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Predictors of self-management in patients with chronic low back pain

Anirban Banerjee, MPhty, AFHEA, MCSP

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ABSTRACT

Background: Self-management (SM) is a key strategy for managing chronic low back pain (CLBP) and defines how individuals manage their disease, symptoms, treatment and roles. However, no longitudinal study has examined the predictive relationships between SM and biopsychosocial outcome measures in patients with CLBP. This PhD thesis outlines the body of research that examined the predictive relationship between SM constructs and biopsychosocial outcome measures in patients with CLBP.

Aims: This PhD research had three main aims: 1) synthesise and appraise the literature on outcome measures used to assess change in SM in patients with chronic musculoskeletal pain and to identify a valid and reliable SM outcome measure to be used in this PhD study for assessing a range of SM constructs; 2) to estimate the reliability and agreement between paper and non-paper alternative methods of survey completion for an identified SM measure; and 3) to examine the predictive relationship between SM constructs and biopsychosocial outcome measures in patients with CLBP.

Methods: A systematic review was conducted to identify and synthesise quantitative measures used to assess SM in patients with chronic musculoskeletal pain [Aim 1]. A test-retest study was conducted to estimate the intraclass correlation and Bland and Altman Limits of Agreement between paper and non-paper alternative methods of survey completion for a SM measure [Aim 2].

Finally, a multi-site longitudinal cohort study was conducted collecting self-reported validated measures for SM, pain intensity, disability, physical activity level, kinesiophobia, catastrophising, and depression at baseline and six-months, including working age individuals (n=270, 18-65 years) who attended physiotherapy for their CLBP [Aim 3].

Results: The systematic review identified 14 different outcome measures. The Health Education Impact Questionnaire (heiQ) assesses eight different SM constructs and was utilised in this PhD research [Aim 1]. The heiQ demonstrated good reliability (Cronbach's α 0.89-0.95 and intraclass correlation 0.89-0.96) and acceptable Limits of Agreement between paper and non-paper alternative survey completion methods [Aim 2]. Physical activity level and healthcare use (positively); and levels of disability, depression, kinesiophobia, catastrophising (negatively) predicted (p<0.05, adjusted R^2 ranged from .07 to .55) SM constructs at baseline in patients with CLBP. At six-month follow-up, SM constructs were improved (p<0.05, adjusted R^2 ranged from .30 to .55) in those patients who had higher scores on SM constructs at baseline; lower levels of depression or kinesiophobia; were educated, living as married; of white ethnic background; and attended a pain-management programme. Changes in SM constructs (from baseline to six months) were predicted (p<0.05, adjusted R^2 ranged from .13 to .32) by changes in levels of depression, kinesiophobia, catastrophising, physical activity, use of analgesics; and presence of leg pain; and being employed and married [Aim 3].

Conclusion: The heiQ is a suitable outcome measure to assess multiple constructs of SM in patients with chronic musculoskeletal pain conditions [Aim 1]. The paper and non-paper alternative methods of survey completion produced equivalent data quality for the heiQ in patients with CLBP [Aim 2]. The main results indicate levels of disability, physical activity, depression, catastrophising and kinesiophobia predicted multiple constructs of SM measured using the heiQ in working-age adults with CLBP [Aim 3]. This is the first longitudinal study investigating predictive relationship between SM constructs and biopsychosocial outcome measures. Future research is required to validate these results.

SCHOLARLY OUTPUT FROM THIS THESIS

Publications:

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LIST OF CONTENTS

LIST OF APPENDICES

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

Abbreviation	Full form
95% CI	95% Confidence Interval
ASA-A	Appraisal of Self Care Agency Scale
ASES	Arthritis Self-Efficacy Scale
BCa	Bias Corrected and Accelerated
CLBP	Chronic low back pain
CPCI	Chronic Pain Coping Inventory
CPSE	Chronic Pain Self-Efficacy Scale
CSQ	Coping Strategies Questionnaire
GLM	Generalised Linear Model
GPMQ	German Pain Management Questionnaire
HDA	Health-Directed Activities
heiQ	Health Education Impact Questionnaire
HSN	Health Service Navigation
IARB	Inventory of Adult Role Behaviours
IBM	International Business Machines Corporation
ICC	Intraclass Correlation Coefficient
IPAQ-SF	International Physical Activity Questionnaire- Short Form
LBP	Low Back Pain
LoAs	Limits of Agreement
NCCP	Nottingham CityCare Partnerships CIC.
NHS	National Health Service
NPA	Non-Paper Alternative
NPS	Numeric Pain Scale
NUH	Nottingham University Hospitals
PCI	Pain Coping Inventory
PCS	Pain Catastrophising Scale
PES	Psychological Empowerment Scale

PGIC	Patient Global Impression of Change
PHQ-9	Patient Health Questionnaire-9
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRO	Patient reported outcome
PROM	Patient Reported Outcome Measure
PROMIS	Patient Reported Outcome Measure Information System
RCT	Randomised Controlled Trial
RMDQ	Roland Morris Disability Questionnaire
SCT	Social Cognitive Theory
SD	Standard Deviation
SES	Self-Efficacy Scale
SEW-RES-23	Swedish Rheumatic Disease Empowerment Scale
SFH	Sherwood Forest Hospitals NHS Foundation Trust
SIS	Social Integration and Support
SM	Self-management
SMI	Self-Monitoring and Insight

1 INTRODUCTION

The overarching aim of this PhD thesis is to investigate predictive relationship between self-management constructs and biopsychosocial outcome measures in patients with chronic low back pain. This chapter describes the context of this PhD research and overview of this thesis.

1.1 The context of this study

Chronic low back pain (CLBP) is defined as activity-limiting pain (Dionne et al., 2008) in the lower back with or without pain in the one or both lower limbs (Hoy et al., 2014) lasting more than three months (Saragiotto et al., 2016b). Low back pain is a common condition (Hartvigsen et al., 2018) affecting around 12% (point prevalence) of the population worldwide (Hoy et al., 2012) and the leading cause of disability measured using years lived with disability (Vos et al., 2016).

The majority of the patients with CLBP have no attributable structural source for pain or nociception (termed as non-specific CLBP) (Maher et al., 2017). The national guidelines (Bernstein et al., 2017, NICE Guideline, 2016, SIGN, 2013) recommend employing a biopsychosocial model for assessment and management (Foster et al., 2018) and self-management as a key treatment strategy for patients with non-specific CLBP (Buchbinder et al., 2018).

Self-management (SM) defines an individual's ability to manage the condition, symptoms, treatment and social and emotional roles when living with a long-term condition (Barlow et al., 2002). Measuring the change in SM is complex and widely variable (Nolte et al., 2013a) due to a lack of consensus on constructs of SM. Change in SM in patients with CLBP have almost exclusively measured disease severity outcomes using change in pain and disability measures (Du et al., 2017, Oliveira et al., 2012), which are not directly linked with the SM constructs (Taylor et al., 2016b). Thus measuring SM in patients with chronic pain conditions remains inconclusive and requires further research on outcome measures used to assess change in SM.

Further, programmes aiming to enhance SM use different delivery platforms- face-to-face, telephone and online (Du et al., 2017), thus an outcome measure used to assess change in SM may need to be utilised in different survey completion methods. Mixed mode surveys, employing paper-and-pen and non-paper alternative methods (telephone and online) of survey completion for patient reported outcomes, are popular and accepted by patients, clinicians and researchers (Gwaltney et al., 2008, Hox et al., 2015, Dillman et al., 2014). Mixed mode surveys not only minimise the chance of missing data (Engan et al., 2016) but also maximise response rate (McCabe et al., 2006). The reliability and agreement between paper and non-paper alternative survey methods of completion for an SM outcome has not been established in patients with CLBP.

Further, SM programmes have at best small (Oliveira et al., 2012) to moderate (Du et al., 2017) benefits for reducing pain and disability in patients with CLBP. The benefits of the SM programme can potentially be optimised by measuring the change in SM with appropriate outcome (Taylor et al., 2016b) and identifying specific sub-groups of patients who are 'best responders' (Kawi, 2014). A secondary analysis of cross-sectional data analyses exploring predictors of SM in patients with CLBP indicated that age, education, overall health, and attendance at a pain management programme had a predictive association with SM (Kawi, 2014), which the authors suggested warranted longitudinal cohort study.

Identifying biopsychosocial, which may include biophysical, psychological, social, economic, comorbidities and pain mechanisms (Hartvigsen et al., 2018), factors predicting SM in patients with CLBP will potentially help to identify sub-group of patients suitable for SM programme.

The research questions of this PhD research are- 1) how to measure SM in patients with chronic musculoskeletal pain conditions, 2) are paper and non-paper alternative methods of survey completion for an identified SM measure equivalent, 3) what are the predictors of SM and its change in patients with CLBP.

1.2 Overview of this thesis

This thesis is presented in the following eight chapters.

This current chapter introduces the context of this PhD research and the layout of this PhD thesis.

Chapter 2 outlines the body of literature on the definition, prevalence, socioeconomic impact and national guidelines on treatment strategies of CLBP. This chapter also presents an overview of the definition, theories and constructs of SM. Further, chapter 2 presents the benefits and challenges of SM in patients with CLBP and leads to the rationale and aims of this PhD research.

Chapter 3 presents the methods, results and discussion on the systematic review of outcome measures used to assess change in SM in patients with chronic musculoskeletal pain. The systematic review appraises the 14 outcome measures, including their psychometric properties, used to measure SM in patients with chronic musculoskeletal pain. The Health Education Impact Questionnaire (heiQ) is a SM outcome measure which measures eight constructs of SM and demonstrated good validity (Cronbach's α 0.70-0.88) and reliability coefficients (0.80-0.92) as an outcome measure for patients with chronic pain. The heiQ was utilised to measure SM in this PhD study. This chapter has been published (Banerjee et al., 2018). [Aim 1]

Chapter 4 presents the methods, results and discussion regarding the test-retest study to estimate the reliability and agreement between paper and non-paper alternative (telephone and online) survey modes for measuring SM using the heiQ in patients with CLBP. The heiQ has good reliability (Cronbach's α 0.89-0.95 and intraclass correlation 0.89-0.96) and acceptable Limits of Agreement between paper and non-paper alternative survey completion methods, indicating their equivalence to measure SM using the heiQ without losing the data quality in patients in CLBP. This test-retest study has been submitted for publication. [Aim 2]

The methods of the longitudinal cohort study employed to identify predictors of SM in patients with CLBP are presented in Chapter 5. This chapter provides the aims, patient selection criteria, recruitment process, ethics, outcome measures and data analyses plan. This study protocol has been registered and published (Banerjee et al., 2016).

The results of the longitudinal cohort study are presented in Chapter 6. The main study describes demographic and clinical characteristics of the 270 patients with CLBP recruited into the main study, the correlation between the heiQ sub-scales, predictors of SM at baseline and follow-up and predictors of change in SM between the two measurements. Overall, the findings highlight that the following factors physical activity, disability, depression, kinesiophobia, catastrophising significantly ($p<0.05$, adjusted R^2 ranged from .07 to .55) predict different constructs of SM in patients with CLBP. [Aim 3]

Predictors of SM identified and discussed in Chapter 7. The chapter also presents and discusses the recruitment issues, generalisability of the results, strength and limitations of the study. Despite its limitations, this was the first prospective longitudinal study identifying predictors of SM in patients with CLBP. The findings are generalisable to patients seeking treatment within the UK National Health service for non-specific CLBP.

Chapter 8 presents the overarching conclusion including clinical implication and future research of this PhD research.

1.3 Chapter summary

Chapter 1 presented the context of this PhD research and an overview of this thesis. Chapter 2 will elaborate the body of literature the definition, prevalence, socioeconomic impact and treatment strategies of CLBP and definition, theories and constructs of SM before leading to the rationale and aims of this PhD thesis.

2 LITERATURE REVIEW

2.1 Chronic low back pain

Low back pain is a very common symptom experienced by people of all age and all over the world (Hartvigsen et al., 2018). Despite ongoing research over the last few decades, the definition of the chronic low back has considerable variations in the literature. The four major areas of these variations are the location of the pain, the frequency of the symptoms, activity limitations and duration of the pain (Dionne et al., 2008). Knowing these variations may contribute to the heterogeneity, the present study used the following definition. Low back pain is defined as pain in the posterior aspect of the body between the lower margins of the twelfth ribs and the gluteal folds with or without pain in the one or both legs (Hoy et al., 2014). So the term low back pain is a description of the symptom (Maher et al., 2017) rather than the disease. Further, when low back pain persists for more than the tissue healing time, it is considered chronic (Loeser et al., 2018). There are different cut off points between one month and six months in the literature. Again, for the purpose of the study, low back pain persisting for more than three months was defined as chronic low back pain (CLBP) (Saragiotto et al., 2016b). In the majority of the cases, the structural source of pain cannot be identified for CLBP and it is termed non-specific CLBP (Maher et al., 2017, Hartvigsen et al., 2018).

2.1.1 Prevalence of chronic low back pain

Low back pain is a common musculoskeletal condition globally. The prevalence of low back pain was increased by 17.3% from 460.16 million in the Global Burden of Disease (GBD) study in 2005 to 539.91 million in GBD study 2015 (Vos et al., 2016).

Further, the incidence rate of a first-ever new episode of low back pain ranges from 6.3% to 15.4% worldwide (15.4% in the UK) (Hoy et al., 2010). The average point-prevalence, which is the most conservative prevalence estimate, is 18.3% (standard deviation 11.7%) (Hoy et al., 2012).The high variability in prevalence is mainly because of different definitions of low back pain, population characteristics, for example, age, gender and socioeconomic conditions of the responders, sampling method and structure used in the prevalence studies (Hoy et al., 2012). Overall, high prevalence (9.4%), poor remission (54-90%) and high recurrence rates (24-80%) of low back pain (Hoy et al., 2012, Hoy et al., 2010, Hoy et al., 2014) result in high prevalence rates for CLBP.

2.1.2 Socio-economic impact of chronic low back pain

Low back pain has been identified as the leading cause of disability, measured using years with lived with disability (YLDs) in the GBD 2010 and GBD 2015 studies, (Vos et al., 2016, Vos et al., 2012). Further, patients with CLBP use a general physician and other outpatient consultations double that of matched controls without CLBP (Hong et al., 2013).

The total treatment cost related to CLBP in the UK was last estimated to be above £12 billion in 1998 (Maniadakis and Gray, 2000). Similarly, based on general practice research data from 2009, the average direct health care costs for one individual with CLBP was over £1000 per year (Hong et al., 2013). The substantial economic burden of CLBP globally was summarised in a systematic review, and the cost of the physiotherapy was reported to be a significant (17%) contributor for the total cost of treatment for CLBP (Dagenais et al., 2008).

2.1.3 Treatment of chronic low back pain

Chronic low back pain is clinically difficult to manage. Common over-the-counter medication like paracetamol is not effective (Saragiotto et al., 2016a) and non-steroid anti-inflammatory drugs has a small effect on pain intensity and disability in patients with CLBP (Enthoven et al., 2016). Opioids are only effective in short-term in patients with CLBP (Chaparro et al., 2014) and long-term opioid use is associated with risk of dose-dependent serious harms (Chou et al., 2015). Interventional treatment, for example, discectomy, laminectomy and spinal epidural injection has very limited use in selected patients with CLBP (Foster et al., 2018).

Further, use of electrophysical agents, for example, superficial heat (French et al., 2006), transcutaneous electrical nerve stimulation (Khadilkar et al., 2008), therapeutic ultrasound (Ebadi et al., 2014) and traction (Wegner et al., 2013) has no benefit in patients with CLBP. Use of other passive physiotherapy treatment strategies, for instance, spinal manipulation (Rubinstein et al., 2011), massage (Furlan Andrea et al., 2015), muscle energy technique (Franke et al., 2015) and acupuncture (Furlan Andrea et al., 2005) are not effective in managing CLBP.

Hence a biopsychosocial approach towards assessment and treatment of CLBP is recommended (Foster et al., 2018). There is moderate quality evidence that exercise with education is effective to manage CLBP (Foster et al., 2018, Bernstein et al., 2017, NICE Guideline, 2016, SIGN, 2013). Different forms of exercise including motor control exercise (Saragiotto et al., 2016b), pilates (Yamato et al., 2015), yoga (Wieland et al., 2017), and exercise therapy (Hayden et al., 2005) are effective improving pain and disability. However, there is no evidence that one form of exercise is better than the other. Thus the exercise prescription should consider individuals' capabilities, preferences and needs (Foster et al., 2018).

Behavioural treatment (Henschke et al., 2010) and combinations of behavioural and exercise therapy (Kamper et al., 2014) are also effective in managing CLBP. Recognising the evidence, along with education, exercise, behavioural treatment, supported SM is recommended as an important treatment strategy for CLBP (Bernstein et al., 2017, NICE Guideline, 2016, SIGN, 2013).

2.2 Self-management

2.2.1 Definition of self-management

The term self-management (SM) is often inconsistently defined (Audulv et al., 2016) as there is no agreed definition (Barlow et al., 2002). Nakagawa-Kogan (Nakagawa-Kogan et al., 1988) and team defined SM a combination of biological, psychological and social intervention techniques to alter chronic conditions by retraining self-regulating body process to maximise disease management. This SM definition was based on the process model of therapy (Kanfer and Grimm, 1980) which included role restructuring, formation of the therapeutic alliance, developing commitment for change, analysing behaviour, negotiating treatments objectives, executing treatment, maintaining motivation, monitoring progress and generalisation and termination of treatment. Clark defined SM as day-to-day home-management tasks to minimise the impact of disease as guided by healthcare providers (Clark et al., 1991) which highlighted both social and cognitive SM (Corbin and Strauss, 1988).

The UK National Health Service views SM as the 'actions taken' by individuals to recognise, treat and manage health and disease either independently or in partnership with the healthcare system (NHS England, 2018). The UK NHS promotes SM to manage minor illness including low back pain (Department of Health, 2005).

For the purpose of this research, SM is defined as a dynamic and continuous ability to manage the disease, its symptoms, its treatment, physical, psychological and lifestyle changes (Barlow et al., 2002) when living with a chronic disease.

According to Lorig and Holman (2003), SM involves medical management, behavioural management, role management, and emotional management by solving day-to-day problems, making conscious decisions, using appropriate health care resources, forming patient and healthcare provider partnerships and taking appropriate actions towards healthy lifestyle (Lorig and Holman, 2003).

Recently, Ko and colleague (Ko et al., 2018) conducted a systematic review of peer-reviewed literature aiming to operationalise SM in individuals with multiple chronic conditions. The authors operationalised SM in two main domains- prerequisites for SM and SM behaviour. The prerequisites for SM included attitude, self-efficacy, perceived ability and knowledge. The actual SM behaviour included health-related behaviour, healthcare use, medication adherence, symptoms management, communication with healthcare providers and others, for example, action planning, problem-solving (Ko et al., 2018).

2.2.2 Theories of self-management

Self-management programmes are commonly underpinned by various theories (Table 1) including social cognitive theory (Bandura, 1991), self-efficacy (Bandura, 2004, Barlow et al., 2002), coping strategy (Lazarus, 1993), learned helplessness and social support (Gonzalez et al., 1990, Purdie and McCrindle, 2002). These theories are briefly discussed below for the purpose highlighting the constructs of SM.

Recently, Richardson and colleagues (Richardson et al., 2014) in a scoping review found 57 clinical studies on SM programmes, which were designed or delivered by physiotherapists and/or occupational therapists in adults with chronic pain or chronic diseases. They reported most of those 57 studies utilised the social cognitive theory and self-efficacy theory as a framework and a quarter of the studies on chronic pain did not report any underlying theoretical framework. A fewer number of studies included in that review used the Health Belief Model and Trans-Theoretical Model of Behaviour Change, although these models are criticised due lack of validity in explaining variation in complex health behaviours (Armitage, 2009, Sniehotta et al., 2014).

Table 1: Theories or models of self-management

Year	Theory/ Model	Psychological or behavioural Factors
1940	Social Learning Theory	Psychological situation
1950	Health Belief Model	Negative beliefs
1967	Learned Helplessness	Subjective norms and perceived behavioural control
1970	Behaviour Modification	Deficits on skills required to change
1977	Transtheoretical or Stages of Change Model	Readiness to change
1982	Self-Efficacy Theory	Self-efficacy
1985	Theory of Planned Behaviour	Subjective norms and perceived behavioural control
1986	Social Cognitive Theory	Physiological factors and self-efficacy
1986	Coping Theory/ Strategy	Emotions
1991	COM-B model	physical and psychological capabilities
2010	Behaviour Change Wheel	physical and psychological capabilities

2.2.2.1 Social cognitive theory

According to Social cognitive theory (SCT), developed by Albert Bandura in the 1980s, intentional human behaviours are the result of forethought and self-regulation. Self-regulatory processes work with two major complex but interactive psychological sub-functions- self-regulation (relates to goal setting and assessing any progress made towards the goals) and judgmental sub-function (refers to the formation of personal standards through a complex combination of self-evaluation and social sanctions) (Bandura, 1991).

Positive SM behaviour can be induced by changing self-judgmental sub-function through direct instruction or intervention. This self-judgment is grossly influenced by referential comparison with past personal or other's performance (Bandura, 1998). In short, SCT works with 'triadic reciprocal causation' among cognitive or individual factors, behaviours, and environmental factors and their bidirectional interactions (Figure 1) (Bandura, 1998).

Self-observation	Judgemental process	Self-reaction
▪ Performance dimensions (quality, productivity, originality, sociability, morality, deviancy) ▪ Quality of monitoring (informativeness, regularity, proximity, accuracy)	▪ Personal standards (level, explicitness, proximity, generality) ▪ Referential performances (standard norms, social comparison, self-comparison, collective comparison) ▪ Valuation of activity (valued, neutral, devalued) ▪ Performance determinants (personal, external)	▪ Evaluations of self-reactions (positive, negative) ▪ Tangible self-reactions (rewarding, punishing) ▪ No self-reaction

Figure 1: Components of the social cognitive theory

2.2.2.2 Self-efficacy

Self-efficacy, an important self-regulatory process, is one's beliefs about his/her ability 'to exercise control', which is maintained by 'interpretation of causal attribution' (Bandura, 1991, Bandura, 2004). Self-efficacy relates to the outcome, physiological factors, persuasion and vicarious experience. Self-efficacy is controlled by anticipatory control of effort expenditure and self-evaluation of personal performances and efficiency; and further mediated by motivation, performance expectations, self-evaluations, socioeconomic status and task difficulty (O'Sullivan 2009). Another important factor is 'self-reflective metacognitive activity' regarding efficacy appraisals, sustainability and standard setting. Activation of this cognitive process depends on both personal standards and knowledge about performances. These two factors lead to self-reactive cognitive process, which self-regulates the motivation level. Self-motivation thus depends on 'discrepancy production' and 'discrepancy reduction'(Bandura, 1991).

2.2.2.3 Application in health behaviour change

According to SCT, SM is strongly influenced by one's belief system. One who believes that SM ability can be acquired by knowledge and practising SM strategies are able to set learning goals and monitor their progress against them (Bandura, 1991, Bandura, 2004). These beliefs are challenged by social norms and organizational agency. SCT can be applied in health behaviour change or SM programme in three different ways. Firstly, for people with high perceived self-efficacy need little support to achieve the desired change. Secondly, people with low perceived self-efficacy need a considerable amount of support through a SM programme in behaviour change. Finally, people who do not have faith in their control need substantial individual support to change their health behaviours (Bandura, 2004). However, SCT does not categorise people in different stages of change rather it wants to follow a process model (Bandura, 1998).

2.2.2.4 Behaviour change wheel

Self-management incorporates promoting healthy living by uptake of desired health behaviour. More recently, Michie and colleagues (Michie et al., 2011, Michie et al., 2013) conceptualised behaviour change based on the capability, opportunity, motivation and behaviour (COM-B) model. In this COM-B behavioural system, capability defines one's physical and psychological ability to engage in the activity; opportunity defines cognitive processes including analytical decision-making, habits, emotional responding that direct behaviour; and opportunity defines external influence to engage in certain behaviour.

The authors used this COM-B model to link existing 18 frameworks in their systematic review (Michie et al., 2011). They found nine intervention functions (education, persuasion, incentivisation, coercion, training, restriction, environmental restructuring, modelling and enablement) and seven policies (communication, guidelines, fiscal, regulation, legislation, social planning and service provision) used in behaviour change interventions in their systematic review. This led them to propose a Behaviour Change Wheel (Figure 2) framework for theory- and evidence-based intervention mapping to target health behaviour change.

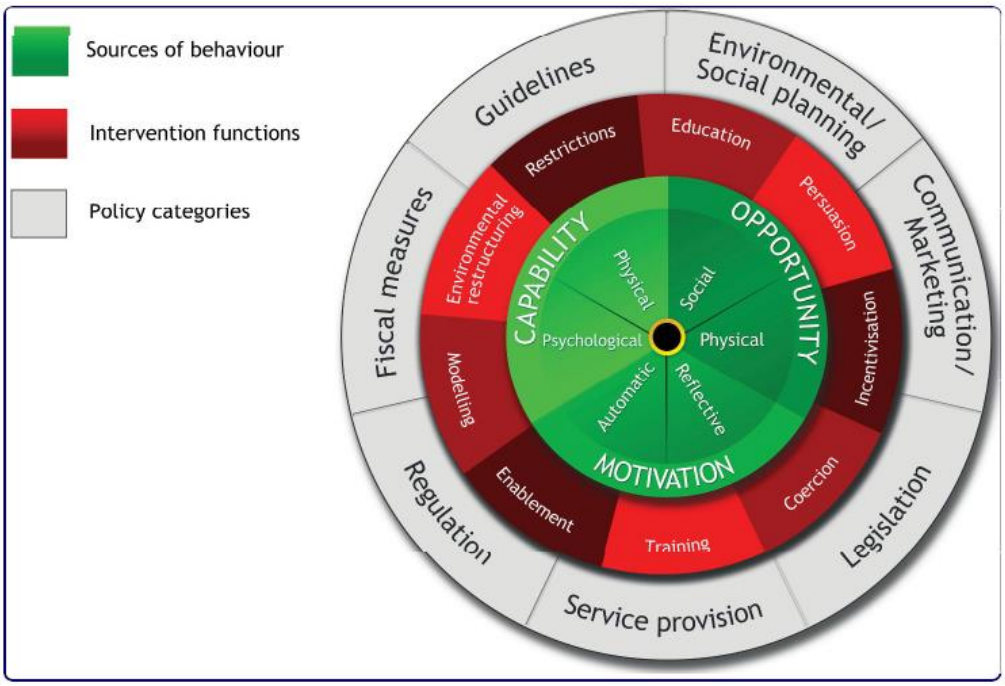


Figure 2: Behaviour Change Wheel (Michie 2011)

A recent systematic review examining the effectiveness of behaviour change techniques demonstrated had significant effect for maintaining physical activity behaviour (Murray et al., 2017) but research is lacking on the use and effectiveness of theoretically driven behaviour change interventions in patients with CLBP (Keogh et al., 2015) especially by physiotherapists (Kunstler et al., 2018). Another difficulty identified in application of behaviour change strategies in SM in patients with CLBP is heterogeneity of SM definitions (Mansell et al., 2016).

2.2.2.5 The Transtheoretical Model

The desired change in SM behaviour also depends on the preconditions, process of change, the content of SM support training and relationship between the patient and the provider (Prochaska and Velicer, 1997). The stages of change according to the Transtheoretical Model or the Stages of Change Model are pre-contemplation, contemplation, preparation, action, maintenance and termination (Prochaska et al., 2013). The patients at different stages of change may require different types of strategy or intervention in enhancing their SM. For example, patients at the pre-contemplation stage may benefit with awareness of consequences for not engaging in SM and contemplators may benefit by monitoring their motivation in engaging in the SM behaviours (Elder et al., 1999). Therefore, along with promoting healthy living and physical activity (Buchbinder et al., 2018), the psychological and behavioural factors should be targeted to enhance SM in patients with CLBP.

2.2.2.6 Coping strategies

Coping is defined as a continuous cognitive and behavioural process to self-manage particular internal or external needs, which are more than one's ability to resolve (Lazarus, 1993). The strategies, for example, confrontive coping, distancing, self-controlling, seeking social support, accepting responsibility, planful problem solving, may be adaptive or non-adaptive in chronic disease. These strategies primarily focused on problem and emotion. Coping can be viewed either as a hierarchical style or as a process (Lazarus, 1993). On the one hand, the hierarchical view focuses on the trait, or style, which are mainly two types- a less regressed (defence) and more regressed style (ego-failure). On the other hand, coping as a process believes coping is heavily influenced by the context and does not tend to dichotomise the coping in either health or illness. Lazarus (Lazarus, 1993) suggests a few meta-theoretical principles. Firstly, coping thoughts should always be measured and seen in the context. Secondly, coping measurement, therefore, should include both the thoughts and actions. Finally, the process viewpoint of coping does focus on relational meaning in two major ways- problem-focused and emotion-focused (Lazarus, 1993). Thus coping was often used as proxy measure for SM.

2.2.2.7 Learned helplessness and social support

The theory of learned helplessness, originating from animal experiments, indicates inability to avoid repeated painful stimuli due to false causal attribution (Abramson et al., 1978). This later modified to explain health behaviours as an internal specific and stable undesired response to a noncontingent chronic condition (Abramson et al., 1978).

Learned helplessness could be managed by using self-control, coping, and identifying and restructuring irrational self-beliefs and statements (Gonzalez et al., 1990). In the theory of social supports importance is given to effects of perceived and actual availability or adequacy of (formal and informal) support from the personal, professional and healthcare networks. The social support could be enhanced by providing a support group and involving family members in lifestyle changes (Gonzalez et al., 1990).

2.2.2.8 Self and family management

Self and family management are conceptualised as one dynamic process, which is influenced by risk and protective factors (Grey et al., 2006). These factors can be further divided into five domains: disease or condition (severity, regimen, trajectory and genetics), individual (age and gender), psychological (depression, self-efficacy, integration and diversity), family (socioeconomic status, structure and function) and environmental (social networks, community and healthcare system). The authors proposed effect of any self and family management intervention should measure four different aspects, such as condition (disease control, morbidity and mortality), individual (quality of life and adherence) family outcome (function and lifestyle) and environment (access, utilization, and care provider relationships). As these factors are interactive with one another, the factors impose further difficulty in measurement.

2.2.2.9 Psychological factors and SM

In summary, the above mentioned theories of SM indicate emotions (Lazarus, 1993), negative beliefs (Gonzalez et al., 1990), psychological capability (Michie et al., 2008, Michie et al., 2011) to ability change (Prochaska et al., 2013) potentially influence individuals' SM ability. Further, the psychological constructs including depression, kinesiophobia and catastrophising were found to moderate or mediate pain and disability in patients with CLBP (Beneciuk et al., 2013, Heymans et al., 2010, Pinto-Meza et al., 2005, Van Der Hulst et al., 2008). However the predictive association between SM and these psychological factors (depression, kinesiophobia and catastrophising) was not investigated in patients with CLBP (Kawi, 2014), which warrants further research.

2.2.3 Self-management programme

Self-management support broadly defines strategies and approaches involving governments, health service or system, professional organisations and charities to enhance SM in individuals living with chronic disease (Mills et al., 2017). SM support includes infrastructure and policies to minimise the chronic disease and reduce the barriers for SM, resources and networks to support individuals (and their families) with chronic disease, and programmes aiming to enhance SM (Mills et al., 2017).

Education programme or course, based on behavioural change or cognitive behavioural strategies, aiming to enhance SM is called SM programme. Alderson (Alderson et al., 1999) defined a SM programme as interdisciplinary group education to enhance SM and self-efficacy by utilising principles of adult learning, case-management theory and individualised treatment. Self-management programmes allow and encourage individuals to manage their long-term conditions (Foster et al., 2007). Chronic Pain Self-Management Programme were developed based on the earlier Chronic Disease Self-Management Programme, based on self-efficacy theory, at the Stanford University by Lorig and team (Lorig et al., 1989b). Similarly, the Arthritis Self-Management Programme, based on social cognitive theory, was developed by Barlow (Barlow et al., 2002).

Self-management programmes include disease-specific information, desirable health behaviour for tertiary prevention, goal planning, problem solving and decision making skills delivered through a wide range of learning strategies in form of either face-to-face group-based or internet-based interventions and delivered by professionals or expert patients, for patients and their significant others (Lorig, 2002, Lorig and Holman, 2003, Marks and Allegrante, 2005). SM programmes are generally delivered based on a formal curriculum in group settings to cover broad knowledge about the disease and its treatment, monitoring and managing advice, care participation and health promotion, and signposting and navigating locally available healthcare services (Nolte and Osborne, 2013).

2.2.4 Self-management programme in patients with chronic low back pain

The recommendation for SM in patients with CLBP in national guidelines is supported by findings of a number of systematic reviews (Du et al., 2017, Foster et al., 2007) and randomised controlled trials (Carpenter et al., 2012, Chiauzzi et al., 2010, Kroenke et al., 2009, Moore et al., 2000, Von Korff et al., 1998).

Du and colleagues (Du et al., 2017) found moderate-quality evidence for patients with CLBP that SM reduced pain intensity [standardised mean difference- (SMD) -0.29 immediate in nine studies, -0.20 in long-term in four studies] and disability (SMD -0.28 immediate in nine studies, -0.19 in long-term in four studies). Foster and colleague (Foster et al., 2007) reported a reduction of pain intensity (11 studies, SMD -0.10), disability (eight studies, SMD -0.15) and self-efficacy (ten studies, SMD -0.30) when SM programme had been delivered by lay leaders. However, the benefit of an SM programme, at best, is small and short-term in managing pain, disability and self-efficacy in patients with CLBP.

2.2.5 Challenges in self-management in chronic pain

Further, Taylor and colleague asserted potential reasons for the small benefit of SM programmes could be due sub-optimal content and delivery of SM programmes; SM programmes are effective only for some patients; outcome measures are not reflecting change in SM; poor targeting of the interventions; and SM programmes are inherently ineffective (Taylor et al., 2016b). To address the deficits of SM programmes, the authors (Taylor et al., 2016a) developed a theory-driven SM programme and tested its cost-effectiveness in 652 patients with chronic musculoskeletal pain.

They found no significant difference in pain-related disability, measured with Chronic Pain Grade disability sub-scale. Pain-related self-efficacy (Pain Self-Efficacy Questionnaire, difference 2.3, 95%CI 0.6 to 4.1), anxiety (Hospital Anxiety and Depression Scale-anxiety subscale, −0.7, 95%CI −1.3 to −0.2), depression (Hospital Anxiety and Depression Scale depression subscale, −0.7, 95%CI −1.2 to −0.2), pain acceptance (Chronic Pain Acceptance Questionnaire, 3.4, 95% CI 1.3 to 5.5), and social integration (Health Education Impact Questionnaire, Social Integration and Support subscale, 0.6, 95% CI 0.1 to 1.0) had improved more in the intervention group that the control group at six-month follow-up, who received pain toolkit and a relaxation CD. The improvement in the intervention group was sustained for depression and social integration at 12-month follow-up in the intervention group. However, the effect size of benefits in the intervention group was small at all time-points (Taylor et al., 2016a). Their findings potentially highlight research is needed on SM measurement and on identifying predictors SM.

2.2.6 Measurement of self-management in patients with chronic low back pain

The potential reason for the small effect size found for the change in SM is potentially due to the fact that the outcome measures are not able to detect the desired change (Nolte and Osborne, 2013, Taylor et al., 2016b). The effectiveness of a SM programme is measured predominantly by using a range of outcome measures in relation to CLBP (pain and disability), psychological attributes (depression, coping and locus of control) and quality of life (Oliveira et al., 2012, Du et al., 2017). Single scales are also employed to measure change in SM including; self-efficacy (Barlow et al., 2002), Patient Activation Measure (PAM) (Hibbard et al., 2004) and Health Education Impact Questionnaire (heiQ) (Osborne et al., 2007). Self-efficacy has been criticized for its inability to detect the desired changes in chronic diseases (Nolte et al., 2013a, Nolte and Osborne, 2013). However, there is no systematic review on the outcome measures used to assess change in SM in randomised and non-randomised clinical trials in patients with chronic musculoskeletal pain.

2.2.7 Predictors of self-management in patients with chronic low back pain

The small benefits of SM programmes potentially due to the fact that SM programmes are effective only for some patients and poor targeting of the SM interventions (Taylor et al., 2016b). These deficits can be addressed by increasing understanding of the predictive relationships between SM constructs and biopsychosocial (biophysical, psychological and social)(Hartvigsen et al., 2018) outcome measures in patients with CLBP.

Further, the effectiveness of a treatment strategy in patients with CLBP depends upon causal and/or mediation effects of the attributes (Mansell et al., 2013). Turk and colleagues have emphasised the importance of careful patient selection and treatment matching in patients with CLBP to achieve clinically meaningful cost-effective treatment results (Turk and Okifuji, 2002, Turk et al., 1993).

However, predictors (variables used to predict values of another variable) of SM have not been investigated thoroughly in CLBP, except in one recent report from Kawi (Kawi, 2014) which demonstrated that age ($\beta = -0.197$, SE = .074) and poor overall health negatively and education attained at college and SM support positively ($\beta = 2.292$, SE = .965) predicted SM when measured using Patient Activation Measure (PAM) in 230 patients with CLBP, although these predictive associations did not include psychological characteristics as potential cofounders.

Psychological characteristics, for example, depression negatively predicted SM in a range of conditions including; diabetes (Mut-Vitcu et al., 2016, Schinckus et al., 2018b, Oh and Ell, 2018), long-term conditions (including rheumatism, asthma, orthopaedic disorders and inflammatory bowel syndrome) (Musekamp et al., 2016), in people with epilepsy (Robinson et al., 2008) and in older adults (Blakemore et al., 2016). Despite theoretical support and empirical evidence from other long term conditions that psychological characteristics potentially influence SM, the predictive association between SM and psychological characteristics yet to be investigated for patients with CLBP.

2.3 Rationale for the study

Chronic low back pain is a common and costly condition causing substantial socioeconomic burden. The national guidelines recommend SM as a key strategy for managing patients with CLBP. SM programmes in patients with CLBP have demonstrated small benefits in pain and disability. The questions which remain unanswered are what are the optimal measure(s) of SM in patients with chronic pain conditions and do biopsychosocial outcome measures predict SM and its change over time in patients with CLBP. One major reason is that the change in SM is difficult to detect using change in pain and disability scores in patients with CLBP. To date, there is no systematic review of outcome measures used to assess change in SM in patients with chronic musculoskeletal pain. And an increased understanding of the predictive relationship between the SM constructs and biopsychosocial predictors is necessary to select a sub-group of patients who would favourably respond to SM programmes.

2.4 Aims

The overarching aim of this PhD thesis was to investigate predictive relationship between SM constructs and biopsychosocial outcome measures in patients with chronic low back pain. This overarching aim was achieved through:

1. First synthesising and appraising the literature on the outcome measure used to measure the change in SM in randomised and non-randomised controlled trials in chronic pain. This would help to identify a SM outcome measure to be utilised in the PhD study (Chapter 3).

2. Then to examine the reliability and agreement of the identified SM measure between paper and non-paper alternative survey modes in patients with CLBP (Chapter 4).

3. Finally, to examine the predictive relationship between SM constructs and biopsychosocial outcome measures in patients with CLBP (Chapter 5, 6 and 7).

3 A SYSTEMATIC REVIEW OF OUTCOME MEASURES UTILISED TO ASSESS SELF-MANAGEMENT IN CLINICAL TRIALS IN PATIENTS WITH CHRONIC PAIN

3.1 Introduction

Chronic pain is a common (Breivik et al., 2006, Bridges, 2012) and challenging condition associated with high health care usage (Mann et al., 2016) and socioeconomic burden (Breivik et al., 2013, Dueñas et al., 2016). Given the known benefits in reducing pain and disability (Du et al., 2017, Oliveira et al., 2012), the clinical practice guidelines (2013, Bernstein et al., 2017, NICE Guideline, 2016) recommend self-management as a treatment strategy for chronic pain along with other treatments.

Self-management (SM) is one's dynamic ability to manage the chronic condition and its treatment, adapt to physical and psychological changes and adhere to lifestyle modifications (Barlow et al., 2002). SM involves a number of constructs, which include managing the disease, healthy lifestyle behaviours, changes in social and vocational roles and emotion by solving day-to-day problems, making conscious decisions, using appropriate health and social care resources, forming a good relationship with the health care providers and importantly taking appropriate actions (Bodenheimer et al., 2002), for example, pacing or increasing physical activity.

Measuring the effectiveness of an intervention to enhance SM in chronic conditions is complex and widely variable (Nolte et al., 2013a). Change in SM in chronic pain is predominantly measured using a wide range of outcome measures for pain, physical functioning, psychological well-being and quality of life, which are not designed specifically to measure SM. Different scales are commonly employed to measure SM for example, Arthritis Self-Efficacy Scale (Barlow et al., 2002), Patient Activation Measure (PAM) (Hibbard et al., 2004) and the Health Education Impact Questionnaire (heiQ) (Nolte et al., 2007); however, there is currently neither a single validated measure nor a collection of constructs agreed to measure overall SM. National guidelines in CLBP do not recommend the use of any particular scale/ tool for assessing SM (2016).

Therefore, the purpose of this systematic review was to identify, synthesise and appraise the literature on outcome measures used to assess change in SM in patients with chronic musculoskeletal pain. This would help to identify a SM outcome measure to be utilised in the PhD study.

3.2 Methods

The review was conducted following the registered protocol (Banerjee et al., 2015). Additionally, Patient Reported Outcome Measure Information System (PROMIS) framework (PROMIS, 2017), which is based on World Health Organization's physical, mental and social health categories (Tugwell et al., 2011), was used in the review to appraise the domains targeted by the measures assessing SM.

3.2.1 Search strategy

Medline, Embase, CINAHL, PsycINFO, the Cochrane Library (since inception to February 2016) and Google Scholar were electronically searched. The search strategy was developed with a combination of Medical Subject Headings and keywords, using a randomised controlled trial (RCT) filters from the Cochrane Back Review Group (Furlan et al., 2015). Further, the references of selected articles were hand-searched for eligible studies, and experts in the area of SM research were contacted for any potential additional unpublished studies. Table 2 describes the search results for Medline via OVID.

Table 2: Search results from the Medline via OVID

No	Search terms	No of hits
1	randomized controlled trial.pt.	384488
2	controlled clinical trial.pt.	88564
3	randomized.ab.	282890
4	placebo.ab.	148676
5	drug therapy.fs.	1738271
6	randomly.ab.	200610
7	trial.ab.	291422
8	groups.ab.	1282844
9	or/1-8	3275738
10	(animals not (humans and animals)).sh.	3894169
11	9 not 10	2787987
12	exp Chronic pain/	4216
13	(chronic adj5 pain).mp.	38379
14	("low back pain" or "back pain" or "neck pain" or "knee pain" or "shoulder pain" or "hip pain" or "ankle pain" or "elbow pain" or "hand pain" or "temporomandibular$ joint$ pain" or "temperomandibular$ joint$ pain" or "tempromandibular$ joint$ pain" or fibromyalgia or neuralgia or polymyalgia or neuropath$ or osteoarthritis).ti,ab,kw.	178217
15	chronic.ti,ab,kw.	776046
16	14 and 15	25699
17	12 or 13 or 16	51350
18	exp Self Care/	40898
19	self-management.mp.	7865
20	self-care.mp.	29344
21	care self.mp.	331
22	self help.mp.	14462
23	self treatment.mp.	916
24	or/18-23	62551
25	11 and 17 and 24	340
26	limit 25 to the English language	320

Search hits from 1946 to February Week 4 2016

3.2.2 Inclusion criteria of studies

Full-text primary research reports available in English language of randomised and non-randomised controlled trials were included, where effectiveness of any non-surgical interventions was purposefully measured with quantitative outcome measures to assess change in SM in adult (more than 18 years with no upper age limit) patients with chronic pain (at least three months duration). Given this review targeted outcome measures used to assess SM, studies reporting outcomes of any non-surgical interventions were considered for inclusion, including SM support programmes, educational interventions, physical, psychological, cognitive therapy, cognitive-behavioural therapy, behavioural therapy and their combinations.

3.2.3 Exclusion criteria of studies

Studies involving participants with carcinoma, episodic pain (including post-surgical pain), traumatic and surgical conditions, substance abuse and addiction, AIDS and end-of-life care conditions (or terminal illnesses) were excluded because of the potential difference in the nature of pain and variation in the motivational factors associated with self-regulation of pain. Validation and feasibility studies were excluded as they were not designed to investigate the change in SM. Book chapters, stand-alone abstracts, opinions and correspondence and previous reviews were excluded from the review, as these are not primary research reports.

Studies published in languages other than English were excluded due to limited resources. As the review aimed at appraising the outcome measures utilised, multiple publications from any single research study were excluded to minimise bias (Egger and Smith, 1998). Table 3 summarises the selection criteria of the systematic review.

Table 3: Study selection criteria for the systematic review

Inclusion criteria	Exclusion criteria
▪ Participants: adults (≥18 years) with chronic pain (pain duration ≥ 3 months) ▪ Intervention: any non-surgical interventions ▪ Comparison: any comparisons ▪ Outcome: change in self-management measured using a composite quantitative outcome measure ▪ Studies: randomised and non-randomised controlled trials	▪ Observational, validation, feasibility and qualitative studies ▪ Studies including patients with cancer, trauma, surgical and episodic pain; substance abuse and addiction; AIDS and end-of-life care conditions (or terminal illnesses) ▪ Secondary research and multiple publications ▪ Limits: (full-text) research reports available in the English language

3.2.4 Selection of studies

The Cochrane Handbook (2011) and the Cochrane Back Review Group (Furlan et al., 2015) guidelines were followed in this review process. The review findings are reported in keeping with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al., 2009). Electronic search yields were imported into an Endnote file. After deleting duplicates, potential studies were screened at two stages- firstly, a brief screening by titles and abstracts, and finally, at detailed screening, by reading full-text articles. Articles were screened by two independent reviewers (AB and PB) for inclusion in the review. Any disagreement in study selection was resolved by consensus or by consulting a third reviewer (PH and HB). The reasons for exclusion were reported only at the full-text screening stage.

3.2.5 Risk of bias assessment of the selected studies

Two reviewers assessed the quality of the individual studies using the Cochrane Risk of Bias tool (2011). The Cochrane Risk of Bias assessment tool guides the reviewers to rate selection bias, performance bias, detection bias, attrition bias and reporting bias in 'low risk', 'high risk' and 'unclear risk' categories. Disagreements were resolved by consensus or by consulting a third reviewer.

3.2.6 Data extraction

One reviewer (AB) extracted study details (type of study, aims and sample size), population characteristics (age, gender, level of education, employment status, condition, symptoms duration), SM outcome measures (name, constructs measured, source and psychometric properties reported in the selected studies) and other outcome measures (for example, pain, disability, disease severity). Further, the characteristics of the interventions including SM support programmes (description, mode of delivery, duration and follow-up) were extracted. A second reviewer (PB) verified the extracted data.

Psychometric properties of the included outcome measures were extracted by the first reviewer (AB) from three sources: the individual articles, relevant citations and additional search in Ovid Medline (1996 to present). Extracted psychometric data were verified with the source by a second reviewer (PB) at random 50% of the fields. Psychometric properties of these included measures were reported using modified criteria following Terwee and colleague (Terwee et al., 2007). The criterion validity was not assessed in the absence of a 'gold standard' measure for assessing change in SM. Any disagreement in data extraction was resolved by discussion between the reviewers (AB and PB).

3.3 Results

3.3.1 Study selection

A total of 2383 search yields were imported into Endnote, where duplicates were deleted. 1633 reports were screened by title and abstract, and 110 reports were selected for full-text review. 85 studies were excluded after reading full-text versions (reasons outlined in Table 4), and 25 studies were included in this systematic review. The PRISMA flow diagram is presented in Figure 3. All included 25 studies were RCTs published between 1998 and 2016 and conducted in Western developed countries (USA, Canada, Australia, Germany, Switzerland, Sweden, Norway, Belgium and UK).

Table 4: Reasons for exclusion at the detailed screening stage

Reasons for exclusion	Number of studies
Not in chronic pain as defined in the protocol	30
No self-management outcome measure used	16
Not randomised or non-randomised controlled trials	19
Study protocol	05
Secondary analysis or multiple publications	08
No full text available even through interlibrary loan services	07
Total excluded articles at the full-text screening	85

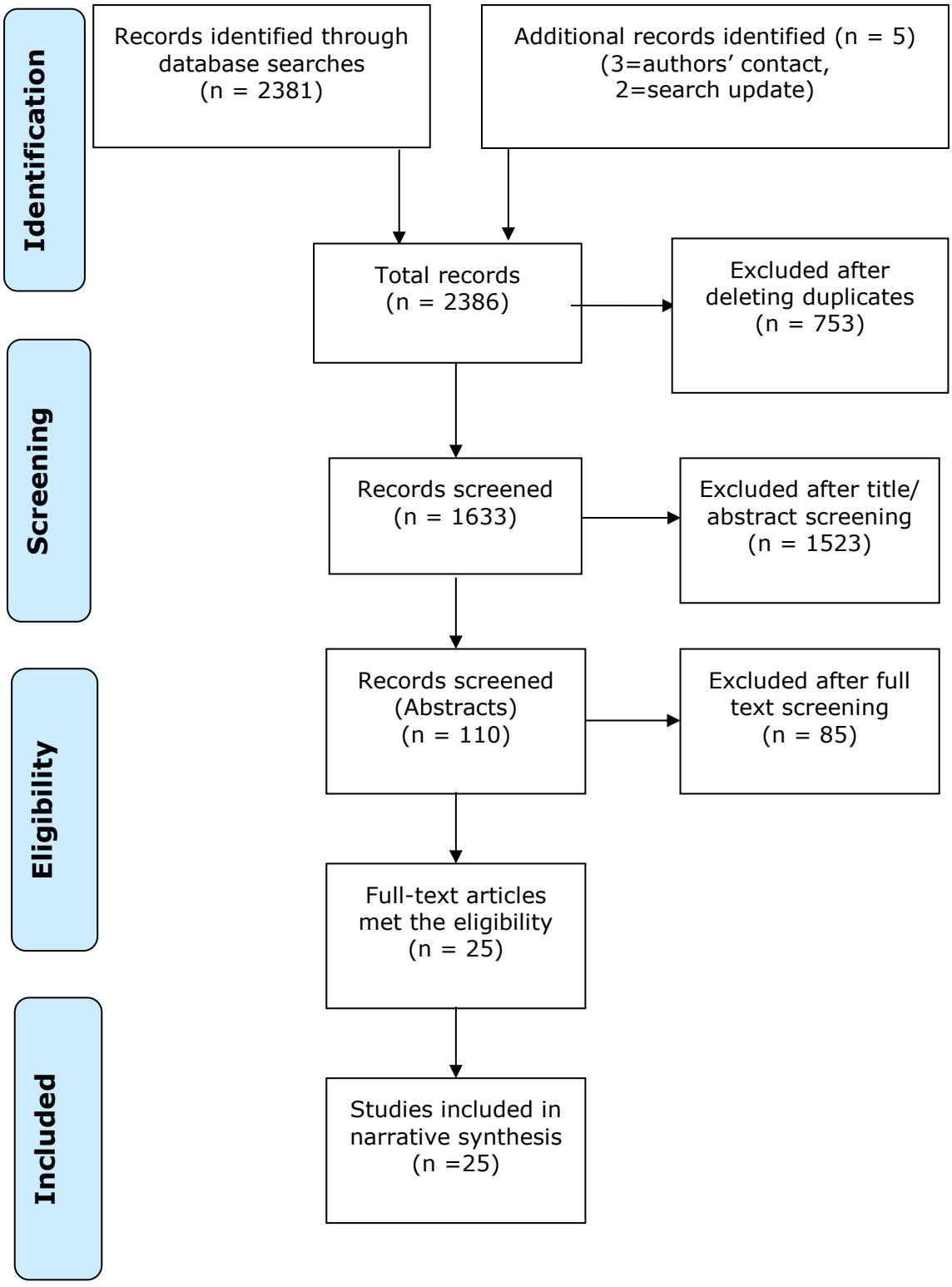


Figure 3: PRISMA Flow Diagram

3.3.2 Risk of bias assessment of the selected studies

The majority of included studies were categorised with 'low risk' for selection bias, detection bias, attrition bias and reporting bias. However, the overall high risk of performance bias was found in the majority of included studies, as blinding of the personnel and patients were not attempted due to practical reasons in a majority of the individual studies. Baseline differences in the clinical and demographic details among the treatment groups were low risk in the majority of the included studies. Details of the risk of bias assessment are summarised in Figures 4 and 5.

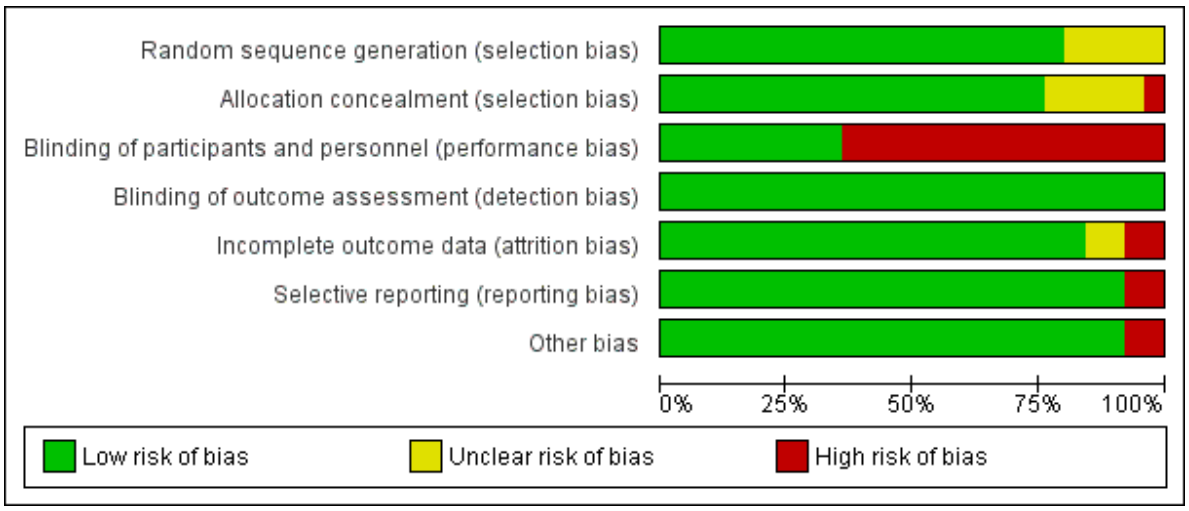


Figure 4: Risk of bias summary

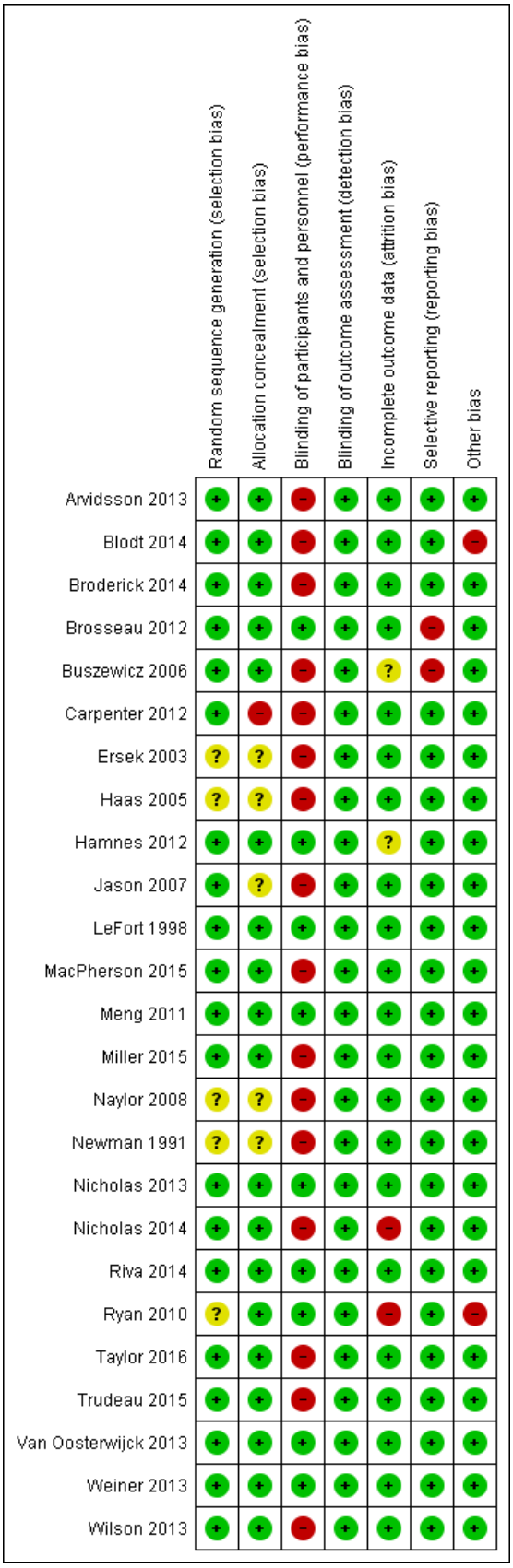


Figure 5: Risk of bias in the included studies

3.3.3 Participants

The sample sizes in the included studies ranged between 30 (Van Oosterwijck et al., 2013) and 812 (Buszewicz et al., 2006). The participants in the included studies were patients with hip/knee osteoarthritis and/or rheumatoid arthritis (six studies) (Broderick et al., 2014, Brosseau et al., 2012, Buszewicz et al., 2006, Newman, 1991, Trudeau et al., 2015, Weiner et al., 2013), CLBP (six studies) (Blodt et al., 2014, Carpenter et al., 2012, Haas et al., 2005, Meng et al., 2011, Riva et al., 2014, Ryan et al., 2010), fibromyalgia (two studies) (Hamnes et al., 2012, Van Oosterwijck et al., 2013), chronic fatigue syndrome (one study) (Jason et al., 2007) and non-cancer chronic musculoskeletal pain (seven studies) (Arvidsson et al., 2013, Ersek et al., 2003, LeFort et al., 1998, Naylor et al., 2008, Nicholas et al., 2013, Nicholas et al., 2014, Wilson, 2014). The mean age of participants in the individual studies ranged from 39 (LeFort et al., 1998) to 82 years (Ersek et al., 2003). The average duration of symptoms in the included studies varied from three years (Blodt et al., 2014) to over 13 years (Broderick et al., 2014). Table 5 presents the characteristics of the participants in the included studies.

Table 5: Characteristics of the included studies

Author, year [reference]	Total participants (drop out)	Conditions	Mean symptom duration*	Mean age*	Female (%)	Attended college or university (%)	Unemployed (%)	Self-management outcome measures
Arvidsson 2013 (Arvidsson et al., 2013)	202 (40)	Chronic pain/ fatigue	NR	56.4 (7.2) IG, 55.2 (13.2) CG	71 IG, 73 CG	21 in IG, 25 in CG	NR	Swedish Rheumatic Disease Empowerment Scale; Self-Care Agency Scale
Blodt 2014 (Blodt et al., 2014)	128 (14)	Chronic low back pain	2.7 (1.4) IG, 3.2 (1.5) CG	45.7 (10.0) IG, 47.7 (10.8) CG	90.6 IG, 69.8 CG	67.2 IG, 55.6 IG	0	Self-Efficacy Scale
Broderick 2014 (Broderick et al., 2014)	256 (27)	Osteoarthritis-knee/hip	13.95 (10.63) IG, 13.59 (9.09) CG	68.00 (8.67) IG, 66.37 (10.26) CG	74.4 IG, 78.9 CG	71.7 IG, 73.1 CG	78.9 IG, 60.3 CG	Arthritis Self-Efficacy Scale, Coping Strategies Questionnaire
Brosseau 2012 (Brosseau et al., 2012)	222 (100)	Osteoarthritis-knee	10.3 (9.26)	63.4 (8.6)	68.9	72.1	NR	Self-Efficacy- Coping with symptoms, Confidence about doing things
Buszewicz 2006 (Buszewicz et al., 2006)	812 (193)	Osteoarthritis-hip/knee	NR	68.4 (8.2) IG, 68.7 (8.6) CG	63 IG, 63 CG	28 IG, 27 CG	NR	Arthritis Self-efficacy
Carpenter 2012 (Carpenter et al., 2012)	141 (32)	Chronic low back pain	8.64 (7.84)	42.5 (10.3)	83	54	NR	Pain Self-efficacy Scale, Survey of Pain Attitudes
Ersek 2003 (Ersek et al., 2003)	45 (6)	Chronic pain	NR	81.9 (range 65-94)	87	75	NR	Survey of Pain Attitudes

Author, year [reference]	Total participants (drop out)	Conditions	Mean symptom duration*	Mean age*	Female (%)	Attended college or university (%)	Unemployed (%)	Self-management outcome measures
Haas 2005 (Haas et al., 2005)	109 (8)	Chronic low back pain	NR	77.2 (7.7)	84.4	23.8	NA	Self-Efficacy Scale
Hamnes 2012 (Hamnes et al., 2012)	150 (32)	Fibromyalgia	7.03 (7.21) IG, 6.13 (6.53) CG	45.4 (9.4) IG, 49.7 (4.0) CG	92 IG, 100 CG	24 IG, 21 CG	72 IG, 70.8 CG	Arthritis Self Efficacy Scale
Jason 2007 (Jason et al., 2007)	114	Chronic fatigue syndrome	43.8	NR	83.3	90.3	58.3	Self-Efficacy Scale
LeFort 1998 (LeFort et al., 1998)	110 (8)	Chronic pain	6.5 (range 1-28) IG, 5.6 (range 1-20) CG	39 IG, 40 CG	74 IG, 75 CG	75 IG, 66 CG	63 IG, 66 CG	Self-Efficacy Scale
MacPherson 2015 (MacPherson et al., 2015)	517 (89)	Chronic neck pain	6	53.2 (13.8)	69	NR	39.8	Chronic Pain Self-Efficacy Questionnaire
Meng 2011 (Meng et al., 2011)	360 (91)	Chronic low back pain	NR	50.2 (7.6) IG, 49.5 (7.7) CG	65.2 IG, 63.0 CG	18.9 IG, 25.5 CG	9.2 IG, 8.8 CG	German Pain Management Questionnaire
Miller 2015 (Miller, 2015)	102 (22)	Chronic pain	10 (median)	53.4 (13.5)	73.5	32 IG, 21 CG	86 IG, 92 CG	Pain Self-Efficacy Questionnaire
Naylor 2008 (Naylor et al., 2008)	51 (4)	Chronic musculoskeletal pain	11.5 (9.27)	46 (11.47)	86	70	NR	Coping Strategy Questionnaire
Newman 1991 (Newman, 1991)	180 (50)	Osteoarthritis, rheumatoid arthritis	12.9 (1.49)	69.0	87.7	IG 59.2 CG 57.6	IG 1.4, CG 0.0	Arthritis Self Efficacy Scale

Author, year [reference]	Total participants (drop out)	Conditions	Mean symptom duration*	Mean age*	Female (%)	Attended college or university (%)	Unemployed (%)	Self-management outcome measures
Nicholas 2013 (Nicholas et al., 2013)	141 (22)	Chronic pain	6.0 (median)	73.9 (6.5)	63	NR	NA	Pain Self-Efficacy Questionnaire
Nicholas 2014 (Nicholas et al., 2014)	140 (13)	Chronic pain	5.60 (7.26) IG, 6.48 (7.44)	42.05 (12.33) IG, 43.22 (11.08) CG	51 IG, 55 CG	55 IG, 55 CG	68 IG, 70 CG	Pain Self Efficacy Questionnaire
Riva 2014 (Riva et al., 2014)	51 (0)	Chronic back pain	7.9 (7.2) IG, 9.3 (8.7) CG	44(13.6) IG, 51(14.1) CG	51.9 IG, 50.0 CG	33.3 IG, 12.7 CG	40.7 IG, 41.7 CG	Psychological Empowerment Scale
Ryan 2010 (Ryan et al., 2010)	38 (11)	Chronic low back pain	7.6 (7.0) IG, 13.7 (10.2) CG	45.2 (11.9) IG, 45.5 (9.5) CG	70.0 IG, 61.1 CG	NR	NR	Pain Self Efficacy Questionnaire
Taylor 2016 (Taylor et al., 2016a)	703 (82)	Chronic musculoskeletal pain	85% had pain for 3 years or more	60.3 (13.5) IG, 59.4 (13.8) CG	67	40% ended formal education after 20 years	26 IG, 24 CG	Pain Self-Efficacy Questionnaire, Health Education Impact Questionnaire (Social Integration and Support)
Trudeau 2015 (Trudeau et al., 2015)	245 (73)	Arthritis and ankylosing spondylitis	NR	49.9 (11.6)	68.4	61.4	8.8	Arthritis Self Efficacy Scale and Self-Management Behaviours
Van Oosterwijck	30 (4)	Fibromyalgia	13.0 (6.0) IG, 9.67 (3.83) CG	45.8 (9.5) IG, 45.9 (11.5) CG	80 IG, 93.3 CG	NR	66.7 IG, 53.3 CG	Pain Coping Inventory

Author, year [reference]	Total participants (drop out)	Conditions	Mean symptom duration*	Mean age*	Female (%)	Attended college or university (%)	Unemployed (%)	Self-management outcome measures
2013 (Van Oosterwijck et al., 2013)								
Weiner 2013 (Weiner et al., 2013)	190 (31)	Osteoarthritis-knee	5.7 (6.4) IG, 6.2 (6.8) IG1, 7.2 (8.3) CG	67.1 (8.9) IG, 65.8 (8.7) IG1, 66.8 (10.4) CG	12.7 IG, 15.6 IG1, 17.5 CG	58.7 IG, 54.7 IG1, 50.8 CG	NA	Arthritis Self Efficacy Scale
Wilson 2014 (Wilson, 2014)	114 (34)	Chronic pain	NR	49.33 (11.63)	78	51	NR	Pain Self-Efficacy Questionnaire

CG control group, IG intervention group, IG1 another intervention group, NA not applicable, NR not reported, * mean (standard deviation) in years unless mentioned

3.3.4 Interventions and settings

Thirteen of the included studies evaluated the effectiveness of physical activity programmes (Blodt et al., 2014), behavioural interventions (Broderick et al., 2014, Carpenter et al., 2012, Jason et al., 2007, Naylor et al., 2008, Nicholas et al., 2014), pain education programmes (Van Oosterwijck et al., 2013), their combinations (Brosseau et al., 2012, Meng et al., 2011, Ryan et al., 2010, Taylor et al., 2016a), and others non-surgical treatments (MacPherson et al., 2015, Weiner et al., 2013). The remaining 12 studies investigated the effectiveness of SM support programmes. The SM programmes were delivered in face-to-face group settings in nine studies (Arvidsson et al., 2013, Buszewicz et al., 2006, Ersek et al., 2003, Haas et al., 2005, Hamnes et al., 2012, LeFort et al., 1998, Miller, 2015, Newman, 1991, Nicholas et al., 2013), and online in three studies (Riva et al., 2014, Trudeau et al., 2015, Wilson, 2014). All SM support programmes were carried out at outpatient clinics except one study (Hamnes et al., 2012), which was in a specialised inpatient setting. The duration of the programmes ranged from 2.5 hours (Haas et al., 2005) to 16 hours (Nicholas et al., 2013). The follow-up period in the individual studies ranged from three weeks to 12 months (Appendix 22).

3.3.5 Self-management outcome measures

This systematic review identified 14 different scales used to assess change in SM. The majority (18 out of 25) of the included studies used self-efficacy as a proxy measure of SM with other measures for pain, physical function and psychological well-being. Table 6 presents the outcome measures identified in the systematic review.

Table 6: Self-management outcome measures used in the included studies

No.	Name of the instrument (Number of studies which used the instrument)	Number of items	Scoring methods	No of subscales	Administration of the scales	Internal consistency (Cronbach's α)
1.	Arthritis Self-efficacy Scale (6)	20	10-point	3	Pen and paper	0.82-0.91
2.	Self-efficacy Scale (3)	11	10-point	1	Pen and paper	0.76-0.90
3.	Pain Self Efficacy Questionnaire (7)	10	7-point	1	Pen and paper	0.92
4.	Chronic Pain Self-Efficacy Scale (1)*	22	9-point	3	Pen and paper	0.87-0.90
5.	Coping Strategies Questionnaire (2)	50	7-point	8	Pen and paper	0.45-0.84
6.	Pain Coping Inventory (1)	34	4-point	6	Pen and paper	0.53-0.83
7.	Chronic Pain Coping Inventory (1)	42	0 to 7 (days)	8	Pen and paper	0.71-0.89
8.	Survey of Pain Attitudes (2)	30	5-point	7	Pen and paper/ online	0.56-0.83
9.	German Pain Management Strategies (1)	24	6-point	6	Pen and paper	0.73-0.84
10.	Psychological Empowerment Scale (1)	12	7-point	4	Pen and paper/ online	0.87-0.97
11.	Swedish Rheumatic Disease Empowerment Scale (1)	23	5-point	5	Pen and paper	0.59-0.91
12.	Appraisal of Self-Care Agency Scale (1)	24	5-point	1	Pen and paper	0.59-0.87
13.	Health Education Impact Questionnaire** (1)	40	4-point	8	Pen and paper/ telephone	0.70-0.89
14.	Inventory of Adult Role Behaviours (1)	45	100 mm VAS	2	Pen and paper	0.84-0.92

VAS: visual analogue scale, * Pain Management Self-Efficacy subscale was used in the study. ** Social Integration and Support sub-scale was used in the study.

3.3.5.1 Self-Efficacy Scales

Eighteen included studies utilised a validated measure of self-efficacy including Arthritis Self-Efficacy Scale (ASES), Self-Efficacy Scale (SES), Pain Self-Efficacy Questionnaire (PSEQ), Chronic Pain Self-Efficacy (CPSE), Health Related Behaviour Self Efficacy and Body Self Efficacy Scale.

Arthritis Self-Efficacy Scale (ASES) was used in six of the included studies (Broderick et al., 2014, Buszewicz et al., 2006, Hamnes et al., 2012, Newman, 1991, Trudeau et al., 2015, Weiner et al., 2013). The ASES was developed by Lorig and colleague in late 1980s (Lorig et al., 1989a) to measure a patient's perceived self-efficacy or confidence to cope with specific arthritis symptoms or activity. This 20-item scale measures three SM constructs: pain self-efficacy (five items), function self-efficacy (nine items) and other symptoms self-efficacy (six items). Each item can be rated on a 10-point scale from '1 (or 10) = very uncertain' to '10 (or 100) = very certain'. This scale had acceptable internal consistency (Cronbach's α 0.82-0.91) and been widely used in patients with osteoarthritis for measuring self-efficacy (Barlow et al., 1997).

Self-Efficacy Scale (SES) was utilised in three included studies (Haas et al., 2005, LeFort et al., 1998, Brosseau et al., 2012). This 11-item scale was developed by using pain and other symptoms subscales of the original ASES. Each item can be rated using a 10-point graphic/ numeric rating for example, '1 (or 10) = very uncertain' to '10 (or 100) = very certain'. The phrase 'arthritis pain' is usually changed according to the specific disease population, for example, 'chronic pain' or 'back pain'. The internal consistency (Cronbach's α 0.82-0.91) has been estimated at 0.76 to 0.90 (LeFort et al., 1998, Lorig et al., 1989a).

Pain Self-Efficacy Questionnaire (PSEQ) was used in seven included studies (Carpenter et al., 2012, Nicholas et al., 2013, Nicholas et al., 2014, Ryan et al., 2010, Taylor et al., 2016a, Wilson, 2014, Miller, 2015). This 10-item scale was developed by Nicholas and colleague (Nicholas, 2007) to measure a patient's perceived confidence in performing specific activities when living with pain. Each of these items is rated with a 7-point Likert scale where '0 = not at all confident' and '6 = completely confident'. Internal consistency (Cronbach's α 0.82-0.91) was estimated at 0.92 in patients low back pain for more than six months duration (Nicholas, 2007).

Chronic Pain Self-Efficacy (CPSE) scale was utilised in one included study (MacPherson et al., 2015). This 22-item scale was developed to measure self-efficacy in patients with chronic pain (Anderson et al., 1995a). Each item can be scored from 0 to 8. The original scale has three subscales: pain management self-efficacy (PSE), coping self-efficacy (CSE) and physical function self-efficacy (FSE) with internal consistency (Cronbach's α) 0.88, 0.90 and 0.87 respectively (Anderson et al., 1995a) in patients with chronic pain. The included study used only the PSE subscale.

The Health Related Behaviour Self Efficacy and Body Self Efficacy Scale (Schützler and Witt, 2010) were used in one included study (Blodt et al., 2014). These scales have a reported internal consistency (Cronbach's α) of 0.76 and 0.72 respectively (Schützler and Witt, 2010). Jason and colleague (Jason et al., 2007) used a self-efficacy scale with a 5-point Likert scale option (completely disagree to completely agree) modified for patients with chronic fatigue syndrome. This scale has an internal consistency (Cronbach's α) ranging from 0.70 to 0.77 (Prins et al., 2001).

3.3.5.2 Coping Scales

The Coping Strategies Questionnaire (CSQ) scale was used in two included studies (Naylor et al., 2008, Weiner et al., 2013). The original 50-item scale was developed in patients with CLBP. Each item can be rated from '0 = never do that' to '6 = always do that' (Rosenstiel and Keefe, 1983). This scale measures how frequently the six cognitive coping strategies (ignoring pain, reinterpretation, diverting attention, self-statements, catastrophizing, praying/ hoping) and two behavioural coping (increasing activity and increasing pain behaviour- overt pain behaviours that decrease pain) are used and with two single item questions on how effective each of these coping strategies is in controlling and decreasing pain (Lawson et al., 1990). Despite the factor instability (Robinson et al., 1997), this scale measures three main constructs: conscious cognitive coping attempts, confidence in controlling and decreasing pain and diverting attention in non-painful activities (Lawson et al., 1990). Internal consistency of CSQ was estimated between 0.45 and 0.84 (Robinson et al., 1997).

The Pain Coping Inventory (PCI) was utilised in one study (Van Oosterwijck et al., 2013). This 34-item scale measures three active coping strategies (transformation, distraction and reducing demands) and three passive coping strategies (ruminating, retreating and resting). Each item can be rated from '1 = hardly ever' to '4 = very often'. The PCI is reliable with internal consistency (Cronbach's α 0.82-0.91) for subscales (in people attending pain clinic) between 0.53 and 0.83 (Kraaimaat and Evers, 2003).

The 42-item Chronic Pain Coping Inventory was used in one included study (Trudeau et al., 2015) along with the ASES. The CPCI was developed and validated in a chronic pain population by Jenson and colleagues (Jensen et al., 1995, Romano et al., 2003) to measure cognitive and behavioural coping. The CPCI includes 8 sub-scales: three on illness focused coping: Guarding, Resting, Asking for Assistance; four on wellness-focused coping: Relaxation, Task Persistence, Exercises and Stretch, Coping Self-statements; and other coping Seeking Social Support. Items are rated from '0 to 7' as these are used in last one week. This scale provides individual sub-scale scores but does not provide a composite score. This scale is a modified version of an earlier 65-item scale (Jensen et al., 1995). The 42-item scale demonstrates good reliability and internal consistency (Cronbach's α) 0.71-0.89 (Romano et al., 2003).

3.3.5.3 Pain Attitudes and Management Scales

The Survey of Pain Attitudes (SOPA) scale was used in two included studies (Carpenter et al., 2012, Ersek et al., 2003). This scale has seven subscales: Control, Disability, Harm-Exercise (accepts pain means damage and activity can increase damage), Emotion, Medication, Solicitude and Medical Care. Items can be rated with '0 = very untrue for me' to '4 = very true for me'. The longer version of the scale (Jensen et al., 1994) has 57 items, but a reduced version with 30 items is also available (Tait and Chibnall, 1997). The original scale has moderate internal consistency (Cronbach's α 0.71-0.80 for long version (Jensen et al., 1994) and 0.56-0.83 for short version) (Tait and Chibnall, 1997).

The German Pain Management Questionnaire (GPMQ) was used in one included study (Meng et al., 2011). This scale consists of 24 items, and each item can be rated from '1 = do not agree at all' to '6 = fully agree'. This scale has two main domains: a) cognitive strategies consisting of three subscales: action-oriented coping, cognitive restructuring and coping competence and b) behavioural strategies consisting of three subscales: mental distraction, counter activities and relaxation. Each of these subscales can be scored between 4 and 24, where a higher score indicates a stronger agreement with the respective coping strategy. The internal consistency (Cronbach's α) of these subscales range from 0.73 to 0.84 (Meng et al., 2011).

3.3.5.4 Empowerment Scales

The Psychological Empowerment Scale (PES) was utilised in one study (Riva et al., 2014). This scale was originally developed following the Cognitive Empowerment Model in a workplace setting (Thomas and Velthouse, 1990) and later utilised in patients with fibromyalgia syndrome (Camerini et al., 2012). This scale has four different subscales: meaningfulness, competence, self-determination and impact; each subscale has three items, which can be scored using a 7-point Likert scale from '1 = strongly disagree' to '7 = strongly agree' (Riva et al., 2014, Spreitzer, 1995). Each of these subscales has acceptable internal consistency (Cronbach's α 0.87-0.97) (Camerini et al., 2012). In the included study, the PES was translated and contextualised for Italian patients with chronic back pain and a similar internal consistency (Cronbach's α 0.82-0.91) for the translated version was reported between 0.71 and 0.94 (Riva et al., 2014).

The Swedish Rheumatic Disease Empowerment Scale (SEW-RES-23) was used in one included study (Arvidsson et al., 2013). This 23-item scale measures five constructs: goal achievement and overcoming barriers, self-knowledge, stress management, assessing dissatisfaction and readiness to change, and support for care. Each item can be rated from '1 = strongly disagree' to '5 = strongly agree' and a higher total score indicates better empowerment. The Diabetes Empowerment Scale (Anderson et al., 1995b) was translated into Swedish for patients with diabetes (Leksell et al., 2007). This Swedish scale was later modified and validated in the SWE-RES-23 for patients with rheumatic diseases (Arvidsson et al., 2012). The estimated internal consistency (Cronbach's α) ranged from 0.59 to 0.91 for the five sub-scales and 0.92 for the total score (Arvidsson et al., 2012). The SEW-RES was used with the Appraisal of Self Care Agency scale in the included study (Arvidsson et al., 2013).

3.3.5.5 Other Scales

Appraisal of Self Care Agency Scale (ASA-A) was utilised to assess the self-care ability in one included study (Arvidsson et al., 2013). This scale contains 24 questions, and each item can be rated from '1 = totally disagree' to '5 = totally agree' (Evers et al., 1993) with a total possible score between 24 and 120, where higher scores indicate better self-care ability. The Swedish ASA-A has an internal consistency (Cronbach's α 0.82-0.91) of 0.59 (Söderhamn et al., 1996). However, the ASA scale rated by caregivers or nurses has higher than the patient reported internal consistency (Cronbach's α 0.77 or 0.87 respectively) (Söderhamn et al., 1996).

The Social Integration and Support subscale of the Health Education Impact Questionnaire (heiQ) was used in one study (Taylor et al., 2016a). This 40-item scale was purposefully designed for measuring SM, and the development was guided by a Programme Logic Model, Concept Mapping and interviewing stakeholders (Osborne et al., 2007). This scale consists of eight different independent constructs: Positive and Active Engagement in Life (five items), Health Directed Activity (four items), Skill and Technique Acquisition (five items), Constructive Attitudes and Approaches (five items), Self-Monitoring and Insight (seven items), Health Service Navigation (five items), Social Integration and Support (five items), and Emotional Wellbeing (six items). The Internal consistency (Cronbach's α) of these sub-scales ranges between 0.70 and 0.89 (Osborne et al., 2007). Each of the 40 items can be scored on a four-point Likert scale from 'strongly disagree' to 'strongly agree'. This scale does not provide a total score. However, the included study (Taylor et al., 2016a) used only one of these eight constructs along with PSEQ to measure self-management in patients with chronic musculoskeletal pain.

The Inventory of Adult Role Behaviours (IARB) was used in one study (LeFort et al., 1998) to assess self-help along with Self-Efficacy Scale. This 45-item scale (Braden, 1990) includes a modified 22-item Effect Scale (Given, 1984) and 23 newly developed items on social, family, leisure and personal roles. Each item can be rated using a 100 mm visual analogue scale. This scale has excellent internal consistency (Cronbach's α) 0.84-0.92 (Braden, 1990, Given, 1984).

3.3.6 Constructs of the measures

Further, the Patient Reported Outcome Measure Information System (PROMIS) framework (Tugwell et al., 2011) was used to evaluate the constructs or sub-scales of the identified SM measures (Table 7). Twelve out of 14 measures did not assess all three domains of the PROMIS. However, the Chronic Pain Coping Inventory (CPCI) and Health Education Impact Questionnaire (heiQ) cover all three PROMIS domains.

Table 7: Appraisal of the self-management measures following PROMIS framework (Tugwell et al., 2011)

No.	Measures	Physical			Psychological				Social				
		Pain behaviours	Pain experience	Pain impact	Psychological stress	Psychological impact	Cognitive function	Self-Efficacy	Social relationships	Social support	Family relationships	Ability to participate	Participation satisfaction
1.	Arthritis Self-efficacy Scale	+	-	+	-	-	-	+	-	-	-	-	-
2.	Self-Efficacy Scale	+	-	+	-	-	-	+	-	-	-	-	-
3.	Pain Self Efficacy Questionnaire	+	-	+	-	-	-	+	-	-	-	-	-
4.	Chronic Pain Self-Efficacy Scale	+	-	+	-	+	+	+	-	-	-	-	-
5.	Coping Strategies Questionnaire	+	-	+	+	+	+	+	-	-	-	-	-
6.	Pain Coping Inventory	+	-	+	+	+	+	-	-	-	-	-	-
7.	Chronic Pain Coping Inventory	+	-	+	+	+	+	-	-	+	-	+	-
8.	Survey of Pain Attitudes	+	+	+	+	+	-	-	-	-	-	-	-
9.	German Pain Management Strategies	+	-	-	+	+	+	+	-	-	-	-	-
10.	Psychological Empowerment Scale	-	-	-	-	+	+	+	-	-	-	-	-
11.	Swedish Rheumatic Disease Empowerment Scale	-	-	-	+	+	+	-	-	-	-	-	-
12.	Appraisal of Self-Care Agency Scale	-	-	+	-	-	-	-	-	-	-	+	-
13.	Health Education Impact Questionnaire	+	-	+	+	+	+	-	+	+	-	+	-
14.	Inventory of Adult Role Behaviours	-	-	+	-	-	-	-	+	+	+	-	-

3.3.7 Psychometric properties of the measures

Psychometric properties of these included measures were summarised in Table 8 in line with the Terwee criteria (Terwee et al., 2007). The content validity was established as positive or intermediate in 10 out of 13 measures, and nine measures had high internal consistency (Cronbach's α) between 0.70 and 0.95 with each of the sub-scales and/or the total scores. Only eight measures for construct validity and four measures for reliability had positive or intermediate ratings. Agreement, responsiveness, and floor and ceiling effects had either no or negative ratings for all 13 measures. Intermediate quality of interpretability was reported for only two out of 13 measures. These findings highlight, a lack of research in reproducibility, responsiveness and interpretability data for these outcomes. Further, the Arthritis Self-efficacy Scale (ASES), Self-Efficacy Scale (SES), Pain Self Efficacy Questionnaire (PSEQ), Chronic Pain Self-Efficacy Scale (CPSES), Chronic Pain Coping Inventory (CPCI) and Health Education Impact Questionnaire (heiQ) had good psychometric properties than the other included scales (with three or more positive ratings out of eight assessed- in Table 8). Among these six scales CPSES, CPCI and heiQ were developed either for patients with any chronic condition or with chronic pain.

Table 8: Quality criteria of the identified measures following Terwee (modified) (Terwee et al., 2007)

	Measures (target population)	Reference/s	Content validity	Internal consistency	Construct validity	Reproducibility Agreement	Reproducibility Reliability	Responsiveness	Floor and ceiling effects	Interpretability
1.	Arthritis Self-efficacy Scale (Patients with arthritis)	(Lorig et al., 1989a, Barlow et al., 1997)	+	+	+	0	?	0	0	0
2.	Self-Efficacy Scale (All patients)	(Lorig et al., 1989a, Barlow et al., 1997)	+	+	+	0	?	0	0	0
3.	Pain Self Efficacy Questionnaire (Patients with pain)	(Di Pietro et al., 2014, Kortlever et al., 2015, Nicholas, 2007)	+	+	+	0	?	0	-	?
4.	Chronic Pain Self-Efficacy Scale (Patients with chronic pain)	(Anderson et al., 1995a)	+	+	+	0	+	-	0	0
5.	Coping Strategies Questionnaire (All patients)	(Robinson et al., 1997)	-	-	-	0	0	0	0	0
6.	Pain Coping Inventory (Patients with pain)	(Kraaimaat and Evers, 2003)	-	-	-	0	-	0	0	0
7.	Survey of Pain Attitudes (Patients with pain)	(Jensen et al., 1987, Jensen et al., 1994, Tait and Chibnall, 1997)	+	-	?	0	0	0	0	0
8.	Chronic Pain Coping Inventory (Patients with chronic pain)	(Hadjistavropoulos et al., 1999, Romano et al., 2003, Tan et al., 2005)	+	+	+	0	0	0	0	0

	Measures (target population)	Reference/s	Content validity	Internal consistency	Construct validity	Reproducibility Agreement	Reproducibility Reliability	Responsiveness	Floor and ceiling effects	Interpretability
9.	Psychological Empowerment Scale (All patients)	(Spreitzer, 1995, Uner and Turan, 2010)	?	+	?	0	0	0	0	0
10.	Swedish Rheumatic Disease Empowerment Scale (Patients with rheumatoid arthritis)	(Arvidsson et al., 2012)	+	-	-	0	0	0	-	?
11.	Appraisal of Self-Care Agency Scale (All patients)	(Söderhamn et al., 1996, Sousa et al., 2010)	?	+	-	0	0	0	0	0
12	Health Education Impact Questionnaire (Patients with chronic conditions)	(Osborne et al., 2007, Schuler et al., 2014)	+	+	+	0	0	0	0	0
13.	Inventory of Adult Role Behaviours (All patients)	(Braden, 1990, Given, 1984)	-	+	-	0	0	0	0	0

+ = positive, ? = intermediate, - = negative, 0 = no information available; German Pain Management Strategies was not appraised as the paper is not in English.

3.4 Discussion and conclusion

To date, this systematic review identified, synthesised and appraised the outcome measures used to quantify the change in self-management (SM) in patients with chronic pain. The present review identified 25 randomised controlled trials with 14 different patient-reported measures used to detect a change in SM. These 14 measures are quite diverse and measure a variety of underlying constructs including self-efficacy, coping, empowerment and impact on knowledge. This demonstrates a lack of consistency and consensus around the measurement of SM in chronic pain and creates challenges in directly comparing findings of studies assessing SM or related constructs. It is evident that only effects measured by identical instruments can be directly compared.

Findings are in alignment with a prior systematic review by Boger and colleague (Boger et al., 2013) on patient-reported outcome measures used in SM trials in patients with stroke. Boger and colleague found that multiple measures were used to capture the change in SM. They also reported that the majority of their included studies (n=13) measured diverse constructs such as physical function, mood, participation, satisfaction and quality of life, which are not direct measures of SM. In their review, other commonly used proxy measures of SM (such as resource utilization, self-efficacy, the locus of control, health behaviours, knowledge and goal attainment) were not frequently measured. However, this is not consistent with our review findings for SM in chronic pain, since the majority of our included studies used self-efficacy scales as a proxy measure of SM.

Studies included in the current review frequently used more than one scale to capture SM, perhaps due to a lack of validated multi-domain SM scales. Theoretically, SM encompasses multiple constructs including; disease and symptoms management, behaviour management, role and emotional management (Barlow et al., 2002) using problem solving and decision making skills, navigating health and care resources and taking appropriate actions (e.g., pacing or increasing physical activity) (Bodenheimer et al., 2002, Du et al., 2017). A recent systematic review on SM in CLBP has highlighted that the majority of included SM trials did not disclose or follow a priory theoretical model or framework (Du et al., 2017). Future research should aim to select and follow a theoretical framework for interventions which will inform selection of appropriate outcome measures.

Conceptually, the constructs of SM fall into a range of constructs of the physical, mental and social health domains of Patient Reported Outcome Measure Information System (PROMIS) framework (Tugwell et al., 2011). Twelve out of 14 measures did not assess all three domains of the PROMIS, which potentially make these measures less effective to detect changes in SM over time. In contrast, the CPCI and heiQ, covering all three PROMIS domains, are potentially more appropriate than scales measuring individual constructs of SM.

Another potential reason for the complexity in measuring SM in chronic pain is a lack of direct biological measures for pain or disease severity (Nolte et al., 2013a, Nolte and Osborne, 2013). Thus the change in SM may not be measured using the disease severity measures. In some chronic conditions, direct biological measures are available to detect a change in disease severity, for example, glycated haemoglobin (HbA1c) is commonly used to detect clinical changes in diabetes over time that are indicative of improvements in condition management. A review by Nolte and colleague (Nolte et al., 2013a) found outcome measures used in SM trials are mainly perception- or evaluation-based patient-reported outcome measures (PROMs), which require the responders to understand the questions, recall and process relevant information to answer and finally to form the response in keeping with the quality of life appraisal model (Schwartz and Rapkin, 2004). Nolte and colleague also identified that self-efficacy scales, which are most frequently used in our included studies, have high response shifts with small differences in the effect sizes between intervention and control groups, indicating instability across time (Nolte et al., 2013a). In another review, Miles and colleague evaluated the psychometric properties of five commonly used self-efficacy measures (Arthritis Self-Efficacy Scale, Self-Efficacy Scale, Chronic Pain Self-Efficacy Scale and Pain Self-Efficacy Questionnaire) in people with chronic pain (Miles et al., 2011). Self-efficacy scales had acceptable internal consistency and construct validity, although results indicated further research is required on responsiveness and test-retest reliability of the self-efficacy scales. Their results are in alignment with the findings of the present review.

The current review found self-efficacy scales to be the most frequently used as a measure of change in SM, although self-efficacy is a constructs indicative of one's ability to change. These scales were developed and validated in patients with arthritis and later modified for populations with chronic pain. Most of these scales are short, quick to administer in the clinic and easy to score (Miles et al., 2011). However, these scales can only measure perceived confidence in doing specific things despite the pain; therefore there is a tendency that these are activity-specific and lack universal appropriateness to patients with chronic pain in identifying how patients self-manage. The coping scales measure endorsement and frequency of different cognitive and behavioural strategies used to cope with chronic pain. However, these coping scales fail to capture issues of empowerment or pain management skills.

Chronic Pain Coping Inventory (CPCI) is a multi-domain scale covering seven out of 12 PROMIS constructs and demonstrated modest psychometric properties (Cronbach's α 0.71-0.89 and reliability coefficients 0.60-0.81) (Romano et al., 2003). However, the CPCI measures only the frequency of the eight different (illness-focused and wellness-focused) coping strategies used in the last seven days (Jensen et al., 1995, Romano et al., 2003). The Heath Education Impact Questionnaire (heiQ) designed to measure effect of any educational or SM programme in all patients and covers eight out of 12 SM related constructs across all three PROMIS domains (Table 7). The heiQ demonstrated ability to measure person related change in SM constructs independent of measurement situation and high psychometric properties (Cronbach's α 0.70-0.88 and reliability coefficients 0.80-0.92) (Schuler et al., 2014) than the CPCI. Therefore, the heiQ was utilised in this PhD study to measure the change in SM over time.

3.4.1 Strength and limitations

This review identified the wide range of measures used to assess change in SM in chronic non-cancer pain. It assessed both the quality of the included studies and the identified measures flowing published quality assessment criteria. The reviewers carried out a thorough search; two independent reviewers conducted the study selection and the quality assessment; and synthesised the majority of validated scales used to measure the change in SM. It is possible that articles may have been missed due to the search strategy and selection criteria of the review. Although every effort was made to seek additional information from authors where required, not all attempts of communication with authors were successful. Furthermore, seven abstracts were not available in full-text version; and non-English articles were not considered for inclusion.

3.4.2 Conclusion

This review identified and evaluated the measures used to detect change in SM in patients with non-cancer chronic musculoskeletal pain. Included measures are diverse, targeting different SM constructs, highlighting the complexity, inconsistency and lack of consensus in definitions of SM.

Despite some evidence on internal consistency, content and construct validity these SM measures significantly lack research in reproducibility, responsiveness and interpretability. These three core psychometric properties of the SM measures should be prioritised in future research. Whilst single construct scales are more commonly used, they do not cover multiple PROMIS domains which potentially make these measures less effective to detect changes in SM over time. The Health Education Impact Questionnaire is valid, internally consistent and cover multiple SM constructs across all three PROMIS domains. Future research should aim to gain consensus on constructs of SM, for example using a modified Delphi method.

3.5 Chapter summary

This chapter shows that measuring SM is complex and controversial in patients with chronic pain. The review identified 14 different measures with reported internal consistency and content and construct validity. The review found the multi-construct scale, for example, the heiQ, is suitable to capture the different domains of SM in clinical practice and research. The following chapter will describe the reliability and limits of agreement of the heiQ between paper and non-paper alternative survey modes.

Question	Aim	Main finding
What are the optimal measure(s) of SM in patients with chronic pain conditions?	To identify, synthesise and appraise the literature on outcome measures used to assess change in SM in patients with chronic musculoskeletal pain	The heiQ is a valid and reliable outcome measure to assess multiple constructs of SM and its change in in patients with chronic pain conditions.

4 DO PAPER SURVEY RESPONSES AGREE WITH NON-PAPER ALTERNATIVE SURVEY MODE RESPONSES?

4.1 Introduction

Findings of the systematic review indicated that the Health Education Impact Questionnaire (heiQ) can be used to measure change in self-management (SM) in patients with chronic pain although it is unknown whether the heiQ can be used in a mixed mode survey design. Therefore, the aim of this test-retest study was to examine reliability and agreement of the self-management (SM) measure (Health Education Impact Questionnaire- heiQ) between paper survey and non-paper alternative (NPA) survey completion modes (either online or telephone) in patients with chronic low back pain (CLBP). Mixed-mode survey design employs flexible survey completion in paper-and-pen, online or over the telephone. This design has higher survey response rate than a single mode survey (Chi and Chen, 2015, Greene et al., 2008). Thus mixed-mode survey has a growing popularity in research involving patient-reported outcomes (PROs) (Gwaltney et al., 2008, Hox et al., 2015, Dillman et al., 2014).

With the rapid growth in internet accessibility, use of online PROs within mixed-mode survey are trending among patients, clinicians and researchers (Engan et al., 2016, Gwaltney et al., 2008, Hox et al., 2015, Dillman et al., 2014). Online PROs optimise resource utilisation (Zuidgeest et al., 2011), minimise missing data (Engan et al., 2016), and maximise the response rate by facilitating reach of different groups (McCabe et al., 2006) and decreasing non-response bias (Baines et al., 2007). However, mixed-mode survey designs require an assessment of equivalence between the survey completion modes to examine any measurement error or survey mode bias (Eremenco et al., 2014, Chi and Chen, 2015).

Mixed-mode survey equivalence studies used product-moment correlation (Cronbach's α, kappa or intraclass correlation coefficients- ICC) (Gwaltney et al., 2008) with a null hypothesis that the measurements were not linearly correlated (Bland and Altman, 1986). For instance, a systematic review comparing paper and computer survey response showed the mean difference between the survey modes was 0.2% across the 65 studies, and 94% of the estimates of correlation were more than 0.75 (Gwaltney et al., 2008). These product-moment correlation coefficients examine the strength of association between two modes but not their agreement (Bland and Altman, 1986). Bland and Altman proposed Limits of Agreement (LoAs)(Bland and Altman, 1986, Bland and Altman, 1999) analysis although that remains less popular in mixed-mode survey equivalence studies.

Despite the evidence of a high association between survey modes, the LoAs may not be favourable for within-subject comparison and analysis. For example, Messih and colleagues (Messih et al., 2014) compared the survey responses between paper and telephone survey in patients waiting for knee or hip replacement surgery. They found ICC 0.79 (95% confidence interval 0.70-0.86) and LoAs -8.6 to 8.2 for Oxford Knee Score and ICC 0.87 (95% confidence interval 0.79-0.92) and LoAs -7.7 to 5.3 for Oxford Hip Score. Their results indicated 'good to high' ICC and wide LoAs between paper and telephone survey responses. Similarly, wide LoAs (mean difference 0.05, 95% confidence interval -3.76 to 3.67) was found between paper and telephone survey modes for health-related quality of life measured using the Visual Analogue Scale in patients waiting for hip or knee replacement surgery (Chatterji et al., 2017). Therefore, both LoAs and ICC are important for comparison between survey modes.

The purpose of this study was to estimate the reliability and agreement between paper and non-paper alternative methods of survey completion for the heiQ.

4.2 Methods

This study was conducted between March 2016 and June 2017 as a part of a multi-centre longitudinal cohort study as described in the following Methods Chapter (Banerjee et al., 2016). The protocol was approved by a UK National Health Service Ethics Committee (14/ES/0167). This study followed a test-retest design.

4.2.1 Participants

The cohort study included working-age adults between 18 and 65 years who had attended outpatient physiotherapy for their CLBP (≥ three months). These patient were community ambulant without using any walking aid and were able to read and write English to complete the questionnaire.

Participants were excluded from the cohort study if they had been diagnosed with: cancer or other self-reported specific cause for their CLBP including major trauma, fracture, inflammatory condition, ankylosing spondylitis, grade III or IV spondylolisthesis, severe spinal canal stenosis, lumbar intervertebral disc protrusion or extrusion or spinal deformity. Patients were also excluded if they had: undergone spinal surgery within the preceding year, were scheduled for any major surgery in six months, were pregnant or had given birth within the preceding year, had cognitive impairment, had a neurological disease or if they had severely impaired hearing and vision.

Participants were included in this agreement study if they had completed the baseline paper and they consented to complete an optional additional NPA survey. Participants were excluded if they had completed their baseline survey more than two weeks prior to completing the NPA survey.

4.2.2 Measures

Demographic information collected in the longitudinal cohort study (discussed in 5.11) was used to describe the participants. Three of the measures- pain intensity, physical disability and SM, used in the cohort study, were utilised to measure the reliability and agreement between the paper and NPA survey modes. These measures were selected due to a variety of the response options available in these scales, for example, an eleven point scale (for pain), yes no answer options (for disability) and 4-point Likert scale (for SM).

4.2.2.1 Pain intensity

Pain intensity was measured using the Numeric Pain Rating Scale (NPS). An 11-point (0 to 10) Numeric Pain Rating Scale (NPS) where '0 means no pain' and '10 means worst possible pain imaginable' was used in this study. Patients rated their worst pain intensity in the last 24 hours. The high relative validity of the NPS against the Visual Analogue Scale (VAS) (correlation coefficients 0.94-0.96) was established in experimental pain(Ferreira-Valente et al., 2011), and high test-retest reliability (correlation coefficients 0.94-0.96) was found in patients in an outpatient rheumatology clinic (Ferraz et al., 1990). Further, NPS is acceptable to patients with chronic pain for ease of reporting(Williams et al., 2000), and appropriate to use in patients with CLBP (Dworkin et al., 2008, Farrar et al., 2001). Unlike VAS, NPS can be used in various survey modes- including paper, online and telephone surveys.

4.2.2.2 Physical disability

Physical function limitation (or disability) was assessed using a 24-item Roland Morris Disability Questionnaire (RMDQ). The 24 statements of the questionnaire can be scored 'yes- if that describes the patient on that day' or 'no- otherwise' producing a possible total score between 0 and 24. Internal consistency (Cronbach's α) was reported between 0.84-0.94 and reliability (intraclass correlation) between 0.86 and 0.90 for RMDQ in patients with CLBP in short interval (Chiarotto et al., 2016, Roland and Fairbank, 2000). RMDQ is a measure of choice assessing physical function and its change over time in patients with CLBP (Chapman et al., 2011, Ostelo and de Vet, 2005). However, despite having high intraclass correlation 0.91 (95% CI: 0.82 to 0.96), a wide LoAs (+5.4 to -5.4) were reported for test-retest agreement of a Dutch version of the Roland Morris Disability Questionnaire in patients with CLBP (Brouwer et al., 2004).

4.2.2.3 Self-management

Self-management (SM) is one's dynamic ability to manage the chronic condition and its treatment, adapt to physical and psychological changes and adhere to lifestyle modifications (Barlow et al., 2002). SM involves several constructs, which include managing the disease, health behaviours, changes in social, vocational roles and emotion by solving day-to-day problems, making conscious decisions, using appropriate health and social care resources, forming a good relationship with the healthcare providers and importantly taking appropriate actions (Bodenheimer et al., 2002).

Self-management was measured using a multi-domain scale – the Health Education Impact Questionnaire (heiQ) version 3 (Osborne et al., 2007). The scale (version 3) consists of 40 items. Each of the items can be scored using four-point ordinal scale options from 'strongly disagree' to 'strongly agree'. Each independent construct total score is divided by the number of items on it. The heiQ has high internal consistency (Cronbach's α 0.70-0.89) and discriminant validity in patients with chronic diseases (Osborne et al., 2007, Elsworth et al., 2015).

The heiQ measures eight different constructs: Health-Directed Activities (HDA), Positive and Active Engagement in Life (PAEL), Emotional Distress (ED), Self-Monitoring and Insight (SMI), Constructive Attitudes and Approaches (CAA), Skill and Technique Acquisition (STA), Social Integration and Support (SIS) and Health Service Navigation (HSN).

4.2.2.3.1 Health Directed Activity

The Health Directed Activity measures health lifestyle changes, for example, walking, exercise and physical activity. High scores mean a high level of involvement in healthy behaviour. Internal consistency (Cronbach's α) for the HDA was reported to be 0.80 (Osborne et al., 2007). The HDA subscale has four items:

- On most days of the week, I do at least one activity to improve my health (e.g., walking, relaxation, exercise)
- I do at least one type of physical activity every day for at least 30 minutes (e.g., walking, gardening, housework, golf, bowls, dancing, Tai Chi, swimming)
- On most days of the week, I set aside time for healthy activities (e.g., walking, relaxation, exercise)
- I walk for exercise, for at least 15 minutes per day, most days of the week

4.2.2.4 Positive and Active Engagement in Life (PAEL)

The Positive and Active Engagement in Life measures engagement in doing life fulfilling enjoyable and interesting activities. High scores mean a high level of motivation in engaging in enjoyable activities. Internal consistency (Cronbach's α) for the PAEL was reported to be 0.86 (Osborne et al., 2007). The PAEL sub-scale has five items:

- Most days I am doing some of the things I really enjoy
- I try to make the most of my life
- I am doing interesting things in my life
- I have plans to do enjoyable things for myself during the next few days
- I feel like I am actively involved in the life

4.2.2.5 Emotional Distress (ED)

The Emotional Distress measures any negative affect related to the disease, for example, distress, anger, depression and anxiety. A high score means a high level of anxiety and depression. Internal consistency (Cronbach's α) for the ED was reported to be 0.89 (Osborne et al., 2007). The ED sub-scale has six items:

- I often worry about my health
- My health problems make me very dissatisfied with my life
- I often feel angry when I think about my health
- I feel hopeless because of my health problems
- I get upset when I think about my health
- If I think about my health, I get depressed

4.2.2.6 Self-Monitoring and Insight (SMI)

The Self-Monitoring and Insight measures one's ability to monitor health condition or disease, identify illness-related limitations, and set realistic targets in order to manage the illness. A high score means a high level of self-management ability. Internal consistency (Cronbach's α) for the SMI was reported to be 0.70 (Osborne et al., 2007). The SMI sub-scale has six items:

- As well as seeing my doctor, I regularly monitor changes in my health
- I know what things can trigger my health problems and make them worse
- I have a very good understanding of when and why I am supposed to take my medication
- When I have health problems, I have a clear understanding of what I need to do to control them
- I carefully watch my health and do what is necessary to keep as healthy as possible
- With my health in mind, I have realistic expectations of what I can and cannot do

4.2.2.7 Constructive Attitudes and Approaches (CAA)

The Constructive Attitudes and Approaches measures one's perspective on the impact of the illness on life. A high score means the high level of ability to minimise the impact of the illness. Internal consistency (Cronbach's α) for the CAA was reported to be 0.81 (Osborne et al., 2007). The CAA sub-scale has five items:

- I try not to let my health problems stop me from enjoying life
- My health problems do not ruin my life
- I feel I have a very good life even when I have health problems
- I do not let my health problems control my life

- If others can cope with problems like mine, I can too

4.2.2.8 Skill and Technique Acquisition (STA)

The Skill and Technique Acquisition sub-scale measures the knowledge regarding skills and techniques which help reduce the disease-related symptoms. High scores mean highly developed skills and techniques to reduce symptoms and manage the health condition. Internal consistency (Cronbach's α) for the STA was reported to be 0.81 (Osborne et al., 2007). The STA subscale has four items:

- I have effective ways to prevent my symptoms (e.g., discomfort, pain and stress) from limiting what I can do in my life
- I have a very good idea of how to manage my health problems
- When I have symptoms, I have skills that help me cope
- I have a good understanding of equipment that could make my life easier

4.2.2.9 Social Integration and Support (SIS)

The Social Integration and Support sub-scale measures one's helpful social interaction and support from the community. A high score means high levels of helpful social interaction and confidence in seeking support. Internal consistency (Cronbach's α) for the SIS was reported to be 0.86 (Osborne et al., 2007). The SIS sub-scale has five items:

- If I need help, I have plenty of people I can rely on
- I have enough friends who help me cope with my health problems
- When I feel ill, my family and carers really understand what I am going through
- Overall, I feel well looked after by friends or family
- I get enough chances to talk about my health problems with people who understand me

4.2.2.10 Health Service Navigation (HSN)

The Health Service Navigation measures one's ability to interact with healthcare providers, including organisations and professionals. The HSN also captures the confidence in those communicating the health care needs and negotiating the healthcare providers to meet those needs. Internal consistency (Cronbach's α) for the HSN was reported to be 0.82 (Osborne et al., 2007). The HSN sub-scale has five items:

- I have very positive relationships with my healthcare professionals
- I communicate very confidently with my doctor about my healthcare needs
- I confidently give healthcare professionals the information they need to help me
- I get my needs met from available healthcare resources (e.g., doctors, hospitals and community services)
- I work in a team with my doctors and other healthcare professionals

4.2.3 Recruitment

Patients were recruited from the outpatient physiotherapy clinics within six UK National Health Service Trusts. The study was introduced to the eligible patients either by the treating therapists or the PhD candidate. Eligible patients who wanted to complete the survey in hardcopy were provided with a Participant Information Sheet, the baseline forms and business reply envelope. Written informed consent was obtained from the participants. Participants who had completed the baseline paper survey were invited to NPA survey in their preferred mode of delivery- online or over the telephone - within two weeks of the baseline survey being completed. Appendix 15 provides a copy of the NPA questionnaire survey.

4.2.4 Procedure

For patients who preferred to complete the NPA survey over the telephone, the survey was completed over the telephone at a time convenient to patient. If participants had chosen to complete the measures online, the survey link was sent to them via email. The survey platform used was the Bristol Online Survey (BOS).

Only nine participants chose to complete the NPA survey over the telephone. Therefore, the data for online and telephone NPA administration methods were combined and compared as a single group with paper survey responses.

4.2.5 Data analyses

4.2.5.1 Reliability

The intraclass correlation coefficient (ICC) two-way mixed effect model with absolute agreement and 95% confidence intervals was employed for estimating test-retest reliability between two survey modes for each variable assuming participants were random and effect of using different survey modes were fixed (Trevethan, 2017). The Cronbach's α was used to estimate reliability between the paper and NPA survey modes.

4.2.5.2 Limits of agreement

Bland and Altman (Bland and Altman, 1986, Bland and Altman, 1999) introduced Limits of Agreement (LoAs) analysis for investigating repeatability of measurements or comparing methods using descriptive statistics techniques (Carkeet and Goh, 2016). The agreement between the two methods is estimated by plotting the between-method differences along the *y*-axis against their mean along the *x*-axis as measured on the same subjects (Bland and Altman, 1986, Bland and Altman, 1999). LoAs are estimated by the following equation:

LoAs = d ± 1.96 Sd, (Bland and Altman, 1999)…(1),

where *d* is the mean difference between two measurements and *Sd* is the standard deviation of the differences. For small sample size (n<60), the LoAs is precisely estimated by using:

LoAs = d ± (t0.5,d.f. n-1) Sd√(1+1/n) (Ludbrook, 2010) (2)

Any potential uncertainty in LoAs is measured by 95% confidence limits of LOAs (95%CL_{LoA}). To estimate 95%CL_{LoA} , Ludbrook used partial tables for two-sided tolerance factors (Ludbrook, 2010). Later Carkeet has given the following precise estimates (Carkeet and Goh, 2016).

95%CL_{LoA} = d ± k Sd (Carkeet and Goh, 2016, Ludbrook, 2010) (3)

The value of k can be obtained and is higher than 1.96 for sample size 40 or less (Carkeet and Goh, 2016).

The LoAs with 95%CL_{LoA} between paper and NPA survey modes were calculated using the following equations:

LoAs = d ± ($t_{0.5,d.f.\ n-1}$) Sd√(1+1/n) (2) and 95%CL_{LoA} = d ± k Sd (3).

4.3 Results

4.3.1.1 Demographic characteristics

A total of 39 patients with CLBP completed the NPA survey. Five patients who had completed the online survey after 14 days from the baseline were excluded from the analysis. The remaining 34 (25 via online and 9 over the telephone) participants were included in the analysis. The mean age of the study cohort was 41.8 (SD 13.1) years and mean pain duration was 5.4 (SD 5.3) years. Twenty-one (62%) participants were female; 32 (94%) participants were from White ethnic background; 25 participants (74%) received education at college or university level; 19 (54%) participants were employed; and 23 (68%) participants had related leg pain associated with their CLBP.

4.3.1.2 Intraclass correlation coefficients

The Cronbach's α between paper and NPA survey modes for the study variables ranged between 0.89 and 0.95. The ICC values between paper and NPA survey modes for the study variables ranged from 0.89 to 0.96 (Table 9).

Table 9: Intraclass correlation coefficients (ICC) between paper and non-paper alternative survey modes

	Variables	Cronbach's α	ICC	95% confidence intervals	
				Lower	Upper
1.	Pain intensity	0.89	0.89	0.78	0.95
2.	Physical disability (RMDQ)	0.96	0.96	0.92	0.98
3.	Health Directed Activity	0.93	0.93	0.87	0.97
4.	Positive and Active Engagement in Life	0.92	0.92	0.84	0.96
5.	Emotional Distress	0.95	0.94	0.88	0.97
6.	Self-monitoring and Insight	0.91	0.91	0.82	0.96
7.	Constructive Attitudes and Approaches	0.95	0.95	0.90	0.98
8.	Skill and Technique acquisition	0.92	0.92	0.83	0.96
9.	Social Integration and Support	0.96	0.96	0.93	0.98
10.	Health Service Navigation	0.93	0.93	0.87	0.97

* ICC intraclass correlation coefficient, RMDQ: Roland Morris Disability Questionnaire

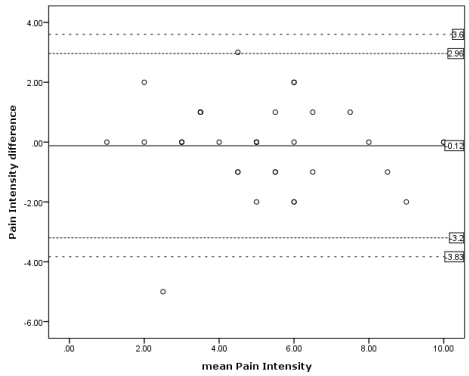
4.3.1.3 Limits of agreement (LoAs)

The linear regression (ordinary least squares) of differences over the mean differences between paper and NPA survey modes were analysed. The limits of agreement with 95% confidence interval between paper and NPA survey modes are presented in Table 10 and Figure 6.

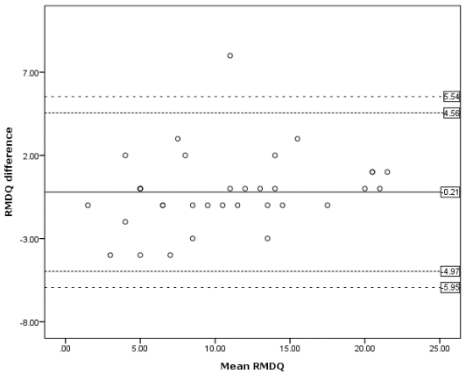
There was no significant difference for any study variables except for the Health Directed Activity (HDA) (Figure 7). Results for HDA [F (1,32) 6.61, *p*-value 0.02, R^2 0.17] indicated a chance of proportional bias between paper and NPA survey modes. However, the proportional bias in HAD scores was not present after removing three outliers from the data [F (1,29) 3.51, *p*-value 0.07, R^2 0.33]. These outliers were visually identified.

Table 10: Limits of agreement with 95% confidence interval between paper and non-paper alternative survey modes

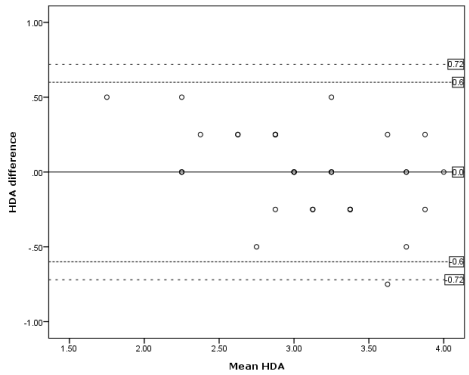
	Variables	Mean difference	Standard deviation	Effect size	Limits of agreement		95% confidence interval	
					Upper	Lower	Upper	Lower
1.	Pain intensity	-0.12	1.49	0.05	2.96	-3.20	3.60	-3.83
2.	Physical disability	-0.21	2.31	0.04	4.56	-4.97	5.54	-5.95
3.	Health Directed Activity	0.00	0.29	0.00	0.60	-0.60	0.72	-0.72
4.	Positive and Active Engagement in Life	-0.04	0.38	0.05	0.75	-0.82	0.91	-0.98
5.	Emotional Distress	0.11	0.33	0.16	0.79	-0.56	0.93	-0.70
6.	Self-monitoring and Insight	0.02	0.25	0.06	0.53	-0.48	0.64	-0.59
7.	Constructive Attitudes and Approaches	-0.02	0.25	0.04	0.48	-0.53	0.59	-0.63
8.	Skill and Technique acquisition	0.10	0.32	0.17	0.76	-0.56	0.90	-0.70
9.	Social Integration and Support	0.03	0.27	0.04	0.59	-0.53	0.70	-0.64
10.	Health Service Navigation	0.03	0.27	0.05	0.60	-0.54	0.71	-0.65



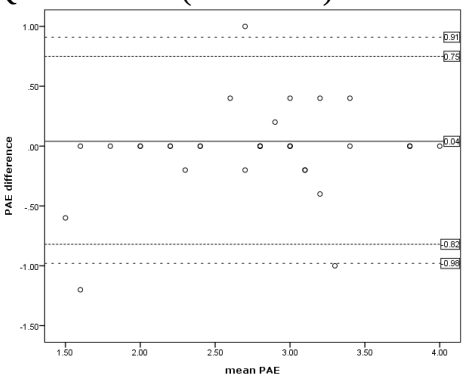
Numeric Pain Scale (0-10 scale)



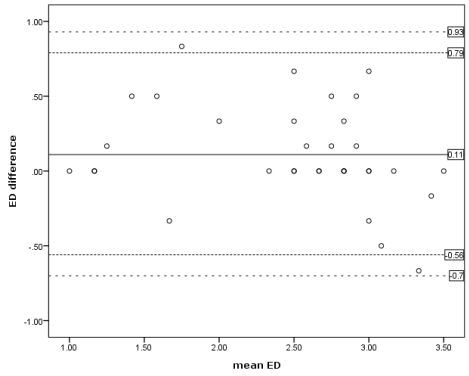
Roland Morris Disability Questionnaire (0-24 scale)



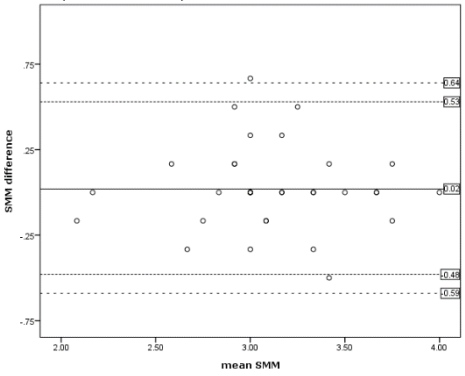
Health Directed Activity (0-4 scale)



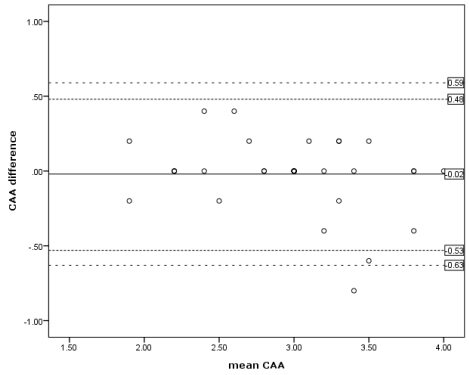
Positive and Active Engagement in Life (0-4 scale)



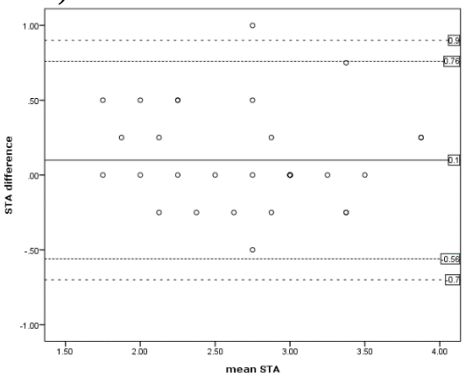
Emotional Distress (0-4 scale)



Self-monitoring and Insight (0-4 scale)

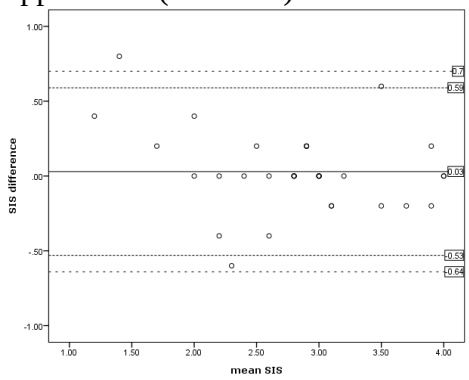


Constructive Attitudes and



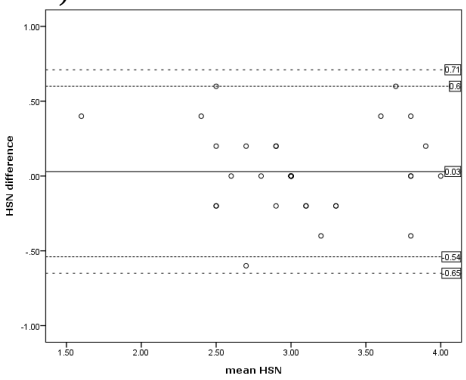
Skill and Technique acquisition (0-4

Approaches (0-4 scale)



Social Integration and Support (0-4 scale)

scale)



Health Service Navigation (0-4 scale)

Figure 6: Limits of agreement with 95% confidence interval between paper and non-paper alternative survey mode

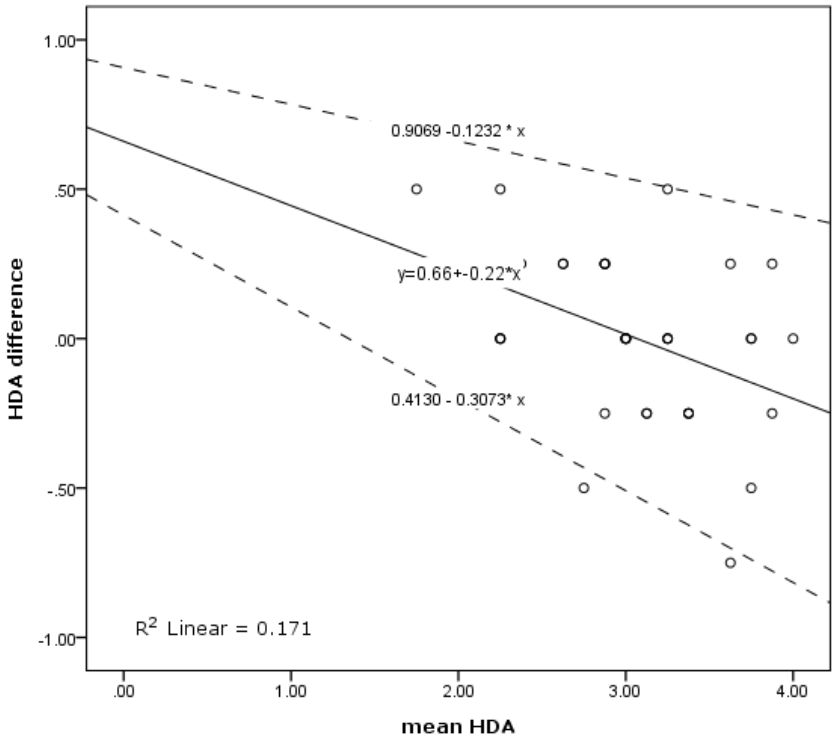


Figure 7: Plot of Health Directed Activity difference paper and non-paper alternative survey modes against its mean with V-shaped limits of agreement

4.4 Discussion

4.4.1.1 Differences between survey modes

The paper survey responses were neither statistically nor clinically different from the NPA survey responses in the present study (Table 9). Similarly, Messih *et al.*(Messih et al., 2014) reported no statistically significant difference between postal and telephone survey modes for Oxford Hip Scores (mean difference -1.2, n=85) and Oxford Knee Scores (mean difference -0.2, n=61) in patients undergoing total hip and knee arthroplasty, respectively. Chatterji and colleagues (Chatterji et al., 2017) also found paper and telephone survey modes were statistically equivalent for EuroQuol and Utility Index in patients (n=76) waiting for hip or knee arthroplasty. No statistically significant difference was reported between paper and online surveys recording dietary intakes in pregnant volunteers (Benedik et al., 2014) and assessing the quality of life (Short-Form 36) in men with prostate cancer (Broering et al., 2014). They reported statistically significant ordering effect for physical function (p=0.02) and physical component scores (p=0.01); and interaction effect (between order and survey modes) for mental component (p=0.01), role emotional (p=0.03), social function (p=0.02), vitality (p=0.01), and mental health (p=0.01) scores. However, these differences were not clinically meaningful.

4.4.1.2 Intraclass correlation coefficients

The results showed high consistency (Cicchetti, 1994) between paper and NPA survey modes with Cronbach's α between 0.89 and 0.95 for all variables. The ICCs between paper and NPA survey modes ranged from 0.89 to 0.96, and all lower 95% confidence interval of the ICC values were above 0.78. These results indicate 'high' to 'excellent' level of clinical significance (Cicchetti, 1994) and equivalence (Lee et al., 1989) between paper and NPA survey modes. These results are similar to other studies (Gwaltney et al., 2008, Messih et al., 2014, Benedik et al., 2014, Broering et al., 2014). For example, Messih found ICCs for OKS and OHS were 0.79 and 0.87 (Messih et al., 2014). These ICCs were lower than ICCs for the Roland Morris Disability Questionnaire 0.96 of the present study. This difference in ICCs for Roland Morris Disability Questionnaire could be due to a higher proportion of older participants (more than 50% older than 65 years old).

4.4.1.3 Limits of agreement and their 95% confidence interval

Nine out of ten study variables demonstrated no proportional bias between paper and NPA survey modes in this study. A proportional bias was observed in ordinary least squares regression between the 'differences between the measurements' against 'their mean' for HDA. The V-shaped LoAs between the paper and NPA survey modes for HDA were plotted in Figure 7 (Ludbrook, 2010). However, the removal of three visually identified outliers in a sensitivity analysis resulted in no proportional bias between the survey modes for HDA.

The LoAs for Roland Morris Disability Questionnaire (RMDQ) in Dutch version reported between 6.23 and -4.56 in 30 patients with CLBP (Brouwer et al., 2004). In another study comparing online and paper survey modes, the LoAs for RMDQ ranged from -2.77 to 2.83 (Bishop et al., 2010). In the present study, LoAs for RMDQ were between 4.56 and -4.97 and within the range of the values in the literature. The differences could be due to random error, the formulae used, sample size and variability of the differences between the survey modes. The LoAs for the pain intensity in the present study ranged from 2.96 to -3.20, which is wider than the clinically meaningful difference in pain intensity of a raw change of 1.74 points or 28% (Farrar et al., 2001). There were no data available for comparing LoAs between the survey modes for heiQ scores. However, the LoAs with 95% CL_{LoA} between the paper and NPA survey modes were open to interpretation according to the scope of the research and perceived benefit of using a mixed-mode survey design.

4.4.2 Strength and limitations

This study examined an important issue of using mixed-mode surveys in chronic pain research. The NPA survey was completed by 34 patients with CLBP and they were predominantly white (94%), female (62%) and educated at college or university level (54%), which might not be a representative sample of patients with CLBP. As this study was interested to estimate the reliability and agreement between the paper and NPA survey modes, these demographic characteristics might not affected the results.

Telephone survey was not separately compared the paper survey due to a small sample size (n=9). In the absence of a cross-over design, the effect of the survey mode and the interaction between the mode and order on the LoAs were not examined in the present study. Future studies may employ all possible comparisons in a random-cross over design and use a larger sample.

Despite these limitations, this was the first study to assess test-retest reliability and agreement between paper and NPA survey modes for the heiQ used to assess SM in patients with CLBP. This study estimated both the product based correlation (ICC) and Limits of Agreement (LoAs). Further, the potential uncertainty in LoAs was also estimated by 95% confidence limits of LOAs using precise formulae. Estimation of the 95% confidence limit of the LOAs for the heiQ. Pain and disability measures were not estimated in patients with CLBP in earlier research.

4.5 Conclusion

This study showed a high level of reliability and no statistically significant or clinically meaningful difference between paper and NPA survey modes in patients with CLBP. The Limits of Agreement results of the heiQ indicate that the paper and NPA surveys may be used in research without affecting the data quality for within- and between-group analysis in patients with CLBP.

Chapter summary

This test-retest study showed that the heiQ is reliable and suitable to measure SM in patients with CLBP when used in a mixed mode survey. The findings also highlight that the pain (NPS) and disability (RMDQ) measures are reliable and suitable too. These findings indicate that the paper and NPA survey can be used in the clinic, service evaluation and clinical research involving patients with CLBP. The following chapter will describe the methods of the main study aiming to identify the predictors of SM in patients with CLBP using a mixed-mode survey.

Question	Aim	Main finding
Are paper and non-paper alternative methods of survey completion equivalent for an identified SM measure in patients with CLBP?	To estimate the reliability and agreement between paper and non-paper alternative methods of survey completion for a SM measure	Both paper and non-paper alternative methods of survey completion produced equivalent (equally reliable and acceptable Limits of Agreement) quality data for the heiQ in patients with CLBP.

5 METHODS

This chapter presents the methods and procedures employed in the main longitudinal cohort study. The chapter begins with the rationale, aims and objectives- as discussed in chapter 2; and patient selection criteria; measures used; selection and recruitment processes. It also highlights the ethical aspects of research and data management.

5.1 Aim

The primary aim of this study was to examine the predictive relationship between SM constructs and biopsychosocial outcome measures in patients with CLBP.

5.1.1 Objectives

The main objectives of the longitudinal cohort study were:

- To determine whether biopsychosocial factors including: demographic factors (age, gender), disease-related information (duration of the CLBP, healthcare use, medication use, pain intensity, physical disability, physical activity level), socioeconomic factors (living arrangement, marital status, employment status, income), psychological factors (such as depression, kinesiophobia, catastrophising) are associated with SM constructs measured using the Health Education Impact Questionnaire (heiQ)
- To test whether the biopsychosocial factors predict concurrently measured SM constructs using the heiQ
- To test whether a change in these biopsychosocial factors over time predicts change in SM constructs measured using the heiQ.

5.2 Study design

A multi-centre prospective (non-experimental) longitudinal cohort study design was employed.

5.3 Research ethics and governance approvals

The study was conducted in keeping with the ethical principles that have their origin in the Declaration of Helsinki, 2013 (World Medical Association, 2013); the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social Care, 2005.

This study protocol was approved by the National Health Service Research Ethics Committee (Ref No 15/ES/1067- November 2015) (Appendix 1). The protocol was registered in ClinicalTrials.gov (ID: NCT02636777) and published in an open-access physiotherapy journal (Banerjee et al., 2016). The study was brought under the Health Research Authority (HRA), UK approval in April 2016, soon after integrated HRA ethics and governance approval process had been introduced. Research governance approvals were obtained from the site-specific Research & Innovation (R&I) departments and HRA.

The study protocol was amended three times- The first substantial amendment included mixed mode survey completion options at the baseline data collection (April 2016- Appendix 2) which enables additional analysis to compare methods of data collection (see chapter 4). Further, two minor amendments were sought to include four additional sites following initial slow recruitment (November 2016) and extend the end of the study date (in January 2017).

5.4 Study components

Mixed mode questionnaire surveys were utilised to collect data in this study. Participants completed two surveys: one at baseline and another at six months follow up. Both surveys consisted of measures of pain intensity, physical disability, SM and psychological constructs, for example, depression, kinesiophobia and catastrophising. The details of these measures are discussed later in this chapter. Demographic and socioeconomic details were collected at the baseline survey.

An additional non-paper alternative (NPA) (see chapter 4) survey was used to evaluate the test-retest reliability and agreement between responses from the paper-based survey and NPA (online/telephone) survey. Measures of pain intensity, physical disability and SM were utilised in the agreement survey to minimise participant burden (see chapter 4). This agreement survey was offered to willing patients who completed the paper copy at the baseline and invited to complete the agreement survey either online or over telephone within two weeks from baseline survey completion.

5.5 Study duration

Baseline recruitment was conducted between February 2016, and May 2017 and the six-month follow up surveys were completed by December 2017.

5.6 Study settings

Patients recruitment was started in February 2016 at two sites- Nottingham University Hospitals (Queen's Medical Centre and City Hospital) - an acute care hospital; and Nottingham CityCare Partnership CIC.- a social enterprise offering musculoskeletal outpatient patient services within National Health Service (NHS) to the Nottingham City Clinical Commissioning Group area. Due to slow recruitment at the outset, four additional sites were included in November 2016: Nottinghamshire Healthcare Foundation Trust, Royal Free London NHS Foundation Trust, Tameside and Glossop Integrated Care NHS Foundation Trust and Sherwood Forest Hospitals NHS Foundation Trust (Kings Mill Hospital). In consultation with the authorities of the Sherwood Forest Hospitals NHS Foundation Trust, the study data collection at Kings Mill Hospital was embedded within a wider service evaluation at this site, which took place between March 2017 and December 2017. Figure 8 presents the recruitments sites.

Figure 8: Recruitment sites across Midland and London

5.7 Sample size calculation

A priori sample size was estimated using G*Power (version 3.1.5) software with the assumptions that all exposures could be dichotomised into binary variables, and that the prevalence of exposures would be about 50% for at least 80% power (Scrivener et al., 2001)and significance level at 5% using Health Directed Activities (HDA) subscale of the Health Education Impact Questionnaire (heiQ) (Elsworth et al., 2015).

It was estimated the study would require at least 130 participants to detect a change of 0.5 (effect size d), 200 participants to detect a change of 0.4 (effect size d) and 324 participants to detect a change of 0.5 (effect size d).

5.8 Participants

Participants were recruited from the outpatient physiotherapy clinics within two primary/ community care and four acute care NHS Trusts in the UK.

5.8.1 Inclusion criteria

For the purpose of the study low back pain was defined as pain in the posterior aspect of the body between the lower margins of the twelfth ribs and the gluteal folds with or without pain in the one or both legs (Hoy et al., 2014). Patients were included if they:

- had low back pain for more than three months (Saragiotto et al., 2016b);
- were aged between 18 and 65 years at baseline (to recruit from the working-age population associated with high socioeconomic impact and recognising the changing SM needs in the presence of another comorbidity in older adults);
- were community ambulant without walking aids (to minimise confounding of the changing SM needs in the presence of mobility restriction);
- were attending or attended outpatient physiotherapy treatments for their CLBP; and
- were able to read, write and understand English to enable completion of the questionnaires.

5.8.2 Exclusion Criteria

Patients were excluded if they:

- were diagnosed with cancer or other known or self-reported specific causes for their low back pain (major trauma, fracture, inflammatory condition, ankylosing spondylitis, grade 3 & 4 spondylolisthesis, severe spinal canal stenosis, or lumbar intervertebral disc protrusion or extrusion, spinal deformity) (Maher et al., 2017);
- had undergone surgery within the last one year for the lower back or planned/ scheduled for any major surgery in the coming six months (as surgery may drastically change the usual SM);
- were pregnant women or women who had childbirth in the last one year (to avoid the confounding effects of pregnancy-related low back pain);
- had cognitive impairment and/or neurological diseases (to avoid the confounding effects of neurological condition); and
- had severely impaired vision and hearing, preventing them from completing the survey in any form even with maximum assistance.

5.9 Measures

A selection of the biopsychosocial measures were included based on known predictors for chronicity of low back pain (Campbell et al., 2013, Kovacs et al., 2011), validated measures recommended for CLBP research (Chapman et al., 2011, Grotle et al., 2005), consultations with clinical stakeholders and Outcome Measures in Rheumatology (OMERACT) recommendations (Boers et al., 2014).

5.9.1 Demographic and socioeconomic characteristics

In keeping with the consensus report for prospective cohort studies in patients with low back pain (Pincus et al., 2008) the following demographic variables were selected to adequately describe the study population- duration of CLBP, presence of related leg pain, age, gender, ethnicity, postcode, educational level, current employment status, annual household income, marital status, and living arrangements. Additionally, the amount and nature of treatment received and medication usage for CLBP was collected both at baseline and follow up survey.

5.9.2 Health Education Impact Questionnaire

Self-management was measured using a multi-domain scale- Health Education Impact Questionnaire (heiQ) version 3 (Appendix: 3) (Osborne et al., 2007). The scale (version 3) consists of 40 items, which measure eight different constructs of SM: Health-Directed Activities (HDA), Positive and Active Engagement in Life (PAEL), Emotional Distress (ED), Self-Monitoring and Insight (SMI), Constructive Attitudes and Approaches (CAA), Skill and Technique Acquisition (STA), Social Integration and Support (SIS) and Health Service Navigation (HSN). Table 11 describes the each SM construct.

Each of the 40 items can be scored using four-point ordinal scale options from 'strongly disagree' to 'strongly agree' with no neutral option given. Each independent construct total score is further divided by the number of items on it.

The heiQ was developed using the 'Program Logic Model', grounded theory based interviews with stakeholders and concept mapping for evaluation of patient education programme in broad range chronic conditions (Osborne et al., 2007).

This scale has high internal consistency (Cronbach's α 0.70-0.89) and discriminant validity in patients with chronic diseases (Osborne et al., 2007, Elsworth et al., 2015). The heiQ scale has been chosen for its ability to capture multiple SM constructs across physical, psychological and social domains (Banerjee et al., 2018) and low response bias (Nolte et al., 2013b).

Table 11: Self-management constructs as measured with the Health Education Impact Questionnaire

Constructs		Questions
HDA	1.	On most days of the week, I do at least one activity to improve my health (e.g., walking, relaxation, exercise)
	9.	I do at least one type of physical activity every day for at least 30 minutes (e.g., walking, gardening, housework, golf, bowls, dancing, Tai Chi, swimming)
	13.	On most days of the week, I set aside time for healthy activities (e.g., walking, relaxation, exercise)
	19.	I walk for exercise, for at least 15 minutes per day, most days of the week
PAEL	2.	Most days I am doing some of the things I really enjoy
	5.	I try to make the most of my life
	8.	I am doing interesting things in my life
	10.	I have plans to do enjoyable things for myself during the next few days
	15.	I feel like I am actively involved in life
ED	4.	I often worry about my health
	7.	My health problems make me very dissatisfied with my life
	12.	I often feel angry when I think about my health
	14.	I feel hopeless because of my health problems
	18.	I get upset when I think about my health
	21.	If I think about my health, I get depressed
SMI	3.	As well as seeing my doctor, I regularly monitor changes in my health
	6.	I know what things can trigger my health problems and make them worse
	11.	I have a very good understanding of when and why I am supposed to take my medication
	16.	When I have health problems, I have a clear understanding of what I need to do to control them
	17.	I carefully watch my health and do what is necessary to keep as healthy as possible
	20.	With my health in mind, I have realistic expectations of what I can and cannot do
CAA	27.	I try not to let my health problems stop me from enjoying life
	34.	My health problems do not ruin my life
	36.	I feel I have a very good life even when I have health problems
	39.	I do not let my health problems control my life
	40.	If others can cope with problems like mine, I can too

Constructs		Questions
STA	23.	I have effective ways to prevent my symptoms (e.g., discomfort, pain and stress) from limiting what I can do in my life
	25.	I have a very good idea of how to manage my health problems
	26.	When I have symptoms, I have skills that help me cope
	30.	I have a good understanding of equipment that could make my life easier
SIS	22.	If I need help, I have plenty of people I can rely on
	28.	I have enough friends who help me cope with my health problems
	31.	When I feel ill, my family and carers really understand what I am going through
	35.	Overall, I feel well looked after by friends or family
	37.	I get enough chances to talk about my health problems with people who understand me
HSN	24.	I have very positive relationships with my healthcare professionals
	29.	I communicate very confidently with my doctor about my healthcare needs
	32.	I confidently give healthcare professionals the information they need to help me
	33.	I get my needs met from available healthcare resources (e.g., doctors, hospitals and community services)
	38.	I work in a team with my doctors and other healthcare professionals

5.9.3 Numeric Pain Rating Scale

Pain intensity, recognising as an important dimension of pain, was measured using the Numeric Pain Rating Scale (NPS). An 11-point (0 to 10) Numeric Pain Rating Scale (NPS) with two end-point descriptors- '0 means no pain' and '10 means worst possible pain' was used in this study. Patients were requested to rate their worst pain intensity in the last 24 hours.

The development of the NPS is rooted back in the 1970s (Downie et al., 1978) in patients with rheumatic diseases in the UK. Further development and validation work were done in patients with chronic pain (Jensen et al., 1986) and the 11-point version of NPS was introduced later in the 1990s to improve measurement properties (Jensen and McFarland, 1993).

The high relative validity of the NPS against Visual Analogue Scale (VAS) (correlation coefficients 0.94-0.96) was established in experimental pain (Ferreira-Valente et al., 2011) and high test-retest reliability (correlation coefficients 0.94-0.96) was found in outpatient rheumatology clinic population (Ferraz et al., 1990). Further, NPS is acceptable to patients with chronic pain for ease of reporting (Williams et al., 2000) and appropriate to identify the magnitude of change in pain intensity in patients with CLBP (Dworkin et al., 2008, Farrar et al., 2001).The NPS is easy and quick to administer. Unlike VAS, NPS can be used in various formats- paper, online and telephone.

5.9.4 Roland Morris Disability Questionnaire

Physical function limitation (or disability) was assessed using a 24-item Roland Morris Disability Questionnaire (RMDQ) (Appendix 4). The 24 statements of the questionnaire can be scored 'yes- if that describes the patient on that day' or 'no- otherwise' producing a possible total score between 0 and 24.

The RMDQ was developed in the early 1980s for measuring physical disability patients with low back pain (Roland and Morris, 1983). There is a debate regarding the underlying constructs or dimensions of the RMDQ. Magnussen and colleague showed a good fit to a three-factor model with symptoms, limitations of daily activities and avoidance of activity and participation (Magnussen et al., 2015). However, other researchers found poor fit to multi-domain models for the RMDQ (Yamato et al., 2017). The RMDQ was claimed to be better than Oswestry Disability Index for patients with less severe physical disability (Roland and Fairbank, 2000), though there is not enough evidence to say one scale is better than the other (Chiarotto et al., 2016).

Internal consistency (Cronbach's α) was reported to be between 0.84-0.94, and test-retest reliability correlation was reported (intraclass correlation) between 0.91 (same day) and 0.83 (three weeks) in patients with CLBP for short time-interval (Chiarotto et al., 2016, Roland and Fairbank, 2000). The RMDQ is recommended for assessing physical function and its change over time in patients with CLBP (Chapman et al., 2011, Ostelo and de Vet, 2005).

5.9.5 International Physical Activity Questionnaire Short Form

Physical activity level was measured using the International Physical Activity Questionnaire-Short Form (IPAQ-SF) (Appendix 5). The IPAQ-SF contains seven items asking the last seven days' physical activities. The total self-reported physical activity in the last week (in minutes) can be used to calculate estimated metabolic equivalent (MET) or to categorise in 'active (>150 minutes/week)' or inactive group.

The IPAQ was developed in late in the late 1990s after a consensus on the need of developing physical activity measures useful across the world. IPAQ-SF showed to be reliable for use over the telephone (correlation 0.87) and self-administered (correlation 0.69) in the UK. The reliability was estimated higher for categorical data (>150 minutes of workout/ week) 0.81 and 0.93 respectively in the UK. The scores of the IPAQ-SF were comparable with the scores from the IPAQ long form (Craig et al., 2003). Despite limitations of self-reported physical activity questionnaires (Bauman et al., 2009, Lee et al., 2011), IPAQ-SF over last seven days is valid (Kim et al., 2013), reliable and most useful in assessing the physical activity level (Silsbury et al., 2015).

The truncated (with 4 hours per activity per recording day) MET score was calculated and used in the preliminary analysis. Further, Kilo MET (1000 MET = 1 Kilo MET) was utilised in the regression analysis for better representation of the results.

5.9.6 Tampa Scale of Kinesiophobia

Kinesiophobia defines an unreasonable amount of pain-related fear of physical movement/ activity (Kori et al., 1990). Kinesiophobia was measured using the Tampa Scale of Kinesiophobia (TSK) (Appendix 6). The TSK (Miller et al., 1991) consists of 17 four-point Likert scale items and each item can be scored from '1 or strongly disagree' to '4 or strongly agree'. A total score can be obtained after an inversion of scores for items 4, 8, 12 and 16. The total score varies from 17 to 68, and a score of ≥ 37 indicates high kinesiophobia (Vlaeyen et al., 1995).

A different versions are available for the TSK, including one-factor model with 17 items, four-factor model with 17 items and one-factor model with 13 items (Vlaeyen et al., 1995, French et al., 2007). As tow- or four-factor models had high correlation between the factors and poor internal consistency of the factor sub-scales (French et al., 2007), the 17-item one factor model was utilised in the present study.

The internal consistency (Cronbach's α) was reported as 0.84 for the 17-item total score (French et al., 2007) and test-retest reliability intraclass correlation coefficient 0.72 (Lame et al., 2008). The smallest detectable change was estimated at 9.2 (or 18%) of the total score in patients with low back pain (Ostelo et al., 2007). The total score of the TSK moderately correlates with disability and performance testing (correlation coefficient 0.43) in patients with CLBP (Crombez et al., 1999, Roelofs et al., 2004, Vlaeyen and Linton, 2000).

5.9.7 Pain Catastrophising Scale

Catastrophising defines as intensified negative feeling or emotion in relation to pain. Catastrophising was measured using the Pain Catastrophising Scale (PCS) (Appendix 7) in this study (Picavet et al., 2002). The PCS consists of 13 items, which is scored with a five-point Likert scale from '0 or not at all' to '4 or all the time' (Sullivan et al., 1995). The PCS provides three sub-scores: rumination (sum of items 8, 9, 10, 11), magnification (sum of items 6, 7, 13), and helplessness (sum of items 1, 2, 3, 4, 5, 12) and a total score (sum of items 1 to 13) for catastrophizing. The total score ranges between 0 and 52, where high scores indicate high catastrophising (Osman et al., 1997).

The PCS was developed in undergraduate student populations (Sullivan et al., 1995). Further, the factor structures and psychometrics were tested and validated in treatment-seeking student population (Osman et al., 1997) and patients attending outpatients pain clinics (Osman et al., 2000). The internal consistency (Cronbach's α) for the three subscales and the total score were estimated between 0.88 and 0.95 (Osman et al., 2000). The test-retest intraclass correlation was reported as 0.73 for the total score and between 0.63 and 0.71 for the subscale scores (Lame et al., 2008). PCS demonstrates high criteria related validity with correctly classifying over 77% of the patients (Osman et al., 2000) and the total score can be used as interval data (Walton et al., 2013). The PCS was utilised in outpatient settings and including patients with CLBP (Picavet et al., 2002, Turner et al., 2016).

5.9.8 Patient Health Questionnaire-9

Depression was assessed using the Patient Health Questionnaire-9 (PHQ-9) (Appendix 8) in this study. The PHQ-9 consists of nine items with four-point Likert scale: from '0 or not at all' to '3 or nearly every day'. The total score ranges between 0 and 27 and can be interpreted in five different categories: no depression (0-4), mild (5-9), moderate (10-14), moderately severe (15-19) and severe depression (20-27) (Smarr and Keefer, 2011).

The PHQ-9 was developed following the Primary Care Evaluation of Mental Disorder and Diagnostic and Statistical Manual of Mental Disorder Fourth Edition diagnostic criteria (Spitzer et al., 1999). In that large sample of the primary care patient population (n=3000) the PHQ-9 had 73% sensitivity, 98% specificity, 93% overall accuracy for major depressive disorder and the self-administered PHQ had an agreement of 0.54 with a health professional diagnosis (Spitzer et al., 1999). The PHQ-9 demonstrates good validity (internal consistency Cronbach's α 0.86), reliable (>0.8), good diagnostic ability (positive likelihood ratio 7.1 for scores > 10) and is quick to administer (Kroenke and Spitzer, 2002, Kroenke et al., 2001). A score of 10 or above can be used to categorise the data set for the presence of depression (Arroll et al., 2010). This scale has also been used extensively in other studies involving patients with CLBP (George et al., 2010, Choi et al., 2014).

5.9.9 Patient Global Impression of Change

Patients' global impression of change in SM at the follow-up survey was assessed using the Patient Global Impression of Change (PGIC) scale modified for SM. The single item 7-point rating scale can be scored from '1 meaning no change or the condition has gotten worse' to '7 meaning a great deal better and a considerable improvement that has made all the difference'.

The original scale was described by Hurst and Bolton (Hurst and Bolton, 2004). The scale is based on previous research showing a seven-item scale is adequate to obtain a reliable correlation coefficient 0.93) and valid (Cronbach's α 0.85 and criteria validity correlation coefficient 0.87) score (Preston and Colman, 2000) for change. The PGIC ratings were used to dichotomise patients into 'improved' ('moderately better' to 'a great deal better') and 'unchanged' ('somehow better' to 'no change or worse') (Fritz and Irrgang, 2001). This dichotomous classification was associated with a reduction in pain intensity (numeric scale rating) with 0.85 area under the curve with 77% sensitivity and 78.6% specificity (Farrar et al., 2001). PGIC is shown to be useful in understanding the global clinical perceived change in patients with chronic pain (Dworkin et al., 2008, Rampakakis et al., 2015) and is also a valid measure of global change for patients with chronic pain in the UK (Scott and McCracken, 2015). This outcome measure was added for future secondary data analysis using a logistic regression. This outcome was not analysed in this PhD study.

Table 12 summarises the different outcome measures used in the baseline, agreement and follow-up survey questionnaires.

Table 12: The validated outcome measures used in the study

Measures	Baseline survey	Agreement survey*	Follow up survey**
Numeric Pain Scale (NPS)	☑	☑	☑
Roland Morris Disability Questionnaire (RMDQ)	☑	☑	☑
Health Education Impact Questionnaire (heiQ)	☑	☑	☑
International Physical Activity Questionnaire-Short Form (IPAQ-SF)	☑		☑
Patient Health Questionnaire-9 (PHQ-9)	☑		☑
Tampa Scale of Kinesiophobia (TSK)	☑		☑
Pain Catastrophising Scale (PCS)	☑		☑
Patient Global Impression of Change (PGIC)			☑

* within two weeks from baseline; ** at six months from baseline

5.10 Procedures

5.10.1 Mixed-mode survey

Patients were requested to complete the surveys at two time points: one at baseline and another at follow-up after six months from the baseline. Mixed mode questionnaire surveys using paper, online and telephone survey modes were used in the study to maximise the survey completion rate and participants' convenience. The Bristol Online Survey (BOS) platform was utilised for the online survey in this study.

Mixed-mode survey has higher survey response rate than a single mode survey (Chi and Chen, 2015, Greene et al., 2008) and is common in researching with patient-reported outcome (Gwaltney et al., 2008, Hox et al., 2015, Dillman et al., 2014). The online versions patient-reported outcomes are well accepted by patients and by researchers (Engan et al., 2016, Gwaltney et al., 2008, Hox et al., 2015, Dillman et al., 2014). Online surveys optimise resource utilisation (e.g., time, cost) (Zuidgeest et al., 2011), minimise missing data (Engan et al., 2016), and maximise the response rate by reaching different groups (McCabe et al., 2006) and decreasing non-response bias (Baines et al., 2007).

5.10.2 Screening the patients

The researcher screened the willing patients at the recruitment sites (NUH, NCCP) following the patient selection criteria. Further, the researcher presented the patient selection criteria to the therapists at the recruitment sites. Patients were screened using the selection criteria by the researcher or therapists at the recruitment sites. The study was introduced to the eligible patients either by the researcher or therapists. Eligible and willing patients provided their contact details and preferred way of contact for survey completion to the researcher by completing the Expression of Interest form (Appendix 9).

5.10.3 Consenting and survey completion

Eligible patients who preferred to complete the survey in hardcopy were provided with a study pack containing Participant Information Sheet (Appendix 10), the consent form (Appendix 11), the demographic information questionnaire (Appendix 12), and the baseline questionnaire survey (Appendix 13) and return stamped business reply envelope by the treating therapists or the researcher (AB). Additionally, the researcher (AB) introduced the study and provided a study pack to willing patients, at the Queen's Medical Centre, a site within the Nottingham University Hospitals Trust and Nottingham CityCare Cic. Patients were encouraged to discuss their involvement in the study with their family or friends. Written informed consent was obtained from patients who completed the questionnaire in paper-and-pen either face-to-face or via post.

Eligible patients who chose to complete the survey via the online form were contacted by the researcher via an email containing the survey link. Completion of the online survey was considered to be implied informed consent. Patients who wanted to complete the survey over the telephone were called by the researcher at their convenient time and the survey completed over the telephone. Verbal informed consent was obtained at the beginning of all telephone surveys by the researcher. The telephone survey took around 20-30 minutes to complete.

Additionally, the study was also advertised within the physiotherapy outpatient clinics of the recruitment sites using a pre-approved poster (Appendix 14). The researcher screened using the selection criteria the patients who directly contacted him over the telephone/ email and provided the baseline survey in their preferred options.

The researcher reminded the patients to complete the questionnaire surveys using text messages, telephone calls and emails (up to five attempts in total) (Chen et al., 2011, Robinson et al., 2007) to maximise completion rate.

5.11 Follow-up survey

The researcher contacted the participants at six months from their baseline survey, according to their preferred mode of contact. The researcher sent the follow-up questionnaire to the participants as they preferred: (Appendix 16) via email for online survey completion, by post for paper and pen, and completed over the telephone. Figure 9 summarises the recruitment of the study.

1. **Screening** eligibility by therapists and research team members

2. Willing patients completed Expression of Interest forms

3. Patients **consenting** to take part

4- **Baseline survey**
- Survey completing options: paper/ online/ telephone
- Survey timeline: February 2016 to April 2017
- Survey components: contact information, demographic details, treatment received and medication usage, pain intensity, physical disability, self-management, physical activity level, catastrophising, kinesiophobia, depression and follow up survey completion preferences
- Total items: 130, estimated time: 15-20 minutes

5. **Agreement survey** (optional- within 2 weeks from baseline)
- Survey completing options: online/ telephone
- Survey timeline: February 2016 to May 2017
- Survey components: pain intensity, physical disability, self-management, physical activity level
- Total items: 85, estimated time: <10 minutes

6. **Follow up survey** (at 6 months from baseline)
- Survey completing options: paper/ online/ telephone
- Survey timeline: August 2016 to January 2018
- Survey components: treatment received and medication usage, pain intensity, physical disability, self-management, physical activity level, catastrophising, kinesiophobia, depression and global impression of change
- Total items: 119, estimated time: 15-20 minutes

Figure 9: Flowchart of recruitment processes for the main longitudinal study and the test-retest study

5.11.1 Non-completion of the follow up survey

Participants who did not complete the follow-up survey were considered as non-completers. The researcher reminded the patients using text messages, telephone calls and emails (every week up to five times in total). Further, a prize draw (total 20 prizes, each for £10 high street vouchers) was utilised to maximise compliance rates in completion of the final follow-up questionnaire (Edwards et al., 2002).

Furthermore, to minimise missing responses, the online survey was designed with 'required to answer' options in the Bristol Online Survey platform. For the telephone survey, items were manually checked together with the patient. Completed questionnaires received by post were checked for missing items, and the researcher contacted the patients attempts were made to complete the missing items. Missing data handling will be discussed later in this chapter (Section 5.15.3.1).

5.11.2 Participant withdrawal

Participant was withdrawn from the study due to personal reasons. The participant was made aware that this would not affect the future clinical care. The participant was also informed (via the Information Sheet and explanation given at the time of withdrawal) that the anonymised data collected to date could not be erased and would be used in the final analysis. Two participants were withdrawn by the investigators as one was involved in major trauma and another had undergone surgery. The data already collected for these three participants were utilised in the analysis.

5.12 Ethical considerations

The present study was a purely quasi-experimental and as such there was a very low anticipated risk to participants. However, there was a possibility that answering some sensitive questions (for example, on depression using the PHQ-9) might generate distress or increase individual awareness of negative aspects of their condition. Patients were routinely encouraged to contact their GP if needed. Despite the anticipated low risk of feeling distress involved in the study, completion of the questionnaires could be considered as a burden to the participants. However, prior to the study, ten patients with CLBP and ten healthy individuals were requested to complete the baseline questionnaire. These individuals completed the survey in around 10-15 minutes and considered the potential burden was minimum and acceptable.

5.13 Data analysis plan

5.13.1 Data management

In the present study, three different survey modes were utilised at the baseline: paper, telephone and online. The paper survey data were entered and verified in an Excel file. Telephone data were also recorded in another Excel file. Online data from the Bristol Online Survey platform were downloaded as an Excel file. The data from paper, telephone and online surveys were gathered into an Excel file and imported into an SPSS file to create the baseline survey database.

Similarly, the data from the agreement survey from telephone and online platform were collated into an Excel file and imported into the agreement survey SPSS database. The follow-up survey data were also collated into an Excel file and imported into the follow-up survey SPSS database.

5.13.2 Change variables

The baseline and agreement databases were merged using the unique study code to create the 'agreement' database. The baseline and follow up databases were merged using the unique study code to create the 'follow-up' database for analysis. In the follow-up database, the 'change' (follow-up score –baseline score) (Glymour et al., 2005) variables were created for SM constructs and other model variables.

5.13.2.1 Categorical variables

Further, the binary categorical variables created from the demographic data collected for analysis and ease of interpretation.

- College/ university educated (1=yes and 2= no)
- Employed (1=yes and 2= no)
- White (1=yes and 2= no)
- Married (1=yes and 2= no)
- High income (1=yes and 2= no)
- Leg pain (1=yes and 2= no)
- Living as married (1=yes and 2= no)
- Receiving physiotherapy (1=yes and 2= no)
- Receiving pain management (1=yes and 2= no)
- Sites (according to the recruiting sites)
    - 1= Sherwood Forest Hospital Trust, Back Pain Unit
    - 2= Nottingham University Hospitals Trust and
    - 3= Nottingham CityCare and other primary care trusts

- Postcode was modified using an online explorer available from http://dclgapps.communities.gov.uk/imd/idmap.html to Index of Multiple Deprivation and analysed as an indicator of patients' socioeconomic status. Further, another binary variable was generated for patients living in the 'top 20% most deprived areas in the UK'.

5.13.3 Preliminary assessment

Data analyses were performed with significance set at $p<0.05$ into statistical software [International Business Machines Corporation, Statistical Package for the Social Sciences (IBM SPSS 24.0)]. Data were screened using stem-and-leaf plots and summaries to identify the presence of an impossible value. Scatter plots were visually assessed for any outliers, and if found, were screened for data entry or imputation errors.

5.13.3.1 Missing values

Missing data found in the study was less than 1% for each variable, except for the annual household income (missing values n=19, 7.03%). The missing values were below 10%; therefore, no imputation was performed in the analyses.

5.13.3.2 Normality testing

As the sample size was large (n>100) the normality was assessed using histograms and Q-Q plots. In the case of non-symmetrical or non-normal distribution, a Shapiro-Wilk test was utilised (Razali and Wah, 2011) for normality and . Levene's test for homogeneity of variance.

5.13.4 Bootstrapping

As data showed minor deviation from normality, bootstrapping was utilised to create robust confidence intervals (Carpenter and Bithell, 2000). The bootstrapped and accelerated intervals (n=1000) were reported in for all analysis. Despite its own disadvantages, bootstrapping is capable of increasing the strength of the results when there is a minor violation of the assumptions (Efron, 2003).

5.13.5 Difference in the mean

For baseline and follow up survey data, descriptive statistics (mean with standard deviation) were reported (Larson, 2006). The between-group differences for the model variables were analysed with Mann-Whitney for two groups and Kruskal Wallis H-test for more than two groups (Dancey et al., 2012). For parametric data the between-group differences at baseline were investigated using an independent *t*-test for two groups and one-way between-group analysis of variance (ANOVA) with *post hoc* Bonferroni correction for more than two groups (Dixon et al., 2013b).

5.13.6 Main analysis

Bivariate correlations (pairwise) were assessed between the SM constructs (Dixon et al., 2013a). Correlation between the model variables and each of the SM constructs was also estimated. Model variables having significant ($p \leq 0.05$) correlation with the SM scores were utilised into regression analysis (Tabachnick and Fidell, 2007).

A multivariate regression analysis using the General linear model (GLM) was performed (Tabachnick and Fidell, 2007) for each of the SM constructs in order to identify baseline predictors. For identifying, the follow-up predictors of the SM constructs, the baseline values of the respective construct and other significant ($p \leq 0.05$) baseline variables were utilised. For identifying the predictors of change in SM constructs, respective SM construct at baseline and the change scores of the significant ($p \leq 0.05$) variables and demographic variables were utilised.

Assumptions of the multiple regression were checked by plotting the standardised residuals against the standardised predicted values. Further, the normality of the residuals was checked by looking at the histograms and probability plots (Field, 2009b).

5.14 Chapter summary

This chapter connected reports the details of methods and procedures employed in the main longitudinal cohort study, in alignment with the rationale and aims of the study. This chapter explained the patient selection and recruitment, processes of conducting the surveys, ethical considerations, and three main statistical analyses. The following chapter will present the results of the longitudinal cohort study.

6 RESULTS

6.1 Introduction

This chapter presents the results of the longitudinal cohort study including recruitment details, demographic characteristics of the participants, the correlation between self-management (SM) constructs and biopsychosocial factors, and the difference in SM constructs between baseline and follow-up measurements. This chapter also presents the results for the univariate and multivariate analysis using General linear models (GLM) for factors are predictive of SM constructs at baseline and six-month follow-up and also for change in SM constructs (follow-up – baseline) over time.

6.2 Participants

A total of 434 patients with chronic low back pain (CLBP) expressed an interest in taking part in the study. Forty-nine (n=49, 11.29%) patients were excluded at the screening stage for the following reasons: not meeting the inclusion criteria (n=20, 4.61%), declined to participate (n=15, 3.46%) and not contactable (n= 14, 3.23%). The remaining willing patients (n=385, 88.71%) were invited to complete the baseline survey, and 270 patients (n=270, 62.21%) completed the baseline survey from the six recruitment sites (Table 13 and Figure 10).

Table 13: Participants recruited in the six sites

Site	No. of participants
Nottingham CityCare Cic. (NCCP)	112
Nottingham University Hospitals Trust (NUH)	99
Sherwood Forest Hospitals NHS Foundation Trust (SFH)	52
Nottinghamshire Healthcare Foundation Trust	4
Royal Free London NHS Foundation Trust	2
Tameside, Glossop Integrated Care NHS Foundation Trust	1

CIC: Community Interest Company

Participants from the Nottingham CityCare Partnership CIC., Nottinghamshire Healthcare Foundation Trust, Royal Free London NHS Foundation Trust and Tameside and Glossop Integrated Care NHS Foundation Trust were grouped together for analysis, as these are primary care trusts. Out of 270 participants, 153 completed the six-month follow-up survey. The flow of the participants in the study is presented in Figure 10.

The present study recruited 270 participants, which was sufficient to detect a change of 0.4 (effect size d) at baseline. And 153 completed follow up survey, which was sufficient to detect a change of 0.5 (effect size) at the follow up.

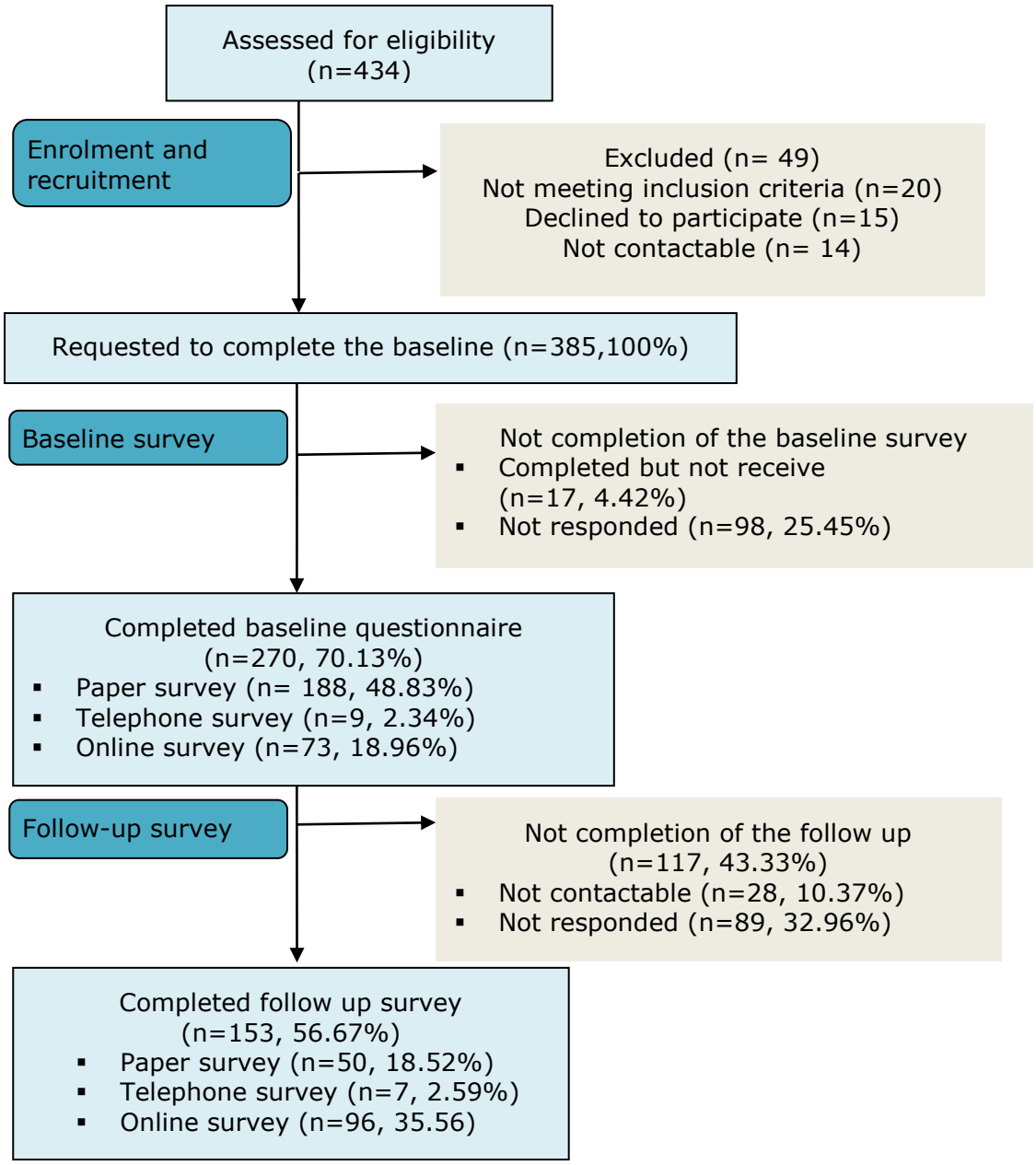


Figure 10: Flow of the participants in the study

6.3 Demographic characteristics at baseline

The mean age of the participants (n=270) was 43.74 (SD 11.89) years. Sixty-one per cent of the participants were female, and 83.7% participants were from a white ethnic background. More than half of the participants were married or living as married (56.3%). Over two-thirds (70.3%) of the participants were employed at either full-time or part-time work and over a one-third (38.5%) of the participants declared an annual household income of £30,000 or more. One-third (33.3%) of the participants lived in the 20% most deprived areas of the UK.

6.4 Baseline clinical characteristics for all participants

The participants reported a mean pain intensity of 5.8 (SD 2.44) on the Numeric Pain Scale and the mean duration of their low back pain was 6.43 (SD 7.82) years. More than a third of the participants reported moderate depression (38.5%) on the Patient Health Questionnaire (PHQ) and catastrophising (36.7%) on the Pain Catastrophising Scale (PCS). Two-thirds of the participants had significant kinesiophobia (61.5%) on the Tampa Scale of Kinesiophobia (TSK). The demographic details and clinical characteristics are presented in Table 14.

6.5 Demographic characteristics at baseline across the different sites

There was no significant difference in participants' demographics and clinical characteristics at baseline except for the following factors: a) participants from Sherwood Forest Hospitals NHS Foundation Trust were significantly older than Nottingham CityCare Partnership Cic. (mean difference 6.32 years, $p<.01$) and reported higher physical disability (mean difference 2.84 on RMDQ, $p<.05$) and higher levels of prescribed medication for their low back pain (mean difference 0.67, $p<.05$); and b) participants from the Nottingham University Hospitals Trust were from less deprived areas than the Sherwood Forest Hospitals NHS Foundation Trust (mean difference IMD 1.83, $p<.05$) and Nottingham CityCare CIC (mean difference IMD 2.50, $p<.05$).

6.6 Baseline demographic characteristics and their differences between completers and non-completers of the follow-up survey

Table 14 shows no significant difference between completers and non-completers of the follow-up survey, except for the level of the highest education obtained. A higher proportion of the completers (n=107, 40.1% of the total recruited patients) obtained an educational qualification at college and university than non-completers (n=68, 25.5% of the total the total recruited patients).

Table 14: Demographic characteristics of the participants at baseline and comparison between completers and non-completers (of the follow-up survey)

	All participants		Non-completers		Completers	
Variables	Frequency	%	Frequency	%	Frequency	%
Gender (n=269)						
Female	165	61.1	70	26.0	95	35.3
Male	104	38.5	46	17.1	58	21.6
Ethnicity (n=269)						
White (for British, Irish, Polish, Italian or any other White background)	226	84.1	95	35.3	131	48.7
Black or Black British (for Caribbean, African and other Black background)	13	4.8	10	3.7	3	1.1
Asian or Asian British (for Indian, Pakistani, Bangladeshi or any other Asian background)	16	5.9	5	1.9	11	4.1
Mixed (for White and the Black Caribbean; White and Black African; White and Asian Any other Mixed background)	11	4.1	6	2.2	5	1.9
Chinese	1	0.4	0	0.0	1	0.4
Other	2	0.7	0	0.0	2	0.7
White ethnicity (n=269)						
Yes	226	84.0	95	35.3	131	48.7
No	43	16.0	21	7.8	22	8.2
The highest level of education obtained (n=267)*						
No formal education	1	0.4	1	0.4	0	0.0
Primary school	1	0.4	1	0.4	0	0.0
Secondary school	72	27.0	36	13.5	36	13.5
High school	18	6.7	10	3.7	8	3.0
College/ professional	77	28.8	38	14.2	39	14.6

	All participants		Non-completers		Completers	
University	98	36.7	30	11.2	68	25.5
Education in college/ university (n=267)*						
Yes	175	65.5	68	25.5	107	40.1
No	92	34.5	48	18.0	44	16.4
Marital status (n=268)						
Single	81	30.3	42	15.7	39	14.6
Married	118	44.0	44	16.4	74	27.7
Living as married	34	12.7	15	5.6	19	7.1
Widowed	2	0.7	2	0.7	0	0.0
Divorced/ separated	28	10.4	11	4.1	17	6.3
Other	5	1.9	3	1.1	2	0.7
Married or living as married (n=268)						
Yes	152	56.7	59	22.0	93	34.8
No	116	43.3	58	21.6	58	21.6
Living arrangements (n=267)						
Living alone	49	18.4	25	9.4	24	9.0
Living with spouse or partner	164	61.4	70	26.2	94	35.3
Living with relative or friend	38	14.2	15	5.6	23	8.6
Living in shared accommodation	9	3.4	3	1.1	6	2.2
Others	7	2.6	3	1.1	4	1.5
Living with a spouse or partner (n=267)						
Yes	164	61.7	70	26.3	94	35.4
No	102	38.3	45	16.9	57	21.4
Employment status (n=268)						

	All participants		Non-completers		Completers	
Retired	14	5.2	3	1.1	11	4.1
Student	14	5.2	5	1.9	9	3.4
Unemployed	46	17.2	19	7.1	27	10.1
Job searching	4	1.5	2	0.7	2	0.7
Working part-time	53	19.8	22	8.2	31	11.6
Working full-time	137	51.1	65	24.3	72	26.9
Employed in a full- or part-time job (n=268)						
Yes	190	70.9	87	32.5	103	38.4
No	78	29.1	29	10.8	49	18.3
Annual household income (n=251)						
< £15,000	68	27.1	29	11.6	39	15.5
£15,000-19,999	37	14.7	19	7.5	18	7.2
£20,000-29,999	42	16.7	23	9.1	19	7.6
£30,000-39,999	41	16.3	17	6.7	24	9.6
£40,000-49,999	17	6.8	7	2.8	10	4.0
£50,000-59,999	22	8.8	8	3.2	14	5.6
£60,000-69,999	2	0.8	1	0.4	1	0.4
£70,000-99,999	15	6.0	3	1.2	12	4.8
£100,000-149,999	6	2.4	3	1.2	3	1.2
£150,000+	1	0.4	0	0.0	1	0.4
Annual household income >£30,000 (n=251)						
Yes	104	41.4	39	15.5	65	25.9
No	147	58.6	71	28.3	76	30.3
Living in 20% most deprived areas (n=269)						

	All participants		Non-completers		Completers	
Yes	90	33.5	46	17.1	44	16.4
No	179	66.5	71	26.4	108	40.1
Patients with depression (n=268)						
Yes	164	61.2	71	26.5	93	34.7
No	104	38.8	44	16.4	60	22.4
Patients with kinesiophobia (n=269)						
Yes	166	61.7	77	28.6	89	33.1
No	103	38.3	39	14.5	64	23.8
Patients with catastrophising (n=269)						
Yes	99	36.8	49	18.2	50	18.6
No	170	63.2	68	25.3	102	37.9

* Significant difference between the completers and non-completers, % calculated of the total sample

The Mean, standard deviation and Bootstrapped 95% confidence interval of the mean of age, duration of CLBP and the clinical characteristics of the participants (n=270) are presented in Table 15.

Table 15: Characteristics of the participants at baseline

Variables	N	Mean	SD	Bootstrap	
				BCa 95% CI of mean	
				Lower	Upper
Age (year)	270	43.74	11.89	42.30	45.19
Pain duration (year)	260	6.43	7.82	5.63	7.23
NPS	262	5.80	2.44	5.53	6.10
RMDQ	270	11.63	5.86	10.96	12.28
PHQ	268	8.68	6.41	7.86	9.51
TSK	269	38.73	7.43	37.91	39.65
PCS	269	18.10	13.00	16.57	19.58
Pr. analgesic	250	1.22	1.27	1.07	1.39
OTC analgesic	250	0.31	0.63	0.23	0.38
Healthcare use	258	5.34	5.52	4.68	6.14
IMD	269	4.55	2.95	4.22	4.91
IPAQ	268	2.92	3.68	2.48	3.40

N: sample size, SD: standard deviation, BCa 95%CI: bias corrected and accelerated 95% confidence interval, NPS: Numeric Pain Scale, RMDQ: Roland Morris Disability Questionnaire, PHQ: Patient Health Questionnaire, TSK: Tampa Scale of Kinesiophobia, PCS: Pain Catastrophising scale, Pr. Analgesic: No of prescribed analgesics, OTC analgesic: No of Over the counter analgesic, IMD: Index for Multiple Deprivation, IPAQ: International Physical Activity Questionnaire (in Kilo Metabolic Equivalent)

6.7 Self-management constructs at baseline

The Kolmogorov-Smirnov and Shapiro-Wilk tests for normality were significant ($p<0.0001$) for the eight SM constructs, indicating deviation from normality. Histogram and Q-Q plot for the SM constructs are presented in (Appendix 17). Visual examination of the histograms and Q-Q plots suggested that these normality deviations were not major deviations (Field, 2009a). Mean, standard deviation, bootstrapped Standard Error of Mean (SEM) and 95% confidence interval for the mean for eight SM constructs measured with the Health Education Questionnaire (heiQ) are reported in Table 16. There was no significant difference ($p<.05$) in SM constructs at baseline between the three recruitment sites (SFH, NUH, NCCP).

Table 16: Descriptive statistics for self-management constructs at baseline

Variables N=270	Mean	SD	Bootstrap		
			SEM	BCa 95% CI	
				Lower	Upper
Health Directed Activity†	2.87	0.66	0.04	2.78	2.95
Positive and Active Engagement in Life†	2.78	0.61	0.04	2.70	2.85
Emotional Distress	2.41	0.70	0.04	2.32	2.50
Self-Monitoring and Insight	2.98	0.45	0.03	2.92	3.03
Constructive Attitudes and Approaches	2.83	0.59	0.04	2.76	2.90
Skill and Technique Acquisition	2.64	0.54	0.03	2.57	2.70
Social Integration and Support	2.76	0.60	0.04	2.68	2.83
Health Service Navigation	2.86	0.50	0.03	2.80	2.92

N: sample size, SD: Standard Deviation, SEM: Standard Error of Mean, BCa: Bias Corrected and accelerated (for 1000 samples), 95%CI: 95% confidence interval, †N=269

The bivariate association between the eight SM constructs were significant and ranged from 0.15 to 0.59 (Table 17). The difference in mean of the eight SM constructs across the categorical variables was calculated using the Mann-Whitney test for variables with two categories and Kruskal-Wallis was employed for variables with more than two categories (Table 18). Variables with a significant difference ($p<.05$) in the SM constructs were used in the multivariate regression analysis (Field, 2009b).

Table 17: Spearman correlation for the self-management constructs as measured with heiQ at baseline

	HDA	PAEL	ED	SMI	CAA	STA	SIS
Health Directed Activity (HDA)	--	--	--	--	--	--	--
Positive and Active Engagement in Life (PAEL)	0.50**	--	--	--	--	--	--
Emotional Distress (ED)	0.31**	0.57**	--	--	--	--	--
Self-Monitoring and Insight (SMI)	0.39**	0.34**	0.17**	--	--	--	--
Constructive Attitudes and Approaches (CAA)	0.41**	0.66**	0.59**	0.31**	--	--	--
Skill and Technique Acquisition (STA)	0.35**	0.47**	0.34**	0.54**	0.48**	--	--
Social Integration and Support (SIS)	0.28**	0.44**	0.26**	0.32**	0.50**	0.42**	--
Health Service Navigation (HSN)	0.41**	0.36**	0.15*	0.50**	0.37**	0.53**	0.46**

** Correlation is significant at 0.01 level (2-tailed)

Table 18: Non-parametric comparisons of the eight self-management constructs at the baseline

	HDA	PAEL	ED	SMM	CAA	STA	SIS	HSN
Ethnicity†	.36	.28	.29	.08	.46	0.1	0.3	.41
Education†	.23	.01*	.00*	.26	.00*	.25	.33	.30
Employment†	.15	.00*	.00*	.31	.00*	.00*	.01*	.01*
Marital status†	.23	.11	.47	.01*	.53	.06	.03*	.21
Living arrangements†	.91	.02*	.12	.04*	.26	.33	.04*	.22
Income†	.82	.00*	.00*	.54	.01*	.31	.17	.58
Gender‡	.62	.18	.79	.00*	.88	0.8	.22	.23
White ethnicity‡	.42	.09	.05*	.31	.13	.09	.03*	.44
Leg pain‡	.62	.03*	.00*	.63	.00*	.33	.33	.17
College/university‡	.04*	.00*	.00*	.07	.00*	.09	.18	.11
Employed‡	.81	.00*	.00*	.99	.00*	.07	.00*	.26
Married‡	.98	.02*	.13	.01*	0.2	.04*	.02*	.26
Living as married‡	.96	.00*	.03*	.00*	.06	.06	.01*	.21
Income >£30,000‡	.92	.00*	.00*	.13	.00*	.04*	.05*	.46
From top 20% deprived areas‡	.63	.53	.06	.60	.19	.76	.77	.45
Physiotherapy treatment	.52	.83	.25	.40	.13	.90	.81	.69
Pain management	.53	.77	.06	.79	.08	.95	.65	.02*
Recruitment site	.42	.85	.30	.64	.16	.24	.29	.20

†Kruskal-Wallis test for categorical variables with more than two categories, ‡ Mann-Whitney test for categorical variables with two categories, HDA: Health Directed Activity, PAEL: Positive and Active Engagement in Life, ED: Emotional Distress, SMI: Self-Monitoring and Insight, CAA: Constructive Attitudes and Approaches, STA: Skill and Technique Acquisition, SIS: Social Integration and Support, HSN: Health Service Navigation

6.8 Predictors of self-management constructs at baseline

One of the primary aim of this study was to identify predictors of SM in patients with CLBP. Multivariate regression was calculated using the GLM to predict each of the SM constructs at baseline based on their significant univariate predictor variables ($p<.05$) and categorical variables with significant differences ($p<.05$). These results are summarised in Figure 11. Full details of these results are presented in Appendix 18.

A significant regression equation was found for baseline HDA [F (7,260) = 7.70, p<.01] with an adjusted R^2 .15. IPAQ score in Kilo-MET was a significant predictor of HDA. HDA increased by 0.04 for each Kilo MET increase in physical activity.

A significant regression equation was found for baseline PAEL [F (14,223) = 12.25, p<.01] with an adjusted R^2 .41. RMDQ, PHQ and IPAQ (Kilo MET) were significant predictors of PAEL. PAEL decreased 0.03 for each unit increase in physical disability measured with RMDQ and depression measured with PHQ. PAEL increased by 0.02 with each Kilo MET increase in physical activity measured using IPAQ.

A significant regression equation was found for baseline ED [F (16,215) = 17.09, p<.01] with an adjusted R^2 .55. PHQ and PCS were significant predictors ED. ED decreased 0.03 for each unit increase in depression measured with PHQ, and ED decreased 0.02 for each unit increase in catastrophising measured with PCS.

A significant regression equation was found for baseline SMI [F (11,252) = 3.73, p<.01] with an adjusted R^2 .11. Gender and healthcare use were significant predictors of SMI. SMI increased 0.01 for each visit to healthcare providers. SMI was 0.12 significantly higher in females compared with males.

A significant regression equation was found for baseline CAA [F (13,216) = 13.81, p<.01] with an adjusted R^2 .44. RMDQ, PHQ, TSK and PCS were significant predictors of CAA. CAA decreased 0.02 for each unit increase in physical disability measured with RMDQ and depression measured with PHQ. Further, CAA decreased 0.01 with each increase in kinesiophobia measured with TSK and catastrophising measured with PCS.

A significant regression equation was found for baseline STA [F (10,235) = 5.71, p<.01] with an adjusted R^2 .17. PHQ was a significant predictor of STA. STA decreased 0.02 for each unit increase depression measured with PHQ.

A significant regression equation was found for baseline SIS [F (12,242) = 4.82, p<.01] with an adjusted R^2 .16. RMDQ was a significant predictor of SIS. SIS decreased 0.02 for each unit increase in physical disability measured with RMDQ.

A significant regression equation was found for baseline HSN [F (4,266) = 6.35, p<.01] with an adjusted R^2 .07. TSK was a significant predictor of HSN. HSN decreased 0.01 for each unit increase in kinesiophobia measured with TSK.

Normality and homogeneity assumptions were met for all baseline regression analyses, except a minor heteroscedasticity was observed for HDA (Appendix 21).

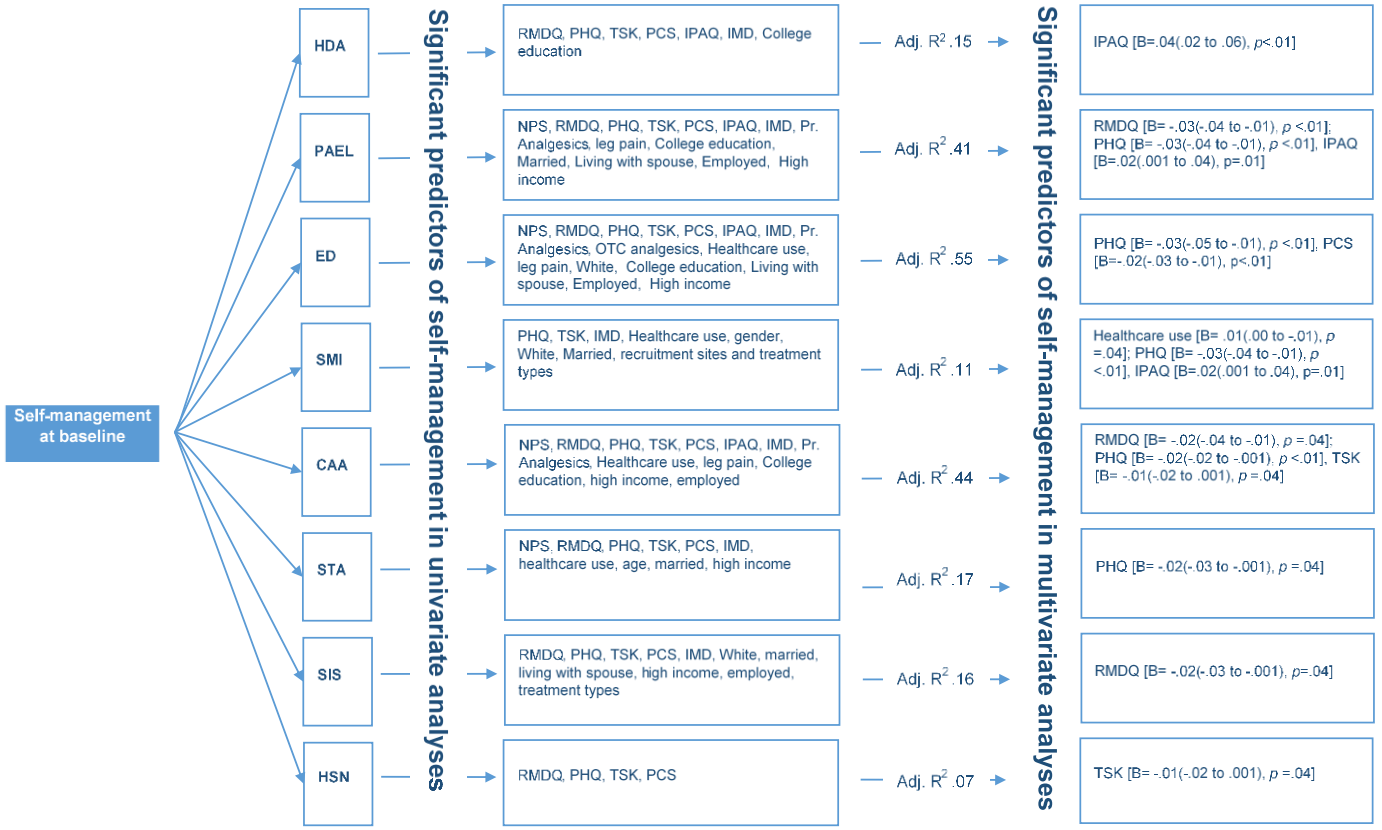


Figure 11: Predictors of self-management constructs at baseline

B: unstandardised coefficient, *p*: *p*-value, Adj. R^2: Adjusted R^2, RMDQ: Roland Morris Disability Questionnaire; NPS: Numeric Pain Scale; PHQ: Patient Health Questionnaire-9; TSK: Tampa Scale of Kinesiophobia; PCS: Pain; Catastrophising scale; Pr. Analgesic: No of prescribed analgesics; OTC Analgesics: No of Over the Counter analgesics; IMD: Index for Multiple Deprivation; IPAQ: International Physical Activity Questionnaire (in Kilo Metabolic Equivalent; Healthcare use: No. of visits to healthcare providers in last 3 months; HDA: Health Directed Activity; PAEL: Positive and Active Engagement in Life; ED: Emotional Distress; SMI: Self-Monitoring and Insight; CAA: Constructive Attitudes and Approaches; STA: Skill and Technique Acquisition; SIS: Social Integration and Support; HSN: Health Service Navigation, Married: Married and living with partner, Living as married: Living with spouse or partner, Employed: Full- or part-time employed, High income: Household income >£30000 in a year, College: Highest level of education at college or university, treatment type; Physiotherapy only or pain management only, White: White ethnic background, Gender: Female vs. male

6.9 Predictors of self-management constructs at follow up

One of the primary aims of this PhD study was to identify what baseline biopsychological factors predicted SM at the follow-up. Multivariate regression was calculated using GLM to predict each of the SM constructs at follow up adjusted for their baseline values and based on their significant (p<.05) univariate predictor variables and categorical variables with significant differences (p<.05). These results are summarised in Figure 12. Full details of these results are presented in Appendix 19.

A significant regression equation was found for HDA at follow up [F (4,151) = 17.18, p<.01] with an adjusted R^2 .30. Baseline HDA [B=.49 (.33 to .67), p <.01] was a significant predictor of follow up HDA.

A significant regression equation was found for PAEL at follow up [F (10,138) 11.26, p <.01] with an adjusted R^2 .43. Baseline PAEL [B= 49 (.31 to .68), p =.001] and baseline TSK [B= -.02 (-.03 to -.003, p=.02] were significant predictors of PAEL follow up.

A significant regression equation was found for ED at follow up [F (14,121) 6.48, p <.01] with an adjusted R^2 .39. Baseline TSK [B=.03 (.01 to .04, p=.003] was a significant predictor of follow up ED.

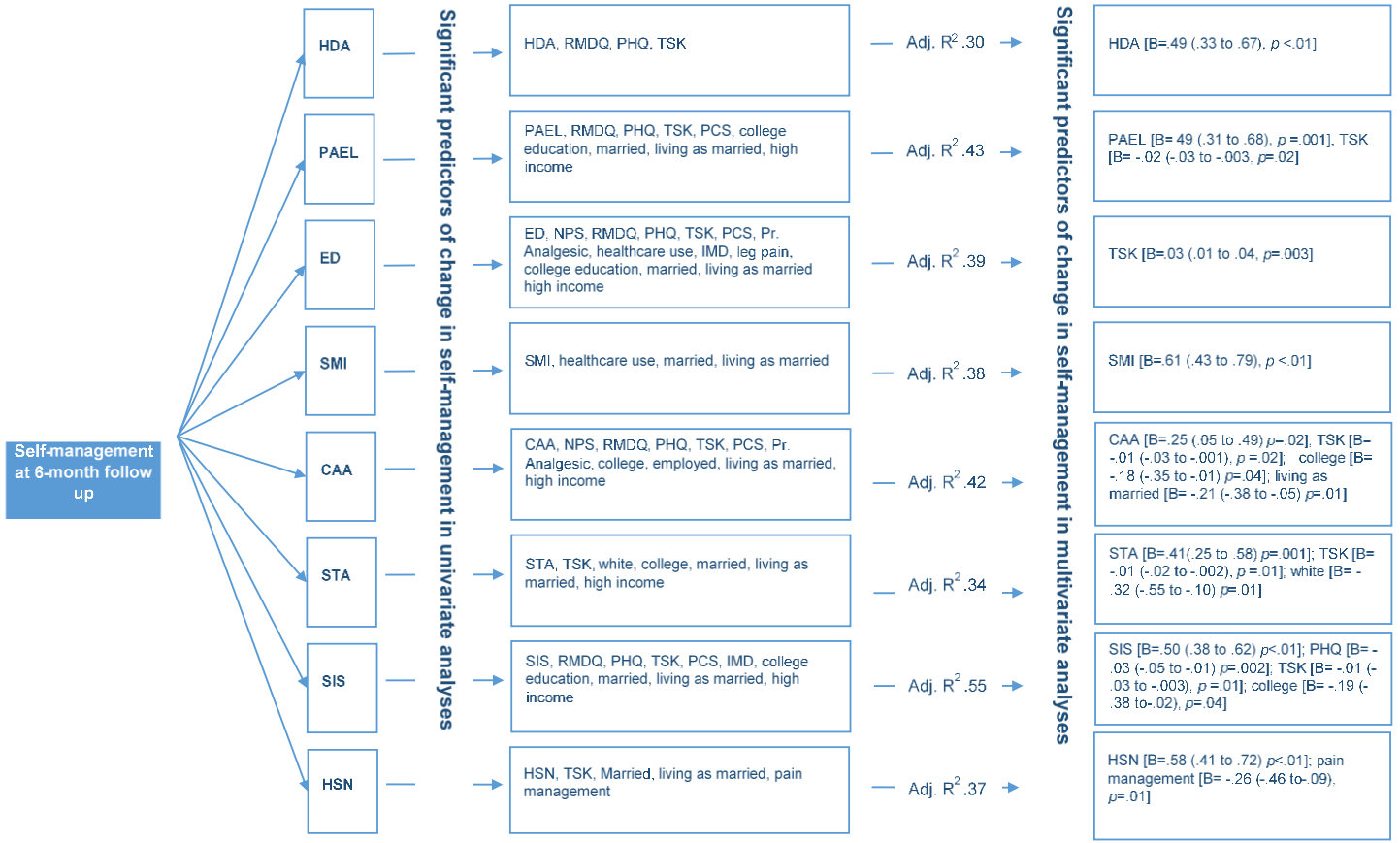
A significant regression equation was found for SMI at follow up [F (4,143) 22.41, p <.01] with an adjusted R^2 .38. Baseline SMI [B=.61 (.43 to .79), p <.01] was a significant predictor of follow up SMI.

A significant regression equation was found for CAA at follow up [F (11,128) 9.43, p <.01] with an adjusted R^2 .42. Baseline CAA [B=.25 (.05 to .49) p=.02], baseline TSK [B= -.01 (-.03 to -.001), p =.02], college [B= -.18 (-.35 to -.01) p=.04] and living as married [B= -.21 (-.38 to -.05) p=.01] were significant predictors of follow up CAA.

A significant regression equation was found for STA at follow up [F (7,139) 11.17, p <.01] with an adjusted R^2 .34. Baseline STA [B=.41(.25 to .58) p=.001], baseline TSK [B= -.01 (-.02 to -.002), p =.01] and white ethnic background [B= -.32 (-.55 to -.10) p=.01] were significant predictors of follow up STA.

A significant regression equation was found for SIS at follow up [F (10,138) 17.75, p <.01] with an adjusted R^2 .55. Baseline SIS [B=.50 (.38 to .62) p<.01], baseline PHQ [B= -.03 (-.05 to -.01) p=.002], baseline TSK [B= -.01 (-.03 to -.003), p =.01] and college [B= -.19 (-.38 to-.02), p=.04] were significant predictors of follow up SIS.

A significant regression equation was found for HSN at follow up [F (5,144) 18.19, p <.01] with an adjusted R^2 .37. Baseline HSN [B=.58 (.41 to .72) p<.01] and pain management [B= -.26 (-.46 to-.09), p=.01] were significant predictors of follow up HSN.



B: unstandardised coefficient, *p*: *p*-value, Adj. R^2: Adjusted R^2, RMDQ: Roland Morris Disability Questionnaire; NPS: Numeric Pain Scale; PHQ: Patient Health Questionnaire-9; TSK: Tampa Scale of Kinesiophobia; PCS: Pain; Catastrophising scale; Pr. Analgesic: No of prescribed analgesics; OTC Analgesics: No of Over the Counter analgesics; IMD: Index for Multiple Deprivation; IPAQ: International Physical Activity Questionnaire (in Kilo Metabolic Equivalent; Healthcare use: No. of visits to healthcare providers in last 3 months; HDA: Health Directed Activity; PAEL: Positive and Active Engagement in Life; ED: Emotional Distress; SMI: Self-Monitoring and Insight; CAA: Constructive Attitudes and Approaches; STA: Skill and Technique Acquisition; SIS: Social Integration and Support; HSN: Health Service Navigation, Married: Married and living with partner,
Living as married: Living with spouse or partner, Employed: Full- or part-time employed, High income: Household income >£30000 in a year, College: Highest level of education at college or university, treatment type; Physiotherapy only or pain management only, White: White ethnic background, Gender: Female vs. male

Figure 12: Predictors of self-management constructs at follow up

6.10 Change in self-management and biopsychosocial factors

Table 19 summaries the change between the follow up and baseline survey scores in the heiQ and the biopsychosocial factors. Pain intensity, physical disability, depression, kinesiophobia, catastrophising, healthcare use and use of prescribed statistically significantly ($p<.05$) decreased between the baseline and follow up surveys in the study cohort. Physical activity level as measured using the IPAQ increased between the baseline and follow up measurements but the increase was not statistically significant. However, these changes in pain intensity, physical disability (Ostelo et al., 2008), depression (Löwe et al., 2004), kinesiophobia (Monticone et al., 2016) were not clinically meaningful. The heiQ scores (HAD, PAEL, SMI, STA) significantly ($p<.05$) increased between the two surveys. The clinical meaningfulness of these changes were difficult to interpret due to lack of research on minimal important change of the heiQ (Banerjee et al., 2018).

Table 19: Change scores in the Health Education Impact Questionnaire sub-scales and biopsychosocial factors

Change scores (follow up – baseline)	N	Minimum	Maximum	Mean	SD	Minimally important change (Reference)
NPS*	143	-8.00	6.00	-1.07	2.70	2.0 (Ostelo et al., 2008)
RMDQ*	153	-16.00	8.00	-1.87	4.66	5.0 (Ostelo et al., 2008)
HDA*	152	-1.50	2.50	0.11	0.64	NA
PAEL*	152	-1.80	1.60	0.09	0.54	NA
ED	153	-2.83	3.00	-0.10	1.26	NA
CAA	153	-1.60	2.40	0.09	0.56	NA
SMI*	153	-0.83	1.83	0.09	0.40	NA
SIS	153	-1.20	1.60	0.07	0.52	NA
STA*	153	-1.00	2.00	0.18	0.54	NA
HSN	153	-1.80	1.40	-0.04	0.52	NA
PHQ*	153	-14.00	14.00	-0.81	5.07	5.0 (Löwe et al., 2004)
TSK*	153	-21.00	20.00	-1.20	7.28	5.5 (Monticone et al., 2016)
PCS*	152	-42.00	22.00	-3.50	9.85	NA
IPAQ	150	-14.42	17.71	0.60	4.46	NA
Pr. Analgesic*	142	-4.00	3.00	-0.47	1.20	NA
OTC Analgesic	142	-2.00	2.00	0.01	0.80	NA
Healthcare use*	108	-38.00	6.00	-3.26	4.79	NA

N: sample size, SD: standard deviation, NPS: Numeric Pain Scale, RMDQ: Roland Morris Disability Questionnaire, HDA: Health Directed Activity; PAEL: Positive and Active Engagement in Life; ED: Emotional Distress; SMI: Self-Monitoring and Insight; CAA: Constructive Attitudes and Approaches; STA: Skill and Technique Acquisition; SIS: Social Integration and Support; HSN: Health Service Navigation, PHQ: Patient Health Questionnaire, TSK: Tampa Scale of Kinesiophobia, PCS: Pain Catastrophising scale, Pr. Analgesic: No of prescribed analgesics, OTC analgesic: No of Over the counter analgesic, IMD: Index for Multiple Deprivation, IPAQ: International Physical Activity Questionnaire (in Kilo Metabolic Equivalent), NA: not available.

6.11 Predictors of in change in self-management constructs

One of the primary aims of the PhD study was to identify what biopsychosocial factors predicted change in SM. Multivariate regression was calculated using the GLM to predict change (follow up scores - baseline scores) in each of the SM constructs based on their significant (p<.05) univariate predictor variables for change (follow up scores - baseline scores) and categorical variables with significant differences (p<.05). These results are summarised in Figure 13. Full details of these results are in Appendix 20.

A significant regression equation was found for change in HDA [F (6,139) 6.18, p <.01] with an adjusted R^2 .18. Change in PCS [B= -.02(-.03 to -.01), p=.004] and change in IPAQ [B= .03 (.01 to .05), p=.001] were significant predictors of change in HDA.

A significant regression equation was found for change in PAEL [F (6,139) 12.09, p <.01] with an adjusted R^2 .32. Change in PHQ [B = -.02 (-.04 to -.01), p =.01]; change in PCS [B= -.02 (-.03 to -.01), p =.001] and change in IPAQ [B=.02 (.004 to .04), p=.02] were significant predictors of change in PAEL.

A significant regression equation was found for change in ED [F (6,138) 7.00, p <.01] with an adjusted R^2 .21. Leg pain [B= .76 (.36 to 1.11), p .002] and college [B= -.60 (-1.02 to -.18), p=.01] were significant predictors of change in ED.

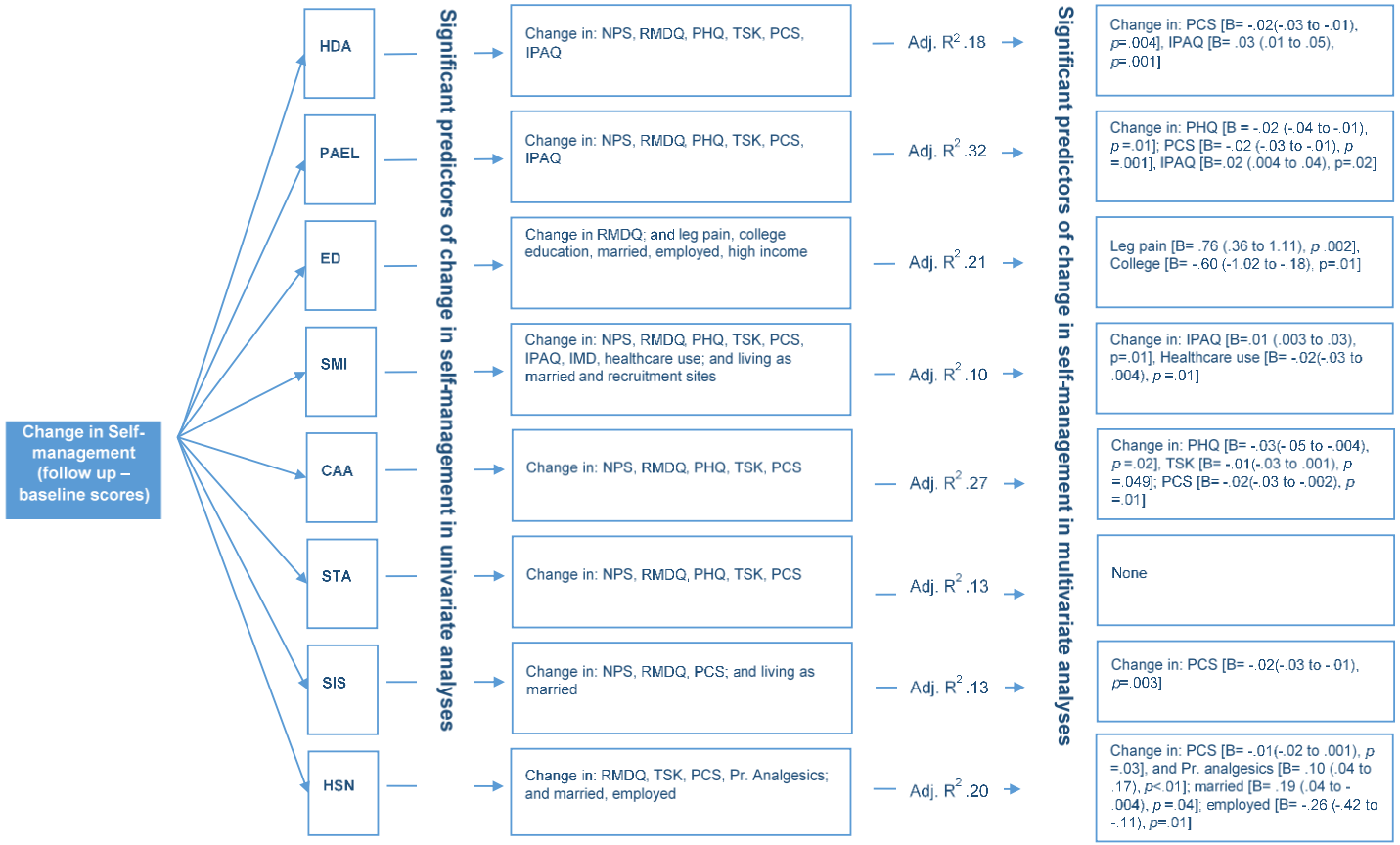
A significant regression equation was found for change in SMI [F (11,99) 2.03, p =.04] with an adjusted R^2 .10. Change in: IPAQ [B=.01 (.003 to .03), p=.01] and change in healthcare use [B= -.02(-.03 to .004), p =.01] were significant predictors of change in SMI.

A significant regression equation was found for change in CAA [F (5,141) 11.52, p <.01] with an adjusted R^2 .27. Change in PHQ [B= -.03(-.05 to -.004), p =.02], change in TSK [B= -.01(-.03 to .001), p =.049] and change in PCS [B= -.02(-.03 to -.002), p =.01] were significant predictors of change in CAA.

A significant regression equation was found for change in STA [F (5,141) 5.23, p <.01] with an adjusted R^2 .13. However, there was no significant predictor of change in STA.

A significant regression equation was found for change in SIS [F (4,141) 6.11, p <.01] with an adjusted R^2 .13. Change in PCS [B= -.02(-.03 to -.01), p=.003] was a significant predictor of change in SIS.

A significant regression equation was found for change in HSN [F (6,139) 6.83, p <.01] with an adjusted R^2 .20. Change in PCS [B= -.01(-.02 to .001), p =.03], change in number of prescribe analgesics [B= .10 (.04 to .17), p<.01], married [B= .19 (.04 to -.004), p =.04]; employed [B= -.26 (-.42 to -.11), p=.01] were significant predictors of change in HSN.



B: unstandardised coefficient, *p*: *p*-value, Adj. R^2: Adjusted R^2, RMDQ: Roland Morris Disability Questionnaire; NPS: Numeric Pain Scale; PHQ: Patient Health Questionnaire-9; TSK: Tampa Scale of Kinesiophobia; PCS: Pain; Catastrophising scale; Pr. Analgesic: No of prescribed analgesics; OTC Analgesics: No of Over the Counter analgesics; IMD: Index for Multiple Deprivation; IPAQ: International Physical Activity Questionnaire (in Kilo Metabolic Equivalent; Healthcare use: No. of visits to healthcare providers in last 3 months; HDA: Health Directed Activity; PAEL: Positive and Active Engagement in Life; ED: Emotional Distress; SMI: Self-Monitoring and Insight; CAA: Constructive Attitudes and Approaches; STA: Skill and Technique Acquisition; SIS: Social Integration and Support; HSN: Health Service Navigation, Married: Married and living with partner, Living as married: Living with spouse or partner, Employed: Full- or part-time employed, High income: Household income >£30000 in a year, College: Highest level of education at college or university, treatment type; Physiotherapy only or pain management only, White: White ethnic background, Gender: Female vs. male

Figure 13: Predictors of change in self-management constructs at follow up

6.12 Sensitivity analyses using mean substitution and baseline observed carried forward data imputations for lost to follow up cases

A total of 153 participants (56.7% of the recruited) completed the follow up survey. There was no significant differences between the completers and non-completers of the follow up survey except for level of education. To examine the robustness of the main results, two sensitivity analyses were conducted using two data imputation algorithms for lost to follow up cases- follow up mean (mean substitution) and baseline carried forward (baseline observation carried forward) for each model variable. Table 20 summaries the mean and standard deviation of the SM constructs and biopsychological factors at follow up after the data imputations.

Multivariate regression was calculated using GLM to predict each of the SM constructs at follow up adjusted for their baseline values and based on their significant ($p<.05$) univariate predictor variables and categorical variables with significant differences ($p<.05$) for both the imputed datasets.

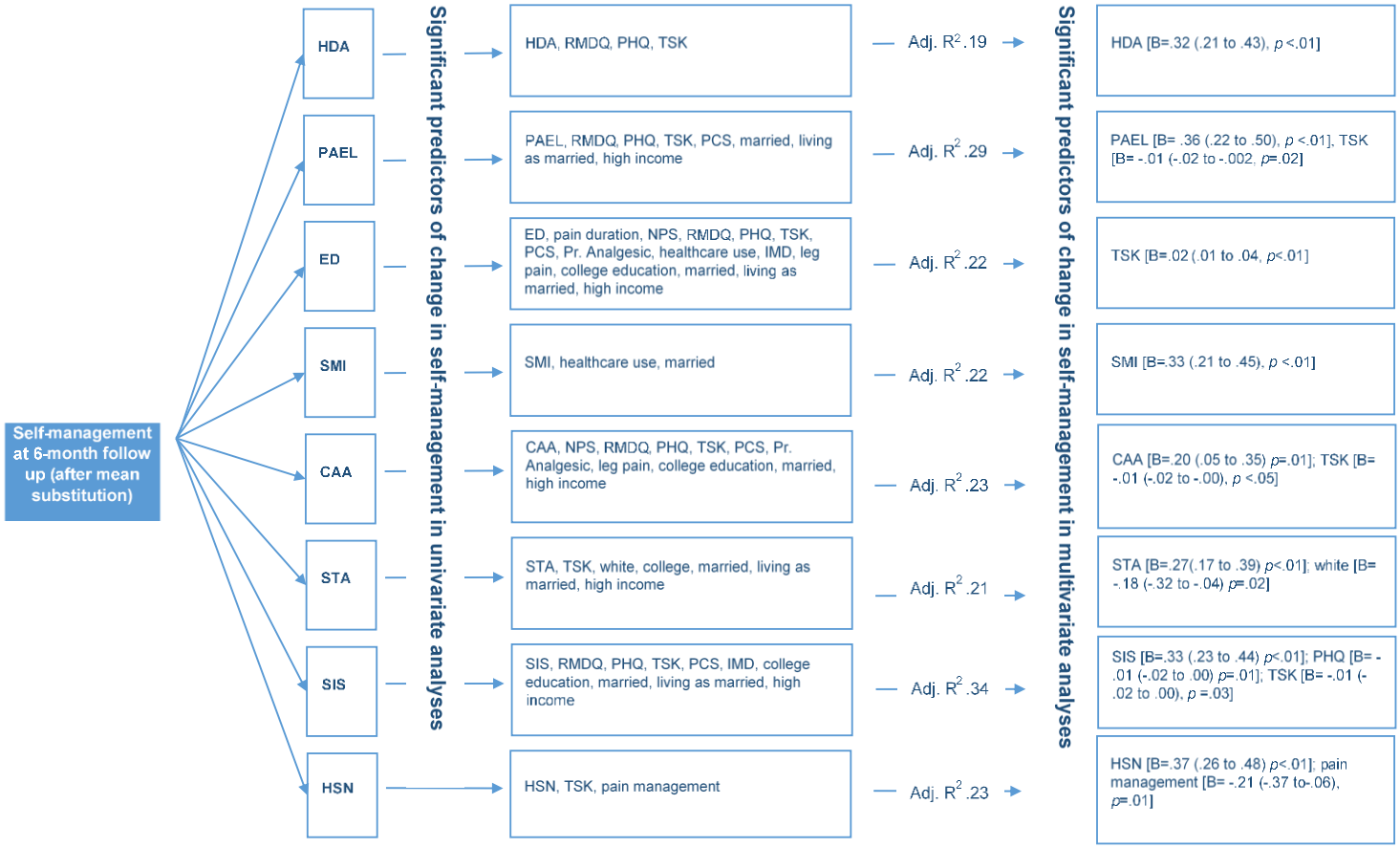
Figure 14 and 15 summaries the significant predictors of the SM constructs at the follow up for the mean substituted dataset and baseline observation carried forward dataset, respectively. Similarly, Figure 16 and 17 summarises the predictors of change in SM constructs between the follow up and baseline survey based the heiQ scores and the biopsychosocial factors after the mean substitution and baseline observation carried forward, respectively.

Results of these sensitivity analyses showed difference in the variance (adjusted R^2) of the predictive association between the SM constructs (or their changes) and the biopsychosocial factors, although the overall direction of the results supported the main results that the physical disability, depression, catastrophising and kinesiophobia predicted SM constructs and their change over time.

Table 20: Descriptive statistics after lost to follow up data imputation

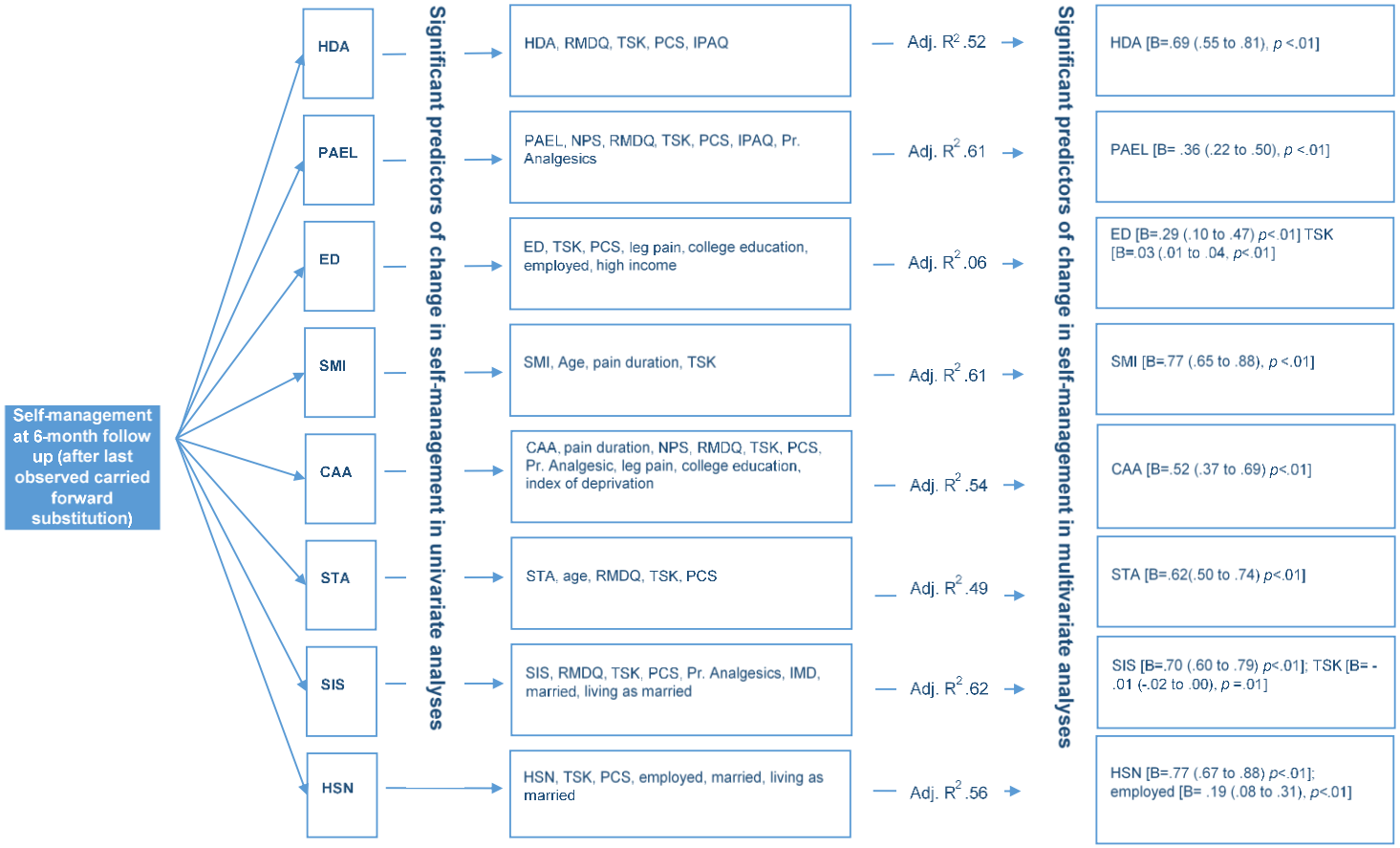
Mean substitution	N	Min	Max	Mean	SD	Last observed observation substitution	N	Min	Max	Mean	SD
NPS	270	0.00	10.00	4.32	2.05	NPS	264	0.00	10.00	5.17	2.71
RMDQ	270	0.00	24.00	9.14	5.08	RMDQ	270	0.00	24.00	10.57	6.55
HDA	270	1.00	4.00	2.97	0.50	HDA	270	1.00	4.00	2.93	0.64
PAEL	270	1.20	4.00	2.88	0.47	PAEL	270	1.00	4.00	2.83	0.60
ED	270	1.00	4.00	2.38	0.55	ED	270	1.00	4.00	2.35	0.70
CAA	270	1.20	4.00	2.94	0.43	CAA	270	1.00	4.00	2.88	0.55
SMI	270	1.00	4.00	3.09	0.32	SMI	270	1.00	4.00	3.03	0.45
SIS	270	1.20	4.00	2.76	0.45	SIS	270	1.00	4.00	2.79	0.57
STA	270	1.50	4.00	2.79	0.39	STA	270	1.00	4.00	2.74	0.51
HSN	270	1.00	4.00	2.81	0.44	HSN	270	1.00	4.00	2.84	0.55
PHQ	270	0.00	26.00	7.86	5.32	PHQ	268	0.00	27.00	8.21	6.73
TSK	270	7.00	59.00	36.84	6.09	TSK	269	7.00	59.00	38.04	7.46
PCS	270	0.00	49.00	13.35	9.89	PCS	270	0.00	52.00	16.15	13.58
IPAQ	270	0.00	21.71	3.64	3.37	IPAQ	267	0.00	21.71	3.29	4.10
Pr. Analgesic	270	0.00	4.00	0.77	0.84	Pr. Analgesic	260	0.00	4.00	0.95	1.21
OTC Analgesic	270	0.00	3.00	0.33	0.44	OTC Analgesic	260	0.00	3.00	0.31	0.61
Healthcare use	270	0.00	32.00	1.89	2.64	Healthcare use	229	0.00	32.00	3.54	4.38

N: sample size, SD: standard deviation, Min: Minimum, Max: Maximum, NPS: Numeric Pain Scale, RMDQ: Roland Morris Disability Questionnaire, HDA: Health Directed Activity; PAEL: Positive and Active Engagement in Life; ED: Emotional Distress; SMI: Self-Monitoring and Insight; CAA: Constructive Attitudes and Approaches; STA: Skill and Technique Acquisition; SIS: Social Integration and Support; HSN: Health Service Navigation, PHQ: Patient Health Questionnaire, TSK: Tampa Scale of Kinesiophobia, PCS: Pain Catastrophising scale, Pr. Analgesic: No of prescribed analgesics, OTC analgesic: No of Over the counter analgesic, IMD: Index for Multiple Deprivation, IPAQ: International Physical Activity Questionnaire (in Kilo Metabolic Equivalent)



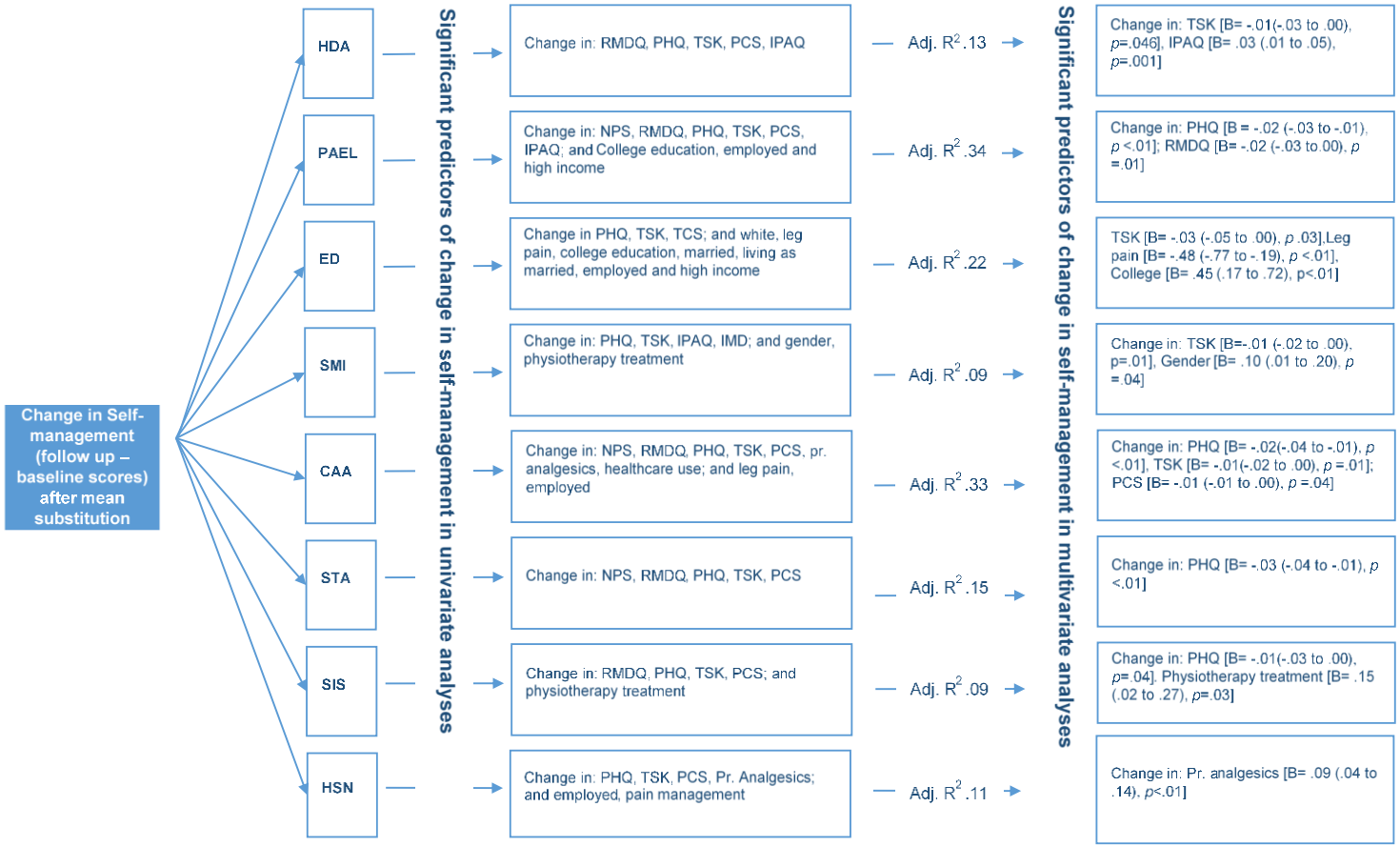
B: unstandardised coefficient, *p*: *p*-value, Adj. R^2: Adjusted R^2, RMDQ: Roland Morris Disability Questionnaire; NPS: Numeric Pain Scale; PHQ: Patient Health Questionnaire-9; TSK: Tampa Scale of Kinesiophobia; PCS: Pain; Catastrophising scale; Pr. Analgesic: No of prescribed analgesics; OTC Analgesics: No of Over the Counter analgesics; IMD: Index for Multiple Deprivation; IPAQ: International Physical Activity Questionnaire (in Kilo Metabolic Equivalent; Healthcare use: No. of visits to healthcare providers in last 3 months; HDA: Health Directed Activity; PAEL: Positive and Active Engagement in Life; ED: Emotional Distress; SMI: Self-Monitoring and Insight; CAA: Constructive Attitudes and Approaches; STA: Skill and Technique Acquisition; SIS: Social Integration and Support; HSN: Health Service Navigation, Married: Married and living with partner, Living as married: Living with spouse or partner, Employed: Full- or part-time employed, High income: Household income >£30000 in a year, College: Highest level of education at college or university, treatment type; Physiotherapy only or pain management only, White: White ethnic background, Gender: Female vs. male

Figure 14: Predictors of self-management constructs at follow up after mean substitution of the lost to follow up cases



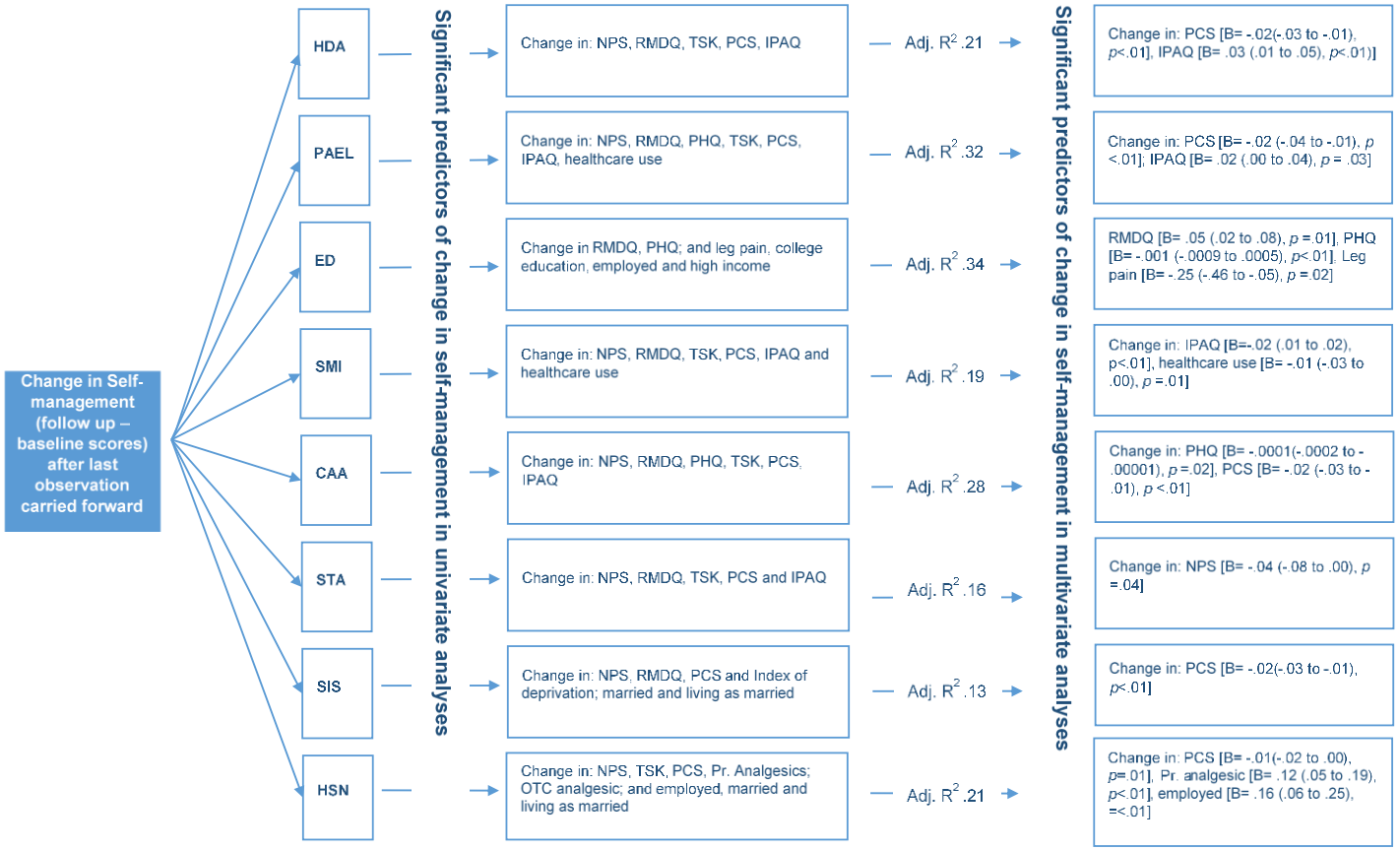
B: unstandardised coefficient, *p*: *p*-value, Adj. R^2: Adjusted R^2, RMDQ: Roland Morris Disability Questionnaire; NPS: Numeric Pain Scale; PHQ: Patient Health Questionnaire-9; TSK: Tampa Scale of Kinesiophobia; PCS: Pain; Catastrophising scale; Pr. Analgesic: No of prescribed analgesics; OTC Analgesics: No of Over the Counter analgesics; IMD: Index for Multiple Deprivation; IPAQ: International Physical Activity Questionnaire (in Kilo Metabolic Equivalent; Healthcare use: No. of visits to healthcare providers in last 3 months; HDA: Health Directed Activity; PAEL: Positive and Active Engagement in Life; ED: Emotional Distress; SMI: Self-Monitoring and Insight; CAA: Constructive Attitudes and Approaches; STA: Skill and Technique Acquisition; SIS: Social Integration and Support; HSN: Health Service Navigation, Married: Married and living with partner, Living as married: Living with spouse or partner, Employed: Full- or part-time employed, High income: Household income >£30000 in a year, College: Highest level of education at college or university, treatment type; Physiotherapy only or pain management only, White: White ethnic background, Gender: Female vs. male

Figure 15: Predictors of self-management constructs at follow up after last observation carried forward substitution of the lost to follow up cases



B: unstandardised coefficient, *p*: *p*-value, Adj. R^2: Adjusted R^2, RMDQ: Roland Morris Disability Questionnaire; NPS: Numeric Pain Scale; PHQ: Patient Health Questionnaire-9; TSK: Tampa Scale of Kinesiophobia; PCS: Pain; Catastrophising scale; Pr. Analgesic: No of prescribed analgesics; OTC Analgesics: No of Over the Counter analgesics; IMD: Index for Multiple Deprivation; IPAQ: International Physical Activity Questionnaire (in Kilo Metabolic Equivalent; Healthcare use: No. of visits to healthcare providers in last 3 months; HDA: Health Directed Activity; PAEL: Positive and Active Engagement in Life; ED: Emotional Distress; SMI: Self-Monitoring and Insight; CAA: Constructive Attitudes and Approaches; STA: Skill and Technique Acquisition; SIS: Social Integration and Support; HSN: Health Service Navigation, Married: Married and living with partner, Living as married: Living with spouse or partner, Employed: Full- or part-time employed, High income: Household income >£30000 in a year, College: Highest level of education at college or university, treatment type; Physiotherapy only or pain management only, White: White ethnic background, Gender: Female vs. male

Figure 16: Predictors of change in self-management constructs at follow up after mean substitution of the lost to follow up cases



B: unstandardised coefficient, *p*: *p*-value, Adj. R^2: Adjusted R^2, RMDQ: Roland Morris Disability Questionnaire; NPS: Numeric Pain Scale; PHQ: Patient Health Questionnaire-9; TSK: Tampa Scale of Kinesiophobia; PCS: Pain; Catastrophising scale; Pr. Analgesic: No of prescribed analgesics; OTC Analgesics: No of Over the Counter analgesics; IMD: Index for Multiple Deprivation; IPAQ: International Physical Activity Questionnaire (in Kilo Metabolic Equivalent; Healthcare use: No. of visits to healthcare providers in last 3 months; HDA: Health Directed Activity; PAEL: Positive and Active Engagement in Life; ED: Emotional Distress; SMI: Self-Monitoring and Insight; CAA: Constructive Attitudes and Approaches; STA: Skill and Technique Acquisition; SIS: Social Integration and Support; HSN: Health Service Navigation, Married: Married and living with partner, Living as married: Living with spouse or partner, Employed: Full- or part-time employed, High income: Household income >£30000 in a year, College: Highest level of education at college or university, treatment type; Physiotherapy only or pain management only, White: White ethnic background, Gender: Female vs. male

Figure 17: Predictors of change in self-management constructs at follow up after last observation carried forward substitution of the lost to follow up cases

6.13 Chapter summary

This chapter presented the recruitment and demographic characteristics of the participants. The predictors of SM at baseline, follow-up and change in SM over time were also reported in this chapter. The following chapter will discuss and interpret these results.

Question	Aim	Main finding
Do biopsychosocial outcome measures predict SM and its change over time in patients with CLBP?	To examine the predictive relationship between SM constructs and biopsychosocial outcome measures in patients with CLBP	The SM constructs measured utilising the heiQ were predicted ($p<0.05$, adjusted R^2 ranged from .07 to .55) (positively) by physical activity level and (negatively) by disability, levels of depression, kinesiophobia and catastrophising in patients with CLBP.

7 DISCUSSION

This chapter presents an interpretation of the results in the context of the key patterns, existing literature relating to self-management (SM) in chronic low back pain (CLBP) and in other long-term conditions. Findings are discussed in line with the aims of the PhD thesis- identifying predictors of SM in patients with CLBP.

The objective of the present longitudinal cohort study was to determine what biopsychosocial factors predict SM constructs at baseline and follow up and change in SM over time (between baseline and follow up measurements). In the present study, SM was measured using the Health Education Impact Questionnaire (heiQ) at baseline and follow-up. The heiQ is comprised of eight SM constructs: Health-Directed Activities (HDA), Positive and Active Engagement in Life (PAEL), Emotional Distress (ED), Self-Monitoring and Insight (SMI), Constructive Attitudes and Approaches (CAA), Skill and Technique Acquisition (STA), Social Integration and Support (SIS) and Health Service Navigation (HSN).

7.1 Main results

At baseline, physical activity level and healthcare use positively predicted SM constructs at baseline. Disability, depression, kinesiophobia, catastrophising negatively predicted SM constructs at baseline in patients with CLBP. At six-month follow-up, SM constructs were positively predicted by their respective baseline SM constructs scores and negatively predicted by kinesiophobia and depression. At the follow-up, SM constructs were higher in patients who were educated at college or university (for CAA and SIS, comparing with not educated in college or university); living as married (for CAA for comparing with who were not living with spouse or partner), from white ethnic background (for STA comparing with who were not from white ethnic background) and who attended pain- or self- management programme (for HSN, comparing with did not attend any programme). Further, change in SM constructs was predicted by the following factors; change in depression, kinesiophobia, catastrophising, physical activity level, use of analgesics and the presence of leg pain, being employed and married.

7.1.1 Predictors of SM at baseline

The present study investigated the predictors of SM at the baseline. Physical activity level, physical disability, depression, kinesiophobia, catastrophising and health care use predict SM constructs in patients with CLBP. Baseline multivariate GLM results indicate these predictive associations explain from 7% to 55% of the SM constructs (Figure 11). Among the SM constructs, ED (adjusted R^2 .55), CAA (adjusted R^2 .44) and PAEL (adjusted R^2 .44) were the three constructs with good (>25% variance explained) predictive association, where increase in depression, kinesiophobia and catastrophising predicted a decrease in six out of eight SM constructs (PAEL, ED, SMI, CAA, STA, HSN) and increased in physical activity predicted an increase in three out of eight SM constructs (HDA, PAEL, SMI) (Figure 11).

7.1.1.1 Depression

In this study, depression at baseline had a significant negative predictive association in the multivariate General linear model (GLM) for five out of eight SM constructs measured using heiQ. However, depression was not examined as an explanatory variable in a previous study investigating predictors of SM in patients with CLBP (Kawi, 2014). There is no research investigating depression as a predictor of SM in patients with CLBP; but there is moderate evidence in other long-term conditions (for example, diabetes, rheumatism, asthma, orthopaedic disorders and inflammatory bowel disease) and in studies with healthy older adults.

Depression is common in patients with diabetes mellitus (Whitworth et al., 2017) and depression is an established negative predictor of diabetes SM in children (Guo et al., 2013) and adults (Mut-Vitcu et al., 2016, Schinckus et al., 2018b, Oh and Ell, 2018). A multi-site cross-sectional study on 136 children aged between eight and 19 years with type I diabetes, showed depression (measured using a Chinese version of Depression Self-rating Scale for Children) had a significant predictive association with diabetes care activities in youth (Guo et al., 2013). In a cross-sectional study, depression, measured using PHQ-9, showed a significant ($p<.05$) negative association (correlation coefficient ranged from .2 to .4) with diabetes-related self-care activities, diet and exercise in 184 patients with diabetes (Mut-Vitcu et al., 2016). In another recent multi-site cross-sectional mixed mode survey in 128 patients with diabetes, depression (measured using Beck Depression Inventory) mediated health literacy (measured using 6-item European Health Literacy Questionnaire and a diabetes-specific health literacy questionnaire) for diabetes self-care behaviour (Schinckus et al., 2018b).

Further, depression predicted SM, when measured as patient activation using Patient Activation Measure, in 3293 older adults in the UK (Blakemore et al., 2016). Depression significantly predicted SM, measured using the Skill and Techniques Acquisition (STA) subscale of the German version of the heiQ, in 580 patients with chronic conditions including rheumatism, asthma, orthopaedic disorders and inflammatory bowel disease (Musekamp et al., 2016). These research studies, support the findings that depression is a key predictor of certain constructs of SM at baseline in patients with long-term conditions.

7.1.1.2 Catastrophising and Kinesiophobia

Baseline kinesiophobia negatively predicted Constructive Attitudes and Approaches (CAA) and Health Service Navigation (HSN) in the present study. Baseline catastrophising positively predicted Emotional Distress (ED) in the study. The kinesiophobia and catastrophising have not previously been investigated as predictors of SM in patients with CLBP. However, distress and/or anxiety were investigated as a predictor for SM in patients with diabetes (Schinckus et al., 2018a, Albright et al., 2001). An earlier study by Albright et al.(Albright et al., 2001), found stress had a significant negative predictive association with exercise and diet SM in 392 type II diabetes patients. Similarly, Schinkus et al. (Schinckus et al., 2018a), found distress (measured using Diabetes Distress Scale) and anxiety (measured using State-Trait Anxiety Inventory) were significant predictors of overall diabetes SM (measured using Diabetes Self-Management Questionnaire) in 146 patients with type-I and type-II and gestational diabetes. These studies highlight the importance to measure distress or anxiety or related variables as an explanatory variable in SM predictor studies.

7.1.1.3 Physical disability and physical activity

Perceived physical disability predicted three out of the eight SM constructs in the present study. However, physical disability measured using the Oswestry Disability Index was not found to be a significant predictor of SM measured using the Patient Activation Measure in 230 patients with CLBP (Kawi, 2014).

This difference in the findings could be due to the populations and use of different scales to measure SM and disability. For example, Kawi measured SM using PAM (Hibbard et al., 2004), which measures only patients' activation and engagement in 230 patients from primary care and specialist pain centre in the USA. And the present study found three different constructs of SM measured using Positive and Active Engagement in Life (PAEL), Constructive Attitude and Approaches (CAA) and Social Integration and Support (SIS) subscales of the heiQ (Osborne et al., 2007) were predicted by physical disability in 270 patients from the UK NHS. Further, physical disability in the present study was measured using Roland Morris Disability Questionnaire.

Further, physical activity level measured using International Physical Activity Questionnaire-Short Form had a significant predictive association with three of the eight SM constructs-HDA, PAEL and SMI. Physical activity level has not been investigated as an explanatory predictor variable predicting SM in patients with CLBP. Further research is required to validate physical activity and disability as predictors for SM.

7.1.1.4 Healthcare use

In the present study, healthcare use measured using the self-reported number of sessions attended at the general physician, physiotherapist, specialist and other practitioners for CLBP significantly predicted the SMI construct of SM. Healthcare use has not previously been examined as a predictor for SM in patients with CLBP.

7.1.1.5 Demographic characteristics

In the present study education, income, living arrangements, being employed, being married, high annual income (>£30,000) and white ethnicity had significant association at univariate GLM analysis. These results are in agreement with the previous cross-sectional study, where age, education and income were significant predictors of SM in patients with CLBP (Kawi, 2014).

However, in the present study, no significant predictive association was found at the multivariate GLM analysis for demographic and socioeconomic factors as predictors of SM constructs. Due to the lack of study exploring demographic and socioeconomic factors as predictors of SM in patients with CLBP, future research is required to investigate these factors as predictors.

In the present study, education was not a baseline predictor for SM constructs in the multivariate analyses using GLMs. However, the highest education obtained was a positive predictor of SM (measured using Patient Activation Measure) at baseline in patients with CLBP (Kawi, 2014).

A similar trend has been observed in other long-term conditions, including patients with chronic kidney disease (Chen et al., 2018), diabetes (Maneze et al., 2016). In patients with diabetes, the highest education more than secondary schooling (odds ratio 2.30, p=.04) (Maneze et al., 2016) had a positive predictive association with SM. Education at college or university in patients with chronic kidney disease positively predicted (beta 0.19, p<.001) SM (Chen et al., 2018).

7.1.2 Predictors of SM at follow-up

Overall, the adjusted R^2 ranged from .30 to .55 in the GLM analysis for predictors of SM constructs at the six-month follow-up. Baseline scores for SM constructs predicted the respective follow-up SM scores for all SM constructs, except for ED in the multivariate GLM analysis. The ED at follow-up was positively predicted by baseline kinesiophobia- high kinesiophobia at baseline indicated high ED at follow-up.

Other than the respective baseline SM constructs, kinesiophobia at baseline predicted five out of eight SM constructs at the follow up: PAEL, ED, CAA, STA and SIS. Further, depression at baseline predicted follow up SIS. Education obtained at college and university also predicted CAA and SIS. Similarly, white ethnicity predicted SAT and living as married predicted CAA at follow up. Attendance at a pain management programme negatively predicted HSN at follow up.

No previous research has investigated predictors of SM in a longitudinal study design in patients with CLBP. However, psychological variables, for example, depression negatively predicted SM longitudinally in a range of conditions including; diabetes (Oh and Ell, 2018), long-term conditions (including rheumatism, asthma, orthopaedic disorders and inflammatory bowel syndrome) (Musekamp et al., 2016), in people with epilepsy (Robinson et al., 2008) and in older adults (Blakemore et al., 2016). Geobers et al. found that the low education level was significantly associated with low SM measured with Self-Management Ability Scale in older adults (Geboers et al., 2016). Similarly, education also predicted SM in older adults with arthritis (Hewlett et al., 2008). The lack of longitudinal studies in chronic pain highlights the need for further longitudinal studies, exploring depression, anxiety, kinesiophobia, catastrophising, to confirm the findings of the present study.

7.1.3 Predictors of change in SM

Multivariate GLMs can explain between 10% and 32% of the change in SM constructs in the present study. These results are important in that they demonstrate that the model variables can explain up to one-third of the change in various SM constructs over time and are potentially useful in developing and/or modifying targeted SM programme for patients with CLBP.

Change in catastrophising predicted change in five out of eight SM constructs measured: HDA, PAEL, CAA, SIS and HSN. Therefore, researchers should target catastrophising in future SM programme development. Catastrophising is a poor prognostic predictor for patients with CLBP and might contributed to delayed recovery (Wertli et al., 2014a). Patients with CLBP who had high catastrophising showed significantly high disability measured using Roland Morris Disability Questionnaire in a UK population at 12 months follow-up (Grotle et al., 2010). Further, patients with CLBP reported fluctuating negative pain-related thoughts affecting their coping and pain-related meta-cognition in a recent qualitative study (Schütze et al., 2017), which could a potential reason to influence the following SM constructs- HDA, PAEL, CAA, SIS and HSN.

Change in depression predicted change in PAEL and CAA. Change in TSK predicted the change in CAA. Change in physical activity level predicted change in HDA and PAEL. Education obtained at a college or university (ED), health care use (SMI), change in a number of prescribed analgesics (HSN), being employed (HSN) and being married (HSN) predicted one of the constructs of SM in multivariate GLM analysis. Change score for depression measures predicted SM in patients with diabetes (Oh and Ell, 2018), epilepsy (Robinson et al., 2008) and long-term conditions (Musekamp et al., 2016). Due to a lack of longitudinal research investigating predictors SM these results could not be compared.

7.1.4 Age, pain and treatment types

Age did not predict SM constructs at baseline and follow-up and the change in SM constructs. In a secondary analysis for within a cross-sectional survey data for patients with CLBP age was found to be a significant negative predictor of SM (Kawi, 2014). In another cross-sectional survey of patients with diabetes, younger patients (≤ 60 years) were found to have higher diabetes SM skills than older adults (>60 years) (Maneze et al., 2016). This difference in findings could be related to that the present study included patients in the working-age adults, recognising the impact of CLBP is the highest in this age range.

Pain duration and pain intensity also did not predict SM constructs at baseline and follow-up, and change in SM constructs in the present study, which is in agreement with the previous research in patients with CLBP (Kawi, 2014). In that cross-sectional study pain duration and pain intensity were not significant predictors of SM (Kawi, 2014).

Patients in the present study receive three types of treatment: physiotherapy alone, physiotherapy and other treatment, and attending pain-management programme. Types of treatment received were not found to be significant predictors in the present study, except for the finding that the Health Service Navigation (HSN) at follow-up was significantly less improved in patients who attended pain management treatment than those who did not. However, attending pain management programme was not a significant predictors of change in HSN, when adjusted for baseline HSN score.

However, since this was a multi-centre observational study, the treatment received was not standardised. Attendance at SM programme predicted SM when measured with Patient Activation Meassure in patients with CLBP compared to the patient who were treated in the primary care (Kawi, 2014). Similarly, patients who attended SM programme had better SM ability for conditions including diabetes (Maneze et al., 2016) and chronic heart failure (Siabani et al., 2016).

A recent study found SM measured with the Social Integration and Support sub-scale of heiQ was better in patients with chronic musculoskeletal pain in the intervention group treated with a brief SM programme than the control group treated with pain toolkit and a relaxation CD (Taylor et al., 2016a). However, SIS score were not predicted by attending a pain management programme in the present study. Therefore, the effect of a structured SM programme on SM constructs as measured by the heiQ needs further research.

7.1.5 Recruitment issues in the study

Based on a power calculation, the initial recruitment target was 400 patients with CLBP. Due to the challenges beyond researcher's control, the present study recruited only 270 (67.5% of the target) patients with CLBP in an extended period (February 2016 to June 2017 for the baseline recruitment) of data collection in multiple sites, although only 434 patients were approached and screened for the study. The completed survey was not received from 103 (26.7% of the eligible patients) patients with CLBP. Overall, using multiple sites, in-clinic recruitment, participation from the local trusts and assuring patients regarding their anonymity in the research disseminations yielded 70.13% (n=270) of the 385 willing and eligible patients completing the baseline survey.

7.1.5.1 Survey related challenges in the recruitment

The present study used a mixed mode survey including pen and paper, telephone and online to maximise reach and return of the survey, which increased the survey completion rate. A total of 270 (62.2%) out of an eligible 385 patients completed the baseline survey. The following strategies were employed to increase the baseline survey completion rate: a) sending personalised invitation by post/ email/ telephone / text message, according to the patients' preference; b) sending up to three reminders using emails/ letters/ text messages/ telephone calls; c) informing patients regarding the time required ("less than 15 minutes"), d) embedding the survey link in to the email reminders; e) providing stamped return envelope for survey return; and f) providing alternative survey mode in all communication (Edwards et al., 2002, Kelley et al., 2003, McPeake et al., 2014, Sauermann and Roach, 2013, van Gelder et al., 2018). These strategies increased the response rate in the present study.

For the follow-up survey, all the above strategies were used in addition to contacting the patients in their preferred time and mode (Sauermann and Roach, 2013). None of the participants updated their contact details when changed during the study period, which resulted in 28 (10.4%) patients being not contactable during the follow-up survey. A future longitudinal study should pay attention on how to collect dynamic real-time contact information for the participants, for example, contacting their GP practices or checking in the NHS clinical records, although which needs a separate ethical approval. Further, the conditional incentive in the form of 'lucky draw' after the follow-up survey was offered to increase the retention rate. However, due to budgetary limitations of the present study, no unconditional financial incentive was provided after each survey completion, which could potentially increase the survey response rate (Sauermann and Roach, 2013).

The survey on average took around 10-15 minutes to complete. This resulted in a majority of the patients taking the survey home to complete (n=303, 188 returned by post, 17 posted but not received and 98 did not return). Completing a survey from home might resulted in high non-return surveys (n=92), despite up to five reminders.

Another reason for not completing a survey could be the questionnaire length. However, a recent systematic review (van Gelder et al., 2018) showed the odds ratio of increasing the response rate by using a shorter questionnaire than a longer version was only 1.02 (1.02-1.06).

The present study failed to encourage one-out-of-four willing and eligible patients to complete the baseline survey. A conceptual framework (Howcutt et al., 2018b) for recruitment of subjects in the research proposed five main decision-making stages for the participants: motivation (problem recognition), perception (engage with the information), attitude formation (accept the survey invitation), integration (complete the survey) and learning (encourage others). One of the key stages is the integration where participants' desire translate into practice, for example, completing a survey. The present study lost 29.87% of participants between the attitude formation and the integration stage.

The present study used the 'opt-in' method for introducing the study to potential participants in five out of six sites. In one site (Sherwood Forest Hospital Trust), the study was nested in service evaluation and thus used an 'opt-out' method (Hunt et al., 2013). This site (Sherwood Forest Hospital Trust) produced faster recruitment in the study. However, this was not possible in the other sites mainly due to operational issues at the sites. Further, lack of unconditional financial incentive for completing the survey could have contributed to the recruitment rate (Tolonen et al., 2015).

In adjunct to in-person recruitment, where possible, the present study used in-clinic screening using the clinician time and enterprise. In-clinic screening produced a cohort of eligible patients although reliance on the clinicians' time and interest plausibly affected recruitment in the distant sites and only seven patients completed the baseline questionnaire survey from the distant sites. The clinicians were trained through face-to-face interaction, where possible, in the local sites. However, training by sharing information through email and telephone was used in the distant sites. The distant sites recruited a very low number of participants (n=7), despite regular reminders through the follow-up meetings (with Nottinghamshire Healthcare Foundation Trust) or telephone calls and emails (with Royal Free London NHS Foundation Trust and Tameside, Glossop Integrated Care NHS Foundation Trust).

The telephone survey mode was not preferred by most of the patients in the present study and connecting to patients was difficult even when calls were made in their 'preferred time'.

7.1.5.2 Site-related challenges in recruitment

The present was introduced to 434 patients, which was lower than the expected. One of the reasons for not reaching beyond 434 patients was introducing the study to eligible patients, which was based on the identification of the eligible patients and introduction of the study to them. The time required to identify eligible patients and to introduce the present study was anticipated around five to ten minutes. The time taken to introduce the study to patients was longer than anticipated in the present study, as gathered from the feedback in follow-up meetings with the recruiting therapists and via emails from the site leads. A previous study in acute care also found that the recruitment time was longer than anticipated (O'Brien and Black, 2015). Releasing the time required to introduce the study to the eligible patients was not always possible due to lack of time in a busy clinical day, which was also observed in a trial in patients with CLBP (Abdel Shaheed et al., 2014). Future research should focus on the optimal estimation of the time required to introduce the study in the feasibility stage.

The recruitment rate was higher in the sites within Nottingham city (211 participants) than the three sites outside the Nottingham (69 participants). One of the reasons for variation in the recruitment rate could be due to the delivery of the training provided for introducing and recruiting patients. Sites within Nottingham were agreed to receive face-to-face training from the researcher during their team meetings for the treating therapists. Sites outside Nottingham only agreed to receive information pack via emails and reminder telephone calls during the study period. Face-to-face training in the Nottingham based sites, helped the therapists to identify and recruit patients (n=211) as per the protocol than the sites outside Nottingham. Future survey research recruiting patients from the outpatient clinics should emphasise the face-to-face training for recruitment in all sites.

Further, there were challenges of staffing changes in clinical settings for the present study. A lead clinician went on maternity leave in a distant site (Tameside, Glossop Integrated Care NHS Foundation Trust) and a lead liaison person was made redundant in a distant site (Royal Free London NHS Foundation Trust), which could have contributed to the poor recruitment from these two distant sites. The third distant site (Nottinghamshire Healthcare Foundation Trust) was decommissioned during the recruitment period and started redesigning the musculoskeletal service during the recruitment period, which negatively impacted the recruitment in that site. And considerable variation in identifying eligible patients was seen around Christmas, Easter and school holiday periods, although this variation was not unexpected.

7.1.5.3 Health system related challenges in the recruitment

Before and during recruitment, the study experienced a significant delay in securing governance approval due the process changes in ethics and governance approvals. Further, the introduction of the Health Research Authority approval resulted in a further delay in adding new sites and allowing baseline data to be collected via an online survey. Time loss in the governance delays resulted in an extension of the study period in the pragmatic; and loss of motivation and a reduction of enterprise in the distant sites (Randell et al., 2015).

This study was not funded and faced the challenges in recruitment due to being a non-portfolio research study and was therefore not able to attract support for recruitment from the UK Clinical Research Network (UKCRN). Involvement of UKCRN is helpful in securing trial delivery- especially in multicentre studies (Spilsbury et al., 2008, McDonald et al., 2006). Further, a popular physiotherapy service in a local site was decommissioned during the recruitment, which resulted in realigning the clinician in the recruitment, which impacted on the recruitment rate.

7.1.5.4 Attrition rate

A total of 117 patients did not complete the follow-up questionnaire survey. This 43.33% attrition was slightly more than the expected attrition of 30%, which could be due to 10.37% of the patients were not contactable during the follow-up survey. Conditional prize draw was utilised to promote the completion of the follow-up survey, which was partially effective. Prize draw was shown to increase the odds of follow up in randomised controlled trials (Morgan et al., 2017) where patients received an intervention. Conditional prize draw might not be that effective as the patients were not receiving an intervention as a part of the research study. Future longitudinal study may consider unconditional incentive to all patients who complete the follow-up questionnaire to improve the attrition rate.

High level of attrition could be due to the health problems (Goldberg et al., 2006), level of education (Gustavson et al., 2012), sampling (Goodman and Blum, 1996) and age or gender-related variations (Young et al., 2006). In this study, baseline characteristics of the patients who completed the follow-up survey were not statistically different from the patients who did not, except for the level of education. In this study, 107 (out 175 at baseline) patients completed the follow-up survey who had education at college or university level comparing to 44 (out of 92 at baseline) patients completed the follow-up survey who did not have education at college or university.

7.2 Generalisability of the results

The study had 84% participants from white ethnic background and 70% working, which was comparable to the UK 2011 Census data (2012) proportion of the white and working citizens. The study had 56% participants who reported being married or living as married, that was similar to the census data of 51% married. The study had more educated (attended college or university) participants (55.5%) compared to the national average of 39% and significantly fewer participants (0.4%) with no formal qualification than the national average of 23%. The study population broadly represents the general population in the UK, although the representativeness of a population with CLBP could not be estimated due to the lack of national data on patients with CLBP.

The present study recruited patients attending physiotherapy in primary and secondary care. Patients who did not attend physiotherapy were excluded due to the potential confounding of the patients attending different services and variations in the service delivery within primary and secondary care. There is no recent data from the UK census on people with low back pain. The age and gender characteristics matched with the compiled data in the systematic reviews included patients who were attending physiotherapy for their chronic pain (Hall et al., 2018, Meade et al., 2018). However, the ethnic make-up of the study cohorts was not looked at in those systematic reviews. The present study did not include older adults (>65 years), patients with known specific causes of CLBP and cancer-related LBP.

The results of this study may be generalised to working-age (18-65 years) patients attending physiotherapy outpatient appointments, both in the primary and secondary care with different ethnic make-up in the UK NHS, for non-specific non-cancer CLBP (>3 months). The generalisability of these results in other countries and health systems, in older adults and for patients with other known specific cause of CLBP needs to established.

7.3 Theoretical support

The psychological factors, including depression, anxiety, catastrophising are predictors or mediators of CLBP (Pincus et al., 2002, Ferreira and Pereira, 2014, Spinhoven et al., 2004, Pinheiro et al., 2016, Wertli et al., 2014a, Wertli et al., 2014b). The findings of the present study indicated psychological factors predict certain constructs of SM in patients with CLBP.

According to the Social Cognitive Theory SM is achieved by modifying the self-judgement, which is influenced by one's cognitive factors and psychological state (Bandura, 1998, Bandura, 2004). So, theoretically, depression, excessive negative pain-related emotions or catastrophising and fear related to pain or re-injury or kinesiophobia may theoretically influence one's SM ability. Similarly, self-efficacy is influenced by four factors: outcome, modelling, persuasion and physiological factors, which may include depression, kinesiophobia and catastrophising (Bandura, 2004, O'Sullivan and Strauser, 2009). Thus psychological constructs may theoretically influence SM constructs.

Furthermore, the results of the study also indicated physical activity level and disability in patients with CLBP predicted certain constructs of SM. From a behaviourist point of view, capability, opportunity and motivation 'interact to generate' behaviour, where capability includes one's physical and psychological abilities to engage in (SM) activity (Michie et al., 2011). So SM programme can utilise the Behaviour Change Wheel to create opportunity using the interventions and policies motivating individuals to engage change in their capability (Michie et al., 2011).

The desired change in SM behaviour also depends on the preconditions, process of change, the content of SM support training and relationship between the patient and the provider (Prochaska and Velicer, 1997). The stages of change according to the Transtheoretical Model or the Stages of Change Model are pre-contemplation, contemplation, preparation, action, maintenance and termination (Prochaska et al., 2013). The patients at different stages of change may require different types of strategy or intervention in enhancing their SM. For example, patients at the pre-contemplation stage may benefit with awareness of consequences for not engaging in SM and contemplators may benefit by monitoring their motivation in engaging in the SM behaviours (Elder et al., 1999). Therefore, along with promoting healthy living and physical activity (Buchbinder et al., 2018), the psychological and behavioural factors should be targeted to enhance SM in patients with CLBP.

7.4 Limitations of the study

Firstly, in the present study, SM was measured using a multi-dimensional construct scale producing eight different subscale scores without a composite score (Osborne et al., 2007). The heiQ was used to record the different constructs of the SM. The heiQ is a comprehensive measurement tool for SM and its change (Schuler et al., 2014), although a lack of a composite score resulted in eight outcome measures and eight different GLMs. As the constructs of the heiQ were not weighted, the importance of an individual predictor influencing overall SM could not be estimated. Therefore, the results of the study could be influenced by choice of the measurement tool. For example, if a single construct measure had been used to capture SM (Kawi, 2014), then study might find a different set of predictors.

Further, the treatment received by the participants were not standardised in the study and within each of the site(s). This variation in treatment increases the ecological validity although the impact of treatment type as a predictor of SM could not be examined in within this pragmatic longitudinal cohort study. The present study found that attending a pain management programme had no predictive association for baseline and follow-up SM constructs, except for HSN at the follow-up. However, further research is needed to investigate whether different treatment approaches/processes have any predictive ability.

The study had a poor representation of the south-east Asian (Quay et al., 2017) and male gender (Howcutt et al., 2018a, Thornton and Dixon-Woods, 2002). Further, patients who required an interpreter were excluded due to lack of funding in the present study. Excluding patients without good working English, is believed to result in lower numbers of south-east Asian and other European nationals, who lack English language proficiency (Sheikh et al., 2009). The effect of these demographic variations and excluding the patients from non-English background on the study results is difficult to interpret.

The study recruited 270 participants and 153 of these participants completed the follow up survey. With the high loss to follow-up (43.3%), the sample size was only adequate to detect a moderate effect (0.5) size of the change in the analysis for the follow-up predictors of SM and change in SM. However, there was no significant differences between the completers and non-completers of the follow up survey and the sensitivity analyses using mean substitution and baseline carried forward data imputation algorithms supported the main results.

Further, the study found a minor deviation from normality in the SM scores at baseline and follow up, although non-normality of the data is not uncommon in health research. The study did not attempt to bring 'interaction' items by combing and mediator analysis, mainly due to the small size and time limitations of the PhD study project.

Three out of six sites, in the study, failed to recruit to their target numbers. These sites were distant and received less in-person interaction. So the data generated were mainly limited to the East Midland region of the UK. Generalising the results beyond the East Midlands needs further understanding of the demographic characteristics and ethnicity make-up.

Lastly, the study, excluded patients older than 65 years, with a history of cancer and known causes of CLBP due to a potential wide variation in SM ability in the heterogeneous populations. Therefore extrapolating the results of the study for those groups of patients has limitation till further verification studies.

7.5 Strength of the study

Despite the above limitations, this was the first prospective longitudinal cohort study investigating predictors of SM in patients with CLBP. This multi-centre study recruited a representative sample from the UK NHS. The results are generalizable for working-age patients who attended outpatient physiotherapy appointments for non-specific CLBP. Recognising the non-specific subgroup of CLBP is the largest subgroup (Deyo and Phillips, 1996), the results of the study are generalizable to a wide population with CLBP attending for physiotherapy.

The present study used a multi-construct scale to measure SM. This scale captures eight different constructs and able to detect a change in SM (Osborne et al., 2007, Schuler et al., 2014). A multi-construct scale was not used in previous studies investigating predictors of SM in patients with CLBP (Kawi, 2014) or other chronic conditions (Schinckus et al., 2018b, Whitworth et al., 2017, Musekamp et al., 2016, Blakemore et al., 2016). Using a single construct SM measure might have resulted in missing different dimensions of SM in the previous studies. For example, Patient Activation Measure, used in a cross-sectional study (Kawi, 2014) exploring predictors of SM in patients with CLBP, designed to measure individual's activation and engagement in SM, but not the other constructs of SM.

Conceptually, the constructs of SM fall into a range of constructs which incorporate physical, mental and social health domains of Patient Reported Outcome Measure Information System (PROMIS) framework (Tugwell et al., 2011) and the heiQ covers all three PROMIS domains. Therefore, it can be argued that the heiQ is a more appropriate tool than scales measuring individual constructs of SM in exploring predictors of SM.

The present study employed GLM and bootstrap in the data analysis. Use of GLM is an accepted way to identify predictors (Nelder and Baker, 1972, Zheng and Agresti, 2000), which was adopted in the previous research to identify predictors of SM in patients with CLBP (Kawi, 2014).

7.6 Chapter summary

This chapter interpreted the results of the longitudinal cohort study. This can be claimed that the physical activity level, disability, depression, catastrophising, kinesiophobia, education, marital and employment status predicted SM constructs and their change over the six-month follow-up. The magnitude of the predictors' contributions was varied at baseline, follow-up and change between follow-up and baseline. These results are generalisable to working-age patients attending outpatient physiotherapy for their non-specific CLBP. The following chapter presents the conclusion and clinical implication of the PhD study.

8 CONCLUSIONS

The overarching aim of this PhD thesis was to investigate predictive relationship between self-management constructs and biopsychosocial outcome measures in patients with chronic low back pain. The questions, aims and the main findings of the PhD thesis are summarised in Table 19.

Table 21: Summary of the questions, aims and main findings of the PhD thesis

Questions	Aims	Main findings (Chapter Number)
What are the optimal measure(s) of SM in patients with chronic pain conditions?	1. To identify, synthesise and appraise the literature on outcome measures used to assess change in SM in patients with chronic musculoskeletal pain	The heiQ is a valid and reliable outcome measure to assess multiple constructs of SM and its change in in patients with chronic pain conditions. (Chapter 3)
Are paper and non-paper alternative methods of survey completion equivalent for an identified SM measure in patients with CLBP?	2. To estimate the reliability and agreement between paper and non-paper alternative methods of survey completion for a SM measure	Both paper and non-paper alternative methods of survey completion produced equivalent (equally reliable and acceptable Limits of Agreement) quality data for the heiQ in patients with CLBP. (Chapter 4)
Do biopsychosocial outcome measures predict SM and its change over time in patients with CLBP?	3. To examine the predictive relationship between SM constructs and biopsychosocial outcome measures in patients with CLBP	The SM constructs measured utilising the heiQ were predicted ($p<0.05$, adjusted R^2 ranged from .07 to .55) (positively) by physical activity level and (negatively) by disability, levels of depression, kinesiophobia and catastrophising in patients with CLBP. (Chapter 6 and 7)

8.1 Systematic review findings

The systematic review identified 14 different patient-reported measures used to detect a change in SM from 25 included studies (discussed in Chapter 3). These 14 measures are quite diverse and measure a variety of underlying constructs including self-efficacy, coping, empowerment and impact on knowledge. This diversity in measuring SM demonstrates a lack of consistency and consensus around the definition and measurement of SM, especially in chronic pain. A recent systematic review on effectiveness of SM programmes in patients with CLBP highlighted that the majority of included studies did not disclose or follow a theoretical model or framework (Du et al., 2017). This lack of a theoretical support potentially contributes to the difficulty in operationalising and defining an optimal measure for SM.

Theoretically, SM consists of multiple constructs including; disease and symptoms management, behaviour management, role and emotional management (Barlow et al., 2002) using problem solving and decision making skills, navigating health and care resources and taking appropriate actions (e.g., pacing or increasing physical activity) (Bodenheimer et al., 2002, Du et al., 2017).

However, the majority of the identified 14 measures fail to capture all three main domains (physical, psychological and social) of SM. Only two scales were identified- Chronic Pain Coping Inventory (CPCI) and Health Education Impact Questionnaire (HeiQ) which included the three key domains (physical, psychological and social).

The CPCI measures the frequency of coping strategies used and the heiQ measures the impact of an education or SM programme. The heiQ demonstrated an ability to measure person related change in SM constructs over time independent of measurement situation (Schuler et al., 2014). The heiQ (Cronbach's α 0.70-0.88 and reliability coefficients 0.80-0.92) (Osborne et al., 2007, Schuler et al., 2014) also demonstrated higher psychometric properties than the CPCI (Cronbach's α 0.71-0.89 and reliability coefficients 0.60-0.81) (Romano et al., 2003). Therefore, the heiQ was utilised in this PhD study to measure SM and its change over time.

8.2 Agreement between paper and non-paper survey modes for self-management

The reliability and agreement between paper and non-paper alternative (NPA) survey modes for measuring SM using the heiQ (along with pain intensity and disability) were estimated in sample of 34 patients with CLBP. The results showed a high level of reliability and no statistically significant or clinically meaningful difference between the paper and non-paper alternative survey methods of data collection for the heiQ. The Bland and Altman Limits of Agreement (LoAs) of the heiQ indicate that the paper and NPA survey modes may be used in research without affecting the data quality for within- and between-group analysis in patients with CLBP. These findings are in agreement with other musculoskeletal research (Messih et al., 2014, Chatterji et al., 2017) (as discussed in Chapter 4). Therefore, these findings indicate that the non-paper alternative survey modes can be used in mixed mode survey for patients with CLBP for the heiQ.

8.3 Predictors of self-management

As discussed in chapter 7, the present longitudinal study found a predictive association between SM constructs and biopsychological factors including levels of disability, physical activity, depression, kinesiophobia and catastrophising in patients with CLBP. The potential clinical implications and future research questions are discussed below.

8.4 Clinical implications

Results of the systematic review (Banerjee et al., 2018) highlight the complexity of measuring SM. The review findings recommend measuring SM in patients with chronic pain research using a multi-construct scale, for example, the Health Education Impact Questionnaire (heiQ). The heiQ is valid, reliable and able to assess change in SM in chronic conditions although further research is required to develop responsiveness and interpretability of the heiQ, which will make the measure more useful in for both research and clinical practice.

The study estimating the reliability and agreement between paper and NPA survey modes for patient-reported outcome measures showed both survey modes produce equivalent quality of data in patients with CLBP. Therefore, researchers, clinicians and commissioners can consider the use of NPA surveys alongside traditional paper surveys in clinical setting for measuring SM outcomes in patients with CLBP.

The main study identified levels of disability, physical activity, depression, kinesiophobia and catastrophising predicted SM constructs. These biopsychosocial predictors, if measured at baseline, may potentially help to screen and triage patients with CLBP into targeted SM programmes.

The study also identified that these biopsychosocial factors predicted change in SM constructs over time. Hence these predictive factors can potentially be prioritised in the management of patients with CLBP.

8.5 Future research

The systematic review highlighted that the heiQ is a valid, reliable measure to assess SM constructs and their change, although the question remains how to identify individuals with high or poor SM ability based on the heiQ score. The heiQ provides scores for each of the eight subscales without a composite score. Further research is required to better understand responsiveness and interpretability of the heiQ scale.

This study is the only longitudinal study exploring predictors of SM in patients with CLBP, and thus a future longitudinal study would be needed to validate these results in other cohorts and clinical contexts. Since the national guidelines recommend facilitating SM for patients of any age and with type of low back pain (Bernstein et al., 2017), these results need to be replicated for further generalisation to patients with acute, sub-acute and chronic low back pain. To overcome the restrictive selection criteria of the main study, a future longitudinal study may attempt to include patients of all age groups and types (acute, sub-acute and chronic) of low back pain, thus increasing generalisability.

This study identified the predictors of SM constructs, although it is not known whether these predictors interact with each other to moderate or mediate the SM outcome in patients with CLBP. Thus, future research may investigate the underlining mechanisms of the predictive relationships.

8.6 Concluding remark

This PhD research identified and appraised available outcome measures assessing SM in patients with chronic pain. This is the first systematic review appraising the outcome measures used to assess SM. The systematic review identified 14 diverse patient-reported outcome measures used to measure a variety of constructs including self-efficacy, coping, empowerment and impact on knowledge. The findings identified that the heiQ is valid, reliable and capable to assess multiple constructs of SM.

Further, the test-retest study estimated agreement and reliability between paper and non-paper modes of survey completion for the heiQ. The findings of the study indicated that heiQ is suitable to complete in paper and non-paper alternative survey methods without compromising the data quality for within- and between-group analyses. Assessing test-retest reliability and agreement between survey modes was not attempted earlier for the heiQ in patients with CLBP.

The main longitudinal study identified that levels of disability, physical activity, depression, catastrophising and kinesiophobia predicted multiple constructs of SM in working-age adults who attended physiotherapy for their CLBP within the UK NHS context. Since this is the first ever longitudinal study for identifying predictors of SM in patients with CLBP, future research is required to validate these findings in patients with low back pain of any duration and age group.

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10 APPENDICES

Appendix 1: Ethics approval letter

NHS SCOTLAND
Research Ethics Service

East of Scotland Research Ethics Service *(EoSRES)*

TAyside medical Science Centre
Residency Block Level 3
George Pirie Way
Ninewells Hospital and Medical School
Dundee DD1 9SY

Dr Paul Hendrick
B90 Clinical Sciences Building
The University of Nottingham
City Hospital Campus
NOTTINGHAM
NG5 1PB

Date: 19 November 2015
Your Ref:
Our Ref: **LR/15/ES/0167**
Enquiries to: Mrs Lorraine Reilly
Direct Line: 01382 383878
Email: eosres.tayside@nhs.net

Dear Dr Hendrick

Study Title:	**Predictors of self-management in patients with chronic low back pain**
REC reference:	**15/ES/0167**
Protocol number:	**15084**
IRAS project ID:	**188664**

Thank you for your letter of 15 November 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Alternate Vice-chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Mrs Lorraine Reilly, eosres.tayside@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Copies of advertisement materials for research participants [A3 POSTER Predictors of self-management in patients with chronic low back pain v2.0 date 27.10.15]	2	27 October 2015
Copies of advertisement materials for research participants	2	27 October 2015

15/ES/0167	Please quote this number on all correspondence

Yours sincerely

pp
Dr Roberta Littleford
Alternate Vice-chair

Email: eosres.tayside@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Ms Angela Shone
Dr Maria Koufali, Nottingham University Hospitals NHS Trust

Appendix 2: Ethics amendment letter

NHS SCOTLAND
Research Ethics Service

East of Scotland Research Ethics Service *(EoSRES)*

TAyside medical Science Centre
Residency Block Level 3
George Pirie Way
Ninewells Hospital and Medical School
Dundee DD1 9SY

Dr Paul Hendrick
Lecturer, Division of Physiotherapy and Rehabilitation Sciences
School of Health Sciences, The University of Nottingham
B90 Clinical Sciences Building
City Hospital Campus
Nottingham
NG5 1PB

Date: **20 April 2016**
Your Ref:
Our Ref: AG/15/ES/0167
Enquiries to: Arlene Grubb
Direct Line: 01382 383848

Dear Dr Hendrick

Study title:	**Predictors of self-management in patients with chronic low back pain**
REC reference:	**15/ES/0167**
Protocol number:	**15084**
Amendment number:	**AM01(REC Reference only)**
Amendment date:	**01 April 2016**
IRAS project ID:	**188664**

The above amendment was reviewed at the meeting of the Sub-Committee held on 20 April 2016 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMP)	AM01	01 April 2016
Other [Demographic information]	2.0	26 March 2016
Other [Expression of Interest Form]	3.0	26 March 2016
Participant consent form	3.0	26 March 2016
Participant information sheet (PIS)	3.0	26 March 2016

Research protocol or project proposal	3.0	26 March 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

15/ES/0167:	**Please quote this number on all correspondence**

Yours sincerely

For **Dr Stuart Paterson**
Alternative vice-chair

E-mail: eosres.tayside@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Maria Koufali, Nottingham University Hospitals NHS Trust (Research & Innovation)
Ms Angela Shone

East of Scotland Research Ethics Service REC 2

Attendance at Sub-Committee of the REC meeting on 20 April 2016

Committee Members:

Name	Profession	Present	Notes
Dr Stuart Paterson	Consultant Physician	Yes	Alternative vice-chair
Mr Jeremy Wickins	Lecturer in Law	Yes	

Also in attendance:

Name	Position (or reason for attending)
Mrs Arlene Grubb	Assistant Co-ordinator

Appendix 3: Health Education Impact Questionnaire

Health Education Impact Questionnaire

This section will ask questions to identify your ability to self-manage your low back pain.

Instructions

Please indicate how strongly you disagree or agree with the following statements by checking the response that best describes you now. Check a box by crossing it: ☐ ☐ ☐ ☒

Example: Ms Jane Citizen has answered these questions in the following way:

No.	Questions	Strongly disagree	Disagree	Agree	Strongly agree
1.	I am doing some of my hobbies	☐	☐	☒	☐
2.	I have a plan to do physical activity	☐	☒	☐	☐

For Question 1, Jane's answer shows that right now she agrees that she has been doing some of her hobbies lately.

For Question 2, Jane disagrees with the statement that right now she has no plan to do physical activity.

Please answer the following questions:

Check a box by crossing it: ☐ ☐ ☒ ☐

No.	Questions	**Right <u>now</u>**			
		Strongly	**Disagree**	**Agree**	**Strongly**
1.	On most days of the week, I do at least one activity to improve my health (e.g., walking, relaxation, exercise)	☐	☐	☐	☐
2.	Most days I am doing some of the things I really enjoy	☐	☐	☐	☐
3.	As well as seeing my doctor, I regularly monitor changes in my health	☐	☐	☐	☐
4.	I often worry about my health	☐	☐	☐	☐
5.	I try to make the most of my life	☐	☐	☐	☐
6.	I know what things can trigger my health problems and make them worse	☐	☐	☐	☐

7.	My health problems make me very dissatisfied with my life	☐	☐	☐	☐
8.	I am doing interesting things in my life	☐	☐	☐	☐
9.	I do at least one type of physical activity every day for at least 30 minutes (e.g., walking, gardening, housework, golf, bowls, dancing, Tai Chi, swimming)	☐	☐	☐	☐
10.	I have plans to do enjoyable things for myself during the next few days	☐	☐	☐	☐
11.	I have a very good understanding of when and why I am supposed to take my medication	☐	☐	☐	☐
12.	I often feel angry when I think about my health	☐	☐	☐	☐
13.	On most days of the week, I set aside time for healthy activities (e.g., walking, relaxation, exercise)	☐	☐	☐	☐
14.	I feel hopeless because of my health problems	☐	☐	☐	☐
15.	I feel like I am actively involved in life	☐	☐	☐	☐
16.	When I have health problems, I have a clear understanding of what I need to do to control them	☐	☐	☐	☐
17.	I carefully watch my health and do what is necessary to keep as healthy as possible	☐	☐	☐	☐
18.	I get upset when I think about my health	☐	☐	☐	☐
19.	I walk for exercise, for at least 15 minutes per day, most days of the week	☐	☐	☐	☐
20.	With my health in mind, I have realistic expectations of what I can and cannot do	☐	☐	☐	☐
21.	If I think about my health, I get depressed	☐	☐	☐	☐
22.	If I need help, I have plenty of people I can rely on	☐	☐	☐	☐
23.	I have effective ways to prevent my symptoms (e.g., discomfort, pain and stress) from limiting what I can do in my life	☐	☐	☐	☐
24.	I have very positive relationships with my healthcare professionals	☐	☐	☐	☐
25.	I have a very good idea of how to manage my health problems	☐	☐	☐	☐
26.	When I have symptoms, I have skills that help me cope	☐	☐	☐	☐
27.	I try not to let my health problems stop me from enjoying life	☐	☐	☐	☐
28.	I have enough friends who help me cope with my health problems	☐	☐	☐	☐

29.	I communicate very confidently with my doctor about my healthcare needs	☐	☐	☐	☐
30.	I have a good understanding of equipment that could make my life easier	☐	☐	☐	☐
31.	When I feel ill, my family and carers really understand what I am going through	☐	☐	☐	☐
32.	I confidently give healthcare professionals the information they need to help me	☐	☐	☐	☐
33.	I get my needs met from available healthcare resources (e.g., doctors, hospitals and community services)	☐	☐	☐	☐
34.	My health problems do not ruin my life	☐	☐	☐	☐
35.	Overall, I feel well looked after by friends or family	☐	☐	☐	☐
36.	I feel I have a very good life even when I have health problems	☐	☐	☐	☐
37.	I get enough chances to talk about my health problems with people who understand me	☐	☐	☐	☐
38.	I work in a team with my doctors and other healthcare professionals	☐	☐	☐	☐
39.	I do not let my health problems control my life	☐	☐	☐	☐
40.	If others can cope with problems like mine, I can too	☐	☐	☐	☐

Appendix 4: Roland Morris Disability Questionnaire

The Roland-Morris Disability Questionnaire

This section will ask questions for information on your present functional level.

Instruction

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 cross against 'Yes', otherwise please cross against 'No'. Remember, only to put a cross 'YES' the sentence if you are sure it describes you **today**.

No.	Items	Yes	No
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.	☐	☐

No.	Items	Yes	No
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.	☐	☐

Appendix 5: International Physical Activity Questionnaire

International Physical Activity Questionnaire

This section will ask questions for information on your present physical activity level.

Instruction
These questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

*Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.*

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ days per week ☐ No vigorous physical activities, skip to Question 3

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ hours per day _____ minutes per day ☐ Don't know/ Not sure

*Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.*

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ days per week ☐ No moderate physical activities, skip to Question 5

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ hours per day _____ minutes per day ☐ Don't know/ Not sure

*Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.*

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ days per week ☐ No walking, skip to Question 7

6. How much time did you usually spend **walking** on one of those days?

_____ hours per day _____ minutes per day ☐ Don't know/ Not sure

*The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.*

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ hours per day _____ minutes per day ☐ Don't know/ Not sure

Appendix 6: Tampa Scale for Kinesiophobia

E) Tampa Scale for Kinesiophobia

Kinesiophobia means the fear related with pain or re-injury. This section will ask questions for information on your present physical activity level.

No.	Questions	Strongly disagree	Disagree	Agree	Strongly agree
1.	I'm afraid that I might injure myself if I exercise	1☐	2☐	3☐	4☐
2.	If I were to try to overcome it, my pain would increase	1☐	2☐	3☐	4☐
3.	My body is telling me I have something dangerously wrong	1☐	2☐	3☐	4☐
4.	My pain would probably be relieved if I were to exercise	1☐	2☐	3☐	4☐
5.	People aren't taking my medical condition seriously enough	1☐	2☐	3☐	4☐
6.	My accident has put my body at risk for the rest of my life	1☐	2☐	3☐	4☐
7.	Pain always means I have injured my body	1☐	2☐	3☐	4☐
8.	Just because something aggravates my pain does not mean it is dangerous	1☐	2☐	3☐	4☐
9.	I am afraid that I might injure myself accidentally	1☐	2☐	3☐	4☐
10.	Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	1☐	2☐	3☐	4☐
11.	I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	1☐	2☐	3☐	4☐
12.	Although my condition is painful, I would be better off if I were physically active	1☐	2☐	3☐	4☐
13.	Pain lets me know when to stop exercising so that I don't injure myself	1☐	2☐	3☐	4☐
14.	It's really not safe for a person with a condition like mine to be physically active	1☐	2☐	3☐	4☐
15.	I can't do all the things normal people do because it's too easy for me to get injured	1☐	2☐	3☐	4☐
16.	Even though something is causing me a lot of pain, I don't think it's actually dangerous	1☐	2☐	3☐	4☐
17.	No one should have to exercise when he/she is in pain	1☐	2☐	3☐	4☐

1= strongly disagree, 2= disagree, 3= agree, 4= strongly agree

Appendix 7: Pain Catastrophising Scale

Pain Catastrophising Scale

Catastrophising means inappropriate amount of negative emotion regarding your pain. This section will ask questions for information on your present physical activity level. Please put a cross to mark for the most appropriate choice for you.

No.	Questions	Not at all	To a slight degree	To a moderate degree	To a great degree	All the time
1.	I worry all the time about whether the pain will end	0☐	1☐	2☐	3☐	4☐
2.	I feel I can't go on	0☐	1☐	2☐	3☐	4☐
3.	It's terrible and I think it's never going to get any better	0☐	1☐	2☐	3☐	4☐
4.	It's awful and I feel that it overwhelms me	0☐	1☐	2☐	3☐	4☐
5.	I feel I can't stand it anymore	0☐	1☐	2☐	3☐	4☐
6.	I become afraid that the pain will get worse	0☐	1☐	2☐	3☐	4☐
7.	I keep thinking of other painful events	0☐	1☐	2☐	3☐	4☐
8.	I anxiously want the pain to go away	0☐	1☐	2☐	3☐	4☐
9.	I can't seem to keep it out of my mind	0☐	1☐	2☐	3☐	4☐
10.	I keep thinking about how much it hurts	0☐	1☐	2☐	3☐	4☐
11.	I keep thinking about how badly I want the pain to stop	0☐	1☐	2☐	3☐	4☐
12.	There's nothing I can do to reduce the intensity of the pain	0☐	1☐	2☐	3☐	4☐
13.	I wonder whether something serious may happen	0☐	1☐	2☐	3☐	4☐

0= not at all, 1= to a slight degree, 2= to a moderate degree, 3= to a great degree, 4= all the time

Appendix 8: Patient Health Questionnaire-9

F) Patient Health Questionnaire-9

This section will ask questions for information on your present physical activity level.

Over the **last 2 weeks**, how often have you been bothered by any of the following problems?

No.	Questions	Not at all	Several days	More than half the days	Nearly every day
1.	Little interest or pleasure in doing things	1☐	2☐	3☐	4☐
2.	Feeling down, depressed, or hopeless	1☐	2☐	3☐	4☐
3.	Trouble falling or staying asleep, or sleeping too much	1☐	2☐	3☐	4☐
4.	Feeling tired or having little energy	1☐	2☐	3☐	4☐
5.	Poor appetite or overeating	1☐	2☐	3☐	4☐
6.	Feeling bad about yourself — or that you are a failure or have let yourself or your family down	1☐	2☐	3☐	4☐
7.	Trouble concentrating on things, such as reading the newspaper or watching television	1☐	2☐	3☐	4☐
8.	Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	1☐	2☐	3☐	4☐
9.	Thoughts that you would be better off dead or of hurting yourself in some way	1☐	2☐	3☐	4☐

1= not at all, 2= several days, 3= more than half the days, 4= nearly every day

Appendix 9: Expression of interest form

School of Health Sciences
B Floor, South Block Link
Queen's Medical Centre
Nottingham, NG7 2HA

Study: Predictors of self-management in patients with chronic low back pain

Expression of Interest: I would like to take part in future and/or would like to receive further information about this study. I furnish my contact details below for the research team to get in touch with me. (Please use **BLOCK** letters)

Name: ……

Address: ……

Phone number: …….

Email: ……

Preferred contact time: .....

I would you like to complete the survey:

☐ **In paper copy** ☐ **Via telephone** ☐ **Online**

(For office use) Questionnaire pack: ☐ handed in ☐ posted on…….....

Expression of Interest Form: Predictors of self-management in patients with chronic low back pain Final Version 3.0 date 26.03.16

Appendix 10: Participant Information Sheet

School of Health Sciences

B Floor, South Block Link
Queen's Medical Centre
Nottingham, NG7 2HA.

Participant Information Sheet
(Final version 3.0: 26th March 2016)

Title of Study: Predictors of self-management in patients with chronic low back pain

Researchers:

Dr Paul Hendrick, *Lecturer*, Division of Physiotherapy and Rehabilitation, School of Health Sciences
Dr Holly Blake, *Associate Professor of Behavioural Sciences,* School of Health Sciences
Mr Anirban Banerjee, *PhD Student*, School of Health Sciences

We would like to invite you to take part in our research study. This study is part of Anirban Banerjee's Doctor of Philosophy (PhD) course in The University of Nottingham. Before you decide we would like you to understand why the research is being done and what it will involve for you. One of our team will go through the information sheet with you and answer any questions you have. Please feel free to talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?
Self-management refers to how people manage their chronic low back pain and its treatment, and how they manage their physical and (mental) psychological wellbeing, and day-to-day activities. Self-management is recommended as a key treatment focus for patients to better manage their chronic low back pain. The purpose of this study is to better understand how people self-manage their back pain over time and how people who are more likely to self-manage their back pain can be identified earlier. This will help us to design services which help to support people to manage their chronic low back pain in the future.

Why have I been invited?
You are being invited to take part because you have had low back pain (with or without leg/s pain) for more than three months and are attending (or have attended) NHS healthcare treatment (outpatient physiotherapy or pain management). We are inviting 400 participants like you to take part in this research study.

Do I have to take part?
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 your consent will be recorded by signing a printed consent form, or agreeing to an online consent form, or taking an informed verbal

consent (if you want to complete the survey via telephone). We will also collect and store your contact details (address, email and phone number) for inviting you to complete the follow-up questionnaire 6 months later and (if you wish) an additional questionnaire survey within 2 weeks from the baseline questionnaire survey. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights or your clinical care.

What will happen to me if I take part?
If you choose to take part, we would require you to complete two questionnaires, one at the start of the study and one 6 months later. These will include questions about your health and wellbeing. The questionnaires take approximately 20 to 30 minutes each to complete. We may invite you to complete an additional survey within two weeks after you have completed the first one. This would take approximately 10 minutes to complete. You can continue your normal treatment for your low back pain.

Expenses and payments
Participants will not be paid to participate in the study. If you complete both initial and the six-month surveys on time you would be eligible for entry into a prize draw, in which 20 of our participants will be randomly selected to receive a £10 gift voucher.

What are the possible disadvantages and risks of taking part?
We are simply asking questions about your health and wellbeing and as such, there are no expected risks in this study. There is some burden in completing a questionnaire, although this is minimal and will ultimately benefit the future care of patients with chronic low back pain.

What are the possible benefits of taking part?
We cannot promise the study will help you but the information we get from this study may help other patients with low back pain in the future. This is because the information you provide will help us to design better services for people to help them better manage their low back pain.

What if there is a problem?
If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek any resulting compensation through the University of Nottingham who is acting as the research sponsor. Details about this are available from the research team. Also, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the Patient Advice and Liaison Service, NUH NHS Trust, c/o PALS, Freepost, NEA 14614, Nottingham NG7 1BR (Free phone 0800 183 0204 free from a UK landline or 0115 924 9924 ext. 65412 or 62301 from a mobile or abroad). Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed, and this is due to someone's negligence, you may have grounds for legal action against NUH NHS Trust, but you may have to pay your legal costs.

Will my taking part in the study be kept confidential?
All information about you will be handled in confidence. If you join the study, the information you provide to us will be accessed only by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty

of confidentiality to you as a research participant, and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password-protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised), and a unique code will be used so that you cannot be recognised from it. Your personal data (address, email and telephone number) will be kept for up to one year after the end of the study so that we are able to contact you about the findings of the study *and possible follow-up studies* (unless you advise us that you do not wish to be contacted).

All anonymised data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Further, data collected in this study could be utilised in future research may be carried out by researchers other than current team of Dr Paul Hendrick, Dr Holly Blake and Anirban Banerjee, who ran the first study, including researchers working for commercial companies. Any samples or data used will be anonymised, and you will not be identified in any way. If you do not agree to this, any remaining data will be disposed of in accordance with the Research Ethics Committee's codes of practice.

What will happen if I don't want to carry on with the study?
Your participation is voluntary, and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw, then the anonymised data collected so far cannot be erased, and this information may still be used in the project analysis. Your identifiable data will be destroyed.

What will happen to the results of the research study?
Data collected in the survey will help us to understand the predictors of self-management in patients with chronic low back pain. The findings will be published in peer-reviewed journals and as a part of the PhD thesis. The results will also be presented at various national and international conferences.

Who is organising and funding the research?
The researcher (Anirban Banerjee) is being supported by the Vice-Chancellor's Scholarship for Research Excellence (International) from The University of Nottingham, UK.

Who has reviewed the study?
The East of Scotland Research Ethics Service REC 2, which has responsibility for scrutinising all proposals for medical research on human subjects, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research be made available for scrutiny by monitors from Research Governance, University of Nottingham and Nottingham University Hospitals NHS Trust Research and Innovation, whose role is to check that research is properly conducted, and the interests of those taking part are adequately protected. (REC reference: 15/ES/0167)

Further information and contact details

Researcher
Mr Anirban Banerjee
PhD Student,
School of Health Sciences,
South Block,
Queen's Medical Centre
The University of Nottingham,
Derby Road, NG7 2HA, UK.
Email: msxab7@nottingham.ac.uk
Phone: 074 9014 2678

Chief Investigator
Dr Paul Hendrick, *Lecturer*,
Division of Physiotherapy and Rehabilitation Sciences, School of Health Sciences
The University of Nottingham
B90, Clinical Sciences Building
City Hospital Campus
Nottingham NG5 1PB
Phone: +44 (0) 115 8231827
Email: ntzph@nottingham.ac.uk

Appendix 11: Consent Form

School of Health Sciences
B Floor, South Block Link
Queen's Medical Centre
Nottingham, NG7 2HA

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CONSENT FORM
(Final version 3.0: 26th March 2016)

Title of Study: Predictors of self-management in patients with chronic low back pain
REC ref: 15/ES/0167
Name of Researchers:
Dr Paul Hendrick, *Lecturer*, Division of Physiotherapy and Rehabilitation, School of Health Sciences
Dr Holly Blake, *Associate Professor of Behavioural Sciences*, School of Health Sciences
Mr Anirban Banerjee, *PhD Student*, School of Health Sciences
Name of Participant: _____ **Please initial**

1. I confirm that I have read and understand the information sheet version 3.0 dated 26th March 2016 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that data collected in the study may be looked at by authorised individuals from the University of Nottingham and the research group where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand I will be contacted by the research team to complete the study questionnaires. ☐
5. I agree to take part in the above study. ☐
6. I would like to receive a study summary. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person recording consent	Date	Signature

2 copies: 1 for participant and 1 for the project notes

Appendix 12: Demographic Information

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B Floor, South Block Link
Queen's Medical Centre
Nottingham, NG7 2HA.

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Predictors of self-management in patients with chronic low back pain

Demographic Information

Thanking you for your consent to participate in this research study. This information will inform better care for patients in future. Please put a cross against the best available option to mark your choice. Please do not leave anything blank. Each section will ask a different set of questions, and you may find a few questions are similar.

A) Demographic information

This section will ask questions to identify your descriptor and background information.

1.	**Study code**	
2.	Postcode of residence	
3.	Name	
4.	Date of birth	D D M M Y Y Y Y
5.	Gender	☐ Female ☐ Male
6	Ethnicity	☐ White (for British, Irish, Polish, Italian or any other White background) ☐ Asian or Asian British (for Indian, Pakistani, Bangladeshi or any other Asian background) ☐ Chinese ☐ Black or Black British (for Caribbean, African and other Black background) ☐ Mixed (for White and Black Caribbean; White and Black African; White and Asian Any other Mixed background) ☐ Any other ethnic group: _____
7.	Highest level of education attained:	☐ Did not attend school ☐ Primary school ☐ Secondary school ☐ High school ☐ Professional/ college ☐ University
8.	Present employment status	

☐ Retired ☐ Student ☐ Unemployed

☐ Job searching ☐ Part-time job ☐ Full-time job

9. Marital status

☐ Single ☐Married ☐ Living as married

☐ Widowed ☐ Divorced/ separated ☐ Other

10. Social circumstances

☐ Living alone ☐ Living with spouse/ partner ☐ Living with relative/ friend

☐ Living in shared accommodation ☐ Others, please specify _____

11. Household income

☐ < £15,000 ☐£15,000-19,999 ☐ £20,000-29,999

☐ £30,000-39,999 ☐ £40,000-49,999 ☐ £50,000-59,999

☐ £60,000-69,999 ☐ £70,000-99,999 ☐ £100,000-149,999

☐ £150,000+

12. Duration of low back pain: _____Years _____ Months

13. Do you have any leg pain related with your low back pain now?

☐ Yes ☐ No

14. Mark your worst pain intensity in the last 24 hours on '0=no pain' to '10=worst pain' scale.

0	1	2	3	4	5	6	7	8	9	10

15. Please identify the nature of treatment you receive for your low back pain?

☐ Physiotherapy ☐ Physio and other therapy ☐ Multidisciplinary treatment

16. Where do you receive most of your low back pain treatment?

_____

17. In the last 3 months, how many times have you seen health care providers for your low back pain?

GP: _____ Specialist: _____ Physio: _____ Others: _____

18. Please list all your pain medication or ointment you used for your low back pain below:

Name and strength of the medication or ointment you used for your low back pain in the last 7 days	Is this prescribed for your low back pain?	Write number of tablets (or applications) of each medication (or ointment) have you used each day.						
		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
	Yes / No							
	Yes / No							
	Yes / No							
	Yes / No							

Appendix 13: Baseline Questionnaire

School of Health Sciences
B Floor, South Block Link
Queen's Medical Centre
Nottingham, NG7 2HA.

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Predictors of self-management in patients with chronic low back pain

Baseline Questionnaire

(Office use only)

Study code | | | | |

Completed on | D | D | M | M | Y | Y |

Expected follow up | D | D | M | M | Y | Y |

Thanking you for your consent to participate in this research study. This information will inform better care for patients in future. Please put a cross against the best available option to mark your choice. Please do not leave anything blank. Each section will ask a different set of questions and you may find a few questions are similar.

Willing to complete the agreement survey via ☐ **on line** ☐ **telephone** ☐ **not applicable**

(Convenient date and time _____)

A) Health Education Impact Questionnaire

This section will ask questions to identify your ability to self-manage your low back pain.
Instructions

Please indicate how strongly you disagree or agree with the following statements by checking the response that best describes you now. Check a box by crossing it: ☐ ☐ ☐ ☒

Example: Ms Jane Citizen has answered these questions in the following way:

No.	Questions	Strongly disagree	Disagree	Agree	Strongly agree
1.	I am doing some of my hobbies	☐	☐	☒	☐
2.	I have a plan to do physical activity	☐	☒	☐	☐

For Question 1, Jane's answer shows that right now she agrees that she has been doing some of her hobbies lately.

For Question 2, Jane disagrees with the statement that right now she has no plan to do physical activity.

Please answer the following questions:

Check a box by crossing it: ☐ ☐ ☒ ☐

Right now

No.	Questions	Strongly disagree	Disagree	Agree	Strongly agree
1.	On most days of the week, I do at least one activity to improve my health (e.g., walking, relaxation, exercise)	☐	☐	☐	☐
2.	Most days I am doing some of the things I really enjoy	☐	☐	☐	☐
3.	As well as seeing my doctor, I regularly monitor changes in my health	☐	☐	☐	☐
4.	I often worry about my health	☐	☐	☐	☐
5.	I try to make the most of my life	☐	☐	☐	☐
6.	I know what things can trigger my health problems and make them worse	☐	☐	☐	☐
7.	My health problems make me very dissatisfied with my life	☐	☐	☐	☐
8.	I am doing interesting things in my life	☐	☐	☐	☐
9.	I do at least one type of physical activity every day for at least 30 minutes (e.g., walking, gardening, housework, golf, bowls, dancing, Tai Chi, swimming)	☐	☐	☐	☐

10.	I have plans to do enjoyable things for myself during the next few days	☐	☐	☐	☐
11.	I have a very good understanding of when and why I am supposed to take my medication	☐	☐	☐	☐
12.	I often feel angry when I think about my health	☐	☐	☐	☐
13.	On most days of the week, I set aside time for healthy activities (e.g., walking, relaxation, exercise)	☐	☐	☐	☐
14.	I feel hopeless because of my health problems	☐	☐	☐	☐
15.	I feel like I am actively involved in life	☐	☐	☐	☐
16.	When I have health problems, I have a clear understanding of what I need to do to control them	☐	☐	☐	☐
17.	I carefully watch my health and do what is necessary to keep as healthy as possible	☐	☐	☐	☐
18.	I get upset when I think about my health	☐	☐	☐	☐
19.	I walk for exercise, for at least 15 minutes per day, most days of the week	☐	☐	☐	☐
20.	With my health in mind, I have realistic expectations of what I can and cannot do	☐	☐	☐	☐
21.	If I think about my health, I get depressed	☐	☐	☐	☐
22.	If I need help, I have plenty of people I can rely on	☐	☐	☐	☐
23.	I have effective ways to prevent my symptoms (e.g., discomfort, pain and stress) from limiting what I can do in my life	☐	☐	☐	☐
24.	I have very positive relationships with my healthcare professionals	☐	☐	☐	☐
25.	I have a very good idea of how to manage my health problems	☐	☐	☐	☐
26.	When I have symptoms, I have skills that help me cope	☐	☐	☐	☐
27.	I try not to let my health problems stop me from enjoying life	☐	☐	☐	☐
28.	I have enough friends who help me cope with my health problems	☐	☐	☐	☐
29.	I communicate very confidently with my doctor about my healthcare needs	☐	☐	☐	☐
30.	I have a good understanding of equipment that could make my life easier	☐	☐	☐	☐
31.	When I feel ill, my family and carers really understand what I am going through	☐	☐	☐	☐
32.	I confidently give healthcare professionals the information they need to help me	☐	☐	☐	☐

33.	I get my needs met from available healthcare resources (e.g., doctors, hospitals and community services)	☐	☐	☐	☐
34.	My health problems do not ruin my life	☐	☐	☐	☐
35.	Overall, I feel well looked after by friends or family	☐	☐	☐	☐
36.	I feel I have a very good life even when I have health problems	☐	☐	☐	☐
37.	I get enough chances to talk about my health problems with people who understand me	☐	☐	☐	☐
38.	I work in a team with my doctors and other healthcare professionals	☐	☐	☐	☐
39.	I do not let my health problems control my life	☐	☐	☐	☐
40.	If others can cope with problems like mine, I can too	☐	☐	☐	☐

Please proceed to section B and answer all the questions.

B) The Roland-Morris Disability Questionnaire

This section will ask questions for information on your present functional level.

Instruction

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 cross against 'Yes', otherwise please cross against 'No'. Remember, only to put a cross 'YES' the sentence if you are sure it describes you **today**.

No.	Items	Yes	No
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.	☐	☐

No.	Items	Yes	No
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.	☐	☐

Please proceed to section c and answer all the questions.

C) International Physical Activity Questionnaire

This section will ask questions for information on your present physical activity level.

Instruction
These questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

*Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.*

8. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ days per week ☐ No vigorous physical activities, skip to Question 3

9. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ hours per day _____ minutes per day ☐ Don't know/ Not sure

*Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.*

10. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ days per week ☐ No moderate physical activities, skip to Question 5

11. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ hours per day _____ minutes per day ☐ Don't know/ Not sure

*Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.*

12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ days per week ☐ No walking, skip to Question 7

13. How much time did you usually spend **walking** on one of those days?

_____ hours per day _____ minutes per day ☐ Don't know/ Not sure

*The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.*

14. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ hours per day _____ minutes per day ☐ Don't know/ Not sure

Please proceed to section D and answer all the questions.

D) Pain Catastrophising Scale

Catastrophising means an inappropriate amount of negative emotion regarding your pain. This section will ask questions for information on your present physical activity level. Please put a cross to mark for the most appropriate choice for you.

No.	Questions	Not at all	To a slight degree	To a moderate degree	To a great degree	All the time
1.	I worry all the time about whether the pain will end	0☐	1☐	2☐	3☐	4☐
2.	I feel I can't go on	0☐	1☐	2☐	3☐	4☐
3.	It's terrible and I think it's never going to get any better	0☐	1☐	2☐	3☐	4☐
4.	It's awful and I feel that it overwhelms me	0☐	1☐	2☐	3☐	4☐
5.	I feel I can't stand it anymore	0☐	1☐	2☐	3☐	4☐
6.	I become afraid that the pain will get worse	0☐	1☐	2☐	3☐	4☐
7.	I keep thinking of other painful events	0☐	1☐	2☐	3☐	4☐
8.	I anxiously want the pain to go away	0☐	1☐	2☐	3☐	4☐
9.	I can't seem to keep it out of my mind	0☐	1☐	2☐	3☐	4☐
10.	I keep thinking about how much it hurts	0☐	1☐	2☐	3☐	4☐
11.	I keep thinking about how badly I want the pain to stop	0☐	1☐	2☐	3☐	4☐
12.	There's nothing I can do to reduce the intensity of the pain	0☐	1☐	2☐	3☐	4☐
13.	I wonder whether something serious may happen	0☐	1☐	2☐	3☐	4☐

0= not at all, 1= to a slight degree, 2= to a moderate degree, 3= to a great degree, 4= all the time

Please proceed to section E and answer all the questions.

E) Tampa Scale for Kinesiophobia

Kinesiophobia means the fear related to pain or re-injury. This section will ask questions for information on your present physical activity level.

No.	Questions	Strongly disagree	Disagree	Agree	Strongly agree

1.	I'm afraid that I might injure myself if I exercise	1☐	2☐	3☐	4☐
2.	If I were to try to overcome it, my pain would increase	1☐	2☐	3☐	4☐
3.	My body is telling me I have something dangerously wrong	1☐	2☐	3☐	4☐
4.	My pain would probably be relieved if I were to exercise	1☐	2☐	3☐	4☐
5.	People aren't taking my medical condition seriously enough	1☐	2☐	3☐	4☐
6.	My accident has put my body at risk for the rest of my life	1☐	2☐	3☐	4☐
7.	Pain always means I have injured my body	1☐	2☐	3☐	4☐
8.	Just because something aggravates my pain does not mean it is dangerous	1☐	2☐	3☐	4☐
9.	I am afraid that I might injure myself accidentally	1☐	2☐	3☐	4☐
10.	Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	1☐	2☐	3☐	4☐
11.	I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	1☐	2☐	3☐	4☐
12.	Although my condition is painful, I would be better off if I were physically active	1☐	2☐	3☐	4☐
13.	Pain lets me know when to stop exercising so that I don't injure myself	1☐	2☐	3☐	4☐
14.	It's really not safe for a person with a condition like mine to be physically active	1☐	2☐	3☐	4☐
15.	I can't do all the things normal people do because it's too easy for me to get injured	1☐	2☐	3☐	4☐
16.	Even though something is causing me a lot of pain, I don't think it's actually dangerous	1☐	2☐	3☐	4☐
17.	No one should have to exercise when he/she is in pain	1☐	2☐	3☐	4☐

1= strongly disagree, 2= disagree, 3= agree, 4= strongly agree

Please proceed to section F and answer all the questions.

F) Patient Health Questionnaire-9

This section will ask questions for information on your present physical activity level.

Over the **last 2 weeks**, how often have you been bothered by any of the following problems?

No.	Questions	Not at all	Several days	More than half the days	Nearly every day
1.	Little interest or pleasure in doing things	1☐	2☐	3☐	4☐
2.	Feeling down, depressed, or hopeless	1☐	2☐	3☐	4☐
3.	Trouble falling or staying asleep, or sleeping too much	1☐	2☐	3☐	4☐
4.	Feeling tired or having little energy	1☐	2☐	3☐	4☐
5.	Poor appetite or overeating	1☐	2☐	3☐	4☐
6.	Feeling bad about yourself — or that you are a failure or have let yourself or your family down	1☐	2☐	3☐	4☐
7.	Trouble concentrating on things, such as reading the newspaper or watching television	1☐	2☐	3☐	4☐
8.	Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	1☐	2☐	3☐	4☐
9.	Thoughts that you would be better off dead or of hurting yourself in some way	1☐	2☐	3☐	4☐

1= not at all, 2= several days, 3= more than half the days, 4= nearly every day

Please consider consulting your GP if you have any concern about your low mood or distress.

G) Follow up survey preference

This section will ask questions about your preference for the final survey.

1.	Please let us know how you would prefer to complete the follow-up survey.	☐ Online	☐ Telephone	☐ Paper copy
2.	What is your first preference for further contact?	☐ Email	☐ Phone	☐ Text message

Thank you so much for completing the survey. We will be in touch with you around six months.

Appendix 14: Poster

The University of Nottingham
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Interested in participating in a research study?

If you have had low back pain for more than three months and are attending NHS healthcare treatment, we would like to hear from you. The purpose of this study is to understand how people manage their low back pain and how their ability to do so changes over time.

If you choose to take part:
We would ask you to **complete questionnaire surveys** (either 2 or 3 times, each taking about 20-30 minutes*).
These include one at the start of the study in the clinic and another 6 months later over phone or online.

*No inconvenience allowance will be offered; however we will enter you into a prize draw to win some gift vouchers of £10.

For more information
contact **Anirban Banerjee** on:
School of Health Sciences,
South Block, Queen's Medical Centre
The University of Nottingham,
Derby Road, NG7 2HA, UK.
Email: msxab7@nottingham.ac.uk
Phone: 07490142678

A4 Poster: Predictors of self-management in patients with chronic low back pain Final Version 2.0 date 27.10.15

Appendix 15: Agreement Questionnaire

School of Health Sciences
B Floor, South Block Link
Queen's Medical Centre
Nottingham, NG7 2HA.

The University of Nottingham
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Predictors of self-management in patients with chronic low back pain

Agreement Questionnaire

Thanking you for your consent to participate in this research study. This information will inform the similarity of your responses between paper-based and telephone/ online survey.

A) Demographic information

This section will ask questions to identify your descriptor and background information.

1.	Study code								
2.	Name/ Initial								
3.	Date of birth	D	D	M	M	Y	Y	Y	Y

4. Mark your worst pain intensity in the last 24 hours on '0=no pain' to '10=worst pain' scale.

0	1	2	3	4	5	6	7	8	9	10

Please proceed to section B and answer all the questions.

B) Health Education Impact Questionnaire

This section will ask questions to identify your ability to self-manage your low back pain.

Instructions

Please indicate how strongly you disagree or agree with the following statements by checking the response that best describes you now. Check a box by crossing it: ☐ ☐ ☐ ☒

Please answer the following questions:

Check a box by crossing it: ☐ ☐ ☒ ☐

Right now

No.	Questions	Strongly disagree	Disagree	Agree	Strongly agree
1.	On most days of the week, I do at least one activity to improve my health (e.g., walking, relaxation, exercise)	☐	☐	☐	☐
2.	Most days I am doing some of the things I really enjoy	☐	☐	☐	☐

3.	As well as seeing my doctor, I regularly monitor changes in my health	☐	☐	☐	☐
4.	I often worry about my health	☐	☐	☐	☐
5.	I try to make the most of my life	☐	☐	☐	☐
6.	I know what things can trigger my health problems and make them worse	☐	☐	☐	☐
7.	My health problems make me very dissatisfied with my life	☐	☐	☐	☐
8.	I am doing interesting things in my life	☐	☐	☐	☐
9.	I do at least one type of physical activity every day for at least 30 minutes (e.g., walking, gardening, housework, golf, bowls, dancing, Tai Chi, swimming)	☐	☐	☐	☐
10.	I have plans to do enjoyable things for myself during the next few days	☐	☐	☐	☐
11.	I have a very good understanding of when and why I am supposed to take my medication	☐	☐	☐	☐
12.	I often feel angry when I think about my health	☐	☐	☐	☐
13.	On most days of the week, I set aside time for healthy activities (e.g., walking, relaxation, exercise)	☐	☐	☐	☐
14.	I feel hopeless because of my health problems	☐	☐	☐	☐
15.	I feel like I am actively involved in life	☐	☐	☐	☐
16.	When I have health problems, I have a clear understanding of what I need to do to control them	☐	☐	☐	☐
17.	I carefully watch my health and do what is necessary to keep as healthy as possible	☐	☐	☐	☐
18.	I get upset when I think about my health	☐	☐	☐	☐
19.	I walk for exercise, for at least 15 minutes per day, most days of the week	☐	☐	☐	☐
20.	With my health in mind, I have realistic expectations of what I can and cannot do	☐	☐	☐	☐
21.	If I think about my health, I get depressed	☐	☐	☐	☐
22.	If I need help, I have plenty of people I can rely on	☐	☐	☐	☐
23.	I have effective ways to prevent my symptoms (e.g., discomfort, pain and stress) from limiting what I can do in my life	☐	☐	☐	☐
24.	I have very positive relationships with my healthcare professionals	☐	☐	☐	☐

25.	I have a very good idea of how to manage my health problems	☐	☐	☐	☐
26.	When I have symptoms, I have skills that help me cope	☐	☐	☐	☐
27.	I try not to let my health problems stop me from enjoying life	☐	☐	☐	☐
28.	I have enough friends who help me cope with my health problems	☐	☐	☐	☐
29.	I communicate very confidently with my doctor about my healthcare needs	☐	☐	☐	☐
30.	I have a good understanding of equipment that could make my life easier	☐	☐	☐	☐
31.	When I feel ill, my family and carers really understand what I am going through	☐	☐	☐	☐
32.	I confidently give healthcare professionals the information they need to help me	☐	☐	☐	☐
33.	I get my needs met from available healthcare resources (e.g., doctors, hospitals and community services)	☐	☐	☐	☐
34.	My health problems do not ruin my life	☐	☐	☐	☐
35.	Overall, I feel well looked after by friends or family	☐	☐	☐	☐
36.	I feel I have a very good life even when I have health problems	☐	☐	☐	☐
37.	I get enough chances to talk about my health problems with people who understand me	☐	☐	☐	☐
38.	I work in a team with my doctors and other healthcare professionals	☐	☐	☐	☐
39.	I do not let my health problems control my life	☐	☐	☐	☐
40.	If others can cope with problems like mine, I can too	☐	☐	☐	☐

Please proceed to section C and answer all the questions.

C) The Roland-Morris Disability Questionnaire

This section will ask questions for information on your present functional level.

Instruction

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 cross against 'Yes', otherwise please cross against 'No'. Remember, only to put a cross 'YES' the sentence if you are sure it describes you **today**.

No.	Items	Yes	No
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.	☐	☐

Appendix 16: Follow-up Questionnaire

School of Health Sciences
B Floor, South Block Link
Queen's Medical Centre
Nottingham, NG7 2HA.

The University of Nottingham
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Predictors of self-management in patients with chronic low back pain

Follow up Questionnaire

Thanking you for your consent to participate in this research study. This information will inform better care for patients in future. Please put a cross against the best available option to mark your choice. Please do not leave anything blank. Each section will ask a different set of questions, and you may find a few questions are similar.

A) Demographic Information

This section will ask questions to identify your descriptor and background information.

1.	Study code									
2.	Name/ Initial									
3.	Date of birth	D	D	M	M	Y	Y	Y	Y	

4. Mark your worst pain intensity in the last 24 hours on '0=no pain' to '10=worst pain' scale.

0	1	2	3	4	5	6	7	8	9	10

5. Please identify the nature of treatment you receive for your low back pain?

☐ Physiotherapy ☐ Physio and other therapy ☐ Multidisciplinary treatment

6. Where do you receive most of your low back pain treatment?

7. In the last 3 months, how many times have you seen health care providers for your low back pain?

GP: _____ Specialist: ____ Physio: _____ Others: _____

8. Please list all your pain medication or ointment you used for your low back pain below:

Name and strength of the medication or ointment you used for your low back pain in the last 7 days	Is this prescribed for your low back pain?	Write number of tablets (or applications) of each medication (or ointment) have you used each day.						
		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
	Yes / No							
	Yes / No							
	Yes / No							
	Yes / No							

Please proceed to section B and answer all the questions.

B) Health Education Impact Questionnaire

This section will ask questions to identify your ability to self-manage your low back pain.

Instructions

Please indicate how strongly you disagree or agree with the following statements by checking the response that best describes you now. Check a box by crossing it: ☐ ☐ ☐ ☒

Example: Ms Jane Citizen has answered these questions in the following way:

No.	**Questions**	**Strongly disagree**	**Disagree**	**Agree**	**Strongly agree**
1.	I am doing some of my hobbies	☐	☐	☒	☐
2.	I have a plan to do physical activity	☐	☒	☐	☐

For Question 1, Jane's answer shows that right now she agrees that she has been doing some of her hobbies lately.

For Question 2, Jane disagrees with the statement that right now she has no plan to do physical activity.

Please answer the following questions:

Check a box by crossing it: ☐ ☐ ☒ ☐

Right now

No.	Questions	Strongly disagree	Disagree	Agree	Strongly agree
1.	On most days of the week, I do at least one activity to improve my health (e.g., walking, relaxation, exercise)	☐	☐	☐	☐
2.	Most days I am doing some of the things I really enjoy	☐	☐	☐	☐
3.	As well as seeing my doctor, I regularly monitor changes in my health	☐	☐	☐	☐
4.	I often worry about my health	☐	☐	☐	☐
5.	I try to make the most of my life	☐	☐	☐	☐
6.	I know what things can trigger my health problems and make them worse	☐	☐	☐	☐
7.	My health problems make me very dissatisfied with my life	☐	☐	☐	☐
8.	I am doing interesting things in my life	☐	☐	☐	☐
9.	I do at least one type of physical activity every day for at least 30 minutes (e.g., walking, gardening, housework, golf, bowls, dancing, Tai Chi, swimming)	☐	☐	☐	☐
10.	I have plans to do enjoyable things for myself during the next few days	☐	☐	☐	☐
11.	I have a very good understanding of when and why I am supposed to take my medication	☐	☐	☐	☐
12.	I often feel angry when I think about my health	☐	☐	☐	☐
13.	On most days of the week, I set aside time for healthy activities (e.g., walking, relaxation, exercise)	☐	☐	☐	☐
14.	I feel hopeless because of my health problems	☐	☐	☐	☐
15.	I feel like I am actively involved in life	☐	☐	☐	☐
16.	When I have health problems, I have a clear understanding of what I need to do to control them	☐	☐	☐	☐
17.	I carefully watch my health and do what is necessary to keep as healthy as possible	☐	☐	☐	☐
18.	I get upset when I think about my health	☐	☐	☐	☐

19.	I walk for exercise, for at least 15 minutes per day, most days of the week	☐	☐	☐	☐
20.	With my health in mind, I have realistic expectations of what I can and cannot do	☐	☐	☐	☐
21.	If I think about my health, I get depressed	☐	☐	☐	☐
22.	If I need help, I have plenty of people I can rely on	☐	☐	☐	☐
23.	I have effective ways to prevent my symptoms (e.g., discomfort, pain and stress) from limiting what I can do in my life	☐	☐	☐	☐
24.	I have very positive relationships with my healthcare professionals	☐	☐	☐	☐
25.	I have a very good idea of how to manage my health problems	☐	☐	☐	☐
26.	When I have symptoms, I have skills that help me cope	☐	☐	☐	☐
27.	I try not to let my health problems stop me from enjoying life	☐	☐	☐	☐
28.	I have enough friends who help me cope with my health problems	☐	☐	☐	☐
29.	I communicate very confidently with my doctor about my healthcare needs	☐	☐	☐	☐
30.	I have a good understanding of equipment that could make my life easier	☐	☐	☐	☐
31.	When I feel ill, my family and carers really understand what I am going through	☐	☐	☐	☐
32.	I confidently give healthcare professionals the information they need to help me	☐	☐	☐	☐
33.	I get my needs met from available healthcare resources (e.g., doctors, hospitals and community services)	☐	☐	☐	☐
34.	My health problems do not ruin my life	☐	☐	☐	☐
35.	Overall, I feel well looked after by friends or family	☐	☐	☐	☐
36.	I feel I have a very good life even when I have health problems	☐	☐	☐	☐
37.	I get enough chances to talk about my health problems with people who understand me	☐	☐	☐	☐
38.	I work in a team with my doctors and other healthcare professionals	☐	☐	☐	☐
39.	I do not let my health problems control my life	☐	☐	☐	☐
40.	If others can cope with problems like mine, I can too	☐	☐	☐	☐

Please proceed to section C and answer all the questions.

C) The Roland-Morris Disability Questionnaire

This section will ask questions for information on your present functional level.

Instruction

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 cross against 'Yes', otherwise please cross against 'No'. Remember, only to put a cross 'YES' the sentence if you are sure it describes you **today**.

No.	Items	Yes	No
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.	☐	☐

No.	Items	Yes	No
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.	☐	☐

Please proceed to section D and answer all the questions.

D) International Physical Activity Questionnaire

This section will ask questions for information on your present physical activity level.

Instruction
These questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

*Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.*

15. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ days per week ☐ No vigorous physical activities, skip to Question 3

16. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ hours per day _____ minutes per day ☐ Don't know/ Not sure

*Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.*

17. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ days per week ☐ No moderate physical activities, skip to Question 5 ➡

18. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ hours per day _____ minutes per day ☐ Don't know/ Not sure

*Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.*

19. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ days per week ☐ No walking, skip to Question 7 ➡

20. How much time did you usually spend **walking** on one of those days?

_____ hours per day _____ minutes per day ☐ Don't know/ Not sure

*The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.*

21. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ hours per day _____ minutes per day ☐ Don't know/ Not sure

Please proceed to section E and answer all the questions.

E) Pain Catastrophising Scale

Catastrophising means an inappropriate amount of negative emotion regarding your pain.
This section will ask questions for information on the amount of negative emotion you experience regarding your pain.
Please put a cross to mark for the most appropriate choice for you.

No.	Questions	Not at all	To a slight degree	To a moderate degree	To a great degree	All the time
1.	I worry all the time about whether the pain will end	0☐	1☐	2☐	3☐	4☐

2.	I feel I can't go on	0☐	1☐	2☐	3☐	4☐
3.	It's terrible and I think it's never going to get any better	0☐	1☐	2☐	3☐	4☐
4.	It's awful and I feel that it overwhelms me	0☐	1☐	2☐	3☐	4☐
5.	I feel I can't stand it anymore	0☐	1☐	2☐	3☐	4☐
6.	I become afraid that the pain will get worse	0☐	1☐	2☐	3☐	4☐
7.	I keep thinking of other painful events	0☐	1☐	2☐	3☐	4☐
8.	I anxiously want the pain to go away	0☐	1☐	2☐	3☐	4☐
9.	I can't seem to keep it out of my mind	0☐	1☐	2☐	3☐	4☐
10.	I keep thinking about how much it hurts	0☐	1☐	2☐	3☐	4☐
11.	I keep thinking about how badly I want the pain to stop	0☐	1☐	2☐	3☐	4☐
12.	There's nothing I can do to reduce the intensity of the pain	0☐	1☐	2☐	3☐	4☐
13.	I wonder whether something serious may happen	0☐	1☐	2☐	3☐	4☐

0= not at all, 1= to a slight degree, 2= to a moderate degree, 3= to a great degree, 4= all the time

Please proceed to section F and answer all the questions.

F) Tampa Scale for Kinesiophobia

Kinesiophobia means the fear related to pain or re-injury. This section will ask questions for information on your fear related to pain or re-injury.

No.	Questions	Strongly disagree	Disagree	Agree	Strongly agree
1.	I'm afraid that I might injure myself if I exercise	1☐	2☐	3☐	4☐
2.	If I were to try to overcome it, my pain would increase	1☐	2☐	3☐	4☐
3.	My body is telling me I have something dangerously wrong	1☐	2☐	3☐	4☐
4.	My pain would probably be relieved if I were to exercise	1☐	2☐	3☐	4☐

5.	People aren't taking my medical condition seriously enough	1☐	2☐	3☐	4☐
6.	My accident has put my body at risk for the rest of my life	1☐	2☐	3☐	4☐
7.	Pain always means I have injured my body	1☐	2☐	3☐	4☐
8.	Just because something aggravates my pain does not mean it is dangerous	1☐	2☐	3☐	4☐
9.	I am afraid that I might injure myself accidentally	1☐	2☐	3☐	4☐
10.	Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	1☐	2☐	3☐	4☐
11.	I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	1☐	2☐	3☐	4☐
12.	Although my condition is painful, I would be better off if I were physically active	1☐	2☐	3☐	4☐
13.	Pain lets me know when to stop exercising so that I don't injure myself	1☐	2☐	3☐	4☐
14.	It's really not safe for a person with a condition like mine to be physically active	1☐	2☐	3☐	4☐
15.	I can't do all the things normal people do because it's too easy for me to get injured	1☐	2☐	3☐	4☐
16.	Even though something is causing me a lot of pain, I don't think it's actually dangerous	1☐	2☐	3☐	4☐
17.	No one should have to exercise when he/she is in pain	1☐	2☐	3☐	4☐

1= strongly disagree, 2= disagree, 3= agree, 4= strongly agree

Please proceed to section G and H and answer all the questions.

G) Patient Health Questionnaire-9

This section will ask questions for information on your mood or distress.

Over the **last 2 weeks**, how often have you been bothered by any of the following problems?

No.	**Questions**	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1.	Little interest or pleasure in doing things	1☐	2☐	3☐	4☐
2.	Feeling down, depressed, or hopeless	1☐	2☐	3☐	4☐

3.	Trouble falling or staying asleep, or sleeping too much	1☐	2☐	3☐	4☐
4.	Feeling tired or having little energy	1☐	2☐	3☐	4☐
5.	Poor appetite or overeating	1☐	2☐	3☐	4☐
6.	Feeling bad about yourself — or that you are a failure or have let yourself or your family down	1☐	2☐	3☐	4☐
7.	Trouble concentrating on things, such as reading the newspaper or watching television	1☐	2☐	3☐	4☐
8.	Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	1☐	2☐	3☐	4☐
9.	Thoughts that you would be better off dead or of hurting yourself in some way	1☐	2☐	3☐	4☐

1= not at all, 2= several days, 3= more than half the days, 4= nearly every day

Please consider consulting your GP if you have any concern about your low mood or distress.

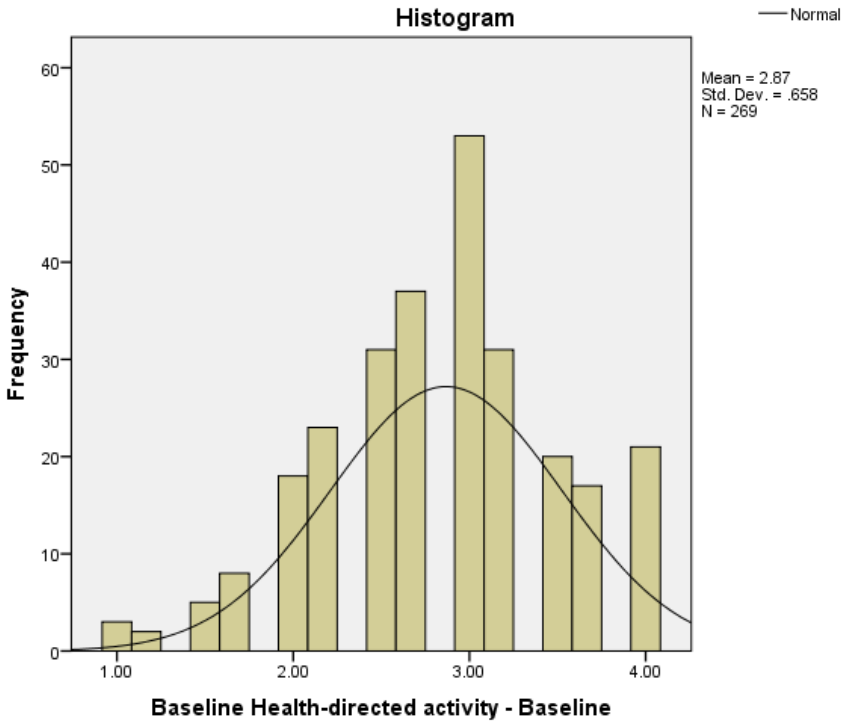
H) Perceived Global Impression of Change

In last six months, how would you describe the change (if any) in your **ability to self-manage your activity limitations, symptoms, emotions and overall quality of life**, related to your low back pain? Please cross **only the most appropriate response** for you.

1 ☐	No change (or condition has gotten worse)
2 ☐	Almost the same, hardly any change at all
3 ☐	A little better, but no noticeable change
4 ☐	Somewhat better, but the change has not made any real difference
5 ☐	Moderately better, and a slight but noticeable change
6 ☐	Better and a definite improvement that has made a real and worthwhile difference
7 ☐	A great deal better and a considerable improvement that has made all the difference

Thank you very much for completing the survey.

Appendix 17: Histograms and Q-Q plots for self-management constructs



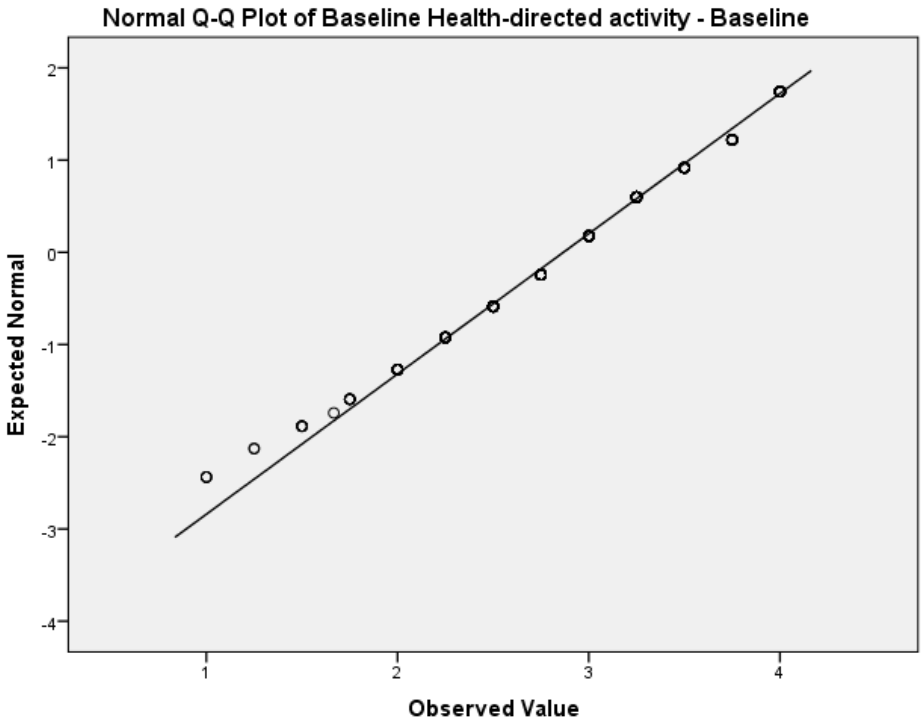


Figure 18: Histogram and Q-Q plot for Health Directed Activity (HDA)

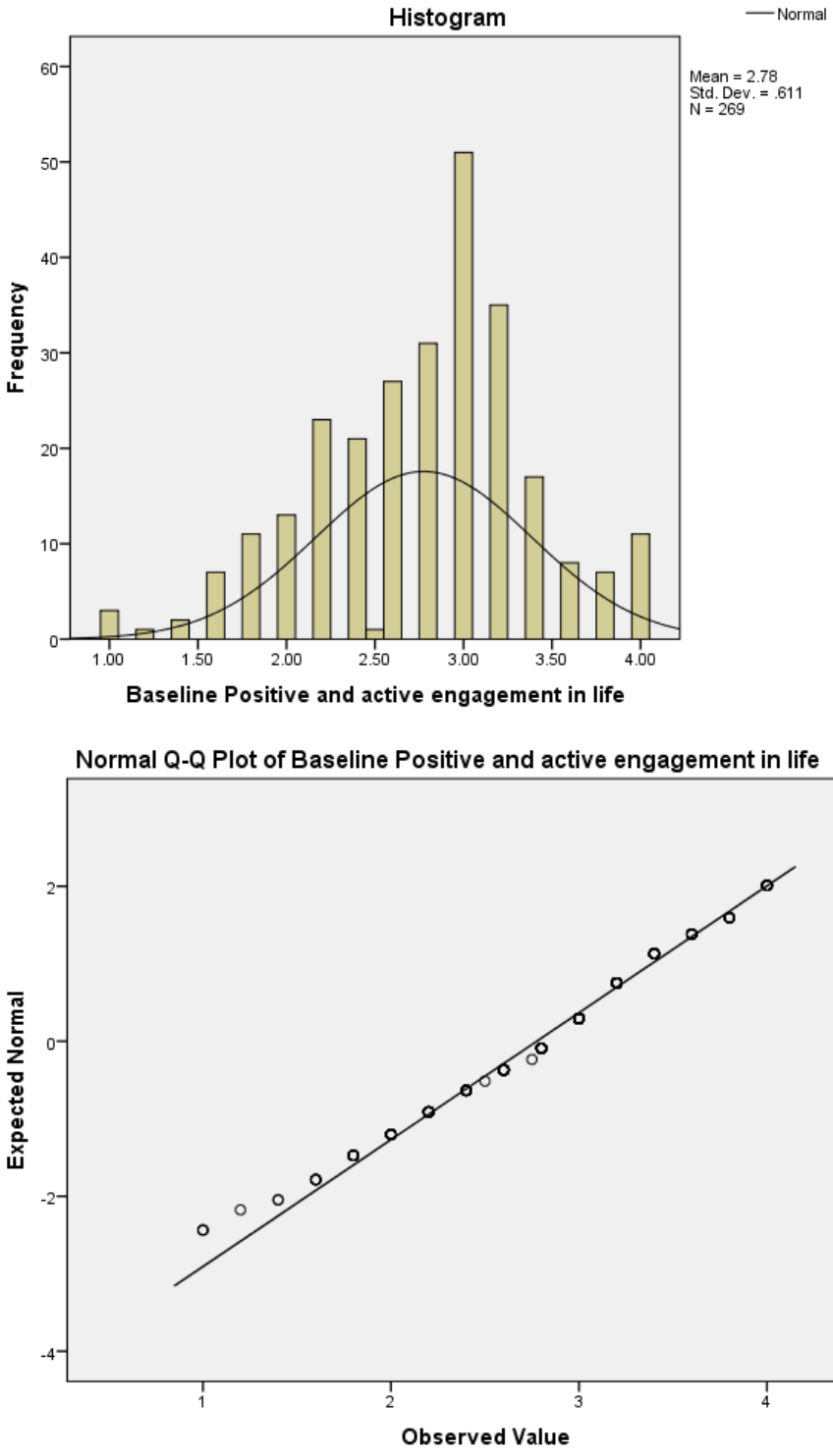


Figure 19: Histogram and Q-Q plot for Positive and Active Engagement (PAEL)

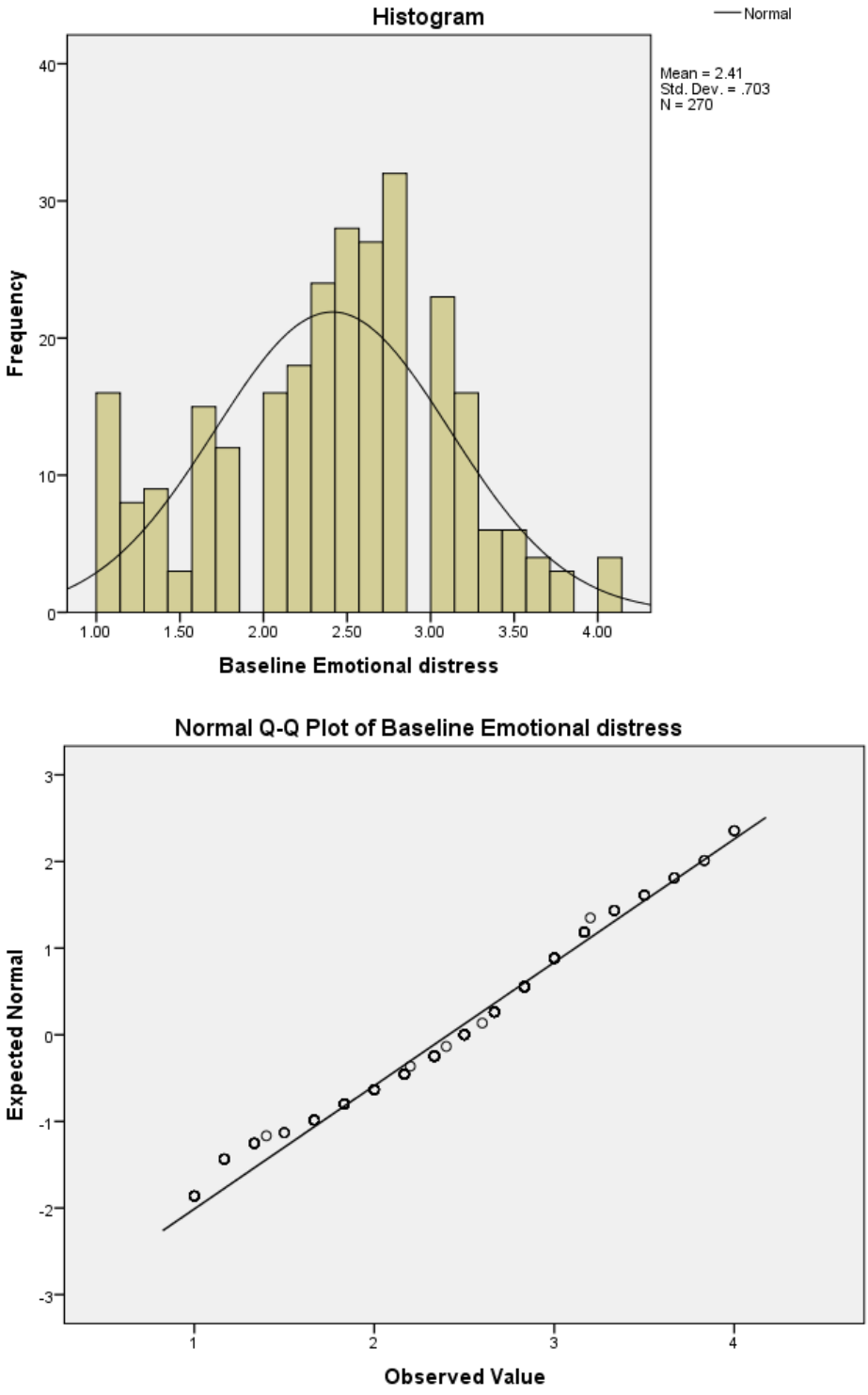


Figure 20: Histogram and Q-Q plot for Emotional Distress (ED)

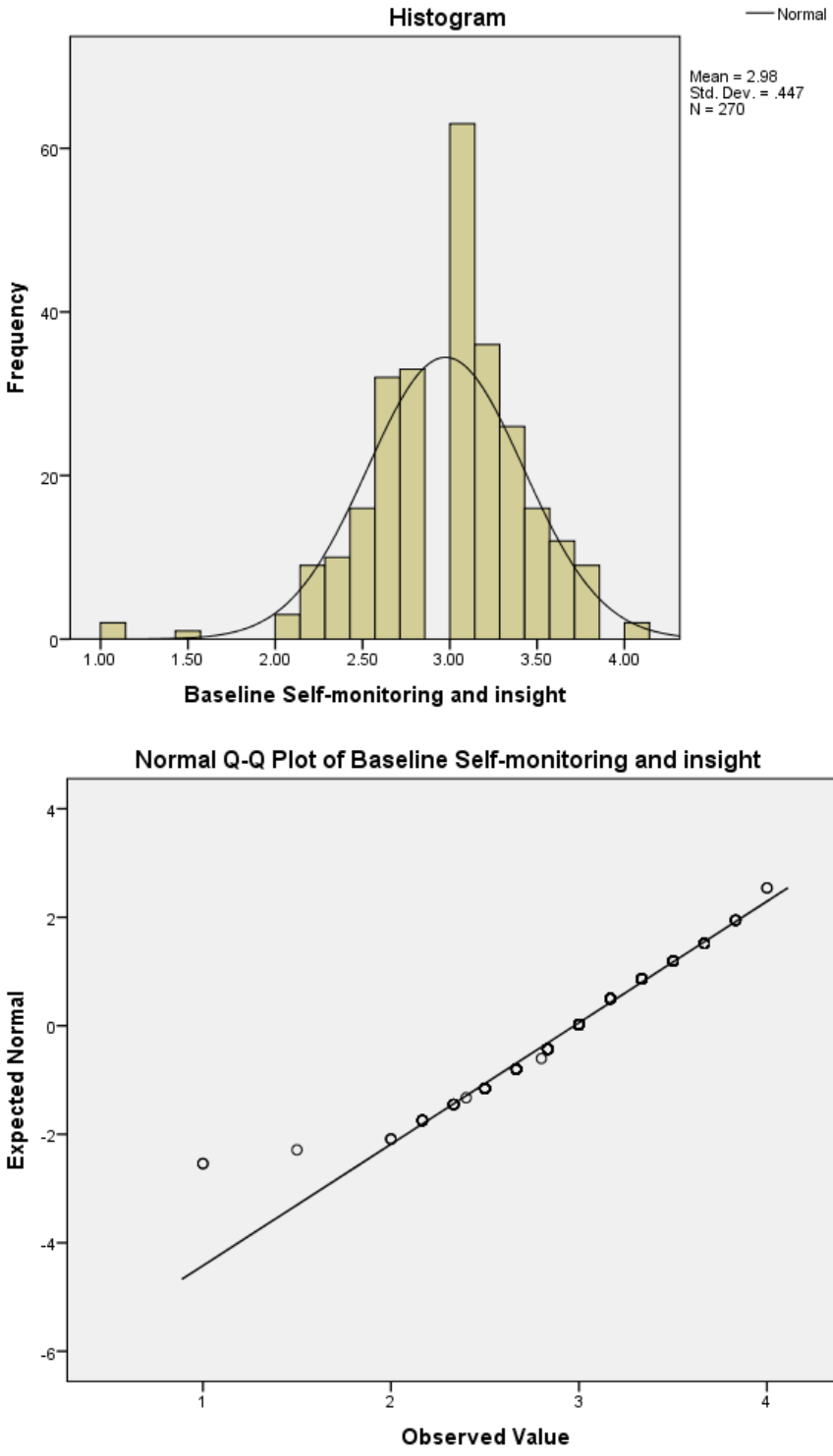


Figure 21: Histogram and Q-Q plot for Self-Monitoring and Insight (SMI)

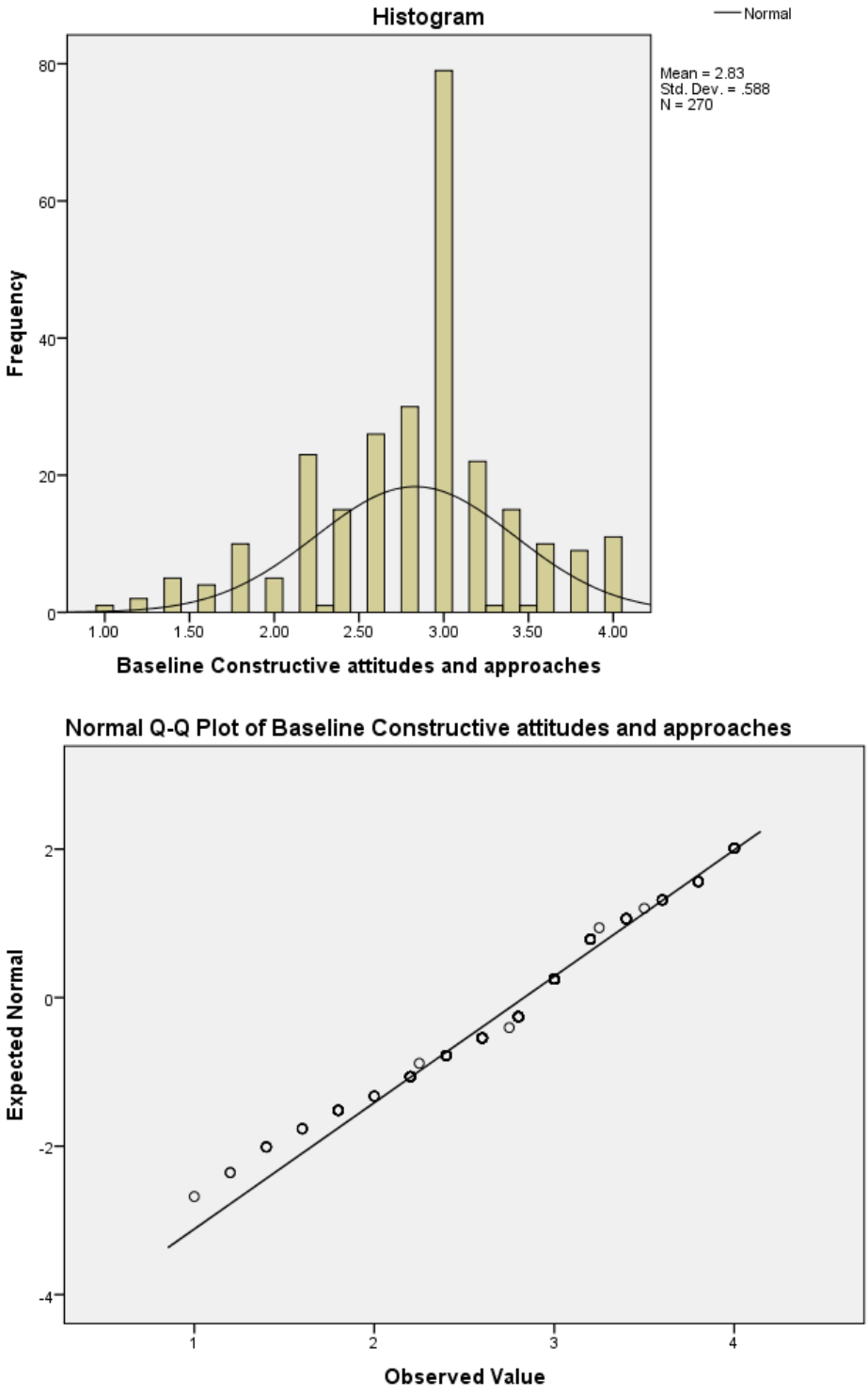


Figure 22: Histogram and Q-Q plot for baseline Constructive Attitudes and Approaches (CAA)

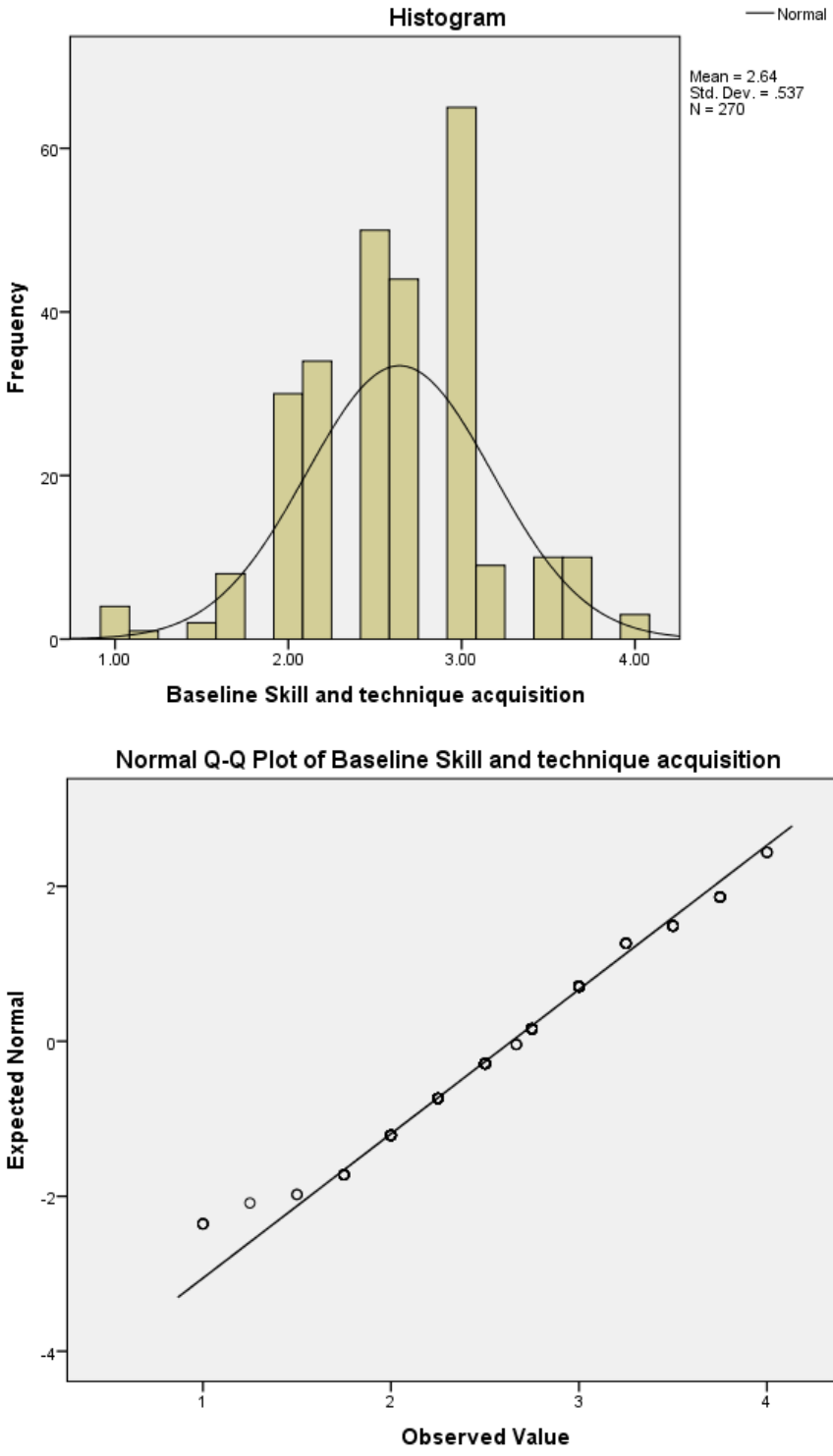


Figure 23: Histogram and Q-Q plot for Skill and Technique Acquisition (STA)

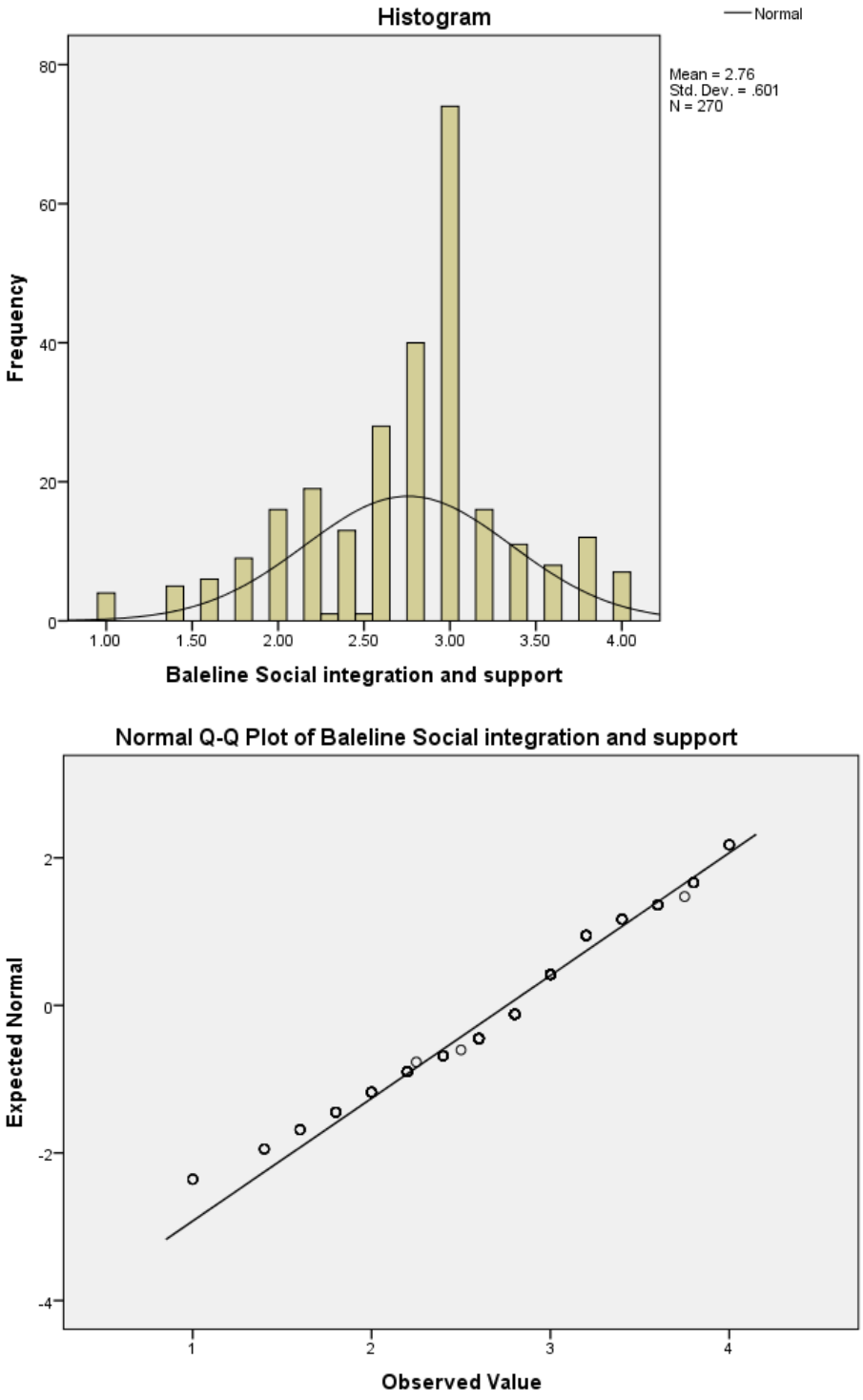
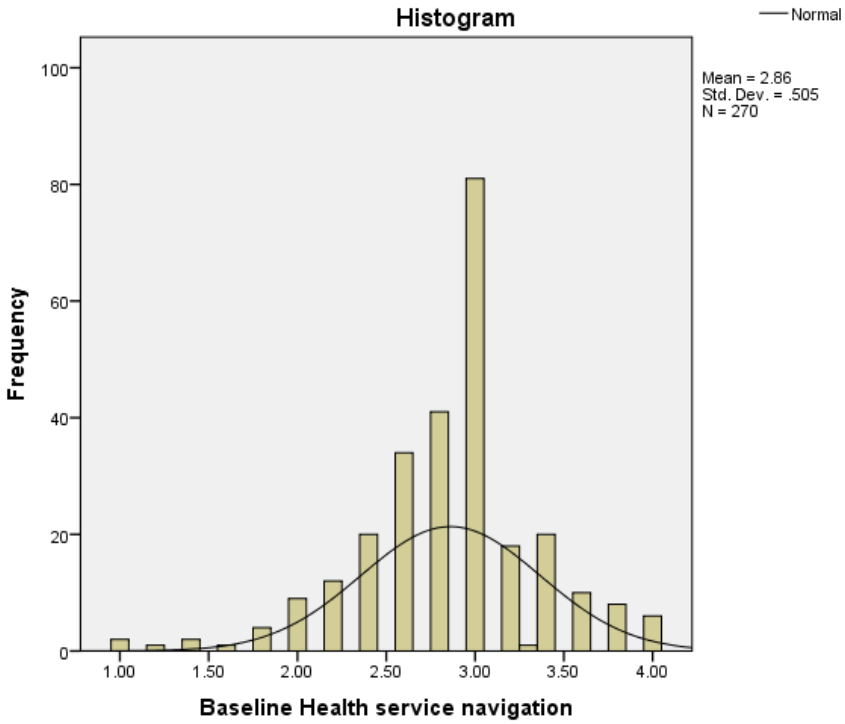


Figure 24: Histogram and Q-Q plot for Social Integration and Support (SIS)



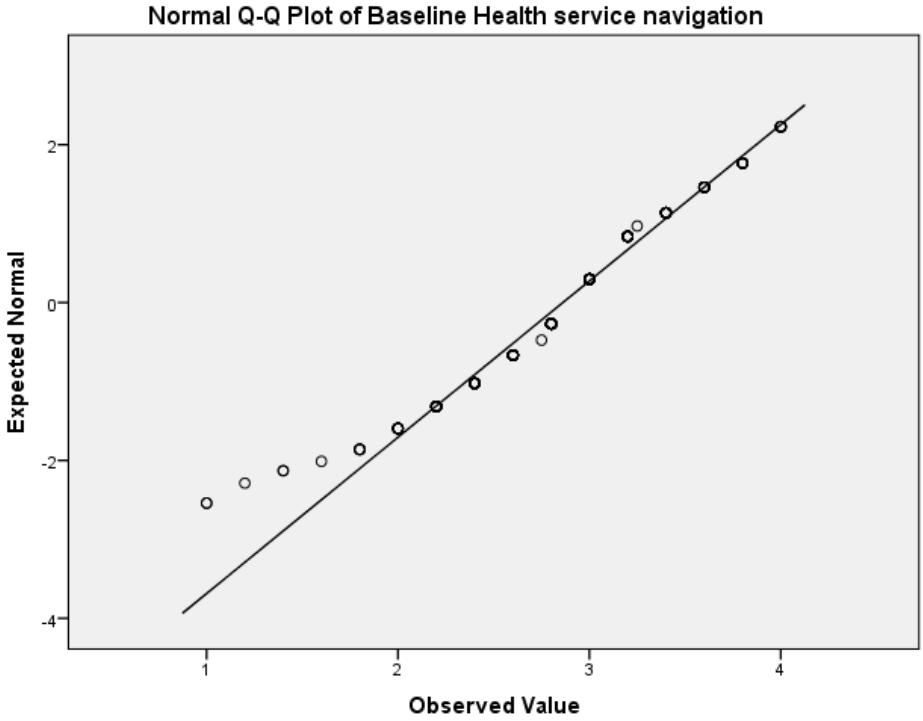


Figure 25: Histogram and Q-Q plot for Health Service Navigation (HSN)

Appendix 18: Details of the univariate and multivariate analyses for the self-management constructs at baseline

Table 22: Results of the univariate regression analyses of self-management constructs at baseline

	HDA						PAEL						ED						SMI					
	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*
Age	.09	.01	-.01	-.01	.00	.10	.00	.00	.00	-.01	.01	.95	.01	.00	.00	-.01	.01	.91	.18	.03	.01	.00	.01	.00
Pain duration	.03	.00	.00	-.02	.01	.73	.05	.00	.00	-.02	.01	.44	.03	.00	.00	-.02	.01	.66	.07	.00	.00	.00	.01	.26
NPS	.14	.02	-.04	-.07	.00	.04	.23	.05	-.06	-.09	-.03	.00	.36	.13	-.11	-.14	-.07	.00	.04	.00	-.01	-.02	-.02	.56
RMDQ	.31	.09	-.03	-.05	-.02	.00	.23	.29	-.06	-.07	-.04	.00	.50	.25	-.06	-.07	-.05	.00	.09	.01	-.01	-.02	.00	.15
PHQ	.28	.08	-.03	-.04	-.02	.00	.59	.35	-.06	-.07	-.05	.00	.59	.35	-.07	-.08	-.05	.00	.21	.04	-.01	-.03	.00	.00
TSK	.29	.09	-.03	-.04	-.01	.00	.45	.20	-.04	-.05	-.03	.00	.50	.25	-.05	-.06	-.04	.00	.21	.04	-.01	-.02	.00	.00
PCS	.25	.06	-.01	-.02	-.01	.00	.52	.27	-.02	-.03	-.02	.00	.63	.40	-.23	-.04	-.03	.00	.11	.01	.00	-.01	.00	.06
MET	.28	.08	.00	.00	.00	.00	.25	.06	.00004	.00002	.00007	.00	.03	.02	.00003	-.00002	-.00005	.03	.12	.01	.00	.00	.00	.06
Prescribed analgesics	.05	.00	-.03	-.09	.04	.42	.24	.06	-.12	-.17	-.05	.00	.30	.09	-.17	-.23	-.10	.00	.09	.01	.03	-.01	.08	.14
OTC analgesics	.05	.00	-.06	-.23	.12	.47	.05	.00	.05	-.07	.16	.40	.02	.00	.02	-.12	.20	.75	.07	.00	-.05	-.13	.02	.27
Healthcare use	.09	.01	.01	.00	.04	.18	.08	.01	-.01	-.02	.02	.22	.13	.02	-.02	-.04	.00	.04	.13	.02	.01	.00	.02	.03
IMD	.13	.02	.03	.00	.06	.03	.18	.03	.04	.01	.07	.00	.17	.03	.04	.01	.07	.01	.17	.03	.03	.01	.04	.01
	CAA						STA						SIS						HSN					
	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*
Age	.00	.00	.00	-.01	.01	.95	.15	.02	.01	.00	.01	.01	.05	.00	.00	-.01	.00	.43	.09	.01	.00	.00	.01	.15
Pain duration	.12	.01	-.01	-.02	.00	.06	.03	.00	.00	-.01	.01	.67	.09	.01	-.01	-.02	.00	.13	.00	.00	.00	-.01	.01	.97
NPS	.25	.06	-.06	-.09	-.03	.00	.22	.05	-.05	-.08	-.02	.00	.07	.01	-.02	-.05	.02	.24	.06	.00	-.01	-.04	.01	.37
RMDQ	.54	.30	-.05	-.06	-.04	.00	.27	.08	-.03	-.04	-.01	.00	.32	.10	-.03	-.05	-.02	.00	.16	.02	-.01	-.03	.00	.03
PHQ	.60	.37	-.06	-.07	-.04	.00	.36	.13	-.03	-.04	-.02	.00	.33	.11	-.03	-.04	-.02	.00	.23	.05	-.02	-.03	-.01	.00
TSK	.51	.26	-.04	-.05	-.03	.00	.30	.09	-.02	-.03	-.01	.00	.31	.10	-.03	-.04	-.01	.00	.27	.07	-.02	-.03	-.01	.00
PCS	.59	.35	-.03	-.03	-.02	.00	.32	.10	-.01	-.02	-.01	.00	.31	.10	-.01	-.02	-.01	.00	.23	.05	-.01	-.01	.00	.00
MET	.15	.02	.00002	.000003	.00005	.01	.11	.01	.00	.00	.00	.08	.07	.01	.00	.00	.00	.24	.12	.01	.00	.00	.00	.05
Prescribed analgesics	.27	.07	-.12	-.18	-.06	.00	.06	.00	-.03	-.08	.02	.34	.08	.01	-.04	-.10	.03	.23	.01	.00	.00	-.05	.05	.91
OTC analgesics	.03	.00	.03	-.09	.14	.67	.02	.00	-.02	-.12	.07	.71	.03	.00	-.03	-.17	.09	.64	.10	.01	-.08	-.19	.02	.14
Healthcare use	.13	.02	-.01	-.03	.01	.03	.14	.02	.01	.00	.03	.03	.06	.00	.01	.00	.02	.30	.06	.00	.01	.00	.02	.21
IMD	.19	.03	.04	.01	.06	.00	.15	.03	.03	.01	.05	.01	.13	.02	.03	.00	.05	.04	.09	.01	.01	-.01	.03	.17

Table 23: Results of the multivariate regression analyses of significant univariate predictors of self-management constructs at baseline

SM Constructs	Health Directed Activity				Positive and Active Engagement in Life				Emotional Distress				Self-Monitoring and Insight				Constructive Approaches and Attitudes				Skill and Technique Acquisition				Social Integration and Support				Health Service Navigation			
Model summary	Adj. R^2 .15 F(7,260) 7.70, p<.01				Adj. R^2 .41 F(14,223) 12.25, p <.01				Adj. R^2 .55 F(16,215) 17.09, p <.01				Adj. R^2 .11 F(11,252) 3.73, p <.01				Adj. R^2 .44 F(13,216) 13.81, p <.01				Adj. R^2 .17 F(10,235) 5.71, p <.01				Adj. R^2 .16 F(12,242) 4.82, p <.01				Adj. R^2 .07 F(4,266) 6.35, p <.01			
Variables	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI
Intercept	3.35	<.01	2.77	3.98	3.16	<.01	2.59	3.74	3.32	<.01	2.64	3.93	3.00	<.01	2.58	3.48	3.69	<.01	3.10	4.19	2.90	<.01	2.42	3.42	3.04	<.01	2.48	3.61	3.45	<.01	3.05	3.83
NPS	x	x	x	x	.02	.35	-.02	.05	.01	.71	-.02	.03	x	x	x	x	.01	.38	-.02	.05	-.02	.21	-.05	.01	x	x	x	x	x	x	x	x
RMDQ	-.01	.25	-.03	.01	-.03	<.01	-.04	-.01	-.002	.83	-.02	.02	x	x	x	x	-.02	.04	-.03	.00	-.005	.57	-.02	.01	-.02	.04	-.03	.00	.01	.49	-.01	.02
PHQ	-.01	.17	-.03	.00	-.03	<.01	-.04	-.01	-.03	.00	-.05	-.01	-.01	.07	-.02	.00	-.02	<.01	-.04	-.01	-.02	.04	-.03	.00	-.01	.14	-.03	.00	-.01	.16	-.02	.00
TSK	-.01	.13	-.03	.00	.003	.62	-.02	.01	-.01	.09	-.02	.00	-.004	.32	-.01	.00	-.01	.04	-.02	.00	-.01	.28	-.02	.00	-.01	.22	-.02	.00	-.01	.03	-.02	.00
PCS	7.10^{-5}	.99	-.01	.01	.004	.31	-.01	.00	-.02	<.01	-.03	-.01	x	x	x	x	-.01	.07	-.02	.00	-.003	.44	-.01	.00	.002	.56	-.01	.01	-.002	.51	-.01	.01
Kilo-MET	.04	<.01	.02	.06	.02	.01	.00	.04	.01	.15	.00	.03	x	x	x	x	.003	.72	-.01	.02	x	x	x	x	x	x	x	x	x	x	x	x
IMD	.02	.18	-.01	.04	.001	.96	-.02	.02	-.004	.69	-.03	.02	.01	.59	-.02	.03	.005	.63	-.02	.02	.01	.39	-.01	.03	.02	.14	-.01	.04	x	x	x	x
Pr. Analgesics	x	x	x	x	.02	.43	-.03	.08	-.03	.43	-.09	.04	x	x	x	x	.01	.72	-.04	.05	x	x	x	x	x	x	x	x	x	x	x	x
OTC Analgesics	x	x	x	x	x	x	x	x	-.05	.54	-.17	.09	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Healthcare use	x	x	x	x	x	x	x	x	-.01	.17	-.03	.01	.01	.04	.00	.02	-.004	.61	-.02	.02	.01	.10	-.001	.04	x	x	x	x	x	x	x	x
Leg pain vs. no leg pain	x	x	x	x	-.003	.97	-.15	.15	-.10	.20	-.24	.06	x	x	x	x	-.08	.23	-.21	.05	x	x	x	x	x	x	x	x	x	x	x	x
Age (years)	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	.005	.15	-.001	.01	x	x	x	x	x	x	x	x
Female vs. male	x	x	x	x	x	x	x	x	x	x	x	x	.12	.03	.02	.21	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
White vs. others ethnicity	x	x	x	x	x	x	x	x	.15	.07	-.01	.30	.05	.43	-.08	.19	x	x	x	x	x	x	x	x	.18	.11	-.05	.43	x	x	x	x
Variables	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI
College/ university vs. others education categories	.01	.91	-.16	.19	.05	.47	-.08	.19	.13	.11	-.03	.27	x	x	x	x	.11	.14	-.02	.23	x	x	x	x	x	x	x	x	x	x	x	x
Married vs. others	x	x	x	x	.19	.05	.01	.38	x	x	x	x	.11	.05	.01	.20	x	x	x	x	.05	.44	-.08	.19	-.05	.18	-.36	.36	x	x	x	x
living with spouse or partner vs. others	x	x	x	x	-.09	.42	-.31	.15	.02	.77	-.14	.18	x	x	x	x	x	x	x	x	x	x	x	x	.21	.26	-.19	.52	x	x	x	x

Annual income >£30K vs. ≤£30K	x	x	x	x	.08	.36	-.08	.25	-.03	.76	-.18	.15	x	x	x	x	-.07	.33	-.07	.21	-.01	.85	-.15	.12	-.06	.45	-.21	.10	x	x	x	x
Employed vs. others	x	x	x	x	.13	.11	-.04	.29	.12	.17	-.06	.28	x	x	x	x	.04	.62	-.11	.17	x	x	x	x	.07	.43	-.11	.25	x	x	x	x
Recruiting site BPU vs. CityCare	x	x	x	x	x	x	x	x	x	x	x	x	-.06	.49	-.21	.09	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Recruiting site NUH vs. CityCare	x	x	x	x	x	x	x	x	x	x	x	x	.07	.29	-.07	.21	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Physiotherapy only treatment vs. others	x	x	x	x	x	x	x	x	x	x	x	x	-.09	.23	-.22	.04	x	x	x	x	x	x	x	x	.06	.52	-.13	.25	x	x	x	x
Pain management programme vs. others	x	x	x	x	x	x	x	x	x	x	x	x	.06	.56	-.13	.24	x	x	x	x	x	x	x	x	-.16	.24	-.41	.08	x	x	x	x

B: unstandardised coefficient, *p*: *p*-value, LCI: Lower Confidence Interval of B with Bootstrap, UCI: Upper Confidence interval of B with Bootstrap, NPS: Numeric Pain Scale, RMDQ: Roland Morris Disability Questionnaire, PHQ: Patient Health Questionnaire-9, TSK: Tampa Scale of Kinesiophobia, PCS: Pain Catastrophising scale, Pr. Analgesic: Prescribed analgesics, OTC analgesic: Over the Counter analgesic, IMD: Index for Multiple Deprivation, Kilo-MET: Kilo Metabolic Equivalent, Healthcare use - no. of visits to healthcare providers for low back pain in last 3 months, BPU: Back Pain Unit, Sherwood Forest Hospital, NUH: Nottingham University Hospitals, x: not applicable

Appendix 19: Details of the univariate and multivariate analyses for the self-management constructs at follow-up

Table 24: Results of the univariate regression analyses for predictors of self-management constructs at the follow-up

	HDA						PAEL						ED						SMI					
	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*
Age	.02	.00	.00	-.01	.01	.83	.07	.01	.00	-.01	.01	.38	.03	.00	.00	-.01	.01	.66	.15	.02	.01	.00	.01	.10
Pain duration	.03	.00	.00	-.01	.01	.74	.06	.00	.00	-.01	.01	.44	.02	.00	.00	-.01	.01	.77	.13	.02	.01	.00	.01	.15
NPS	.12	.01	-.03	.07	.01	.18	.12	.01	-.03	-.06	.01	.13	.29	.09	.08	.03	.14	.00	.01	.00	.00	-.04	.03	.90
RMDQ	.28	.08	-.03	-.05	-.01	.00	.37	.13	-.04	-.05	-.03	.00	.48	.23	.06	.04	.08	.00	.05	.00	.00	-.02	.01	.61
PHQ	.24	.06	-.02	-.04	-.01	.01	.49	.24	-.05	-.06	-.03	.00	.56	.32	.06	.05	.08	.00	.08	.01	-.01	-.02	.01	.29
TSK	.21	.05	-.02	-.03	.00	.02	.41	.17	-.03	-.04	-.02	.00	.50	.25	.04	.03	.06	.00	.15	.02	-.01	-.02	.00	.06
PCS	.15	.02	-.01	-.02	.00	.05	.38	.15	-.02	-.03	-.01	.00	.56	.32	.03	.02	.04	.00	.11	.01	.00	-.01	.00	.19
MET	.15	.02	.03	-.01	.06	.15	.14	.02	.02	-.01	.06	.17	.06	.00	-.01	-.05	.02	.45	.03	.00	.00	-.01	.03	.67
Prescribed analgesics	.04	.00	-.02	-.12	.08	.71	.08	.01	-.04	-.13	.05	.38	.22	.05	.12	.04	.21	.01	.09	.01	.03	-.02	.08	.28
OTC analgesics	.01	.00	-.01	-.20	.18	.93	.09	.01	.09	-.07	.26	.27	.04	.00	-.04	-.24	.14	.67	.05	.00	.04	-.08	.15	.50
Healthcare use	.03	.00	.00	-.02	.05	.72	.06	.00	-.01	-.02	.04	.48	.23	.05	.03	-.01	.04	.02	.20	.04	.01	.00	.04	.04
IMD	.12	.02	.03	-.01	.06	.11	.13	.02	.03	-.01	.07	.11	.17	.03	-.04	-.09	.00	.04	.16	.03	.02	.00	.05	.05
	CAA						STA						SIS						HSN					
	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*
Age	.02	.00	.00	-.01	.01	.84	.15	.02	.01	.00	.01	.10	.01	.00	.00	-.01	.01	.85	.11	.01	.01	.00	.01	.18
Pain duration	.02	.00	.00	-.01	.01	.85	.17	.03	.01	.00	.02	.07	.00	.00	.00	-.01	.01	.97	.10	.01	.01	-.01	.01	.32
NPS	.22	.05	-.05	-.08	-.01	.01	.17	.03	-.03	-.07	.00	.06	.07	.01	-.02	-.05	.02	.43	.10	.01	-.02	-.06	.02	.25
RMDQ	.48	.23	-.05	-.06	-.03	.00	.15	.02	-.01	-.03	.00	.08	.26	.07	-.03	-.04	-.01	.00	.11	.01	-.01	-.03	.01	.20
PHQ	.51	.26	-.04	-.06	-.03	.00	.15	.02	-.01	-.03	.00	.12	.39	.15	-.04	-.05	-.02	.00	.15	.02	-.01	-.03	.00	.08
TSK	.43	.19	-.03	-.04	-.02	.00	.29	.08	-.02	-.03	-.01	.00	.36	.13	-.03	-.04	-.01	.00	.26	.07	-.02	-.03	-.01	.00
PCS	.46	.21	-.02	-.03	-.01	.00	.13	.02	-.01	-.01	.00	.16	.29	.09	-.01	-.02	-.01	.00	.14	.02	-.01	-.01	.00	.13
MET	.14	.02	.02	-.01	.06	.11	.11	.01	.01	-.01	.05	.28	.11	.01	.02	-.01	.05	.22	.14	.02	.02	-.01	.06	.11
Prescribed analgesics	.18	.03	-.08	-.14	-.01	.02	.03	.00	-.01	-.08	.05	.72	.11	.01	-.05	-.13	.04	.21	.05	.00	-.02	-.10	.07	.62
OTC analgesics	.04	.00	.03	-.09	.15	.59	.00	.00	.00	-.11	.11	.96	.08	.01	.07	-.07	.23	.31	.04	.00	-.04	-.18	.10	.54
Healthcare use	.10	.01	-.01	-.02	.03	.27	.18	.03	.01	.00	.04	.11	.09	.01	.01	.00	.02	.13	.11	.01	.01	.00	.05	.16
IMD	.16	.03	.03	.00	.06	.06	.15	.02	.03	.00	.06	.06	.18	.03	.04	.01	.07	.04	.10	.01	.02	-.01	.05	.18

B: unstandardised coefficient, *p*: *p*-value, LCI: Lower Confidence Interval of B with Bootstrap, UCI: Upper Confidence interval of B with Bootstrap, NPS: Numeric Pain Scale, RMDQ: Roland Morris Disability Questionnaire, PHQ: Patient Health Questionnaire-9, TSK: Tampa Scale of Kinesiophobia, PCS: Pain Catastrophising scale, Pr. Analgesic: Prescribed analgesics, OTC analgesic: Over the Counter analgesic, IMD: Index for Multiple Deprivation, Kilo-MET: Kilo Metabolic Equivalent, Healthcare use - no. of visits to healthcare providers for low back pain in last 3 months, BPU: Back Pain Unit, Sherwood Forest Hospital, NUH: Nottingham University Hospitals, x: not applicable

Table 25: Results of the multivariate regression analyses of significant univariate predictors of self-management constructs at the follow-up

SM Constructs	Health Directed Activity				Positive and Active Engagement in Life				Emotional Distress				Self-Monitoring and Insight				Constructive Approaches and Attitudes				Skill and Technique Acquisition				Social Integration and Support				Health Service Navigation			
Model summary	Adj. R^2 .30 F(4,151) 17.18, *p* <.01				Adj. R^2 .43 F(10,138) 11.26, *p* <.01				Adj. R^2 .39 F(14,121) 6.48, *p* <.01				Adj. R^2 .38 F(4,143) 22.41, *p* <.01				Adj. R^2 .42 F(11,128) 9.43, *p* <.01				Adj. R^2 .34 F(7,139) 11.17, *p* <.01				Adj. R^2 .55 F(10,138) 17.75, *p* <.01				Adj. R^2 .37 F(5,144) 18.19, *p* <.01			
Variables	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI	B	*p*	LCI	UCI
Intercept	1.72	<.01	.92	2.48	2.59	.001	1.57	3.50	.63	.36	-.62	1.91	1.29	.001	.69	1.93	3.51	.001	2.64	4.43	2.76	.001	1.92	3.52	2.48	.001	1.79	3.05	2.23	<.01	1.55	3.05
Baseline adjustment	.49	<.01	.33	.67	.49	.001	.31	.68	-.01	.95	-.29	.23	.61	.001	.43	.79	.25	.02	.05	.49	.41	.001	.25	.58	.50	.001	.38	.62	.58	<.01	.41	.72
NPS	x	x	x	x	x	x	x	x	.002	.94	-.06	.07	x	x	x	x	.03	.15	-.01	.07	x	x	x	x	x	x	x	x	x	x	x	x
RMDQ	-.01	.49	.03	.01	.003	.77	-.02	.02	.004	.72	-.02	.02	x	x	x	x	-.02	.14	-.04	.003	x	x	x	x	.02	.06	-.002	.03	x	x	x	x
PHQ	-.003	.76	-.02	.01	-.02	.14	-.04	.01	.03	.07	-.001	.06	x	x	x	x	-.01	.21	-.03	.01	x	x	x	x	-.03	.002	-.05	-.01	x	x	x	x
TSK	-.001	.89	-.02	.01	-.02	.02	-.03	-.003	.03	.003	.01	.04	x	x	x	x	-.01	.02	-.03	-.001	-.01	.01	-.02	-.002	-.01	.01	-.03	-.003	-.01	.07	-.02	.001
PCS	x	x	x	x	.01	.09	-.0002	.02	.005	.43	-.01	.02	x	x	x	x	.003	.61	-.01	.01	x	x	x	x	.01	.10	-.001	.02	x	x	x	x
IPAQ	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
IMD	x	x	x	x	x	x	x	x	.01	.75	-.03	.04	x	x	x	x	x	x	x	x	x	x	x	x	-.01	.63	-.03	.02	x	x	x	x
Pr. Analgesics	x	x	x	x	x	x	x	x	-.04	.43	-.13	.06	x	x	x	x	.01	.79	-.06	.09	x	x	x	x	x	x	x	x	x	x	x	x
OTC Analgesics	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Healthcare use	x	x	x	x	x	x	x	x	.01	.16	-.01	.03	.01	.36	-.01	.02	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Leg pain	x	x	x	x	x	x	x	x	-.20	.07	-.42	.02	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
White	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	-.32	.01	-.55	-.10	x	x	x	x	x	x	x	x
College	x	x	x	x	-.05	.62	-.27	.18	.20	.11	-.05	.46	x	x	x	x	-.18	.04	-.35	-.01	-.12	.16	-.28	.06	-.19	.04	-.38	-.02	x	x	x	x
Married	x	x	x	x	-.11	.23	-.29	.07	-.12	.63	-.64	.39	.02	.89	-.25	.31	x	x	x	x	-.04	.84	-.38	.45	-.03	.84	-.26	.30	-.13	.49	-.49	.28
Living with spouse or partner	x	x	x	x	-.06	.75	-.63	.34	.39	.15	-.14	.92	-.07	.60	-.35	.20	-.21	.01	-.38	-.05	-.15	.47	-.64	.20	-.26	.12	-.57	.02	-.08	.68	-.53	.29

Annual income >£30K	x	x	x	x	-.05	.63	-.25	.18	.01	.92	-.23	.25	x	x	x	x	-.08	.39	-.29	.11	.08	.42	-.12	.25	.07	.41	-.09	.30	x	x	x	x
Employed	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	-.01	.88	-.20	.19	x	x	x	x	x	x	x	x	x	x	x	x
BPU vs. CityCare	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
NUH vs. CityCare	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Pain management	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	-.26	.01	-.46	-.09

B: unstandardised coefficient, *p*: *p*-value, LCI: Lower Confidence Interval of B with Bootstrap, UCI: Upper Confidence interval of B with Bootstrap, NPS: Numeric Pain Scale, RMDQ: Roland Morris Disability Questionnaire, PHQ: Patient Health Questionnaire-9, TSK: Tampa Scale of Kinesiophobia, PCS: Pain Catastrophising scale, Pr. Analgesic: Prescribed analgesics, OTC analgesic: Over the Counter analgesic, IMD: Index for Multiple Deprivation, Kilo-MET: Kilo Metabolic Equivalent, Healthcare use - no. of visits to healthcare providers for low back pain in last 3 months, BPU: Back Pain Unit, Sherwood Forest Hospital, NUH: Nottingham University Hospitals, x: not applicable

Appendix 20: Details of the univariate and multivariate analyses for predictors of change in the self-management constructs

Table 26: Results of the univariate regression analyses of change in self-management constructs

Parameter	HDA						PAEL						ED						SMM					
	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*
Age	.03	.00	.00	-.01	.01	.75	.00	.00	.00	-.01	.01	.98	.03	.00	.00	-.02	.01	.74	.06	.00	.00	-.01	.00	.41
Pain duration	.10	.01	-.01	-.02	.01	.24	.12	.01	-.01	-.02	.01	.28	.10	.01	.01	-.01	.04	.23	.11	.01	.01	.00	.01	.18
Change in NPS	.17	.03	-.04	-.08	.00	.03	.31	.10	-.06	-.09	-.03	.00	.09	.01	.04	-.05	.13	.31	.23	.05	-.03	-.06	-.01	.01
Change in RMDQ	.28	.08	-.04	-.07	-.01	.00	.35	.12	-.04	-.06	-.02	.00	.18	.03	.05	.01	.09	.02	.20	.04	-.02	-.03	.00	.01
Change in PHQ	.24	.06	-.03	-.06	-.01	.01	.41	.17	-.04	-.06	-.03	.00	.02	.00	.00	-.03	.04	.81	.18	.03	-.01	-.03	.00	.05
Change in TSK	.24	.06	-.02	-.04	.00	.03	.26	.07	-.02	-.03	.00	.01	.11	.01	-.02	-.05	.01	.22	.18	.03	-.01	-.02	.00	.04
Change in PCS	.39	.15	-.03	-.04	-.01	.00	.49	.24	-.03	-.03	-.02	.00	.03	.00	.00	-.01	.02	.63	.19	.04	-.01	-.02	.00	.02
Change in MET	.24	.06	.00	.00	0.00	.00	.21	.04	.00	.00	.00	.00	.04	.00	.00	.00	.00	.64	.18	.03	.00	.00	.00	.00
Change in Prescribed analgesic	.12	.01	.06	.00	.14	.08	.07	.00	-.03	-.12	.05	.46	.10	.01	.11	-.06	.28	.20	.01	.00	.00	-.04	.05	.89
Change in OTC analgesic	.01	.00	-.01	-.13	.12	.94	.01	.00	-.01	-.12	.12	.93	.06	.00	.09	-.15	.33	.43	.14	.02	-.07	-.15	.01	.11
Change in Healthcare use	.02	.00	.00	-.04	.02	.80	.11	.01	-.01	-.03	.01	.15	.07	.00	.02	-.04	.15	.69	.18	.03	-.01	-.03	.00	.02
Parameter	CAA						STA						SIS						HSN					
	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*	R	R2	B	LCI	UCI	*p*
Age	.05	.00	.00	-.01	.01	.52	.04	.00	.00	-.01	.00	.66	.01	.00	.00	-.01	.01	.90	.05	.00	.00	.00	.01	.56
Pain duration	.03	.00	.00	-.02	.01	.75	.03	.00	.00	-.01	.01	.66	.10	.01	.01	.00	.02	.22	.04	.00	.00	-.01	.02	.68
IMD	.13	.02	-.03	-.05	.00	.07	.09	.01	-.02	-.04	.01	.26	.00	.00	.00	-.03	.03	1.00	.01	.00	.00	-.03	.02	.87
Change in NPS	.27	.07	-.06	-.09	-.03	.00	.26	.07	-.05	-.09	-.02	.00	.17	.03	-.03	-.07	.00	.03	.23	.05	-.04	-.07	-.01	.00
Change in RMDQ	.30	.09	-.04	-.06	-.02	.00	.24	.06	-.03	-.05	-.01	.01	.17	.03	-.02	-.04	.00	.05	.17	.03	-.02	-.04	.01	.10
Change in PHQ	.37	.14	-.04	-.06	-.02	.00	.31	.10	-.03	-.05	-.02	.00	.19	.04	-.02	-.04	.00	.06	.13	.02	-.01	-.03	.00	.12
Change in TSK	.37	.14	-.03	-.04	-.02	.00	.18	.03	-.01	-.03	.00	.04	.09	.01	-.01	-.02	.01	.31	.22	.05	-.02	-.03	.00	.03
Change in PCS	.43	.18	-.02	-.03	-.01	.00	.32	.10	-.02	-.03	-.01	.00	.33	.11	-.02	-.02	-.01	.00	.26	.07	-.01	-.02	.00	.00
Change in MET	.10	.01	.00	.00	.00	.07	.14	.02	.00	.00	.00	.07	.06	.00	.00	.00	.00	.35	.04	.00	.00	.00	.00	.70
Change in Prescribed analgesic	.06	.00	-.03	-.10	.04	.47	.05	.00	.02	-.05	.10	.54	.03	.00	.01	-.06	.08	.72	.24	.06	.10	.03	.17	.01
Change in OTC analgesic	.01	.00	.01	-.12	.17	.92	.10	.01	-.07	-.17	.04	.26	.03	.00	-.02	-.13	.11	.77	.17	.03	-.10	-.21	.02	.06
Change in Healthcare use	.10	.01	-.01	-.04	.00	.41	.01	.00	.00	-.03	.01	.89	.13	.02	-.01	-.04	.01	.15	.04	.00	.00	-.03	.02	.70

B: unstandardised coefficient, *p*: *p*-value, LCI: Lower Confidence Interval of B with Bootstrap, UCI: Upper Confidence interval of B with Bootstrap, NPS: Numeric Pain Scale, RMDQ: Roland Morris Disability Questionnaire, PHQ: Patient Health Questionnaire-9, TSK: Tampa Scale of Kinesiophobia, PCS: Pain Catastrophising scale, Pr. Analgesic: Prescribed analgesics, OTC analgesic: Over the Counter analgesic, IMD: Index for Multiple Deprivation, Kilo-MET: Kilo Metabolic Equivalent, Healthcare use - no. of visits to healthcare providers for low back pain in last 3 months, BPU: Back Pain Unit, Sherwood Forest Hospital, NUH: Nottingham University Hospitals, x: not applicable

Table 27: Results of the multivariate regression analyses of change in self-management constructs

SM Constructs	Change in Health Directed Activity				Change in Positive and Active Engagement in Life				Change in Emotional Distress				Change in Self-Monitoring and Insight				Change in Constructive Approaches and Attitudes				Change in Skill and Technique Acquisition				Change in Social Integration and Support				Change in Health Service Navigation			
Model summary	Adj. R^2 .18 F(6,139) 6.18, p <.01				Adj. R^2 .32 F(6,139) 12.09, p <.01				Adj. R^2 .21 F(6,138) 7.00, p <.01				Adj. R^2 .10 F(11,99) 2.03, p =.04				Adj. R^2 .27 F(5,141) 11.52, p <.01				Adj. R^2 .13 F(5,141) 5.23, p <.01				Adj. R^2 .13 F(4,141) 6.11, p <.01				Adj. R^2 .20 F(6,139) 6.83, p <.01			
Variables	B	p	LCI	UCI	B	p	LCI	UCI	B	p	LCI	UCI	B	p	LCI	UCI	B	p	LCI	UCI	B	p	LCI	UCI	B	p	LCI	UCI	B	p	LCI	UCI
Intercept	-.01	.87	-.12	.11	-.04	.39	-.12	.06	.37	.27	-.13	.96	.15	.09	-.01	.36	-.003	.93	-.01	.10	.09	.08	-.01	.19	-.10	.17	-.26	.05	.02	.78	-.14	.20
Change in NPS	-.02	.43	-.05	.02	-.03	.06	-.06	.01	x	x	x	x	-.02	.14	-.05	.01	-.02	.18	-.05	.01	-.03	.07	-.07	.004	-.01	.29	-.04	.02	x	x	x	x
Change in RMDQ	.001	.94	-.03	.04	.01	.39	-.01	.03	.03	.26	-.02	.08	-.002	.86	-.02	.02	.01	.50	-.01	.03	.003	.82	-.02	.03	.01	.33	-.01	.03	-.003	.73	-.03	.02
Change in PHQ	-.01	.50	-.04	.02	-.02	.01	-.04	-.01	x	x	x	x	-.003	.73	-.02	.01	-.03	.02	-.05	-.004	-.02	.07	-.04	.002	x	x	x	x	x	x	x	x
Change in TSK	-.01	.30	-.03	.01	.00004	.96	-.02	.01	x	x	x	x	-.001	.78	-.01	.01	-.01	.049	-.03	.001	.00001	.98	-.01	.01	x	x	x	x	-.005	.50	-.02	.01
Change in PCS	-.02	.004	-.03	-.01	-.02	.001	-.03	-.01	x	x	x	x	-.002	.78	-.01	.01	-.02	.01	-.03	-.002	-.01	.09	-.03	.002	-.02	.003	-.03	-.01	-.01	.03	-.02	.001
Change in IPAQ	.03	.001	.01	.05	.02	.02	.004	.04	x	x	x	x	.01	.01	.003	.03	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
IMD	x	x	x	x	x	x	x	x	x	x	x	x	-.01	.63	-.04	.02	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Change in Pr. Analgesics	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	.10	.004	.04	.17
Change in Healthcare use	x	x	x	x	x	x	x	x	x	x	x	x	-.02	.01	-.03	.004	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Leg pain vs. no leg pain	x	x	x	x	x	x	x	x	.76	.002	.36	1.11	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
College/ university vs. others education categories	x	x	x	x	x	x	x	x	-.60	.01	-1.02	-.18	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Married vs. others	x	x	x	x	x	x	x	x	-.38	.08	-.79	.06	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	.19	.04	-.004	.37
Living with spouse or partner vs. others	x	x	x	x	x	x	x	x	x	x	x	x	-.04	.54	-.19	.09	x	x	x	x	x	x	x	x	.16	.09	-.03	.36	x	x	x	x

Annual income >£30K vs. ≤£30K	x	x	x	x	x	x	x	x	-.21	.31	-.60	.12	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Employed vs. others	x	x	x	x	x	x	x	x	-.28	.23	.69	.13	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	-.26	.01	-.42	-.11
Recruiting site BPU vs. CityCare	x	x	x	x	x	x	x	x	x	x	x	x	-.08	.41	-.26	.11	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Recruiting site NUH vs. CityCare													-.13	.13	-.31	.03																

B: unstandardised coefficient, *p*: *p*-value, LCI: Lower Confidence Interval of B with Bootstrap, UCI: Upper Confidence interval of B with Bootstrap, NPS: Numeric Pain Scale, RMDQ: Roland Morris Disability Questionnaire, PHQ: Patient Health Questionnaire-9, TSK: Tampa Scale of Kinesiophobia, PCS: Pain Catastrophising scale, Pr. Analgesic: Prescribed analgesics, OTC analgesic: Over the Counter analgesic, IMD: Index for Multiple Deprivation, Kilo-MET: Kilo Metabolic Equivalent, Healthcare use - no. of visits to healthcare providers for low back pain in last 3 months, BPU: Back Pain Unit, Sherwood Forest Hospital, NUH: Nottingham University Hospitals, x: not applicable

Appendix 21: Results for the assumption testing for the multivariate regression analysis

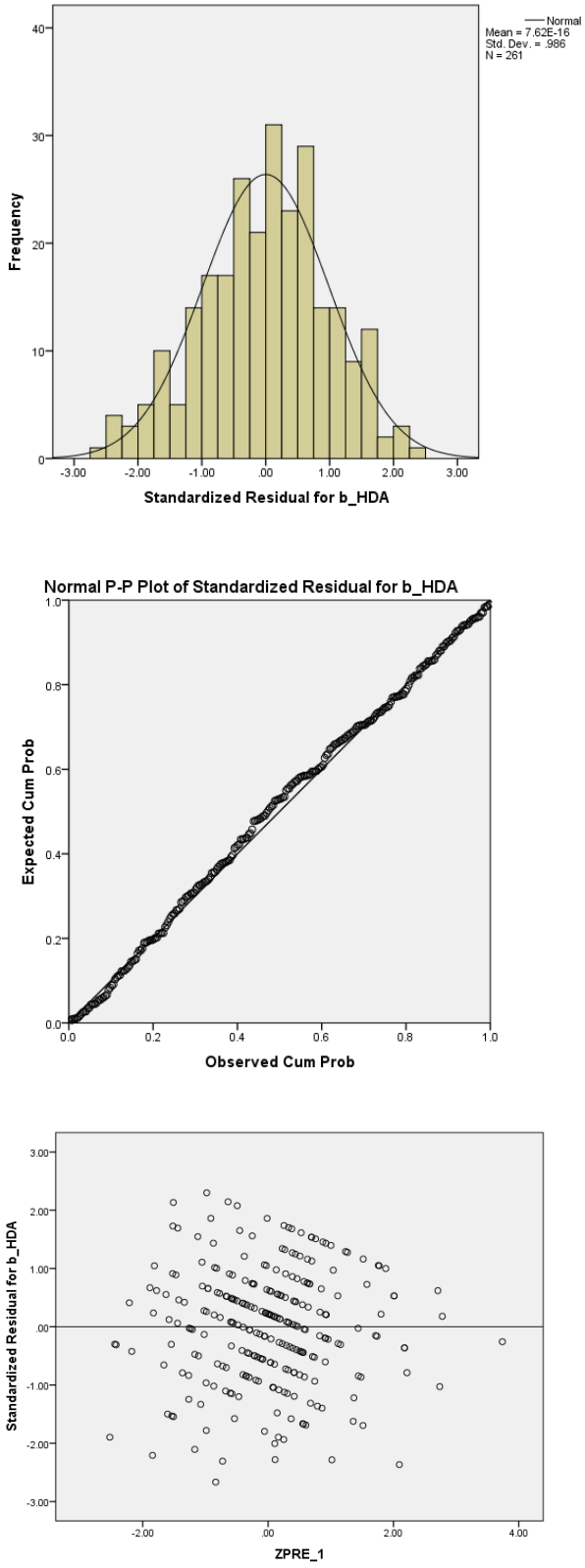
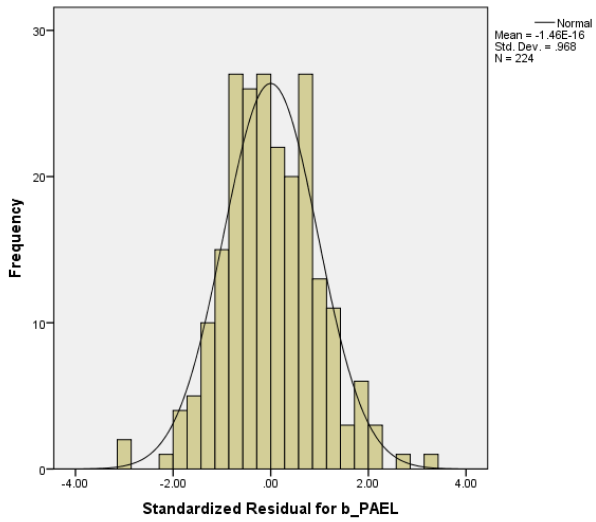
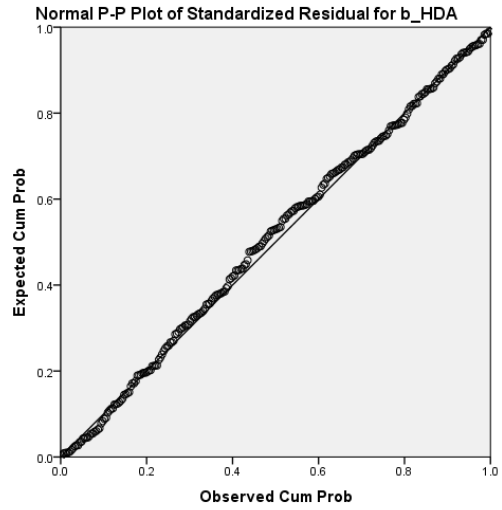


Figure 26: Graphs for checking assumptions for baseline HDA





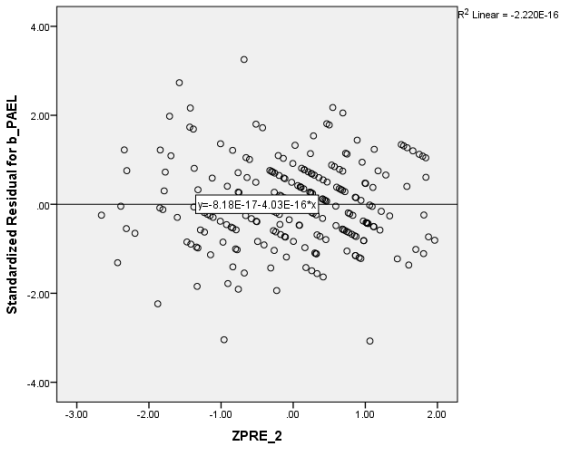
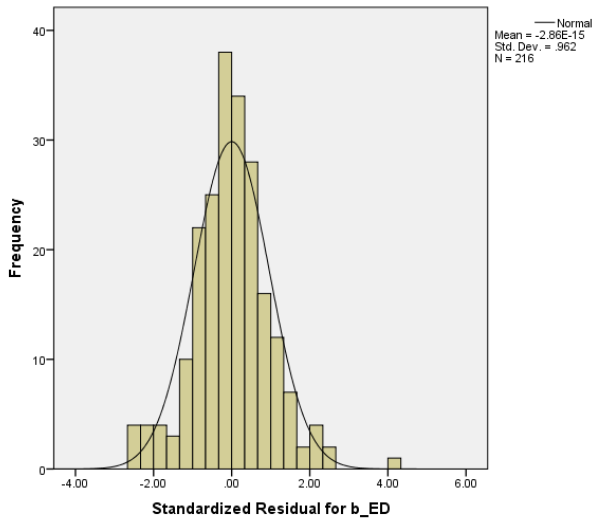
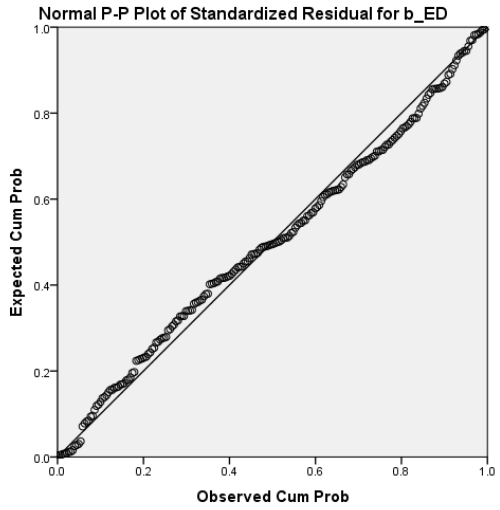


Figure 27: Graphs for checking assumptions for baseline PAEL





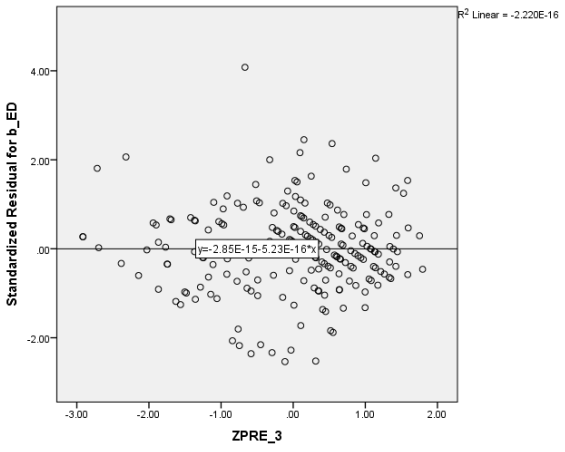
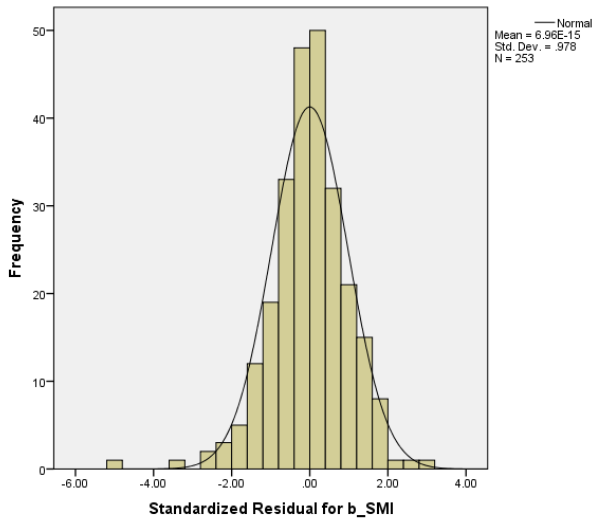
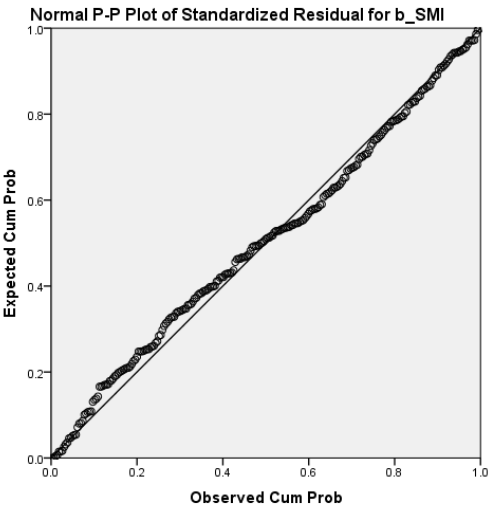


Figure 28: Graphs for checking assumptions for baseline ED





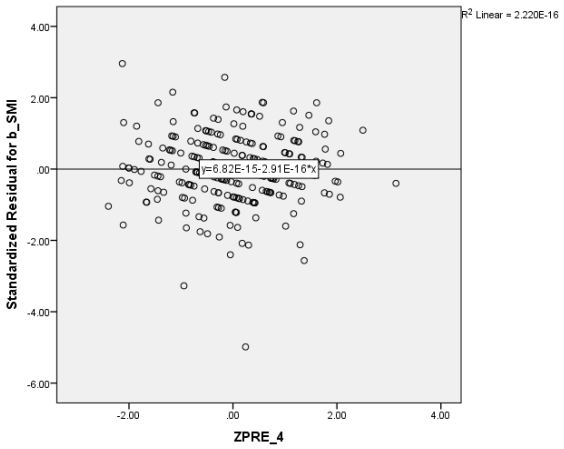
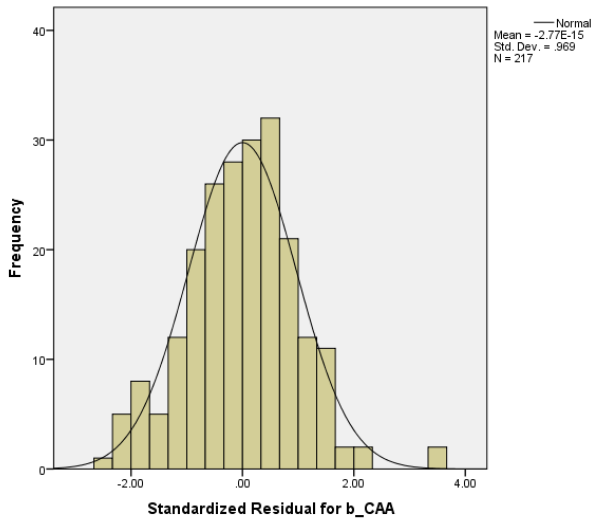
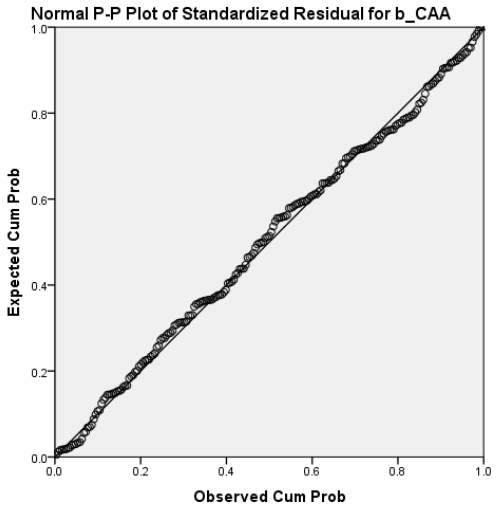


Figure 29: Graphs for checking assumptions for baseline SMI





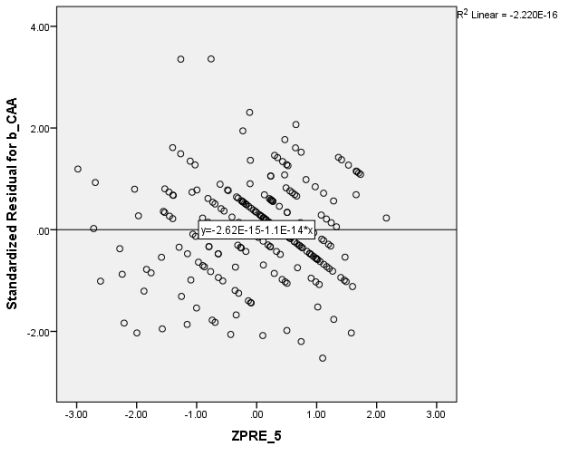
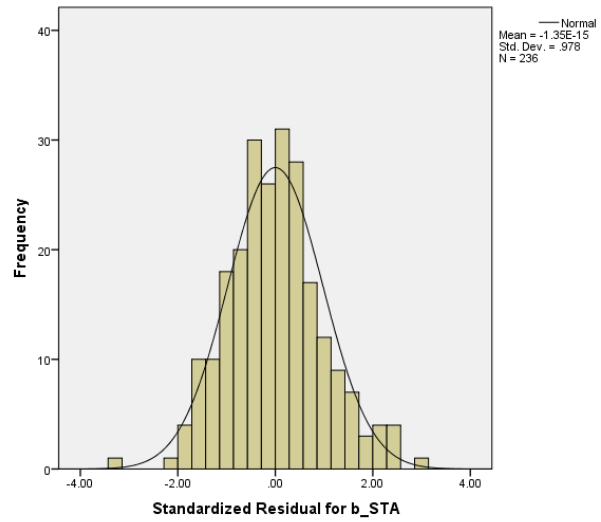
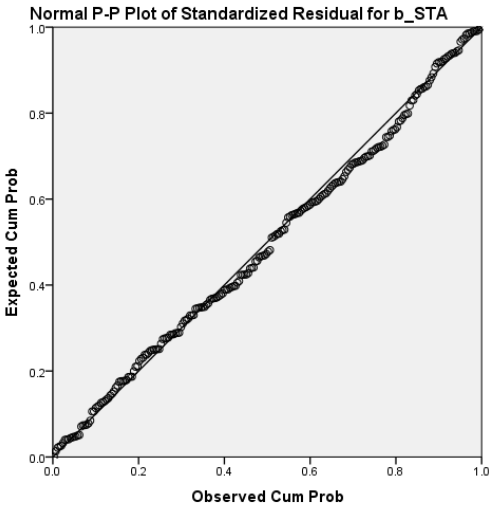


Figure 30: Graphs for checking assumptions for baseline CAA





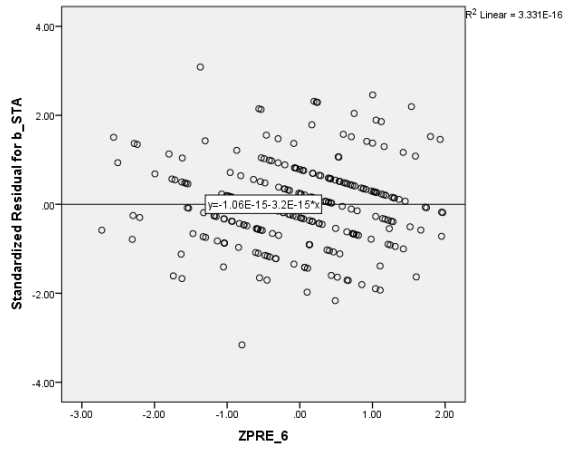
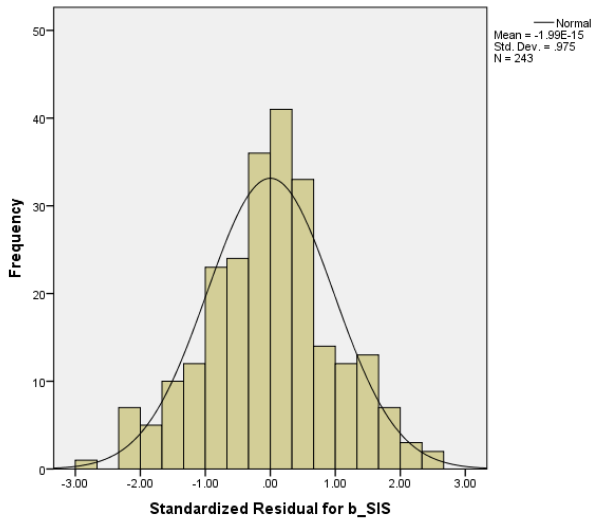
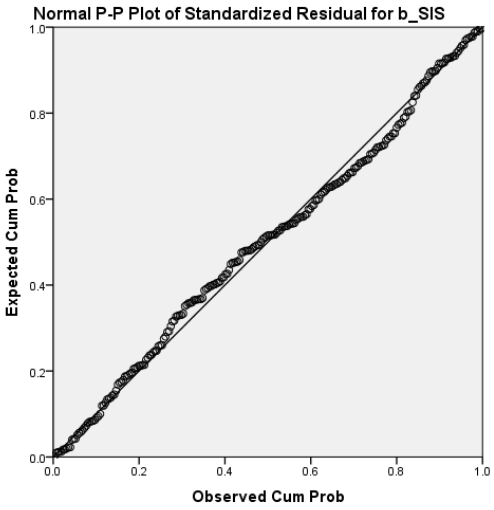


Figure 31: Graphs for checking assumptions for baseline STA





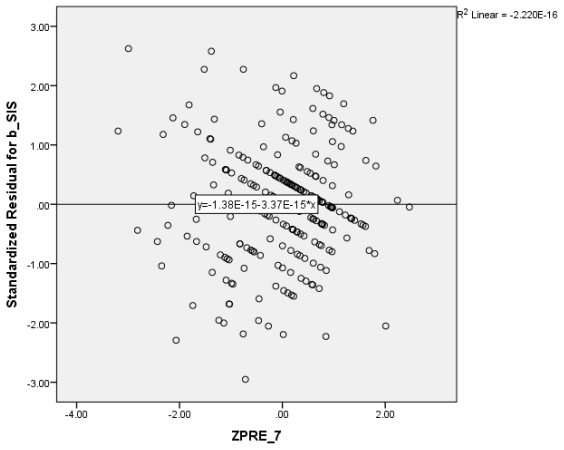
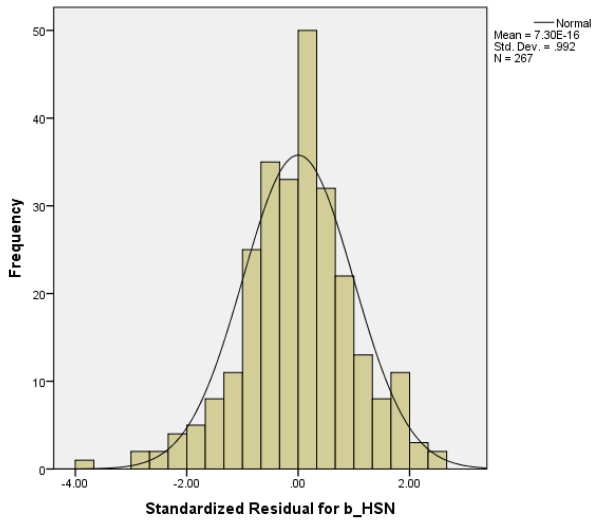
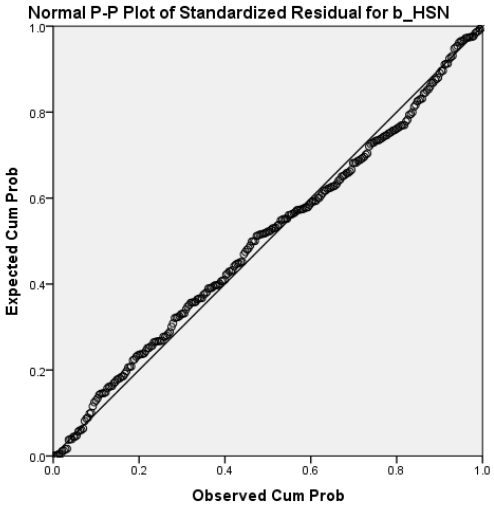


Figure 32: Graphs for checking assumptions for baseline SIS





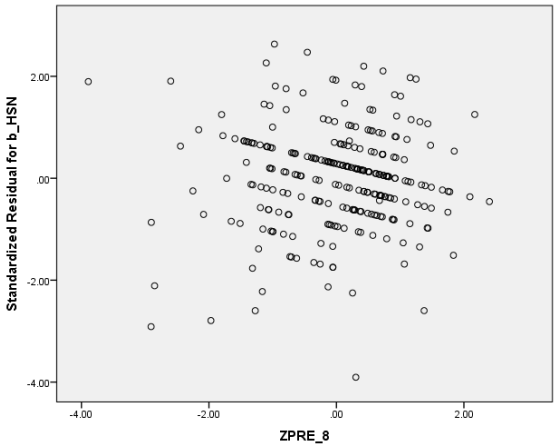


Figure 33: Graphs for checking assumptions for baseline HSN

Appendix 22: Systematic review- self-management intervention in the included studies

Table 28: Details of self-management intervention in the included studies

Author year	Sample size, condition	Self-management programme details	Duration	Follow-ups
Broderick 2014	256, Osteoarthritis knee/ hip	CBT based coping programme, group based	10 sessions, 30 to 45 minutes each	6 and 12 months
Buszewicz 2014	812, Osteoarthritis hips/ knees	Education booklet and course, group based	Not mentioned	4 and 12 months
Carpenter 2014	141, Chronic low back pain	Online CBT based self-management course with 6 sequential chapters	6 to 9 hours	6 weeks
Ersek 2003	45, Chronic pain	group based session in the retirement facilities	8 sessions, each 90 minutes	3 months
Haas 2005	109, Chronic low back pain	group based session led by lay leaders	150 minutes class	6 months
Hamnes 2012	150, Fibromyalgia	Based on CBT and didactic relations model group based	1 week inpatient programme	3 weeks
LeFort 1998	110, Chronic pain	Standardised psychoeducational group based	2 hours each week, for 6 weeks	3 months
Naylor 2008	55, Chronic pain (musculoskeletal)	Self-monitoring, review of skills, guided behavioural rehearsal of pain coping skill, individual via telephone	patient dependent	8 months
Newman 1991	180, Osteoarthritis and rheumatoid arthritis	Arthritis self-help course plus Arthritis Help Book, group based	3 weeks	3 weeks
Nicholas 2013	141, Chronic pain	The Pain Self-Management, group based	2 hours twice a week for 4 weeks (16 hours)	1 month
Nicholas 2014	140, Chronic pain	Led by psychologists, physiotherapists, pain specialists, rehab specialists and nurses, group based	120 hours inpatient	12 months
Riva 2014	51, Chronic back pain	Library and the First Aid section of the programme, and a Frequently Asked Questions, online interactive	not applicable	8 weeks

Trudeau 2015	245, Osteoarthritis, ankylosing spondylitis, rheumatoid arthritis	Online patient education intervention guided by principles of CBT	20 minutes per week for 4 weeks	6 months
Wilson 2014	92, Chronic non-cancer pain	Online Chronic pain management programme	2 months	6 months