18*
- *Engage in regular physical activity.*

We aim to recruit 10 people in this study (5 male, 5 female). It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason and without any consequences to you. Whether you decide to take part or not will not affect your established relationship with the primary researcher in any way. Should you agree to take part and then wish to withdraw, please contact the primary researcher by using one of the options listed in the contact

section of this information sheet. Please note it will not be possible to withdraw after all of the data analysis has been completed and the manuscript has been sent for publication.

What is involved?

You will need to meet with the researcher on 2 separate occasions. You will be asked to travel to meet the researcher at either London South Bank University sports lab (103 Borough Road, SE1 0AA) or Dartfordians Rugby Club gym (Memorial ground, Bourne Road, Bexley, DA5 1LW). Meetings with the researcher will occur at an agreeable time and date, at the location which is suitable and convenient to you.

On the first occasion, you will be asked to meet with the researcher to have your height and weight measured and provide consent to participate in this study. You will be asked to read a set of instructions, with information on how to wear the belt, with an accelerometer in its pouch. You will then be asked to put on the belt as you have understood from the set of instructions given. The researcher will not correct you if the belt is placed differently from the instructions but will note down if it is in the correct position.

Once the belt is in the place, you will be asked to step on the treadmill to complete some controlled activities. The controlled activities are:

Slow walking	Slow running
Normal walking	Normal Running
Fast walking	Fast running
	Ascending and descending stairs

Each of these activities will last around 30 seconds.

Once the activities are complete, you will be given a 5-minute rest period and asked to remove the belt, with the pouch and accelerometer. After 5 minutes, the researcher will proceed to attach another accelerometer to your lower back using double sided hypoallergenic sticky tape. Once the new accelerometer is in place, you will be asked to complete the same controlled activities again. If you have notable hair growth on your lower back, then this will need to be shaved before the accelerometer is taped to your back to ensure the tape sticks to the skin. The researcher will wear gloves, wash the area to be shaved with disinfectant wipes and use a disposable razor to remove the hair. Once the hair has been removed the researcher will again wash the skin with disinfectant wipes. This may provide a small stinging sensation, but this will dissipate quickly. Please note that the researcher is female.

On the second meeting with the researcher, you will be asked to complete the exact same procedure as you did on your first visit.

If you would like to participate in this study, then please contact the primary researcher using one of the options listed in the contact section of this information sheet. Please note that you

are free to withdraw from the study at any time, without consequence or detriment. After you have completed your data collection you will have a period of 1 month to withdraw if you decide to do so.

Possible risks/disadvantages to participation

It is not anticipated that you will be at any disadvantage or suffer any risk from this study. You would be giving up some of your time to meet the researcher and partake in the testing. *The sticky tape/latex free belt, and the shaving (if necessary) may cause some skin irritation and/or redness. If you have sensitive skin or eczema, please consider whether or not you are still happy to participate in this study. Whilst the research is only going to reduce the length of the back hairs (if needed), ingrown hairs may be a side-effect. Please exfoliate the area after the study and apply moisturizer, or another hydrating substance to minimise this. If it is suggested your back should be shaved, and you are not happy with this, please know you are free to withdraw, without consequences or detriment.*

You will not receive any reimbursement for time or travel if you decide to take part in this research.

Possible benefits/advantages to participation

It is not anticipated that you will personally gain any benefit or advantage by partaking in this research project. On a larger scale your participation could lead to new knowledge in the field of accelerometry and physical activity data collection.

Data collection and confidentiality

All the information collected about you and other participants will be kept strictly confidential according to the general data protection regulations (GDPR) (subject to legal limitations). Data generated by the study must be retained in accordance with the University's Code of Practice. All data generated in the course of the research must be kept securely in paper or electronic form for a period of 10 years after the completion of a research project.

All information received from you will be handled in a confidential manner and stored in a locked filing cabinet and on a password protected computer in an environment locked when not occupied. Only the researcher and supervisors of this project will have direct access to the information. Your privacy and anonymity will be ensured by coding any reference to yourself. This information will be held until January 2028 and then destroyed.

What will happen to the results of this study?

The results of the study will be used to inform a larger study which will be undertaken by the primary researcher later on this year. We also aim to disseminate this information to a wider population at conferences, seminars etc. and to publish the results of this study in an academic journal. If you wish to obtain a copy of the published research, then please leave your email at the bottom of the consent form and the primary researcher can send you a copy once the manuscript has been approved.

Who is organising and funding the research?

This research is being conducted as part of a funded PhD research degree at the London Southbank University within the Human Sciences Department of the School of Applied Sciences and is in collaboration with The University of College University.

Study approval:

This study has been reviewed and approved by the School of Applied Sciences Ethics Committee. If you have question or concern about the ethical conduct of this study, then please contact the School of Applied Sciences Ethics Committee on SASethics@lsbu.ac.uk

Contact details:

For further information or if you have any questions you wish to ask, please do not hesitate to contact Sarah using the details below.

Primary Researcher:
Sarah Williamson
Email: willis75@lsbu.ac.uk
Telephone: 020 7815 7937

Academic supervisor for the project:
Professor Ian Albery
Email: alberyip@lsbu.ac.uk
Telephone: 020 7815 5856

Academic Co-Supervisor for the project:
Mr Steven Vogel
Email: s.vogel@uco.ac.uk
Telephone: 0207 089 5331

Academic Co-Supervisor for the project:
Dr Jin Luo
Email: luoj4@lsbu.ac.uk
Telephone: 020 7815 7941

On behalf of myself and my research team, I thank you for taking the time to read this information sheet.

Primary researcher signature: Date:

Appendix M: Consent form (accelerometer pilot 2)

London South Bank University
EST 1892

Research Project Consent Form

Full title of Project: Comparison of two different methods of attaching accelerometers to the human body for the measurement of physical activity – Part 2

Ethics approval registration Number:

Participant ID:

Name:

Researcher Position: Primary researcher

Contact details of Researcher: Email: willis75@lsbu.ac.uk Telephone: 020 7815 7937

Taking part (please tick the box that applies)	Yes	No
I confirm that I have read and understood the information sheet/project brief and/or the student has explained the above study. I have had the opportunity to ask questions.	☐	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without providing a reason.	☐	☐
I agree to take part in the above study.	☐	☐
I understand I may require my back to be shaved to remove excessive hair. The reasons for this have been sufficiently outlined and the possible side-effects have been explained to me. I have had the opportunity to ask questions on this and understand I am free to withdraw if I am not happy to have my back shaved.	☐	☐

Use of my information (please tick the box that applies)	Yes	No
I understand my personal details such as phone number and address will not be revealed to people outside the project.	☐	☐
I agree for the data I provide to be stored (after it has been anonymised) in a specialist data centre and I understand it may be used for future research.	☐	☐
I wish to receive a copy of the published research once the manuscript has been approved. Email:		

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

Project contact details for further information:

Primary Researcher:
Sarah Williamson
Email: willis75@lsbu.ac.uk
Telephone: 020 7815 7937

Academic supervisor for the project:
Professor Ian Albery
Email: alberyip@lsbu.ac.uk
Telephone: 020 7815 5856

Academic Co-Supervisor for the project:
Mr Steven Vogel
Email: s.vogel@uco.ac.uk
Telephone: 0207 089 5331

Academic Co-Supervisor for the project:
Dr Jin Luo
Email: luoj4@lsbu.ac.uk
Telephone: 020 7815 7941

Appendix N: Debriefing sheet

This study was an investigation into two different methods used to collect physical activity data in human subjects. *Research has already demonstrated that by taping an accelerometer to a participant's lower back using double-sided hypoallergenic sticky tape; physical activity data can be adequately captured. There is currently no research or guidance on how effective measuring physical activity is when putting the accelerometer in a pouch and wearing it around the waist using a belt. We aimed to run a validation experiment testing the wearing of an accelerometer in a pouch, attached to a belt, against the already established wearing position of an accelerometer attached to the lower back using double sided hypoallergenic sticky tape. This would have demonstrated if there is a significant difference in the accelerometer's ability to measure physical activity when it is not directly stuck to the participant's lower back.*

We anticipate there will not be a significant difference in data collection between the 2 different methods in wearing the accelerometer. If this demonstrated in the results of this study, then the participants in the feasibility-pilot trial for the primary researchers PhD degree will wear the accelerometer in belt and pouch.

Please remember that all the information collected about you and other participants will be kept strictly confidential (subject to legal limitations). Data generated by the study must be retained in accordance with the University's Code of Practice. All data generated in the course of the research must be kept securely in paper or electronic form for a period of 10 years after the completion of a research project. All information received from you will be handled in a confidential manner and stored in a locked filing cabinet and on a password protected computer in an environment locked when not occupied. Only the researcher and supervisors of this project will have direct access to the information. Your privacy and anonymity will be ensured by coding any reference to yourself. This information will be held until January 2028 and then destroyed.

Y*ou are still free to withdraw at any time and without giving a reason and without any consequences to you. Whether you decide to withdraw will not affect your established relationship with the primary researcher in any way. Should you agree to take part and then wish to withdraw, please contact the primary researcher on the email address below. Please note it will not be possible to withdraw after all of the data analysis has been completed and the manuscript has been sent for publication.*

Please contact the primary researcher (Sarah Williamson) at the following email address willis75@lsbu.ac.uk if you have any further questions. If you have any questions you would like to contact the supervisory team with, please see below for their contact details.

Academic supervisor for the project:
Professor Ian Albery
Email: alberyip@lsbu.ac.uk
Telephone: 020 7815 5856

Academic Co-Supervisor for the project:

Mr Steven Vogel
Email: s.vogel@uco.ac.uk
Telephone: 0207 089 5331

Academic Co-Supervisor for the project:
Dr Jin Luo
Email: luoj4@lsbu.ac.uk
Telephone: 020 7815 7941

Thank you again for your participant and co-operation in this study!

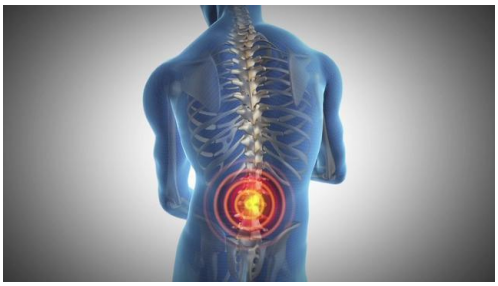
Appendix O: Posters for recruitment

London South Bank University
EST 1892

University College of Osteopathy

New at the UCO or returning with a new episode of back pain?

Are you 18+ years old?



Would you be willing to take part in a research study investigating whether physical activity may be beneficial for low back pain?

Interested, ask the clinician treating you or contact:

Sarah Williamson

Email: willis75@lsbu.ac.uk

Telephone: 020 7815 7937

Appendix P: Cover letter to the patient

London South Bank University
EST 1892

University College of Osteopathy

98-118 Southwark Bridge Road, London, SE1 0BQ **Tel:** 020 7089 5360

Dear potential participant,

The University College of Osteopathy is collaborating with London Southbank University in a research study investigating the effect of physical activity and feedback has on low back pain.

During your appointment today, your osteopath identified that you may be eligible to take part in our study as you have non-specific low back pain.

Thank you very much for expressing an interest in the study.

In order to decide whether or not you want to take part, please read the information about the study (enclosed).

If you are interested in taking part please contact the lead researcher Sarah, directly by e-mail or telephone and we will arrange an appointment discuss any further questions you may have and to enrol you into the study if you wish to take part.

Your decision to take part in the study or not will have no effect on your current or future care at The University College of Osteopathy Clinic.

Many thanks,

Sarah Williamson
PhD student
Lead researcher

Professor Ian Albery
Professor of Psychology at London South Bank University.
Supervisor to Sarah Williamson

Mr Steven Vogel
Deputy Vice-chancellor (Research).
University College of Osteopathy
Co-supervisor to Sarah Williamson

Dr Jin Luo
Co-supervisor to Sarah Williamson

Participant Information Sheet

Study title: Effect of physical activity promotion on people with non-specific low back pain: a randomised controlled feasibility study.

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

Background

This study is a collaboration between The University College of Osteopathy (UCO) and London Southbank University (LSBU). Professor Ian Albery and Dr Jin Luo from Southbank and Steven Vogel from UCO are supervising Sarah Williamson as part of her PhD.

What is the study about?

This study is aiming to run a mini trial to see if the trial of the same design would be viable to run on a larger scale. This study is focussing on the impact physical activity can have on patients with low back pain. We are looking at increasing the amount of physical activity a patient does and monitoring that through the use of an accelerometer (a device that measures physical activity). Research has suggested that physical activity may be beneficial for patients with non-specific low back pain as physical activity has been shown to be effective on other musculoskeletal conditions like osteoarthritis. Current guidance suggests that clinicians recommend physical activity as part of the management of back pain.

Why have I been asked to participate?

You have been asked to participate in this study because you are a new or pre-existing patient (with a new episode of LBP) at the University College of Osteopathy (UCO).

We aim to recruit between 40-70 participants for this study. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

What is involved?

The project involves:

- Your participation for 5 weeks wearing a small device (an accelerometer) daily, which will monitor your physical activity levels during waking hours (apart from when you are showering or engaging in any aquatic based activities, such as swimming as the accelerometer is not waterproof).

- Meeting with the researcher, weekly (coinciding with your osteopath appointment at the clinic) to download the information from the accelerometer, for 5 weeks. If you do not have a weekly appointment, we kindly ask if you would still be available to come to the UCO clinic to meet with the researcher at weekly intervals.

- Fill out a few questionnaires at the start of the study, at the end of the 5 weeks and then again 3 months after your involvement in the study. These questionnaires will be the same.

- After the first 5 weeks, you will be invited to meet with the researcher for an interview. The purpose of these interviews is to get your feedback on the components of the study, so the researcher can gain an appreciation of what works well for the participants and what may need changing for the benefit of the participant.

- Osteopathic treatment will be continued as part of your normal treatment if you decide to participate in this study.

- If you take part, you would be randomly assigned to 1 of 4 groups.

Do I have to take part?

No. It is up to you to decide whether to take part or not. If you do participate in the study, you will be given this information sheet to keep and be asked to sign a consent form. You are free to withdraw at any time and without giving a reason. A decision to withdraw, or a decision not to take part, will not affect the care and treatment you receive at the UCO now or in the future.

What do I have to do?

If you are willing to participate in the study, you will be invited to meet the primary researcher of this study at the University College of Osteopathy Clinic (Southwark Bridge Road in SE1) for a brief interview which lasts approximately fifteen minutes. This interview can take place on the day of your treatment appointment at the UCO clinic or at a mutually agreeable date and time. The interview will provide an opportunity for you to answer questions and give your consent to take part if you decide you would like to be involved in the study. In addition, if you decide to take part, on your first visit with the researcher you will:

- Have some measurements taken (height, weight, waist and hip circumference), using a tape measure and scales
- Fill out a few questionnaires to measure your back pain and back related disability.

- Be given an accelerometer (small device to measure your physical activity levels).

An accelerometer is a small, light device, designed to measure acceleration. You can attach the accelerometer to the low back using a latex-free belt worn around your waist, underneath your clothes. We have enclosed further information about the accelerometer as a frequently asked questions sheet (enclosed). We ask that you would wear this device every day, during waking hours (except for when you are showering or asleep) for 3 days. During this period, we ask that you continue with your normal activity routine. You will then be randomly assigned to one of 4 research groups. You will be invited to meet with the researcher once a week so she can download the data from the accelerometer and answer any questions you may have. These meetings with the researcher will be aligned with your normal osteopathic appointment where possible.

Participants in group 1 will:

- Be given an accelerometer with charging equipment to be worn for a period of 5 weeks. You will need to charge the accelerometer every 24 hours during sleeping hours by plugging it into the USB charging cable similar to cables used to charge phones.
- Be asked to be as physically active as possible, within your pain levels.
- Receive an education sheet on the benefits of physical activity on low back pain.
- Receive normal osteopathic care.

Participants in group 2 will:

- Be given an accelerometer with charging equipment to be worn for a period of 5 weeks. You will need to charge the accelerometer every 24 hours during sleeping hours by plugging it into the USB charging cable similar to cables used to charge phones.
- Be asked to be as physically active as possible, within your pain levels.
- Receive an education sheet on the benefits of physical activity on low back pain.
- Receive weekly feedback on their activity levels with the researcher.
- Receive normal osteopathic care.

Participants in group 3 will:

- Be given an accelerometer with charging equipment to be worn for a period of 5 weeks. You will need to charge the accelerometer every 24 hours during sleeping hours by plugging it into the USB charging cable similar to cables used to charge phones.

- Be asked to be as physically active as possible, within your pain levels.

- Receive an education sheet on the benefits of physical activity on low back pain.

- Will be asked to complete an exercise sheet on how, where, when and for how long they will aim to be more physically active, weekly with the researcher.

- Receive normal osteopathic care.

Participants in group 4 will:

- Be given an accelerometer with charging equipment to be worn for a period of 5 weeks. You will need to charge the accelerometer every 24 hours during sleeping hours by plugging it into the USB charging cable similar to cables used to charge phones.

- Be asked to be as physically active as possible, within your pain levels.

- Receive an education sheet on the benefits of physical activity on low back pain.

- Receive weekly feedback on their activity levels with the researcher

- Will be asked to complete an exercise sheet on how, where, when and for how long they will aim to be more physically active

- Receive normal osteopathic care

All groups will be monitored over a 5-week duration. Participants in each group will need to make weekly visits to the researcher (which can coincide with your osteopathic treatment day) in order for the researcher to download the activity data off of the accelerometer. The researcher will then wipe your accelerometer clean so that more physical activity data can be collected.

After the 5 weeks, we will analyse all of the data obtained from the accelerometer. We will also ask you to re-fill out the questionnaires you completed at the start of your involvement in the study. Participants from both groups will also be invited to attend an interview with the researcher lasting between approximately 30 to 60 minutes. As this is a feasibility study your

investment in the project is highly valued, and we are very keen to find out your thoughts on the study. This interview is to get your point of view on the study and how you found the different processes of the study – i.e., how you found wearing the accelerometer, the questionnaires you had to fill in. These interviews will be digitally recorded so the researcher can write up the relevant information you have provided. Any personal reference or personal information will be anonymised and coded. These interviews will take place at the UCO clinic at a time mutually agreeable between yourself and the researcher.

Once you have completed the study, we will be in touch with you after 3 months to see how you are getting on, and to re-assess your pain and back related disability, with some of the questionnaires you would have filled out previously. We will send you the questionnaires by post. If you do not respond within 2 weeks, we will send you the questionnaires again. No response one week after we have sent you the questionnaires again, we will telephone you to make sure you received them. Should you not respond to this within another week we will not contact you further.

Are there any disadvantages to taking part?

It is not anticipated that you will be at any disadvantage or suffer any risk from this study. You would be giving up some of your time to meet the researcher and complete questionnaires as well as wearing the accelerometer over a period of 5 weeks.

There is no reimbursement available for taking part in this research either for the treatment you are having in the clinic or for the travel to meet with the researcher.

We are unsure if you will experience a reduction in your pain or disability levels in relation to being in a group as part of this study. You are free to withdraw from the study and not have your information included, at any time up to the time of completion of the study.

What if my pain gets worse?

We do not anticipate that taking part in this study will aggravate your symptoms, but recognise that the intensity of back pain can vary day to day.

However, if you agree to participate and you feel that you back pain is increasing you should contact the osteopathic team at the UCO in the first instance or your GP if you have further concerns about your wellbeing. You are also asked to contact the primary researcher so that they are aware of this. You may withdraw from the study at any time without question and without detriment.

In the unlikely event that you come to harm related to your participation in this study you will have insurance cover under LSBU indemnity or if you feel harmed by the treatment/care you received from the osteopaths you are covered by UCO indemnity. If you have private insurance and would like to take part in this study, be sure to let your insurer know that you are taking part in this study, as this may affect your health insurance.

What do I do if I have any concerns or complaints?

If you have a concern about any aspect of this study, you should ask to speak with the following contact(s) who will do their best to answer your questions:

Primary Researcher:
Sarah Williamson
Email: willis76@lsbu.ac.uk
Telephone: 020 7815 7937

If you have any complaints about the way, you have been dealt with during the study or other concerns relating to the research you can contact the following:

Academic supervisor for the project:
Professor Ian Albery
Email: alberyip@lsbu.ac.uk
Telephone: 020 7815 5856

Academic Co-Supervisor for the project:
Mr Steven Vogel
Email: s.vogel@uco.ac.uk
Telephone: 0207 089 5331

Academic Co-Supervisor for the project:
Dr Jin Luo
Email: luoj4@lsbu.ac.uk
Telephone: 020 7815 7941

Finally, if you remain unhappy and wish to complain formally by contacting:

Chair of the Research Ethics Committee of School of Applied Sciences

Dr Lynne Dawkins
Email: dawkinl3@lsbu.ac.uk
Telephone: 020 7815 5422

If you have any complaints about the way, you have been dealt with during your treatment session or other concerns relating to your care you can contact a member of the UCO clinic staff.

For further information please go to https://www.clinic.uco.ac.uk/about-osteopathy/regulations

Data collection and confidentiality

All the information collected about you and other participants will be kept strictly confidential (subject to legal limitations). Data generated by the study will be retained in accordance with the LSBU's Code of Practice. All data generated in the course of the research must be kept securely in paper or electronic form for a period of 10 years after the completion of a research project.

All information received from you will be handled in a confidential manner and stored in a locked filing cabinet and on a password protected computer, in an environment locked when not occupied. Only the researcher and supervisors of this project will have direct access to

the information. Your privacy and anonymity will be ensured by coding any reference to you. This information will be held until January 2021 and then destroyed. Your consent form will be copied and put into your patient file at the clinic. The purpose of this is just to make your treating osteopath aware that you are involved in the study, for their treatment purposes, and so the osteopath is aware that you will be wearing some equipment which can be removed throughout the duration of your treatment session.

What will happen to the results of this study?

The results of the study will be used as part of a PhD thesis for Sarah Williamson (primary researcher). We also aim to disseminate this information to a wider population at conferences, seminars etc. and to publish the results of this study in an academic journal. If you wish to obtain a copy of the published research, then please leave your email at the bottom of the consent form and the primary researcher can send you a copy once the manuscript has been approved.

Who is organising and funding the research?

This research is being conducted as part of a funded PhD research degree at the London Southbank University within the Human Sciences department of the School of Applied Sciences. This research is also part funded by the University College of Osteopathy.

Study approval:

This study has been reviewed and approved by the London Southbank University research ethics committee and the University College of Osteopathy research ethics committee.

Contact details:

For further information or if you have any questions you wish to ask, please do not hesitate to contact Sarah using the details below.

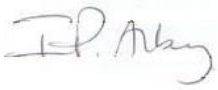
Primary Researcher:
Sarah Williamson
Email: willis76@lsbu.ac.uk
Telephone: 020 7815 7937

Academic supervisor for the project:
Professor Ian Albery
Email: alberyip@lsbu.ac.uk
Telephone: 020 7815 5856

Academic Co-Supervisor for the project:
Mr Steven Vogel
Email: s.vogel@uco.ac.uk
Telephone: 0207 089 5331

Academic Co-Supervisor for the project:
Dr Jin Luo
Email: luoj4@lsbu.ac.uk
Telephone: 020 7815 7941

On behalf of myself and my research team, I thank you for taking the time to read this information sheet.

Sarah Williamson

PhD student

Lead researcher

Professor Ian Albery

Professor of Psychology at London South Bank University.

Supervisor to Sarah Williamson

Mr Steven Vogel

Deputy Vice-chancellor (Research).

University College of Osteopathy

Co-supervisor to Sarah Williamson

Dr Jin Luo

Co-supervisor to Sarah Williamson

Appendix R: Patient participant consent form

Research Project Consent Form

Full title of Project: Effect of physical activity promotion on people with non-specific low back pain: a randomised controlled feasibility study

Ethics approval registration Number: LSBU:SAS1812, UCO: 12/04/18

Participant ID:

Name: Sarah Williamson

Researcher Position: Primary researcher

Contact details of Researcher: Email: willis76@lsbu.ac.uk **Telephone: 020 7815 7937**

Taking part (please initial the box that applies)	Please initial
I confirm that I have read and understood the information sheet/project brief and/or the student has explained the above study. I have had the opportunity to ask questions and my questions have been answered to my satisfaction.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without providing a reason and without detriment to care and legal rights.	
I agree to take part in the above study.	

Use of my information (please initial the box that applies)	Please initial
I understand my personal details such as phone number and address will not be revealed to people outside the project.	
I understand that my data/words may be quoted in publications, reports, posters, web pages, and other research outputs.	
I agree for the data I provide to be stored (after it has been anonymised) in a specialist data centre for 10 years, after which it will be destroyed.	
I agree to the interview being audio recorded.	
I agree to the use of anonymised quotes in publications.	

I wish to receive a copy of the published research once the manuscript has been approved. Email:	

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

Project contact details for further information:
Project Supervisor/ Head of Division name: Professor Ian Albery

Phone: 020 7815 5856
Email address: alberyip@lsbu.ac.uk

1 copy for the researcher and 1 copy for the participant to keep

FAQ for accelerometer

What is an accelerometer?

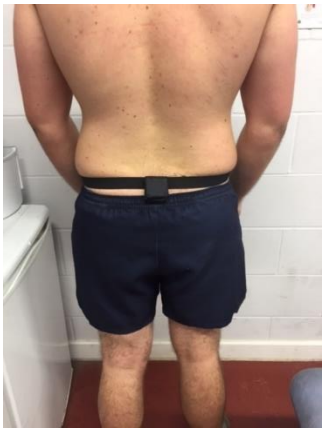
An accelerometer is a small, electromechanical device capable of measuring acceleration forces. The forces an accelerometer can measure may be static – e.g., the constant force of gravity pulling at your feet – or dynamic – e.g., caused by moving or vibrating the accelerometer.

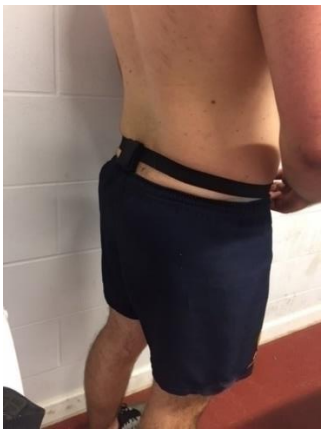
What do they do?

Accelerometers work in a similar way to pedometers or a FitBit, but they do not just simply count steps. For the purposes of this study, the accelerometer will be measuring the intensity of how fast you are moving and the force which you are exerting. This will allow us to calculate and analyse how intense the physical activity you undertake is.

How do I wear it?

We ask that you wear the accelerometer on your lower back, between the 2 dimples of your pelvis. We will provide you with a latex-free belt and pouch in order for you to wear the accelerometer around your waist at your lower back. Please see the images below for guidance or refer to the instruction sheet on how to wear the accelerometers which is in this pack.





When do I wear it?

We ask that you wear the accelerometer during your waking hours. We please ask that you do not wear the accelerometer in a swimming pool or when you are sleeping.

How do I know it's working?

The accelerometer you will be given will already be fully charged and programmed. Accelerometers do not have an on or off button so they will be constantly working 24/7. Should you notice and brief blue or red flashing light on the accelerometer, please contact the primary researcher immediately.

What if I forget to wear it?

If you forget to wear your accelerometer, we will ask if you please could continue to wear the accelerometer for the remainder of the study and try to remember to wear it every day.

Do I need to charge it?

Yes. We will provide you with a USB cable and plug charger for you to charge your accelerometer every 24 hours during sleeping hours.

Can I go swimming with it?

No. The accelerometer is only waterproof up to 1.5 metres.

If you have any more questions, please do not hesitate to get in contact with the primary researcher.

Sarah Williamson

Email: willis76@lsbu.ac.uk

Telephone: 020 7815 7937

Contact details

If you have read the participant information sheet and would like to register an interest in the outlined study, please contact the primary researcher using any of the following methods. We would be delighted to hear from you.

Primary Researcher

Sarah Williamson

Email: willis76@lsbu.ac.uk

Telephone: 020 7815 7937

Please feel free to ask any questions you may have about the study. Sarah will be happy to answer any of your questions or provide further information if there is anything you are unclear about.

Participant Information Sheet

Study title: Effect of physical activity promotion on people with non-specific low back pain: a randomised controlled feasibility study

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

Background

This study is a collaboration between The University College of Osteopathy (UCO) and London Southbank University. Professor Ian Albery and Dr Jin Luo from Southbank and Steven Vogel from UCO are supervising Sarah Williamson as part of her PhD.

What is the study about?

This study is aiming to run a mini trial to see if the trial of the same design would be viable to run on a larger scale. This study is focussing on the impact physical activity can have on patients with low back pain. We are looking at increasing the amount of physical activity a patient does and monitoring that through the use of an accelerometer. Research has suggested that physical activity may be beneficial for patients with non-specific low back pain as physical activity has been shown to be effective on other musculoskeletal conditions like osteoarthritis. Current guidance suggests that clinicians recommend physical activity as part of the management of back pain.

Why have I been asked to participate?

You have been asked to participate in this study because you are either a student osteopath or an osteopathic tutor at the UCO clinic.

All of the student osteopaths and clinic tutors will be invited to participate in this feasibility trial. We aim to recruit 30 student osteopaths and 15 osteopathic tutors in this study. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

Recruit patients with non-specific LBP

We would like you to give new patients who are potential participants (with non-specific low back pain – pain presenting between 6 weeks and 3 months) a participant recruitment pack which will be made available. We do not expect you to talk about the study with the patient in any detail, but invite them to read through the information about the study and to contact the researcher if they would like to take part in the study or would like further information. If you have handed out a recruitment pack, we ask that you please note this on the patient's UCO personal file and complete a brief form to let us know that you have offered the information to a potential participant. In this way we can monitor how successful our recruitment is.

We do not want your or the patient's involvement in the study to interfere with your care of the patient or take up any of your treatment time. We ask that you do not discuss which group your patient is in with either the patient or other osteopaths in your team or your colleagues.

Interviews

We would also like to invite you to be interviewed by the researcher, which will last approximately between 30 to 60 minutes. These interviews are designed to allow you to give your feedback on elements of the study processes and your thoughts about the aims of the study in targeting this population to become more active, if you had any concerns on the study processes or content and, if there were parts you feel could have worked better etc. These interviews will be digitally recorded so the researcher can write up the relevant information you have provided. Any personal reference or personal information will be anonymised and coded. These interviews will take place at the UCO clinic at a time mutually agreeable between yourself and the researcher, after the trial. Please note, that if you graduate before you have been invited for an interview, the researcher would still like you to attend and would be very appreciative if you could make yourself available for the interview.

Do I have to take part?

No. It is up to you to decide whether you participate in this study or not. If you do participate in the study, you will be given this information sheet to keep and be asked to sign a consent form. You are free to withdraw at any time and without giving a reason. A decision to withdraw, or a decision not to take part, will not affect your tuition or position at the UCO.

What is involved in the study?

We are recruiting patients presenting to the UCO clinic with a new episode of non-specific low back pain. Potential participants will be identified by student and tutor osteopaths as having non-specific low back pain and be given a recruitment pack by their treating student osteopath. The researcher will ask potential participants to fill out a series of questionnaires at various time points. The participants will have their Body Mass Index and waist-to-hip ratio

measured and fill out a PAR-Q to make sure they are able to engage in physical activity. A PAR-Q is a short questionnaire used to identify people in which increasing their activity levels could be inappropriate or if have a medical condition where medical advice is needed to determine the right type of activity for them. Participants will be randomly allocated into one of four groups. Group 1 participants will receive their usual osteopathic care and an education sheet on the benefits of being physically active. Group 2 participants will receive their usual osteopathic care; education on the benefits of being physically active and feedback on their activity levels on a weekly basis. Participants in group 3 will receive their usual osteopathic care; be advised to be more physically active; receive an education sheet on the benefits of being physically active; and complete an exercise sheet on how, where, when and for how long they will aim to be more physically active, weekly with the researcher. Participants in group 4 will receive their usual osteopathic care; be advised to be more physically active; receive an education sheet on the benefits of being physically active; and complete an exercise sheet on how, where, when and for how long they will aim to be more physically active, weekly with the researcher and receive weekly feedback on their activity levels.

All of the participants will be given an accelerometer to measure their activity levels throughout the duration of the study. An accelerometer is a small, electromechanical device capable of measuring acceleration forces. The forces an accelerometer can measure may be static – e.g., the constant force of gravity pulling at your feet – or dynamic – e.g., caused by moving or vibrating the accelerometer. We will collect baseline measurements of physical activity for 3 days and then implement the intervention for another 4 weeks.

The researcher will collect the participant at the end of their treatment appointment and escort them to the room in which the researcher will be operating.

The time points which the participants will be measured at, in a separate research room, are as follows:

- Baseline measures (questionnaires, physical activity, BMI and waist to hip ratio): **Week 1**
- Group allocation: **Week 2**
- Every week NRS score recorded, accelerometer data downloaded, osteopathic treatment: **Weeks 3,4,5,6**
- After 4 weeks, baseline measures re-evaluated, accelerometer data downloaded. Accelerometer returned: **Week 6**
- 3 months post intervention: pain, disability and quality of life measure reassessed, by post and semi-structured interviews: **Week 18**

Inclusion criteria for patients

We are recruiting patients, between 18 and 65 years old, who have non-specific low back.

These patients may be experiencing a first episode or reoccurrence of non-specific low back pain (NSLBP). NSLBP is defined as low back pain which is not caused by a recognisable pathology such as cancer, fracture or infection. It includes those people with pain between the lower ribs and the gluteal folds of the buttocks. It also includes commonly made diagnoses that osteopaths may use as a working hypothesis to inform their treatment. For example, facet joint or lumbar muscular or ligamentous pain, and presentations that may

include elements of osteoarthritic change in the spine or suspected minor discal injury without neuropathic leg pain.

Patients must be able to read and understand English language and have a willingness to be involved in the study.

Patients will be excluded from the study if they have any of the following:

- Clinical neurological deficits suggesting nerve root compression
- Spinal deformity (scoliosis, kyphosis, spinal stenosis)
- Previous surgery for back pain, such as lumbar spinal fusion
- Rheumatoid arthritis
- Cauda equina syndrome or spinal cord compression,
- Cardiorespiratory/pulmonary health issues
- Are pregnant
- Have a LBP rating less than a 1 on the numeric rating scale (NRS)

Will this affect my patient's treatment plan?

No.

Osteopathic care is part of the study. You will carry out your treatment plan as usual with your patient.

If you are concerned that a patient's involvement in the study is having a negative effect on their wellbeing, then you are asked to contact the researcher as well as discuss this with the participant concerned. This includes if the participant has complained to you that they have hurt/injured themselves when trying to be more active. In this instance, it would be up to you to modify your care or not as you would normally do as part of your usual practice. Participants may withdraw from the study at any time without detriment to their care or legal rights.

If you have questions about the study, please contact Sarah Williamson in the first instance. If you have unresolved questions or concerns, then please contact one of the study supervisors whose contact details are below.

Data collection and confidentiality

All the information collected about you and other participants will be kept strictly confidential (subject to legal limitations). Data generated by the study must be retained in accordance with LSBU Code of Practice. All data generated in the course of the research must be kept securely in paper or electronic form for a period of 10 years after the completion of a research project.

All information received from you will be handled in a confidential manner and stored in a locked filing cabinet and on a password protected computer in an environment locked when not occupied. Only the researcher and supervisors of this project will have direct access to the information. Your privacy and anonymity will be ensured by coding any reference to yourself. This information will be held until January 2028 and then destroyed.

What will happen to the results of this study?

The results of the study will be used as part of a PhD thesis for Sarah Williamson (primary researcher). We also aim to disseminate this information to a wider population at conferences, seminars etc. and to publish the results of this study in an academic journal. If you wish to obtain a copy of the published research, then please leave your email at the bottom of the consent form and the primary researcher can send you a copy once the manuscript has been approved.

Who is organising and funding the research?

This research is being conducted as part of a funded PhD research degree by the University College of Osteopathy and London Southbank University, at the London Southbank University within the Human Sciences department of the School of Applied Sciences.

Study approval:

This study has been reviewed and approved by the London Southbank University ethics research committee and the University College of Osteopathy research ethics committee.

Contact details:

For further information or if you have any questions you wish to ask, please do not hesitate to contact Sarah using the details below.

Primary Researcher:
Sarah Williamson
Email: willis75@lsbu.ac.uk
Telephone: 020 7815 7937

Academic supervisor for the project:
Professor Ian Albery
Email: alberyip@lsbu.ac.uk
Telephone: 020 7815 5856

Academic Co-Supervisor for the project:
Mr Steven Vogel
Email: s.vogel@buco.ac.uk
Telephone: 0207 089 5331

Academic Co-Supervisor for the project:
Dr Jin Luo
Email: luoj4@lsbu.ac.uk
Telephone: 020 7815 7941

On behalf of myself and my research team, I thank you for taking the time to read this information sheet.

Appendix V. Clinician consent form

Research Project Consent Form

Full title of Project: Effect of physical activity promotion on people with non-specific low back pain: a randomised controlled feasibility study

Ethics approval registration Number: LSBU:SAS1812, UCO: 12/04/18

Osteopath ID:

Name: Sarah Williamson

Researcher Position: Primary researcher

Contact details of Researcher: Email: willis76@lsbu.ac.uk **Telephone: 020 7815 7937**

Taking part (please initial the box that applies)	Please initial
I confirm that I have read and understood the information sheet/project brief and/or the student has explained the above study. I have had the opportunity to ask questions and my questions have been answered to my satisfaction.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without providing a reason and without detriment to my career and standing at the UCO.	
I agree to take part in the above study.	

Use of my information (please initial the box that applies)	Please initial
I understand my personal details such as phone number and address will not be revealed to people outside the project.	
I understand that my data/words may be quoted in publications, reports, posters, web pages, and other research outputs.	
I agree for the data I provide to be stored (after it has been anonymised) in a specialist data centre and I understand it may be used for future research.	
I agree to the interview being audio recorded.	
I agree to the use of anonymised quotes in publications.	
I wish to receive a copy of the published research once the manuscript has been approved.	

Email:	

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

Project contact details for further information:
Project Supervisor/ Head of Division name: Professor Ian Albery

Phone: 020 7815 5856
Email address: alberyip@lsbu.ac.uk

1 copy for the researcher and 1 copy for the osteopath to keep

Study title: Effect of physical activity promotion on people with non-specific low back pain: a randomised controlled feasibility study

FAQ for clinicians

Who can be involved in the study?

Patients with non-specific low back pain

What's the inclusion criteria?

- Must be between 18-65 years of age
- Non-specific low back pain
- Recurrent episode or a new episode of Non-Specific Low Back pain

What are you classing as non-specific low back pain?

Pain which is not caused by a specific pathology – i.e., disc herniation, previous back surgery, neurological conditions etc. This includes those people with pain between the lower ribs and the gluteal folds of the buttocks. Diagnoses such as disc herniation or neurological conditions can either be made by the working diagnosis of the student, should they suspect the patient is suffering with such conditions or via an appropriate medical scan such as an MRI. This also includes commonly made diagnoses that osteopaths may use as a working hypothesis to inform their treatment. For example, facet joint or lumbar muscular or ligamentous pain, and presentations that may include elements of osteoarthritic change in the spine or suspected minor discal injury without neuropathic leg pain.

What do I do if I feel I have a potential participant who is a new patient?

Give them a recruitment pack, located in each of the treatment rooms and complete a participant identification form (included in this pack) to let us know that you have given a potential participant a pack of information.

When handing out the pack to potential participants it is important that the patient is not induced or coerced to participate. For this reason, we suggest that you might like to introduce the study using words like the following:

“The University College of Osteopathy are taking part in a feasibility study about back pain and activity, and you have the characteristics of the type of people that they are wanting to recruit for the study. I have an information pack available, whether or not you take the information pack will have no effect on your current or future care from our clinic. Would you like me to give you the pack?” Should a patient ask further questions about the study, answer them if you feel able with the knowledge you have about the study or invite them to look at the information in the pack and to contact the primary researcher whose contact details are in the pack.

What do I do if I am unsure they meet the inclusion criteria?

Discuss with your tutor whether or not they have non-specific low back pain.

Will I have to cease or change my treatment plan for the patient to take part?

No.

What do I do if I am asked about the study or my patient’s activity?

Answer questions as you would normally and use your best judgement when giving advice to the patient.

We ask that you do not raise the topic of the study with your patient unless they ask you directly. If you are concerned that an individual’s involvement in the study is having a negative effect on their well-being, then you are asked to contact the researcher as well as discuss this with the participant concerned. This includes if the participant has complained to you that they have hurt/injured themselves when trying to be more active. In this instance, it would be up to you to modify your care or not as you would normally do as part of your usual practice.

What if there is a problem?

In the first instance get in touch with Sarah Williamson. If she is unable to resolve your concerns, contact Steven Vogel or Professor Ian Albery.

Primary Researcher:
Sarah Williamson
Email: willis75@lsbu.ac.uk
Telephone: 020 7815 7937

Academic supervisor for the project:
Professor Ian Albery
Email: alberyip@lsbu.ac.uk
Telephone: 020 7815 5856

Academic Co-Supervisor for the project:
Mr Steven Vogel
Email: s.vogel@uco.ac.uk
Telephone: 0207 089 5331

Academic Co-Supervisor for the project:
Dr Jin Luo
Email: luoj4@lsbu.ac.uk
Telephone: 020 7815 7941

Appendix X. Patient identification form

Title: Effect of physical activity promotion on people with non-specific low back pain: a randomised controlled feasibility study

Date: ……

Patient's name: ……

Age: ……

Sex: ……..

Name of tutoring osteopath:……..

Name of student osteopath:……..

Student year:……

This patient is believed to be eligible for the study entitled above and has been given a recruitment pack.

Signed (tutoring Osteopath):……..

Research project:

Effect of physical activity promotion on people with non-specific low back pain: a randomised controlled feasibility study.

Demographics

Participant code :……

Name ……

Date of Birth ……. Age …….

Height……. Weight…….

Waist circumference……

Hip circumference……

Type of LBP:

☐ 1st episode

☐ Reoccurrence/flare-up

Has your low back pain limited the amount of activity that you participate in?

☐ Yes

☐ No

Appendix Z. General practice physical activity questionnaire

Date……

Participant ID……..

1. Please tell us the type and amount of physical activity involved in your work.

		Please mark one box only
a	I am not in employment (e.g., retired, retired for health reasons, unemployed, fulltime carer etc.)	
b	I spend most of my time at work sitting (such as in an office)	
c	I spend most of my time at work standing or walking. However, my work does not require much intense physical effort (e.g., shop assistant, hairdresser, security guard, childminder, etc.)	
d	My work involves definite physical effort including handling of heavy objects and use of tools (e.g., plumber, electrician, carpenter, cleaner, hospital nurse, gardener, postal delivery workers etc.)	
e	My work involves vigorous physical activity including handling of very heavy objects (e.g., scaffolder, construction worker, refuse collector, etc.)	

2. During the *last week*, how many hours did you spend on each of the following activities? *Please answer whether you are in employment or not*

Please mark one box only on each row

		None	**Some but less than 1 hour**	**1 hour but less than 3 hours**	**3 hours or more**
a	Physical exercise such as swimming, jogging, aerobics, football, tennis, gym workout etc.				
b	Cycling, including cycling to work and during leisure time				
c	Walking, including walking to work, shopping, for pleasure etc.				
d	Housework/Childcare				
e	Gardening/DIY				

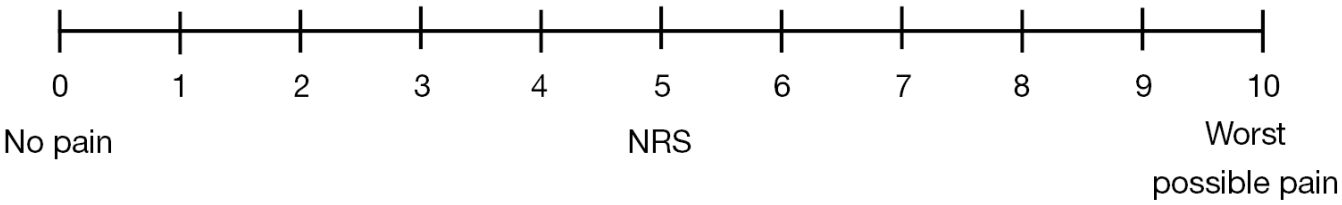
3. How would you describe your usual walking pace? Please mark one box only.

Slow pace (i.e., less than 3 mph)		Steady average pace	
Brisk pace		Fast pace (i.e., over 4mph)	

Appendix AA. Numeric rating scale

The Numeric Pain Rating Scale Instructions

"Please indicate the intensity of current pain levels over the past 24 hours on a scale of 0 (no pain) to 10 (worst pain imaginable)"



EQ-5D Health Questionnaire

Participant Code

Date

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑

I have slight problems in walking about ❑

I have moderate problems in walking about ❑

I have severe problems in walking about ❑

I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑

I have slight problems washing or dressing myself ❑

I have moderate problems washing or dressing myself ❑

I have severe problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g., work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑

I have slight problems doing my usual activities ❑

I have moderate problems doing my usual activities ❑

I have severe problems doing my usual activities ❑

I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑

I have slight pain or discomfort ❑

I have moderate pain or discomfort ❑

I have severe pain or discomfort ❑

I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑

I am slightly anxious or depressed ❑

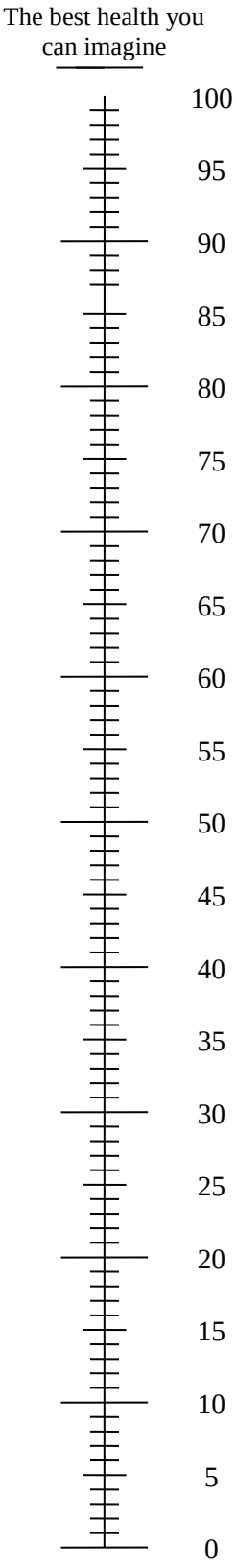
I am moderately anxious or depressed ❑

I am severely anxious or depressed ❑

I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Appendix CC. Roland Morris Disability questionnaire

When your back hurts, you may find it difficult to do some of the things you normally do. This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you *today*.

As you read the list, think of yourself *today*. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only tick the sentence if you are sure it describes you today.

1. I stay at home most of the time because of my back. ☐

2. I change position frequently to try and get my back comfortable. ☐

3. I walk more slowly than usual because of my back. ☐

4. Because of my back I am not doing any of the jobs that I usually do around the house. ☐

5. Because of my back, I use a handrail to get upstairs. ☐

6. Because of my back, I lie down to rest more often. ☐

7. Because of my back, I have to hold on to something to get out of an easy chair. ☐

8. Because of my back, I try to get other people to do things for me. ☐

9. I get dressed more slowly than usual because of my back. ☐

☐

10. I only stand for short periods of time because of my back.

11. Because of my back, I try not to bend or kneel down. ☐

12. I find it difficult to get out of a chair because of my back. ☐

13. My back is painful almost all the time. ☐

14. I find it difficult to turn over in bed because of my back. ☐

15. My appetite is not very good because of my back pain. ☐

16. I have trouble putting on my socks (or stockings) because of the pain in my back. ☐

17. I only walk short distances because of my back. ☐

18. I sleep less well because of my back. ☐

19. Because of my back pain, I get dressed with help from someone else. ☐

20. I sit down for most of the day because of my back. ☐

21. I avoid heavy jobs around the house because of my back. ☐

22. Because of my back pain, I am more irritable and bad tempered with people than usual. ☐

23. Because of my back, I go upstairs more slowly than usual. ☐

24. I stay in bed most of the time because of my back. ☐

Low Back Pain Information

What is low back pain?

Low back pain is a common condition which affects about 85% of the general population in their lifetime. Low back pain can be a distressing condition, but the pain is rarely caused by a serious medical condition. Your clinicians at the UCO have decided that your back pain is not caused by a serious medical condition. Back pain like yours is believed to be related to the function of your muscles, tendons and ligaments as you use them in daily life. This type of back pain is often helped by osteopathic treatment.

How can physical activity help?

Physical activity can help to reduce your low back pain and can reduce tension, stiffness and soreness. Engaging in physical activity is an excellent way of helping to restore the normal function of your back.

By not being active you are at risk of:

- Getting stiff
- Not doing the usual things you enjoy
- Getting depressed
- Weaker bones
- Weaker muscles
- Pain feeling worse
- Losing fitness

By being regularly activity you will benefit from:

- Stronger bones
- Feeling good, about yourself and in your body
- Chemicals in the body being released which can reduce the pain
- Being supple
- Keeping your muscles strong
- Keeping you fit

We advise you to be as physically active as possible, within your pain levels. This will not cause damage to your back. Your body may not be used to moving if you have not been as active recently. Physical activity will help to loosen your joints, muscles and surrounding tissues which for some people may cause achiness. Aches and pains are normal and do not mean harm/damage has happened to your back.

Tips:

- Moving is key!
- Don’t stay in one position too long – get up and move about before you stiffen up!
- Take it slow – do more physical activity gradually
- Do not stop doings you used to enjoy – just adapt the way you do them to suit you and your pain levels

This education sheet has been based on information on the Back Book, NHS websites and Arthritis UK.

Questions?

Please do not hesitate to contact the primary researcher (Sarah Williamson) using the following details:

Email: willis76@lsbu.ac.uk

Tele: 020 7815 7937

Appendix EE. Feedback on weekly activity levels

When the participant has increased their activity levels:

Well done you managed to increase your activity levels this week. *Researcher shows participant the screen displaying their physical activity levels.

To capitalise on this, do you think you could do a bit more activity next week?

Let's refill out your advice sheet with ways you can be more active and identify what may stop you and how you can overcome this.

*Participant refills out the intervention sheet

When the participant has not increased their activity levels:

Unfortunately, it appears you have not managed to increase your activity levels. Do you agree that you did not do more activity this week?

Were there any barriers you faced that stopped you increasing your activity levels? Do you think we could overcome them and get you to be a bit more active?

Let's refill out your advice sheet with ways you can be more active and identify what may stop you and how you can overcome this.

*Participant refills out the intervention sheet

Appendix FF. Implementation intentions

In everyday life there are plenty of opportunities to become more physically active. However, a busy working schedule or having a family may be considered an obstacle to increasing physical activity.

In order to help you think about how you may be more physically active in your daily routine, please critically think about the following subheadings (below) in relation to your life.

Opportunities to increase activity:

- _____
- _____
- _____

Obstacles to increasing activity

- _____
- _____
- _____

Ways to overcome these obstacles:

- _____
- _____
- _____

Benefits for you if you increase your activity levels:

- _____
- _____
- _____

I am going to _____ for_____ on these days_____

_____.

I will commit to _____ for _____

on_____.

I will make the effort to _____ __on _____for _____.

Appendix GG. Debriefing sheet for the patient participants, student and tutor osteopaths

Study title: Effect of physical activity promotion on people with non-specific low back pain: a randomised controlled feasibility study

This study was aiming to run a mini trial to see if a trial of the same design would be viable to run on a larger scale. This study is focussing on the impact physical activity can have on patients with low back pain. We were looking at increasing the amount of physical activity a patient does and monitoring that through the use of an accelerometer (a device that measures physical activity). Research has suggested that physical activity may be beneficial for patients with non-specific low back pain as physical activity has been shown to be effective on other musculoskeletal conditions like osteoarthritis. Current guidance suggests that clinicians recommend physical activity as part of the management of back pain. We were also looking to see if the trial procedure, interventions and associated measurement tools are equipment were acceptable, credible, useable and viable both to patients and osteopaths.

Please remember that all the information collected about you and other participants will be kept strictly confidential (subject to legal limitations). Data generated by the study must be retained in accordance with the University's Code of Practice. All data generated in the course of the research must be kept securely in paper or electronic form for a period of 10 years after the completion of a research project. All information received from you will be handled in a confidential manner and stored in a locked filing cabinet and on a password protected computer in an environment locked when not occupied. Only the researcher and supervisors of this project will have direct access to the information. Your privacy and anonymity will be ensured by coding any reference to yourself. This information will be held until January 2028 and then destroyed.

Y*ou are still free to withdraw at any time and without giving a reason and without any consequences to you. Whether you decide to withdraw will not affect your established relationship with the primary researcher in any way. Should you agree to take part and then wish to withdraw, please contact the primary researcher on the email address below. Please note it will not be possible to withdraw after all of the data analysis has been completed and the manuscript has been sent for publication.*

Please contact the primary researcher (Sarah Williamson) at the following email address willis75@lsbu.ac.uk if you have any further questions.

Thank you again for your participant and co-operation in this study!

Appendix HH. Follow-up Email to the patient participants

Dear xxxx,

Thank you for participating in the research study entitled “Effect of physical activity promotion on people with non-specific low back pain: a randomised controlled feasibility study”. Your time and effort into this study has been greatly appreciated and helpful in our research.

As mentioned in the participant information sheet we are emailing you to ask you to kindly fill out the 3 of the questionnaires you completed at the start of the study. In order for us to capitalise on your investment in our study, we require your answers to the questionnaires. We have attached the questionnaires to this email. We estimate it will take a maximum of approximately 5 minutes to complete these questionnaires.

Could you please send us back the questionnaires with your answers via email using this email address, or by post (send to the UCO clinic addressed to Miss Sarah Williamson) within 2 weeks.

If you have any trouble in accessing the attached questionnaires or have any questions please do not hesitate to contact me using this email address.

Thank you once again for your investment in the study so far. I look forward to receiving your completed questionnaires in due course.

Best wishes,

Sarah Williamson

PhD Research Student
London South Bank University
103 Borough Road,
London, SE1 0AA
Room: E245
Tele: +44 (0)20 7815 7937
Ext: 7937

Appendix II. Letter requesting the return of the accelerometer

98-118 Southwark Bridge Road
London,

SE1 0BQ

Tel: 020 7089 5360

Date:

Dear xxxx,

Thank you very much for your contribution to our research project entitled "Effect of physical activity promotion on people with non-specific low back pain: a randomised controlled trial feasibility study". As your participation in the study has finished we would be grateful if you would return the belt and the accelerometer in the stamped addressed envelope enclosed.

Yours sincerely,

Sarah Williamson

PhD student

Lead researcher

Professor Ian Albery

Professor of Psychology at London South Bank University.

Supervisor to Sarah Williamson

Mr Steven Vogel

Deputy Vice-chancellor (Research).

University College of Osteopathy

Co-supervisor to Sarah Williamson

Dr Jin Luo

Co-supervisor to Sarah Williamson

Appendix JJ. Guided telephone conversation script to remind them about the follow-up

Interviewer: Hello [name of participant]. This is Sarah from the University College of Osteopathy calling you about the physical activity study you have been participating in.

Participant: Hello.

Interviewer: I am just calling you to make sure you have received our questionnaires we sent to your home address and that they didn't get lost in the post.

Participant either answers:

"Yes, I received them"

OR

"Yes, I have received them and should be on their way back to you"

OR

"No, I have not yet received the questionnaires in the post".

Interviewer either answers:

"Ok, would it be possible for you to fill out the questionnaires and send them back to us at the earliest possible convenience for you? In order for us to capitalise on your investment in our study, we require your answers to the questionnaires".

OR

"Excellent, thank you very much, for both your time and effort you invested in our study and for filling out and returning the questionnaires"

OR

"Ok, we will resend you the questionnaires. Can you just please confirm your home address so we can ensure we send the questionnaires to the right person".

Participant either answers:

"Ok, I'll fill them out and return them to you as soon as possible. Good-bye".

OR

"No problem and thank you. Good-bye".

OR

“Ok, my address is…….. I will fill them out and return them to you as soon as possible after I have received them. Good-bye”.

Interviewer: Thank you and good-bye”.

Appendix KK. Semi structured interview script for the patient participant interviews

Questions for all participants

Introduction and physical activity summary

Thank you for agreeing to this interview. Before we begin, can you please tell me what you were asked to do in the study?

How easy was it to understand what you were required to do?

What group were you assigned to?

Can you tell me what physical activity you did before you signed up to the trial?

With the exception of the accelerometer and associated feedback, do you use any of the information or resources you received in the study now?

How, if at all, did your physical activity change during the trial?

What physical activity do you do now?

Clarity and usability:

Now I am going to ask you some questions about the paperwork you were asked to fill out at the start and end of the study.

Do you recall reading the patient information sheet? How easy did this information make it for you to understand what was going to happen in the study?

You were asked to fill out questionnaires pre- and post-trial. How easy were they to fill out? How clear do you think they were?

Let's now discuss the accelerometer you were asked to wear daily on a belt.

Can you please describe your experience of wearing the accelerometer?

How did you find wearing the accelerometer?

How easy was it to remember to wear it daily?

Would you have preferred to wear the accelerometer for a shorter time period? Would this be more or less of a burden?

I am now going to ask you specific questions relating to the group you were assigned to.

Group 1 questions – advice and education sheet

You were assigned to group 1, which meant you received weekly advice on physical activity and a back-pain information sheet.

How easy was it to understand the back-pain information sheet you were given? Did you learn anything from it and of so what did you learn?

Can you please explain what advice you were given during the study?

Group 2 questions - Feedback

You were assigned to group 2. You received advice to be active, a back-pain information sheet and feedback on your activity levels each week.

Interviewer prompt – ask all questions for group 1, then:

Can you tell me what you remember about the feedback I gave you at the weekly sessions?

What impact, if any, did the feedback have on your activity levels>? Prompt – *[Was it helpful and motivating or did it make you feel indifferent? How did the feedback make you feel when you got it?]*

Were you surprised with your activity levels? Prompt – *[Had you expected you were doing more or less activity than what you were shown?]*

Group 3 questions – BCT

You were assigned to group 3. You received advice to be active, a back-pain information sheet and were asked to fill out an implementation intention plan on how, when and where you would be more active each week.

Interviewer prompt – ask all questions for group 1, then:

How helpful did you find it to write down what activity you would do and when?

What was it about that activity which you found helpful, if anything?

Were you able to successfully fill out a plan for each week?

How did you find completing the weekly implementation intention plan?

What were your opinions on completing that task?

Were you bale to follow your plan throughout the week, or did you have to change it around?

Do you think you would continue to complete this kind of plan to structure when you would do activity?

Group 4 questions – All interventions

You were assigned to group 4. You received advice to active, a back-pain information sheet and were asked to fill out an implementation intention plan on how, when and where you would be more active each week and feedback on your activity levels each week.

How did you find the intensity of being given all of these tools?

Which tool would you say was the most helpful, if any, in encouraging you to be more active?

Interviewer prompt – ask all questions for groups 1, 2, & 3

Questions for all participants

Physical activity and low back pain:

Ok, we are going to move on and I'm going to ask you some questions surrounding physical activity and low back pain.

What advice about physical activity from your osteopath or another health professional, if any, had you been given before this study?

Before you joined the study, what were your thoughts towards being physically active when experiencing low back pain?

What were your immediate thoughts or feelings to being more active when you found out this study wanted you to be more active?

What are your thoughts now, if they have changed at all?

What impact would you say taking part in the study has had on your ability to carry out everyday activities?

What impact do you think physical activity had on your low back pain, if any?

Have your episodes of low back changed in frequency and intensity? Prompt – *For example, did you used to feel a sharp pain and now you experience more of a dull ache? Do you feel like you experience less pain or less frequent bouts of pain?*

What do you think we could do to make your experience of the trial better?

What would you change about the study, if anything?

Were there any concerns you had throughout the study which you did not raise with myself or your osteopath?

Were there a y concerns which you did raise?

Prompts

Please explain

Is there anything you wish to add?

This is the end of all my questions. Thank you very much for investing your time and effort into this study and for making time to attend this interview. Are there any questions which you have for me?

Appendix LL. Semi structured interview script for the clinician participants

Thank you for agreeing to this interview. Before we begin, can you please tell me what you were asked to do in the study?

In your opinion, how could we have made it easier and clearer for you to understand what you were required to do in the study?

Do you remember receiving the clinician information sheet?

Can you tell me what you thought of it? Prompt - *clear and concise? Too long? Could we have made the information easier to understand?*

What do you think we could do in making the study more accessible to the student osteopaths and the patient participants? Prompt: more posters?

The study:

Now I'm going to ask you some questions about the study and the demands of taking part in this on both yourself as a student osteopath and your patients.

What were your thoughts on the student osteopath's role in the recruitment process? Prompts - *Would you say it interfered with your other responsibilities in the clinic or was it easy to integrate?*

What is your understanding of the term "non-specific low back pain?" Prompts - *timeline?*

What are your thoughts on using this educational clinic as a recruitment site for this kind of study? Prompts: good idea in this kind of clinic? Should I have used this site in conjunction with another clinic?
In your opinion, (would you say) do you think most of the patients at this clinic have low back pain or are you seeing more peripheral injuries?

Would you change how the participants are recruited, and if so, how?

Can you describe your original thoughts on the keep active advice?

Has taking part in this study changed your awareness of physical activity and the NICE guidelines? Prompt - *Please explain.*

To what extent do you think physical activity can be beneficial for patients with non-specific low back pain? *What are your thoughts on the benefits of being physically active with low back pain? how much of a benefit? In terms of pain? Mental well-being?*

Have your thoughts towards the keep active advice changed in any way, if at all, since being involved in this study?

Has your involvement in this study made you consider physical activity as part of your treatment plan?

To what extent did the study impact on your treatment plan, if at all? Prompt - *Did you have to change what you intended to do, if so please explain the changes you made?*

What are your thoughts on the trial burden for the participants? Prompts - *were we asking too much of them?*

How would you change the study to be more participant friendly, if you would change the study at all?

What are your thoughts on this trial being conducted as a full scale RCT over a few years?

Did you have any questions or thoughts that you wished to raise during the study but did not?

Did you have any questions or thoughts that you did raise? Follow up question – Did you receive clarification or the answers you were looking for?
If we were to run the study again in what way do you think we could improve how we informed you and your colleagues about the study?
Is there anything else you wish to add that we haven't covered?

Prompts:

Please explain

Is there anything else you wish to add?

This is the end of all my questions. Thank you very much for investing your time and effort into this study and for making time to attend this interview. Are there any questions which you have for me?