BACK-to-FIT™
let us help you to help yourself

Development and preliminary evaluation of a digital health intervention to facilitate physical activity and exercise self-management in people with low back pain

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Abstract

Background: Self-management of complex and multifactorial low back pain (LBP) is challenging, and people increasingly use the internet to self-manage LBP. Yet, existing interventions provide only general advice and overall are of poor quality.

Aim: To develop and evaluate an evidence, theory and practice based digital health intervention (DHI) to facilitate exercise self-management (ESM) in people with LBP.

Methods: BACK-to-FIT^{TM} was developed and evaluated in three phases.
Phase-1: Identifying the evidence base using a systematic review and meta-analysis on the effect of seDeveloplf-management interventions (SMIs) with exercise components. *Phase-2:* Identifying the key intervention functions to deliver tailored ESM for LBP using a focus group study and a mixed methods survey involving stakeholders. *Phase-3:* Developing a prototype version and preliminary evaluation of usability, technology acceptance, potential health benefits and user experience.

Results:
Phase-1: SMIs with exercise have moderate but significant, short- intermediate- and long-term positive effect on pain and disability in chronic LBP. Not all SMIs have exercises tailored to persons' needs and capabilities.
Phase-2: Focus group discussions with 14 physiotherapists identified four themes including a holistic LBP assessment, exercise and physical activity in LBP management, education, and optimum LBP self-management. The survey with 71 LBP experts, reported 17 key subjective questions and 5 physical tests as important to be included in the assessment when designing a SMI in LBP.
Phase-3: The BACK-to-FIT^{TM} intervention prototype was developed using findings from phase 1 and 2. Twelve participants used BACK-to-FIT^{TM} for four weeks, demonstrating above average usability, high technology acceptance, promising early results of health benefits and positive user experience.

Conclusion: Whilst the results are promising BACK-to-FIT^{TM} is mainly centred around helping people to be active and exercise. LBP is heterogenous and reasons for poor ESM are varied. Future research needs to better understand this heterogeneity and modify interventions accordingly to address the complexity of ESM.

Publications & Presentations

Publications

- Rathnayake, A.P., Sparkes, V., Sheeran, L., 2021. What is the effect of low back pain self-management interventions with exercise components added? A systematic review with meta-analysis. Musculoskeletal Science and Practice, 56, p.102469.

Presentations

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- Rathnayake, A.P., Sparkes, V., Sheeran, L., The effect of low back pain self-management interventions including exercise components and does tailoring exercises to person's needs matter? A systematic review with meta-analysis. British Orthopaedic Research Society Annual Meeting, London, UK (2020) Oral presentation.

- Rathnayake, A.P., Sparkes, V., Sheeran, L., Back-to-Fit; Development of a web-based self-management tool for Low back pain – Preliminary findings. Society for Back Pain Research Annual conference, Sheffield, UK (2019) Poster presentation.

- Rathnayake, A.P., Sparkes, V., Sheeran, L.: Back-to-Fit; Development of a web-based self-management tool for Low back pain. Speaking of Science Conference, Cardiff University (2019) Oral presentation.

Dedication

This thesis is dedicated to my beloved father, the late Mr W.S Rathnayake, who passed away only five months into this PhD. If you were with us, I am sure you would be the proudest to see this. Your memory forever is a comfort and a blessing.

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Table of Contents

Abstract .... **i**

Publications & Presentations .... **ii**

Dedication .... **iii**

Acknowledgements .... **iv**

Table of Contents .... **v**

List of Tables .... **viii**

List of Figures .... **ix**

List of abbreviations .... **xi**

Chapter 1: Introduction and background **2**

1.1 Low back pain 2
1.2 Self-Management 5
1.3 Digital health interventions 7
1.4 Overview of the thesis 9

Chapter 2: Literature review **12**

2.1 Introduction 12
2.2 Literature search strategy 12
2.3 Low back pain 15
2.4 Assessment of patients with LBP 21
2.5 Management of LBP 24
2.6 Low back pain, physical activity and exercises 25
2.7 LBP self-management 30
2.8 Digital health interventions and LBP self-management 35
2.9 Summary and justification 51
2.10 Aims and research questions 52
2.11 Outline of phases 49

Chapter 3: Methodology **54**

3.1 Introduction 54
3.2 Overview of Research paradigms 54
3.3 Overview of methodological approaches 56
3.4 Sampling 63
3.5 Generating research questions and choosing an appropriate methodology 64
3.6 Chapter Summary 77

Chapter 4: What is the effect of low back pain self-management interventions with exercise components added?: A Systematic Review with meta-analysis **78**

4.1 Introduction 78
4.2 Methods 79
4.3 Results 92
4.4 Outcome analysis 97
4.5 Discussion 99
4.6 Conclusion 103

Chapter 5: Key components in a self-management intervention to encourage people with LBP to be physically active and exercise: Practice and perspectives of clinicians....105

5.1 Introduction 105
5.2 Aims 105
5.3 Methods 106
5.4 Results 112
5.5 Discussion....131
5.6 Strengths and limitations 137
5.7 Conclusion 137

Chapter 6: What are the key assessment components recommended by experts to tailor an exercise self-management programme for people with LBP? A national survey....139

6.1 Introduction 139
6.2 Aims and objectives....140
6.3 Methods 140
6.4 Results 151
6.5 Discussion....162
6.6 Limitations....166
6.7 Conclusion 167

Chapter 7: Development of the BACK-to-FIT^TM intervention prototype....168

7.1 Introduction 168
7.2 Key features of the BACK-to-FIT^TM intervention prototype....168
7.3 The development process of the BACK-to-FIT^TM intervention prototype....172
7.4 Application features 174
7.5 BACK-to-FIT^TM intervention prototype 174
7.6 Behaviour change techniques present in BACK-to-FIT^TM....188
7.7 Chapter Summary....194

Chapter 8: Usability, technology acceptance, potential health benefits and user experience of BACK-to-FIT^TM: A mixed methods study....195

8.1 Introduction 195
8.2 Aims and research questions 195
8.3 Methods 196
8.4 Results 218
8.5 Discussion....240
8.6 Conclusion 257

Chapter 9: Overall Summary 259

9.1 Introduction 259
9.2 Phase 1....260
9.3 Phase 2....261
9.4 Phase 3....263
9.5 Strengths and limitations 264
9.6 Future Recommendations 267

Chapter 10: Conclusion 268

References....270

Appendix 1: Publication 312

Appendix 2: A summary of the existing DHIs focused on LBP self-management................313

Appendix 3: The participant recruitment email - Phase 2: Focus group study.....................320

Appendix 4: The participant information sheet - Phase 2: Focus group study.....................322

Appendix 5: Topic guide - Phase 2: Focus group study 326

Appendix 6: Topic guide - Phase 2: Focus group study: Pilot version 329

Appendix 7: Ethical approval letter - Phase 2: Focus group study and the survey..............332

Appendix 8: The consent form – Phase 2: Focus group study...335

Appendix 9: Codes and themes generated in the data analysis – Phase 2: Focus group study..337

Appendix 10: The thematic map – Phase 2: Focus group study...341

Appendix 11: The online survey questionnaire - Phase 2: Survey study 343

Appendix 12: The participant information sheet - Phase 2: Survey study...........................353

Appendix 13: Downloadable summary of the exercise programmes - BACK-to-FIT^{TM} intervention...358

Appendix 14: Self-screening for red flags and serious pathologies before the use of BACK-to-FIT^{TM} intervention 360

Appendix 15: Recruitment email and e–leaflet - Phase 3: Evaluation study.......................363

Appendix 16: Eligibility check, self-screening, informed consent and baseline questionnaire...365

Appendix 17: The system usability scale items - Phase 3: Evaluation study.......................376

Appendix 18: The system usability scale 378

Appendix 19: The technology acceptance measurement items - Phase 3: Evaluation study..380

Appendix 20: Interview topic guide - Phase 3: Evaluation study 382

Appendix 21: Ethical approval letter – Phase 3: Evaluation study 385

Appendix 22: The participant information sheet – Phase 3: Evaluation study 387

List of Tables

Table 2.1	Search strategies for the literature review
Table 4.1	Literature search strategy
Table 3.1	Behavioural analysis for the project guided by COM-B model
Table 4.2	Characteristics of included studies
Table 5:1	Work experience and work settings of the physiotherapists who participated in focus group discussions
Table 5.2	Themes and subthemes emerged from data
Table 6.1	Keywords and the search strategy used in the literature search
Table 6.2	Survey participants' demographic data
Table 6.3	Summary of descriptive analysis of the responses.
Table 6.4	Summary of the deductive thematic analysis of participants' suggestions on the new items to add for history taking and physical assessment
Table 7.1	Complete list of exercises included the 'Worried back' module
Table 8.1	TAM3 measurement items used in this study
Table 8.2	Summary of how NPT informed focus group topic guide
Table 8.3	SUS Adjective rating scales
Table 8.4	Descriptive data for participant characteristics
Table 8.5	Mean scores, standard deviations and the ranges of individual measurement items of system usability score.
Table 8.6	Mean scores, standard deviations and the ranges for technology acceptance measurement items
Table 8.7	Clinical outcomes and physical activity levels at the baseline and on completion of the 4-week intervention
Table 8.8	Normalisation process theory analysis of BACK-to-FIT^{TM}

List of Figures

Figure 2.1 Multidimensional factors associated with resilience and vulnerability to disabling low back pain
Figure 3.1 Key elements of the development and evaluation process
Figure 3.2 The COM-B model of behaviour
Figure 3.3 Model of action of the proposed intervention prototype
Figure 3.4 Normalisation process theory (NPT) analysis as a "trial killer"
Figure 4.1 PRISMA flow chart of selection of trials
Figure 4.2 Risk of bias summary – evaluated using quality appraisal criteria for RCTs from Cochrane RoB 2 tool
Figure. 4.3 Forest plots of comparison: Short-term, intermediate and long-term effect on pain intensity
Figure. 4.4 Forest plots of comparison: Short-term, intermediate and long-term effect on disability
Figure 6.1 Survey questionnaire layout
Figure 6.2 Agreement on all items within the low back pain domain
Figure 6.3 General health domain- agreement of the items on their importance
Figure 6.4 Work and lifestyle domain- agreement of the items on their importance
Figure 6.5 Exercise/activity planning domain- agreement of the items on their importance
Figure 6.6 Physical assessment tests and movements - agreement of the items on their importance
Figure 7.1 Screenshot of the BACK-to-FIT™ home page
Figure 7.2 A screenshot of the first three sections of module 1 of the BACK-to-FIT™
Figure 7.3 A screenshot of the "Exercise Levels" and "Listen to your body" sections on the module page
Figure 7.4 A screenshot of the last three sections of the module 1 page, information on further help, tabs on BACK-to-FIT™ home page and to the next module
Figure 7.5 A screenshot of the first sections of module 2 showing two scenarios
Figure 7.6 A screenshot showing the three interactive sections with information on LBP and exercising and working with LBP
Figure 7.7 A screenshot of the worried back module page

Figure 7.8 A screenshot of the active back module
Figure 8:1 The original TAM
Figure 8.2 The TAM2 model
Figure 8.3 The TAM3 model
Figure 8.4 BACK-to-FIT™ participants' flow chart
Figure 8.5 Thematic map of the inductive thematic analysis of the interview data

List of abbreviations

BCT	Behaviour Change Technique
CBT	Cognitive Behavioural Therapy
CSP	Chartered Society of Physiotherapists
CI	Confidence Interval
CLBP	Chronic Low Back Pain
DHI	Digital Health Intervention
ESM	Exercise Self-Management
e-Health	Electronic Health
ES	Effect Size
GRADE	Grading of Recommendations Assessment Development and Evaluation
GDPR	General Data Protection Regulation
ICT	Information And Communications Technologies
IMU	Inertial Measurement Unit
IP	Internet Protocol
IPAQ	International Physical Activity Questionnaire
LBP	Low Back Pain
MACP	Musculoskeletal Association of Charted Physiotherapists
MCID	Minimal Clinically Important Difference
mHealth	Mobile Health
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
NPRS	Numerical Pain Rating Scale
NPT	Normalisation Process Theory
NSLBP	Non-Specific Low Back Pain
ODI	Oswestry Disability Index
PA	Physical Activity
PIS	Participant Information Sheet
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomised Controlled Trial
RMDQ	Rolland Morris Disability Questionnaire
RoB	Risk of Bias
SCT	Social Cognitive Theory
SEE	Self-Efficacy for Exercise
SMS	Self-Management Support

SME	Self-Management Education
SLR	Straight Leg Raise
SMD	Standardised Mean Difference
SMI	Self-Management Intervention
SBPR	Society for Back Pain Research
SSL	Security Socket Layers
SUS	System Usability Scale
TA	Thematic Analysis
TAM	Technology Acceptance Model
UK	United Kingdom
USA	United States of America
VAS	Visual Analogue Scale
WHO	World Health Organisation

Chapter 1: Introduction and background

1.1 Low back pain

Low back pain (LBP) is an extremely common and costly condition which affects most people irrespective of their age and gender (Hoy et al. 2012; Hartvigsen et al. 2018). It has a reported lifetime and global prevalence of 84% (Airaksinen et al. 2006) and 31% (Hoy et al. 2012) respectively. In the United Kingdom (UK) around one-third of the adult population is affected by LBP annually, with approximately 20% consulting their general practitioner (Macfarlane et al. 2006). As a result, approximately 2.6 million people in the UK seek advice from primary care on LBP (ArthritisResearchUK 2002).

An array of definitions and terms relating to the location of pain are used interchangeably in LBP research. Dionne et al. (2008) defined LBP pain as being typically between the lower rib margins and buttock creases, whereas Waddle and Schoene (2004) refer to pain which occurs in the lumbosacral region that will not radiate below the knee without signs of nerve root compromise. Hartvigsen et al. (2018) identified LBP as a symptom or unknown abnormalities rather than a disease in itself. For this study, the definition from Van Tulder et al. (2006) was adopted which reflects that LBP is a pain and discomfort, localised below the costal margin and above the inferior gluteal folds, with or without leg pain.

With regards to the chronicity of LBP, there is a lack of agreement between various authors. LBP that lasts for longer than 7-12 weeks is sometimes identified as chronic low back pain (CLBP). Meanwhile, some studies have defined LBP persisting between 6-12 weeks as sub-acute low LBP and pain persisting more than 12 weeks as CLBP (Van Tulder et al. 2006). Nevertheless, it is suggested that defining the chronicity solely by the duration of symptoms is not accurate and should not be considered as chronic due to its complex association with biopsychosocial factors (Hestbaek et al. 2003a). Andersson (1999) argues that CLBP is a recurring back pain as it intermittently affects an individual over a long period. However, existing studies discussed in this thesis have always defined CLBP according to the chronicity of the pain unless mentioned otherwise.

A majority of LBP patients have an unknown nociceptive drive (Maher et al. 2017) hence they are classified as having a ‘non-specific low back pain’ (NSLBP). More than 85% of patients who present in the primary care setting with LBP as their primary complaint, fall into this group and do not have a known pathoanatomical cause (Henschke et al. 2009) or a structural cause confirmed through radiological investigations (Balagué et al. 2012). Nevertheless, some may present with specific and serious causes of LBP including malignancy, infections, vertebral fractures, and cauda equine syndrome. However, these account for only a minor proportion of cases and would require immediate identification and specific management relevant to the cause of the pain and symptoms (Koes et al. 2010). NSLBP is also referred to as mechanical low back pain due to its clear association with movements and mechanical loading of the spine and surrounding soft tissues (Will et al. 2018). For the purpose of this thesis, people with NSLBP will be the population of interest. Therefore, all the literature discussed in this thesis focuses on NSLBP and accordingly the terms LBP and CLBP will always refer to NSLBP and chronic-NSLBP.

NSLBP is often provoked with movement and mechanical loading and can produce a peripherally driven nociceptive sensitisation (McGill 2004) which is principally generated by the activation of peripheral nociceptive sensory fibres (Bogduk 2004). However, there is a growing body of literature which suggests that ongoing nociceptive sensitisation as a result of mechanically provoked pain and abnormal tissue loading can result in CLBP. Accordingly, recurring NSLBP which does not settle as an acute episode can cause ongoing nociceptor sensitisation leading to a chronic pain state (O’Sullivan 2005). Yet, tailored physiotherapy interventions have shown promising outcomes in the management of pain including CLBP (O'Sullivan et al. 1997). However, poorly controlled sustained peripheral nociceptive input that occurs in CLBP can manifest changes at spinal cord and cortical levels causing central sensitisation of pain (Zusman 2002). Such clinical manifestations warrant rather comprehensive interventions addressing both physical and cognitive aspects including approaches such as cognitive behavioural therapy, mindfulness, pain neuroscience education and cognition targeted exercise therapy (Nijs et al. 2017).

Exercise programmes have been found to have moderate effects in reducing LBP and improving function (Hayden et al. 2005a; Van Middelkoop et al. 2011). The most effective treatments for LBP include individually designed exercise programmes delivered with supervision (Hayden et al. 2005b). National Institute for Health and Care Excellence (NICE) guidance (NICE 2019) recommends exercises as the first-line treatment. In addition to exercise, physical activity (PA) has been recognised as a prime strategy in international guidelines for the primary care management of LBP and patients are frequently advised to stay active (Koes et al. 2010).

Furthermore, self-management strategies are highly recommended for long-term management and are considered as a promising solution to improve the outcomes of people living with LBP (May 2010; Beattie and Silfies 2015). However, according to the existing findings, available self-management revealed moderate quality evidence to support moderate effects on pain intensity, small to moderate effects on disability in CLBP (Du et al. 2017) and small effects on pain and disability in people with LBP of any duration (Oliveira et al. 2012).

Adherence is necessary to improve the effectiveness of any exercise programme (Organization 2003). Compared with patients who demonstrated poor compliance, patients who adhered to the prescribed exercise had a greater improvement in physical function (Di Fabio et al. 1995). However, research findings revealed poor exercise adherence amongst people with LBP, thus confirming that between 50% and 70% did not adhere to their prescribed home exercise programmes (Härkäpää et al. 1991; Friedrich et al. 1998). This could be explained by the interplay of various psychological factors associated with LBP, these include fear of movement, emotional distress, low self-esteem and anxiety leading to a vicious cycle of pain and disability (Chen et al. 2018; Linton et al. 2018; O'Sullivan et al. 2018). Hence, despite the recommendations and guidelines, encouraging people in pain to be physically active and exercise is challenging.

Along with the rapid development in the field of digital health technologies, an array of self-management applications and interventions for LBP have been launched in recent years (Chiauzzi et al. 2010; Carpenter et al. 2012; Geraghty et al. 2015; Irvine et al. 2015; Amorim et al. 2016). However, the evidence base for the effectiveness of these interventions to facilitate self-management of LBP remains poor (Nicholl et al. 2017). Furthermore, these existing platforms provide only general guidance and advice, they have failed to acknowledge the complexity of LBP and poor self-management and exercise adherence among people with LBP. Even though tailoring of the digital interventions to individual patient needs is advocated to improve engagement (O'Connor et al. 2016), it is not clear how these existing interventions achieve this within their intervention components (Nicholl et al. 2017). The above evidence indicates the necessity for further research to focus on ways in which these digital interventions could be advanced, more effective exercise-based management strategies could then be incorporated to facilitate self-management of people with LBP.

1.2 Self-Management

Self-management is considered to be a vital and effective strategy in the treatment of chronic illnesses including LBP. (Lorig et al. 2001; Bodenheimer et al. 2002). According to best practice guidelines and established recommendations, similar to exercise, self-management is also recommended as a key element in the LBP management pathway.

The interchangeable use of self-management, self-management support (SMS), patient education, self-management education (SME), self-care, self-monitoring, self-help and social support is noted in the literature (Walker 2003). Nevertheless, an in-depth analysis of this literature revealed a substantial difference in the meanings of the aforementioned terms. Barlow and colleagues (Barlow et al. 2002) identified self-management as the person's ability to deal with the demands of chronic illness including symptoms, treatments, lifestyle changes and physical or social consequences. It has also been recognized as management of the daily impact of these chronic illnesses by the individual (Cooper et al. 2009). Most of the existing definitions of self-management are related to programmes organised by a clinician or respective personnel to facilitate patients with the management of their problem (May 2010). These often include attempts at behavioural and health changes of the patients by teaching them problem-solving, goal setting and planning action with regard to their illnesses (Lorig 2002).

Self-management generally refers to the implementation of multilevel changes in various settings, these include health care systems and the community, to facilitate an individual’s management of their condition (Glasgow et al. 2003; Rothman and Wagner 2003). In LBP self-management most commonly includes patient education. Patient education is essentially based on the delivery of knowledge and information for a specific disease (Bodenheimer, 2002, D’Zurilla, 2010).

The discrepancy between the number of people within the general population who report musculoskeletal pain or LBP, and the number actually seeking care for these conditions, suggests that the remainder are self-managing these conditions. May (2010) describes three types of patient clusters that can be identified within chronic musculoskeletal patient populations. The first group (1) are patients at one end of the continuum of self-management who never seek medical advice or consultation from any healthcare professional. This group uses its own strategies to maintain functionality instead. In the middle of this continuum (2), are those who manage their conditions with minimal support from healthcare professionals and who might seek help occasionally but are largely self-managed. Whereas the last group (3), at the opposite end to (1), on the continuum seek regular support and advice from healthcare professionals to resolve their problems. Consequently, May (2010) explains the self-management in the chronic musculoskeletal patients in two ways, as completely autonomous self-care and as largely self-care whereby the patients collaborate with one or more healthcare workers occasionally. The latter could benefit from the approaches previously discussed to guide them towards collaboration with clinicians in order to achieve the anticipated outcomes.

Several key elements of this process are explained in the literature which distinguishes self-management programmes from traditional patient management. These include (a) self-efficacy building; (b) self-monitoring; (c) goal setting and action-planning; (d) decision-making; (e) problem-solving; (f) self-tailoring; and (g). A significant variation can be noted in the method of delivery of these programmes such as the mode (face-to-face, internet, telephones/mobile phones), the audience (group, individual), the duration (single session, several months, ongoing), the frequency (once a week, once every two months) and the personnel (health care professionals, lay leaders) (Kroon et al. 2014).

1.3 Digital health interventions

According to the World Health Organisation (WHO) (2016), digital health is defined as the use of digital, mobile and wireless technologies to support the achievement of health objectives. This describes the general use of information and communications technologies (ICT) commonly referred to as mhealth or eHealth. At the early stage, most of the web-based interventions were exclusively delivered through computers and therefore named as eHealth (electronic Health). The delivery of health information and interventions via mobile and wireless technologies with or without health apps is commonly known as mHealth (mobile health) ((Bert et al. 2014; Agarwal et al. 2016). The application in digital health technologies ranges from diagnoses of illnesses to medical education or self-management of chronic diseases.

With the exponential growth of internet users across the globe during the past decade, digital health interventions (DHIs) including web interventions and mobile health apps to promote healthy behavioural changes have become extremely popular (Ritterband and Tate 2009). In 2018 an estimated 55.1% of the world population had access to the internet and the Europe only experienced a usage of 85.2% (InternetWorldStats 2018). The ownership and usage of smartphones also increased rapidly during recent years and, in the UK, an average of 83% of the population currently owns a smartphone (Statista 2018). A large proportion of patients with chronic diseases, and also healthy people, engage with mHealth and eHealth applications in order to self-monitor their diseases and access information about their health and activities. To date, many digital interventions are readily accessible for patients, these cover a large spectrum of health conditions including self-management of chronic diseases and healthcare support during pregnancy. LBP is one of the most common conditions with DHIs for self-management (Hamine et al. 2015; Overdijkink et al. 2018). The surge in development and implementation of DHIs has become even more prominent since the COVID-19 pandemic as a response to the increased uptake of technology (Sarbadhikari and Sarbadhikari 2020). With restricted accessibility to conventional face-to-face methods during the pandemic, healthcare providers were challenged to continue their service provision using DHIs as a substitute. The use of many of these DHIs continues and they have become highly relevant tools in the management of chronic conditions including LBP (Dantas et al. 2020; Nagata 2021).

Empirical research suggests there are a number of advantages of DHIs. Some of these are, the ability to deliver more personality relevant tailored information and feedback (de Vries and Brug 1999), the ability to reach a broader population cost-effectively and easy accessibility for individuals at any given point of time or place (Bennett and Glasgow 2009; Krebs et al. 2010; Schulz et al. 2014). Albeit the fact that mHealth interventions cannot replace the patient-to-therapist interaction, they provide many benefits for physiotherapy management of patients. Some of these include the ability to collect reliable outcome measures, that data can be monitored outside the clinical visits, opportunity for posture and biomechanics feedback, patient education and motivation (Dicianno et al. 2015).

Thus, it would be of interest to establish the effectiveness of these DHIs with regard to their expected outcomes. Evidence from a recent systematic review and meta-analysis demonstrated only a small statistically significant effect of internet-based interventions on promoting health-related behaviour changes (Webb et al. 2010). Meanwhile, several studies claim limited or mixed evidence towards the effectiveness of mobile health applications in the management of chronic diseases (Whitehead and Seaton 2016; Overdijkink et al. 2018). Conversely, most of these applications demonstrate great usability and potential to improve treatment adherence of the respective chronic diseases (Whitehead and Seaton 2016; Overdijkink et al. 2018).

In summary, LBP is a common problem with a high global and lifetime prevalence. A recurrence of LBP is seen in many people, this leads to more complex clinical manifestations including centrally sensitised sensations. Therefore, effective management of recurring LBP is vital in which, exercise and self-management play a key role (NICE 2019). With recent advances in technology and the surge in the uptake of using digital devices, DHIs have the potential to deliver self-management programmes to cater for the needs of people with LBP so that they can effectively self-manage their condition. Hence the overall aim of this thesis was to develop and evaluate an evidence, theory and practice based DHI to facilitate both exercise and self-management (ESM) in people with LBP. This was done in three phases as decried below.

1.4 Outline of phases

Phase 1 focused on identifying the evidence base, for this purpose a systematic review and a meta-analysis of the effect of LBP SMIs, including exercise components, was conducted. This phase aimed to answer the first research question, thus informing the development process of the intervention.

Phase 2 was concerned with identifying and developing theory related to the project and answered the second research question. This included two distinct studies which illustrated physiotherapists' perspectives and practices, this fed into the development of the digital intervention to promote PA and ESM in people with LBP. The first study, a focus group study, attempted to identify and explore the key components of LBP ESM and how the optimum ESM can be delivered via a DHI. A national survey, the next study of this phase, looked at the practices and perspectives on LBP assessment among clinicians and researchers. Findings from these studies informed the content and development process of the intervention, it identified recommendations for further development of a tailored digital intervention which would deliver an optimum ESM programme for people with LBP to improve their exercise engagement and level of PA.

Phase 3 was the development and the preliminary evaluation of the prototype of the intervention answering research question 3. This included identifying key elements from the findings of phase 1, 2 and the literature to develop BACK-to-FIT^{TM} intervention prototype as well as evaluating the usability, technology acceptance, potential health benefits and user experience of BACK-to-FIT^{TM}. A single-arm follow-up study was conducted, and the participants were given access for 4 weeks before the evaluation of the BACK-to-FIT^{TM} prototype.

1.5 Overview of the thesis

Chapter 1 is a brief introductory chapter providing the context for the study and outlines the research aims and questions. The topics of LBP, DHIs and self-management are introduced, and definitions are discussed. Lastly, the format of the study and the structure of the thesis is described.

Chapter 2 first presents a review of the relevant literature and provides a background overview of the models of LBP and discusses the problem of LBP. This is followed by literature relevant to LBP assessment and management including PA, exercise self-management and it discusses the associated theories of health behaviour change. The final sections include an up-to-date literature review appraising the currently available DHIs to promote ESM of people with LBP, a justification and the aims of this study.

Chapter 3 discusses the general methodological paradigms and introduces the theories and frameworks used when discussing the methodological origins of the research. It explains how the research questions were generated; this is followed by a discussion of the methodological considerations to justify the most appropriate methods to answer each research question.

Chapter 4 describes the systematic review and the meta-analysis conducted to answer the first research question and corresponds to phase 1 of the study. It aims to identify the effects of SMIs with added exercise components in people with LBP and results are published as open access in Musculoskeletal Science and Practice journal (included as appendix 1).

Chapter 5 describes the first study of phase 2 which is a focus group study to explore musculoskeletal physiotherapists' practice and perspectives on ESM in people with LBP. The chapter contains the methods and results sections followed by a brief discussion. Findings from this study informed the content of BACK-to-FIT™ and helped to determine the intervention functions.

Chapter 6 presents the second study of phase 2, a national survey among clinicians and researchers which aimed to identify the key components of LBP assessment. This chapter contains methods and results sections followed by a brief discussion of the findings. It is assumed that the results of this study will be instrumental in further developing the intervention in order to deliver a more bespoke ESM for people with LBP.

Chapter 7 discusses the process of developing and designing the prototype of BACK-to-FIT™ digital intervention and represents Phase 3. It describes the process of determining the content including behaviour change techniques employed within the intervention using findings from phases 1 and 2.

Chapter 8 explains the preliminary evaluation of BACK-to-FIT™ and also represents phase 3. It contains methods and results sections followed by a brief discussion of each of the outcomes.

Chapter 9 is the overall summary which brings the headline results of all 3 phases together (Chapters 3, 4, 5 and 6). In addition, the strengths and limitations of the overall thesis and considerations for future directions of research and development will be discussed.

This thesis concludes with Chapter 10 which presents an overall conclusion.

Chapter 2: Literature review

2.1 Introduction

As two keystones in the management of LBP, exercise, and self-management have been common research topics in recent years. However, in order to develop a DHI to facilitate ESM, many elements should be considered. This chapter aims to discuss the literature relevant to the background of LBP, assessment, management and self-management of LBP and DHIs in LBP. Finally, it presents the rationale for the development of a novel intervention to improve PA and ESM in people with LBP, aims and research questions for this thesis. Due to the context of this research study the literature review only focuses on non-specific LBP (NSLBP) unless it is specifically mentioned.

2.2 Literature search strategy

A review of the literature was performed to identify literature relevant to LBP on models of LBP diagnosis, its assessment, management, self-management and DHIs to support self-management in LBP. Additionally, literature concerning behaviour change and development of DHIs was also performed. The literature review was comprised of four parts:

1. LBP and models of diagnosis and classification of LBP
2. Assessment of LBP
3. Management, PA and exercise, and self-management of LBP
4. DHIs and LBP self-management

A search strategy was developed for the following electronic databases CINHAL, EMBASE, Medline, AMED, PsycINFO and PubMed for the literature published before 2021, using only English text from established peer-reviewed journals. These articles were reduced based on duplications, then manually searched for relevance. The reference lists from the included articles were also reviewed for relevant studies and also academic books. Table 2.1 details the search strategy combinations of key terms and the inclusion criteria for all four searches.

Table 2.1: Search strategies for the literature review

Search category 1	Boolean search operators	Search category 2	Boolean search operators	Search category 3
Keywords for models of diagnosis and classification of LBP				
Pain **OR** somatosensory **OR** Ache **OR** Backache **OR** lumbago **OR** back pain **OR** low back pain **OR** lumbar spine **OR** lumbar ache **OR** lumbar pain **OR** chronic low back **OR** Non-specific low back pain **OR** Non-specific chronic low back pain **OR** NSCLBP **OR** LBP **OR** CLBP	AND	Definition **OR** diagnosis **OR** history **OR** aetiology **OR** location **OR** duration **OR** response **OR** pain response	AND	Type **OR** subgrouping **OR** classification **OR** biopsychosocial **OR** mechanisms **OR** model
Keywords for assessment of LBP				
Backache **OR** lumbago **OR** back pain **OR** low back pain **OR** lumbar spine **OR** lumbar ache **OR** lumbar pain **OR** chronic low back **OR** Non-specific low back pain **OR** Non-specific chronic low back pain **OR** NSCLBP **OR** LBP **OR** CLBP	AND	Physical examination **OR** manual examination **OR** classification **OR** symptom response or pain response **OR** assessment **OR** subgrouping **OR** questionnaire **OR** physiotherapy assessment **OR** physical therapy assessment **OR** musculoskeletal	AND	Clinical indicators **OR** centralisation **OR** pain mechanisms **OR** pain clinical criteria **OR** peripheral neuropathic pain **OR** nociceptive pain **OR** central mechanisms of pain **OR** clinical reasoning **OR** central sensitisation

		assessment **OR** neuromusculoskeletal examination **OR** musculoskeletal physiotherapy		
Keywords for management and self-management of LBP				
Backache **OR** lumbago **OR** back pain **OR** low back pain **OR** lumbar spine **OR** lumbar ache **OR** lumbar pain **OR** chronic low back **OR** Non-specific low back pain **OR** NSCLBP **OR** LBP **OR** CLBP	AND	Evidence based **OR** guidelines **OR**	AND	Management **OR** self-management **OR** treatment **OR** therapy **OR** exercise OR activity **OR** physical activity **OR** therapeutic exercises **OR** education **OR** advice **OR** care **OR** physiotherapy **OR** physical therapy **OR** intervention **OR** rehabilitation **OR** Self-management intervention
Keywords for digital health interventions and LBP self-management				
Backache **OR** lumbago **OR** back pain **OR** low back pain **OR** lumbar spine **OR** lumbar ache **OR** lumbar pain **OR** chronic low back **OR** Non-specific low back pain **OR** NSCLBP **OR** LBP **OR** CLBP	AND	Mobile health interventions **OR** E-health interventions OR M-Health **OR** Electronic health **OR** digital health **OR** digital health interventions **OR** digital interventions	AND	Self-management **OR** self-care OR self-manage **OR** self-manageable **OR** self-managed **OR** self-help
Key: LBP – Low back pain, CLBP – Chronic low back pain, NSLBP - Nonspecific chronic low back pain, NSCLBP – Nonspecific chronic low back pain				

2.3 Low back pain

2.3.1 The problem of LBP

Over the years LBP has been ranked as the single most significant cause of disability worldwide (Vos et al. 2012) and it affects most people at some point in their lives with up to an 84% of lifetime prevalence (Airaksinen et al. 2006). Global point prevalence of LBP in 2015 has been reported as 7.3%, indicating that 540 million people were affected at any one time (Hartvigsen et al. 2018). It is a leading contributor to the number of years lived with disability worldwide (Vos et al. 2015). In the UK, LBP accounts for 11% of the total disability among the population (Andersson 1999; Juniper et al. 2009) and LBP has been reported as the commonest musculoskeletal problem out of all the general practitioner consultations (Jordan et al. 2010b). Furthermore, many people experience a recurrence of LBP during their lives with only short periods of remission in between (Hestbaek et al. 2003b).

Consequently, LBP has been a significant contributor to the health care costs in many countries, including the UK. According to a retrospective evaluation of 2009 patient data, in the UK alone, the treatment costs of LBP in primary care exceeded £2.8 billion per year (Hong et al. 2013) whereas in the USA, the estimated direct annual loss due to LBP was 34 billion dollars (Medicine 2011). Around 58% of LBP patients experience a rapid improvement in their pain and the level of disability in the first four weeks and slightly further improvements after three months (Pengel et al. 2003). However, LBP epidemiological research figures claim that one year after the first onset of LBP, more than 50% of individuals were still experiencing pain (Costa et al. 2009), and 16% of them were still unable to work one year after the onset of LBP (Hestbaek et al. 2003b). Direct and indirect costs associated with LBP pose an enormous economic burden on society and individuals (Maher et al. 2017). The direct costs related to LBP include medical or healthcare costs, the indirect costs are mainly incurred due to work absenteeism or productivity loss. Nevertheless, the total cost of LBP is likely to be underestimated, most of the studies have failed to capture the other non-medical costs such as transportation, complementary and alternative healthcare (Hartvigsen et al. 2018).

Working-age groups are reported to be the most common group worldwide to be affected by the disabling effects of LBP, irrespective of their country's economic status (Kassebaum et al. 2016). In Europe LBP is the commonest cause of medically certified sick leave and early retirement, whereas, in the United States it accounts for the highest number of lost working days when compared with other musculoskeletal conditions (Bevan et al. 2009; Kern Singh 2014). In addition to the direct or indirect, but significant economic impact, the effect of LBP and associated disabilities on an individual's quality of life are substantial (Stefane et al. 2013). For many individuals with LBP it might cause a disabling and significant negative impact on many aspects of their lives, including psychosocial and personal wellbeing, whilst for some it would only be self-limiting (Bunzli 2013).

2.3.2 Pain response

Knowledge of the underlying pain mechanisms and models used for diagnosing LBP has evolved significantly during recent decades. Pain is now identified as a neurobiological and behavioural response to an actual or perceived threat, where the key attempt would be to restore homeostasis and maintain body functions, rather than a single nociceptive response from an injury or tissue damage (Gifford and Thacker 2002). According to the mature organism model by Louis Gifford (Gifford 1998), pain response is a result of a scrutinising process carried out by the central nervous system. This involves assessment of information gathered from the environment, tissue injuries and the brain itself. The latter may include experience, knowledge, beliefs, culture, and past behaviours relevant to the situation which might influence the individual's ultimate pain response. Hence, currently LBP is acknowledged as a multidimensional complex biopsychosocial disorder with multiple manifestations (Waddell and Schoene 2004; Buchbinder et al. 2018). In the absence of serious or specific pathology it is identified as a "neurobiological and behavioural response to individual's actual and/or perceived threat to their body, lifestyle, or social circumstances and /or disruption to their homeostasis" (O'Sullivan et al. 2015). An acute presentation of disabling LBP is frequently identified as a pain "flare", rather than an injury related to tissue damage (O'Sullivan et al. 2018). This pain response is the output resulting from a combination of multidimensional factors (O'Sullivan et al. 2018), including neurophysiological, cognitive, psychological, social-cultural, contextual and lifestyle factors (O’Sullivan et al. 2015).These together ultimately influence the inflammatory process, levels of pain perception, levels of distress and behavioural responses of the patient (Hodges and Tucker 2011). This explains the significant variation and fluctuation of individual pain characteristics within the same person over time (Rabey et al. 2015). Furthermore, the individual patient responses and reactions to the pain will largely depend on that person's recovery traits and speed (Watson 2000). For example, fear of tissue re-injury or damage to the spine can result in activity avoidant behaviour, this can develop into progressive tissue deconditioning (Gifford et al. 2006). These changes can lead to social and work withdrawal, loss of general and health wellbeing of the individual, and can even cause episodes of depression (Feldt 2003; Gifford et al. 2006).

Whilst pain presents as the main clinical feature, LBP patients demonstrate an array of physical and psychological abbreviations associated with their LBP. Evidence suggests that individuals with LBP have reduced spinal range of motion and proprioception and exhibit a slowness in their movements compared to people without LBP (Laird et al. 2014). Fear of movement/re-injury is common among people with LBP and may subsequently lead to movement avoidance behaviour (Vlaeyen et al. 1995). A deconditioning paradigm in LBP has been a debated issue over many years with controversial evidence (Smeets et al. 2006b). However, it is evident that individuals' catastrophising and fear avoidant behaviour can result in disuse and increase disability as long-term manifestations (Vlaeyen et al. 1995). In addition, disabling LBP is often associated with low self-efficacy, pain distress (Lee et al. 2015), depression, anxiety, and inability to return to work (Andersson 1999; Gore et al. 2012). Despite the substantial recommendations and advice, engaging in exercise and being physically active can be a challenge for people with NSLBP due to the above factors.

Unless managed effectively with appropriately tailored interventions (O'Sullivan et al. 1997), recurrent acute episodes and sustained durations of pain with ongoing peripheral nociceptive sensation cause LBP to become a chronic and centrally sensitised clinical manifestation (Zusman 2002). Consequently, the management of the latter is complex, challenging and associated with increased healthcare costs and economic impact (Nijs et al. 2017). Given this and the complex nature of LBP, it is vital to encourage effective and prompt management of recurrent LBP, with prudently designed tailored interventions to meet the needs of individuals.

2.3.3 Models for the diagnosis and classification of LBP

Attempts at subgrouping or categorising people with LBP have been a widely argued topic. Several authors have proved that classification of patients with LBP into homogenous subgroups and the application of specifically tailored treatment approaches, according to their clinical presentation, enhances treatment efficacy (Leboeuf-Yde et al. 1997; McKinnon et al. 1997; Brennan et al. 2006; Sheeran et al. 2013; Luomajoki et al. 2018). Fillingim (2017) notes that understanding the presence of a spectrum of pain characteristics facilitates an understanding of the multidimensional interactions of an individual's presentation and can assist in guiding management. However, despite the continuous attempts and the untiring attention in LBP research, identifying an accurate sub-group or a classification system for the LBP remains a challenge. This is due to the unique nature of the experience of pain among individuals.

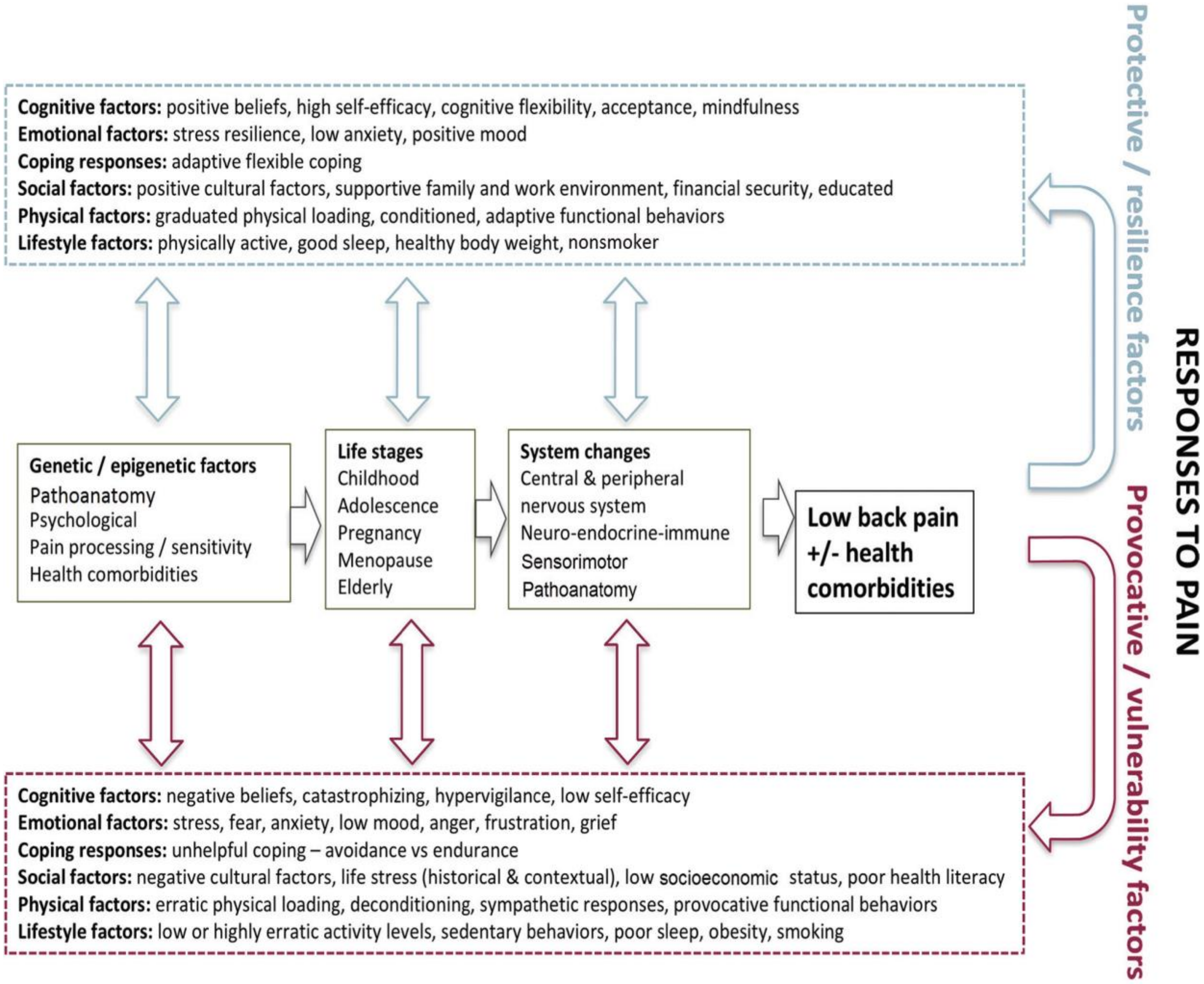
Most of the earliest classification systems were based on a uni-dimensional focus where only a single pathway of driving mechanisms was considered (McKenzie 1981; Bergstrom et al. 2001; Petersen et al. 2003; Van Dillen et al. 2003). Some of these include the patho-anatomical model (Nachemson 1999), Peripheral pain generator model (Laslett and Williams 1994; Bogduk 2004), Neurophysiological model (Woolf and Mannion 1999; Smart et al. 2011), Psychosocial model (Linton 2000; Zusman 2002), mechanical loading model and motor control model (Richardson and Jull 1995; Sahrmann 2002). However, it is clear from the growing evidence that since LBP is a multidimensional bio-psychosocial disorder, a broader approach based on a biopsychosocial model is required to deal with LBP rather than focusing on a unidimensional approach with a single set of dominant characteristics (McCarthy et al. 2004; Waddell and Schoene 2004). It has also been argued that considering a multidimensional framework in LBP classification will pave the way to better inform clinicians in their clinical assessment and management (O'sullivan 2012).

2.3.3.1 The biopsychosocial model of low back pain

Waddell first proposed the biopsychosocial model for LBP in 1987 (Waddell 1987), this conceptual model was the first to explain the interaction of pain, attitudes and beliefs, psychological distress, illness behaviour and social environment. This model emphasised the importance of exploring psychological and social contributors to the pathophysiological changes associated with LBP. Some of the psychosocial factors include fear avoidance behaviour (Boersma and Linton 2006; Leeuw et al. 2007), depression (Grotle et al. 2007; Henschke et al. 2008), pain catastrophising (Smeets et al. 2006a), patient expectation and beliefs about the condition (Symonds et al. 1996; Hilfiker et al. 2007) and self-efficacy (Hilfiker et al. 2007). These psychosocial factors contribute pathophysiological changes such as increased muscle activity and tension, these may alter spinal loading and cause subsequent physiological changes to other spinal structures (Bergenudd and Johnell 1991; Bongers et al. 1993). In line with the most recent research findings, LBP is now identified as a multidimensional health disorder where an interplay of psychological (e.g. negative beliefs, pain-related fear and emotional distress), social (e.g. life stress) and lifestyle factors (e.g. inactivity, poor sleep) coupled with unhelpful behavioural responses to pain (e.g. protective guarding and avoidance behaviours), lead to a vicious cycle of pain, distress and disability (Chen et al. 2018; Linton et al. 2018; O'Sullivan et al. 2018).

Considering the interaction, assessment and modulation of both biological and psychosocial factors is fundamental in LBP management (Gifford et al. 2006) and the prediction of patient outcomes (Watson 1999). This can be achieved using various methods, including interviews, physical examinations combined with or without review of radiological imaging, medical tests, and screening questionnaires (Elvey 2004; Waddell and Schoene 2004). A well-conducted clinical reasoning process, using the above traits, will allow the clinician to determine the predominant factors in the patient and whether the patient has adopted the disorder positively or negatively (O'Sullivan 2005). Given that, the necessity for a flexible, multidimensional clinical reasoning framework, that would enable the clinician to identify the various factors contributing to disabling LBP has been recognised (O'Sullivan et al. 2015). As a result, O'Sullivan and colleagues (2018) proposed a multidimensional framework that considers modifiable and non-modifiable factors associated with an individual's disabling LBP experience (Figure 2.1). This framework illustrates the multidimensional factors associated with resilience and vulnerability to disabling and interaction of modifiable and non-modifiable factors.

Figure 2.1: Multidimensional factors associated with resilience and vulnerability to disabling low back pain (Reproduced from O'Sullivan, P.B., Caneiro, J.P., O'Keeffe, M., Smith, A., Dankaerts, W., Fersum, K. and O'Sullivan, K., 2018. Cognitive functional therapy: an integrated behavioural approach for the targeted management of disabling low back pain. Physical therapy, 98(5), pp.408-423.)



These factors interact with each other with temporary changes influencing inflammatory processes, levels of pain perception, levels of distress, and behavioural responses (Hodges and Tucker 2011). These include physical factors (e.g. levels and patterns of mechanical spinal loading, work and sports activities), pathoanatomical factors (e.g. specific spinal pathologies such as a disc prolapse), psychological factors (e.g. cognitive factors such as negative beliefs, hypervigilance, low self-efficacy and emotional factors like fear of pain, anxiety, depression, heightened levels of frustration and anger etc.), social (e.g. family history of LBP, socioeconomic status, exposure to stressful life events and situations, unhelpful relationships etc.) and lifestyle factors (e.g. poor sleep, low levels of PA, and sedentary behaviour etc.). (O'Sullivan et al. 2015). The above factors could be positive or negative depending on the perception of the individual. Also, it is argued that when it is positive, these factors act as a protective mechanism leading to resilience to the LBP experience. Negative factors will provoke or increase the vulnerability of disabling LBP. Accordingly, this framework enables clinicians to identify modifiable factors unique to the individual and develop a bespoke management programme (O'Sullivan et al. 2018).

2.4 Assessment of patients with LBP

Performing a diagnostic triage as the initial step of any back pain assessment is recommended to rule out any serious (red flags) underlying pathology (e.g. infection, cancer, fracture), it often involves a series of questions with or without a physical examination (NICE 2020). Following the exclusion of any potentially serious pathology, a physiotherapy assessment often comprises a history taking where the physiotherapist collects details of the problem from the patient. A physical assessment is also undertaken in which the physiotherapist collects further data by physically examining the patient. In addition, during the history taking process the physiotherapist may review imaging and other investigations, and will ask about past treatment for the problem and related general medical history (Blackburn et al. 2009). An assessment of psychosocial factors (yellow flags) is also recommended during the assessment using a validated screening tool (Oliveira et al. 2018; NICE 2020). Physiotherapists use a clinical reasoning process during their assessment to reach a clinical judgement, they will observe the patient, process available information, implement the management, and sometimes evaluate the outcomes (Petty and Moore 1998). Hypothetico-deductive approach is one approach used in developing a clinical judgement medicine and also in musculoskeletal physiotherapy (Edwards et al. 2004; Langridge et al. 2015). In the hypothetico-deductive approach the clinicians attend to initial information from or about the patient, this has been gathered during history taking and from this information a tentative hypothesis is generated. This tentative hypothesis is then followed by collection and interpretation of further data during the objective assessment, this might confirm or reject the formulated hypothesis (Edwards et al. 2004). As examination and management continues, this process will also continue, whilst various hypotheses are confirmed or negated.

Beyond expert suggestions as to the appropriate subject matter for chronic pain assessments (Management 2004; Dansie and Turk 2013), there are a paucity of studies reporting the actual content of clinical or physiotherapy assessment in LBP. Bagraith et al. (2018) conducted a qualitative study to determine the content of 42 separate multidisciplinary team assessments of CLBP among 23 clinicians across disciplines to identify Low Back Pain Core Set (LBP-CS) categories assessed according to International Classification of Functioning, Disability and Health framework (Cieza et al. 2004). The authors revealed that all 19/19 body functions, all 5/5 body structures, 26/29 activity and participation and 23/25 environmental factor categories according to LBP-CS were assessed across the disciplines (pain medicine, psychiatry, nursing, physiotherapy, occupational therapy, and psychology). Ferguson et al (2010) conducted a study working towards developing a national framework of physiotherapy assessment and management of LBP. This reported good compliance and percentages in reporting assessment information among physiotherapists including red flags, yellow flags, neurological examination for nerve root pain and use of steroids; but did not report any information on LBP specific subjective or objective questions or tests.

2.4.1 Low Back Pain Self-Assessment Tools

A variety of assessment tools are used in the clinical reasoning process of assessing patients with LBP, these mainly include classification systems and outcome measures. According to a survey by Davies et al (2014), 86% of physiotherapists who participated reported using physiotherapy LBP diagnosis classification systems and 65% reported using multiple classification systems. However the argument over the use of these classification systems in LBP has evolved over recent years, it is now widely accepted that grouping LBP patients into rigid subgroups may miss the crucial interrelationships between factors for individuals (Rabey et al. 2015) and will not reflect the individual and complex nature of disabling LBP (O'sullivan et al. 2016).

Accordingly, adopting a biopsychosocial approach is recommended, this focuses on the patient as a whole rather than trying to identify the pathoanatomic cause of their symptoms (O'Sullivan et al. 2015; O'Keeffe et al. 2019). Yet, it is evident that many physiotherapists still base their chronic pain assessment on biomedical and somatic signs and symptoms instead of a biopsychosocial approach (Bishop and Foster 2005, Anderson et al. 2015, Faller et al. 2016). The use of questionnaires and treatment stratification tools to obtain a holistic picture of the individual is recommended to mitigate this limitation and to minimise the risk of poor outcomes (Dagenais et al. 2010; NICE 2019).

Generic and condition specific self-assessment tools are available. Generic self-assessment tools are used, irrespective of the health condition of the person, to measure their health status or quality of life such as SF-36 health survey (Chiu et al. 2019), where the latter is used in specific conditions like LBP (Brazier et al. 2017). Several LBP specific self-assessment tools exist and they are helpful to guide the physiotherapists and decide the best management pathway for individuals (Wijma et al. 2016). Many are self-administered whilst almost all are paper based or interviews, that are scored by a health professional to utilise the information accordingly. Examples include STarTBack tool (Hill et al. 2008), the Oswestry Disability Index (ODI) (Beurskens et al. 1996), the Roland–Morris Disability Questionnaire (Roland and Morris 1983), Quebec Back Pain Disability Scale (Kopec et al. 1995) and Back Pain Function Scale (Stratford et al. 2000). The majority of these tools will neither stratify people according to the nature of their pain, nor determine the course of an individual treatment programme. They do however provide a general overview of the individual's LBP and functionality. However, STarTBack tool (Hill et al. 2008) identifies a person with LBP as belonging to a low, medium or high risk group according to the person's interpretation of their pain and suggests stratified management. These involve the usual care with analgesics and advice to stay active for the low-risk group, referral for physiotherapy for medium risk individuals and psychologically informed physiotherapy for the high risk group. However, these tools do not empower the individuals with LBP to use them without the advice or guidance of a health professional.

2.5 Management of LBP

As one of the most pressing healthcare challenges, several best practice guidelines have been developed to inform patients, clinicians and the public with regards to LBP management (Airaksinen et al. 2006; Michaleff et al. 2014; Qaseem et al. 2017; Stochkendahl et al. 2018; NICE 2019). It is expected that these recommendations will raise awareness of effective management strategies and will reduce the associated level of disability in LBP. A drastic change in the key recommendations for LBP management can be noted over the past three decades. Almost all the guidelines currently recommend adopting a biopsychosocial model to inform assessment and management in LBP. Furthermore, self-management and exercise are considered as cornerstones in the management of musculoskeletal pain conditions, including LBP (Lin et al. 2019). Use of other therapies, including psychological and behaviour change therapies are also emphasised (Airaksinen et al. 2006) whilst pharmacological, surgical and passive treatments are not encouraged (Foster et al. 2018b).

The recommendations of the clinical guidelines may vary according to the chronicity of LBP and presence/absence of radicular pain. In acute LBP, patients are encouraged to avoid bed rest, to stay active and to continue with daily activities (Qaseem et al. 2017; Stochkendahl et al. 2018; NICE 2019). Further, reassuring patients that they do not have a serious disease is also identified as important during this stage (NICE 2019). For individuals with chronic NSLBP who have persistent pain, graded activity or exercise programmes that target functional improvements and prevent disability is highly advocated as first-line treatment (Foster et al. 2018). Although, there is no substantial evidence to suggest the most effective type of exercises for LBP; consideration of individual needs, preferences and capabilities in designing the exercise programmes is recommended (Hayden et al. 2005b). Additionally, these clinical guidelines recommend considering psychological therapies such as Cognitive Behavioural Therapy (CBT), progressive relaxation and mindfulness-based stress reduction as first-line treatment for CLBP (Qaseem et al. 2017; Stochkendahl et al. 2018; NICE 2019).

Despite the key clinical guidelines and recommendations supported by scientific research and multiple trials, a substantial gap can be identified in practice (Scott et al. 2010). Studies from several countries have confirmed that the standard practice of under prescription of exercises (Carey et al. 2009), over-prescription of medication in primary care/emergency care settings (Michaleff et al. 2012; Nunn et al. 2017) and high rates of use of passive treatments such as electrical modalities (Bernhardsson et al. 2015; Madson and Hollman 2015; Keating et al. 2016) as first-line treatment for chronic LBP. Although it is recommended that LBP be managed in primary care, the presence of LBP patients in emergency departments is common (Friedman et al. ; Snook et al. 1998; Tcherny-Lessenot et al. 2003; Rizzardo et al. 2016). Regardless of the guideline recommendations, overuse of opioids (Jeffrey Kao et al. 2014), high referral rates for imaging (Rosenberg et al. 2015) and frequent practice of spinal surgeries (Machado et al. 2017) in the management of LBP are often reported.

However healthcare providers also administer passive treatments for temporary pain relief (Machado et al. 2008) as a common practice, this often results in recurrence of LBP with patients returning for further treatment (Costa et al. 2009), thus increasing cost. It is believed that patients' uncertainty about where and when to seek support and care (Sharp et al. 2014) is one of the major constraints, this results in a waste of healthcare resources and time. Whilst acknowledging the need for multidisciplinary and collaborative care to reform unhelpful patient clinical pathways, identifying public health strategies to better inform people and change LBP beliefs and behaviours can also offer promising solutions (Buchbinder 2008; Suman et al. 2017).

2.6 Low back pain, physical activity and exercises

It is recommended that patients with LBP maintain PA, as prolonged inactivity can adversely affect recovery (Bekkering et al. 2003). Also, both national and international guidelines endorse exercise as a first-line treatment and a fundamental management approach in the management of LBP (Airaksinen et al. 2006; Maher et al. 2017; Oliveira et al. 2018; NICE 2019). In an overview of the clinical guidelines for the management of LBP in primary care from thirteen countries and two international clinical guidelines, early gradual PA and exercise are consistently recommended for acute and chronic LBP respectively (Koes et al. 2010).

A large number of randomised controlled trials (RCTs) are published each year investigating the effectiveness of exercise for LBP. In these RCTs, the effects of exercise appear comparable, and their findings have been appraised in systematic reviews and meta-analyses. In a Cochrane review conducted by Hayden et al. (2005) investigating 61 RCTs, exercise has proven to be efficacious in improving pain and function in CLBP when compared with no treatment or other conservative treatments (Hayden et al. 2005). However, heterogeneity in the outcome measures and inconsistent reporting of the trials in the above review should be noted. Another review evaluating 37 RCTs on the effectiveness of exercise in chronic LBP also concluded that exercise effectively reduced pain and improved function among chronic LBP patients, but indicated only small effects (Van Middelkoop et al. 2010). These findings are further reinforced in the review by Henchoz and So (2008), confirming that exercise diminishes disability and pain severity whilst improving fitness and occupational status in acute, subacute and chronic LBP patients. In a review and meta-analysis of 45 RCTs, Searle et al. (2015b) found that coordination, stabilisation, and strength exercises effectively reduced CLBP and that cardiorespiratory exercise had no effect on chronic LBP. In addition to improvements in pain and disability, meta-analytical review results have shown evidence that exercise reduces sick leave in LBP patients in the first follow-up year (Kool et al. 2004) and improves mood and combats depression (Hoffman and Hoffman 2007). PA and exercise increase aerobic capacity and muscle strength, especially in the lumbar extensors, which plays a vital role in LBP patients when performing their daily activities (Smeets et al. 2009).

Different types of exercise, and the method of their delivery, have been explored in the treatment of LBP, including back school, motor control exercises (Hodges and Richardson 1998), core stability and core muscle strength training (van der Velde and Mierau 2000; Ferreira et al. 2006), flexibility exercise (Ferreira et al. 2006) low-to-moderate-intensity aerobic exercise (Chan et al. 2011) and high-intensity aerobic exercise (Chatzitheodorou et al. 2007). However, it is unclear which form of exercise is the most effective as a rehabilitation method for LBP, reflecting the complexity of LBP. Some authors have argued that no one specific type of exercise is more effective than another to reduce pain and disability in LBP patients (Nordin and Campello 1999; Airaksinen et al. 2006; Macedo et al. 2009; Saragiotto et al. 2016b).

This view is also reflected in the review conducted by Van Middelkoop et al. (2010), it concludes that there is no evidence that one particular type of exercise is more effective than others. Also, within the review, it is unclear which subgroups of patients benefit most from a specific type of exercise and Henchoz and So (2008) maintain that it is uncertain whether general or specific exercises are preferable.

However, there has been an emerging body of literature to suggest that some types of exercise may have superior outcomes compared to others in LBP. For instance, classification guided postural exercise interventions tailored for each group are shown to be more effective for people with NSLBP compared to general exercises (Leboeuf-Yde et al. 1997; Sheeran et al. 2013; Luomajoki et al. 2018). In the systematic review and the meta-analysis conducted by Luomajoki and colleagues, movement control exercise interventions have been more effective than other interventions in people with CLBP and movement control impairment (Luomajoki et al. 2018). Disability improved both short and long term, while the pain was reduced only in the short term. However, for promising outcomes, the importance of the initial identification of patients with movement control impairment has been highlighted.

Furthermore, a recent systematic review with network meta-analysis by Hayden et al. (2021) has concluded some types of exercise were more effective than other types of exercise treatment for reducing pain intensity and functional limitations in people with CLBP. This study has reviewed more than 200 randomised controlled trials with 20,969 participants and 507 treatment groups. Across all included studies, 11 different types of exercise showed that most exercise types were more effective on alleviating pain and improving functioning, as compared with minimal treatment. Among the different types of exercises that had been included in the review studies, Pilates, McKenzie therapy and functional restoration exercises have shown superior outcomes in improving pain and function limitations in the CLBP. These findings partially reinforce evidence from the network meta-analysis by Owen et al. (2020) demonstrating low quality evidence that Pilates, stabilisation/motor control, resistance training and aerobic exercise training are the most effective treatments for adults with chronic NSLBP. In their systematic review and meta-analysis of 11 RCTs Wong & Geere (2022) reveal evidence with and very low certainty to support that Pilates and direction-specific exercises such as McKenzie therapy are more effective compared to general exercise for pain reduction in people with chronic NSLBP. However, authors have refrained from recommending one type of exercise over another due to the inconsistencies across the exercise programmes, heterogeneity and poor quality of the included trials. Another one of the recent systematic reviews and meta-analyses supports the positive effects and efficacy Pilates might have for pain relief and improvement in function in patients with chronic NSLBP (Yu et al. 2023). Authors have also looked at the improvements in quality of life in these patient groups but have not been able to confirm any significant improvements caused by Pilates.

Research on exercise interventions has also shown evidence of more general or non-specific types of exercises, such as walking, in reducing pain and function in people with NSLBP. For example, a systematic review and a meta-analysis conducted by Andreatta and colleagues (2017) have compared walking to exercise and walking plus exercise against exercise alone in patients with NSLBP. Findings have shown that walking can have similar effects as low back-specific exercises in these patients to reduce their pain and improve function. Moreover, authors have also concluded that walking has slightly superior outcomes on the recovery of function, whereas exercise might be slightly more effective in the reduction of fear-avoidance beliefs. The overall quality of the studies included in this systematic review and meta-analyses have been high.

Interestingly, one of the most recent systematic reviews (Grooten et al. 2022) evaluating outcomes from 45 systematic reviews, including the above-discussed, has concluded that there are no major differences between exercise types used in CLBP on pain and disability. A large heterogeneity, low to moderate quality and high risk of bias has been reported in a majority of the studies reviewed within the included systematic reviews. The types of exercises compared within the trials were aerobic training, motor control exercises, aquatic exercises, Pilates, resistance training, sling exercises, traditional Chinese exercises, walking, and yoga. Regarding comparative interventions, the individual trials included have compared the studied exercise interventions with other comparative therapies such as exercise, manual therapy, and usual care. Usual care has primarily defined as regular physical therapy or general practitioner visits. In addition, comparisons have been made with minimal interventions, including leaflets, educational leaflets, placebo treatment, and waiting list controls. Patients used in these trials have reported pain lasting between 3 and 6 months up to 8.6 years. A majority of the included participants have been female, with a mean age span ranging from 38 to 50 years. Also, a large variation in the dosage of the exercise interventions has been reported involving treatment duration ranging from 6 to 36 weeks and a frequency from 1 o 5 times per week. However, contemporary literature reveals that no specific frequency, duration, length of the intervention or different intensities (high/moderate/low) has clinically superior or meaningful differences in the outcomes compared with others (Hayden et al. 2021, Owen et al. 2020, Ram et al. 2023). Overall, the available literature explains the wide variation in the use of exercise interventions designed for NSLBP. However, the best type of exercise in NSLBP and specific exercise dosages still remain unclear mainly due to the wide heterogeneity of the available exercise interventions.

Despite the type, intensity, duration and frequency of the recommended exercise, poor exercise adherence is common among people with LBP (Härkäpää et al. 1991; Friedrich et al. 1998). This could be due to various psychological factors associated with LBP, including patients' fear of movement, emotional distress, low self-esteem and anxiety (Chen et al. 2018; Linton et al. 2018; O'Sullivan et al. 2018). Hence, encouraging people in pain to be physically active and to exercise could be problematic and challenging and indicates the complexity of PA and exercise as an intervention in LBP. Consequently, LBP can cause further decline in levels of PA and exercise, which may result in increased risk or worsening of an array ay of co-morbidities involving cancer, cardiovascular disease, dementia and arthritis (Cannioto et al. 2018; Cunningham et al. 2020). Dillen and colleagues (2016) found that in people with LBP, improvement in physical function correlated more with the consistency of exercise than with the type of exercise. Accordingly, multiple strategies to improve the attributes of exercise interventions and to achieve expected levels of outcomes have been advised. For example, NICE guidelines recommend considering an individual's specific needs, preferences, and capabilities when designing exercise programmes for people with LBP (NICE 2019). Findings from a systematic review (Hayden et al. 2005b) also maintained that tailored individually designed exercise programmes delivered with supervision were more likely to enhance treatment outcomes in people with LBP.

2.7 LBP self-management

As LBP is one of the most costly and disabling musculoskeletal conditions, self-management strategies are highly recommended in the long-term management of LBP to decrease the burden of the condition (Newman 2008). It is emphasised that LBP management should be biased towards patient involvement and self-management responsibility rather than passive and pain focused treatments (Moffett 2002). Despite extensive literature on the invention, application and monitoring of SMIs, the effectiveness of these interventions remains unclear with inconsistent research findings (May 2010). Du and colleagues (2011) have explored the effectiveness of existing SMIs in a systematic review and a meta-analysis with 13 RCTs. This revealed moderate quality evidence which supported moderate effects (immediate post-intervention, short-term, intermediate and long-term) on chronic LBP and small (intermediate and long-term) to moderate (immediate post-intervention and short-term) effects on disability when compared with waiting list controls, usual care and active interventions including exercise and occupational therapy sessions (Du et al. 2011). In another systematic review which evaluated the effectiveness of self-management, moderate-quality evidence revealed only small effects on pain and disability in people with LBP of any duration compared with minimal intervention (Oliveira et al. 2012). A series of rapid reviews published by Toomy et al (2015b) found no significant difference in effectiveness between group-based physiotherapist-led self-management interventions and usual management in people with chronic LBP. Similar to Du et al. (2011), comparators demonstrated a broad diversity across the studies involving usual medical care, individual physiotherapy, acupuncture, cognitive behavioural therapy, manual therapy and yoga. Overall, the effectiveness of SMIs within the LBP population is weak, with low to moderate quality evidence which indicates they are only slightly beneficial for pain and disability.

However, self-management and SMIs are variably defined in each review. Furthermore, the content of the SMIs being studied differ largely from one another.

For example, one review (Toomey et al. 2015b) used a definition on SMIs developed using existing literature, while the other two reviews (Oliveira et al. 2012; Du et al. 2017) adopted already existing self-management models. Nevertheless, the authors of all three reviews agreed that effective interventions included multiple key components and facilitated autonomy in self-monitoring and managing signs and symptoms inherent to the condition. SMIs in these reviews comprised a wide range of components, including exercise, education and cognitive behavioural therapy techniques either used alone or in combination. They were delivered as individual or group sessions via face-to-face sessions or internet-based interventions.

As recommended within the treatment guidelines for LBP, PA and exercise are essential components of management (May 2010; NICE 2020). However, this has not always been considered in trials reported in the above reviews, most of them did not have any significant exercise component embedded in their self-management programmes (Oliveira et al. 2012; Du et al. 2017). Most of the SMIs found within studies were designed on the premise of CBT as the key element facilitating self-management, while little (Torstensen et al. 1998; Haas et al. 2005) or no attention had been given to exercise (Chiauzzi et al. 2010; Carpenter et al. 2012). Furthermore, it is well established that providing tailored information is the most effective way to enhance self-management in individuals with LBP (Kreuter et al. 2000). But, a majority of the programmes which reported exercise programmes seemed neither tailored nor specific to the individual presentations as recommended in NICE guidelines for LBP management (NICE 2020). One study had tailored their SMI according to the type of participants (Irvine et al. 2015), whilst in another study individualised exercise was discussed during a telephone interview following submission of self-reported baseline measures (Buhrman et al. 2004). Only in a few studies were physical assessments of the subjects carried out by physiotherapists prior to the allocation of tailored exercises (Von Korff et al. 2005; Bronfort et al. 2011; Zadro et al. 2019). Overall, it was apparent that little attention had been given to meeting the individuals’ exercise and PA requirements within existing LBP self-management programmes. Consequently, poor adherence to exercise and PA seemed to be the primary factor limiting the potential effectiveness of long-term active self-management strategies for LBP.

Several studies have investigated patients' perceptions of LBP self-management in qualitative studies. Despite the wide heterogeneity among included participants, the overall findings were largely consistent. For example, in most of the studies, patients expressed a need for information related to their LBP and management (Liddle et al. 2007; Cooper et al. 2009; Slade et al. 2014; Lim et al. 2019). Although the areas of information were diverse, both Lim et al. (2019) and Slade et al. (2014) reported that patients wanted a definitive LBP diagnosis, pathology and prognosis, and in some cases imaging. However, they commonly reported an emphasis on self-management strategies including education delivered in understandable and accurate jargon free material. Furthermore, patients commonly demonstrated a need for the advice delivered to be tailored according to individuals' needs and preferences (Liddle et al. 2007; Cooper et al. 2009; Slade et al. 2014; Lim et al. 2019). Despite expressing an understanding of the importance of self-management LBP they also reported preference for follow-up or an opportunity to contact a physiotherapist following their discharge (Liddle et al. 2007; Cooper et al. 2009). This implies a need for a relationship with the healthcare provider and the utilisation of resources. Follow-ups could be in the form of return visits, e-mails, telephone calls or through digital health applications (Gruman and VonKorff 1999). Nevertheless, it remains unclear whether the patients have the knowledge and skills to decide how and when to utilise these services and resources. Hence it has been suggested that the provision of self-management education and self-management support to LBP patients might better inform and facilitate the self-management of their condition (Cooper et al. 2009). Also, it could be argued that the patient's ambiguity about where and when to seek support and care (Sharp et al. 2014) is a significant constraint for an optimal long-term outcome. Whilst acknowledging the need for multidisciplinary and collaborative support to reform unhelpful patient clinical pathways, there is strong evidence that identifying public health strategies to inform people and change LBP beliefs and behaviours can offer promising solutions (Buchbinder 2008; Suman et al. 2017).

Self-management is considered to be a behaviour or a collection of behaviours that require a person to adhere to recommended lifestyle changes (Keogh et al. 2015). Given the poor adherence to self-management and treatment in chronic conditions, including LBP, incorporating theory and related techniques into SMIs has been suggested in the literature as a mean of altering behaviour, thus promoting long term adherence to these interventions (Desroches et al. 2013; Dziedzic et al. 2014). These suggestions also align with the Medical Research Council (MRC) guidelines to include theory when developing complex interventions (Craig et al. 2008; Skivington et al. 2021). Recent literature has conclusively shown that theory-based interventions are more effective in increasing participant adherence to treatment programmes and can result in improved outcomes in primary care compared with non-theory driven interventions (Jordan et al. 2010a; Carnes et al. 2012). Consequently, integration of several behaviour change theories and techniques can be seen in SMIs designed for people with LBP.

2.7.1 Behaviour change theories and techniques used in LBP self-management

Several existing behavioural change theories and techniques are used in health behaviour interventions. A scoping review identified eighty-two different theories used in health-related behavioural interventions (Davis et al. 2015), with four theories accounting for 63% of the articles within the review; transtheoretical model of change, the theory of planned behaviour , Social Cognitive Theory (SCT) and the information motivation behavioural-skills model. These theories have shown their usefulness in understanding and predicting steps involved in developing interventions to change behaviours (Rhodes and Nigg 2011; Keogh et al. 2015). However, theory-driven interventions in LBP interventions have been poorly reported. In their review of group based SMIs for CLBP and arthritis, Keogh and colleagues (2015) concluded that only three of twenty-five studies were based on theories, and all applied SCT. All these three studies focused on knee osteoarthritis patients and, none of the studies with theory was reported for CLBP. Bandura (1998)'s SCT proposes that human functioning is a complex interaction of the individual's factors, environment and behaviour. Self-efficacy is the key element presented within SCT and has been the main focus and contribution of the exercise and PA domains of the interventions (Rhodes and Nigg 2011). Nevertheless, recent empirical literature on exercise and PA shows increased interest in the use of Self-determination theory in interventions to help understand exercise behaviour and the importance of autonomous regulations in fostering PA behaviours (Teixeira et al. 2012). Self-determination theory envisages that intrinsic motivation to engage with health behaviour change will be enhanced by supporting user autonomy and increasing the intervention's competence and perceived relatedness (Deci and Ryan 1985).

Du et al.'s (2017) review and meta-analysis on CLBP self-management programmes revealed that theory-driven programmes are more effective in reducing pain and disability than those without a theoretical basis. A total of eight studies included in their review adopted theories and these included; one using SCT and theory of planned behaviour, one using SCT alone and six using CBT. However, in the literature, CBT is identified as a type of therapy based on the cognitive-behavioural hypothesis of emotion (Beck 1979) rather than a theory on health behaviour change. SMIs based on SCT and theory of planned behaviour has shown significant effect on CLBP intensity, frequency and duration compared to the control group which only received access to online education articles on CLBP (Irvine et al. 2015). In contrast, another trial based on SCT showed no overall significant effect of the SMI compared with waitlist controls in primary or secondary outcomes, including pain and functional disability (Haas et al. 2005). However, these results should be interpreted with caution as considerable disparities are present in the design, mode of delivery and content of the SMIs of the two studies.

The fear-avoidance model (FAM) is another commonly used theory in CLBP self-management research (Mansell et al. 2016). Thus far, several studies have confirmed the significant effects of using FAM as a part of SMIs for LBP (Lamb et al. 2010; Hurley et al. 2016). However, similarly to SCT, there is a lack of reported SMIs designed for CLBP based on FAM as the theoretical model. Not only is there an absence of robust evidence on superior effects of theory-based interventions on CLBP self-management, but some studies have proved the opposite. For example, an RCT using 170 elderly individuals with CLBP concluded that a transtheoretical model of change based motivation programme in physiotherapy did not have superior outcomes to placebo treatment regarding adherence to activity recommendations (Basler et al. 2007). However, in terms of limitations, existing studies do not describe the process of development of the interventions, nor the criteria used for selecting relevant theories in their interventions. It is apparent that much uncertainty still exists about the use of theory and its effects on SMIs for CLBP, despite the recommendations and guidelines. This indicates that further research is necessary to gain an understanding of the development and evaluation of behaviour change interventions for self-management of CLBP individuals.

There is a degree of ambiguity in the literature concerning the use of terminology in behaviour change techniques (BCTs). For the purpose of this thesis, Michie et al.'s (2013) definition was adopted, this identifies BCTs as observable, replicable and irreducible components of an intervention which can be used on its own, or as part of a complex intervention. In 2013 an extensive taxonomy of ninety-three grouped behaviours was developed for general use within behaviour change interventions (Michie et al.), this addressed the ambiguity caused by vague terms and multiple reporting methods. It identified the function of BCTs and divided them into sixteen sub-groups according to their role and definitions. The review by Keogh and colleagues (2015) reported a total of 33 BCTs involved within the twenty-five articles reviewed, with the highest (13) being reported in a single study. All the studies (100%, n=25) included in the review reported instructions on how to perform the behaviour, demonstration of the behaviour and behavioural practice. Another 80% (n=20), 60% (n=15) and 56% (n=14) of the studies reported credible source, body changes and graded tasks respectively, in their interventions. However, only thirteen papers (twelve trials) of twenty-five RCTs examined CLBP. BCTs included in each of those studies remain unclear due to poor reporting. Although it is likely that most SMIs for CLBP comprised at least some BCTs, similarly to behaviour change theories literature there is a lack of research studies which report these techniques.

2.8 Digital health interventions and LBP self-management

Given that LBP is a multifactorial disorder with a high recurrence rate, it is crucial that interventions are developed to facilitate long-term self-management, whilst promoting a healthy behavioural change. The evidence indicates that digital applications have the potential to offer a promising solution which could enhance self-management in chronic diseases, facilitate better symptom management (Anderson et al. 2016; Whitehead and Seaton 2016) and improve adherence (Hamine et al. 2015). Similarly in LBP, digital approaches with or without healthcare professional support can provide effective support to self-management (Geraghty et al. 2018) by minimising the barriers of access to health care, time and cost for the patients.

Unfortunately a majority of the existing DHIs designed to facilitate LBP self-management provide inaccurate information (Ferreira et al. 2019), do not meet user needs (Costa et al. 2020) and are rated as poor in overall and content quality (Butler and Foster 2003; Machado et al. 2016). Furthermore, many of these DHIs have shown inconsistent outcomes with regard to their effectiveness (Dario et al. 2017; Nicholl et al. 2017; Du et al. 2020). In their systematic review Nicholl and colleagues (Nicholl et al. 2017) failed to identify a significant beneficial effect compared with usual care or active controls with CLBP education resources, for either primary (pain-related disability) or secondary outcomes (pain intensity, quality of life, depression, fear-avoidance etc.). Only one of the included studies reported a positive effect on the primary outcome (Carpenter et al. 2012). They evaluated six RCTs and three protocols (eight web pages and one mobile application) in their review entitled "digital support interventions for the self-management of low back pain". Six included RCTs had recruited a total of 2706 participants (age 42.5 – 52.7 years. Similarly, another review and meta-analysis (Dario et al. 2017) which evaluated the effectiveness of telehealth-based interventions concluded with moderate-quality evidence. It found that currently available telehealth interventions alone were not more effective than minimal interventions for reducing pain or disability in CLBP. Eleven studies, with eight original RCTs, evaluating telehealth interventions in acute, sub-acute or CLBP were included in the review. Eight original RCTs had recruited 2280 participants. However, only the studies with CLBP had been pooled in the meta-analysis due to the heterogeneity of other studies. Pooled effects of four CLBP studies (Lorig et al. 2002; Chiauzzi et al. 2010; Moessner et al. 2012; Krein et al. 2013) with moderate quality confirmed no significant effect of telehealth interventions at the short-term or medium-term follow-ups compared to minimal interventions to improve CLBP or disability.

However, the above findings were challenged by Du and colleagues, they reported clinically significant effects of eHealth-based self-management programmes for CLBP in their recent meta-analyses of eight RCTs (Du et al. 2020). Eight included RCTs had recruited 1238 subjects across the studies with a mean age range of 35-59.5 years. Six of the included studies in the meta-analysis compared electronic health (e-Health) interventions with usual care, while two studies compared against active controls involving LBP education and physiotherapy. Pooled results of individual RCTs revealed moderate quality evidence to support small and moderate effects on pain and disability, respectively, at immediate post-intervention follow-ups. The results showed moderate effects on pain at short-term follow-ups when compared with controls but failed to confirm any significant effects for disability. However, no effects were found at intermediate follow-up points for pain or disability, and none of the studies reported long-term data for pain or disability.

Findings from another systematic review by Garg et al. (2016) agreed with the inconsistency of the above reviews, it reported mixed results for web-based interventions directed at CLBP patients with regard to pain and level of disability. In total, nine RCTs, four trials with online CBT interventions and five other web-based interventions with interactive features, focused on advice and information on CLBP education and exercise and were evaluated in the review. A total of 1796 participants were included in trials (age 42 – 52 years). None of the online CBT intervention studies reported a significant improvement in pain severity, while one (Lorig et al. 2002) of five other interactive web-based interventions showed improvement in pain severity amongst users. Only five trials reported outcomes related to a disability, including two online CBT interventions and three other web-based interventions. Interestingly both CBT interventions failed to confirm any improvements in the level of disability (Chiauzzi et al. 2010; Carpenter et al. 2012). Although one trial (Krein et al. 2013) of other web-based interventions showed only short term effects, two studies (Lorig et al. 2002; Moessner et al. 2012) confirmed long-term effects on CLBP associated disability. Additionally, significant improvements in outcomes such as catastrophisation and control over pain were shown in three and six studies, respectively.

Modesto's systematic review on "Integration of mobile health apps and web-based interventions in the self-management of LBP" complements the above-discussed findings and reports a significant variation in the reported results (Modesto 2018). Nine RCTs were included in this review which evaluated mHealth and web-based interventions, 1659 subjects were recruited with a mean age range between 42.5 and 57.9. The RCTs had a wide range of control groups, including waitlist controls, usually primary care, LBP education and CBT. Four and two studies had reported CBT and SCT as theoretical underpinning, respectively.

However, in their recent systematic review and meta-analysis of nine RCTs, Chen and colleagues argued that using mHealth and usual care interventions simultaneously improves the efficacy of usual care alone in reducing pain intensity and disability in patients with LBP (Chen et al. 2021). 792 subjects had been recruited across nine RCTs with a mean age range between 40-68 years. Three of nine trials were delivered via mobile phone applications, whilst others included two website interventions, two telephone follow-ups and two other wireless technologies. The review failed to elaborate further on the content of the intervention or the theoretical underpinning of these interventions.

Several RCTs were commonly reported across the reviews discussed above. However, the differences in the design and the content of these interventions and trials were apparent. Nevertheless, there is a perceptible trend towards the inclusion of PA and exercise as core elements in the recently evaluated RCTs and protocols of the interventions. Accordingly, only some of the studies relevant to the scope of this thesis are discussed below. A summary of available DHIs focused on LBP self-management is attached as appendix 2.

2.8.1 Evaluation of existing digital health interventions in LBP self-management

One RCT (Chiauzzi et al. 2010) was commonly reported in five of the six reviews discussed above. This painACTION-Back study investigated the effectiveness of a self-management website for people with CLBP compared with standard text-based materials in 209 subjects. Compared with controls, intervention participants reported significant improvements in stress, coping, and social support and produced clinically significant differences in pain, depression, anxiety, and global rates of improvement related to their CLBP. Nevertheless, painACTION-Back is a CBT based intervention delivered via a website and no substantial exercise and PA elements were included. Moreover, according to the intervention design experimental group it received significantly more exposure to the supporting material and monitoring compared with the control group. Therefore, the generalisability and feasibility of such an intervention on a large-scale is problematic due to the warranted extent of the involvement of healthcare professionals.

SelfBACK (Sandal et al. 2021) is a recently developed mobile app, with a focus on a case-based reasoning process which provides tailored self-management for people with CLBP. SelfBACK has several strengths, it includes an attempt to deliver tailored management using an artificial intelligence-based decision support system which matches subjective and clinical data input by the user to the delivered programmes. Furthermore, although there are no published studies, it appears that healthcare professionals and LBP patients were involved in the development process of the intervention (Mork and Bach 2018). How they contributed towards the development or deciding the content and the extent of their involvement remains unclear. Whilst the intervention's primary focus has been on following up and giving feedback on the daily step count, the users had been given an exercise programme with general strengthening and stretching exercises identified by the decision support system. The programme was tailored according to the information obtained from patients through a web-based questionnaire and weekly question and answer session. This aimed to provide the best-tailored self-management option for patients according to their level of symptoms. However, there is no opportunity for the users to select exercises according to their goals and their preferences, nor to progress or regress them as they wish during an exercise programme.

SelfBACK is the only DHI with a focus on exercise which has evaluated usability. It has been tested for its usability in a separate usability study (Nordstoga et al. 2020), this used a 10-item System Usability Scale (SUS) (Brooke 1996) and a 29-item design questionnaire (Reynoldson et al. 2014) at the end of a 4 week period of using the application. Sixteen participants (mean age of 51.1 years) completed the SUS, they had an average score of 64.7 (range 10-95). Item five and six of the SUS reported relatively low scores overall. A further strength of this study was that semi-structured telephone interviews were conducted with ten participants out of the sixteen to further explore their experience and acceptability of the app. Findings revealed four main themes, these emerged during the interview data and included practical and technical factors, limitations and barriers, strengths and facilitators, and suggestions for improvement. The practical and technical factors were related to wearing the PA monitor and general difficulties using the app. Limitations and barriers reported were related to app content, appearance, and LBP symptoms. However overall, participants were positive about the appearance although some believed it could be enhanced. The reported strengths and facilitators reflected the content and appearance of the app, users reported that they liked the simple and easy to understand design and visual representation of the achievement of goals. Suggestions for improvement included proposals for several additions, these included sleep monitoring, ability to view history, a variety of exercises and a more attractive design.

Hodges et al. (2020) reported the development process of MyBackPain, an internet based LBP resource. MyBackPain is a website developed using a rigorous 10 step process with extensive involvement of consumers and healthcare providers. Additionally, during this multistep process the authors often reviewed published evidence and literature during the planning stage and when designing the content. However, similar to many existing LBP SMIs, the main focus of MyBackPain was also on LBP education and key messages related to LBP. Although the website presented some updated and evidence-based information and messages related to LBP (importance of staying active, unnecessary investigations, principles of management, reassurance and red flags), it scarcely presented any advice or guidance with regard to exercise and PA.

Following the completed development of the website, several studies including an RCT (Hodges et al. 2021), were conducted to evaluate the impact of MyBackPain. A qualitative exploration of people’s interactions with the website and its effects was also undertaken. The qualitative investigation of use of the intervention yielded some unanticipated tensions in the design of the website, these included: a stronger focus on reducing the LBP with little discussion on living with LBP, feelings of guilt at not meeting the activity targets, unintended negative impact on participants who used disproven treatments, tension between making users’ own choice and providing explicit guidance. Meanwhile the RCT did not yield any differences in health literacy between controls and the users of MyBackPain, and showed some inconsistent and non-significant group differences in pain intensity, LBP related disability and quality of life.

Another mobile-web application, named Kaia (Huber et al. 2017) attempted to promote multidisciplinary pain treatment for LBP with patient education, video-guided physiotherapy and mindfulness training components within the app. The exercise or physiotherapy category comprised a library of 145 exercises for five regions of the body ranked according to difficulty or strain. They reported a clinically significant reduction of the pain levels in a numerical pain rating scale (NPRS) but failed to consider associated disability level or any other outcomes. However a marked limitation was that the study was conducted as an uncontrolled retrospective study and reported a high rate of dropouts over 12 weeks (Huber et al. 2017). It is not clear whether the app or spontaneous improvements caused the improvements reported in the pain levels by the app users.

Several other trials were commonly reported across the reviews. For example, the IMPACT trial by Amorim et al. (2019) was reported in four of the above-discussed reviews. This was a pilot RCT conducted with 68 subjects, it was comprised of an internet-based application and an activity tracker (Fitbit). This was supplemented by a PA information booklet, plus one face-to-face and twelve telephone-based health coaching sessions. The control group only received the PA information booklet and advice to stay active. Even though the intervention group participants were largely satisfied with the intervention and had a 38% reduced rate of care-seeking compared to standard care, estimates failed to confirm any statistical significance. Interestingly, no between-groups differences have been found for pain levels or activity limitation.

Similarly to the IMPACT trial, the FitBack trial (et al. 2015) evaluated a mobile-web application designed to facilitate non-specific LBP self-management, it was also included in four of the above-discussed reviews (Dario et al. 2017; Nicholl et al. 2017c; Modesto 2018; Du et al. 2020). FitBack application had an interactive framework which focused on delivering self-tailored cognitive behavioural approach-based recommendations to manage current pain and prevent future pain episodes. In addition to the education material on pain and pain management and cognitive and behavioural strategies to manage and prevent pain, it also comprised instructional videos on specific strengthening and stretching exercises which were tailored to the job type of the individuals, which is to be commended.

The RCT by Krein et al. (2013) was also reported in four reviews (Garg et al. 2016; Dario et al. 2017; Nicholl et al. 2017; Du et al. 2020). The trial examined whether a pedometer-based, internet-mediated intervention could reduce disability associated with CLBP using 229 participants. Both intervention and control groups received uploading pedometers whilst the intervention group received additional automated feedback and access to the website. The results revealed a more significant decrease in disability in the intervention group in the six-month follow-up but failed to report any significant difference at 12 months.

SupportBack trial (Geraghty et al. 2018) another study focused on evaluating a DHI related to LBP self-management, determined the feasibility of an internet-based intervention to support LBP self-management. Three patient groups were compared: usual care group, usual care plus internet intervention group, and internet intervention plus usual care plus physiotherapist telephone support group. Patients of the internet intervention, physiotherapist support, and the usual care group demonstrated the most significant improvement between the baseline scores and follow-up scores of the Rolland Morris Disability Questionnaire (RMDQ). At the same time, an intervention plus the usual support group also showed some improvements in the RMDQ scores (Geraghty et al. 2018). However, the level of significance of these outcomes remains unclear. Moreover, small reductions in additional pain-related measures including the NPRS and fear-avoidance were reported in all groups. This trial focused on LBP patients with diagnosed LBP who were recruited from primary care settings where most LBP patients are treated. Overall, the outcomes emphasised the feasibility of a future definitive RCT to evaluate its clinical and cost-effectiveness.

Repetition of the majority of RCTs within existing systematic reviews over the last two decades explains the lack of research trials evaluating these digital technologies, irrespective of their widespread use and the extraordinary rate of available apps. Overall, the trials revealed significant variation in the reported results for the effectiveness of these interventions. Whilst some studies reported no between-group difference at any follow-up point, others seemed to report improvement in outcomes, such as pain catastrophising, pain intensity, disability and physical outcomes. However, a lack of long-term follow-up is evident for most studies.

Altogether, several limitations could be identified in these RCTs. Most of the trials included small sample sizes with a lack of detail on how the sample sizes were calculated and failed to blind the outcome assessors. Also, the demographics of the included samples across the trials have been largely heterogeneous. Subjects with comorbidities were often excluded from the study population of the included RCTs and did not represent the reality of the wider LBP population, thus making it difficult to generalise the outcomes.

The design, content, and delivery methods of the interventions presented in these studies are widely diverse. However, most of the investigated RCTs in the above reviews focused almost exclusively on cognitive behaviour therapy and associated techniques. Even though PA and exercise are considered to be the mainstays of effective treatment of LBP, only a limited number of RCTs across the reviews had included it as a vital component of the design (Krein et al. 2013; Chhabra et al. 2018; Geraghty et al. 2018; Amorim et al. 2019; Yang et al. 2019). Yet outcomes of these interventions, regarding the effects on CLBP, remain controversial with studies revealing mixed results.

Only a few of the reviewed studies reported theoretical underpinning for the interventions involving cognitive behaviour therapy (Chiauzzi et al. 2010; Carpenter et al. 2012) collaborative decision making (Chiauzzi et al. 2010), SCT (Krein et al. 2013; Irvine et al. 2015), theory of planned behaviour (Irvine et al. 2015), and acceptance and commitment therapy (Carpenter et al. 2012). However, some authors identified CBT, collaborative decision-making, and acceptance and commitment therapy as behaviour change approaches rather than theories (Hayes et al. 2004).

Clearly, with the rapid development and widespread use of technology in recent years, the uptake and development of DHIs has dramatically escalated. The WHO has cautioned that DHIs have been implemented amid developing interest, without careful examination of the evidence on their benefit and harm (WHO 2019). In 2019 WHO also presented a series of recommendations and implementation considerations on DHIs based on a critical evaluation of the evidence on emerging DHIs (WHO 2019). Furthermore, NICE published the evidence standards framework for digital health technologies. They described the required types and levels of evidence of effectiveness and impact of a given intervention to be considered for use in the UK health care setting (NICE 2021). Nonetheless, Machado et al. (2016) identified sixty one up-to-date mobile applications offering CLBP self-management in their review. None of the (61) apps were tested in an RCT to evaluate their effectiveness. The authors have concluded that the overall quality of these applications is low. Furthermore, they advocate the necessity for app developers to work closely with healthcare professionals, researchers, and patients to ensure app content is accurate, evidence-based, and engaging.

Another study conducted by the Chartered Society of Physiotherapists (CSP), UK studied the 100 most highly viewed videos on YouTube when searching for 'advice and treatment for LBP. It found that almost half contained a myth (43%), the majority contained false or misleading information (60%), had unhelpful language that was fear evoking or contradictory (42%) and half of them had not stated their qualifications for providing advice (45%) (CSP 2021). It is evident that despite the potential of DHIs to empower patients to take an active role in their self-management, they come with a range of risks and challenges. Hence it is of prime importance to focus on developing novel DHIs which provide reliable, trustworthy, and updated information to the public to support LBP self-management and improve awareness in exercise and PA.

2.8.2 Development of digital health interventions for LBP

Development of an effective intervention is a complex process, it involves multiple studies across a number of development and evaluation stages (Craig et al. 2008). The updated MRC guidance (Skivington et al. 2021) identifies stakeholder input as a key element in the development process of an intervention and highlights the importance of their engagement throughout the development and evaluation stages. Stakeholders often include patients and members of the public as well as those linked to an intervention in a professional capacity. Yet, existing DHIs have rarely adopted any type of framework or involved stakeholders across the development process of the respective interventions. In contrast to recommendations, exploring stakeholders' views on the intervention following the development process is more commonly seen (Geraghty et al. 2020).

However, despite the recommendations for using a systematic approach which includes theory, evidence and stakeholder involvement in the development of complex interventions (Skivington et al. 2021), the number of LBP related digital interventions developed incorporating these elements is low (Hodges et al. 2020). Digital interventions with a focus on LBP self-management seldom report the development process and often proceed to evaluate their effectiveness, acceptability and to obtain user experience feedback of the intervention prior to any stakeholder input on the development process (Krein et al. 2010; Irvine et al. 2015; Amorim et al. 2019; Toelle et al. 2019). Nevertheless, interventions that claim the involvement of stakeholders have not published comprehensive details of their involvement and contributions towards the development (Mork and Bach 2018). SupportBack (Geraghty et al. 2015) intervention only reported involving a group of fifteen patients during the early development process and using their feedback to modify the content of the intervention. Similar to SupportBack, selfBACK also has not published the complete process or details of each stage of the intervention. Solem et al. (2020) described the development of a DHI named EPIO, this employed a multidisciplinary and user-centred design approach. It involved stakeholders including researchers, patients, psychologists, healthcare managers, editors and software developers who had participated in workshops, content development and usability testing. But the EPIO intervention aimed to improve self-management in chronic pain, it did not specifically target people with LBP or improve their exercise and PA.

Regardless of the lack of involvement of stakeholders in the actual development process of DHIs which are related to self-management in people with LBP, numerous studies attempted to explore their perspective on development and evaluation. Whilst some of these focused on healthcare practitioners, others have focused on users or LBP patients. Comparisons of findings of the studies conducted between these two groups revealed few common viewpoints but did reveal some differences. For example, both, healthcare providers (Nielsen et al. 2016) and users (Nielsen et al. 2014; Palazzo et al. 2016; Riis et al. 2018) agreed on the importance of information provision as a key element in a DHI for people with LBP. However, a discordance is evident between the extent and the content of the intervention expected by the two groups. For example, similar to traditional self-management discussed above in 2.7, patients expressed a strong desire for more specific explanatory diagnosis related to their LBP rather than general information (Nielsen et al. 2014; Palazzo et al. 2016; Riis et al. 2018). Whereas healthcare providers stand by the limited value of a diagnostic label to provide necessary self-management education (Nielsen et al. 2016). Furthermore, according to Nielsen et al.'s (2014) qualitative study which evaluated the opinions of twenty-eight LBP patients aged between 24-82 years, they preferred having access to specific and detailed information on treatment and management. In contrast, in their second study (Nielsen et al. 2016) with forty two health-care providers' perspectives on online resources, participants were not certain about the provision of detailed information regarding treatment methods and outcomes, they preferred to keep it general. These findings suggest a clear gap between the knowledge and expectations of the users and the actual practices and perceptions of health-care providers. Previous research advocated improving public access to information as a strategy to reduce the aforementioned knowledge gap (Verbeek et al. 2004) which is one of the greatest potentials of DHIs.

Meanwhile across studies, both health-care providers and LBP patients agreed on the importance of the number of elements that should be considered when designing a DHI. A Danish study (Riis et al. 2018) was conducted with fifteen LBP patients (aged between 22-68 years), to identify preferences for the design, functions and content of a web app with evidence-based information and advice for people with NSLBP. Patients reported that information should be easy to read and not be overloaded with information. Furthermore, the results of the above study emphasized the importance of credibility and usability of provided information, as well as consideration of patient input when deciding the content of interventions. These findings agree with the results of both Nielsen et al. (2014) and Nielsen et al. (2016) which confirmed that trustworthiness of information, readability, visual presentation and interactivity were among key desirable attributes when deciding the content of a DI to facilitate self-management in LBP. Also, authors identified a number of categories of information needs expressed by participants, these included LBP treatment and management options, self-help information and strategies, psychological and social impact of LBP, quality assurance of information, roles of different healthcare providers and locally available healthcare and support services. Meanwhile, another study by Palazzo et al. (2016) explored the opinions of a sample of twenty nine LBP patients (24-85 years). They expected an intervention to provide them with guidance, feedback and reminders of exercises, be enjoyable and to be able to modify programmes according to their performance.

Cal et al. (2021) interviewed nineteen physiotherapists from academic and healthcare backgrounds, they explored their opinions on the efficacy and disadvantages of implementing a web-based tele-rehabilitation programme for chronic LBP. According to findings of this qualitative study, participants believed DHIs such as tele-rehabilitation could be effective in reaching out to a larger group of people thus achieving significant savings of healthcare costs. The importance of active involvement by users including shared decision making, health education and physical exercise and the maintenance of an active life promoting self-management were among perspectives shared by the physiotherapists. However, they also expressed their concerns about potential limitations, these included the difficulty of delivering patient-centred programmes and limited familiarity of older age groups with emerging technologies.

2.8.3. Internet based LBP physiotherapy assessment

Together with the escalated use of digital, internet, or tele-health-based applications, several studies have attempted to conduct various internet-based objective assessments and to evaluate the validity of these assessments compared with face-to-face physical assessments. A systematic review conducted by Mani and colleagues (Mani et al. 2017) evaluated the validity and reliability of a variety of internet-based objective assessments used in musculoskeletal physiotherapy. Eleven articles were appraised, and findings revealed moderate quality evidence for good concurrent validity in internet-based assessments of pain, swelling, range of motion, muscle strength, balance, gait and functional assessment. However, lumbar spine posture, special orthopaedic tests and neurodynamic tests ranged from low to moderate. Eleven studies were included in the review but only two reported LBP related assessment tests (Palacín-Marín et al. 2013; Truter et al. 2014). Of the two studies, Palacín-Marín et al. (2013) reported seven of nine outcomes to have excellent agreement between the face-to-face and telerehabilitation assessments using TPLUFIB-WEB application, with Cronbach α values more than 0.94 (anterior straight leg raise test, Oswestry Disability Index (ODI), visual analogue scale for pain, 12-Item Short Form Health Survey questionnaire and Tampa Kinesiophobia Scale, finger floor distance anterior and finger floor distance lateral). Endurance testing assessed with the Sorensen showed good agreement ($\alpha = 0.80$) and lowest reliability was obtained for the lateral flexion range of motion ($\alpha = 0.75$). All five movement tests (anterior straight leg raise test, finger floor distance anterior and finger floor distance lateral, lateral flexion, Sorensen test for endurance) showed very good results for both intra-rater and inter-rater reliability with intraclass correlation coefficient (ICC) of $\rho = 0.94–0.96$ and $\rho = 0.92–0.93$ respectively. However, these results should be interpreted with caution due to the wide heterogeneity among included studies of the above systematic review involving study populations and physiotherapy assessments reviewed in each study.

Truter et al. (2014) compared face-to-face physical therapist assessment with telerehabilitation assessment of spinal posture, active movements of the lumbar spine, and the straight leg raise (SLR). The results revealed high levels of agreement in specific lumbar movements [$r = 0.89$ (flexion) and $r=0.83$ (extension), $p < 0.001$) and moderate agreement with SLR range of motion ($r=0.64$, $p < 0.001$) and active lateral flexion range of motion [$r = 0.69$ (right side) and 0.67 (left side), $p < 0.001$). Meanwhile, postural analysis (25–75%, kappa ≤ 0.19) revealed poor agreement between face-to-face and remote assessments. In another study (Cottrell et al. 2018) which researched a total of forty-two participants, a high level of agreement was demonstrated between telehealth and in-person assessment of a small number of CLBP patients (14) who were referred to a tertiary advanced-practice physiotherapy screening clinic. Seth et al. (2019) also revealed a percentage agreement of 68.1% between telerehabilitation and face-to-face assessments and moderate interrater reliability ($\kappa = 0.52$; 95% CI, 0.32–0.72) for the overall classification decisions in three groups of mobilization/manipulation, specific exercise, and stabilization. No significant differences were found in judgements of individual variables used for decision making between two methods except for SLR greater than 91°. However, all the internet-based assessments studied in aforementioned studies warrant the involvement of a physiotherapist to remotely conduct a case-by-case assessment.

Nevertheless, the recent growing body of novel research suggests the potential use of wearable sensors and artificial intelligence in automated clinical decision making when assessing LBP (Papi et al. 2017; Tack 2019; Alfakir 2021). Some of these examples are analysis of spinal kinematics using inertial measurement units (IMUs) (Abdollahi et al. 2020), use of electromyography (Velusamy et al. 2021), smartphones, watches and virtual reality techniques (Mallow et al. 2021). Use of these technologies has the potential to tailor the offered self-management to the needs of the individual and to monitor the behaviour with relevant outcome measures (Strecher et al. 2008). Interventions with self-assessment tools which provide tailored feedback are more acceptable, they have a lower dropout rate than those which do not provide tailored feedback (Morrison et al. 2014). Out of many LBP exercise self-management interventions with self-assessment elements, a majority are used as outcome measures to monitor progression, other methods of tailoring such as access to individual coaching sessions are also used (Selter et al. 2018; Amorim et al. 2019; Shebib et al. 2019; Yang et al. 2019).

Meanwhile, a few interventions have used automated self-assessment data to tailor the content and exercise programmes including applications; selfBACK (Mork and Bach 2018), SupportBack (Geraghty et al. 2018), FitBack (Irvine et al. 2015), Kaia (Toelle et al. 2019). Out of these applications SupportBack reported functional limitations in the self-assessment tool which tailors the exercise and walking programmes and goals, while Kaia and selfBACK used personal goals, daily functional ability, pain diary and sleep behaviour to tailor daily exercise and education programmes. In addition, selfBACK also used PA detecting wristband data to give instant feedback on activity levels. In the FitBack intervention, exercises were tailored according to the job type (sitter, stander, driver, lifter). However, participants of all the above studies were screened for eligibility by the researcher (Irvine et al. 2015; Mork and Bach 2018; Amorim et al. 2019; Shebib et al. 2019; Toelle et al. 2019; Yang et al. 2019) or a doctor (Geraghty et al. 2018; Selter et al. 2018) using telephone interviews or face to face appointments. Nevertheless contemporary challenges faced by the healthcare services in the UK include high waiting list times to see a physiotherapist. In Wales about 21.5% patients wait 8-14 weeks and 11.7% patients wait over 14 weeks to see a physiotherapist (StatsWales 2021) whilst in England the average waiting time is about 45 days (Equipsme 2021). Given the above waiting times, manual screening of users or provision of individual support within a largescale self-management intervention is unrealistic.

However, BACKonLINE™ (Alothman et al. 2019) is an autonomous and standalone self-assessment tool, it offers a promising solution to overcome these challenges with an automated screening process which excludes people with associated red flags and distinguishes between people with characteristics of predominantly centrally or peripherally sensitised chronic LBP. However, this tool has not been researched vigorously among people with LBP and its usability is not known. Although BACKonLINE™ offers some general self-management guidance for people who belong to centrally sensitised and peripherally sensitised groups, it is not comprised of any detailed self-management solutions to enable them to continue. In particular, a peripherally sensitised group identified by this tool might benefit significantly from a structured self-management programme which can offer tailored ESM programmes to meet the capabilities and exercise requirements of such patients.

Although a number of self-assessment tools exist, these tools merely stratify people with LBP according to their psychosocial risk factors, functional or fear-avoidance beliefs (Fear-Avoidance Beliefs Questionnaire). Some DHIs related to LBP self-management attempt to integrate these self-assessment tools with objective outcome measures such as daily step count or PA levels measured with wearable monitoring devices to tailor the delivered self-management (Irvine et al. 2015; Amorim et al. 2016; Geraghty et al. 2018; Sandal et al. 2020). However, none of the above have integrated both history taking and physical assessment components to resemble the actual clinical decision-making process and tailor the content delivered. This could be due to the complexity of the LBP assessment and the involvement of the spinal movement testing which is usually conducted during the assessment.

2.9 Summary and justification

Self-management and exercise are cornerstones in the management of LBP and are highly recommended in best practice guidelines. Whilst there is a wide range of existing SMIs, these exhibit mixed outcomes in improving pain and level of disability in people with LBP. Despite the recommendations and evident effectiveness of exercise in LBP, not all SMIs are comprised of exercise. In contrast, psychological and behaviour change theories have been the premise of a majority of these interventions with limited attention to exercise. It is unclear whether the SMIs with exercise components are more effective in improving pain and disability in people with LBP.

People with LBP often find that engaging in exercise and maintaining an active lifestyle is a challenge due to its complex and multidimensional nature. In people with reduced levels of PA this leads to further inactivity, this is recognised as an independent risk factor for multiple comorbidities involving cancer, cardiovascular disease, dementia and arthritis. Whilst there is evidence of the importance of encouraging and motivating people with LBP to exercise and be active, it is crucial to understand that this might not be the most persuasive approach for everyone with LBP. Tools such as BACKonLine™ could be helpful in discerning people, according to the dominance of the centrally sensitised and peripherally induced nature of LBP, before providing them with the most appropriate ESM advice. Furthermore, it is imperative to consider and tailor ESM needs of the people with LBP who are active and attempting to maintain their exercise and PA. Recognition and understanding of different exercise and self-management needs of people with LBP will help deliver effective and tailored management to improve their symptoms and quality of life. However, most of the existing SMIs rarely discern the nature of LBP of the users or their ESM needs before they focus on tailoring the content of their intervention.

With emerging technological advances and the increased accessibility to digital devices by members of the general public over the last decade, DHIs offer a promising opportunity to address increasing health burdens such as LBP in a potentially cost-effective way. They can provide automated and remote support self-management while giving users the benefits of flexible and convenient access. Since the World Health Organization (WHO) declared the Coronavirus Disease 2019 (COVID-19) pandemic in March 2020, the need for effective, well-designed digital interventions in healthcare and the promising role of DHIs has been emphasised more than at any other time. During the COVID-19 crisis, the provision of physiotherapy and other primary and secondary health care services around the world were challenged to continue their services safely. Consequently, many countries have adopted a number of digital and telehealth interventions to assess and provide safe treatment delivery to their patients (Dantas et al. 2020). With extremely high waiting list times and reduced access to healthcare professionals (StatsWales 2021), people with LBP often search the internet for LBP advice and exercise instructions to help relieve their pain. Although there is a plethora of DHIs developed to facilitate self-management in people with LBP, the quality of these interventions and the need for rigorous research to test their effectiveness and acceptability is lacking. Nevertheless, most of them do not report adopting a methodological approach as being recommended in best practice guidelines and MRC guidance. Generally, the evidence base for the effectiveness of these DHIs in improving self-management in people with LBP remains poor.

Further research is needed to explore the potential for delivery of optimum and effective self-management in people with LBP, it is evident that this could improve exercise and PA levels. Accordingly, this study looked at the iterative process involving systematic evaluation of evidence, theory and stakeholder perspectives to develop an evidence, theory and practice-based intervention which would be acceptable and beneficial for people with LBP and would improve ESM.

2.10 Aims and research questions

The aim of this study was to develop and evaluate an evidence, theory and practice based DHI to facilitate ESM in people with LBP. Theory, evidence and expertise of professionals working with LBP were used in the development of the intervention, this occurred at different stages of the process. In addition, this study explored the patient experience whilst using this prospective intervention prototype in terms of usability, acceptability, and user experience together with a preliminary evaluation of potential benefits of the intervention. It was hypothesised that a DHI designed with the collaboration of experts, developed to be evidence-based and theory-informed, is likely to be acceptable to the target end-users, and to merit progression to a larger scale feasibility trial. Furthermore, end-user feedback will inform further development of the intervention to a more bespoke ESM platform.

Therefore, three overarching research questions were generated to achieve these aims.

2.10.1 Research Questions

1. What is the effect of LBP SMIs with exercise added?
2. What are the key components, as recommended by the expert clinicians, required within a self-management intervention to encourage people with LBP to be physically active and exercise and how to tailor them?
3. What is the usability, technological acceptability, potential health benefits and preliminary user experience of a prospective intervention prototype?

Constructing the work related to the thesis focused on these three research questions, this led to the study having three distinct, but related phases as described previously in the introduction chapter. Phase 1 aimed to answer the first research question, thus informing the development process of the intervention. Phase 2 was concerned with identifying and developing theory related to the project and answered the second research question. Phase 3 was the development and the preliminary evaluation of the prototype of the intervention answering research question 3.

Chapter 3: Methodology

3.1 Introduction

This chapter outlines the methodological approach of this research, aiming to develop a novel digital exercise self-management intervention to encourage people with LBP to exercise and be active. In order to develop an appropriate research design, different approaches published in the relevant literature were studied, and their advantages and disadvantages were assessed in detail.

This chapter gives an overview of the general methodological paradigms, it introduces the theories used when discussing the methodological origins of the research. It then explains how the research was conducted to achieve the objectives identified in Chapter 2, followed by a discussion of the methodological considerations to justify the most appropriate methods to answer each research question.

3.2 Overview of Research paradigms

The methodology describes the rationale, rules or procedures for conducting and evaluating research and justifies approaching research in a particular way (Pope and Mays 2020). According to Silverman (2001), a given methodology should not be considered right or wrong but rather more or less beneficial for a given research question. If there is a diversity of research questions then different methodological approaches need to be considered. It is believed that choosing an appropriate methodology is driven by one's ontological and epistemological beliefs (Holden and Lynch 2004). Ontology refers to the nature of reality whereas, epistemology is defined as the nature or the justification of knowledge or how reality can be assessed (Patton 2014).

Based on different ontological and epistemological positions, several overarching philosophical orientations have been identified by authors. These are commonly known as research paradigms or worldviews. However, a definitive way to categorise various paradigms does not exist. For example, Schwandt (2000) has discussed three epistemological stances involving interpretivism, hermeneutics and social constructionism, whilst Lincoln and Guba (2000) distinguish five paradigms, including positivism, post-positivism, critical theory, constructivism and participatory paradigm. Among all of the above, positivism, constructivism, transformative, and pragmatism receive the most attention in the literature (Creswell and Creswell 2017) and is deemed most appropriate for the current research.

Positivism is also called post-positivist research or empirical science. Positivism believes in a stable reality independent of what we think about it, while post-positivism represents the thinking after positivism. It challenges the original concept of a single absolute reality and acknowledges that one cannot be absolutely positive about their claim (Phillips and Burbules 2000). The terms constructivism, social constructivism and interpretivism are often used interchangeably in the literature. Constructivists believe that there is no single reality or truth, and individuals create reality. Therefore, according to constructivism, individuals seek to understand the world and develop subjective meanings of their experiences (Creswell and Creswell 2017). In the transformative research paradigm, research intervenes with politics to implement political changes for whatever social issue is being researched, thus containing an action agenda for reform (Mertens 2007).

Meanwhile, a pragmatic worldview is identified as arising out of actions, situations, and consequences (Creswell and Creswell 2017). It offers a framework to question and evaluate ideas and beliefs by employing their practical functioning. Kelly and Cordeiro (2020) present three methodological principles for a pragmatic paradigm with relevance to organisational process; 1) emphasis on actionable knowledge, 2) recognition of interconnectedness between experience, knowledge and acting, 3) a view of inquiry as an experimental process. In contrast to other paradigms which emphasise the nature of reality, pragmatism is focused on the nature of experience to ensure the practical relevance of research (Morgan 2014). In essence, pragmatism recognises the interaction between experience, knowledge and acting, thus presenting numerous possibilities to develop or combat practices' limitations (Kelly and Cordeiro 2020).

This thesis endeavoured to develop and evaluate a practical solution for people with LBP to be active and exercise. Whilst considering theory and evidence related to the

LBP and the aimed health behaviour change, it also warranted exploring beliefs, knowledge and practices of several groups of stakeholders during the development process. Not only has this research included multiple research components and involved the use of stakeholders to produce an end product, it was also evaluated using further research and theory. Accordingly, adopting a pragmatic approach to answer the research questions of this thesis was deemed more appropriate.

3.3 Overview of methodological approaches

Quantitative and qualitative approaches are the two main methodological approaches (Fox 2001) and they can be applied either on their own or in combination (mixed methodology).

3.3.1 Quantitative approach

The quantitative approach is defined as one of the oldest and most widely accepted research methodologies (Creswell and Creswell 2017), it provides quantified answers to research questions. Objectivity is considered the most significant element of quantitative research and is regarded as a virtue that every quantitative researcher strives to achieve (Sarantakos 2012). The main aim of objectivity is to present the social reality as it is without any personal prejudice and bias by the investigator (Sarantakos 2012). The researcher remains distant and neutral concerning respondents, data collection methods and analysis, this is required in order to maintain objectivity in quantitative research. Also, in order to achieve generalisation of the findings, it is crucial to recruit a sample that reflects the attributes of the target population. Punch (2000) argues that given that a sample is representative of the population, results from quantitative research can be generalised to the whole population and are capable of expressing correlations of variables being tested. Questionnaires and surveys have been commonly used as data collection tools in quantitative research over the years (Silverman and Data 2001). However, these tools may also comprise open questions resulting in a mixture of quantitative and qualitative data.

3.3.1.1 Quantitative analysis – Descriptive statistics

Descriptive statistics are used to describe the characteristics and distribution of data that have been collected, such as the sample characteristics, demographic variables, and the variables of interest. Descriptive statistics summarise data and can describe frequencies and distribution (Prem 1995). Comparing the sample with the study population through descriptive statistics is also important and, if applied correctly, permits the transfer of quantitative study results to the study population (Morris 1989).

3.3.2 Qualitative approach

Qualitative research is defined as a set of material and interpretative practices, such as interviews, field notes, conversations, photographs, recordings, and memos, that make the world visible (Denzin and Lincoln 2011). Emerging during the last three to four decades, the qualitative approach has been widely used to generate ideas and theories. However, not all research questions are theory-based and qualitative methods could be used without being framed to any single epistemological perspective (Patton 2014). In real-world practice, qualitative inquiry methods can be separated from the emerging epistemologies and can stand on their own (Patton 2014). According to Ritchie and Lewis (2013), there is no single accepted way to conduct qualitative research. Whilst interviews are the most common qualitative research method used, group discussions, observations, notes, pictures and other materials are also used (Savin-Baden and Howell-Major 2013). Unlike quantitative research, questionnaires are not strictly defined and conducted using unstructured or semi-structured interviews in qualitative studies.

Both of these approaches have their strengths and weaknesses. For example, a qualitative approach attempts to inductively and holistically understand the human experience and construct meanings to understand a certain phenomenon (Ritchie et al. 2013; Patton 2014). It provides an in-depth understanding and detail without being constrained by predetermined categories. Whereas quantitative research often takes a deductive approach which begins with a hypothesis tested through data collection and analyses to confirm or disprove the hypothesis (Creswell and Creswell 2017). Quantitative methods require standardised measures leading to a limited number of predetermined response categories to which numbers are assigned. However, it is possible to evaluate a larger sample of subjects with a consistent set of data with quantitative approaches, thus facilitating comparison and statistical aggregation of data.

In contrast, qualitative methods usually provide an in-depth understanding of the subjects, often in a smaller population, thus reducing the generalisability. Moreover, validity in quantitative research depends on careful construction and standardised administration of the instrument according to prescribed procedures. Whereas in qualitative methods, the researcher will be the instrument, and therefore credibility of the data and ultimately the study will largely depend on the researcher's skills, competence, and rigour (Patton 2014).

Despite their unique strengths and weaknesses, a combination of qualitative and quantitative approaches can be pursued to obtain more comprehensive knowledge about an issue, this is broader than a single approach and can improve the objectivity of the findings (Flick 2018). This could be instrumental in developing complex interventions often where multiple research questions are studied.

3.3.2.1 Qualitative analysis

Quantitative analysis converts data into results. A broad range of approaches is available to analyse the qualitative data with different schools of thoughts. According to Lacey and Luff (2001) analysis of qualitative data can be pursued at three different levels; content analysis to simply identify the content in the data without going in to further analyse ; thematic analysis to gain a deeper understanding with coding, extraction and examination of data in more detail to identify key themes; theoretical analysis such as a grounded theory approach (Glaser and Strauss 1967) to develop theories following the analysis of data. However, these approaches are not clearly demarcated and overlapping of different approaches is often noted.

Whilst Lacey and Luff (2001) identify content analysis as one of the levels of qualitative analysis Patton (2014) argues that it denotes any effort of data deduction, sense-making and identification of patterns in a volume of qualitative data. In contrast, content analysis has also been identified as another method of analysis (Neuendorf 2017). However, content analysis often crosses paths with thematic analysis and shares common steps within the analysis involving familiarisation, coding and pattern recognition. However one of the significant differences between these two approaches is that content analysis tends to focus more at a micro level and the researcher often counts instances of codes (frequency) to understand the existing word patterns (Wilkinson 2000). Accordingly, findings of the analysis will allow a subsequent quantitative analysis of initially qualitative data (Ryan and Bernard 2003).

In contrast, thematic analysis (TA) tends not to be quantified but explores different dimensions of a phenomenon by actively constructing patterns emerging from the data set. This process involves interpretation of generated codes and constructing overarching themes (Kiger and Varpio 2020). Some authors have highlighted the use of TA only in certain methodological approaches such as ethnography and phenomenology. However, in their highly cited paper Braun and Clarke (2006) argue that TA has the ability to not only stand alone as an analytic method, but also to consider as the foundation for other qualitative research methods. Consequently, TA has been extremely popular in health and social care research and widely used in interpretation of qualitative data. TA is the analysis method used within the qualitative components in this PhD study.

TA has some significant strengths as a method of answering specific research questions. TA also offers a robust but more flexible approach for the qualitative analysis and provides an active choice for the researcher to decide on the engagement with data (Braun and Clarke 2006). It provides a good balance of flexibility and structure for the analyst (Guest et al. 2011). Also, thematic analysis is suitable for a wide range of research questions, including identifying patterns in people's behaviours, analyses of people's experiences, or determining how specific issues are being represented or constructed as an object of interest (Braun et al. 2016). Researchers can adopt either inductive or deductive approaches when using TA (Braun and Clarke 2006). As used in grounded theory, the inductive approach infers the theme from researcher data (Varpio et al. 2020). Because these topics are data-driven, they may not reflect the exact question asked by the participant and do not necessarily reflect the researcher's interests or beliefs. Conversely, the deductive approach uses existing theories, frameworks, or other research-led foci to identify themes of interest (Braun and Clarke 2012).

The grounded theory approach, introduced by Glaser and Strauss (1967), allows generation of theory from data. It involves a continuous process of data collection and analysis, constant comparing of concepts and categories emerging at one stage with ones emerging from the next until no new significant concepts and categories are identified.

Framework analysis is another iterative method of analysing qualitative data used to explore beyond the thematic description of a phenomenon to identify typologies or develop theories (Goldsmith 2021). It is distinguished from grounded theory mainly due to creating a analytic framework and applying this framework within the analysis (Ritchie et al. 1994). However, despite the differences between thematic , content and framework analysis they commonly share several steps of the analysis process involving; familiarisation with the data, identifying, describing and interpreting key patterns grounded in data (Lacey and Luff 2001; Patton 2014; Goldsmith 2021).

3.3.2.2 Maintaining rigour in qualitative data analysis

Although different types of analysis emphasise different elements of the analysis, there are several common key principles applied in qualitative data analysis to maintain or improve the credibility of the analysis. These principles commonly include transparency, maximising the validity, maximising the reliability, comparison and reflexivity (Green and Thorogood 2018). Transparency refers to the clear and explicit manner in which the methods are used and how clearly, they are disclosed in the report for readers. For example, transparency could be achieved by including short descriptions of how codes and other categories/ themes were developed and how the sample was chosen. Maximising validity, although strongly associated with quantitative data, to focus on the essential “truth” of the interpretation. Qualitative interpretation of data also warrants measures to maximise the credibility of the research (Patton 2014). Common approaches utilised in qualitative research to improve validity include providing evidence from the data for each interpretation such as counts, inclusion of deviant cases/disconfirming data and performing a validity check by taking the findings back to the participants to ensure they agree (Green and Thorogood 2018). Maximising reliability refers to the repeatability of the interpretation of the data, this is often achieved by having more than one researcher involved in coding the data, including raw data or quotes in the published reports and comprehensive analysis (Dey 1993). Comparison drives qualitative analysis and enables theoretical analysis to develop. It is recommended that data are constantly compared between and within the cases in the data, also findings should be compared with other relevant studies (Green and Thorogood 2018). Reflexivity refers to recognising the researcher's role in the process of data collection and interpretation and a conscious reflection. Compared to invisible researcher in quantitative research to reduce researcher bias, qualitative researcher plays an active role in both data collection and analysis. Therefore by acknowledging their own influence on the process, the researcher adds reflexivity to the analysis and thus increases trustworthiness and credibility (Murphy, Dingwall et al. 1998).

3.3.3 Mixed methodology approach

Over the years, the separation of qualitative and quantitative research has become less prominent, and two approaches are now seen as complementary instead of rivals (Jick 1983; Clark and Creswell 2004). The use of both approaches in combination is referred to as a mixed-methods design (Creswell and Creswell 2017). Originating in the late 1980s, this approach has gained popularity in the recent decades (Tashakkori and Teddlie 2010), with publications emphasising the method and providing a comprehensive overview that involves the collection of both qualitative and quantitative data and the use of rigorous methods (i.e., data collection, data analysis, and interpretation) followed by integration of two forms of data in the design analysis in response to research questions or hypotheses (Tashakkori and Creswell 2007). According to Punch (2000), the mixed-method approach compensates for the weaknesses in each other, enhancing the overall strength of the study.

In contrast to philosophical suppositions (epistemologies and ontologies), the mixed methods approach stems from the pragmatic viewpoint, which considers answering research questions to be the main priority of research (Johnson et al., 2007). A comprehensive and multifaceted understanding of research questions often warrants the use of pluralistic approaches regardless of philosophical assumptions (Yvonne Feilzer 2010). Pragmatism fulfils this need, allowing multiple embedding methods, different paradigms, assumptions, and forms of data collection and analysis. It allows researchers to draw liberally from quantitative and qualitative assumptions to answer the research questions (Tashakkori and Teddlie 2010).

Given this, there has been a growing appreciation of multiple ways of understanding factors that impact on health and well-being. Many studies now adopt mixed-methods approaches in healthcare and social science research (Collins et al. 2007). Understanding complex phenomena in social and healthcare research requires the use of multiple methods to overcome the limitations of each method. Thus, mixed methods represent a reasonable alternative approach for comprehensively exploring complex phenomena from a practical point of view in order to answer the research questions.

Whilst many reasons have been identified for the use of mixed-methods studies, Greene et al. (1989) claimed five purposes: triangulation, complementarity, development, initiation, and expansion. Ritchie et al. (2003) argued that each of the qualitative and quantitative approaches provided a distinctive kind of evidence and, used together, they can offer a powerful resource to inform and illuminate policy or practice. Additional rationales or benefits identified in the literature include completeness, answering different research questions, illustration of data, hypotheses development and testing, and instrument development and testing (Clark and Creswell 2004; Bryman 2006; Doyle et al. 2009). Many different designs of mixed-method studies are available depending on the dominance of qualitative and quantitative components and the time of quantitative and qualitative data collection (Johnson et al. 2007a).

Three core mixed-method designs have been established; convergent design (single-phase with both qualitative and quantitative data), explanatory sequential design (two phases with initial quantitative data followed by qualitative data) and exploratory sequential design (three phases with initial qualitative phase, followed by building a feature to be tested and a final quantitative phase to test this feature)

(Creswell and Creswell 2017). However, based on critical studies published in social sciences research, this classification has now branched out to accommodate complex study designs involving more steps and procedures such as experimental, intervention trials and evaluation studies (Nastasi et al. 2007; Creswell and Clark 2017). Creswell and Plano Clark (2017) have introduced four examples of complex designs where the three core designs are embedded into more extensive processes involving; mixed methods experimental (intervention) design, case study design, participatory-social justice design and evaluation design. Each design has core designs embedded in them according to a conceptual framework and research priorities. Selection of the method to be used would be determined by the research questions and the researcher's expected study outcomes.

3.4 Sampling

It is crucial to identify the exact population or group/s the researcher is interested in for successful research. However, collecting data from this whole population is not usually possible. Thus, identifying a suitable number of individuals to represent that population and studying them as a group is warranted. According to Howard (1995) a proper sample should have a good representation of the population being studied which reflects the characteristics of the targeted population.

Sampling could be achieved by either probability or non-probability methods. In probability sampling, ideally, the researcher will aim to draw a random sampling so that each individual of the population has an equal probability of being selected (Morris 1998). Whereas in non-probability sampling, the individuals do not have an equal chance of being selected as they are chosen based on their availability and convenience.

Common probability sampling or random sampling techniques are simple random sampling, stratified sampling, cluster sampling and systematic sampling (Saunders 1997). Commonly used non-probability sampling methods include convenience sampling, consecutive sampling, snowball sampling and purposive sampling (Lunsford and Lunsford 1995). Overall, each sampling method has its own unique advantages and disadvantages, and the selection of the most appropriate sampling technique will depend on the needs of the individual research question to be answered.

3.5 Generating research questions and choosing an appropriate methodology

This PhD study aimed to develop a DHI to help people with LBP to be physically active and exercise using a pragmatic research approach. According to Feilzer (2010), compared to research philosophies with a sole emphasis on theory generation, pragmatism offers an “alternative, a flexible and more reflexive guide to research designs” (Feilzer 2010 p.7). Instead of interrogating the validity of specific methodologies and methods, a pragmatic approach encourages researchers to emphasise the research problem and question. To achieve this, multiple approaches are recommended, and researchers are given the freedom to select methods, techniques, and procedures that best answer the research questions (Morgan 2014; Patton 2014). As outlined in Chapter 1, this thesis proposes multiple research questions and clearly demands a mix of methodologies to answer them adequately. The following section describes the rationale for generating the above-mentioned research questions.

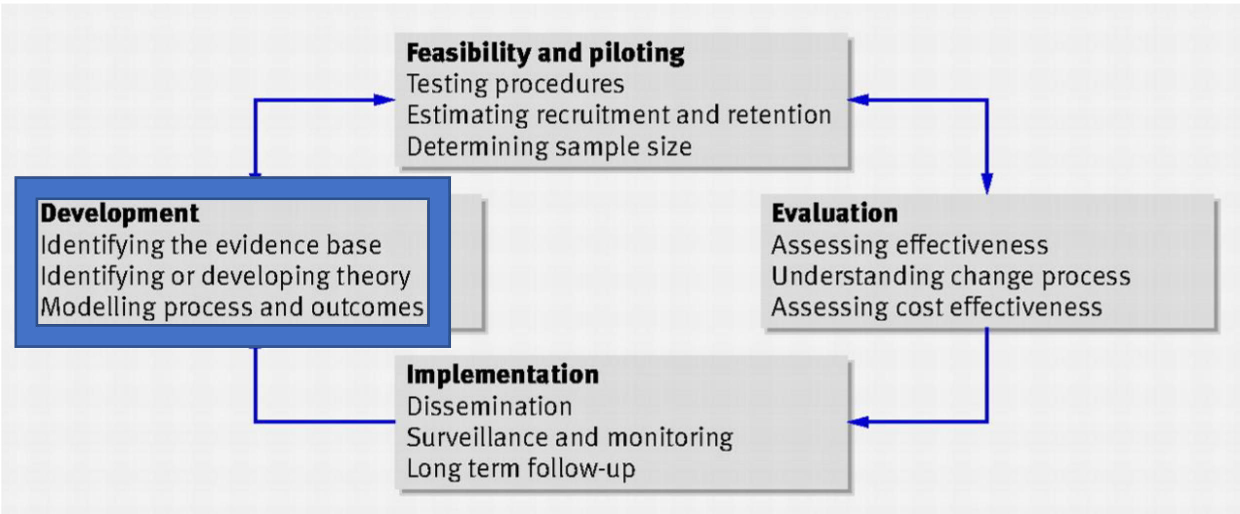
The obvious place for guidance and key framework for developing this intervention and the preliminary evaluation process was the Medical Research Council (MRC) guidance on developing and evaluating complex interventions (Craig et al. 2008) and the updated version published by Skivington et al. (2021). Only the 2008 MRC guidance (Craig et al. 2008) was available when the study planning and data collection were taking place. The 2021 update, which contains key recommendations and considerations advocated within the new framework (Skivington et al. 2021), has been acknowledged and is discussed throughout the thesis.

3.5.1 Medical research council guidance 2008

According to MRC guidelines (Craig et al. 2008), the development and evaluation of a complex intervention can often be a lengthy process involving multiple stages. The main stages of the development and evaluation process identified in the 2008 MRC guidance include development, feasibility and piloting, evaluation and implementation. The authors highlight the importance of each of these stages and caution that neglecting any will result in weaker and less worthy interventions.

This guidance recommends three main phases in the development stage: 1) identifying the evidence, 2) identifying or developing theory, and 3) modelling process and outcomes. The feasibility and piloting stage includes testing procedures for their acceptability, estimating the likely recruitment and retention rates of subjects, and calculating appropriate sample sizes. This Ph.D. project tackled the first stage of this process involving: 1) identifying the evidence base, 2) identifying or developing theory, 3) modelling process and outcomes. Figure 3.1 illustrates the key stages of the development and evaluation process as presented in MRC guidance, and the components covered in this Ph.D. are featured with boxes. Section 3.3.2 outlines the steps of the process concerning each of the specific research questions and methods deployed.

Figure 3.1: Key elements of the development and evaluation process. Stage covered in this PhD project is featured with the box. (Reproduced from Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M, Medical Research Council G: Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008, 337: a1655.)



3.5.2 Development - Phase 1: Identifying the evidence base

The first step in the MRC guidance highlights the importance of identifying existing knowledge related to intervention to ensure the worthwhile effect of the new intervention. A systematic review of relevant evidence is also recommended (Craig et al. 2008). The effectiveness of exercise in the management of LBP is well established in the literature. As well as a large number of RCTs on this topic (Frost et al. 1995; O'Sullivan et al. 1997; Niemisto et al. 2003), several systematic reviews have also proven positive effects of exercise and PA in LBP (Kool et al. 2004; Hayden et al. 2005b). Further, tailoring exercise according to individual need is considered of critical importance (Hayden et al. 2005b) ,it is endorsed in best practice guidelines including NICE guidelines for managing LBP (NICE 2019) to achieve superior outcomes. Self-management programmes are also recommended for the management of LBP. However, the literature provides a mixture of evidence on the effectiveness of existing exercise-based self-management programmes for LBP. Notably, most existing self-management programmes predominantly do not contain any exercise (Rathnayake et al. 2021). Given this, according to MRC guidelines, it was essential to identify whether developing a digital ESM intervention to support people with LBP to help to be active and exercise is necessary. Considering the above information acquired from the literature, research question 1 was generated:

What is the effect of LBP self-management interventions with exercise added?

Given the focus of this project, the literature was explored to review evidence of SMIs with an exercise component. Despite the large number of LBP self-management systematic reviews identified in the preliminary literature search, none specifically explored how exercise was incorporated in self-management programmes for LBP and what effect did that have on patient outcomes. As a result, it was necessary to consider conducting a systematic review and potentially a meta-analysis (Chapter 4).

3.5.3 Development - Phase 2: Identifying or developing theory

In this step, the importance of incorporating theory to better understand the intervention mechanism, drawing on existing evidence and theory supplemented by new primary research where necessary, is highlighted. Furthermore expected changes and how a change is to be achieved are discussed (Craig et al. 2008). Whilst the theory is claimed to aid both intervention design and evaluation (Davis et al. 2015), previous studies have shown that theoretically-based studies are more effective in increasing participant adherence to treatment advice than control interventions (Albarracín et al. 2005; Craig et al. 2008). However, “a theoretical understanding of the likely process of change” regarding ESM in this study was not straightforward in the beginning, and it was necessary to understand relevant behaviour change theories and potential use of them within this PhD.

3.5.3.1 Behaviour change theories

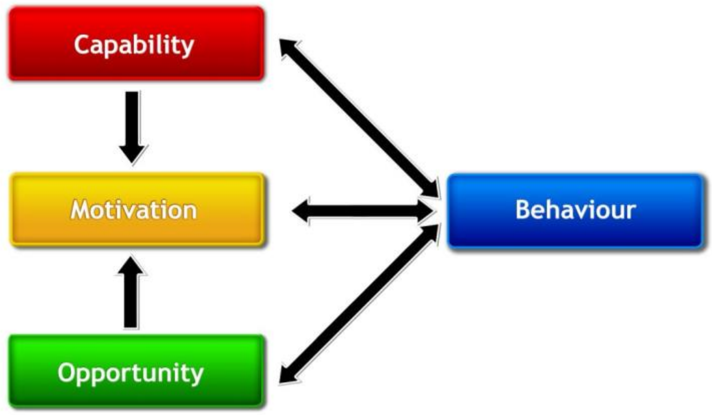
A theory is defined as a system of ideas or concepts to explain phenomena and how they relate to each other (Pope and Mays 2020) and sometimes to predict phenomena (Davis et al. 2015). For this study, intervention aiming to elicit change in exercise and PA behaviours in people with LBP, exploration of behaviour change theories was necessary to optimise the intervention design (Rosenstock et al (1990).

Despite advocating drawing on theory when designing complex interventions, MRC guidance does not give specific details on selecting and applying theory. In practice, the use of theory within interventions is minimal (Michie and Prestwich 2010). Moreover, even when using a selected theory, it might not cover the full scope of potential influences, thus excluding important variables (Michie et al. 2014). Therefore, to understand the process of change, it was essential to identify a framework which would provide a holistic approach to describe the application of theory in the intervention.

3.5.3.2 COM-B model of behaviour

COM-B model of behaviour; Capability, Opportunity and Motivation, by Michie et al (2011) has been used to understand behaviour, it offers a comprehensive and coherent framework that can be applied to design and refine behaviour change interventions (Figure 3.2). This model denotes the influence on behaviour and requirement for a certain behaviour to occur.

Figure 3.2: The COM-B model of behaviour (Reproduced from Michie, S., Van Stralen, M. M. and West, R. 2011. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implementation Science 6(1), pp. 1-12.)



According to COM-B model (Michie et al. 2011) capability, motivation and opportunity interact to prompt a certain behaviour which influences these elements, as shown in Figure 3.2. To address important distinctions that have been identified in the literature, authors have distinguished two subdivisions of each of the components. Thus, the model comprises 6 subdivisions involving physical capability, psychological capability, physical opportunity, social opportunity, reflective motivation, and automatic motivation. A behaviour analysis guided by the COM-B model was conducted in order to understand the behaviour and identify which components of the behaviour need to be changed. Table 3.1 describes the behavioural analysis of this study according to the COM-B model.

Table 3.1: Behavioural analysis for the project guided by COM-B model

Target Behaviour: To help people with LBP to be physically active and exercise.		
COM-B components	**What needs to happen for the target behaviour to occur?**	**Is there a need for change?**
Physical capability	A person needs to have the physical ability to engage in exercise and PA that will help their LBP.	Yes. The screening process to use the intervention to rule out clinical indicators of potentially serious pathologies and contraindications.
Psychological capability	A person needs to understand and feel confident about how exercise and PA helps their LBP.	Yes. Guiding people with LBP in selecting the right exercise for them with options to progress or regress exercises safely as poor cognition and beliefs are the main predictors of LBP.
Physical opportunity	Have access to an exercise intervention. To have an appropriate space (home/outside/gym) to exercise.	Yes. Change needed to provide easy and timely access to exercise and PA resources. Yes. Exercises that can be performed in range of settings of their choice or available, without restricting to one setting
Social opportunity	Option to access health professional advice if required.	Yes. Option to get quick access to healthcare professionals to reassure, offer feedback, refer if and when needed
Reflective motivation	Lack of motivation is critical in this population. A person needs to feel motivated to continue to exercise and supported in learning from the experience of taking part in exercise and PA.	Yes. Goal setting and offering feedback on progress to keep a person with back pain motivated. Ability to self-determine what exercise PA to take up.
Automatic motivation	Have established regular exercise routines and PA habits in users.	Yes. Need to establish regular exercise and PA habit formation.
Key: LBP – Low back pain, PA – Physical activity		

Above behavioural analysis illustrated how the target behaviour change needs to occur across the components of the COM-B model. The next phase was to identify what intervention functions should be included in the intervention to achieve the target behaviour.

3.5.3.3 Overview of potential behaviour change techniques

BCTs act as the primary "active ingredient" of an intervention function. Michie et al. (2013) published an extensive taxonomy of 93 grouped BCTs with sixteen different sub-headings or hierarchies. Given the extensive number of BCTs, primary research was required to determine the most appropriate BCTs to capitalise within the intervention. Based on the updated MRC guidance by Skivington et al. (2021), healthcare stakeholder experience-based recommendations are considered instrumental in ensuring that interventions are effective within the healthcare model they are required to work in, also to ensure that any subsequent intervention can be implemented into clinical practice. Therefore, it was decided to involve healthcare professionals in the decisions on which BCTs should be included in the intervention.

In practice a broad range of BCTs are embedded within management and self-management programmes conducted by physiotherapists, these aim to encourage people with LBP to improve their level of PA and exercise (Harman et al. 2014). However, there is a lack of detail in the literature related to the clinical reasoning process and allocation of most appropriate BCTs (Harman et al. 2014; Keogh et al. 2015). Hence, to answer the second research question, it was vital to explore the practices and opinions of physiotherapists on the management of LBP with an emphasis on ESM.

Tailoring of exercise programmes results in superior outcomes in pain and associated disability in people with LBP (Hayden et al. 2005b). An assessment provides the basis to understand the needs of the individual and informs a tailored exercise programme (Kent et al. 2009). Given this, it was appropriate to add a self-assessment component to make BACK-to-FIT™ a more tailored intervention to encourage people with LBP to exercise and be active. Although it was expected that the above qualitative study would trigger a discussion related to assessment, further research with a deductive approach was necessary to understand the components of assessment to tailor already identified BCTs and offer a bespoke ESM. Following the standard clinical assessment (Dagenais et al. 2010; Koes et al. 2010) to prescribe exercise to people with LBP, determining key subjective questions and objective tests that would contribute to planning an ESM programme seemed appropriate.

Considering all of the points above, the second research question was as follows:

What are the key components, as recommended by the expert clinicians, required within a self-management intervention to encourage people with LBP to be physically active and exercise and how to tailor them?

The dialogue between experts was anticipated to be the most valuable source of knowledge to answer the first element of the research question. Thus, a qualitative study using focus groups seemed appropriate. Compared with interviews, focus groups benefit from the exchange of opinions and interactions between participants, in addition to the available variety of individual viewpoints and the number of opinions gathered (Pett et al. 2003). Physiotherapists are the health care professionals who most commonly advise people on exercise and PA, they are thus in a better position to explain practice and perspectives and to understand the most appropriate intervention function elements and BCTs. Therefore homogenous focus groups with musculoskeletal physiotherapists, who had a background in treating patients with LBP, were conducted as the first study to answer research question two.

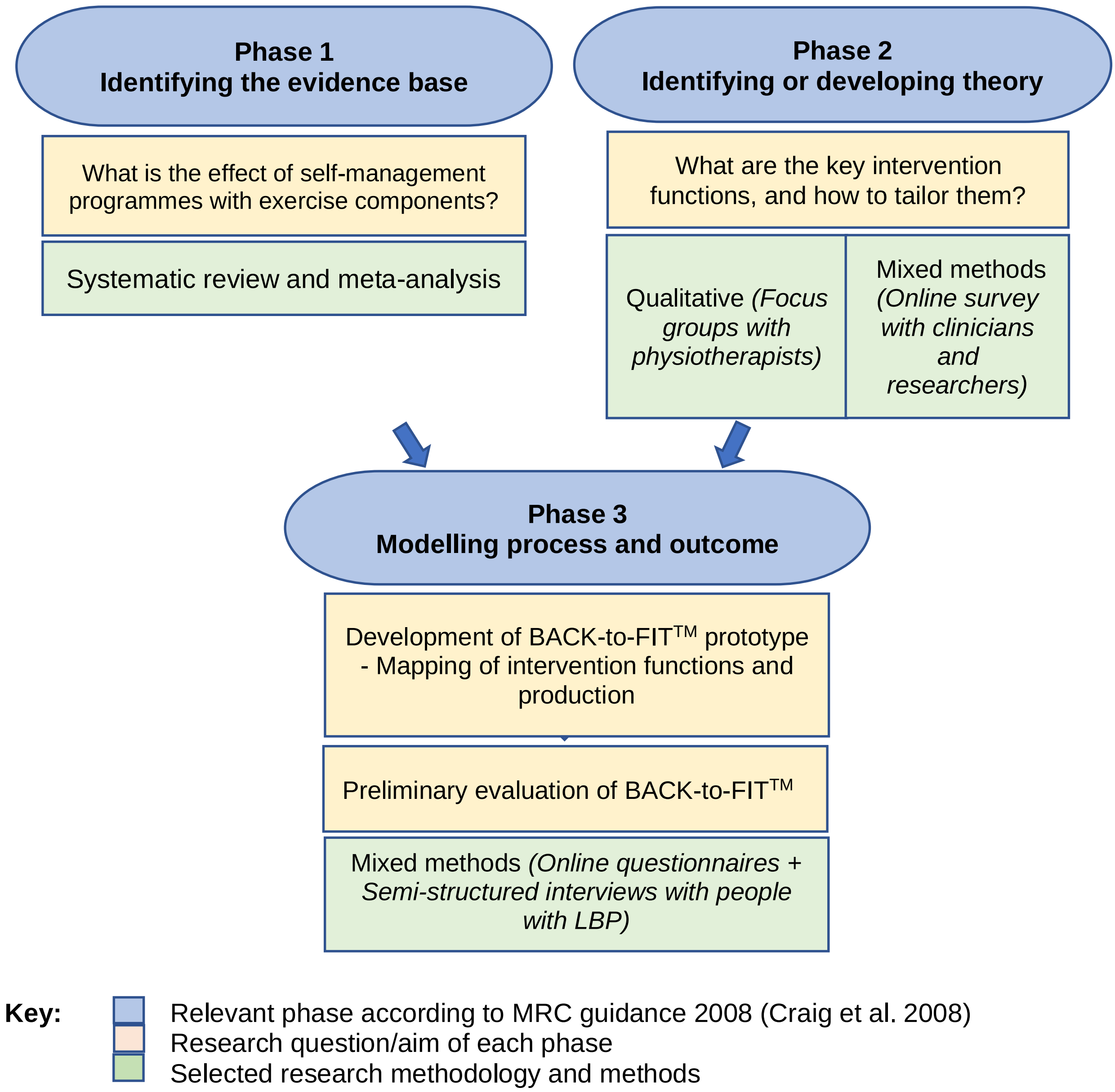
Although a qualitative approach gives the advantage of offering in-depth, detailed and complex information on a particular research area (Blair et al. 2013), it was not the scope of this part of the study. A survey provided the opportunity to reach a larger group of stakeholders to identify the key elements of an assessment using a deductive approach. Even though the survey is one of the most common quantitative research methods (Fink 1995), the use of mixed-methods in LBP related surveys is well established (Davies et al. 2014; Setchell et al. 2017). Whilst quantitative surveys predominantly comprise closed-ended questions with predetermined answer options, the addition of open-ended questions with a qualitative research element transforms it into a mixed-methods study. The use of open-ended questions will enable participants to express and articulate less common opinions or simply ones that were overlooked by the researcher when creating the survey, thus providing rich and relevant data (Albudaiwi 2017). Given the above facts, a mixed-methods cross-sectional survey design with descriptive qualitative methods was used as the second study to answer research question two.

3.5.4 Development - Phase 3: Modelling process and outcomes

MRC guidelines recommend developing and modelling an intervention up to a level where it has a worthwhile effect before embarking on any large scale evaluation (Craig et al. 2008). Also, the importance of assessing and/or refining these models throughout the iterative development process has been emphasised (Campbell et al. 2007; Craig et al. 2008a; Skivington et al. 2021). Answering the first two research questions provided the knowledge to understand how this intervention should work and its 'active ingredients'. The logical next step was modelling and constructing the prototype of the intervention, in this case, a digital platform that would include these 'active ingredients and promote changes in the target behaviours. Even though a prototype version of the intervention could be developed based on knowledge and evidence gathered in previous steps, further input with potential end-users was essential to develop further and refine the intervention, assessing whether this interpretation of the literature, theory and stakeholders' views resonated with potential end-users. A model of action which describes the process focused on the development and the preliminary evaluation of the prototype is illustrated in Figure 3.3 along with the appropriate steps of MRC guidelines, aims for each phase and selected research methodologies/methods.

As the first step of the modelling process, evidence, theory and knowledge from previous steps were translated to produce the prototype intervention and represents Phase 3 of the above model. Accordingly, mapping an array of intervention functions identified through research questions 1 and 2, with expected behaviour change outcomes of the intervention was carried out, thus deciding the intervention structure, features, and content. Given the limited time and resources, only a few intervention functions identified using the COM-B components were included in the prototype. This approach is considered appropriate based on the MRC guidance (Craig et al. 2008) and has been adopted previously when developing DHIs (Lyon and Koerner 2016; Jansen-Kosterink et al. 2020; Solem et al. 2020). After mapping the intervention functions, the prototype of the website was developed. Due to the author's lack of experience, or a background in computer programming, it was decided to obtain professional service in this task. Phase 3, consisted of the mapping process, the subsequent development process of the intervention prototype has been described in detail in Chapter 7.

Figure 3.3: Model of action of the proposed intervention prototype



The second step corresponds to phase 4, it involved obtaining end-user feedback on the intervention to refine the prototype and optimise it prior to any larger-scale evaluation. New interventions often report problems with acceptability, compliance, delivery of the intervention, and smaller than expected effect sizes and it is believed that these would have been predicted through early-stage evaluation (Eldridge et al.

2005). The importance of ongoing evaluation and feedback to improve the implementation potential of interventions is emphasised in the literature (Mair et al. 2012) and in best practice guidelines, including Evidence Standards Framework for Digital Health Technologies, UK (NICE 2019).

The effective engagement required for a behaviour change via a digital intervention such as BACK-to-FIT^{TM} is likely to depend on the action context and the user. This can only be determined by analysing the context and the complex relationships between user experience and outcomes (Michie et al. 2017). Therefore, it was crucial to evaluate the intervention's user experience (Anderson et al. 2016; Geraghty et al. 2020). Moreover, it was vital to evaluate the ease of use (usability) (Sousa and Lopez 2017) and the level of acceptance as in any novel technological intervention these are fundamental in ensuring e user uptake (Davis 1989; Kim and Park 2012). All the above resulted in the generation of a third and final research question:

What is the preliminary user experience, usability, acceptability, potential health benefit of a prospective intervention prototype?

According to MRC guidelines, a mixture of qualitative and quantitative methods and a series of studies are recommended at the early stages of evaluation of a complex intervention. This process aims to progressively refine the design before embarking on a full-scale evaluation (Skivington et al. 2021). Whilst quantitative analyses are often helpful in informing the efficacy of the intervention, a qualitative investigation is essential to explore users' understanding of the intervention and interpret their experience Craig et al. 2008; Michie et al. 2017). These qualitative components play a key role in participatory user-centred research designs and are important in evaluating health behaviour interventions to ensure they are effective and engaging as expected (Yardley et al. 2015). Given these facts, it was apparent that this research question was best answered using multiple research methods due to the nature of the intervention aspects being evaluated.

The objective of this part of the study was to obtain preliminary evidence and understanding of the initial use and potential benefits, rather than confirmation of the effectiveness of the intervention. For this reason, a single-arm study in which individuals were given the opportunity to use the intervention and then followed over time to observe their response was appropriate (Evans 2010). A quantitative approach was used to evaluate usability and acceptance of technology, potential health benefits were assessed online using existing, validated questionnaires. As an alternative to traditional data collection, online data collection is efficient, convenient, and cost-saving (Mertler 2002). It is also argued that online data collection minimises data loss and simplifies the transfer for the analysis (Ilieva et al. 2002). Online surveys have become an important alternative tool for research during the pandemic where traditional methods of obtaining participant data were not feasible (Hlatshwako et al. 2021).

A qualitative approach was selected to assess user experience using semi-structured interviews. This method was deemed most appropriate as, according to Harrell and Bradley (2009), interviews offer an opportunity to discuss specific aspects around the intervention, allowing a deeper understanding of any necessary modifications and improvements through user feedback. During piloting this aids in refining the intervention (Craig et al. 2008). Semi-structured interviews allow the researcher to pose specific questions to address pre-defined research questions whilst allowing the interviewee to provide open responses in their own words. Semi-structured interviews with multiple participants were selected over structured interviews to avoid any preconceived ideas, they were led by the participants' agenda to a greater extent, thus allowing a range of perspectives (Gill et al. 2008).

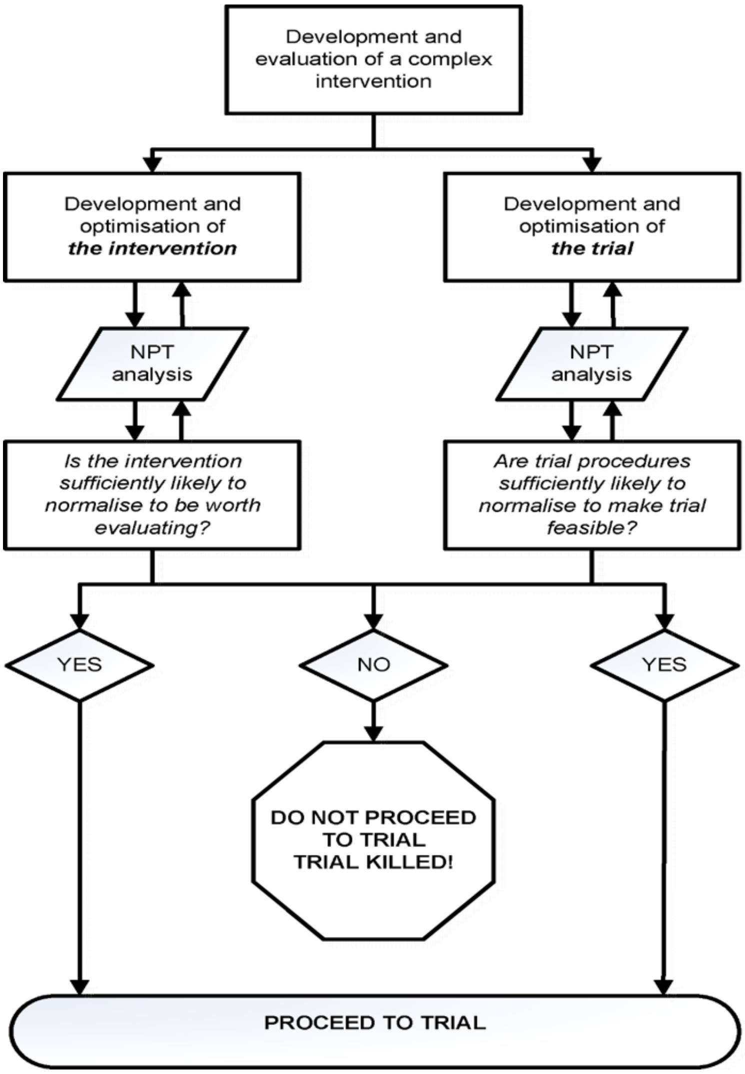
3.5.4.1 Normalisation process theory (NPT) framework

An important element of user experience was to understand the implementation of this complex intervention and how it would potentially be operationalised in practice (Craig et al. 2008). To this end, normalisation process theory (NPT) (May and Finch 2009) was selected to inform the semi-structured interview topic guide and the analysis of the results. First introduced in 2009 (May and Finch), NPT is concerned with the social organisation of work (implementation), of routinising elements of practice into everyday life (embedding), and of sustaining (integrating) embedded practices in their social contexts. Over recent years, NPT has been increasingly applied in healthcare intervention research as an implementation theory to understand the implementation and integration of complex interventions (Farr et al. 2018; Gillespie et al. 2018). NPT aims to explain the implementation of routine practices by reference to the role of four constructs: coherence, cognitive participation, collective action and reflexive monitoring.

Coherence refers to the work of making a complex intervention hold together and cohere to its context or how people ‘make sense’ or not of the new ways of working. Cognitive participation is the work of engaging and legitimizing a complex intervention, exploring whether participants buy into and/or sustain the Intervention. Collective action examines how innovations help or hinder users in performing various aspects of their work, issues of resource allocation, infrastructure and policy, how workload and training needs are affected and how the new practices affect confidence in the safety or security of new ways of working.
Reflexive monitoring refers to understanding and evaluating a complex intervention in practice and how individuals or groups come to decide whether the new ways of working are worth sustaining.

The application of NPT analysis can be used both at the development of the intervention, in which the analysis would continue if the intervention is then implemented and to optimise the evaluation of the intervention, which would not continue (Murray et al. 2010). Carrying out an NPT analysis during the development stage informs the researchers of subsequent iterations of the intervention to enhance its chances for normalisation. However sometimes, an NPT analysis will render this impossible, and researchers might have to abandon the intervention without proceeding to further development or to the evaluation stage, therefore well-known for its role as a ‘trial killer’ (Figure 3.4).

Figure 3.4: Normalisation process theory (NPT) analysis as a "trial killer" (Reproduced from Murray, E. et al. 2010. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC medicine* 8(1), pp. 5).



3.6 Chapter Summary

The purpose of this methodology chapter was to describe the rationale behind the choice of research questions and the following methods for each question, providing a more in-depth understanding of the decisions made within this study. As this study involves the development of a novel and complex intervention, it was necessary to follow recommended guidelines to achieve a successful outcome even though it comprises multiple phases of research. This illustrates the excellent learning experience that occurred through challenges and evolving decision-making processes.

Chapter 4: What is the effect of low back pain self-management interventions with exercise components added?: A Systematic Review with meta-analysis

4.1 Introduction

This chapter describes the systematic review and the meta-analysis conducted to answer the first research question. As discussed in the literature review, exercise is considered to be the most effective intervention compared with other LBP management approaches (Hayden et al. 2005a; Van Middelkoop et al. 2010; Searle et al. 2015a). Existing LBP SMIs have demonstrated an inconsistency in their findings (Oliveira et al. 2012; Toomey et al. 2015b,a; Du et al. 2017). Similarly, a lack of consistency can be seen in the content of these SMIs with a significant variation in delivery such as in mode, audience duration, frequency and personnel delivering the intervention (Kroon et al. 2014). However, it is not clear how the mode of delivery will impact the outcomes of the SMIs with exercise programmes in LBP. Moreover tailoring exercises to an individual's profile, as recommended within NICE guidelines (NICE 2019) is not always considered within these SMIs, most likely because of its inherent challenges when it comes to SMI designs (May 2010). Subsequently the role of tailoring exercise according to a person's needs and its specificity to the individual's profile within SMIs also remains unclear.

Despite the known benefits and recommendations of exercise for LBP (Oliveira et al. 2012), not all SMIs include exercise or PA within their structure. Those that do include exercise vary in their delivery from very generic advice to individualised and graded exercise (Du et al. 2017). To date, no reviews have determined the effect of SMIs on pain and disability in people with CLBP when an exercise component has been included. Therefore, the aims of this review were to estimate the effect of SMIs with exercise components on pain and disability at short, intermediate and long-term follow-up in patients with CLBP and to summarise the characteristics of the SMIs with exercise including content and mode of delivery.

4.3.3 Study characteristics

The included nine RCTs and descriptive information of the included trials is given in Table 4.2. In total 09 trials recruited 1866 participants. The trials recruited study participants from the community (Buhrman et al. 2004; Haas et al. 2005; Bronfort et al. 2011; Irvine et al. 2015; Zadro et al. 2019), from primary care, hospital and healthcare settings (Von Korff et al. 1998; Von Korff et al. 2005; Johnson et al. 2007b), through employers (Shebib et al. 2019) and healthcare workers from hospitals (Chaleat-Valayer et al. 2016). The most frequently reported outcome measure for pain was Visual Analogue Scale (VAS) and NPRS ranging from 0 – 10 or 0 – 100 with higher scores indicating more severe pain intensity. For disability, the most frequently used scales were RMDQ (23 and 24 item versions) and modified Von Korff disability score with higher scores indicating more severe disability.

Table 4.2: Characteristics of included studies

Authors, Year	Subjects	Follow up duration	Self-management intervention	Exercise component in the experimental group self-management intervention	Control	Outcome measures
Buhrman et al, 2004	51 CLBP patients from the community Mean(SD) age 44.6 ± 10.4 years EG: n=22 CG: n=29	8 weeks 3 months post-randomisation	A 6-week internet-based cognitive behavioural self-help treatment with telephone support including treatment consisted of education, cognitive skill acquisition, behavioural rehearsal, generalisation and maintenance.	Stretching and physical exercises on an individualised graded activity basis with structured information, relaxation exercises	Usual care consisting of access to primary care, pain medication, exercise, manual therapy and advice	Pain: Pain diary (0–100) ↓ = better Disability: Pain Interference subscale of MPI (0–6) ↓ = better
Chaleat-Valayer et al, 2016	342 healthcare workers with recurrent LBP EG: n=171 Mean (SD) age 47.1 ± 8.5 years	12 months 18 months 24 months post randomization	2-hour education session, five weekly 90-minutes group exercise training sessions in the workplace, and a home-based self-management programme.	One physiotherapist led five weekly 90-minute training sessions with coaching 8-10 participants based in the workplace. Each session composed of a 15-minute	Usual care consisting of access to primary care, pain medication,	Pain: VAS (0–100) ↓ = better Disability: QBPDS

	CG: n=171 Mean(SD): age47.3 ± 8.5			warm-up with rhythmic exercises, followed by 60 minutes of stretching and mobilising the spine (including relaxation of the lumbar spine and stretching of the hamstrings, gluteal, quadriceps, psoas and adductors, as well as pelvic tilt awareness exercises) and 15 minutes involving respiratory and postural work. A booklet for self-managed home exercises (at least 10 mins) and the French version of the *Back Book.*	exercise, manual therapy and advice	(Score of 0 – 100) ↓ = better
Irvine et al, 2015	398 CLBP patients from public EG: n=199 CG: n=199.	8 weeks 16 weeks post-randomisation	An 8-week multiple-visit online FitBack intervention Based on the self-tailored cognitive-behavioural approach, designed aiming to encourage users to adopt appropriate pain prevention	Instructional videos on specific strength and stretching exercises tailored by job type (siting , standing, driving , lifting).	Usual care consisting of access to primary care, pain medication,	Pain: 10-point "pain dial" (1–10) ↓ = better

			behaviours. Participants also received 8 programme emails with content and prompt related to CLBP self-management.	Messages in the weekly emails, links within the activity picker, and recommendations within the FitBack programme repeatedly link users to the video content.	exercise, manual therapy and advice	Disability: A 10- item scale (1–10) ↓ = better.
Johnson et al, 2007	234 LBP patients consulting their GPs EG: 116 Mean (SD) age: 47.3 $\pm$ 10.9 years CG: n =118 Mean age: 48.5 $\pm$ 11.4	3 months 9 months 15 months post-randomisation	A 6-week community-based programme including eight 2-hour group exercise session comprised of active exercise and education led by 2 physiotherapists using a CBT approach to cover self-management elements of back pain, including problem-solving, pacing and regulation of activity, challenging distorted cognitions, and help to identify helpful and unhelpful thoughts.	2-hour group exercise session focused on independent control of LBP and resumption of normal activities and home exercise and PA plan including paced activity programmes, engagement in previously voided activities of daily living and resumption of hobbies and leisure activities.	Usual care consisting of access to primary care, pain medication, exercise, manual therapy and advice supplemented by an educational pack	Pain: 100 mm VAS ↓ = better Disability: RDQ (0-24) ↓= better

Haas et al, 2005	109 community-dwelling seniors with CLBP Mean (SD) age 77.2 $\pm$ 7.7 years EG: n=60 CG: n=49	26 weeks (6 months) post-randomisation	A 6-week workshop led by 2 trained laypeople with a weekly class of 2.5 hours taught from a structured protocol designed to enhance self-efficacy including general principles of chronic conditions, an overview of self-management principles, care-seeking options; community resources; exercise; relaxation; nutrition; medication and side-effects; skills-building; learning fi-om others; sharing with others; goal setting; action plans; feedback; and problem-solving.	General exercises and relaxation exercises	Usual care consisting of access to primary care, pain medication, exercise, manual therapy and advice Online education on LBP	Pain: MVK pain scale (0– 100) ↓ = better Disability: MVK disability scale (0–100) ↓ = better
Von Korff et al, 1998	255 back pain patients enrolled in a health maintenance organisation EG: 129	3 months 6 months 12 months post randomization	Four 2-hour classes 1 time a week led by 2 trained volunteer laypersons with knowledge delivery, action planning goal setting, professionally developed self-care materials including a self-care book, videotape on LBP self-management and exercises	A 25 minute videotape demonstrating LBP exercises	Usual care consisting of access to primary care, pain medication, exercise, manual therapy	Pain: NPS (0-10) ↓ = better Disability: RDQ (0-23) ↓= better

	Mean(SD) age: 49.4 + 11.7 CG: 126, Mean (SD) age: 50.3 + 10.9 years				and advice with a book on back care	
Von Korff et al, 2005	240 CLBP patients enrolled in a health maintenance organisation EG: 119 Mean (SD) age: 49.7 + 9.0 years CG: 121, Mean (SD) age: 49.8 + 9.8	2 months 6 months 12 months 24 months post-randomisation	4 in-person visits including a visit with a 90-minute visit with a psychologist, a 60 minute and a 30 minute visit with a PT and a last 30-minute visit with a psychologist 7–10 days later.	A 25 minute videotape demonstrating LBP exercises, Home exercise programme with stretching and strengthening exercises relevant to the action plan and goals by a PT after a standardised mechanical examination of the back.	Usual care consisting of access to primary care, pain medication, exercise,manual therapy, advice and physical therapy	Pain: NPS (0-10) ↓ = better Disability: RDQ (0-23) ↓= better
Shebib et al, 2019	177 Employees and their dependents	12 weeks post-randomisation	A 12-week digital care programme consisting of exercises, CBT, education articles, peer support discussions, activity and symptom	Sensor-guided physical therapy exercises and aerobic activities; 3 times per week	Usual care consisting of access to primary care, pain medication	Pain: VAS (0 – 100) ↓ = better

	at participating employers, across 12 locations in the US with CNSLBP Mead (SD) age: 43.0 ± 11.0 years EG: 113 CG: 64		tracking through a digital app on a tablet computer		, exercise, manual therapy , and advice , 3 digital education articles	Disability: MVK disability scale (0 – 100) ↓ = better
Zadro et al, 2019	60 CLBP patients from the local community and waiting list of an outpatient Physiotherapy Department Mean (SD) age: 67.8±6.0 years EG: 30 CG: 30	weeks 3 months 6 months post-randomisation	An 8-week unsupervised home-based exercise programme using Nintendo Wii U console with Wii Fit U software including 3 home visits by a PT	A standardised programme of 60 minutes including 5 minutes Yoga, 25 minutes strengthening, 10 minutes Aerobic and 20 minutes balance exercises with video and audio instructions and feedback according to the pressure on the balance board; 3 times per week. Flexibility to remove the exercises during the initial	Usual care consisting of access to primary care, pain medication , exercise, manual therapy and advice	Pain: NRS (0-11) ↓ = better Disability: RMDQ (0-24) ↓= better

				functional assessment by the PT and add any from the remaining exercises.		
Key: CLBP - Chronic low back pain, EG - Experimental group, CG - Control group, PT- Physiotherapist VAS - Visual analogue scale, NPS - Numerical pain scale, NRS - Numerical rating scale, CBT - Cognitive Behavioural Therapy, QBPDS - Quebec back pain disability scale, RDQ - Rolland disability questionnaire, MVK scale - Modified Von Korff scale, MRQ - Modified Roland Questionnaire, SD - Standard deviation						

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4.2 Methods

4.2.1 Literature Search strategy

A computerized search was performed in the following databases from the earliest record to April 2020 to retrieve evidence including grey literature: PUBMED, MEDLINE (OVID), CINHAL, EMBASE (OVID) and Cochrane Central Register of Controlled Trials. Standard search strategy recommended by the Cochrane Collaboration Back Review Group (Furlan et al. 2009) was followed to identify LBP RCTs, followed by search for "self-management ", "self-care" and "self-management interventions" as text words and Medical Subject Headings (MeSH) terms. The detailed search strategy is given below in Table 4.1. Cited reference retrieval was also conducted. Initially, two reviewers (author and LS) independently screened all titles, abstracts, and full texts for eligibility. Any disagreement was resolved through a consensus meeting or consulting the third reviewer (VS). Authors were contacted necessarily, to obtain further information. References and trial reports were managed using EndNote (EndNoteX9 2013).

Table 4.1: Literature search strategy

Medline and Cochrane (Ovid)	CINAHL (EBSCO)	EMBASE (Ovid)	PubMED
1. controlled clinical trial.pt. 2. randomised. ab. 3. randomised controlled trial.pt. 4. randomised controlled trial.mp. 5. controlled clinical trial.mp. 6. trial.ab 7. groups.ab 8. clinical trial$.mp. 9. 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8	S1. "low back pain" S2. "lumbar pain" S3. "non specific low back pain" S4. "lumbar spine pain" S5. back pain S6. chronic low back pain S7. S1 OR S2 OR S3 OR S4 OR S5 OR S6 S8. self-management S9. self care	controlled clinical trial.pt. randomised.ab. randomised controlled trial.pt. randomly.ab. trial.ab. groups.ab. 1 OR 2 OR 3 OR 4 OR 5 OR 6 (animals not (humans and animals)).sh. 7 not 8	low back pain"[MeSH Terms] OR "back pain"[MeSH Terms] OR spinal[All Fields] AND ("pain"[MeSH Terms] OR self-management" [MeSH Terms] OR ("self care"[MeSH Terms] OR "self"[All Fields]) support) OR "self-management strategies[All Fields])

10. (animals not (humans and animals)).sh. 11. 9 not 10 12. Backache.mp. OR Back Pain/ 13. low back pain.mp. OR Back Pain/ OR Low Back Pain/ 14. lumbar spine pain.mp. 15. 12 OR 13 OR 14 16. self-management.mp. 17 self-management.mp. OR Self Care/ OR Self-Management/ 18. Self-Care/ OR self-treatment.mp. 19. 16 OR 17 OR 18 20. 11 and 15 and 19	S10. self support S11. self-management support S12. self care strategies S13 self manage* S14. S8 OR S9 OR S10 OR S11 OR S12 OR S13 S15. randomised control trial OR controlled trial S16. clinical trial OR trial S17. RCT S18. S15 OR S16 OR S17 S19. S7 AND S14 AND S18	back pain.mp. OR Back Pain/ low back pain.mp. OR Back Pain/ OR Low Back Pain/ 10 OR 11 self-management.mp. OR Self Care/ OR Self-Management/ Self Care/ OR self-treatment.mp. 13 OR 14 9 and 12 and 15	randomised controlled trial[All Fields] OR "control groups"[MeSH Terms] OR ("control"[All Fields] AND "groups"[All Fields]) OR "control groups"[All Fields])

4.2.2 Eligibility criteria

Only RCTs published in full by peer reviewed, English language journals were eligible. They were selected according to the following inclusion criteria as described below.

4.2.3 Population

Trials that examined adults (>18 years) with CLBP (LBP persisting for more than six weeks) were included. LBP is defined as “pain occurring in the lumbosacral region with radiation limited to above the knee, without signs of nerve root compromise" (Waddell and Schoene 2004). Studies that included participants with specific causes for LBP such as previous surgeries, infection, malignancy, fractures, osteoporosis, inflammatory disease, pregnancy or neurological deficits were excluded (Henschke et al. 2009).

4.2.4 Intervention

When selecting the studies, the definition proposed by Jonkman et al. (2016) was considered, only studies of interventions with active participation and control by individuals in the management of their CLBP were included. Therefore , to meet the inclusion criteria, SMIs were required to have an element of knowledge provision and a combination of at least two from; stimulation of independent symptom monitoring, medication management, enhancing problem-solving and decision-making skills for medical treatment management, and changing their behaviour (Jonkman et al. 2016). Moreover, only trials that included an exercise programme as a part of the SMI qualified for the review.

4.2.5 Comparison

RCTs were included if they investigated an SMI, as described above, and had a control intervention which included standard care or usual care consisting of advice and education, access to medication, physiotherapy, supervised exercise and acupuncture Trials with multiple experimental arms were also considered.

4.2.6 Outcomes

Primary outcomes of interest were pain intensity and disability. Trials in which at least one of the above were not considered as primary or secondary outcomes were excluded.

4.2.7 Study protocol

The protocol for this review was registered and published (Rathnayake 2019) in PROSPERO - International prospective register of systematic reviews. The study was conducted according to the protocol during each step. The protocol title was changed from 'The effectiveness and specificity of exercise interventions in low back pain self-management programmes’ to the current title to reflect the review questions more clearly. The searches were performed in the five databases using the standard search strategy (Furlan et al. 2009). Following the removal of duplicates, abstracts and titles were screened for inclusion from those retrieved during the searches. Studies were then evaluated and selected according to the inclusion criteria.

4.2.8 Risk of bias assessment

The methodological quality was evaluated using the revised Cochrane risk of bias (RoB) tool 2 for RCTs (Sterne et al. 2019). This tool criterion includes five domains (i) bias arising from the randomisation process, (ii) bias due to deviations from intended interventions, (iii) bias due to missing outcome data, (iv) bias in the measurement of the outcome and (v) bias in the selection of the reported results. A RoB judgement was assigned to each of these domains as one of three levels of ‘Low risk of bias’, ‘Some concerns’, or ‘High risk of bias’. Due to the nature of the SMIs, it was difficult to blind the researcher or participants to the interventions. However, to judge the bias in the measurement of the outcome, blinding of the outcome assessors was required. Outcome assessor could be intervention provider or patient (in self-reported outcomes). RevMan software package 5.3 was used in quality appraisal, statistical analysis and meta-analysis (Revman5.3.5 2015).

4.2.9 Data Extraction

Data were extracted using a standardised form, including details regarding participant characteristics, study design, follow-up, self-management intervention (type, duration, and number of sessions), exercise component characteristics, control group and outcomes. Outcome data of pain intensity and disability including their mean scores, SDs, and sample sizes were extracted at 3-time points: short-term (closest to 4 weeks), intermediate (closest to 6 months) and long term (closest to 1 year) (Furlan et al. 2009). The trials which fitted into any of the above follow-up periods were considered adequate without necessarily needing to fit all the time points.

4.2.10 Data analysis

In the RevMan interface, standard deviations, and numbers of participants in both control and experimental arms of the trials were entered for each time point of both outcomes to generate the pooled results. Standardised mean difference (SMD) and the 95% confidence intervals (95% CI) were calculated, and SMD was used to interpret the clinical relevance. A negative value of SMD indicates a mean difference in the outcomes favouring SMIs. The Cochrane guidelines acknowledge that the term ‘effect sizes’ (ES) typically refers to versions of the standardised mean difference and recommend using the term SMD in preference to ES (Chandler et al. 2019). SMD < 0.2 was considered a small effect, 0.2–0.5 moderate, and > 0.5 large (Warsi et al. 2003). Inconsistency between trials was estimated by looking at both I^2 tests and P values of the $\chi2$ tests. A random-effects model was used for the meta-analysis, this assumes that some of the dispersion in observed effects reflects real differences in effect size across studies irrespective of their I^2 values (Borenstein (Borenstein et al. 2010; Deeks et al. 2019). This approach also assumes that the different studies estimate different, yet related, intervention effects (DerSimonian and Laird 1986; Borenstein et al. 2010).

4.2.11 Quality of evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework was used to assess the quality of evidence across studies (Schunemann et al. 2013). According to this framework, meta-analyses of RCTs were initially categorised as high-quality evidence and were downgraded by one level for each serious flaw present in the following overall domains. This was based on; limitations in study design or execution (1–2 levels) when less than 80% of trials reported high risk of bias according to Cochrane RoB tool 2, inconsistency of results (1–2 levels) when $I^2 > 50\%$ and $p < 0.05$ on the $\chi2$ tests with minimal or no overlap of confidence intervals, indirectness of evidence (1–2 levels) if participants, interventions, or outcomes measures from included studies were essentially different, imprecision (1–2 levels) based on wide confidence intervals and publication bias (1–2 levels) if funnel plot presented asymmetrical distribution or due to selective outcome reporting (Schunemann 2013). Based on this, the GRADE approach results in an assessment of the quality of a body of evidence in one of four grades, including high, moderate, low and very low (Schunemann et al. 2013).

4.2.12 Adherence to reporting guidelines

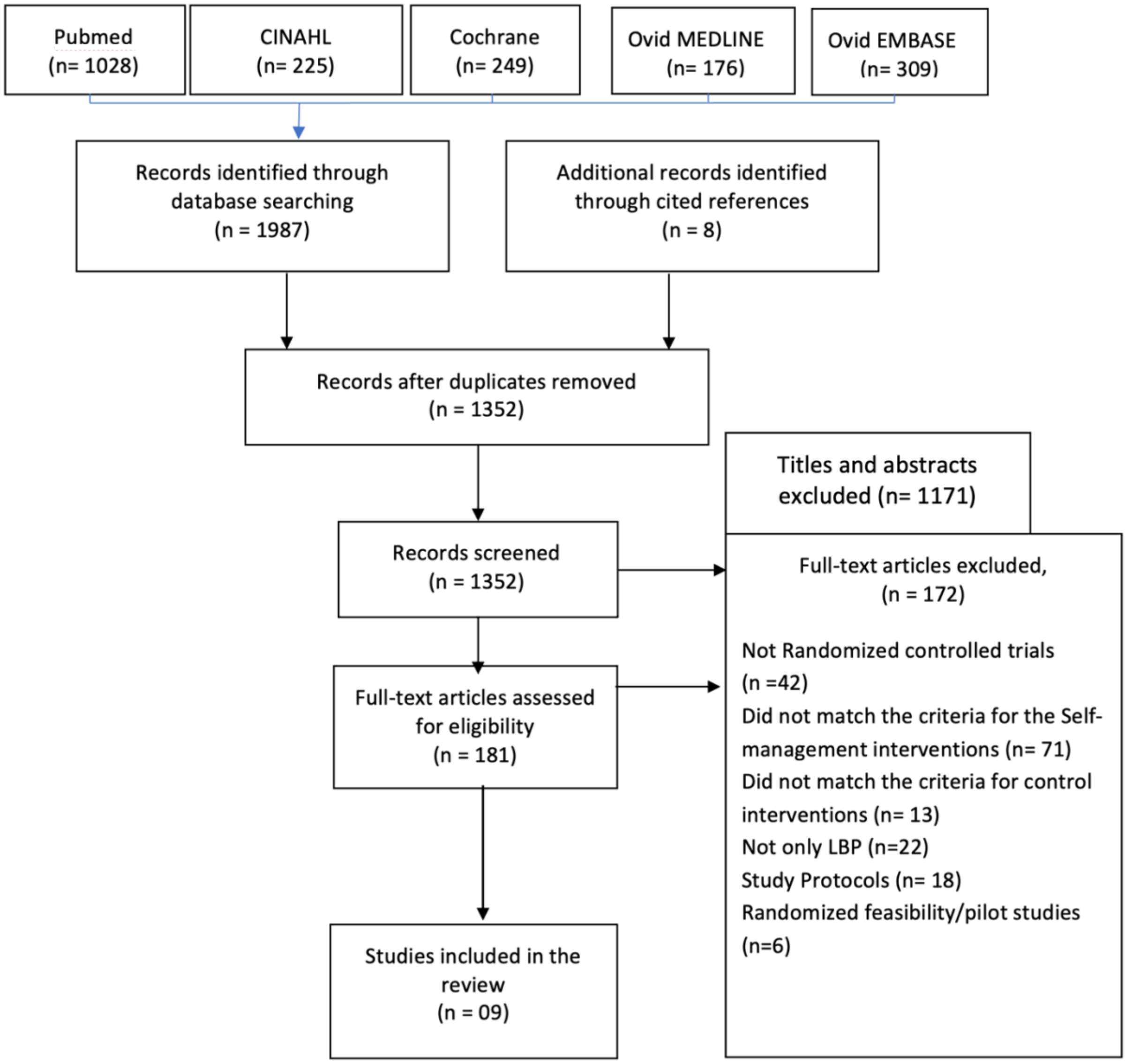
This review was organized and presented according to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) (Moher et al. 2009). This review met all the points of the criteria of the 27-item checklist.

4.3 Results

4.3.1 Search results

The search process and the results are presented in Figure 4.1. The search of the five databases, using the search strategies, identified 1987 articles and 8 articles were identified through cited references. After removing the duplicates, 1352 articles were screened for titles and abstracts. This screening identified 181 potentially eligible articles. The full text of these articles was scrutinised for eligibility according to the inclusion/exclusion criteria. After consideration, author and LS agreed that 172 articles should be excluded from further analysis. Out of these 172 studies, 42 studies were not RCTs, 71 did not fulfil the SMI criteria, 22 studies had used subjects with multiple conditions, 24 articles were study protocols or feasibility studies, and 13 studies did not fulfil the requirements for the comparison group. Therefore, 09 original studies were fully critically appraised.

Figure 4.1: PRISMA flow chart of selection of trials



4.3.2 Risk of bias assessment

The risk of bias judgements of the included trials is summarised in Figure 4.2. For the randomisation process bias, five trials (5/12) (Buhrman et al. 2004; Johnson et al. 2007b; Bronfort et al. 2011; Chaleat-Valayer et al. 2016; Zadro et al. 2019) had sufficient details of the random allocation sequence generation and four (4/12) (Haas et al. 2005; Bronfort et al. 2011; Chaleat-Valayer et al. 2016; Zadro et al. 2019) described the concealment of allocation sequence. For measurement of the outcome bias, only two (4/12) (Von Korff et al. 2005; Chaleat-Valayer et al. 2016) trials reported using blinded assessors to obtain pain and disability outcome data. The remaining studies had self-reported outcome measure tools submitted by patients using online tools (Buhrman et al. 2004; Irvine et al. 2015; Shebib et al. 2019), by post or email (Haas et al. 2005; Johnson et al. 2007b; Zadro et al. 2019) or during the follow-up visits (Bronfort et al. 2011). For participant-reported outcome measures such as pain and disability, the participant is considered as the outcome assessor and considered as at high risk of bias as the reported outcomes are likely to be influenced by knowledge of the intervention received (Chandler et al. 2019). All trials were reported according to pre-defined results, and five trials (5/12) (Johnson et al. 2007b; Irvine et al. 2015; Chaleat-Valayer et al. 2016; Shebib et al. 2019; Zadro et al. 2019) had pre-registered trial protocols. For missing outcome data bias, three studies (3/12) (Bronfort et al. 2011; Irvine et al. 2015; Zadro et al. 2019) had >5 participant dropout rate. Only one study reported a statistically significant difference in the baseline characteristics of the participants in their gender, ethnicity and health status (Von Korff et al. 1998). Overall, all nine studies showed low quality.

Figure 4.2: Risk of bias summary – evaluated using quality appraisal criteria for RCTs from Cochrane RoB 2 tool (Sterne et al. 2019).

4.3.4 Control interventions

All included studies (Von Korff et al. 1998; Buhrman et al. 2004; Haas et al. 2005; Von Korff et al. 2005; Bronfort et al. 2011; Irvine et al. 2015; Chaleat-Valayer et al. 2016; Shebib et al. 2019; Zadro et al. 2019) reported broadly similar content in their control interventions across the trials. Participants of these studies had the usual care with access to primary care including pain medication, advice, education, exercise and ancillary services such as physiotherapy or chiropractic treatments. Out of these nine, four studies provided supplementary education material designed for LBP management and education (Johnson et al., 2007; Haas et al., 2005; Von Korff et al., 1998; Shebib et al., 2019).

4.3.5 Content of the self-management interventions

4.3.5.1 Theoretical frameworks

In addition to the exercise component, most SMIs were based and developed using cognitive behavioural models. Examples of the claimed models were the cognitive-behavioural model of chronic pain (Buhrman et al., 2004), chronic disease self-management programme (Haas et al., 2005) and cognitive behavioural approach (Irvine et al., 2015; Johnson et al., 2007).

4.3.5.2 Exercise component characteristics

The types of exercise that were included were stretching (Buhrman et al., 2004; Chaleat-Valayer et al., 2016; Irvine et al., 2015; Von Korff et al., 2005), strengthening (Irvine et al., 2015; Von Korff et al., 2005; Zadro et al., 2019), aerobic or cardiorespiratory exercises (Chaleat-Valayer et al., 2016; Shebib et al., 2019; Zadro et al., 2019) and relaxation exercises (Buhrman et al., 2004; Chaleat-Valayer et al., 2016; Haas et al., 2005). The majority of programmes included combinations of different types. One study used a Nintendo Wii U console with Wii Fit U software (Zadro et al., 2019), and another trial used Bluetooth wearable motion sensors guided exercises (Shebib et al., 2019). Exercises were focused on encouraging graded activity (Buhrman et al., 2004; Johnson et al., 2007), staying active (Chaleat-Valayer et al., 2016), management of flare-ups (Von Korff et al., 2005), adaptive coping (Chaleat-Valayer et al., 2016) and resumption of ceased daily or leisure activities (Johnson et al., 2007; Von Korff et al., 1998). Six studies declared that the exercises were individualised for the participants (Buhrman et al. 2004; Von Korff et al. 2005; Johnson et al. 2007b; Bronfort et al. 2011; Irvine et al. 2015; Zadro et al. 2019).

However, a variation in the criteria of tailoring the exercise can be seen across the studies. In one study the content of the exercise components was tailored according to the type of job being undertaken by the participants (Irvine et al. 2015) whilst in another study individualised exercise was discussed during a telephone interview following submission of self-reported baseline measures (Buhrman et al. 2004). In only two trials were physical assessments of the subjects carried out by physiotherapists prior to allocation of the tailored exercises (Von Korff et al. 2005; Bronfort et al. 2011; Zadro et al. 2019). One trial reported the availability of a personal coach for all the participants to give unlimited remote support through the intervention, it failed to mention whether the exercise programmes were individualised for the subjects (Shebib et al. 2019).

Only three trials provided the frequency and duration of home exercises. Reported frequencies included daily (Chaleat-Valayer et al., 2016) and three times per week (Zadro et al., 2019). The duration of each session of the home exercises ranged from 10 (Chaleat-Valayer et al., 2016) to 60 min (Zadro et al., 2019). Only one study detailed the expected level of intensity during the home exercises, which was reported as 12–13 on the Borg scale (Zadro et al., 2019).

4.3.6 Delivery of self-management interventions

The trials used various forms of delivery, these included: audio-visual materials (Buhrman et al., 2004; Irvine et al., 2015; Von Korff et al., 1998, 2005; Zadro et al., 2019), written (Chaleat-Valayer et al., 2016; Von Korff et al., 1998) and digital education material (Buhrman et al., 2004; Irvine et al., 2015; Shebib et al., 2019). The sessions were facilitated by physiotherapists (Chaleat-Valayer et al., 2016; Johnson et al., 2007; Von Korff et al., 2005; Zadro et al., 2019), psychologists (Von Korff et al., 2005) and trained lay people (Haas et al., 2005; Von Korff et al., 1998).

The duration of the intervention was six weeks (Buhrman et al., 2004; Johnson et al., 2007; Haas et al., 2005), eight weeks (Irvine et al., 2015; Zadro et al., 2019) and twelve weeks (Shebib et al., 2019). Details of the delivery of the intervention were not available in three studies (Chaleat-Valayer et al., 2016; Von Korff et al., 1998, 2005).

4.4 Outcome analysis

4.4.1 Effect on pain intensity

Seven (Buhrman et al., 2004; Irvine et al., 2015; Johnson et al., 2007; Von Korff et al., 1998, 2005; Shebib et al., 2019; Zadro et al., 2019), five (Irvine et al., 2015; Johnson et al., 2007; Haas et al., 2005; Von Korffet al., 1998, 2005) and four (Chaleat-Valayer et al., 2016; Johnson et al., 2007; Von Korff et al., 1998, 2005) trials reported short-term, intermediate and long-term data of pain intensity, respectively (Fig. 3). SMIs showed significant and moderate effects on pain in all short term [SMD = − 0.28, 95%, CI (− 0.52, − 0.05), I 2 = 74%,], intermediate [SMD = − 0.36, 95% CI (− 0.60, − 0.12), I 2 = 75%] and long-term [SMD = − 0.21, 95% CI (− 0.36, − 0.07), I 2 = 18%] based on low quality of evidence according to GRADE framework (downgraded for risk of bias and inconsistency at short-term, intermediate and long-term follow-up points).

4.4.2 Effect on disability

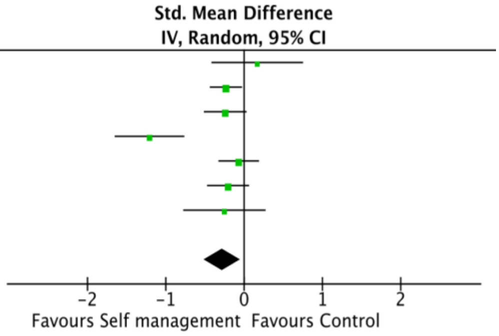
Seven (Buhrman et al., 2004; Irvine et al., 2015; Johnson et al., 2007; Von Korff et al., 1998, 2005; Shebib et al., 2019; Zadro et al., 2019) five (Irvine et al., 2015; Johnson et al., 2007; Haas et al., 2005; Von Korff et al., 1998, 2005) and four (Chaleat-Valayer et al., 2016; Johnson et al., 2007; Von Korff et al., 1998, 2005) trials reported short-term, intermediate and long-term data of disability, respectively (Fig. 4). Similar to the effects on pain intensity SMIs yielded significant and moderate effects on disability in all short term [SMD = − 0.30, 95% CI (− 0.52, − 0.08), I 2 = 70], intermediate [SMD = − 0.25,95% CI (− 0.37, − 0.13), I 2 = 0%] and long-term [SMD = − 0.20 95% CI (− 0.33, − 0.07), I 2 = 0%], based on low quality of evidence according to the GRADE framework (downgraded for risk of bias and inconsistency at short-term, intermediate and long-term follow-up points).

Figure. 4.3: Forest plots of comparison: Short-term, intermediate and long-term effect on pain intensity

Short-term effect

	Experimental			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Buhrman 2004	36.2	20.4	21	32.6	21.6	26	9.1%	0.17 [−0.41, 0.74]
Irvine 2015	2.23	1.2	199	2.52	1.29	199	18.3%	−0.23 [−0.43, −0.04]
Johnson 2007	29.1	24.5	110	35.3	26.7	113	16.6%	−0.24 [−0.50, 0.02]
Shebib 2019	16.5	15.5	69	39.2	23.6	36	12.1%	−1.21 [−1.64, −0.77]
Von Korff 1998	3.87	2.21	124	4.02	2.13	121	16.9%	−0.07 [−0.32, 0.18]
Von Korff 2005	4.9	2	110	5.3	1.9	120	16.7%	−0.20 [−0.46, 0.05]
Zadro 2018	3.8	2.4	30	4.4	2.3	28	10.3%	−0.25 [−0.77, 0.27]
Total (95% CI)			**663**			**643**	**100.0%**	**−0.28 [−0.52, −0.05]**

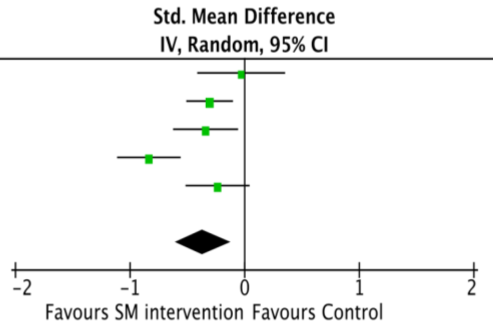
Heterogeneity: $Tau^2 = 0.07$; $Chi^2 = 22.73$, df = 6 (P = 0.0009); $I^2 = 74\%$
Test for overall effect: Z = 2.41 (P = 0.02)



Intermediate effect

	Experimental			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Haas 2005	41.4	28.9	54	42.3	29.3	54	16.4%	−0.03 [−0.41, 0.35]
Irvine 2015	2.11	1.46	199	2.55	1.41	199	23.1%	−0.31 [−0.50, −0.11]
Johnson 2007	26.1	23.5	105	35	28.4	98	20.1%	−0.34 [−0.62, −0.06]
Von Korff 1998	3.37	0.82	119	4.07	0.85	109	20.3%	−0.84 [−1.11, −0.56]
Von Korff 2005	4.2	2	101	4.7	2.2	106	20.2%	−0.24 [−0.51, 0.04]
Total (95% CI)			**578**			**566**	**100.0%**	**−0.36 [−0.60, −0.12]**

Heterogeneity: $Tau^2 = 0.06$; $Chi^2 = 15.81$, df = 4 (P = 0.003); $I^2 = 75\%$
Test for overall effect: Z = 2.94 (P = 0.003)



Long-term effect

	Experimental			Control				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
ChalÃ©at-Valayer 2016	36.2	21	139	36.7	21	141	30.3%	−0.02 [−0.26, 0.21]
Johnson 2007	27.9	26.1	102	36.4	27.3	94	22.5%	−0.32 [−0.60, −0.04]
Von Korff 1998	3.22	2.03	112	3.79	2.35	106	24.6%	−0.26 [−0.53, 0.01]
Von Korff 2005	4	2.3	99	4.7	2.1	98	22.6%	−0.32 [−0.60, −0.04]
Total (95% CI)			**452**			**439**	**100.0%**	**−0.21 [−0.36, −0.07]**

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 3.67$, df = 3 (P = 0.30); $I^2 = 18\%$
Test for overall effect: Z = 2.87 (P = 0.004)

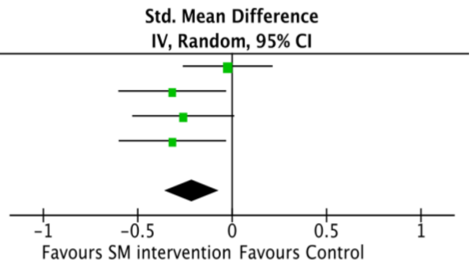
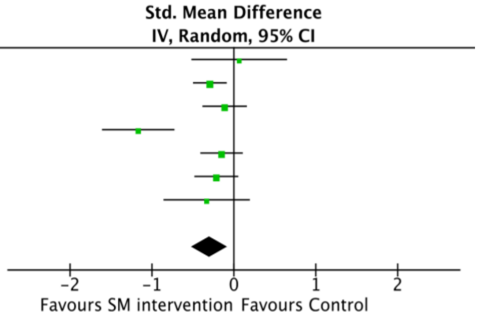


Figure. 4.4: Forest plots of comparison: Short-term, intermediate and long-term effect on disability

Short-term effect

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Buhrman 2004	4	1.4	21	3.9	1.6	26	8.7%	0.06 [−0.51, 0.64]
Irvine 2015	3.27	1.69	199	3.85	2.22	199	18.8%	−0.29 [−0.49, −0.10]
Johnson 2007	7.4	5.3	110	8	5.3	113	16.8%	−0.11 [−0.38, 0.15]
Shebib 2019	15	15.5	69	37.3	24.3	36	11.8%	−1.17 [−1.60, −0.73]
Von Korff 1998	6.5	5.61	124	7.4	6.3	121	17.1%	−0.15 [−0.40, 0.10]
Von Korff 2005	10.2	6.3	110	11.5	5.8	120	16.9%	−0.21 [−0.47, 0.05]
Zadro 2018	4.9	4.5	30	6.4	4.4	28	9.9%	−0.33 [−0.85, 0.19]
Total (95% CI)			**663**			**643**	**100.0%**	**−0.30 [−0.52, −0.08]**

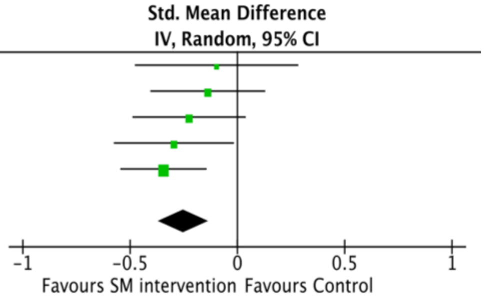
Heterogeneity: $Tau^2 = 0.06; Chi^2 = 20.28, df = 6 (P = 0.002); I^2 = 70\%$
Test for overall effect: Z = 2.70 (P = 0.007)



Intermediate effect

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Haas 2005	32.8	29.6	54	35.8	31.7	54	9.4%	−0.10 [−0.47, 0.28]
Von Korff 2005	9.2	6.6	110	10.1	6.4	110	19.1%	−0.14 [−0.40, 0.13]
Von Korff 1998	5.83	5.89	119	7.23	6.52	109	19.7%	−0.23 [−0.49, 0.04]
Johnson 2007	6.5	4.7	105	8	5.4	98	17.5%	−0.30 [−0.57, −0.02]
Irvine 2015	3.03	1.88	199	3.74	2.22	199	34.2%	−0.34 [−0.54, −0.15]
Total (95% CI)			**587**			**570**	**100.0%**	**−0.25 [−0.37, −0.13]**

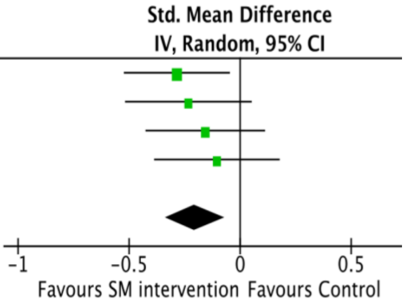
Heterogeneity: $Tau^2 = 0.00; Chi^2 = 2.34, df = 4 (P = 0.67); I^2 = 0\%$
Test for overall effect: Z = 4.23 (P < 0.0001)



Long-term effect

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
ChalÃ©at-Valayer 2016	19.8	15.8	139	24.4	16.4	141	31.3%	−0.28 [−0.52, −0.05]
Johnson 2007	6.7	5.6	101	8	5.5	94	21.9%	−0.23 [−0.52, 0.05]
Von Korff 1998	5.75	6.31	112	6.75	6.39	106	24.6%	−0.16 [−0.42, 0.11]
Von Korff 2005	8.4	7	99	9.1	6.3	98	22.2%	−0.10 [−0.38, 0.17]
Total (95% CI)			**451**			**439**	**100.0%**	**−0.20 [−0.33, −0.07]**

Heterogeneity: $Tau^2 = 0.00; Chi^2 = 1.10, df = 3 (P = 0.78); I^2 = 0\%$
Test for overall effect: Z = 3.00 (P = 0.003)



4.5 Discussion

Self-management has been the cornerstone for many national and international guidelines for the management of LBP (Airaksinen et al. 2006; Van Tulder et al. 2006; NICE 2019). Yet, systematic review evidence indicates that SMIs have failed to provide worthwhile effects even when compared with minimal interventions (Oliveira et al. 2012). Despite exercise and PA being a key recommendation in the management of LBP for improving function and disability, many of the prevailing

SMIs have paid no or minimum attention to incorporating exercise and PA in their programmes. This review is the first to systematically investigate the effect of SMI's specifically with an exercise component added for pain and disability in CLBP patients.

4.5.1 Effects of self-management interventions with exercise on pain and disability

The results demonstrate low-quality evidence for SMIs with added exercise components having moderate but significant positive effect both on pain and disability of individuals with CLBP, across short-term, intermediate and long-term periods compared with control interventions involving usual care. These typically consist of access to medication, exercise, advice, education, and manual therapy. The results are generally in agreement with conclusions of previous systematic reviews that SMIs are generally effective in the management of CLBP (Du et al., 2017; Oliveira et al., 2012), however, there are some differences. A meta-analysis by Du et al. (2017), evaluating SMIs in CLBP reported moderate effect on pain at all follow-up points but, in disability the moderate effects were maintained only short-term and no longer present at the intermediate and long-term follow up. In contrast, Oliveira and colleagues (Oliveira et al., 2012) found that self-management had only small effects on pain and disability compared to minimal interventions in CLBP patients across short and long-term points. Out of the total 26 trials included in Du et al. (2017), and Olivera et al. (Oliveira et al., 2012), meta-analyses, less than half (twelve studies) evaluated SMIs with exercise added. The remaining 14 trials evaluated SMIs which centred on education and cognitive behavioural approaches.

This current study of meta-analysis of SMIs including exercise and demonstrating moderate but significant positive short-term, intermediate and long-term effects both in pain and disability, compared with standard care which consists of access to medication, advice, education, exercise and manual therapy, suggests that SMIs with exercise added are superior in improving pain and disability of patients with CLBP. This agrees with the existing large body of evidence which demonstrates that exercise alone can bring long-term benefits in managing LBP (Hayden et al., 2005a; Van Middelkoop et al., 2010; Searle et al., 2015), including reducing disability and pain while improving fitness and occupational status of people with CLBP (Henchoz and So, 2008). Therefore, SMIs and exercise in combination may be critical in maximising the potential for long-lasting benefits of complex and multifactorial CLBP.

4.5.2 Exercise component characteristics

Considerable heterogeneity both in content and mode of delivery of SMIs, reviewed in this current study, was observed with a significant variation in the theories used to design the exercise components. Overall, most studies included in this review failed to report exercise prescription details such as frequency, intensity or duration of the exercises. Two of the above studies (Bronfort et al. 2011; Zadro et al. 2019) mentioned the frequency of the exercises whilst one study mentioned the duration of each session and the expected level of intensity (Zadro et al. 2019). Only 3 of the included trials of this review were delivered via internet (Buhrman et al. 2004; Irvine et al. 2015; Shebib et al. 2019). Even though all these interventions included exercise components 2 of the above 3 trials were centred on a cognitive behavioural approach (Buhrman et al. 2004; Irvine et al. 2015) where structured information on exercises was given to the participants. One of the 3 trials had a sensor-guided physical exercise and aerobic exercise three times per week (Shebib et al. 2019), whereas the others included combinations of stretching, strengthening and relaxation exercises and stretching and strengthening exercises. One trial provided the support of a personal coach through the intervention app, emails and telephone calls (Shebib et al. 2019) whilst the other 2 interventions offered support and follow up through weekly telephone calls (Buhrman et al. 2004) and an intervention platform including weekly emails (Irvine et al. 2015). Exercise instructions were given in the form of information on web pages with telephone advice (Buhrman et al. 2004), instructional videos (Irvine et al. 2015) and real time feedback from sensors (Shebib et al. 2019). In addition, although recommended within guidelines and management approaches for CLBP (NICE, 2021), tailoring exercises to a person's needs and capabilities was not always considered. Six trials included in this review declared that exercise components were tailored according to the individuals. Exercises were tailored using different criteria across the trials, these included job type (Irvine et al. 2015), self-reported measures (Buhrman et al. 2004) and physical assessments (Von Korff et al. 2005; Bronfort et al. 2011; Zadro et al. 2019). Whether the content of exercise programmes was changed according to their feedback during the intervention remains unclear. Given the considerable variation of studies included, it is difficult to ascertain the effect that tailoring exercises had on the CLBP and associated disability from these study results. Nevertheless, there is growing evidence that subgrouping of CLBP to target management, leads to superior improvements in pain and disability in CLBP populations compared to generalised management approaches (Sheeran et al., 2013; Luomajoki et al., 2018; Leboeuf-Yde et al., 1997). Therefore, it would be worth considering the inclusion of tailored exercise programmes within SMIs to produce superior outcomes in CLBP.

None of the participants in the programmes were included in the selection, nor did they have the autonomy to select the type or the content of the exercise programme to be followed. All three programmes had been developed with the involvement of professionals including physiotherapists whilst two programmes had clinical psychologists involved (Buhrman et al. 2004; Irvine et al. 2015; Shebib et al. 2019). Of concern was that none of the studies had been pre-tested with users, nor had there been any involvement of end users in the process of developing the intervention.

4.5.3 Limitations

Although this study indicates a positive effect of SMIs with exercise on pain and disability, the quality of evidence is still low, with substantial heterogeneity amongst studies and the SMIs evaluated. Whilst measures were taken to minimise the statistical interference in the analyses including use of random-effect models for meta-analysis (Deeks et al. 2019), the heterogeneity of the reviewed articles still means that clinical application of these study results remains uncertain. Given the varied, multiple time-points of the follow-up periods, only a small number of studies were eligible for the one time-point analysis of the outcome measures. This study also demonstrated the importance of sufficiently describing the comparator intervention. In future research, as well as experimental intervention, greater care must be taken when selecting and describing the comparator to allow for conducting high quality evidence synthesis and clinical applicability.

4.5.4 Clinical and research implications

This study focused on the role of SMIs, with exercise added, in managing pain and disability of patients with CLBP. Although of low-quality evidence, the SR and meta-analysis demonstrates that SMIs with an exercise component have moderate but significant short, intermediate, and long-term effects on pain and disability in patients with CLBP. Whilst heterogeneity of included trials does not allow for direct comparisons, the study outcomes are superior when compared with recent systematic reviews and meta-analyses including SMIs, both with and without exercise. Given the overwhelmingly positive physical and psychological benefits of exercise, adding exercise to SMIs is a favourable option for management CLBP and is in line with the existing recommended clinical guidelines (Airaksinen et al. 2006; NICE 2019).

Of consideration, however, is the low-quality evidence compounded by the vast heterogeneity and limited theoretical underpinning of the existing SMIs and insufficient intervention detail both in content and mode of delivery. Future research needs to focus on following a stepwise approach for the development of SMIs for CLBP including the theoretical basis of the proposed intervention effect, detailing the action of each component included. High quality SMIs should be evaluated in future high-quality RCTs with concealed allocation, blinded assessor and intention to treat analysis. The sample size should be appropriate to increase the certainty of evidence about the effects of different types of exercise included within CLBP interventions, tailored or not tailored, and compared with varying modes of delivery of the interventions.

4.6 Conclusion

This study reviewed RCTs to explore the effect of SMIs, with an added exercise component, on pain and disability in patients with CLBP. This was compared with control interventions which involve usual care, typically consisting of access to medication, exercise, advice, education, and manual therapy. The review found low quality evidence that SMIs with exercise added have a moderate but significant, short, intermediate and long-term positive effect both on pain and disability in patients with CLBP. Vast heterogeneity in the SMIs' content, frequency, duration and intensity was demonstrated, also not all exercise programmes were tailored according to a person’s need and capabilities. More high-quality studies are necessary to strengthen the evidence regarding the effects of SMIs with exercise added to manage patients with CLBP.

Chapter 5: Key components in a self-management intervention to encourage people with LBP to be physically active and exercise: Practice and perspectives of clinicians

5.1 Introduction

This chapter describes the first study of phase 2 of this PhD project which answers research question two, “what are the key components, as recommended by the expert clinicians, required within a digital ESM intervention to encourage people with LBP to be physically active and exercise and how to tailor them?” The overall aim of phase 2 was to identify or develop theory, thus determining the essential intervention functions and the BCTs of a potential intervention as recommended by expert clinicians. Accordingly, this study aimed to inform the content of the intervention by qualitatively exploring physiotherapists’ practice and perspectives on ESM of people with LBP. Although the focus of this study is on the ESM of LBP, the essential role of the assessment in the decision making process is well established (Strender et al. 1997; Carlsson and Rasmussen-Barr 2013). Hence it was appropriate to inquire briefly about the assessment to obtain a better understanding of physiotherapists’ practices and perspectives on the ESM in LBP. Findings of the study informed the design and development of the structure and the content of a potential intervention. In this chapter, the study aims are followed by methods and results, together with a concluding summary of the study findings.

5.2 Aims

This study aimed to explore musculoskeletal physiotherapists’ practice and perspectives on the key components required in a SMI which would encourage people with LBP to be physically active and to exercise.

The key research questions addressed were;

1. What does the assessment of a people with LBP look like?
2. How do physiotherapists manage people with LBP with exercise?
3. What should the optimum ESM for people with LBP look like, and how should it feature within a digital intervention?

5.3 Methods

As discussed in Chapter 3, the MRC guidance (Craig et al. 2008; Skivington et al. 2021) on the development and evaluation of complex interventions was central to this project's methods. In response to this guidance, it was crucial to conduct primary research to explore stakeholder insight into integrating various BCTs drawn from literature.

5.3.1 Study Design

Three focus groups were conducted between May and July 2019, these were comprised of musculoskeletal physiotherapists who were currently engaged in clinical practice treating LBP patients. A semi-structured interview guide was used in data collection. Focus groups were held at the premises of Eastgate House, School of Healthcare Sciences, Cardiff University.

5.3.2 Subjects

5.3.2.1 Recruitment

Clinically active physiotherapists with a background in LBP management from NHS/private/sports/academic settings were identified through academic networks and invited to participate in the study by email (Appendix 3). All recruited physiotherapists were currently practising as musculoskeletal physiotherapists and frequently treated people with LBP. The participant information sheet (Appendix 4) was emailed to the interested physiotherapists who responded to the invitation email. Focus groups were conducted outside of their working hours. The sample was selected purposefully to achieve a broad spectrum of views and represent the diversity in practice. The inclusion and exclusion criteria for physiotherapists taking part in the study were as follows:

Inclusion criteria

- A minimum professional qualification level of a Bachelor of Science (BSc) degree and with CSP and HCPC registration.
- Active clinical experience in LBP management.

Exclusion criteria

- Not fulfilling the inclusion criteria.
- Inability to provide informed consent.
- Physiotherapy undergraduates.

5.3.3 Data collection tools

A topic guide was prepared, this included a series of open-ended questions to achieve the study's aims and was informed by relevant literature. However, it should be noted that most of these questions were probing questions and used only to guide the discussion. A pilot study was conducted to identify any gaps in the topic guide and evaluated the participants' understanding of the questions. The final version of the topic guide was comprised of three main sections containing questions which explored participant opinions on physical examination, exercise-based treatments and exercise self-management strategies for LBP (Appendix 5). However, the sequence of the questions was flexible, this allowed a natural flow of conversation and participants were allowed to discuss topics as they emerged during the discussion. All focus groups were moderated, recorded and transcribed verbatim by the researcher. The first focus group lasted 1 hour and 30 minutes, and the second and third lasted one hour and 20 minutes.

5.3.3.1 Piloting

The first draft of the topic guide was prepared after studying the relevant literature. Questions were listed under four main sections, these included physical examination, self-monitoring, exercise-based treatments and self-management strategies related to LBP (Appendix 6). A pilot focus group was conducted with three physiotherapists, all of whom fulfilled the inclusion and exclusion criteria as noted above, to evaluate the clarity of the questions. Following feedback from the physiotherapists, several changes were made to the series of probing questions in the topic guide and some changes were also made in the sections. There were several overlapping probing questions in this first draft of the topic guide which repeated similar data. This was apparent mainly in the self-monitoring section, the questions overlapped with the questions in the self-management strategies section of the topic guide. As a result the questions from both sections were combined and modified to achieve more clarity. Thus, the modified topic guide comprised only three sections: physical examination, exercise-based treatments, and exercise self-management strategies. Also, the context of some questions was too broad and the pilot study physiotherapists needed a further explanation of those questions. The questions were rewritten and split into several discrete questions if the focus was too broad to be discussed as one. One physiotherapist from the pilot focus group required clarification on the focus of the opening question in the physical examination section.

“Do you need us to keep the focus away from red flags and neurological stuff and just focus on assessment?”

The researcher further clarified it, and during the focus groups, necessary steps were taken to clarify the above question to the physiotherapists.

5.3.4 Ethical considerations

5.3.4.1 Ethical approval

Ethical approval for this study was obtained from Cardiff University, School of Healthcare Sciences Ethics Review Committee on 09/04/2019 (Appendix 7).

5.3.4.2 Data collection

Written informed consent was obtained from the physiotherapists prior to the focus groups (Appendix 8). They were informed that all discussions would be audio recorded. Participants were asked to initial each box of the statements in the consent forms to confirm that they had read and understood the information given and consented to take part in the study.

5.3.4.3 Data Storage and handling

Each participant was given a unique participation number when the audio files were transcribed. Focus group transcripts were anonymised and held on a password protected Cardiff University computer and in a locked filing cabinet on the school premises. According to the research integrity and governance policies of Cardiff

University, all collected anonymised data is retained for a maximum period of 15 years. Arrangements are put in place to secure data disposal or destruction after a fixed period of 15 years.

5.3.5 Data analysis

The researcher transcribed the audio recordings of the focus groups using the intelligent verbatim method (i.e. coughs, laughs etc. were omitted). Transcripts were cross-checked against the audio recordings to determine the accuracy and completeness of data. The transcripts were then sent back to the groups for validation and for any discrepancies to be identified, none were reported. All participants were given subject numbers to ensure anonymity and were identified by these numbers throughout this project. Transcripts were coded and analysed using NVivo-12 software designed for qualitative data analysis.

Focus group data were analysed using thematic analysis (TA) (Braun et al. 2016). The TA can use an inductive approach or a deductive approach. Inductive coding, also known as a bottom-up approach is driven by what is in data, it starts with observing data and identifying patterns within the data set (Braun and Clarke 2012). The patterns are then used to generate themes and ultimately reach a conclusion or a theory. In a deductive approach, commonly termed a top-down process, the researcher starts with a predetermined framework or structure to guide data analysis. Here, codes and themes tend to derive more from a researcher's concepts and ideas in their data. Hence, the researcher's final analysis mapping might not directly link to the raw data (Braun and Clarke 2012).

TA of data with a deductive approach (Fereday and Muir-Cochrane 2006) was adopted for this study. This approach was suitable for this phase of the study as it answered the research questions by identifying specific answers which emerged from the discussion and that would be employed to develop the intervention. Analysis of data comprised six phases including familiarisation with data, generating initial codes, searching for themes, reviewing potential themes, defining and naming themes and producing the report (Braun et al. 2016).

5.3.5.1 Familiarisation with data

The data was transcribed immediately after each focus group had taken place. The process of becoming familiar with data allowed recognition of recurrent codes and understanding of the data set as a whole. This permitted an analytic engagement with data which is crucial to the next stage of developing codes. The complete audio recordings of each focus group were listened to twice, and the transcripts were read three times noting recurrent concepts and ideas.

5.3.5.2 Generating initial codes

Systematic analysis of data began by tagging each piece of text with codes. At this phase of the study a semantic approach to coding was more appropriate, due to the pragmatic nature of the study outcomes (Terry et al. 2017). Coding of each transcript was conducted initially using the NVivo -12 software package, this was followed by manual coding of the printed transcript. The text was highlighted, and nodes were generated for each highlighted phrase using the NVivo-12 software. During the manual coding, text in the transcript copies was highlighted using coloured pens and notes were written in the margin for all potential codes arising from the text. These initial codes were mainly descriptive. The two sets of codes were done independently, the first round of codes generated with the NVivo-12 software was not revisited during the second round of manual coding. Finally, the codes were pooled together to create the final set of codes, these were analysed based on a more conclusive interpretation of the data. This complete process of coding was done separately for each focus group, they were then re-evaluated during the subsequent steps of identifying patterns and common themes in the data set. Codes were cross-checked retrospectively to check whether they were factual and made sense in the absence of the original text or the full transcript (Flick 2018).

5.3.5.3 Searching for Themes

Clustering codes addressed this step, this identified higher-level patterns and common patterns in the data from potential themes and sub-themes. A theme can be identified as an implicit topic that organises a group of repeating ideas, it enables one to answer a specific study question (Ryan and Bernard 2003). Keeping in mind that generating themes is an active process (Braun and Clarke 2006), sub-themes and potential themes were generated by clustering codes which shared unifying features to explain the coherent and meaningful pattern in the data set. After identifying the codes of each focus group, they were tabled under three main sections of the discussion to enhance the clarity of the data. A coherent analysis of data obtained from a fixed set of questions would not necessarily predict the themes in the final analysis (Dey 1993). In fact, even though the codes were listed under different sections, the search for sub-themes and themes focused on the main study aim and the research question i.e. are the key components to include essential elements to be considered when designing the content of a comprehensive exercise self-management intervention for people with LBP. This involved an intensive process of constantly constructing and reconstructing sub-themes and themes whilst continuously returning to highlighted items, original transcripts, and coding tables.

5.3.5.4 Reviewing potential themes

This step involved a recursive process and was essentially concerned with the quality of the analysis. Once a distinctive and coherent set of themes had been established a second stage was carried out, a review of the themes in relation to the whole data set (Braun and Clarke 2006). The aim was to ensure that the consistency of the analysis was preserved, and the data was not misinterpreted. Several changes were made to some of the existing sub-themes during this stage. Several potential themes were merged to make the overall themes more coherent and inclusive.

5.3.5.5 Defining and naming the themes

Following review of the final set of themes the scope of each theme was clarified and refined, a descriptive and an interpretative commentary of the themes was used for this task (Braun et al. 2016). This phase involved selecting quotes from the participants to provide a vivid, compelling example which would illustrate the analytic points made in the analysis. Additionally, during this last stage of the analysis themes were named to capture their essence for the readers.

5.3.5.6 Producing the report

In the majority of cases this last step and the above steps overlap, this is due to the fact that the analytic process of the data requires a considerable amount of writing during each stage. This phase would include compiling, developing, and editing existing writing and situating it within a comprehensive report.

Multiple coding was conducted in two of the three focus group data, this ensured the rigour of the data analysis process. Multiple coding involved coding by a second independent researcher trained in TA (MM), codes were cross-checked for similarity with the original codes. Multiple coding is equivalent to "inter-rater reliability" in quantitative research, it is considered to be a response to address the subjectivity in qualitative research (Barbour 2001).

5.4 Results

Three focus groups were conducted involving 14 physiotherapists. Two focus groups consisted of 5 physiotherapists each, and one group comprised 4. After the third focus group it became clear that information redundancy had been reached; that is when no new relevant information emerges from the interviews (Lincoln and Guba 1985). Table 5.1 outlines the participants, it indicates which focus group they participated in, their work setting and the number of years of experience.

Table 5.1: Work experience and work settings of the physiotherapists who participated in focus group discussions

Focus group	Physiotherapist	Gender	Years of experience	Work setting
01	PT01	Male	11	Royal ballet school / Private
	PT02	Female	09	Academic / Private
	PT03	Female	05	NHS / Private
	PT04	Male	05	Private
	PT05	Female	07	NHS
02	PT06	Female	15	NHS
	PT07	Male	14	NHS
	PT08	Female	21	Private
	PT09	Male	08	Private
	PT10	Male	08	Private
03	PT11	Female	16	Private
	PT12	Female	08	NHS
	PT13	Female	18	NHS/Academic
	PT14	Female	12	Private/Academic
Key: PT – Physiotherapist, NHS – National health services				

Four overarching themes emerged; these were:

- A holistic approach to the assessment
- Exercise and physical activity-based management
- Education and awareness
- Optimum exercise self-management and digital interventions

Themes were generated using fourteen sub-themes and forty-seven codes extracted from the qualitative data. These themes and subthemes are listed the below in table 5.2.

Table 5.2: Themes and subthemes emerged from data

Themes	Sub-themes
A holistic approach to the assessment	1. Being vigilant about biopsychosocial factors 2. Lifestyle, expectations, and level of PA 3. Motivation, willingness and readiness to exercise 4. Looking at functional tasks, fearful or challenging movements
Exercise and PA-based management	1. Deciding the best for the individual 2. Type of exercise and physical activities to include 3. Gradual desensitisation to overcome the resistance
Education and awareness	1. Individual's understanding on their condition 2. Myth-busting and improving awareness 3. Educating the individuals with updated knowledge 4. Desensitisation of the pain experience and managing flare-ups
Optimum ESM and digital interventions	1. Strategies to improve adherence and monitoring in ESM 2. Digital interventions as a catalyst in ESM 3. Unhelpful attributes and limitations
Key: PA – Physical activity, ESM – Exercise self-management	

When exploring the overall results, it became evident that there was an overlap between the main themes and subthemes, this indicated an interrelationship between assessment, management and ESM components. For example, assessment often informs the content and decision making of exercise-based treatments and the design of self-management strategies for people with LBP. This was apparent when analysing the repetitive patterns of some codes and sub-themes across the data set. Individual codes which formed the themes and subthemes were tabled together with the representing focus group and the serial number of the transcript lines (Appendix 9). A detailed mind map showing the links between codes and subthemes was also generated (Appendix 10).

5.4.1 Theme 1: A holistic approach to the assessment

Participants in all three focus groups agreed on a holistic approach to the assessment to ensure optimum and tailored self-management in LBP. Physiotherapists also noted that the assessment should focus on elements that would assist them in understanding an individual’s experience of LBP and its effects. They expressed thoughts on the assessment, they suggested adopting a patient-specific biopsychosocial approach whilst considering individuals' choices and preferences, goals, motivation, readiness to exercise, the current level of PA, functional tasks, and fearful and challenging movements.

5.4.1.1 Sub theme 1 - Being vigilant about biopsychosocial factors

Eight of the fourteen participants discussed the importance of being attentive to the biopsychosocial factors of individuals during the assessment. This allows the physiotherapist to understand the big picture before deciding on the best management options and better compliance in the management.

“Biopsychosocial things are a big component for me when it comes to deciding what I give people in terms of exercise. A big part of my assessment, you can't just cut them short. Because it is so important. They need an outlet sometimes before they get on board and get them in because If that's the main issue, no matter how good exercise you are going to show they are not going to do it. And it’s not going to change the outcomes much anyway….”

(FG1 -PT 4)

“I would consider their overall wellness in my decision-making process because affectively a good day bad day for me is going to make a big difference. If they are having a terrible day, we will probably going to do a lot less than overall if they had a good day…”

(FG1-PT 1)

Also, 3 out of 14 participants mentioned that they tried to understand the individual's journey with their problem and address any issues they might be having before they proceed with exercise or self-management.

“I really focus on to understand my self, their journey of what their problem is…and why it is like this, talk about their stresses, so it’s not completely brushing under the carpet and just focus on and just give some exercise…. we need to understand the big picture of what is happening… ”

(FG3 -PT 2)

"So it's more looking…a bit more holistically than simply checking range…. where I think we've moved away from that because it's meaningless…"

(FG2 -PT 3)

Participants agreed upon the significance of looking at the individual's general well-being, including their sleep and other co-morbidities during the assessment as these elements will inform their management.

"*understanding how well that general well-being of the individual is key… So, thinking about it I suppose it is a more holistic thing than just going "how is your back?", they might have so many other things both physical and mental, or maybe poor sleep …these will have an impact on deciding what I am going to do next …for example if they have a bad knee pain at the same time, if I give them an exercise that will provoke their knee pain they are never going to do it…in fact it will make things worse…"*

(FG1-PT 1)

5.4.1.2 Sub theme 2 - Lifestyle, expectations, and level of physical activity

Physiotherapists established the importance of finding out about the patient's lifestyle, including their level of PA, jobs, leisure activities and knowing their expectations for ESM. Five participants mentioned, and all others agreed, that information on the current level of PA is crucial to deciding their approach to the management of the individual.

"I think probably one of the main subjective things about the what approach I will take is their current level of activity…"

(FG1-PT 5)

"I *see a spectrum of patients from very sedentary kind of people who really don't want to do exercise or have time to exercise or afraid of moving to people who are highly active and want to get back to in sports in two days or participate in a marathon…so level of physical activity will be a key one…."*

(FG2-PT 2)

5.4.1.3 Sub theme 3 - Motivation, willingness, and readiness to exercise

Understanding the level of motivation to engage in exercise and their willingness and readiness to exercise were considered necessary before continuing with the plan of ESM. All three elements seemed to be overarching and were often mentioned together during the discussion.

"I well .. a key thing that I consider quite obviously is motivation. Motivation and also their readiness to do the activities. Because that can be a great determinant to what I give them and how I'm going to prescribe it..."

(FG1-PT 4)

"Yeah..I would probably agree with the room, I think the behaviour I suppose, that you said already and used the term motivation, readiness and behaviours around and their willingness to move …and obviously their willingness around here about general movement of their back is quite important. Hmm I think it is pretty key."

(FG1-PT 1)

In addition to the willingness and readiness to move in general, one participant also mentioned that she would be interested in specific and directional spinal movements.

"Also, willingness to exercises, what they will find more comfort in doing or getting an understanding of how they like to move in specific directions before I give them any specific exercises …."

(FG3-PT 2)

5.4.1.4 Sub theme 4 - Looking at functional tasks, fearful or challenging movements

Nine of fourteen participants explicitly mentioned the importance of assessing the functional task as it would give them a more comprehensive understanding of the way the individual moves.

"The first thing would be looking at how they are walking, taking a seat or getting up for further examination, transfers I mean like sit to stand. Because my clinic has a small bed, so how they are going to negotiate that makes a big picture. Whether they are holding their back stiff or they are using the arms or if they are more or less hesitant to even to move .it gives a lot than just going to a typical random SLR or something…"

(FG1-PT 3)

One participant mentioned that early observation of functional movement and their level of functioning would influence her decision-making process in the ESM.

“I would agree that functional movement stuff probably influences more which exercises I give rather than a specific a kind of assessment modalities. So that’s something I would do pretty fairly earlier on but I suppose you can combine them with they told you about level of functioning as well.”

(FG1-PT 5)

Four participants mentioned during their assessment that they would be looking at movements or tasks considered challenging and which they would modify continuously. They acknowledged that this could be any movement or task in daily life or something related to their jobs or hobbies.

“I would really like to make them do whatever they feel as more challenging.. if it’s lifting weight, I mean lifting every person with back pain has trouble either lifting correctly or has fear of lifting or it could be literally a person an athlete or sports field going for that specific movement which is more painful.. Well, do the movement in front of me. So, I can see what’s going wrong…”

(FG2-PT 1)

One participant also emphasised evaluating the quality of the movement rather than the range of movement when assessing people with LBP, particularly in tasks that involve spinal movements.

“we tend to look at is not how far they can move but if they've got fair less freedom of movement. . And that's really hard to quantify because you could have a good range, but you could be quite fearful you could have a limited range…but it could be functional enough ...”

(FG3-PT 4)

5.4.2 Theme 2: Exercise and physical activity-based management

The second theme revolved around practice experience and perspectives of physiotherapists on exercise and PA-based management of LBP. Subthemes which emerged included; factors they would consider when deciding the best ESM for an individual with LBP, what type of exercise and PA to include, how to begin, progress and regress the exercises, and tailoring of the exercise programmes.

5.4.2.1 Sub theme 1 - Deciding the best for the individual

Whilst many interesting facts were discussed concerning the decision-making process and underlying clinical reasoning that participants would employ when deciding the best ESM for the individual with LBP, only the most common viewpoints are represented here. For example, the importance of considering personal choice and exercise preference when deciding the best approach for the individual, this commonly featured across all three focus groups.

Nine out of fourteen mentioned that they would consider an individual's preference or choice of exercise or PA before prescribing. The discussion revealed that physiotherapists often began their ESM programmes with exercise and PA that they felt individuals would enjoy, this was based on their preference. They then slowly progressed further into more demanding and challenging training.

"Usually, I start with …. saying that there is no real evidence that one type of exercise is much better than the other…. so probably choosing something that they enjoy...and progress from there..."

(FG2-PT 5)

"Patient preference... I always ask what they would like…I often say to patients, there are some very good gyms we can refer you in as in if there's something you would like to take part in like circuit-based machines or swimming, or you know. exercise DVDs or different things they can link to…

(FG3-PT 1)

Also, the participants believed engaging in their preferred exercise options and PA would increase the compliance of the management.

"*So I think if they do something they enjoy that's really important as they sort of latch on to that… it is about really having to explore what they could then do try and enjoy rather than doing absolutely no activity what so ever.. I think that's probably where my reasoning process leads to"*

(FG1-PT 1)

Meanwhile, three participants mentioned they would also focus on individual preferences, what they enjoy doing and have missed doing or are struggling to do because of their pain before deciding what would be the best ESM approach.

"Based on what they say, what they are enjoying and what they are struggling with so as if they can't do it, and it impacts on the life. And then build the programme based around that and whatever the movements it takes…"

(FG2-PT 1)

Participating physiotherapists also claimed that they would consider time and access to exercise before designing an exercise programme for individuals with LBP.

"Obviously it is very important to understand the timing…So the programme you are developing for exercises just need to , maybe to categorise who can afford only a few minutes per day, also ones who can maybe afford some extra time… So basically, how busy they are… and whether they have an opportunity to go to the gym, pool, etc."

(FG2-PT 3)

5.4.2.2 Sub theme 2 - Type of exercise and physical activities to include

The focus groups appreciated the importance of both general and specific types of exercise and PA, most of them used a combination of both. They included a wide range of exercises and PA, including strengthening, stretching, mobilisation, direction-specific exercises, Pilates, group aerobic exercise classes and walking. However, some members favoured either general or specific exercises while others used both approaches according to the needs of the individuals. Eight members mentioned that they would encourage the individuals to engage in some sort of activity such as walking to help them overcome their fear of movement.

"And if someone is not doing any exercise at all then you can probably get them to do anything you know probably will help…some general exercise. So, like that probably I would go specific versus general in choosing an approach to their exercise…"

(FG1-PT 3)

"Whatever they like is important. If anything walk… just walk, but happy…. It's going to be difficult at times. …I try to convince them.. I know how difficult it could be it's going to get easier. That's generally how I approach. Of course, there are specific things depending on

presentation. But for me especially elderly population I say keep walking, keep moving. Make sure you walk a little bit every day…"

(FG1-PT 4)

Whilst most of them agreed that they begin by introducing some general PA and exercise to progress into specific exercise programmes, there were participants (2/14) who claimed to use specific exercise to improve their exercise engagement before proceeding in to complex tasks or PA.

"I would still use things like pelvic tilts in sitting for someone who is really not moving at all, I think it's really nice quite gentle introduction if you do you know slouch and correct them while they are sitting on their chairs. .This is mostly because I work with old people at homes. So it's nice to start gently and then gradually build up more functional things', So yes I do use all specific exercises…"

(FG2-PT3)

"I suppose may be an explanation is … your little exercise helps you to do some functional thing. Something like pelvic control. If you do this you are going to sit better. Perhaps they can see that when they start. It's really basic but it is all a part of getting up and going. What is the purpose of doing that, walking your dog, getting back in the rugby pitch…So that is tailor made for each patient's goal and they are getting that feedback to themselves rather than being very generic…"

(FG3-PT1)

Furthermore, four participants highlighted the fact that they would be more concerned about the total volume of activity rather than the type of exercise they prescribe.

"probably it is about the volume of activity rather than they must do one type of exercise over other. That would be my approach, sort of long-term general exercises but I still give them some specific exercise…"

(FG2-PT1)

There were some conflicting ideas of sub-grouping the individuals or using classification systems-based exercises across the focus groups. Whilst four members of the first focus group clearly agreed upon the usefulness of this exercise when managing their patients, two participants in the third focus group strongly opposed the idea of prescribing ESM based on sub-grouping or a classification system.

"*even though I don't probably wholly sit to certain to classification models I do feel it is helpful to specially when you think of reasoning it's helpful to sort of look whether someone is potentially got a movement issue ie: they have got some restriction or stiffness or they got a control issue either i.e: they got a lack of control in to a particular direction and or a movement pattern. I do think helps you to be able to try and to be a bit more specific as to a way you might send some of those activities …"*

(FG1-PT1)

"Patient will have a pattern specific to that patient. And if you look at the research … .So that's where subgrouping has come from looking at a very small portion of the population where the excluded kind of 99%, so they can say in this 1 percent of patients then doing this particular exercise works…….the only subgroup you have to look at is the person sitting opposite you. That's your subgroup….And I would shy away from putting a subgroup, because as soon as you label people the label for life"

(FG3-PT1)

All members across the three focus groups agreed that despite the approach used, it must be tailored to meet the needs of the individual. They mentioned they would specifically consider their job/carrier, expectations, hobbies and values when designing the ESM programme.

"if *you are with dancers and athletes there is a level of expectation in themselves. There will be a specific set of movements and activities that will help resolve their problem. And If I was to tell those people just to go for a run or just go and have a walk-in my population it won't be appropriate …there would be a value thing around thinking that isn't going to make my back pain any better…"*

(FG1-PT1)

"Some of them have some expectations. They come and they tell you I swim already, I just came for Pilates. Or there are others well….I sit on there don't want to move, they don't want to do exercise and they don't want to walk... And then you ask them do you like something else ..yes I like to draw, so paint standing instead of sitting!..."

(FG1-PT5)

5.4.2.3 Sub theme 3 - Gradual desensitisation to overcome the resistance

The importance of starting with enjoyable and less fearful exercise to overcome the resistance in people with fear of moving was firmly established across all three focus groups. From the data it was evident that fearful behaviour in people with LBP was common amongst all the participants.

"I think in populations that would be afraid to move that would be more appropriate to do something gentle and mild. Because you don't want them to feel that their symptoms are provoked and then obviously to discourage them more. Yes, if they are motivated, they can just choose straight away whatever they like…"

(FG2-PT4)

According to the data, another common practice among the participants was to introduce small movement elements of a complex or a fearful task and improve an individual's confidence before progressing to more functional and challenging tasks.

"If they are fearful of bending, trying and do posterior pelvic tils and reaching to the floor from sitting. Sort of trying to convince them and do little movements, make confident and yes then exposure ..."

(FG1-PT3)

5.4.3 Theme 3: Education and awareness

Participants identified that education and improved awareness of LBP were vital to improving ESM in people with LBP. The discussions were guided by their clinical experience and with some recommendations considering the public. The prominent foci which surfaced during the discussion were; ensuring individual's understanding of their condition, busting LBP myths and improving awareness, educating the individuals with updated knowledge, normalisation and desensitisation of the pain experience.

5.4.3.1 Sub theme 1 – individual's understanding of their condition

Physiotherapists strongly agreed on the importance of ensuring that the individual had a thorough understanding of the LBP related issues they experience, their underlining causes and how to address these during management.

“I really want to make sure that patients fully understand and agree with me to some extent, if they don't agree, then you can have a discussion about it, - what’s happening to them? And they can explain back during the assessment, why you are having this? why it is coming like that ? does that make sense to you ? And as this happens I proceed on”

(FG1 -PT4)

Although some of the participants recognised that it there could be challenges in educating patients with regard to their condition, they would ensure that they agreed with the onward management approaches.

“…Yes, there's been a lot of times when you explain the problem to a patient, and you say you really think you've got them on board. And then they say well I don't know what it is..I don't know what my problem is… So make them understand that actually a lot of it falls with them and making sure they agree with you what the next step is key…”

(FG3 -PT1)

5.4.3.2 Sub theme 2 - Myth-busting and improving awareness

Several unhelpful beliefs commonly held by people with LBP were discussed. Furthermore, the importance of addressing these during the management of LBP was emphasised.

“People don't bend at all... Because there is this massive sort of -it's my back we can't move- I'm not allowed to move belief…”

(FG2 -PT2)

Three participants mentioned the common misconception of “hurt equals harm” with exercise and PA in LBP and highlighted the necessity of busting similar myths associated with LBP practices.

“Only if there is a way, they could get over that message of fearless movement and hurt doesn't equal harm….”

(FG1 -PT3)

5.4.2.3 Sub theme 3 - Educating the individuals with updated knowledge

All participants agreed on the importance of providing patient education with updated and evidence-based knowledge. Furthermore, two members raised the importance of limiting this to a succinct amount of education which does not overwhelm the users with information.

“.A little bit of education without being a big education. Because people don’t want all of it, smaller more succinct you make something it’s more effective..”

(FG1 -PT2)

Four participants raised concerns about the public not having access to the most up to date information and how this reinforces negative societal beliefs related to LBP.

“We know there is an emerging body of research, particularly the work by X, they talk about manual handling and how you should not brace your back and how strong your spine is for you to bend instead of going down with knees.. there was a previous letter that wrote about these types of issues in a very prolific Sunday newspaper and was very much slaughtered by the public for those viewpoints…that’s the problem, the societal belief is still very much the other way. ..”

(FG1 -PT1)

5.4.3.4 Sub theme 4 - Desensitisation of the pain experience and managing flare-ups

Pain education including how to manage flare-ups and pain associated with exercise, was one of the prominent subthemes that emerged from the discussion data. Six physiotherapists mentioned the significance of preparing the individuals with prior advice about the pain that might occur with exercising, up to what extent it is safe to continue and when to seek help.

“I normally warn them. I normalise that saying discomfort is part of the process. So don’t be surprised...I use VAS scale as marker...there’s going to be some level of discomfort and that’s normal. Anything within that as VAS of ...is fine. If you go above that maybe you are doing a little bit too much. Scale it back…”

(FG3 -PT1)

Eight of fourteen participants talked about the importance of educating individuals with LBP about pain flare-ups. They highlighted the importance of not stopping exercise and PA completely but regressing at flare-up and progressing later appropriately.

"I tell them that it's ok to have a flare-up, it doesn't mean you are going back to square 1. It's just something like a rule book, You need to just scale down the intensity, pace your exercises it's more about giving them the control and making them aware and listening to their body rather than depending on the clinician or depending on google to find out you know each time they have a problem…"

(FG2 -PT1)

Apart from the pain associated with exercise and flare-ups, participants also emphasised the necessity to normalise the idea of LBP among the public to prepare them for a shared experience which might be experienced by most people at least once in their lifetime.

"You prepare someone for it, you know… if they are not prepared and then not ready for it then rehab and prognosis is much worse. The people who are ready for it and have that readiness tend to do a lot better. And I think with back pain if you can say if you are ready for BP, it sounds odd ..but if they are ready to accept that there is a problem that happens and that can be very quickly be resolved I think you see that your prognosis is get a lot better than the people that really aren't ready.."

(FG1 -PT4)

5.4.4 Theme 4: Optimum exercise self-management and digital interventions

Theme 4 emerged from the discussion and focused on participants' viewpoints on optimum ESM in LBP and how these could be employed within digital interventions. It broadly covered a range of subthemes discussing strategies used to ensure optimum ESM in LBP, how these strategies could be drawn into digital interventions and barriers to using a digital intervention in LBP.

5.4.4.1 Sub theme 1 - Strategies to improve adherence and monitoring in ESM

All the participants agreed upon the importance of adherence and of monitoring their patients' ESM, they used a range of tools in practice. These involved using exercise calendars, exercise diaries with daily goals to achieve, demonstrating and performing exercise together with patients, video recording, taking photos and written instructions.

"I use advice calendars. I tell them you don't have to have happy faces every day because fluctuation is good. If we have all happy days, it's not normal. So, I say give yourself five days. Did I manage it today? Do that and see how you feel… even a half of it."

(FG1 -PT3)

"If they come to clinic with a smartphone and they're happy, I will take a photograph of them on their phone doing it, and I've used everything from little private access only YouTube clips and physical descriptions or sometimes with very few patients talking through …..if they are struggling. But the reaction to all of them is very different…"

(FG3 -PT4)

Furthermore, physiotherapists believed that their patients' involvement in a shared decision-making process regarding their management would improve adherence. Seven of the participants mentioned that they try to offer a range of options to the individuals during their discussion so that they can choose the one they preferred.

"I would sit down with patients and say well you know exercise would be beneficial. There are several routes to getting there from you doing it yourself and providing some guidance, and you go into the local gym, to social settings to one to one with a physio or technical instructor or a class-based session. So the patient will then often self-select which one they feel is best for them"

(FG2 -PT4)

"Another important thing about monitoring and technology again in my perspective is what will be the step forward? Its ability to give feedback to people so, if I come back to the wellness system that we use about their general wellness, the disadvantage or the feedback from it about using something like is that they put the numbers in, they even have a space to make comments. Some of them even like a pain diary would make comments how they would feel what's going on"

(FG3 -PT3)

5.4.4.2 Sub theme 2 - Digital interventions as a catalyst in ESM

All participants were keen to discuss the potential role that digital interventions and technology could play in providing a promising solution to enhance ESM in people with LBP. They identified and discussed a wide array of features and strategies that could be adopted within these interventions and their potential benefits.

"They are in your phones... Technology is accelerating and is available, We carry it every day. We can use it better. Monitoring change, creating a chance for them to become more independent in the management as a catalyst…."

(FG2 -PT2)

However two participants expressed conflicting viewpoints concerning the use of digital devices, by the individuals, such as activity trackers. They highlighted the need to link them with their clinical findings.

"My view is I do not see a huge importance in fit-bits and things like that unless it is really linked with patients' findings…. If it is LBP patients, they just have to move. You have to use your brains remember to move. Can't they do that? Do we need technologies to tell us to move?"

(FG2 -PT1)

In response to the above argument another participant highlighted the importance of considering an individual's choice and their lifestyle. Whilst ten participants discussed use of the digital interventions in monitoring their ESM, five participants suggested the need to provide feedback for individuals to acknowledge the monitoring process and the observed results. Some of the common examples mentioned included advice on their general wellness, PA levels and sleep.

"Other important thing about monitoring and technology again in my perspective is what will be the step forward? It's ability to give feedback to people....what are you going to do about it"

(FG1 -PT5)

"Because it's self-management, I think the clever part would be to give people a feedback so they don't have to rely on an email or a phone number or some sort of thing where they have to go to the practitioner to get the feedback that if it's the right thing or what's going on what they've done…I think.. where it would be clever…"

(FG2 -PT4)

Whilst some members expressed a certain degree of uncertainty about the ability of digital interventions to provide a patient-specific management option, as a whole participants highlighted the positive role of a digital intervention with evidence-based, reliable information to facilitate ESM in people with LBP. Whilst identifying some of the limitations, they identified several blended approaches and features from their experience that could be adapted when designing a digital intervention. One of the suggestions was to create a platform to provide reliable and evidence-based information with access to resources related to LBP.

"And support on them with evidenced-based information, trustworthy to make them confident. Most of these patients they go into the internet and looking in to this all these stuffs…and wondering if they should have been doing those exercises or not.."

(FG2 -PT4)

Whilst recognising the limited capacity of a digital intervention to deliver a wholly tailored management for the individual, participants advocated a number of potential features that could be introduced as a healthy behaviour change intervention to improve ESM. Some of the most commonly mentioned features included goals to achieve knowledge and awareness of LBP, progression and regression of exercises, exercise feedback, access to exercise, and other resources with clear instructions.

"May be separate modules.. One with more holistic stuff like your education and general advice like activity levels, mental health, relaxation and those sorts of things. CBT (cognitive behavioural therapy) kind of things that they can, patient can relate to. And may be another module for exercise you can go on to say ok these are the exercises for my back and maybe videos attached to them with progression, regression. And feedback attached i.e:10 reps tick for green if you do it comfortably, or maybe red if it was uncomfortable. With the feedback"

(FG3 -PT3)

"It might be good to have goals and things they can work towards. This is what I'm struggling with, this is what I can't do. So what can I plan… and they should do and it should always be linked back to what that matters to me. It's more like motivation. If there's something that they miss doing. I love the idea of progression and regression as long as they have some way that can keep the direction that would inspire them and to maintain it…"

(FG2 -PT3)

Furthermore, one participant also highlighted the potential opportunity to provide a range of general and specific exercises, this would allow the individual to select exercises of their choice to improve their activity level and overcome the fear of moving.

"If we're going for generic advice you can ask the patient then to self-select, do you want exercises to increase movement? do you want ones to strengthen? Do you want one to improve global fitness? And then it's categorised into those broad categories. So there's an element of self-selection in the patient choosing their exercises and then underneath that they're generalist exercises and the whole will do no harm and they're not patient-specific but they may be specific to flexibility, strengthen and cardiovascular … And then trying to get over that message of fearless movement and hurt doesn't equal harm …"

(FG3 -PT2)

5.4.4.3 Sub theme 3 - Unhelpful attributes and limitations

In addition to the possible positive aspects of the digital intervention ESM for LBP sufferers, participants also discussed limitations and disadvantages. Two participants mentioned how some digital devices, such as activity trackers and over monitoring could cause a heightening of the symptoms.

"The biggest challenge with the monitoring systems is the escalation of the symptoms because of how much they monitoring their symptoms… Because, more you monitor sometime the problem is you are feeding to the fact that that is always there and that become a part of your life. If I'm writing something about every day and If I'm feeding back into it, you always going to be aware of that, of that challenge and reinforce challenge…"

(FG1 -PT3)

Furthermore, four participants raised their concerns over practical issues related to the implementation of digital interventions. Some of these involved managing patient expectations, digital literacy, and infrastructure such as access to the internet and devices.

"*I think you have to look at the climate and the environment that you're actually developing this resource for…I think the other thing you have to consider is the digital literacy... Because actually most people are not. It is not stereotyping someone…but specially with the older age group"*

(FG2 -PT2)

One participant expressed their view that people will not meet their expectations of a personal engagement with a professional to seek advice when using a digital intervention.

> "*You know using the self-service check out. You know you're not getting that human interaction…. And once you understand the computer system we devalue the advice because you know it's a pre-set algorithm giving you the advice. Whereas with a human being you know that human being is actually supposedly have thought about you the person. It is so you sometimes put more worth than that human interaction…"*

(FG3 -PT3)

5.5 Discussion

5.5.1 Summary of the findings

The ultimate purpose of this present study was to use the findings to inform the content of the planned intervention, this was achieved to a great extent. In general there was agreement amongst the members of all three focus groups. Four overarching themes and fourteen subthemes emerged from the data. The physiotherapists emphasised the importance of understanding the individual as a whole whilst considering biopsychosocial factors, this would enable them to receive an appropriate and tailored ESM programme. Apart from the biopsychosocial aspect of the assessment, physiotherapists also highlighted the importance of assessing the functional tasks and challenging movements. In terms of the exercise based management in LBP, participants used both general and specific exercise approaches and PA depending on the presentation of the individual. Participants emphasised the importance of starting an exercise programme by choosing an exercise preferred by the individual and progressing it further. Educating the individuals regarding LBP and elements of its management were identified as a crucial component for management and noted several key topics, these included awareness managing flare-ups, myth-busting and providing updated knowledge to the public. Furthermore, the physiotherapists discussed what the optimum ESM would look like and how those features could be employed in a digital intervention to facilitate ESM in people with LBP. Nevertheless, some unhelpful attributes and limitations of digital interventions were also identified from the results.

This study highlighted important aspects of musculoskeletal physiotherapists' practices and perspectives on ESM in people with LBP. Only a limited number of studies have explored the practices and perceptions of the key components of self-management interventions in physiotherapists or other healthcare providers (Nielsen et al. 2016; Cal et al. 2021). Physiotherapists in this study broadly discussed the LBP assessment, exercise and PA based management in LBP, the role of patient education and awareness and features of optimum ESM and digital interventions. Although the focus of the study could have centred around exploring physiotherapists' perceptions on the merit of developing a digital intervention and investigating key features that could be implemented, the author believed it would have limited the scope of the discussion. It was felt that more realistic data could be obtained by exploring their actual practices and perceptions on how they design ESM programmes for their patients with LBP. Nevertheless, as the study progressed more specific topics related to the delivery of ESM via digital interventions were discussed.

Despite being involved in the management of LBP patients with varying levels of chronicity and service needs, the beliefs of physiotherapists were consistent with evidence and recent guidelines (Airaksinen et al. 2006; NICE 2019) and emphasized the importance of PA and exercise in LBP (Van Middelkoop et al. 2010). Furthermore, they highlighted the complex, multifactorial nature of LBP (O'sullivan et al. 2016) and agreed upon the importance of adopting a biopsychosocial approach (Waddell 2004) in the assessment and management of these patients. There is moderate and low quality evidence to confirm the effectiveness of the biopsychosocial approach compared with conventional care and physical treatment such as heat, massage, manual therapies and back school exercise (Kamper et al. 2015).

5.5.2 Theme 1: A holistic approach to the assessment

Although the main focus of the study was to explore physiotherapists' ESM practices and perspectives in LBP, a significant proportion of the discussion focused on the subject of assessment, this subsequently led to the discussion of the ESM of these patients. Physiotherapists highlighted the importance of adopting a holistic approach to assessment which gives a more complete picture of the individual and enables them to better tailor the management and self-management programme. The views of the physiotherapists in this study align with recent evidence that confirms the benefits of embracing patient-centred and biopsychosocial therapeutic models (Hayden et al. 2005b; Liddle et al. 2007b; O'Sullivan et al. 2015). Existing evidence confirms that patients with LBP preferred their self-management programme to be tailored to them individually (Liddle et al. 2007; May 2010). Physiotherapists discussed several aspects which they would assess to gain an understanding of the overall picture of the individual, this mainly involves their current level of PA, motivation and willingness to engage in exercise, their lifestyle and expectations and any psychological factors such as stress, anxiety and fear of movement. Generally, physiotherapists were more interested in looking at functional tasks or challenging movement specific to the individual, not only to facilitate tailoring of the exercise and self-management but also to use as an outcome measure. This observation is consistent with some of the findings reported by Davies et al (2014) that suggests the use of functional tasks as an outcome measure in patients with LBP. Clearly, integrating an assessment component in the intervention would give a better opportunity to tailor the delivered ESM programme for the patient. However, it was deemed inappropriate to select a few elements to integrate to the intervention from the overwhelming amount of data which emerged from the focus groups and which covered a wide range of aspects of the assessment. This was an anticipated outcome and therefore as mentioned in the methodology, a separate second study was conducted to identify the key components of the LBP assessment.

5.5.3 Theme 2: Exercise and physical activity-based management

In line with established literature, physiotherapists highlighted the importance of improving exercise and PA in people with LBP and used a wide range of exercises and activities in their practice (Hayden et al. 2005a; Airaksinen et al. 2006; NICE

2020). This observation supports previous findings from a national survey conducted among 419 Irish physiotherapists in which 98% of them reported use of exercise when managing their LBP patients (Liddle et al. 2009).

Unlike some reported studies, no single method (Battié et al. 1994) seemed more popular than others and physiotherapists used a wide range of exercises in the management of patients with LBP. This observation can be explained by the inconsistency of the types of exercise programmes delivered as reported in the literature (Henchoz and So 2008; Van Middelkoop et al. 2010; Saragiotto et al. 2016b). Given the absence of evidence that one type of exercise is superior to others (Hayden et al. 2005a; Foster et al. 2018), physiotherapists agreed that it is more important to encourage people to be active and start or continue exercising with something they prefer and are less fearful of. Whilst a majority of the physiotherapists opted to start with general programmes such as walking, a few preferred to introduce simple specific movements or exercises like pelvic tilt exercises. Both strategies were deemed appropriate since previously published studies have not recommended general exercise and PA over specific types of exercise or vice versa (Henchoz and So 2008). In general, physiotherapists agreed that time, access to exercise, preference of exercise type and PA type should be considered when designing an ESM programme for people with LBP. They agreed that total volume of activity is more important than the type of exercises the individual is engaged in. Interestingly there was a disagreement between the physiotherapists regarding exercise prescription based on subgroups of individuals. Whilst some of them were using classification systems and subgrouping their patients with LBP when deciding the most appropriate management programme, some of them opposed this. This observation is supported by previously published literature that confirms the inconsistent use of classification systems among physiotherapists, despite them having the knowledge and understanding to deliver a tailored management programme (Davies and Howell 2012; Sheeran et al. 2015). It is possible that irrespective of the use of a standard classification system, patients are still classified into groups using individual physiotherapist's experience , level of clinical reasoning skills and knowledge (Sheeran et al. 2015). Interestingly, the movement and control impairment classification by O' Sullivan (2005) was commonly used by the physiotherapists, they preferred subgroup based targeted management as opposed to the commonly reported choice of the McKenzie approach (McKenzie 1981; Davies et al. 2014).

5.5.4 Theme 3: Education and awareness

Physiotherapists appeared to believe in the vital role of educating the individual and improving their awareness of LBP management. This emerged as the third theme of the analysis. One of the key points identified during the discussion on education and awareness was the need to explain the condition, goals and treatment plan to the individual, ensuring that they understand the context. Consistent with recommendations and endorsed in the guidelines (Buchbinder et al. 2018), physiotherapists highlighted the importance of patient education and enlightening them with the most up to date knowledge. In accordance with published literature with regards to the practices of physiotherapists in the UK (Murtagh et al. 2021) and Northern Ireland (Gracey et al. 2002), all the physiotherapists who participated in the study seemed to deliver some form of education and advice to their patients. However, contrasting findings have also been reported where patient education and advice was not always provided as part of LBP management (Swinkels et al. 2005). As recommended by O'Sullivan et al (2020), physiotherapists highlighted the necessity of busting myths associated with LBP. However, in general, findings showed that a wide range of advice and information was delivered to their patients, these included desensitisation of pain, managing a flare up and gradual progression and regression of exercise. This finding broadly supports existing evidence studies (Kerssens et al. 1999; Liddle et al. 2009) and could be explained by the absence of definitive clinical guidelines on the specific information which should be included when educating people with LB. Theme 4: Optimum exercise self-management and digital interventions

5.5.5 Theme 4: Optimum exercise self-management and digital interventions

All physiotherapists emphasized the importance of ESM, they discussed what optimum exercise self-management should look like and how this can be featured in a digital intervention thus making it the fourth and final theme. Since the focus of this study is exercise and PA, discussion mainly centred on self-management pertaining to improving and maintaining exercise and PA engagement. In accordance with previous research (Nielsen et al. 2016; Cal et al. 2021), physiotherapists in the present study strongly believed that a well-designed digital intervention had a great potential to effectively reach people with LBP and to facilitate their self-management. There were further similarities between the attitudes expressed by the physiotherapists in this study and those described by Nielsen et al. (2016) in their qualitative study with 42 health-care providers. For example, both groups identified the need to provide information and knowledge related to LBP, both wanted LBP related myths to be challenged. Furthermore, similar to the physiotherapists in this study, Nielsen's study participants also valued providing information on self-management strategies such as acute pain flare-up management and prevention of recurrence. These findings are further reinforced by similar views expressed by people with low back pain when asked about information needs of an online resource (Nielsen et al. 2014). However, in contrast to findings from this study, Nielsen et al. (2016) reported that study participants expressed concern about the provision of specific details on treatments including types of exercises such as strengthening and stretching. Opposed to this current study, the above sample comprised a range of healthcare professionals including physiotherapists, chiropractors and doctors. It is possible physiotherapists have different views about giving specific instructions and are more comfortable including them in a digital intervention. Furthermore, physiotherapists in the present study highlighted strategies which would improve adherence and monitoring and suggested ways that digital interventions could be used as a catalyst of ESM in people with LBP.

In a national survey conducted amongst Australian physiotherapists, 90% recognized the importance of self-management which aimed to enhance patient outcomes but estimated that only 67% of their patients had adhered to recommended self-management strategies (Peek et al. 2017). Self-management itself is considered as a behaviour or a collection of behaviours that require a person to adhere to recommended lifestyle changes (Keogh et al. 2015). Poor adherence to management strategies is common amongst people with LBP (Härkäpää et al. 1991; Friedrich et al. 1998). In accordance with published literature, physiotherapists believed a patient-centred and holistic approach would improve users' adherence to ESM. However, few physiotherapists were certain that this could be achieved as expected via a digital intervention.

Despite the many benefits and usefulness of DHIs in the self-management of LBP several limitations were also discussed. A concern expressed by one of the physiotherapists was the fear of lack of interaction between the healthcare provider and the individual if the care was replaced with a digital intervention. Similar concerns have been reported by the patients with CLBP in previously conducted studies, patients believed digital technologies are not a substitute for the human relationship between patients and care providers (Palazzo et al. 2016).

5.6 Strengths and limitations

This study has several strengths, these include the total number of physiotherapists who participated across three focus group discussions, the mixture of work settings including private and academic sector represented by the physiotherapists and the wide range of work experience which contributed to a good balance in the data. However, the scope of this study was limited to exploring only physiotherapists' views on the management of LBP. A larger scale implementation should involve all primary healthcare professionals who treat LBP patients. Further discussions with these members would be beneficial to inform any further developments of the iterative versions of the intervention and to discuss implementation of such an intervention.

5.7 Conclusion

The current study provided an insight into physiotherapists' practice and perspectives on the key components of a self-management intervention which they believed would encourage people with LBP to be active and to exercise. Furthermore, they discussed how these functions could be integrated into a digital intervention. Whilst the physiotherapists largely agreed on most topics and shared common opinions, some disparities were also noted. Assessment of the individual was discussed extensively and deemed essential in order to design a more appropriate and tailored intervention. Hence it was appropriate to conduct a separate study to identify and narrow down the key components of an LBP assessment which will be useful in the development of the intervention. Therefore, a national survey was conducted to identify key subjective history and objective components of an LBP assessment, this is described as a separate study in the next chapter. Additionally, a number of relevant BCTs and features to be included as intervention functions were identified from the data of this focus group study. This process of selecting BCTs and other intervention features and integrating them within the intervention is also discussed separately in Chapter 7.

Chapter 6: What are the key assessment components recommended by experts to tailor an exercise self-management programme for people with LBP? A national survey

6.1 Introduction

This chapter describes the second study of phase 2 of the development of BACK-to-FIT™. The first study of phase 2, described in Chapter 5, gave an insight into the plethora of potential behaviour change techniques and features to be included in an optimum ESM intervention for people with LBP. The rationale for this study was to identify how these behaviours change techniques and features could be tailored to individuals within an ESM intervention. Existing research evidence has revealed that tailoring exercise programmes will result in superior outcomes in pain and associated disability in people with LBP (Hayden et al. 2005b). Kent et al. (2009) showed that assessment provides the basis to understand the needs of the individual and informs tailored management (Kent et al. 2009). Therefore, it was apparent that an ideal digital intervention would benefit from an assessment component to tailor the ESM content for people with LBP to be active and exercise. Furthermore, integrating an assessment component will result in a standalone intervention allowing the users to receive efficient but tailored ESM.

The results of the first study in phase 2, the focus group discussions with physiotherapists, demonstrated the importance of a comprehensive LBP assessment. However, given the nature of the digital interventions, there is a clear need to adopt a succinct but inclusive assessment to tailor the content of the ESM programme and achieve optimum outcomes. Furthermore, stakeholder involvement in the design stage of a complex intervention is highly recommended in both new and old versions of MRC guidelines for developing complex interventions (Craig et al. 2008b; Skivington et al. 2021). Therefore, this study was designed to obtain input from LBP experts on tailoring of the intervention using assessment components.

This chapter describes the aim, objectives and methods used in the study, this is followed by the results and a summary of the findings.

6.2 Aims and objectives

This study aimed to identify the key components of the assessment recommended by experts in order to tailor an ESM programme for people with LBP. Accordingly, the main research questions of the study were as below.

1. What are the key questions asked in the assessment of LBP?
2. What are the key physical tests used in the assessment of LBP?

6.3 Methods

6.3.1 Study design

Even though a survey is one of the most common quantitative research methods (Fink 1995), the use of mixed-methods in LBP related surveys is well established (Davies et al. 2014; Setchell et al. 2017). Whilst quantitative surveys are predominantly comprised of closed-ended questions with predetermined answer options, the addition of open-ended questions with qualitative research elements transforms it into a mixed-methods study. The use of open-ended questions enabled participants to express and articulate opinions or simply ones that had been overlooked by the researcher when creating the survey, thus providing rich and relevant data (Albudaiwi 2017). The use of focus groups and interviews when collecting data gives the advantage of offering in-depth, detailed and complex information on a specific research area (Blair et al. 2013). However, the results of the focus group discussions with physiotherapists had already triggered a discussion and revealed the comprehensiveness of LBP assessment. This second part of the study warranted a deductive approach to identify the key assessment components. Therefore, a mixed-methods cross-sectional survey with descriptive qualitative methods was used to achieve the study objectives. The survey questionnaire used in this study provided a list of items for the participants to indicate whether they agreed that the item was an important question/test when designing a tailored ESM intervention, it also provided the opportunity to suggest any additional items for inclusion. The survey was self-administered, and an online survey was considered for the data collection method. The below section further discusses the use of online surveys and their suitability in this study.

6.3.2 Online surveys

Online surveys are less time-consuming, convenient, cost-saving, and able to cover a wider geographical area over a larger sample size when compared with traditional paper surveys (Mertler 2002). It is also argued that online data collection minimises data loss, simplifies the transfer for the analysis and reduces data entry errors (Ilieva et al. 2002; Creswell and Creswell 2017). Furthermore, online survey instruments are identified as an effective way to measure attitudes (Aiman-Smith and Markham 2004). However, online surveys often face a unique set of overarching challenges, including lack of access for participants who do not have internet, low response rates and incomplete responses (Couper 2000; Fricker and Schonlau 2002). Online surveys usually have a much lower response rate when compared with paper-based ones; on average 33% compared with 56% (Nulty 2008). Nevertheless, studies have introduced measures that can be taken to boost response rates, including having short survey questionnaires, using graphically enhanced questionnaires when possible, providing incentives, reassurance of participant anonymity, and sending reminder emails (Göritz 2006; Nulty 2008). This survey was designed and distributed using a free cloud-based software for online survey development (Onlinesurveys 2019).

6.3.3 Item generation and construction of the survey questionnaire

This section explains the process for generating items used in the survey. Items were generated using a combination of data extracted from study one and a review of the available literature related to surveys and LBP assessments performed by healthcare professionals managing LBP patients. The standard search strategy recommended by the Cochrane Collaboration Back Review Group (Furlan et al. 2009) was adapted for this search combined with “history taking”, “clinical history”, “clinical reasoning” "assessment", "physical assessment", and "objective assessment" as text words and Medical Subject Headings (MeSH) terms. The detailed search strategy is given below in Table 6.1. Cited reference retrieval was also conducted. Articles published before October 2019 were searched via Cinahl, EMBASE, Medline, and PubMed. Following this search, the resulting articles were manually searched for relevant references; only literature written in English using the keywords listed above in an abstract, title or both were covered.

Table 6.1: Keywords and the search strategy used in the literature search

Search category 1		**Search category 2**
Backache **OR** lumbago **OR** back pain **OR** low back pain **OR** lumbar spine **OR** lumbar ache **OR** lumbar pain **OR** chronic low back **OR** Non-specific low back pain **OR** Non-specific chronic low back pain **OR** LBP **OR** CLBP **OR** NSLBP	AND	Physical examination **OR** manual examination **OR** physical tests **OR** assessment **OR** physiotherapy assessment **OR** physical therapy assessment **OR** musculoskeletal assessment **OR** neuromusculoskeletal examination **OR** history taking **OR** objective assessment **OR** subjective questions **OR** questions **OR** clinical reasoning **OR** reasoning **OR** subjective assessmnet
Key: LBP- Low back pain, CLBP – Chronic low back pain, NSLBP – Nonspecific low back pain		

The literature search identified 654 articles, and after removing duplicates 221 articles remained. Abstracts of the remaining articles were manually assessed for relevant information, this resulted in only 15 articles.

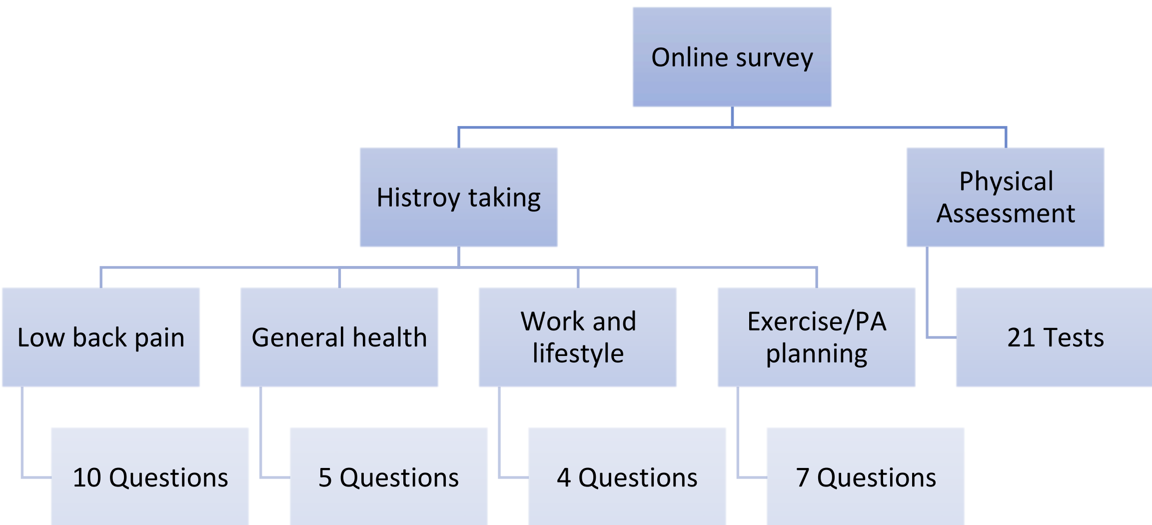
After reviewing the 15 articles on LBP and assessment-related data emerged from the focus group study, 47 items were grouped under two sections; history taking , and physical assessment (Dagenais et al. 2010; Davies et al. 2014). Six demographic data questions were included: occupation, age, gender, level of qualification, years of experience and work setting. The items included in the history taking were grouped into four main domains and included twenty-six proposed questions across four main domains. The history taking domains included were:

- Low back pain
- General health
- Work and lifestyle
- Exercise/activity planning

The physical assessment component was comprised of twenty-one proposed posture and movement tests. The participants were given instructions on how to rate their agreement, this was based on the importance of each listed item when designing a tailored ESM programme for people with LBP, 5-point Likert scale was used for this purpose (Likert 1932). After the last question of each domain of the history taking items and the physical assessment component, participants were asked, "would you add anything to the list above?" If the participants answered "Yes", they were asked to "please explain" before proceeding to the next section. If they answered "No," they were allowed to continue answering the questions.

There was no limit to the number of words or characters they could use when answering these questions. Figure 6.1 details the layout of the survey questionnaire with components and domains.

Figure 6.1: Survey questionnaire layout



6.3.4 Likert scale

As the most popular scaling procedure used in attitude measurement, Likert scales provide more precise information on a respondent's degree of agreement or disagreement compared to a simple agree/disagree response (Oppenheim 2000). Likert scale was originally developed in 1932 as a five-point response scale and often achieves good reliability (Likert 1932; Oppenheim 2000). Although there have been debates about which offers the greatest usability between five-point and seven-point Likert scales, both are used extensively in research (Dawes 2008). The number of scale points is informed by the subject being evaluated, the capacity for discerning, and the level of knowledge present in the target population (Komorita and Graham 1965, Weng 2004). For this survey questionnaire, a 5-point Likert scale was selected to represent levels of importance, including "strongly disagree", "disagree", "agree nor disagree", "agree", and "strongly agree". The middle response, which was a neutral option, indicated indecision and was helpful in avoiding forced answers, which could produce untrue results or lead to participants failing to complete the survey (Pett et al. 2003).

6.3.5 Piloting

To ensure the clarity and accessibility of the online survey, a pilot study was conducted with six UK based physiotherapists (four qualified from the UK, and two qualified from United Arab Emirates and Kuwait). All the physiotherapists were emailed the link to the survey and asked to follow instructions in the link, accordingly, including submitting an e-consent. Physiotherapists were asked to record, via email, any technical defects they may have encountered whilst completing the survey and any challenges to clarity, comprehension, and accessibility of the survey question, also to assess the ease of completing it. Given the lower response rate associated with online surveys compared with traditional paper-based surveys (Nulty 2008), it was also vital to consider the time required to complete the survey as a priority to ascertain a maximum response rate. Therefore, the time it took for each physiotherapist to complete the survey was monitored.

The physiotherapists identified several page setting problems and minor technical issues in the survey answer options. Furthermore, pain provocation tasks and pain easing tasks were added to the list of objective tests as suggested by one of the physiotherapists. No 12.3 question was changed from "BMI" to "height and weight" to make it more straightforward, as proposed by three physiotherapists. All physiotherapists who completed this pilot survey were happy with the time it took to complete the survey which had an average completion time of 7.6 minutes.

6.3.6 Study subjects and sampling

Online surveys pose a unique set of challenges in guaranteeing a random sample (Kaye and Johnson 1999) due to them being internet-based, thus suggesting they may be better suited for non-probability samples. According to Van Selm (2006), these non-probability samples could still be valuable as they represent a subgroup of the total population. Despite the disadvantage of selection and sampling bias, non-probability sampling has several advantages: it is more conducive and practical in the real world, faster responses and cost-effectiveness (Couper 2000). Kaye and Johnson (1999) have suggested a variety of strategies that can be employed to achieve an acceptable level of randomness and representativeness in sampling. These include: random selection of email addresses, using a sampling frame from lists of users and using a stratified random sample of individuals from the email addresses obtained (Van Selm and Jankowski 2006) .

For this study, a purposive sample using a sampling frame was obtained. Aiming to represent the highest competency related to the management of LBP, the sampling frame comprised of members of Society for Back Pain Research (SBPR), UK and Musculoskeletal Association of Charted Physiotherapists (MACP), UK. SBPR is an affiliated specialist society of British Orthopaedic Association and is comprised of a range of clinicians who engage in scientific research related to back pain. MACP is a specialized group of the Chartered Society of Physiotherapists who have had extensive postgraduate and clinical training to reach a recognized standard of excellence in neuro-musculoskeletal physiotherapy. In total, both societies comprised about 1200 members at the time of the study.

6.3.6.1 Inclusion and exclusion criteria

Participants with a minimum professional qualification level of a Bachelor of Science (BSc) degree and post-qualification clinical/research experience in LBP management were included in the study. Subjects who failed to provide informed consent were excluded.

6.3.6.2 Recruitment

An email with the invitation to participate in the survey was sent to all members of both societies by their administrators, with the link for the online survey (https://cardiff.onlinesurveys.ac.uk/back-to-fit-a-digital-tool-to-improve-exercise-self-mana-3). The first page of the survey included the screening questions and the participant information sheet. The survey content was available only to the clinicians/researchers who fulfilled the inclusion criteria. Participants were encouraged to contact the investigator if they had any queries related to the study. The survey was open for two months in order to obtain a higher number of responses (Cook et al. 2000).

The survey started with an introduction, the purpose of the PhD study and the survey, a brief outline of the survey sections, and anticipated outcomes. At the end of the first page, they were directed to complete the consent form if the subjects were willing to participate in the study. The second page was the e-consent form, followed by the demographic questions on page 3. Pages 4 and 5 consisted of items related to LBP history taking and the physical tests respectively. Each section had a brief explanation of what was required from the participants. The survey concluded by thanking the participants and providing them with the researcher's details in case if they had queries or if they wished to contact the researcher with regard to anything related to the study. The complete survey questionnaire is attached as appendix 11.

6.3.7 Ethical considerations

Ethical approval for this study was obtained from Cardiff University, School of Healthcare Sciences Ethics Review Committee on 09/04/2019 (Appendix 7).

Anonymity: Only the Internet Protocol (IP) addresses were visible to the author and were not shared with the other respondents or third parties under any circumstances. All survey responses were given a unique number which was used in the data analysis and onwards.
Confidentiality: A Secure Sockets Layer (SSL) encrypted internet connection was used to ensure the cybersecurity of the collected data and personal details. Management of personal data complied with the rules of the GDPR and was not

divulged to any third parties. Access to participant's data was restricted to the principal investigator only.

Informed consent: The participant information sheet was the first page of the survey and followed the pattern of a paper-based information sheet. It covered the identity of the researchers, contact details, the reason for conducting the survey and the use to be made of the data (Appendix 12). Following the information sheet, the consent form enclosed in the online survey presented the details and the items, this is similar to the paper-based consent form (Appendix 11). It was mandatory to endorse these items and provide consent before the survey could be opened.

Right to withdraw: Participants could exit at any stage during the survey. The respondents had to backtrack the survey to change their response to a particular question if needed and it was not possible to delete or change it after the point of submission.

Storage and management of data: Data processing complied with the data protection principles of the General data protection regulation (GDPR), and fair, lawful and transparent handling of the data was ensured. According to the research integrity and governance code of practice at Cardiff University, the collected data will be retained for 15 years after completion of the study. Arrangements have been put in place to secure data disposal or destruction after a fixed period of 15 years.

6.3.8 Data analysis

The survey consisted of two types of data, quantitative and qualitative (Patton 2014; Creswell and Creswell 2017) . Accordingly, quantitative and qualitative data analyses were conducted.

6.3.8.1 Quantitative analysis

Survey response rate was calculated as the number of completed responses divided by the number of subjects sent the survey link. The survey link was sent to all members of SBPR and MACP; therefore, the denominator used was the total of registered members of both groups at the time of the research. The survey host platform, www.online surveys.ac. UK is being configured not to accept any missing or duplicate responses from the same IP address. Also, during the design of the survey, software logic was put in place to remind participants to choose only one option or point out empty fields before they were able to proceed with the survey. Therefore, there were no missing and duplicate responses. Quantitative analysis of data was done by applying descriptive statistics to employ univariate analysis which analyses a single variable (Heeringa et al. 2017). According to Trochim (2006), distribution, central tendency, and dispersion are the key components of univariate analysis. The most common way to describe a single variable is the distribution or the sum of the frequency of individual data or ranges of data for a variable. The central tendency is a single value that best represents the data's characteristics and an approximation of the centre of the distribution. This is commonly measured by the mean, median, and mode. The mean is the average arithmetic value, median the middle value and the mode is the most occurring value of the data set (Trochim 2006).

Dispersion is how much the data is dispersed away from the central tendency as opposed to those which are centrally distributed and are commonly measured by range, standard deviation (SD), standard error (SE) and confidence interval (CI) (Ali et al. 2019). The data with a normal distribution tend to gather symmetrically around the mean value and have a bell shape distribution in a histogram. Skewness (Ali et al. 2019) measured this symmetric distribution around the centre(Ali et al. 2019). Normally distributed data usually has zero or near zero skewness. Data skewed to the left are termed negatively skewed, whilst data skewed to the right are positively skewed. Data from Likert-type scales will often show skewed or polarised data as respondents are expected to select either positive or negative positions of the continuum. The median best measures the central tendency of an asymmetrical or skewed data set and the distribution of data set is explained better using percentiles or quartiles. The data was ranked with percentiles into 100 equal parts and then described as 25%, 50%, 75% or any other percentile amount, while the median is taken as the 50th percentile. With quartiles, similar to percentiles above, ranked data are divided into four equal quarters of 25% each at 25%, 50% and 75% and called Quartiles (QI, Q2, Q3). Thus, the interquartile ranges (IQRs) are the observations in the middle 50% of the median, between the first and third quartiles (Ali et al. 2019).

Kurtosis measures whether data are heavy-tailed or light-tailed relative to a normal distribution. High kurtosis data are likely to have heavy tails, and low kurtosis data likely to have light tails. Since this study data is ordinal and expected to be skewed due to the agreement or the disagreement with the importance of the items, central tendency was best measured by median and IQRs were used to plot distribution and dispersion, respectively.

The response options for all the questionnaire items were dichotomized into two categories; those who agreed that the corresponding question or test was important (agree/strongly agree) and those who didn't agree (agree nor disagree/disagree/strongly disagree) (Jenkins 2016; Östhols et al. 2019). In order to determine the importance of each subjective question and physical test of the assessment component, a level of agreement was predetermined before the data analysis to reduce researcher bias (Williams and Webb 1994). Although a cut-off point of ≥ 80% is recommended when assessing adherence to practice (Spitaels et al. 2017; Bahns et al. 2021), a standard benchmark for a similar survey in NSLBP assessment was non-existing. Therefore, a level of agreement of ≥ 80% was decided upon by a team of three researchers, including the author, and set a priori as the cut-off point for each item to determine as a key question/test. Powell (2003) argues that this is an appropriate measure when there is a lack of standard benchmark or literature advocating a specific agreement level. Therefore, for a single item to be determined as a key subjective question or as a key physical test, 80% or more of participants had to either agree or strongly agree on the importance of that item to design a tailored ESM programme to improve the level of PA and exercise for people with LBP.

Prior to data analysis, survey questionnaire Likert scale data were exported from the Online Surveys and transferred to Microsoft® Excel and IBM SPSS Statistics® version 27 (SPSS Inc., Chicago, Illinois). Since these original responses are in ordinal or categorical format (strongly agree/agree/agree nor disagree/ disagree/ strongly disagree) in SPSS these data were re-coded into numeric values as below.

1 = strongly disagree
2 = disagree
3 = agree nor disagree
4 = agree
5 = strongly agree

Descriptive analysis of the data were performed using these ordinal values to obtain the median, skewness values and histograms to illustrate the distribution of each of the items.

6.3.8.2 Qualitative data analysis

Data were analysed with TA (Braun and Clarke 2006). Braun and Clarke's (2006), thematic analysis procedure discussed in the previous chapter (Chapter 5) was followed when analysing the Open-ended questions. Here codes and themes tend to derive more from researchers' concepts and ideas in their data. Hence the researcher's final analysis mapping might not directly link to the raw data (Braun and Clarke 2012). For this study's qualitative analysis a deductive approach was applied. Since this data was already linked to the previous focus group study and closed-ended questions of the questionnaire, this approach was deemed more appropriate.

Accordingly, four domains of the history taking component, "Low back pain", "General health", "Work and lifestyle", "Exercise/activity planning", and "physical assessment" were used as codes.

1. Before starting the analysis of data, all participants' responses for open-ended questions were collected in a Microsoft word document and extracted data from those responses were then transferred into NVivo 11.
2. These responses were then coded using above mentioned five codes thus categorising into each domain.
3. Next, with further analysis it was evident that data within these domains could be further coded to identify similar categories. The codes assigned matched what was represented in the individual phrases.
4. Then, these similar codes within each domain were gathered and promoted to create new themes and subthemes accordingly.
5. Finally, a table was created to illustrate the identified themes.

The author carried out the coding and then discussed it in collaboration with another two researchers (VS, LS). Codes and themes were settled when the agreement was achieved among all three.

6.4 Results

In total, seventy-one participants completed the survey. The majority of participants were physiotherapists (n=64), with the remainder being a doctor (n=1), researchers (n=3), a nurse (n=1), chiropractors (n=4) and an osteopath (n=1). Other demographic data, including the number of years of experience with LBP, how many years qualified, highest qualification achieved and work setting at the time of the study, are given below in Table 6.2. Questions regarding the highest qualification obtained and work setting allowed multiple answers if applied.

Table 6.2: Survey participants' demographic data

Demographic variable	Number	Percentage
How many years of qualified		
0-5	14	19.7%
6-10	13	18.3%
11-20	25	35.2%
20+	19	26.8%
Highest qualification obtained		
PhD	08	11.4%
MSc	30	42.9%
BSc	41	58.6%
MD	01	01.4%
Work setting		
Private	28	41.7%
University (Higher Education Institute)	14	19.7%
Sports Institutes	06	07.0%
NHS	42	53.5%
How many years of experience with people with low back pain?		
0-5	16	22.5%
6-10	15	21.1%
11-20	24	33.8%
20+	16	22.5%

Participants needed to rate their agreement on 47 items in total to denote the importance of each item. Out of these 47 items, for 22 items (17 history taking questions; 5 physical assessment tests), participants agreed (strongly agree/agree) that they were essential questions and tests when designing a tailored ESM programme for people with LBP. The participants' rate of agreement for individual items in each domain in the history taking component and physical assessment component are outlined below.

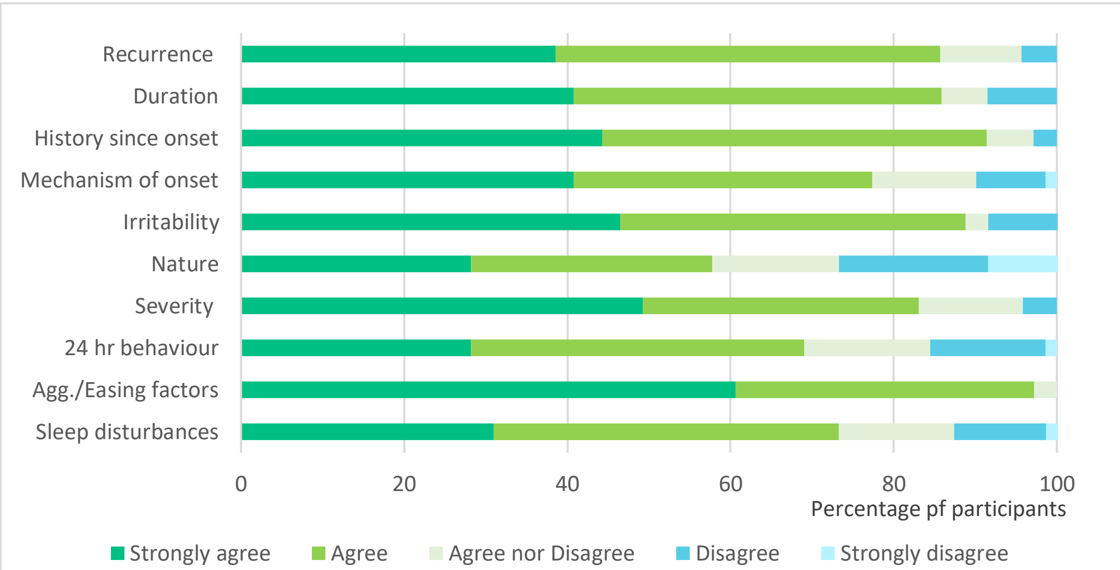
6.4.1 Quantitative analysis findings

6.4.1.1 History taking

6.4.1.1.1 Low back pain

Out of ten, six items within the low back pain domain received agreement ≥ 80% (those responding agree and strongly agree), indicating their importance in the assessment. These included “recurrence” (85.7%), “duration of low back pain” (85.9%), “history since onset” (91.4%), “irritability” (88.8%), “severity” (83.1), and “aggravating/easing factors” (97.2%). The lowest level of agreement on the importance of the “nature of the pain” (57.8%). Figure 6.2 illustrates the percentages of the level of agreement by the participants for each of the listed items.

Figure 6.2: Agreement on all items within the low back pain domain

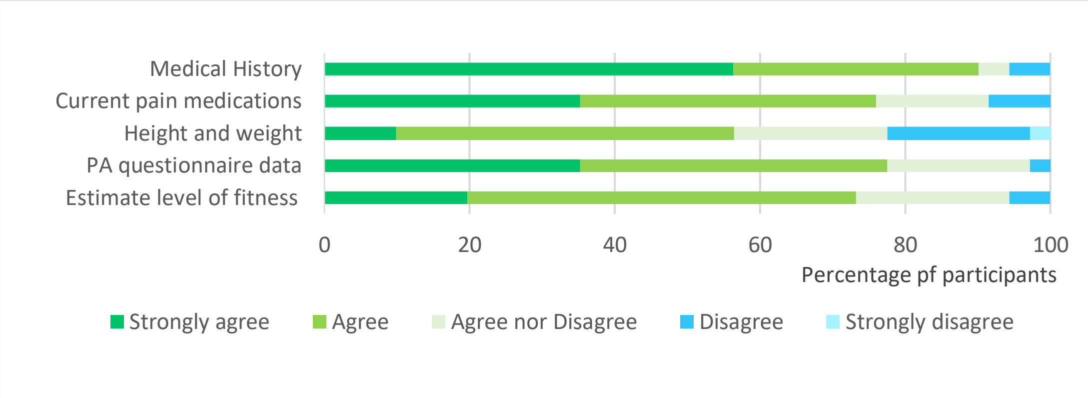


Key: ‘strongly agree’ and ‘agree’ responses indicate agreement

6.4.1.1.2 Domain: General health

Only one of the five questions in the general health domain received > 80% agreement, which is “medical history” (90.2%). The lowest agreement was received for “height and weight” (56.4%). Figure 6.3 illustrates the percentages of the level of agreement by the participants for each of the listed items in the general health domain.

Figure 6.3: General health domain- agreement of the items on their importance

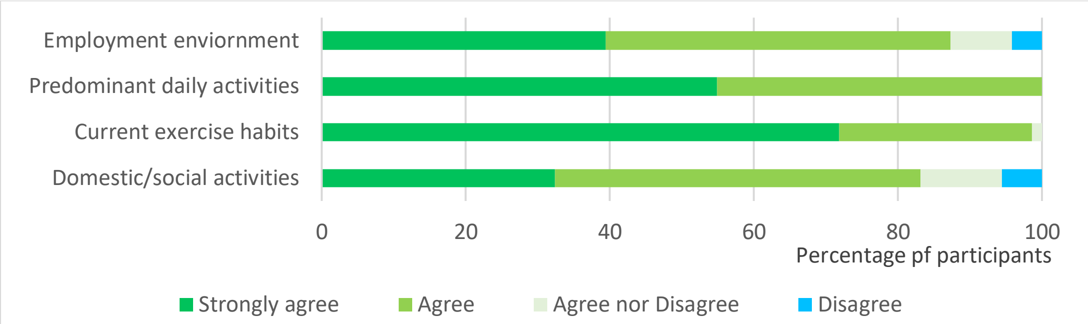


Key: ‘strongly agree’ and ‘agree’ responses indicate agreement

6.4.1.1.3 Domain: Work and lifestyle

All four questions of the work and lifestyle domain were scored with more than 80% agreement, with the highest score being given for the ‘predominant daily activities’ with all participants (100%) agreeing on its importance in the assessment. This was followed by “current exercise habits’ (98.6%), employment environment (87.3%) and ‘domestic/social activities’ (83.1%). Figure 6.4 illustrates the percentages of level of agreement by the participants for each of the listed items of the work and lifestyle domain.

Figure 6.4: Work and lifestyle domain- agreement of the items on their importance

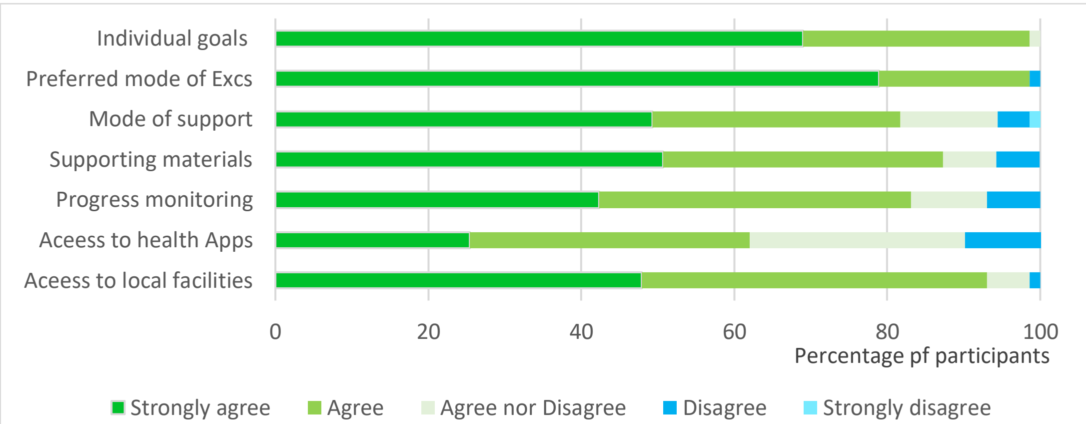


Key: ‘strongly agree’ and ‘agree’ responses indicate agreement

6.4.1.1.4 Domain: Exercise/activity planning

Six out of seven items in the exercise activity planning domain were considered necessary by the participants and achieved ≥80 levels of agreement involving: “individual goals” (98.6%), “preferred mode of exercise” (98.6%), “mode of support” (81.7%), “choice of supporting material” (87.4%), “progress monitoring” (83.1%) and “access to local sports/leisure facilities” (93%). The only item the participants did not agree as important to include in the history taking was access to health apps (62%). Figure 6.5 illustrates the percentages of the level of agreement by the participants for each of the listed items of the exercise/activity planning domain.

Figure 6.5: Exercise/activity planning domain- agreement of the items on their importance

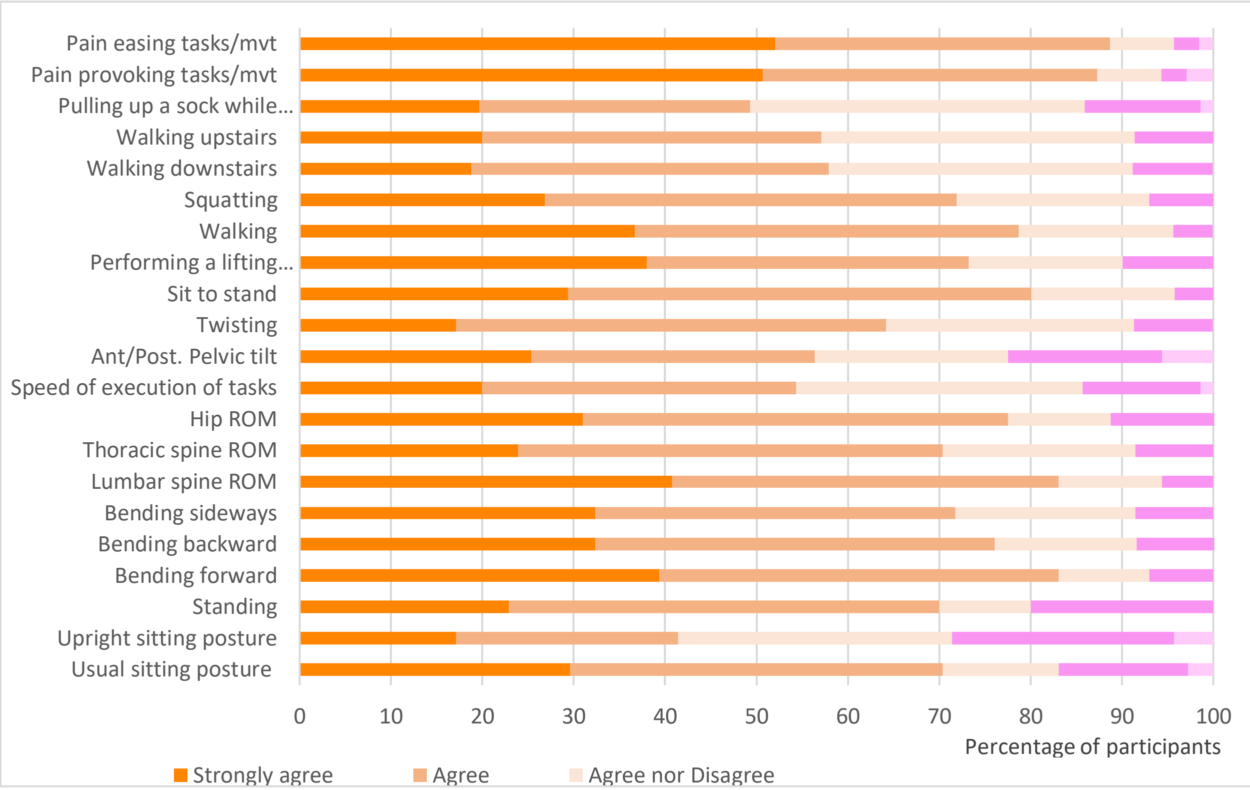


Key: ‘strongly agree’ and ‘agree’ responses indicate agreement

6.4.1.2 Physical assessment

Only five out of twenty-one listed physical assessment test items received agreement ≥80%. These five tests included 'pain provoking tasks or movements' (87.4%), 'pain easing tasks or movements' (88.8%), 'sit to stand' (80.1%), 'lumbar spine range of motion' (83.1%) and 'bending forward' (83.1%). Figure 6.6 illustrates the percentages of the level of agreement by the participants for each of the listed physical tests/movements.

Figure 6.6: Physical assessment tests and movements - agreement of the items on their importance



Key: 'strongly agree' and 'agree' responses indicate agreement

Participants' percentages indicating who agreed and who did not agree based on the dichotomized responses and the values for the median, distribution of responses, dispersion and skewness for each item are presented in Table 6.3. Most items are negatively skewed, this is expected in a survey with a Likert scale seeking agreement on each item. Percentage agreement > 80% are given in bold.

Table 6.3: Summary of descriptive analysis of the responses.

Domain / Item	Agree % (agree/strongly agree)	Disagree % (agree nor disagree/ disagree / strongly disagree)	Median	Inter-quartile range	Skewness
History taking					
Low back pain					
Sleep disturbances	73.2	26.8	4	2	-0.81
Aggravating/Easing factors	**97.2**	2.8	5	1	-0.84
24-hour behaviour	69	31	4	2	-0.66
Severity	**83.1**	16.9	4	1	-1.02
Nature	57.7	42.3	4	3	-0.47
Irritability	**88.8**	11.2	4	1	-1.34
Mechanism of onset	77.4	22.6	4	1	-1.01
History since onset	**91.4**	8.6	4	1	-1.07
Duration	**85.9**	14.1	4	1	-1.14
Recurrence	**85.7**	14.3	4	1	-0.92
General health					
Estimate level of fitness	73.2	26.8	4	1	-0.48
PA questionnaire data	77.5	22.5	4	1	-0.51
Height and weight	56.4	43.6	4	1	-0.47
Current pain medications	76	24	4	1	-0.72
Medical History	**90.2**	9.8	5	1	-1.53
Work and lifestyle					
Domestic/social activities	**83.1**	16.9	4	1	-0.84
Current exercise habits	**98.6**	1.4	5	1	-1.28
Predominant daily activities	**100**	0	5	1	-0.20

Employment environment	**87.3**	12.7	4	1	-0.98
Exercise / Activity planning					
Access to local sports/leisure facilities	**93**	7	4	1	-0.95
Access to health Apps	62	38	4	2	-0.26
Preferred method of progress monitoring	**83.1**	16.9	4	1	-1.01
Preferred type of supporting materials	**87.4**	12.6	5	1	-1.27
Preferred mode of support	**81.7**	18.3	4	1	-1.26
Preferred mode of exercise	**98.6**	1.4	5	0	-2.76
Individual goals	**98.6**	1.4	5	0	-1.12
Physical assessment					
Usual sitting posture	70.4	29.6	4	2	-0.78
Upright sitting posture	41.4	58.6	3	2	-0.02
Standing	70	30	4	1	-0.56
Bending forward	**83.1**	16.9	4	1	-0.97
Bending backward	76	24	4	1	-0.70
Bending sideways	71.8	28.2	4	2	-0.57

Lumbar spine ROM	**83.1**	16.9	4	1	-0.94
Thoracic spine ROM	70.4	29.6	4	1	-0.49
Hip ROM	77.4	22.6	4	1	-0.79
Speed of execution of tasks	54.3	45.7	4	1	-0.24
Anterior/Posterior Pelvic tilt	56.4	43.6	4	2	-0.44
Twisting	64.2	35.8	4	1	-0.32
Sit to stand	**80.1**	19.9	4	1	-0.58
Performing a lifting manoeuvre	73.2	26.8	4	2	-0.69
Walking	78.7	21.3	4	1	-0.72
Squatting	71.9	28.1	4	2	-0.49
Walking downstairs	57.9	42.1	4	1	-0.11
Walking upstairs	57.1	42.9	4	1	-0.08
Pulling up a sock while seated	49.3	50.7	3	1	-0.10
Pain provoking tasks or movement	**87.4**	12.6	5	1	-1.72
Pain easing tasks or movement	**88.8**	11.2	5	1	-1.62
Key: PA - Physical activity, ROM – Range of motion					

6.4.2 Qualitative analysis findings

A number of participants suggested other areas to include within the history taking and the physical assessment. 29 participants (40.8%) for low back pain, 13 (18.3%) for general health, 15 (21.1%) participants for work and lifestyle and 5 (7%) participants for exercise and PA planning, suggested adding new items for each of the domains. Furthermore, 15 participants (21.1%) had suggested new items for the physical assessment.

Participants' suggestions and opinions for additional items were obtained from the responses provided for the open-ended question at the end of each domain of the history taking component and at the end of the physical assessment component. These responses were gathered and analysed using deductive thematic analysis. A summary of the findings of the analysis is outlined in Table 6.4.

Table 6.4: Summary of the deductive thematic analysis of participants' suggestions on the new items to add for history taking and physical assessment.

Assessment /Domain	**Suggested new item/s**
History taking	
Low back pain	• Previous self-management experience • Individuals' beliefs & perception • Pain location
General health	• Psychological and social well-being • Pain response to exercise
Work and lifestyle	• Hobbies • Travel and mode of transportation
Exercise and PA planning	• Outcome measures
Physical assessment	• Combined movements • Individual specific functional tasks • Avoiding movements due to fear

From the analysis of twenty-nine responses, three new themes for suggested new items were identified in the low back pain domain in the history taking component involving: previous self-management experience, individuals' beliefs and perception of their pain and pain location.

"I also need to understand their previous experience with physiotherapy and exercise and how successful their self-management was"

(Participant 54)

"Knowing the exact location of pain and type of pain will be helpful"

(Participant 27)

Two themes for suggested new items emerged from the analysis of thirteen responses in the general health domain analysis, including psychological and social well-being and pain responses to exercise. Participants suggested that it was essential to have an in-depth understanding of the mental health and social well-being of the individual for a better management, despite any early yellow flag screening.

“Psychological status applies to NSLBP as much as more complex cases. Excluding it based on yellow flag screen misses an important factor in the management of NSLBP"

(Participant 06)

Participants suggested that it would be helpful to inquire about their previous responses to exercise programmes in terms of pain, when planning a future ESM programme.

“Their response towards exercise being utilized previously will be an important one to consider before planning on any new exercise programmes...”

(Participant 62)

Analysis of the fifteen responses from the work and lifestyle domain also revealed two new themes, these included hobbies and travel/mode of transportation. Although the items already included in this domain give some focus on lifestyle and daily activities, participants suggested finding out more about any individual specific hobbies or leisure activities as these might impact upon their pain and ESM engagement.

“I will want to know if they have any particular hobbies, sports or activities they would do, and if there have been any changes to these recently, so I can tailor the exercise I am going to give them accordingly."

(Participant 33)

Also, the participants were interested in asking about their travelling, including mode of transport and duration, to better understand their lifestyle.

"I think it is important to know about their history of travel time and mode of transportation."

(Participant 58)

Only one theme was identified from analysing the five responses in the exercise. The PA planning domain, including outcome measures, highlighted the importance of monitoring changes in the individual’s outcomes and symptoms.

“There has to be some sort of outcome measure to determine the effects of any programme the patient is going to continue, to see if it is really working or not”

(Participant 21)

Analysis of the fifteen responses from the physical assessment component identified another three main items. One of the themes focused on looking at combined movements of the spine.

“Combined movements or 3D movements of the spine will give a better idea of the direction of the pain and how comfortable the individual with functional activities”

(Participant 10)

Another theme that emerged was the assessment of movements that the individual might avoid performing due to pain, showing fear avoidance behaviour.

“You need to determine what they can’t do or what they avoid doing – and whether there’s a functional reason as to why they are avoiding it – i.e. mechanical cause, or a psychological fear avoidance behaviour?”

(Participant 42)

A final theme that emerged from the analysis of responses in the physical assessment component was assessing individual-specific functional tasks/movements, this highlighted the patient-specific approach in the assessment.

“Would consider all functional movements that are important to the patient in the context of a functional exercise therapy approach. So, it is very patient-specific"

(Participant 19)

6.5 Discussion

6.5.1 Summary of the findings

This chapter described methods and results of the online survey, this was conducted to explore clinical assessment of LBP previously suggested in the focus groups as a method to tailor any subsequent ESM intervention. The study provided preliminary evidence of potential subjective questions and the physical tests which should be included in the assessment. This would enable a future ESM intervention to be tailored for people with LBP so that they engage with exercise and PA. The survey responses revealed that out of forty-seven total items listed, agreement of over 80% on their importance was achieved on twenty-two items. These included seventeen questions in the history taking and five physical assessment tests.

6.5.2 LBP Assessment

Overall, the findings of this study were useful to understand the key components that could help to deliver a tailored ESM for people with LBP. This survey explored the discussion on assessment of LBP that emerged from the focus group study discussed in the previous chapter. Whilst subsequent findings of the survey seemed to be relevant and to reinforce the focus group findings, it also narrowed down the comprehensive assessment and identified the key components for tailoring the potential intervention. Evaluation of red flags and yellow flags are extremely important during an LBP assessment (Oliveira et al. 2018; NICE 2020). However, it should be noted that participants of the survey were instructed to consider assessment of red flags and yellow flags as already completed, hence, to focus only on the history taking and physical assessment in LBP. A recent qualitative study discussed the value of history taking and interacting with the individual to personalize and guide them through the self-management, mainly focusing on patient education (Horler et al. 2022). Overall, the present survey study findings agreed with the focus group findings as well as established literature (Deyo et al. 1992; Widerström et al. 2019; Widerström et al. 2021) indicating that subjective and physical assessment details lead to a better understanding. The individual can decide on the most appropriate and tailored self-management programme for themselves. However, there are no studies to date which have established what specific subjective information or questions would be explored during an assessment.

When considering an LBP assessment, the majority of studies have looked at the use of classification systems (Davies et al. 2014; Sheeran et al. 2015) and clinical reasoning models (Noll et al. 2001; Langridge et al. 2015) among physiotherapists and healthcare professionals who are treating people with LBP. Use of classification systems or clinical reasoning models were not included as questionnaire items. However, they were also not suggested as new items when responding to open ended questions of this study.

An understanding of LBP characteristics is clearly shown to be important to the survey participants. Not only were six out of ten items in the LBP domain agreed beyond 80%, pain location was also suggested as a new item. These observations concur with the findings from a qualitative study where physiotherapists highlighted that understanding an individual's LBP has appeared to influence their decisions for individualized management of patients with LBP in primary care (Widerström et al. 2019).

Consistent with this study, findings by Deyo et al. (1992) have also established the use of pain related information as well as responsiveness to previous management strategies. Interestingly all four items regarding work and lifestyle were identified as important to consider in the assessment. This can be explained by the high prevalence of LBP among the working population and the association with life style (Buchbinder et al. 2018).

Moreover, Lim et al.'s (2019) systematic review exploring the expectations of people with LBP confirms that people have a clear preference for advice from health professionals and management which has been tailored to match their employment status and lifestyle. Participants of this survey had an understanding and were considerate of the needs of the individuals, as well as the evidence base, when designing a tailored self-management programme. Individual preferences were a frequent concern of the participants when planning the exercise and PA programme. In addition to the recommendations to involve individual preferences and interests in the clinical reasoning process (Haynes et al. 2002), combining them with recommended exercise management and advice to tailor the content is suggested to be effective in LBP self-management (Van Tulder et al. 2006). Individual preference was one of the main areas which emerged in the focus group discussion (in Chapter 5). However, the literature also consists of some contradictory findings that challenge this stance, suggesting a compliance based approach encouraging the individuals to comply with the recommendations rather than a collaborative process which involves a shared decision making process contemplating individual preferences (Stenner et al. 2016).

Similar to the history taking, physical assessment is considered crucial in people with LBP to better equip and guide individuals through LBP management (Sahrmann 2002; Van Dillen et al. 2016). A large body of evidence has focused on identifying predominant physical assessment items or tests to categorise various subgroups of LBP including movement control (Sahrmann 2002; O'Sullivan 2005), clinical instability (Cook et al. 2006) and impairment dysfunction (Van Dillen et al. 1998). However only a few studies have attempted to establish key physical tests and movements carried out in real life practice by health professionals with a focus on LBP self-management and exercise (Sheeran and Robling 2019).

Despite the poor reliability of pain provocation tasks (Strender et al. 1997), participants of the present study reported a high level of agreement on the importance of pain provoking and easing movements and tasks which is also consistent with some previously reported literature (Östhols et al. 2019). This agreement together with the stated agreement on the importance of bending forward movement implies that participants regard pain patterns as important (Daykin and Richardson 2004; Widerström et al. 2019) as well as direction specific approaches (McKenzie 1981) when planning exercise programmes. Classification systems were not directly listed as an item under physical or history taking. Also, no participants suggested the use of a classification system as an extra item in response to the open-ended questions. However popular agreement on the above findings, together with the assessment of avoiding movements due to fear, suggests there is potential for subgrouping individuals according to their clinical presentation when designing exercise and self-management (Luomajoki et al. 2018; Sheeran and Robling 2019).

The literature has shown good reliability for bending forward as a test with intraclass Kappa correlation of 0.74 for the physiotherapists and 0.66 for the physicians (Strender et al. 1997). However in contrast to Osthols et al. (2019) study, participants where 99% had used posture assessment in their physical assessment, the present study participants did not consider this aspect important and marked agreement < 80% for both siting and standing posture tests.

Findings from both the history taking, and physical examination components determined the key assessment components which could be used to form an assessment tool within a self-management intervention for delivering a tailored ESM for people with LBP. However due to the complex nature of the clinical reasoning process, adopting a comprehensive assessment as a self-assessment tool to match the design of the intervention could be challenging. Therefore, if it is proposed to develop and adopt a self-assessment tool, further research evaluate the reliability is warranted before progressing into a largescale intervention.

6.6 Limitations

This study has some limitations. One of the major limitations was restricting the study to a single round of questionnaires due to time restraints rather than continuing as a multiple round Delphi study (Williams and Webb 1994). Adopting a Delphi approach is appropriate in order to obtain a consensus from the participants and identify the most important items for inclusion in an assessment when designing an ESM programme for people with LBP (Sheeran and Robling 2019). Despite the attempts to recruit a larger number of participants, only seventy-one responses were obtained, which corresponded to a response rate of 6%. Although the total number of participants was 1200, according to the membership details of both SBPR and MACP, it is possible there were a smaller number of active participants, and it was unclear how many members had accessed the invitation email sent by the administrators of MACP and SPBR. This response rate is considered as poor compared with existing similar surveys (Bishop et al. 2008; Davies et al. 2014; Bishop et al. 2016). However, Nulty (2008) argues that the adequacy of a response rate in a survey depends on the use that is being made out of the data. Accordingly, when considering the purpose of this survey, the amount of data generated appeared sufficient to achieve the primary aim of this study. Furthermore, a majority of the participants of this study were physiotherapists (90,14%). This may have under-represented the other healthcare professionals and largely represent the viewpoints of one group. However, it might be that physiotherapists were more interested in taking the survey due to being more involved in design and delivery of self-management programmes for people with LBP compared to other professionals. Since the breakdown of the numbers of each professional reached was unclear, it is possible the total population of interest had more physiotherapists compared to others.

6.7 Conclusion

Overall, the above results helped to inform how an intervention can be tailor based on assessment, it reinforced the findings from the previous focus group study in Chapter 5. In particular the qualitative analysis findings emphasise the importance of a comprehensive assessment with a patient-specific approach. However, the findings of this study will be instrumental when designing an integrated self-assessment tool within BACK-to-FIT^{TM} to deliver more tailored behaviour change techniques and ESM solutions according to the needs of the individuals with LBP. Although integrating an assessment tool is beyond the scope of this present PhD study, it will be considered in the next iteration of the intervention.

Chapter 7: Development of the BACK-to-FIT^{TM} intervention prototype

7.1 Introduction

Following Phase 1 and 2 the next step was to proceed to Phase 3 which was the actual development of the intervention. Development of a digital intervention can be very resource-intensive and require substantial technical support, including the expertise of software developers and web designers. During the given timeframe of this thesis, it was understood that it would be unrealistic to design and develop the final and comprehensive version of the intervention due to the cost, time and labour involved in the process. Therefore, a decision was made to develop an initial prototype of the intervention named BACK-to-FIT^{TM}, with a few selected but key features identified in Phase 1 and Phase 2 of this PhD project. This chapter first describes the process of determining the content and the development of BACK-to-FIT^{TM} intervention. Next, this chapter discusses the features of BACK-to-FIT^{TM}, and content of each of the modules within the BACK-to-FIT^{TM} intervention. Finally, linkage between the content, features and integrated behaviour change techniques are outlined. The BACK-to-FIT^{TM} intervention prototype was developed from the phase 1 and 2 results during the lifetime of this PhD project and can be accessed at https://back-to-fit.cardiff.ac.uk/.

7.2 Key features of the BACK-to-FIT^{TM} intervention prototype

7.2.1 Content focus - Education and exercise

The phase 1 and 2 results revealed that education and exercise management were among the main themes which emerged from the focus group study (Chapter 5) with musculoskeletal physiotherapists. The results also showed that these two components are interdependent and represent the core elements of a successful ESM programme for people with LBP. Furthermore, the above stance is also supported by evidence highlighting the importance of including both exercise and education within LBP interventions (Moseley 2002; Foster et al. 2018; Shipton 2018). Consequently, the initial BACK-to-FIT^{TM} prototype included patient education and exercise as the main components to promote PA and exercise in people with LBP.

Previously reported research with both users (LBP patients) and healthcare providers, including physiotherapists (Nielsen et al. 2014,2016; Lim et al. 2019; Cal et al. 2021), agreed with the viewpoints on the need for information related to LBP. According to phase 2 focus group discussions with physiotherapists, a greater emphasis is needed on the following areas: myth busting, need to normalise LBP by highlighting the high prevalence, managing pain flare-ups, need to stay active and continuing work and appropriate use of analgesics to help continuing with PA and exercise. All these facts are well established, supported by previous research and advocated in best practice guidelines (Chou 2010; Hartvigsen et al. 2018; NICE 2019; O'Sullivan et al. 2020). LBP impacts on working age people in particular (Buchbinder et al. 2018), therefore a focus on work and LBP in work was deemed important. Existing literature and LBP guidelines continuously advocate the need to continue work and daily activities (Van Tulder et al. 2006). Effects of simple workplace ergonomic modifications and modification of job tasks to facilitate recovery and self-management are also well established (Shariat et al. 2018). Additionally, advice to engage in simple exercise at the workplace or during work, as recommended in the literature (Jakobsen et al. 2015), were also integrated into the education. All of the above was considered when developing the content of the LBP education module of BACK-to-FIT™ (https://back-to-fit.cardiff.ac.uk/#/id/5f451940391d572fdf5ba827).

Addition of exercise was seen as a critical component included in the BACK-to-FIT™ intervention prototype, this was based on the meta-analysis results which indicated there was a lack of existing LBP SMIs with exercise components. Interviews with physiotherapists in Phase 2 of this study also indicated this as did relevant literature. Many different types of exercises are proven to be effective in the management of LBP, these include motor control exercises (Hodges and Richardson 1998), core stability and core muscle strength training (van der Velde and Mierau 2000; Ferreira et al. 2006), stretching [25,26,27] low-to-moderate-intensity aerobic exercise (Chan et al. 2011) and high-intensity aerobic exercise (Chatzitheodorou et al. 2007).

The best type of exercise for NSLBP has always been a debate. Several studies have confirmed the absence of robust evidence to support the effectiveness of one type of exercise (Airaksinen et al. 2006; Macedo et al. 2009; Saragiotto et al. 2016a) and this viewpoint has again been corroborated in a most recent systematic review of systematic reviews looking at NSLBP exercises (Grooten et al. 2022). However, a few more recent research evidence also suggest pilates type exercise, functional restoration exercises, stabilisation/motor control, resistance training and aerobic exercise training have superior outcomes compared to other types of exercise (Hayden et al. 2021, Owen et al. 2020). Best practice guidelines (NICE , 2029) recommend considering individual's preference when prescribing exercises. Also given the empirical evidence advocating the importance of individual preference and autonomy (Hayden et al. 2005a, Liddle et al. 2007) when selecting exercise, it was crucial to have a pool of exercise within the intervention to select from. Accordingly, a decision was made to include a wide range of exercise types and allow individuals with LBP to select their preferred option. This approach was also directly informed by the focus group interviews with physiotherapists who utilised a range of exercise approaches. Importantly in self-management they used a combination of both, general exercises such as walking and specific exercises including stretching, strengthening and mobility exercises based on individual preference of patients in their care. The pool of exercises comprised a large number of different exercises which involved but not limited to upper body and core strengthening, spinal mobility exercises and functional restoration exercises (Hayden et al. 2005a, Huepper 2022, Kennedy and Levesque 2015). Although the number of repetitions, frequency and duration of each exercise might largely depend on the individual, a table with these details for each exercise programme was produced using American College of Sports Medicine (ACSM) guidelines (Liguori 2020) exercise prescription. A panel of three which included the author and two other musculoskeletal physiotherapists (LS,VS) discussed and agreed the progression of the exercises included in the different levels of exercise programmes.

Several features were integrated within the intervention to increase its usability and overall quality. Some of these included keeping the content clear, using a simple language without jargon, giving only a limited amount of information to ensure text is not overwhelming, good visual presentation and easy navigation (Nielsen et al. 2014;

Anderson et al. 2016; Riis et al. 2018; Lim et al. 2019) . Making it accessible via computers and other devices, including mobile phones and tablets, ensured that opportunities to access the intervention were maximised as identified in the behavioural analysis using the COM-B model (Michie et al. 2011) outlined in Chapter 3.

7.2.2 Features focus - Individualisation

The Phase 1 and 2 results indicated that both self-assessment and self-management components were critically important in offering digital based self-management interventions focused on exercise, this ensures an individualised approach. This is in agreement with previous research which stresses the importance of an individualised approach to ensure safety and successful engagement with self-management designed for people with chronic pain conditions (Chou et al. 2007; Geraghty et al. 2018; Mork and Bach 2018). Given the time and resource restraints, the individualisation component was realised only through the development of the self-management component, leaving out any form of self-assessment other than simple methods of individualisation based on user choice. This elementary level of individualisation is common practice in DHI development (Riis et al. 2018; Hodges et al. 2020).

The first method involved individualisation by stratifying exercise based on a person's perceived ability to exercise, exercises were divided into two modules (i) 'Worried Back' module (https://back-to-fit.cardiff.ac.uk/#/id/5f451940391d572fdf5ba819) described as to be accessed by those whom you may be worried about their pain being made worse by exercise and module (ii) 'Active Back' module (https://back-to-fit.cardiff.ac.uk/#/id/5f451940391d572fdf5ba81b) designed for access by individuals who are already active and confident in engaging with PA and exercise. This method of stratification was considered important to allow users to engage at an appropriate level to facilitate positive exercise experience and maintain their motivation (Ahlqwist and Sällfors 2012; Slater et al. 2016).

The second method involved stratification of the exercise by level of difficulty. This method was based on the focus groups with physiotherapists' findings around the importance of organising the exercises to allow users to move through the exercises in a logical way according to their experience of performing the exercises. Based on this, exercises were based on level of difficulty and types of exercises were developed and organised to enable the user to select and modify an exercise programme according to their changing needs and level of competence as they follow the programme over time. For example, an exercise programme with the progression of a chair based exercise split into 4 different levels can be found at https://back-to-fit.cardiff.ac.uk/#/id/5f451940391d572fdf5ba823.

Allowing people to choose their own exercise programme and move freely though the exercises is considered important within the behaviour change theory model (Michie et al. 2013). This is because preference for exercise is a significant factor in a successful self-management programme, it improves individual motivation and effectiveness of the exercise (Henchoz and So 2008). Accordingly, the users were given multiple opportunities to select their preferences and to tailor their exercise programmes. These included identifying goals they wanted to achieve by selecting the module they preferred and choosing which exercise programme they would like to follow and which matched their individual needs Michie et al. 2011).

7.3 The development process of the BACK-to-FIT^{TM} intervention prototype

After deciding on the content, preliminary discussions were held with a team of graphic designers and a software developer from an approved CU list of approved suppliers. Details of the expected final version of the platform were discussed in detail and a presentation with a stepwise flow of the content was submitted to them prior to the discussions. After identifying specific exercises for each programme, detailed illustrations with details of each exercise animation with captions to be included were given to the developers. Video-recordings of the initial exercises, informed by the focus groups with physiotherapists, were made by the author and submitted to the software developer. Animations of the exercise were developed to match these videos.

Dynamic visualisations, such as animations, could be highly supportive in learning complex movement processes such as physical exercises. Previous work with patients with musculoskeletal conditions has shown that using animations to give exercise instructions enhanced the accuracy of the execution of those exercises (Beaulieu e al. 2006). Compared to graphics and written information, animations have significant advantages when providing motion and trajectory information (Mayer & Moreno, 2002), making them a popular exercise instructional tool. Social cognition theory has been widely used in movement learning research and suggests that knowledge acquisition happens through observational learning and imitation (Bandura 1986). This theoretical perspective suggests that visually interpreting and copying exercises will enable the users to learn and perform the exercise accurately. Users' confidence in performing an accurate exercise is also believed to improve exercise compliance and adherence (Chen et al. 1999). However, according to another theoretical approach named cognitive load theory, (Sweller 1988) three types of cognitive loads that can have effects on learning can be identified: Intrinsic cognitive load - load imposed by the information elements, Extraneous cognitive load - load imposed on learners when mental activities, which are not directly related to learning are required to understand the material, Germane cognitive load - load imposed when information is presented in a way that learning is enhanced. Outcomes of instructional animations can often fail due to high extraneous cognitive load. Nevertheless, they have the potential to have high intrinsic cognitive load and Germane load resulting in an optimum level of cognitive loading to facilitate learning (Sweller 1988). Hence, adding cues to animations facilitates intrinsic and germane cognitive load. Cueing is defined as the addition of non-content information that captures attention to those important aspects in an animation (e.g. colouring, text, arrows) (Koning et al. 2007). Therefore, cues are intended to guide the learners' cognitive processing is not intended to provide new information (Mautone & Mayer, 2001). Whilst endless opportunities exist to build new technologies with dynamic visualisations, extensive research has shown that using animations without cues results in poor outcomes among learners and is not instructional superior to a static graphic (Mayer et al. 2005). Furthermore, an emerging body of evidence supports the effects of visual cues within animations (involving arrows, instructional texts and colours) to enhance movement and exercise learning (Semeraro and Turmo Vidal 2022). Visual cues have been argued to provide information on the body and performance and improve peoples' understanding and memory retention of the information provided (Björn et al. 2009). Accordingly, several visual cues involving arrows, instructional texts within the animation, and exercise-specific graphics were included in the animations developed for this intervention.

Each animated video was screened for accuracy by the author and supervisors with feedback given to make any necessary modifications. This process was repeated, several versions of preview animations were produced before arriving at the final product (Figure 7.1). The software developer regularly communicated with the author and supervisors via email and zoom video calls to monitor the progress and discuss necessary modifications. Furthermore, content of all the modules including exercise instructions embedded in the videos were written by the author, proofread, and finally revised. Finally a website domain with a Security Socket Layers (SSL) certificate to host the platform was purchased via Cardiff University.

7.4 Application features

Several user interactive features were embedded within the platform to ensure smooth navigation. The home page included access to all four modules and briefly introduces the application. Each exercise programme is on a single page containing exercise information, animations and collapsible box with stepwise illustrations of each exercise. The home page is accessible from each page and a menu bar provides quick access to all exercise animations. Finally, user access includes shortcut links for all exercise videos and a downloadable summary of the exercise programmes, including frequency and repetitions for individual exercises, via tabs in the task bar (Appendix 13). The next section offers details of the user journey through the BACK-to-FIT™ intervention prototype website.

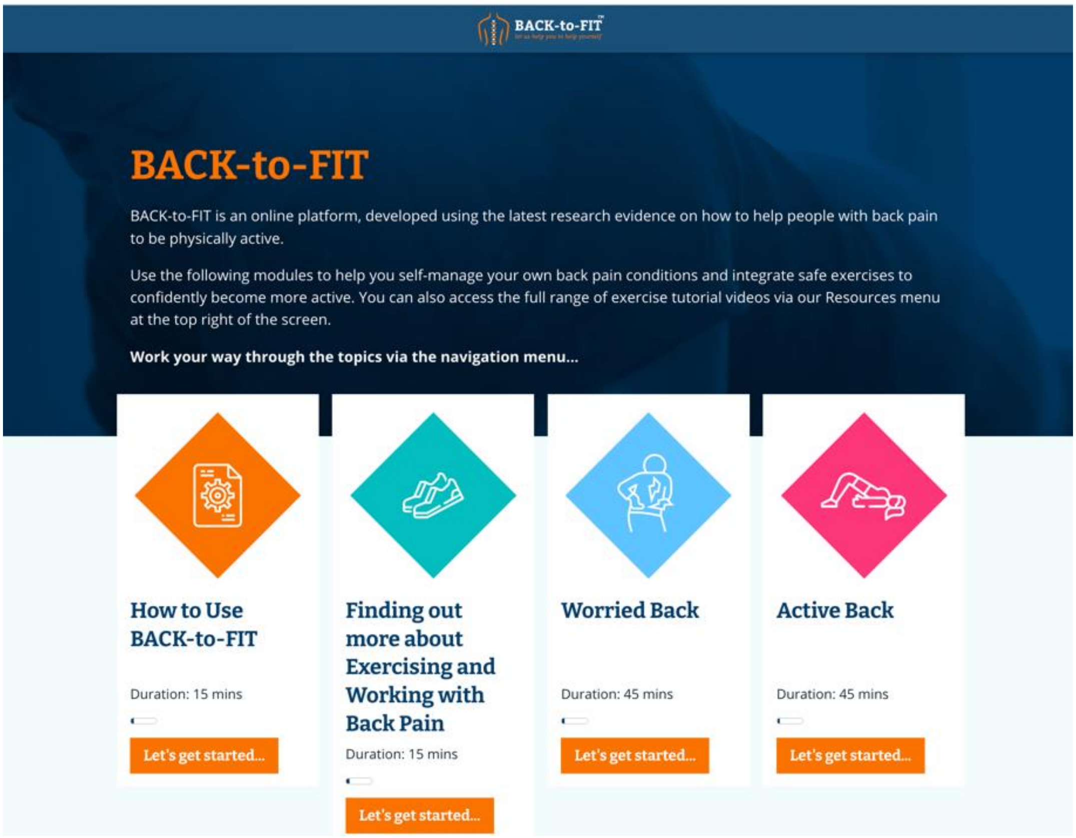
7.5 BACK-to-FIT™ intervention prototype

Prior to use the study participants performed a mandatory self-screening to confirm their suitability. This included a confirmation that they did not have any complaints that may be indicative of a potentially specific cause of pain and excluded any potential red flags (Appendix 14).

Following the screening the participants would access BACK-to-FIT™ intervention prototype home page (Figure 7.1), this gives a brief description of the intervention and its purpose and access to four stand-alone modules:

1. How to use BACK-to-FIT™
2. Finding out more about exercising and working with back pain
3. Worried back
4. Active back

Figure 7.1: Screenshot of the BACK-to-FIT™ home page



7.5.1 Module 1 - How to use BACK-to-FIT^{TM}

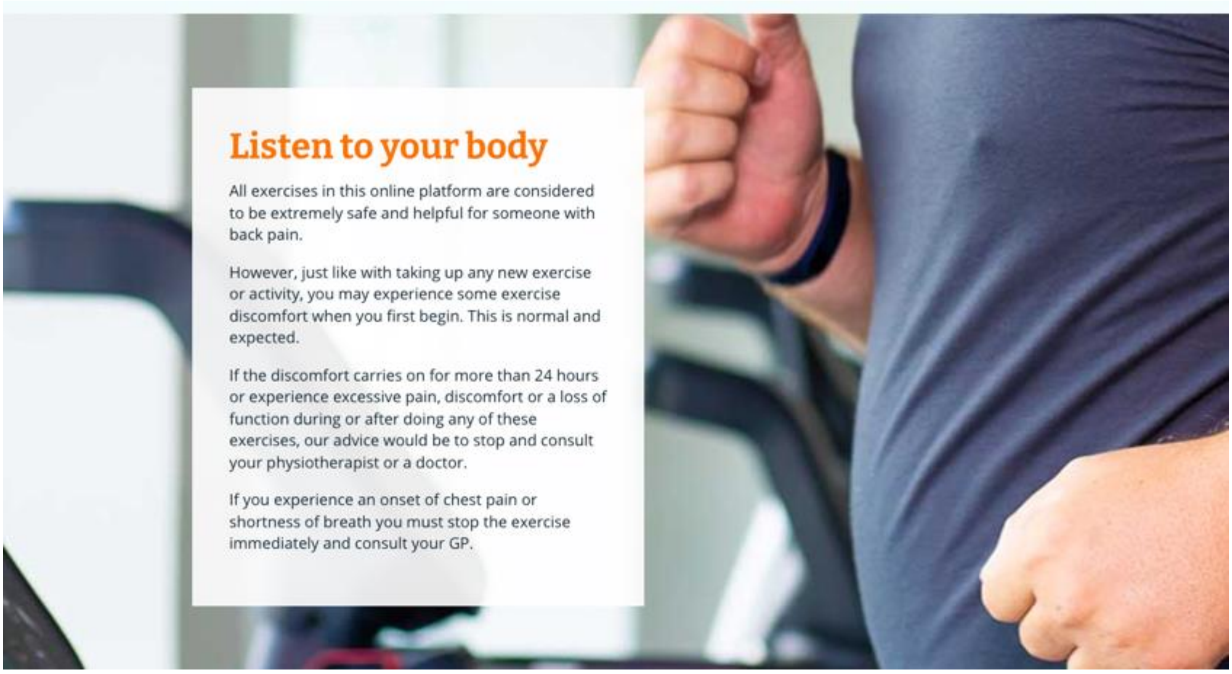
This module introduces the intervention and its key characteristics, this enables the users to gain an understanding of how to get started with BACK-to-FIT^{TM}. Firstly it briefly describes BACK-to-FIT^{TM}, its purpose, how it was designed using evidence and expert opinions and introduces the next three modules (Figure 7.2).

Figure 7.2: A screenshot of the first three sections of module 1 of the BACK-to-FIT^{TM}

The ‘Exercise Levels’ section explains that the exercises are organised into different levels and gives information on how to navigate within these levels. All exercises in both the ‘Worried back’ and ‘Active back’ modules are organised according to level of difficulty. Users are advised to start with level 0 and work their way up or down within the levels according to their personal experience of the difficulty of the exercise. Level 0 represents exercises with a moderate level of difficulty in each programme. If the user can perform the level 0 exercise, without difficulty, for the duration of the exercise with the recommended number of repetitions, they are advised to try level +1 exercises. Once completing level +1 they could continue similarly with the subsequent levels. However, if the user feels uncomfortable with level 0 exercise, they are advised to visit level -1 which contains a less challenging version of the exercise. Depending on the exercise difficulty level, the user can ‘regress’ to lower levels or progress once they are comfortable. This option of regression and progression is one of the most important value propositions of BACK-to-FIT^{TM} which was adapted from recommendations identified during the focus group discussions with physiotherapists. They highlighted the importance of responding to an individual's feedback on exercises. The focus groups also discussed the fact that people with LBP might often be unsure what to do during a flare-up of their symptoms, this could result in a relapse of exercise and PA. Thus, it is believed that having the option to select exercise they want to engage in would give the user a sense of self-control allowing them to decide on the best exercise for them according to their actual level of pain and confidence at any given time.

“Listen to your body” (Figure 7.3), this section is about readiness to exercise where users are advised of the usual side effects of exercise to be expected and gives advice on how to seek medical help.

Figure 7.3: A screenshot of the “Exercise Levels" and “Listen to your body” sections on the module page



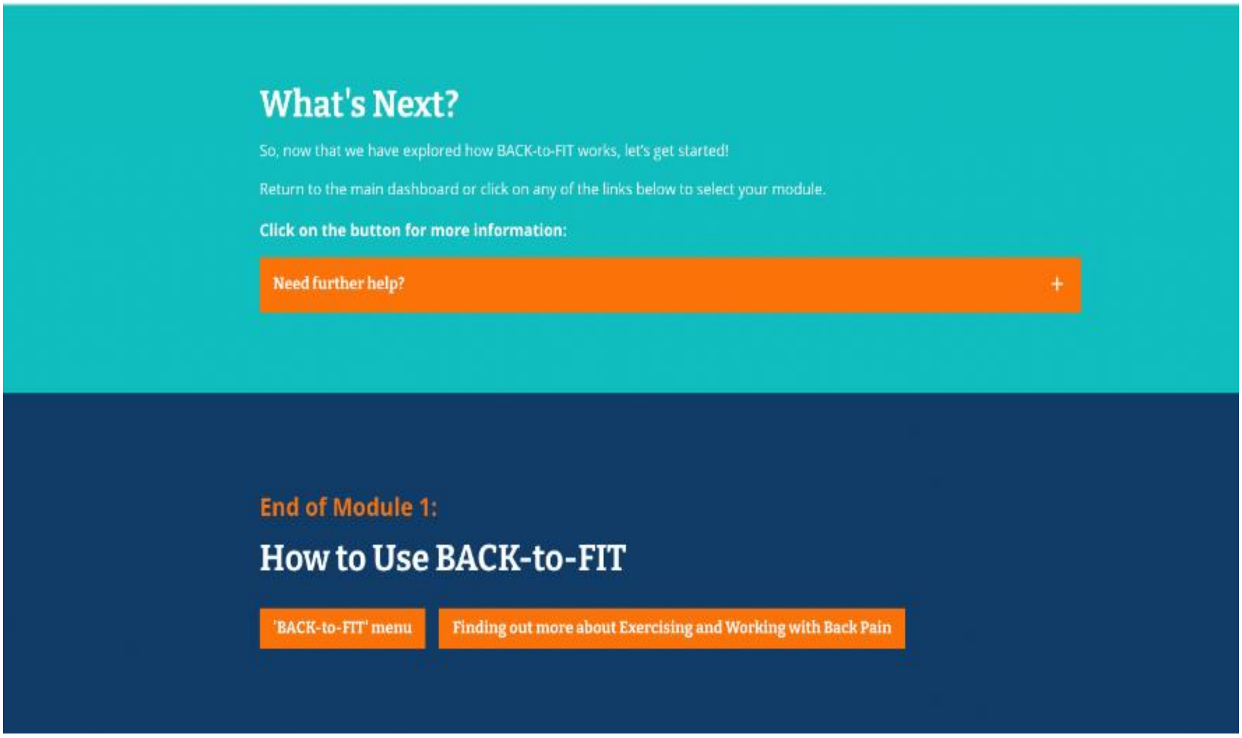
The next step is for the users to submit their preference by clicking on one of the following statements:

1. "**I would like to know more before I start the exercise programme"** if this statement is selected the users are directed to "Back pain, PA and work" module which covers a broad spectrum of general pain-related and back pain-specific education.
2. **"I am worried about my back pain, but I would like to start getting more physically active and exercise".** If this option is selected, users are directed to the "Worried Back" module, where they will find a series of low-intensity exercises.
3. The final option is **"I am not worried about my back pain and would like to start getting physically active and exercising" is given.** If this is submitted,

the user is directed to the "Active Back" module which consists of the exercise of moderate intensity.

Further advice on how to contact the author is also provided (Figure 7.4).

Figure 7.4: A screenshot of the last three sections of the module 1 page, information on further help, tabs on BACK-to-FIT^{TM} home page and to the next module.



7.5.2 Module 2 - Finding out more about exercising and working with back pain

Module 2 is the LBP education module. The module content was planned and delivered in line with the cognitive restructuring method. Cognitive restructuring, first developed by Beck (1979) is a common and essential technique often used in CBT for pain management (Turner and Jensen 1993). As the term suggests, this explicitly involves the modification of patient cognitions and in this case related to their pain. Individuals' pain-related cognitions and beliefs play a crucial role in their response and adjustments toward pain (Jensen et al. 1999). Numerous studies utilising correlational and regression analyses have consistently shown a strong relationship between maladaptive beliefs/cognitions and negative pain and disability outcomes (Gron et al. 2019). Similarly, beliefs, attitudes, fears and emotional responses are constantly encountered across all types of LBP presentations (O'Keeffe et al., 2019). A growing body of evidence confirms that negative beliefs and misconceptions are strongly associated with more severe LBP and disability (Gron et al., 2019).

In the health behaviour change process, cognitive restructuring usually involves individuals becoming more aware of their beliefs and thoughts, this helps them to actively change their internal dialogue (Foreyt and II 1998). The primary aim of cognitive restructuring is to acknowledge and change negative thoughts or misconceptions to reduce anxiety and promote reasoned practice (McCaffrey et al. 2005). The overall strategy of cognitive restructuring is to identify the misconceptions and biases in thoughts and beliefs and to guide the individual to change those misconceptions and biases so that they will have a better understanding of evidence and use it in practice. This is achieved using a variety of techniques, including identification of unhelpful cognitions/beliefs, defining and evaluating thoughts, gathering evidence for and against thoughts, developing balanced thinking using evaluation of evidence, developing adaptive thoughts and strategies and setting up behavioural experiments to test the beliefs (Leahy and Rego 2012). Numerous studies have proven that cognitive restructuring used alone or as a part of CBT successfully promotes healthy behaviour changes among individuals with chronic pain conditions, including LBP (Ehde and Jensen 2004; Rundell and Davenport 2010; Hall et al. 2018).Module information, that focused on myths about LBP and general background knowledge on LBP, was also delivered using cognitive restructuring strategies (Foreyt and II 1998). This included identifying thoughts, providing evidence for and against these thoughts/beliefs and helping to develop adaptive strategies to overcome the negative beliefs.

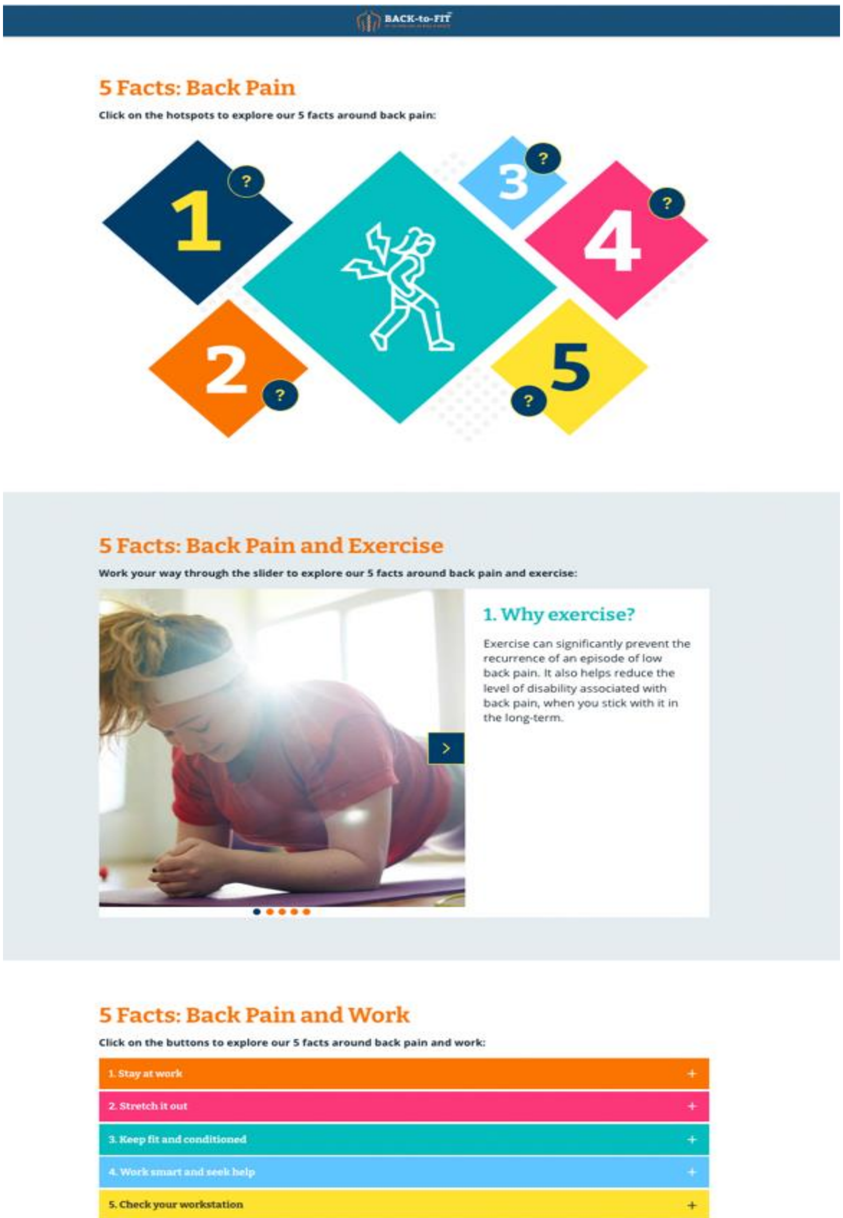
The module page begins with a self-test on individual's opinions about LBP (Figure 7.5). Upon submission of their answers users were given feedback, this pointed them to information addressing unhelpful beliefs (Nick’s selection) or alternatively offering encouragement (Joe’s selection). Following this task is the section containing information on LBP and exercising and working with LBP.

Figure 7.5: A screenshot of the first sections of module 2 showing [two scenarios](#).

After consideration of information suggested by the evidence from meta-analysis and systematic review and focus group findings with physiotherapists in phase 1 and 2 respectively, three interactive, informative sections were designed to provide users with up-to-date, evidence-based knowledge (Figure 7.6). These three sections were:

1. Five facts: Back pain
2. Five facts: Back pain and exercise
3. Five facts: Back pain and work

Figure 7.6: A screenshot showing the three interactive sections with information on LBP and exercising and working with LBP.



Five facts on LBP were based on sub-themes which emerged during focus groups with physiotherapists, these included the normalisation of the idea of LBP, reassurance, myth-busting, provision of updated knowledge, the importance of a positive attitude for a better prognosis, and advice on painkillers.

LBP and exercise facts were based on evidence from the phase 1 systematic review and meta-analysis and phase 2 focus group discussions with physiotherapists, both claimed that there were widespread misconceptions about exercise and PA engagement amongst individuals with LBP. It commented that patients with LBP often lacked understanding of how and when to engage in exercise and would limit their movement due to fear of re-injury or pain. In addition, based on other research, carefully selected and presented information and advice can affect patients' beliefs positively, particularly with regard to fear-avoidance beliefs about PA and exercise (Burton et al. 1999; Goubert et al. 2004). Five facts related to LBP and exercise are presented as separate interactive boxes informed by focus group discussions, these include concepts around reassurance, myth-busting, presenting updated information to raise awareness, hurt does not mean harm, safe zone to exercise or flare-up management, as well as how to begin exercising.

LBP and work information was based on phase 2 focus group discussions with physiotherapists, stressing the importance of providing reassurance and up-to-date knowledge on returning to work and prevention of LBP, associations with LBP were highlighted. Accordingly, the five facts included advice to staying in work when possible and obtaining necessary help at work, the importance of taking regular posture breaks to avoid unnecessary prolonged loads, being fit to meet the demands of the job, seeking help and use of equipment and workplace modifications.

7.5.3 Module 3 - Worried back

As proposed by the phase 2 focus groups with physiotherapists, both specific exercise and general exercise were used in the ‘Active back’ and ‘Worried back’ modules to offer users the opportunity to select exercise based on their preferences. In line with progression and regression of exercise highlighted during the focus group with physiotherapists, users were given the options to continue with easier exercise levels during any pain flare-up situations without termination of engagement with exercise/activity.

Four exercise programmes each with sixteen individual exercises all generally requiring low level of exercise capacity (Figure 7.7, Table 7.1) are included. Exercise programmes 1 and 2 are focused on improving mobility and level of fitness whereas level 3 and 4 are focused on getting the individual ready to start walking

Figure 7.7: A screenshot of the worried back module page

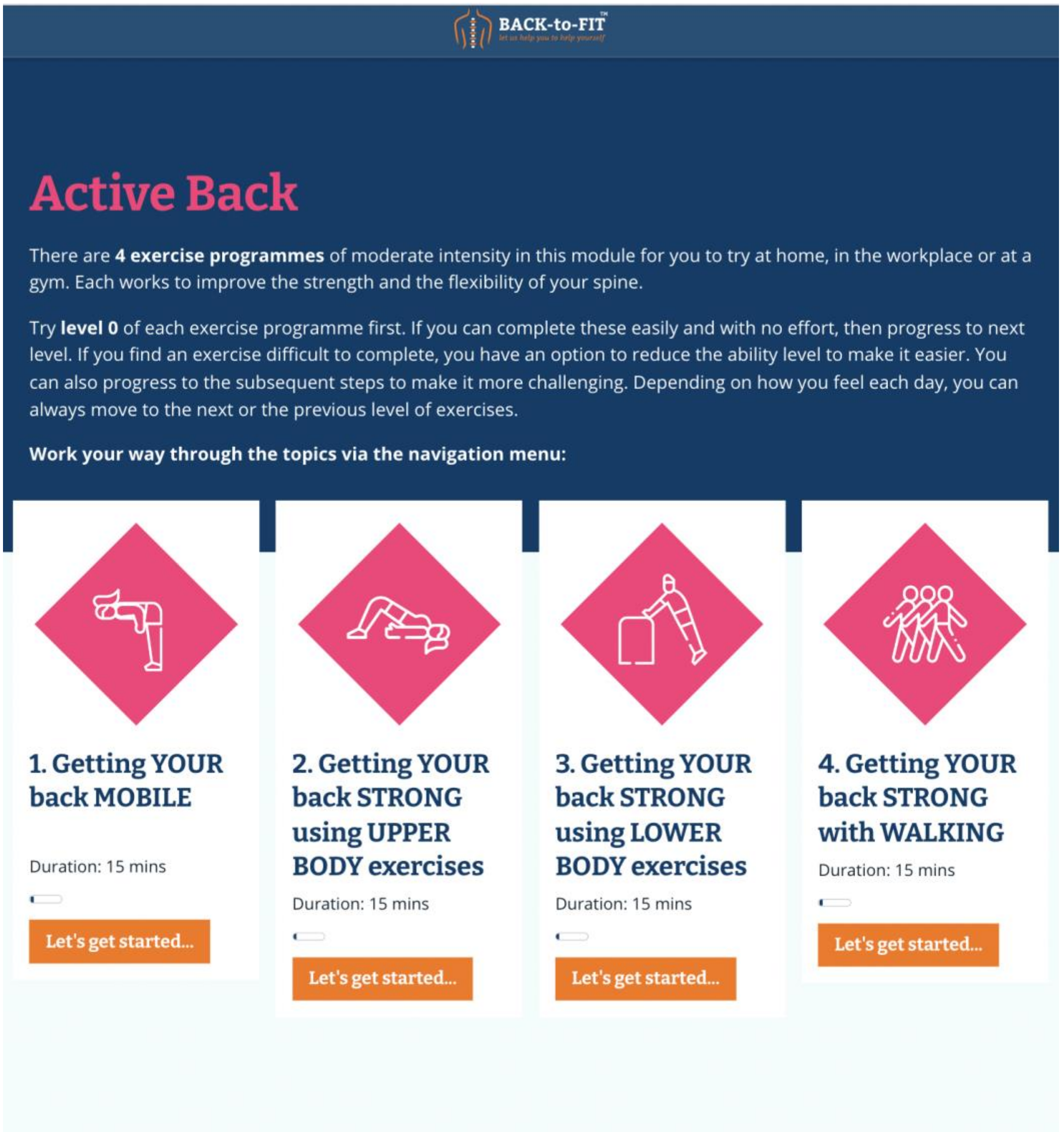
Table 7.1: Complete list of exercises included the 'Worried back' module.

Exercise programme 1. Getting back to fitness using a chair exercise	
Level	**Exercise name**
-2	Seated slump and sit up
-1	Sit to stand
0	Reaching down
1	Seated back rotations
2	Seated back side bends
Exercise programme 2. Getting back to fitness using a staircase exercise	
Level	**Exercise name**
-1	Step-ups
0	Step up and over
1	walking up and down a flight of stairs
Exercise programme 3. Getting ready to walk with a bad back	
Level	**Exercise name**
-2	Double heel raise (holding on)
-1	Single heel raise (holding on)
0	Step up and over
1	Wall Squat
2	Bodyweight squats
Exercise programme 4. Getting back into walking with a bad back	
Level	**Exercise name**
-1	Walking at your own pace
0	Walking with a friend
1	Walking with a backpack

7.5.4 Module 4 - Active back

The layout of the module was similar to the worried back module and the same principles were followed when determining the content of the module. The main aim of these exercises was to improve the level of fitness and restore the exercise capacity of the individuals who were less worried about their pain. Accordingly, this module contained four exercise programmes of moderate intensity that were more challenging than the ones in the worried back module. This module also contains four exercise programmes with 26 individual exercises between them. (Figure 7.8).

Figure 7.8: A screenshot of the active back module page.



Exercise programme 1 was focused on improving spinal mobility and programmes 2 and 3 aimed to improve strength and endurance using upper and lower body biased exercise respectively. Exercise programme 4 focused on enhancing back strength and endurance while walking. Similar to worried back module, each of these single exercises is arranged according to the level of difficulty ranging from -3 to +3. A collapsible text box with a step-by-step description of the exercise was given below each animation. The list of exercises at each level for each programme are given below in table 7.2.

Table 7.2: Complete list of exercises included within the four programmes of the active back module.

Exercise programme 1. How to improve your back mobility and range of movement	
Level	**Exercise name**
-3	Knee rolling
-2	Seated Back Rotations
-1	Seated forward bend
0	Standing forward & backward bend
1	Standing rotations
2	Standing side-bends
3	Backward bend in prone
Exercise programme 2. How to improve your back strength and endurance - upper body bias	
Level	**Exercise name**
-2	Biceps curls with weights
-1	Desk hold
0	Desk superman
1	Desk press
2	Bodyweight triceps curls
Exercise programme 3. How to improve your back strength and endurance – lower body bias	

Level	Exercise name
-3	Double leg bridge
-2	Mini squat
-1	Single leg bridge
0	Wall squat
1	Bodyweight squat
2	Lunge
3	Split squat
Exercise programme 4. How to improve your back strength and endurance with walking	
Level	**Exercise name**
-3	Double heel raise
-2	Single heel raise
-1	Step up and over
0	Wall Squat
1	Lunge
2	Bodyweight squats
3	Walking progression

7.6 Behaviour change in BACK-to-FIT™

Several key behaviour changes identified through the behavioural analysis conducted using the COM-B model described in chapter 3 (section 3.5.3.2) have been addressed within the content and features of BACK-to-FIT™. The physical capability of the users was ensured by screening them prior to using BACK-to-FIT™ to rule out clinical indicators of potentially serious pathologies and contraindications. The psychological capability was addressed by guiding the users to select the appropriate exercise for them with options to progress or regress exercises. This was addressed as poor cognition and beliefs are among the strong predictors of poor prognosis in LBP. The physical opportunity was also facilitated within this intervention as BACK-to-FIT™ offers the users timely and convenient access to exercise and PA resources as well as a range of options of exercises that can be performed in a setting of their choice or available, without restricting to one setting. It also provides users with an opportunity for reflective motivation as it offers them goals and feedback on progression and regression to keep a person with back pain motivated and enhances their ability to self-determine what exercise PA to take up. However, at this stage, BACK-to-FIT™ does not facilitate social opportunity and automatic reflection. However, it will be achievable trough potential further developments of BACK-to-FIT™ in future.

As discussed in the methodology section 3.3.3, BCTs act as the primary active ingredient of an intervention function. Therefore, a range of BCTs together with other intervention features drawn predominantly from the findings of Phase 2 were included across the four modules of BACK-to-FIT™. Subsequently, all four modules were mapped to Michie and colleagues' BCT taxonomy (Michie et al. 2013), in order to describe which BCTs were present. It is understood that there is limited capacity to integrate a large number of BCTs within the intervention at this prototype stage of the intervention. Altogether sixteen BCTs out of 93 individual BCTs identified by Michie et al.'s (2013) taxonomy has been incorporated into BACK-to-FIT™ intervention and mapping of these BCTs are outlined in Table 7.3.

Table 7.3: Behaviour change techniques mapping of BACK-to-FIT™

Behaviour change technique	Definition	Module / Section	Example within BACK-to-FIT™
Goals and planning			
1.1 Goal setting (behaviour)	Set or agree on a goal defined in terms of the behaviour to be achieved	Module 1	Users are asked about their preference of what to be achieved and select the option accordingly before proceeding to the relevant module.
1.2 Problem Solving	Analyse, or prompt the person to analyse, factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators (includes ‘Relapse Prevention’ and ‘Coping Planning’)	Module 2	Users are asked to appraise the scenarios of two individuals who have back pain and mark their agreement on their opinion on back pain. Users are then presented with the better option and explained why.
1.3 Goal setting (outcome)	Set or agree on a goal defined in terms of a positive outcome of wanted behaviour	Module 3 & 4	Users are given the option to select the appropriate exercise programme according to their expected outcome e.g.: strength, mobility, walking etc.
1.6 Discrepancy between current behaviour and goal	Draw attention to discrepancies between a person’s current behaviour (in terms of the form, frequency, duration, or	Module 2	Several unhelpful beliefs related to back pain, exercising with back pain and progressing are discussed while providing updated knowledge to address common myths around back pain.

	intensity of that behaviour) and the person's previously set outcome goals, behavioural goals or action plans		
Shaping knowledge			
4.1 Instruction on how to perform a behaviour	Advise or agree on how to perform the behaviour (includes 'Skills training')	Module 3 & 4	Users are given step by step instructions and video animations on how to perform the exercises safely and effectively. Users are also provided with the option to download the exercise plans as a summary document.
4.3 Re-attribution	Elicit perceived causes of behaviour and suggest alternative explanations (e.g. external or internal and stable or unstable)	Module 2	Discusses common misconceptions related to back pain illustrating that these beliefs are mistaken and providing alternative explanations and management advice.
Natural consequences			
5.1 Information about health consequences	Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour	Module 2	Information on how being active and exercising/ pain killers help recovery after an episode of back pain.

5.3 Information about social and Environmental Consequences	Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behaviour	Module 2	Information on how to manage back pain associated with work and possible work and workplace modifications.
5.6 Information about emotional consequences	Provide information (e.g. written, verbal, visual) about emotional consequences of performing the behaviour	Module 2	Information on the impact of positive thinking on the recovery and impact of exercise on good mental health.
Comparison of behaviour			
6.1 Demonstration of the behaviour	Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate (includes 'Modelling').	Module 3 & 4	Users are given step by step instructions and video animations on how to perform the exercises safely and effectively across 2 module containing 42 individual exercises. Users are also provided with the option to download the exercise plans as a summary document
Associations			
7.1 Prompts/cues	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of	Module 3 & 4	Written cues on how to perform the exercise correctly are displayed during all the exercises.

	performance		
Repetition and substitution			
8.2 Behaviour substitution	Prompt substitution of the unwanted behaviour with a wanted or neutral behaviour	Module 2, 3 & 4	Examples of how simple exercises could be performed during work and how walking can be adapted to an exercise.
8.1 Behavioural rehearsal/practice	Prompt rehearsal and repetition of the behaviour in the same context repeatedly so that the context elicits the behaviour	Downloadable PDF document	A document with the schedule of each exercise programme is provided.
8.7 Graded tasks	Set easy tasks, and increase difficulty until target behaviour is performed	Module 3 & 4	Layout of the exercise programmes in different levels to allow the user to progress or regress the exercises.
Regulation			
11.1 Pharmacological support	use of medication to support the wanted behaviour	Module 2	Explains the benefits of taking pain killers and continuing with exercising
Antecedents			
12.1 Restructuring the physical environment	Advice on ways of changing the physical environment to promote the wanted behaviour	Module 2	Information on possible workplace modifications to prevent and better self-manage back pain.

7.7 Chapter Summary

This chapter briefly described how the BACK-to-FIT™ intervention prototype was developed. It briefly discussed the key features of the intervention and the development process. Then it also described each module of the intervention. The development of the BACK-to-FIT™ intervention prototype enabled the author to gather early user feedback and evaluation of the usability and technology acceptance that follows in the next chapter.

Chapter 8: Usability, technology acceptance, potential health benefits and user experience of BACK-to-FIT™: A mixed methods study

8.1 Introduction

This chapter outlines the methods and results from the preliminary evaluation of usability, technology acceptance, potential health benefits and user experience of the BACK-to-FIT™ intervention and discusses the findings in the context of the current literature. Early-stage evaluation, using a mixture of qualitative and quantitative methods, to subsequently refine the interventions is recommended by MRC guidelines as part of the iterative process when developing new complex interventions (Skivington et al. 2021). This chapter corresponds to Part 2 of the "Modelling process and outcomes" stage (Craig et al. 2008b) in the model of action of the BACK-to-FIT™ intervention prototype (section 3.3.4), it includes the aim, research questions, methods, results of the usability and acceptability study followed by discussion.

8.2 Aims and research questions

This study's aim was to obtain preliminary evidence primarily of usability followed by technological acceptability, potential health benefits and overall user experience of the BACK-to-FIT™ intervention rather than to establish its effectiveness. Accordingly, primary and secondary research questions for this study were identified.

Primary research question

1. What is the usability of BACK-to-FIT™?"

Secondary research questions

1. What is the technological acceptability of BACK-to-FIT™?
2. What is the potential benefit, if any in terms of pain intensity, level of disability, exercise self-efficacy and level of PA?
3. What is the user experience of BACK-to-FIT™?

8.3 Methods

A mixed-methods approach was adopted for reasons which are justified in the methodology section (3.3). In short, usability, acceptance of technology and potential health benefits were evaluated using quantitative measures, whilst a qualitative approach was used to explore user experience and recommendations.

8.3.1 Study design

A single-arm pre-post interventional study was conducted. It is common practice to conduct single-arm pre-post studies at the early stages of an intervention development to obtain an overview of the intervention functions (Higgins et al. 2020; Sandal et al. 2020). Absence of a control group to compare the potential health benefits was a disadvantage. However, the focus at this stage of the study was to obtain preliminary data rather than testing for the efficacy of the intervention. Hence, adding a control group at this stage was not deemed necessary. Typically usability, technology acceptance, and any user feedback and recommendations are assessed while using, or immediately after use of the technology (Kushniruk and Patel 2004). Therefore, data to evaluate usability, technology acceptance and user feedback were collected immediately after using the intervention for a period of 4 weeks. Considering the progressive nature of the in-built exercise programmes, the period between the baseline and follow-up data collection was 4 weeks (Edwards et al. 1992; DeFreitas et al. 2011). A typical intervention period for exercise which aims to demonstrate an effect is 4-6 weeks (Geraghty et al. 2018; Rabbi et al. 2018; Yang et al. 2019; Nordstoga et al. 2020).

8.3.2 Participants

8.3.2.1 Inclusion criteria

Participants had to meet the following criteria to be eligible for inclusion in the study:

- Age over 18 years
- Self-reported LBP experienced within the last four weeks
- Absence of serious red flags clinical indicators
- Currently not receiving active medical/surgical treatments or physiotherapy for LBP.

- Have access to the internet and a computer/tablet or mobile phone
- Able to read and understand English

8.3.2.2 Exclusion criteria

Participants were not enrolled if:

- Under 18 years of age
- Currently pain-free/asymptomatic
- Clinical indicators of potentially serious spinal pathology or systemic illness [screened during the recruitment process using recommended by National Institute for Health and Care Excellence (NICE) guidelines (NICE 2020) to be clinical indicators of specific pathology including cauda equina syndrome, spinal fractures, cancer and Infection such as discitis, vertebral osteomyelitis, or spinal epidural abscess]
- Pregnancy, breastfeeding
- Involved in any other back pain research

8.3.2.3 Recruitment

An e-leaflet and an email invitation (Appendix 15) to participate in the study were advertised through Cardiff University staff and student email communications. Also, previous spine group study participants and Biomechanics and Bioengineering Research Centre Versus Arthritis database participants who had consented to be contacted for future research were contacted. Social media platforms, including Facebook and Twitter were also utilised, an e-leaflet containing a link with eligibility check, self-screening, study information, e-consent forms and the baseline questionnaire was circulated (Appendix 16). Eligibility checks and the self-screening procedure involving the screening for serious spinal pathologies or systemic illnesses (red flags) were conducted online via part of the baseline questionnaire and are fully described in appendix 14. Interested participants had the opportunity to contact the researcher via email or telephone to clarify any queries or discuss further.

8.3.2.4 Sampling

The sample was selected using convenience sampling, this allowed any volunteer with LBP who fulfilled the eligibility criteria to participate in the BACK-to-FIT^{TM} study. As a preliminary evaluation study, selecting a probability sample was not necessary; thus, a non-probability sampling technique was adopted. Convenience sampling was deemed more appropriate due to its emphasis on generalisability whilst other non-probability sampling techniques such as purposive and snow-balling focus more on saturation of data (Etikan et al. 2016). Eligible participants were selected on a first-come, first-served basis and recruitment and advertising were stopped after meeting the required sample size. This was set at twenty for the following reasons: Evidence indicates that 70% of severe usability problems can be uncovered within the first five users and up to 85% by eight users (Virzi 1992). The yield of identified problems tends to drop and is also less significant (Virzi 1992; Kushniruk and Patel 2004). In this study however, the additional aim was to gather feedback on the intervention for further refinement. Similar studies recruited samples of sixteen (Nordstoga et al. 2020) and fifteen (Higgins et al. 2020). Therefore, a sample of twenty was deemed sufficient with an anticipated dropout rate of 25%.

8.3.3 Data collection procedure

All data were collected online using a baseline and a post-intervention questionnaire hosted by Online surveys (Onlinesurveys 2019), a General Data Protection Regulation (GDPR) compliant cloud-based software (previously known as Bristol Online Survey [BOS]). Following informed consent and completing and submitting the baseline questionnaire, participants were emailed a web link to the BACK-to-FIT^{TM} intervention. Within 48 hours of receiving the above link, subjects were contacted again via telephone/email to ensure they were clear of any technical problems or access issues. Participants were advised to follow modules of their choice as per the given instructions within the website for a duration of 4 weeks. Usability and technology acceptance outcome measures were included in the post-intervention questionnaire in addition to the outcome measures that were already included in the baseline questionnaire. Semi-structured interviews were conducted within one week after the 4-week intervention period to explore user experience.

8.3.4 Outcome measures

8.3.4.1 Participant demographics

Participant demographics including age, gender and type of employment were assessed in the baseline questionnaire. Type of employment was assessed since the intervention had exercises included that were appropriate for individuals to perform from their work settings.

8.3.4.2 Primary Outcome measure

The primary outcome measure was self-reported usability of BACK-to-FIT™ collected using the SUS (Brooke 1986) as a part of the post-intervention questionnaire (Appendix 17). The SUS remains the most popular tool to assess the system usability in a variety of fields and since its release, the tool has been used widely to measure the usability of hardware, software, mobile devices, websites and applications (Bangor, Kortum and Miller, 2008; Lewis and Sauro, 2009; Peres, Phamand Phillips, 2013; Orfanou, Tselios and Katsanos, 2015). According to a recent systematic review SUS is the most commonly used scale for assessing the usability of mobile health applications (Azad-Khaneghah et al. 2021). Furthermore, Sousa and Lopez (2017) have also concluded that SUS has the highest quality out of the fifteen questionnaires evaluated in their systematic review. SUS is a Likert scale questionnaire which consists of ten items which are ranked on a 5-point Likert scale, from strongly disagree to strongly agree. Nine items measure usability, while one item also assesses the degree of learnability. To reduce the risk of bias thought to potentially arise from lack of attention whilst completing the scale (Brooke 2013), the SUS alternates between positive and negative statements; items 1,3,5,7 and 9 are associated with positive aspects, while items 2,4,6,8 and 10 concern negative aspects. Score calculation instructions are given in the appendix 18. The purpose of the SUS is to produce a single number that represents a composite measure of an intervention's degree of usability, each item should not be interpreted separately as they are meaningless in isolation (Brooke 1986). Research has consistently shown high reliability ($r \geq 0.90$) and validity ($r = 0.80$) for SUS (Bangor et al. 2008; Lewis et al. 2015a; Lewis et al. 2015b).

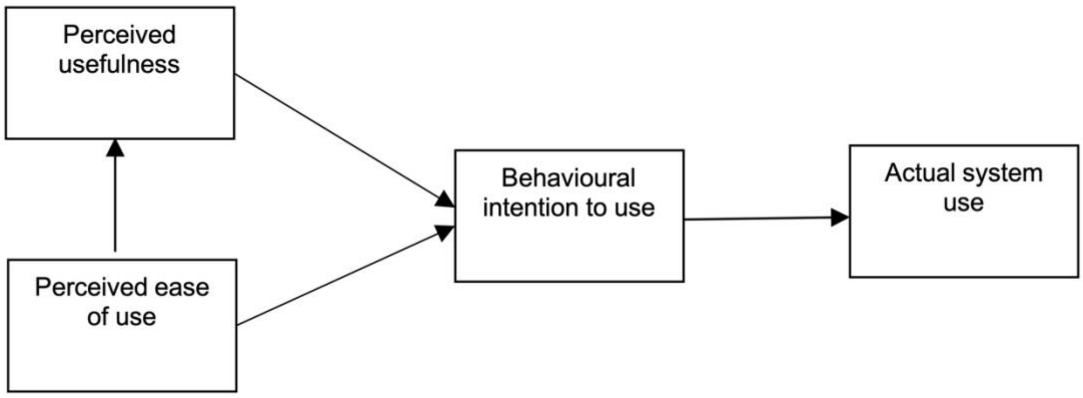
8.3.4.3 Secondary outcome measures

8.3.4.3.1 Technology acceptance

Participants' acceptance of using technology in BACK-to-FIT^{TM} was evaluated using Technology Acceptance Model (TAM), a questionnaire was completed by the participants following the 4-week intervention period. TAM is an extension of the Theory of Reasoned Action (Madden et al. 1992) that was originally proposed and developed by Davies et al (Davis 1989), to describe the intention to use software, corresponding to its acceptance. It provides a framework for evaluating how different factors may influence an individual's use and acceptance of specific forms of technology, previously used to evaluate acceptability of for example wearable activity trackers, social media or digital health information platforms (Rondan-Cataluña et al. 2015). TAM is considered to be the best model to help understand and predict users' behaviour and acceptance of the use of information technology (Legris et al. 2003), it has been applied in both quantitative and qualitative studies of health applications (Yarbrough and Smith 2007).

TAM model describes the relationship between two independent variables of perceived usefulness (PU), perceived ease of use (PEOU) and two dependent variables of behavioural intention (BI) to and subsequent actual usage (AU). In TAM, PU refers to the degree to which a user believes that using a particular technology would improve their job performance. It suggests that people will decide whether or not to use a technology based on their belief about the expected utility and the positive impact the technology will have on the task (Davis 1989). PEOU refers to how effortless a user perceives that using the technology will be. Davis (1989) argued that if technology is perceived to be easy to use, it is more likely to be accepted by the users. The figure 8.1 below conceptualizes the constructs in the original TAM model.

Figure 8:1 The original TAM (Reproduced from Davis, F. D. 1989. Perceived usefulness, perceived ease of use, and user acceptance of information technology. *MIS quarterly*, pp. 319-340.)

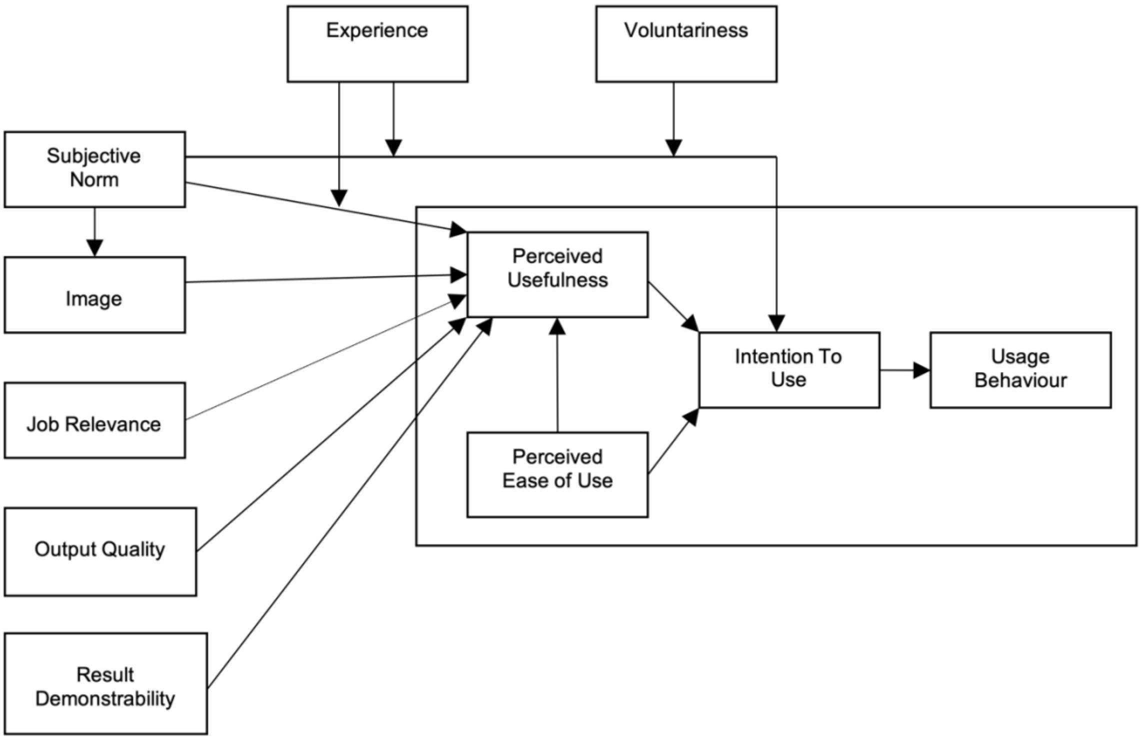


As a theory TAM has evolved over the years, there have been several subsequent versions of TAM involving Technology Acceptance Model 2 (TAM2) and Technology Acceptance Model 3 (TAM3). For the purpose of this study TAM3 model was adopted. TAM2 and TAM3 models are briefly described below.

Technology Acceptance Model 2

In 2000, TAM2 was introduced by Venkatesh and Davis (Venkatesh and Davis 2000), it presents an extended model of the original TAM which incorporates other theoretical constructs which determine the PU. These determinants include subjective norm (SN), image (IMG), job relevance (REL), output quality (OUT) and result demonstrability (RES). The SN construct is also an indicator of social influence and indicates the extent to which an individual perceives that other people who are important to them think they should or should not use the technology (Venkatesh and Davis 2000). The second determinant IMG has also been identified as an indicator of social influence. It refers to the extent to which an individual recognizes that the use of the technology will improve their position in the social system (Moore and Benbasat 1991). Job Relevance is to what extent the user believes that the technology applies to his or her job or the given task (Venkatesh and Davis, 2000). Output Quality refers to whether people believe that the system is doing its job well (Venkatesh and Davis, 2000). According to Moore and Benbasat (1991) RES explains that the degree of user belief in the results of using a system is tangible, observable, and communicable. The authors also introduced two moderators' experience and voluntariness. Figure 8.2 illustrates the constructs in the TAM2 model.

Figure 8.2: The TAM 2 (Reproduced from Venkatesh, V. and Davis, F.D., 2000. A theoretical extension of the technology acceptance model: Four longitudinal field studies. Management science, 46(2), pp.186-204)



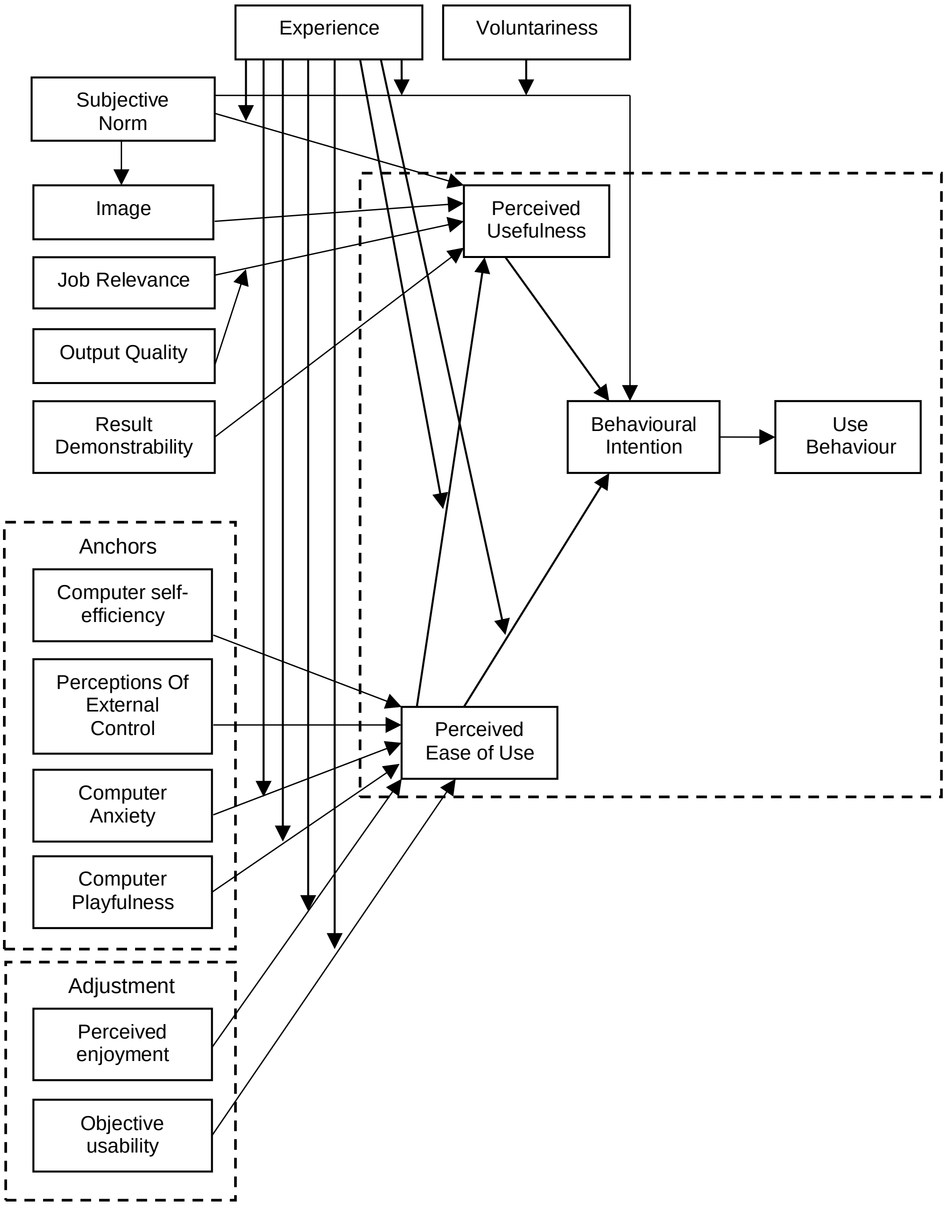
Technology Acceptance Model 3

In 2000, Venkatesh (Venkatesh 2000) introduced the determinants of PEOU, and later Venkatash and Bala (2008) combined the above determinants with the TAM2 model to develop Technology Acceptance Model 3 (TAM 3). The determinants proposed by Venkatesh to influence the PEOU included several anchors involving computer self-efficacy (CSE), perceptions of external control (PEC), computer anxiety (CANX), and computer playfulness (CPLAY). Venkatesh proposed that end-users should form their perception on the PEOU about the system by anchoring their perceptions to the above beliefs. One of the four anchors to PEOU, suggested by Venkatesh (2000) is CSE which refers to users' beliefs about their personal ability to use technology. The second anchor, PEC, indicates the users' beliefs on the availability of resources and support to facilitate the use of the technology (Venkatesh 2000). The third anchor is CANX and refers to the degree of an individuals' apprehension or fear when faced with the possibility of using technology. According to Webster and Martocchio (1992), the final anchor CPLAY denotes the extent of cognitive spontaneity in microcomputer interactions.

Additionally two adjustment factors which influence the PEOU were identified, these include objective usability and enjoyment (ENJ). In TAM 3, the determinants of PEOU did not influence the determinants of PU, and vice versa. Furthermore, according to TAM3 a user’s experiences moderate the relationships between (i) PEOU and PU; (ii) computer anxiety and PEOU; and (iii) PEOU and BI. The original TAM 3 is shown in Figure 8.3. The original TAM3 has been validated with the questionnaire involving 50 validated measurement items across fourteen constructs *(Venkatesh and Bala 2008)*. Out of fourteen, eight constructs including PEOU, PU, CSE, PEC, CANX, CPLAY, SN and RES have included four items in each construct, while ENJ, VOL, IMG, REL, OUT and BI have had three items in each.

There is extensive research on applying all iterations of TAM in an array of technologies used in health care, especially in relation to the adoption of electronic medical record systems and DHIs (Holden and Karsh 2010; Rahimi et al. 2018; Klaic and Galea 2020). However, there is poor evidence to support the use of TAM and its extensions within digital interventions focusing on self-management. Despite the growing evidence-base using TAM to predict technology acceptance of novel interventions, none of the published studies used it as a model. As discussed in Chapter 2, some of the studies discussed technology acceptance as a theory that has been evaluated using qualitative approaches (Lunney et al. 2016; Jansen-Kosterink et al. 2019). Furthermore, most of the studies using TAM and its extensions are focused on identifying predictors of usability and acceptance of technologies or interventions using factor analysis.

Figure 8.3: The TAM3 (Reproduced from Venkatesh, V. and Bala, H., 2008. Technology acceptance model 3 and a research agenda on interventions. *Decision sciences*, *39*(2), pp.273-315)



As TAM3 explores a wider range of constructs compared to original TAM or TAM2, it was deemed appropriate to consider TAM3 to select the most relevant constructs applicable to this intervention. Also, to ensure validity, this study adopted the original TAM3 questionnaire to explore technology acceptance using only sixteen measurement items across eight constructs. Similar to the original TAM3 questionnaire (Venkatesh and Bala 2008) all items were answered through a 7-point

Likert scale with responses ranging from 1-7 representing 1=Strongly disagree, 2=Moderately disagree, 3=Somewhat disagree, 4=Neutral , 5=Somewhat agree, 6=Moderately agree and 7=Strongly agree. The 7-point Likert scale is also the most recommended (Oppenheim 1992; Bowling 2002) method of attitude scaling for assessing participants' attitudes to a specified subject. A 7-point Likert scale guarantees a higher sensitivity of the scale items by providing more options to the users. A higher score represents a higher positive attitude towards the item and the construct being measured. Table 8.1 presents the measurement items and their relevant constructs used in this study. The 7-point Likert scale and the list of TAM3 items included in the post-intervention questionnaire is attached as appendix 19.

Table 8.1: TAM3 measurement items used in this study

Construct		Statements used in the study
Perceived Usefulness (PU)	PU1	Using BACK-to-FIT improves my exercise and PA engagement
	PU2	Using BACK-to-FIT increases my awareness of exercise and PA in back pain
	PU3	Using BACK-to-FIT enhances the effectiveness of my back pain self-management
	PU4	I believe that BACK-to-FIT is useful in helping me to be physically active and exercise to better self-manage my low back pain.
Perceived Ease of Use (PEOU)	PEOU1	I find that interacting with BACK-to-FIT does not require a lot of mental effort
	PEOU2	I find the BACK-to-FIT easy to use
	PEOU3	I am comfortable with interaction and navigation of BACK-to-FIT
Computer Self-efficacy (CSE)	CSE1	I am confident in using BACK-to-FIT without any further manuals or instructions
Perceptions of External Control (PEC)	PEC1	I have control over using the platform.
Computer Anxiety (CANX)	CANX1	I am comfortable using computer devices and internet

Perceived Enjoyment (ENJ)	ENJ1	I enjoy using digital devices and applications to help my exercise and physical activity engagement
	ENJ2	The actual process of using BACK-to-FIT is pleasant
Subjective Norm (SN)	SN1	People who influence my behaviour think that I should use BACK-to-FIT
	SN2	People who are important to me think that I should use BACK-to-FIT
Behavioural Intention (BI)	BI1	I intend to use BACK-to-FIT to self-manage my back pain
	BI2	I plan to use BACK-to-FIT in the next few months

8.3.3.3.2 Potential health benefits

Assessment of potential health benefits was assessed using a battery of validated LBP-related outcome measures at baseline and post-intervention on pain intensity: Numerical pain rating scale (NPRS) (Price et al. 1994; Childs et al. 2005; Kahl and Cleland 2005), level of disability: Oswestry disability index V2.0 (ODI V2) (Beurskens et al. 1996), exercise self-efficacy: Self-Efficacy for Exercise (SEE) Scale (Resnick and Jenkins 2000) and PA levels: International Physical Activity Questionnaire Short Form (IPAQ-SF) (Craig et al. 2003).

The NPRS is a scale of 11-points from 0 (no pain) to (10) maximum pain (Price et al. 1994; Childs et al. 2005; Kahl and Cleland 2005) used to determine pain intensity as reported by participants. The literature evidenced the numeric pain scale of 11-points as a simple reliable, self-reporting and subjective tool to quantify pain intensity/severity across patients with chronic pain (Labus et al., 2003, Gramling and Elliott, 1992). Overall there are three widely used unidirectional scales to report pain severity or intensity: visual analogue scales (VAS), NPRS and verbal rating scales (VRS). Visual analogue scale is a measure consisting of a 10-centimetre line where the scale begins with no pain (score 0) and ends with the worst possible pain (score 100). A higher score indicates a greater pain intensity (McCormack et al., 1988). However, literature has shown that VAS measures demonstrated more missing and incomplete data and are less preferred by patients (Dworkin et al., 2005). The NPRS has been the preferred choice in most research studies due to its ability to be administered both verbally and in writing (Hawker et al. 2011) and due to its greater sensitivity to change (Jensen et al. 1986). NPRS and VAS are the most widely used pain outcome measures in LBP (Chapman et al. 2011) while NPRS demonstrates moderate to high test-retest reliability varying from 0.67 to 0.96 and convergent validity of 0.79 to 0.95 correlated to VAS (Good et al. 2001; Finch 2002).

ODI V2 was used in this study to measure the level of functional disability associated with LBP. The original version of ODI invented in 1980 by Fairbank et al. (1980) has seen multiple modifications including substitution of a statement relating to the usage of pain medication with a question dealing with pain intensity (Beurskens, De Vet et al. 1996) and a statement on sex life was changed to one concerning altering pain patterns (Beurskens, De Vet et al. 1996, Resnik and Hart 2003). Although a 3rd version has been introduced by a chiropractic study group in the UK (Hudson-Cook 1989), it has been criticised by the developers of the original ODI for confusing impairment with disability, having complex wording, and not allowing for the absence of symptoms (Fairbank and Pynsent 2000) . Versions 1 and 2 of the ODI have shown excellent test-retest reliability tested extensively across a variety of study settings and samples with reported high correlation coefficients (r=0.99 reported by Fairbank et al. (1980), r=0.83 reported by Baker, Pynsent et al. (1989), and ICC=0.94 reported by Kopec, Esdaile et al. (1995). The ODI V2 comprises ten sections of questions dealing with activities of daily living and pain. Each section has six statements, which describe the level of pain severity experienced during a particular activity and are scored from 0 to 5 where no difficulty = 0 and maximum difficulty = 5.

Since the main purpose of BACK-to-FIT™ was to help people to improve their level of PA, determining any potential change in users' PA levels was warranted. International IPAQ was selected as the outcome measure to compare baseline and post intervention levels of PA, it has received high recognition as a self-reported instrument developed and used internationally and, in any population (Craig et al., 2003). It was developed as a result of an international expert consensus study, producing a self-report PA questionnaire suitable to be used in different clinical and non-clinical populations across the world (Booth et al., 2003). A short version of IPAQ (IPAQ -SF) is also available. Both forms can be either self-administered or telephone administered (Craig et al., 2003). The reliability and validity of both IPAQ and IPAQ-SF have been tested extensively across twelve different countries. Reliability scores of IPAQ-SF are reported to be between 0.61 and 0.83 (Craig et al., 2003), thus indicating acceptability to use in many settings in different languages. IPAQ is split into five separate sections of PA, including: job-related PA, PA for transport, housework activities, leisure time sports, and time spent sitting (Craig et al., 2003). The IPAQ -SF contains four sections: two on vigorous and moderate PA, one on walking and one on time spent sitting within the last seven days (Booth et al., 2003). As this was only a part of the full online questionnaire completed by the participants prior to and after using the intervention, the IPAQ -SF was selected to ensure a short questionnaire completion time.

Improved self-efficacy is associated with better functional and pain outcomes in people with LBP in long-term management (Altmaier et al. 1993). Therefore, it was appropriate to measure participants' level of exercise self-efficacy before and after using the intervention. The self-efficacy for exercise (SEE) (Resnick and Jenkins 2000) scale is a 9-item questionnaire that evaluates self-efficacy expectations for exercise for older adults, specifically, the ability to continue to exercise despite barriers. The participant is asked about their confidence level, on a scale from 0 (not confident) to 10 (very confident), if they would exercise three times per week for 20 minutes during each of the nine situations. The SEE scale has shown sufficient construct validity, criterion validity and reliability, while it also significantly predicts exercise activity (Resnick et al. 2004).

8.3.4.3.2 User experience

User experience of BACK-to-FIT™ was explored to assess the ease with which the intervention could be implemented, gather feedback on what did and did not work when using the intervention and suggestions improvement. Interviews were used because they have been shown to be more effective at generating a broad range of items (Guest et al. 2017) and are appropriate for exploring an individual's experience compared with focus groups (Gill et al. 2008). Participants were contacted by email and telephone to arrange the interviews, this was done at the end of the 4-week intervention period. COVID-19 pandemic related restrictions prevented conducting face-to-face interviews and interviews were conducted online using Zoom.us 5.0 (San Jose, CA: Zoom Video Communications Inc) with Cardiff University log in facility. During and after the unforeseen circumstances caused by COVID-19 pandemic, teleconferencing platforms like Zoom - as an alternative method to face-to-face data collection have become an increasingly utilised and successful practice among qualitative researchers (Boland et al. 2021). In their study Archibald et al. (2019) confirm that participants found Zoom to be highly satisfactory and higher rated when compared with alternative video-conferencing methods including face-to-face and telephone interviews. Using Zoom technology as a method of data collection has several advantages including time and cost effectiveness, ability to share files and documents, ability to maintain a good rapport with the researcher and among participants and the ability to securely record and store sessions without recourse to third-party software (Archibald et al. 2019). However, at the same time there are some disadvantages to using technology such as Zoom, it involves technical and access difficulties and challenges associated with privacy and confidentiality (Boland et al. 2021). Therefore, measures were taken to ensure confidentiality during the interviews and whilst storing interview data. Prior to the interview each participant was sent a meeting ID and a password to join the meeting. Participants were held in a virtual waiting room until the meeting started. Individual interviews were audio and video recorded using Zoom technology, and notes were taken during the interview. Recordings of each interview were saved to a password-protected computer and stored in encrypted folders so that only the author had access.

The interview topic guide (Appendix 20) was developed utilising normalization process theory (NPT) (May and Finch 2009) as previously described in the methodology section (section 3.5.4.1).This encouraged consideration of a range of questions that would not have been possible otherwise. For example, using the NPT ensured that relevant exploratory questions were asked about how the intervention could work in practice, who could potentially use it, and could its use be sustained in the long term. NPT provides a theoretical framework to review the feasibility of implementing the Intervention with or without further improvement or, if necessary, simply accepting the lack of intervention implementability. Over recent years NPT has been popular in healthcare intervention research as an implementation theory to understand the implementation and integration of complex interventions (Farr et al. 2018; Gillespie et al. 2018). The topic guide is in full in appendix 20 and summarized in Table 8.2. In accordance with the NPT constructs, additional questions were asked to obtain user feedback on potential further improvements to the intervention.

Table 8.2: Summary of how NPT informed focus group topic guide

NPT Construct	Construct explanation	Interview guide
Coherence	Meaning of the Intervention and making sense by users	Explore the response to the information and content presented, gain an understanding of the role of
Cognitive participation	Commitment and engagement of users	Discover users' views of an online LBP self-management website, including barriers and facilitators to utilization
Collective action	The work users do to make the intervention function	Investigate how people currently using BACK-to-FIT^{TM} to manage their back pain and exercise
Reflexive monitoring	Users' reflection or appraisal of the Intervention	Discover what participants did/did not like about BACK-to-FIT^{TM} and provide evidence that the Intervention is helpful (reflexive monitoring)

8.3.5 Pilot study

All the questionnaires used in the study to measure both primary and secondary outcomes were pre-existing questionnaires. However, the online questionnaires were piloted by six volunteers (3 for baseline and 3 for post-intervention) to ensure the format clarity and readability, and wording of instructions to monitor any potential intervention defects or malfunctions. In addition, responsiveness and data quality decline was demonstrated if a survey took longer than fifteen to twenty minutes

(Parsons 2007). The volunteers were therefore also asked how long it took to complete the questionnaires. Research shows that responsiveness and data quality decline for surveys that take longer than fifteen to twenty minutes to complete (Parsons 2007).

According to the feedback of participants of the pilot study, the questions were easy to understand, had high readability, were not complicated and took a maximum of 10 minutes to complete. However, several malfunctions within and between pages were identified by the participants, particularly in response numbers of the outcome measures. All these were rectified before the questionnaire was distributed among actual study participants. The topic guide for the interviews was also piloted with two individuals (1 male and 1 female of age 29 and 53) to identify any difficulty in understanding the terms used and to recognise any issues with the flow of the questions. Although they did not complete any of the exercise programmes, these two individuals had the opportunity to go through the whole BACK-to-FIT™ intervention prototype before piloting the topic guides.

8.3.6 Ethical considerations

Ethical approval for this study was granted from Cardiff University, The School of Healthcare Sciences Research Ethics Committee on 18/09/2020, SREC reference: REC745 (Appendix 21).

8.3.6.1 Informed consent

After the online eligibility check and the self-screening, potential participants were directed to PIS, which was held on the Online surveys (Onlinesurveys 2019) platform. The information sheets followed a pattern of a paper-based information sheet and covered the identity of the researchers, contact details, rationale for the project, the voluntary nature of participation, planned use of the data, the process of data collection and respondents' right to withdraw before, during and after the research process. As mentioned above in the "recruitment" section, participants had the option to consent for the study immediately after reading the PIS, had an opportunity to discuss any queries with the investigator or declined the invitation to participate in the study.

Consent was obtained using e-consent and was available when the potential participant scrolled down to the last page of the PIS and clicked "I've read the information sheet, and I want to participate in the study" option. E-consent was hosted by the Online surveys (Onlinesurveys 2019) platform, this presented the details and the items in a similar way to the paper-based consent form. Endorsement of all the items in the consent form was required. At the end, they signified their consent by inputting their full name, email address, date of birth and date and then clicking on the 'submit' button and print/download the PIS and e-consent. Informed e-Consent was obtained to participate in all stages of the study including baseline and post quantitative data collection and interviews.

8.3.6.2 Right to withdrawal

Participants were informed in PIS (Appendix 22) they can exit at any stage during the study without a penalty. Further, all participants were informed they had the right to withdraw their consent at any time against the data being collected, processed or stored. As had been explained in the PIS, any data gathered up to the point of the withdrawal are used in the study.

8.3.6.3 Compliance with data sharing and confidentiality regulations

Baseline and post-intervention questionnaires and online interviews included the collection and processing of personal data, including names and email addresses. Access to participants' data and survey responses was restricted to an authorized person only (AR). Additionally, SSL encrypted connection and a server was used. According to the GDPR rules, details involving; information of the researchers handling data, the purposes for which the data are intended to be processed, intended recipients with whom the anonymised data will be shared in the future, the period in which the data will be stored and participants’ rights under the GDPR to access their data were explained to all participants in the PIS.

Data processing was in compliance with the data protection principles of the GDPR, and a fair, lawful and transparent handling of the data was ensured. Following data collection, all data was anonymised by assigning a subject code and all data were identified and stored under that code. The document holding both the code and participants names was held separately from the anonymous dataset.

8.3.6.4 Anonymity

Personal information, including respondents' names, IP) addresses, email addresses and telephone numbers of the participants, were not shared outside under any circumstances. All participants were given a unique participation number, these were used when transcribing data and onwards.

8.3.6.5 Confidentiality, storage and management of data

An SSL encrypted internet connection was used during all data collection, an online survey format was used to ensure the cybersecurity of the collected data and the personal details. Interviews were held online using Zoom technology. Each participant was sent a unique passcode to access the zoom link and the online zoom room locked for the 20 – 30 minutes duration of the interview. Video recording via zoom was stored securely on a university computer. The video file was password protected and accessible only to the researcher. Only the author had access to audio and video files, the online survey account and responses, and confidential personal information and data were securely stored in password-protected personal computers. Collected information was not shared in a way that would allow individuals to be identified or by a third party. All collected data except personal data will be retained for up to 15 years. Arrangements will be put in place for secure disposal or destruction of data after this period.

8.3.7 Risk assessment

Whilst it was not envisaged that this study would present any significant risks, the following issues were considered:

- The self-screening questionnaire at the start of BACK-to-FIT™ may indicate a more serious condition, and if this is the case participants were advised to seek medical advice. Also they could contact the research team anytime if they have any questions about the study.
- The study holds sensitive information relating to participants' health. All data including online interview and survey data were anonymised, fully encrypted,

stored and back up on a secure web-based server operated from Cardiff University. Participants were informed of personal data policy and provided informed consent.

- If participants had not been active for a while, there was a minimum risk of a flare up in their low back pain symptoms during the 4-week exercise programme of the intervention. However, necessary advice and guidance to manage symptoms in case of an LBP flare up were given in module 1 and 2 of the BACK-to-FIT^{TM}.

8.3.8 Data processing and analysis

8.3.8.1 Participant characteristics

Descriptive statistics were reported to describe the characteristics of the study sample. Before processing the data, BMI was calculated using the height and weight values provided by the participants. Reported descriptive statistics included, mean values and standard deviations for age and BMI and categorical values for gender (male and female) and job type (desk job, manual job and a mix of desk and manual jobs).

8.3.8.2 Usability

SUS scores were processed and calculated using individual item scores as per instructions by Brooke (1986). Interpretation of the score for this study was as per the thresholds proposed and validated by Bangor et al (2009). Table 8.3 details Bangor's (2009) interpretation with scores less than 25 indicating worst imaginable usability and scores above 92 assuming best imaginable usability. Furthermore according to another interpretation by Sauro (2011), 68 is considered as an average SUS score for an intervention.

Table 8.3: SUS Adjective rating scales

SUS Score	Adjective Ratings
Best imaginable	92
Excellent	85
Good	72
OK/ fair	52
Poor	38
Worst imaginable	25

8.3.8.3 Technology Acceptance

Although most studies used TAM as a method of factor analysis to predict acceptance of interventions, this was not the expectation of this study. Thus, a descriptive analysis of acceptance of technology in BACK-to-FIT™ intervention prototype was performed employing the TAM3 model. Each score given by the participants for TAM items in the 7-point Likert scale (ranging from strongly disagree to strongly agree) was entered into IBM SPSS Statistics® version 27 (SPSS Inc., Chicago, Illinois). The maximum possible score for an individual item was 7 and a higher score represented a higher positive attitude towards the item being measured. Eight TAM constructs were covered in the questionnaire and out of these some constructs consisted of only one item while others consisted of multiple items. For the constructs with multiple items, the mean score of all the items was first calculated and then the average of those mean values was obtained (Kuyoro and Kasali 2015; Domingos et al. 2022). Furthermore, standard deviations of each of the mean values and the percentages of the participants marked on each scale position was calculated.

Despite the wide use of TAM, there are no published benchmarks for TAM overall scores or for individual constructs (Sauro 2019) and a higher score is considered to indicate higher acceptance.

8.3.8.4 Potential health benefits

The 11-point NPRS gives continuous scale data as a score out of 10 and has the anchors 0 = no pain and 10 = extreme pain/worst possible pain. NPRS scores were averaged using mean and SD values and interpreted as; no pain = 0, mild pain = 1-3, moderate pain = 4-6, severe pain = 7-10. Although the use of these categories to set targets for intervention outcomes has been accepted, the categories do not necessarily reflect patient meaning and are poor for any assessment of change (Price et al. 1994; Childs et al. 2005; Kahl and Cleland 2005).

To calculate the total score of ODI, each statement score was multiplied by 2 to obtain a score from 0 to 100. Average score was then calculated as mean, standard deviation, and range. Categories of the level of disability that have been imposed on these scores are as below (Fairbank et al. 1980).

- 0 to 20 : Minimal disability
- 21 to 40 : Moderate Disability
- 41 to 60 : Severe Disability
- 61 to 80 : Crippling back pain
- 81 to100 : Either bed-bound or have an exaggeration of their symptoms

The score for IPAQ-SF is given as a continuous score in the metabolic equivalent (MET) which is a measure of PA intensity per minute, per week (METS-1min-1week). This allows scores to be directly interpreted into the frequency, duration and intensity of PA over a week and be compared to recommendations for levels of PA (Ainsworth et al., 1993). The IPAQ-SF was used to calculate a total met/minute score for a week using formulae outlined in Ainsworth et al. (1993).

These formulae are as follows:

Walking MET - minutes/week = 3.3 * walking minutes * walking days

Moderate MET - minutes/week = 4.0 * moderate-intensity activity minutes * moderate days Vigorous MET - minutes/week = 8.0 * vigorous-intensity activity minutes * vigorous-intensity days

Total physical activity MET - minutes/week = sum of walking + Moderate + Vigorous MET minutes/week scores.

The SEE scale (Resnick and Jenkins 2000) has nine items and is scored from 0 – 10 for each item. Thus, the total score for the SEE scale is calculated by summing up the responses to each question and has a range of total scores from 0-to 90. Standard deviation and range values were calculated using the total score. A higher score indicates higher self-efficacy for exercise.

Given the small sample size it was considered appropriate to analyse all baseline and post intervention quantitative data using descriptive statistics only to identify any preliminary potential for health benefits. Therefore, mean values, percentages, standard deviations and ranges were calculated. Qualitative data from the interviews were analysed using inductive thematic analysis and is discussed below.

8.3.8.5 User experience

User experience was evaluated qualitatively using individual semi-structured interviews. Recordings from individual interviews were transcribed verbatim by the author. Data from the transcripts were first analysed using inductive thematic analysis described by Braun and Clarke (2006) and secondly NPT analysis was completed. Identifying or developing a theory or framework was not the primary focus of this study. Furthermore, this part of the evaluation study was informed by NPT and used as framework to analyse the final outcomes. To this end, thematic analysis deemed appropriate for the analysis of the data since it allows interpretation of data by means of description and categorisation without extending to the point of developing a theory, as in grounded theory (Glaser and Strauss 1967). Framework analysis was not employed due to NPT already being used as an analytic framework and did not indicate the necessity of a further iterative analysis process drawing from both themes and data (Ritchie et al. 1994). Content analysis was not suitable as the analysis warranted exploring themes representing different dimensions of user experience rather than building up on the frequencies of presented data (Patton 2014).

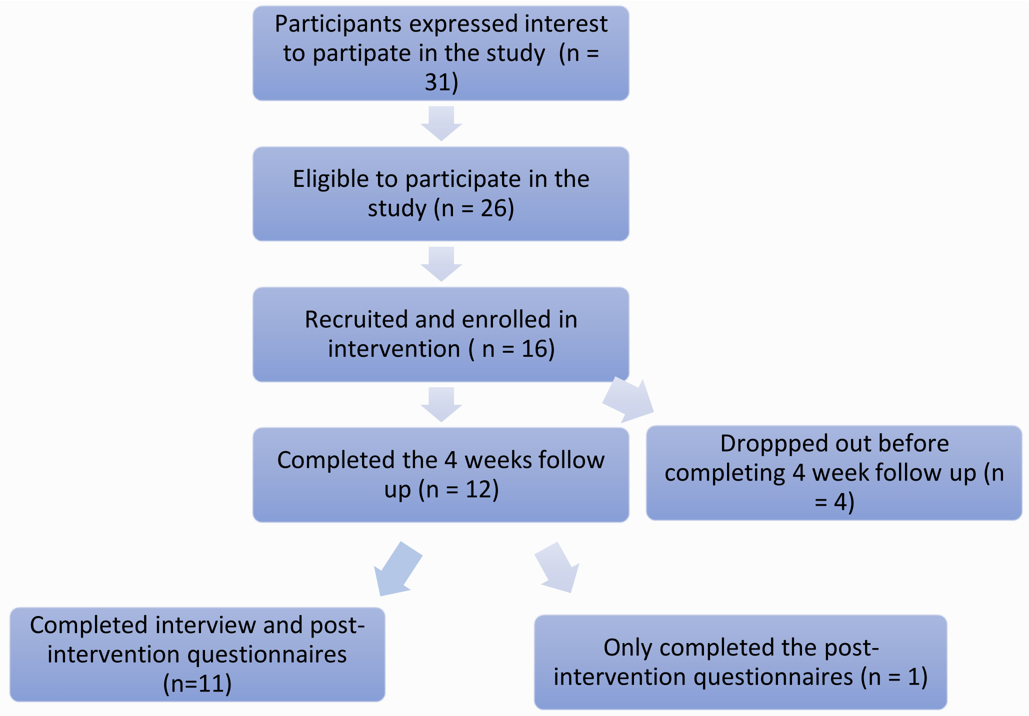
Although NPT was applied as the working analysis approach, limiting the analysis only to NPT constructs would have restricted the breadth of the identified viewpoints. Therefore, data were initially coded inductively to ensure data were not forced into predefined NPT constructs using deductive analysis (Gillespie et al. 2018). Subsequently, NPT analysis of the intervention was undertaken as outlined in Murray's framework paper (2010).

The six-step process of TA recommended by Braun and Clarke (2006) was followed when conducting the thematic analysis: 1) familiarisation with data 2) Initial code generation 3) identifying sub themes and themes 4) reviewing all themes 5) defining and naming of the themes 6) final analysis including the interpretation and write up. Both coding and interpretation was cross-checked. NVivo 12 software was used in the analysis.

8.4 Results

Thirty-one people from different geographical areas within the UK expressed their interest in participating in the study between the 14th of April and the 21st of May 2021. Out of that, twenty-six were eligible to participate in the study, and five people were automatically eliminated during the screening stage due to not meeting the criteria (i.e.: Answered "yes" to self-screening questions including red flags). Out of twenty-six, a sample of sixteen participants were recruited. Finally, eleven participants completed the 4-weeks follow up using BACK-to-FIT^{TM}, returned the post-intervention questionnaires and participated in interviews. One additional participant completed the 4-weeks follow up of using BACK-to-FIT^{TM} and returned the post-intervention questionnaires but was unable to participate in the interview. Four participants dropped out before completing the follow-up programme. The flow of participants is given in the figure 8.4.

Figure 8.4: BACK-to-FIT participants' flow chart



Descriptive data for the participant characteristics are presented in Table 8.4. The mean age of the subjects was 38.83 years and the sample included an equal number of males (n=6) and females (n=6). A majority of the sample had desk jobs while only one participant claimed a full-time manual job. All participants had LBP at the time of the study, and this was not the first episode. The duration since the first time they experienced LBP ranged from 3 months to 180 months.

Table 8.4: Descriptive data for participant characteristics

Characteristic		Mean/Number (%)	Range	Standard Deviation
Age		38.83	25 -50	2.59
Gender	Male	6 (50%)	n/a	n/a
	Female	6 (50%)	n/a	n/a
Type of job	Desk job	8 (66.70%)	n/a	n/a
	Manual job	1 (8.30%)	n/a	n/a
	The mix of desk and manual	3 (25.00%)	n/a	n/a
Body mass index (kg/m2)		26.38	18.35 -34.62	4.67

8.4.1 Usability

The mean usability score measured by SUS was 81.87 (SD 12.65, range 50.50 – 95.00). This is considered to be an above-average score and falls between good and excellent on SUS scale. Six users had total SUS scores $\geq$ 85. Reviewing individual measurement items identified the lowest score for item 4; needing assistance to be able to use the programme. The average item score for all items was 3.27. Table 8.5 summarises the mean scores, standard deviations and the ranges of the mean score of each item of the SUS and the total SUS score out of hundred.

Table 8.5: Mean scores, standard deviations and the ranges of individual measurement items of system usability score.

Measurement Item	Mean Score (Standard Deviation)	Range
1. I think that I would like to use the BACK-to-FIT platform frequently.	3.08 (0.83)	2 - 4
2. I found this programme unnecessarily complex.	3.32 (0.75)	2 - 4
3. I thought this programme was easy to use.	3.23 (1.11)	1 - 4
4. I think that I would need assistance to be able to use BACK-to-FIT	2.91 (1.05)	1 - 4
5. I found the various functions in this platform were well integrated.	3.33 (0.93)	2 - 4
6. I thought there was too much inconsistency in this programme.	3.25 (0.90)	2 - 4
7. I would imagine that most people would learn to use BACK-to-FIT platform very quickly.	3.25 (0.90)	2 - 4
8. I found this programme very awkward to use.	3.33 (1.02)	2 - 4
9. I felt very confident in using this platform.	3.50 (0.88)	3 - 4
10. I needed to learn a lot of things before I could get going with BACK-to-FIT programme.	3.41 (0.77)	2 - 4
Total	**32.75 (5.06)**	**19 - 38**
SUS score	**81.87 (12.65)**	**50.50 - 95.00**
To convert the scores to 0 -100 item mean score were summed, and then multiplied by 2.5 (Brooke 1996)		

8.4.2 Technology acceptance

Table 8.6 outlines the number of participants who agreed to each of the statements in the Likert scale of TAM3 questions, mean scores of each item and mean scores of each of the TAM3 constructs. Values in bold represent the construct mean values obtained by the average mean scores of multiple items or the single mean score for constructs with a single item. The highest possible score to achieve for each item of TAM3 constructs was 7. The mean value for the PU construct was 5.71 (SD =1.19), while PEOU construct had a mean of 6.06 (SD = 1.09). The CSE, PEC, CANX had only one item in each construct and mean scores were 5.9 (0.99), 6.0 (1.16) and 6.6 (SD = 0.51) respectively. Final construct mean scores for ENJ, SN and BI obtained were 5.58 (SD= 1.23), 5.04 (SD=1.05) and 5.67 (SD = 1.06), respectively.

Table 8.6: Mean scores, standard deviations and the ranges for technology acceptance measurement items

TAM Constructs and Measurement Items		Number of participants agreed to each of the statements in the Likert scale (%)							Measurement Item Mean	Standard Deviation
		SD	MD	SWD	N	SWA	MA	SA		
Perceived Usefulness (PU)	PU1	0 (0)	0 (0)	1 (8.3)	1 (8.3)	3 (25.0)	3 (25.0)	4 (33.3)	5.6	1.3
	PU2	0 (0)	0 (0)	1 (8.3)	2(16.6)	3 (25.0)	4(33.3)	2 (16.6)	5.3	1.2
	PU3	0 (0)	0 (0)	1 (8.3)	0 (0)	1 (8.3)	8 (66.6)	2 (16.6)	5.8	1.0
	PU4	0 (0)	0 (0)	1 (8.3)	0 (0)	2 (16.6)	4 (33.3)	5 (41.6)	6.0	1.2
	Construct mean								**5.7**	1.1
Perceived Ease of Use (PEOU)	PEOU1	0 (0)	0 (0)	1 (8.3)	0 (0)	0 (0)	9 (75.0)	2 (16.6)	5.9	0.9
	PEOU2	0 (0)	0 (0)	1 (8.3)	0 (0)	1 (8.3)	5 (41.6)	5 (41.6)	6.0	1.1
	PEOU3	0 (0)	0 (0)	1 (8.3)	0 (0)	0 (0)	6 (50.0)	5 (41.6)	6.2	1.1
	Construct mean								**6.0**	1.0
Computer Self-efficacy (CSE)	**CSE1**	0 (0)	0 (0)	2(16.6)	0 (0)	0 (0)	5 (41.6)	5(41.6)	**5.9**	1.4
Perceptions of External Control (PEC)	PEC1	0 (0)	0 (0)	1 (8.3)	0 (0)	0 (0)	7 (58.3)	4(33.3)	**6.0**	1.0
Computer Anxiety (CANX)	**CANX1**	0 (0)	0 (0)	0 (0)	0 (0)	5 (41.6)	7 (58.4)	0 (0)	**6.6**	0.5
Perceived Enjoyment (ENJ)	ENJ1	0 (0)	1(8.3)	0 (0)	4(33.3)	5 (41.6)	2 (16.6)	0 (0)	5.5	1.3
	ENJ2	0 (0)	0 (0)	1 (8.3)	4(33.3)	4 (33.3)	3 (25.0)	0 (0)	5.7	1.1
	Construct mean								**5.5**	1.2
Subjective Norm (SN)	SN1	0 (0)	0 (0)	0 (0)	5(41.6)	4 (33.3)	2 (16.6)	1 (8.3)	4.9	0.9
	SN2	0 (0)	0 (0)	0 (0)	4 (33.3)	4 (33.3)	2 (16.6)	2 (16.6)	5.1	1.1
	Construct mean								**5.0**	1.0
Behavioural Intention (BI)	BI1	0 (0)	0 (0)	1 (8.3)	1 (8.3)	2 (16.6)	6 (50.0)	2(16.6)	5.6	1.1
	BI2	0 (0)	0 (0)	0 (0)	2(16.6)	1(8.3)	7 (58.3)	2(16.6)	5.8	0.9
	Construct mean								**5.6**	1.0

Key: SD = strongly disagree **MD**= moderately disagree **SWD**= somewhat disagree **N**= neutral **SWA**= somewhat agree **MA**= moderately agree **SA** = strongly agree

The above table shows that participants in the study had a high impression of perceived usefulness of the BACK-to-FIT™. More than 75% participants agreed with all four items: PU1= 10/12, PU2=9/12, PU3=11/12, PU4=11/12 indicating the usefulness of BACK-to-FIT™ intervention in improving their exercise self-management.

The frequencies also indicate that respondents' perception of the ease of use of BACK-to-FIT™ is also very high, eleven participants (91%) had agreed with each of the three statements; PEOU1=11/12, PEOU2=11/12, PEOU3=11/12.

The results also indicate that participants in this study did not have computer anxiety from the use of BACK-to-FIT™ as all of them (100%) agreed with the statement. Eleven participants (91%) agreed having control of using BACK-to-FIT™ and ten participants (83%) agreed with the statement that they were confident about using the intervention.

The results also show that seven participants (58%) agreed with each statement indicating that they enjoyed using BACK-to-FIT™ (ENJ1) and digital interventions in self-managing their LBP (ENJ2).

Two TAM3 items measuring subjective norm had the lowest mean scores reported. However, seven participants (58%) agreed with each subjective norm items (SN1, SN2) indicating that people who are important to them thought they should use BACK-to-FIT™.

Ten participants (83%) agreed with each of the statements (BI1, BI2) and indicated a strong intention to use BACK-to-FIT™ in future (Table 8.6).

8.4.3 Potential health benefits

Table 8.5 illustrates the mean, standard deviation and range values for pain (NPRS), disability (ODI V2), exercise self-efficacy scale (SEE) and PA (IPAQ-SF) scores at the baseline and after a 4-week follow up period.

Table 8.7: Outcome measures for pain, disability, exercise self-efficacy and physical activity levels at the baseline and on completion of the 4-week intervention

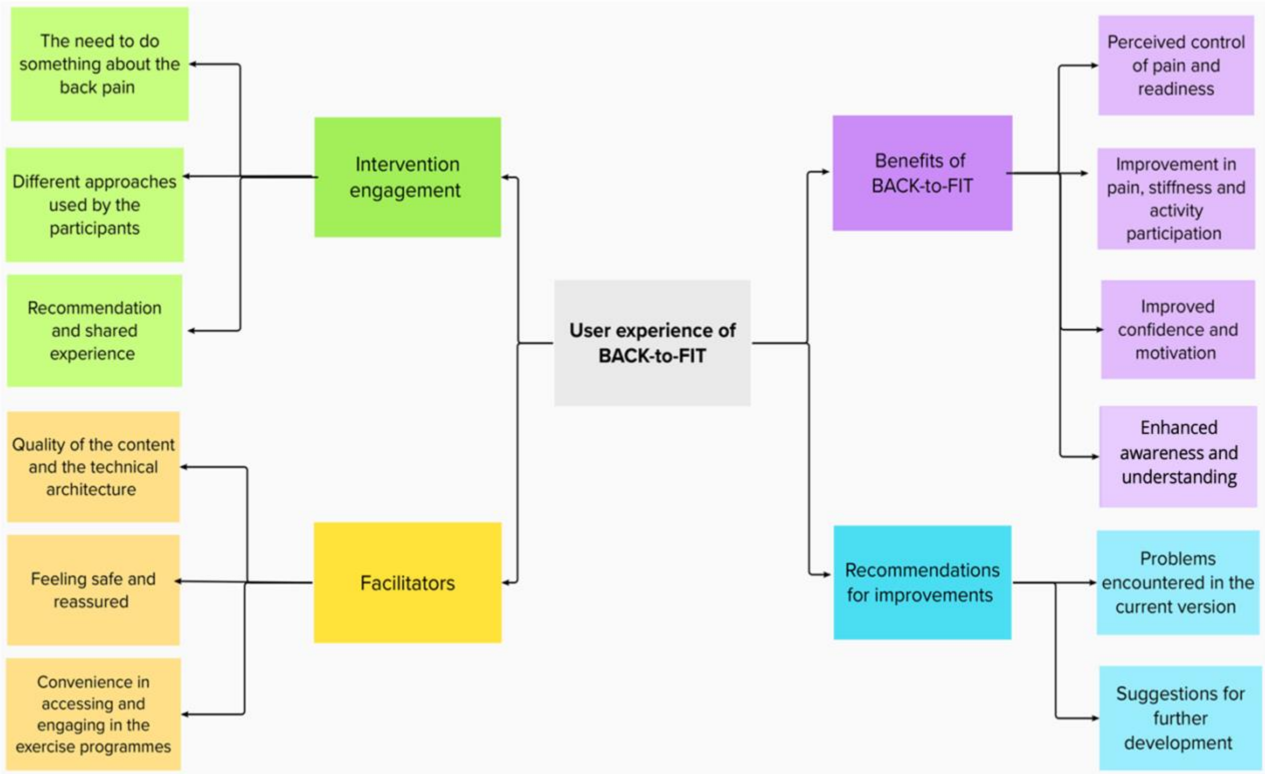
Outcome Measure	Baseline n=12			Follow Up (4 weeks) n=12		
	Mean	Standard Deviation	Range	Mean	Standard Deviation	Range
Pain intensity (NPRS)	4.16	1.85	2-8	2.27	1.69	0-4
Low back pain-related disability (ODI V2)	15.33	4.99	10 - 28	9.00	3.95	4 - 16
Self-Efficacy for exercise (SSE)	37.5	20.59	19 - 46	59.6	14.87	40 - 90
Physical activity level (IPAQ-SF) MET minutes/week						
- Vigorous	386	676	8 - 1440	753	990	0 – 2880
- Moderate	248	257	0 - 600	516	612	0 -1920
- Walking	820	437	296 – 1286	668	780	396 -2772
- Total	1455	992	495 - 2106	1938	408	773 – 5013

8.4.4 User experience

8.4.4.1 Thematic Analysis of interview data

Four overarching themes were developed through inductive thematic analysis of interview data. These were 1) Intervention engagement, 2) Facilitators, 3) Benefits of BACK-to-FIT^{TM}, and 4) Recommendations for improvement and potential barriers. Several subthemes emerged from data that formed the themes, and a few of the subthemes were interrelated, as shown in the thematic map in Figure 8.5

Figure 8.5: Thematic map of the inductive thematic analysis of the interview data



8.4.4.1.1 Theme 1: Intervention engagement

Participants discussed how they used the intervention and engaged in the exercise programmes whilst using BACK-to-FIT™ intervention. Three sub-themes arose from those discussions:

Sub-theme 1: The need to do something about LBP

Four participants said they had been actively seeking advice at the time of the study as they felt the need to do something about their LBP. Two participants mentioned that they had already tried some advice they found on the internet before enrolling in the study and had failed to see any difference in their pain, thus were glad they decided to engage in the programme.

"So.I actually looked up to it because I actively wanted to do something, my back pain is there all the time and that is ..that just doesn't feel good , so really wanted to get rid of it.. "

Participant 1

"I wanted to gain some information and some programmes I could do…I was looking at some of the resources from you tube and even tried a couple…but you know there are so many of them and I really didn't know what to choose or continue…I was glad I did these exercises instead"

Participant 2

Sub-theme 2: Different approaches used by the participants

Since a definitive exercise schedule was not provided to follow during the four weeks, it was evident that all participants used the intervention and engaged in the exercise programme differently. This subtheme was also interconnected with another subtheme: convenience of accessing and engaging in the programme, which comes under the theme "Facilitators". Nine participants stated that they progressed and/or regressed the exercises when they felt appropriate and believed this was helpful.

"I started with the worried back and I did then sort of dip into the active back. didn't really get into the high-level ones too much..certainly not all of them but I progressed to the upper body ones and though they were really good"

Participant 8

" it is funny I started with active back +1 as I thought I am a bit active even though I had the pain, but soon I realised that was too much , so I had to go down a bit further and started with a low level and progressed slowly.."

Participant 9

One participant mentioned that after three weeks of using BACK-to-FIT™, she tried a dancing class which she had stopped earlier due to pain and continued to do the exercises from BACK-to-FIT™ as a warm-up programme before the class.

"I couldn't wait to start my spin class. It is because I really wanted to lose my weight.so as soon as I felt a bit better, I started the class again but still continued with the BACK-to-FIT™ exercise as a warm up before the class"

Participant 6

Sub-theme 3: Recommendation and shared experience

All participants claimed that they would highly recommend this intervention to their family, friends and acquaintances. Four participants mentioned that they have already mentioned this to their friends and family and they believed it would be a very helpful programme for them to follow.

"I would certainly recommend it to anybody who had back pain, like I said specially the way it helped reduce stiffness in my back was amazing. So, I believe I will be doing a big help for them by recommending this programme"

Participant 6

8.4.4.1.2 Theme 2: Facilitators

Three sub-themes which discussed different aspects that facilitated BACK-to-FIT^{TM} emerged from data. All these features have collectively increased the usability of the intervention and appear to have motivated the participants to continue the use of the intervention.

Sub-theme 1: Quality of the content and the technical architecture

Participants commented on the useful content and the good technical architecture of the intervention, including several features which they found beneficial. Regarding the content, they highlighted the fact that the overall content was explicit, straight forward, succinct, easy to understand and self-explanatory. One participant mentioned that the intervention has everything in one place and works as a stand-alone platform.

"I could navigate through it and it all seemed quite self-explanatory. It seems quite well laid out and structured...."

Participant 3

"it wasn't overloaded with information I think sometimes when you go on these websites and they are very busy you tend to get lost in the information that is there it was very succinct. You would know exactly where you needed to be for your level of training or on how to look at the different levels and the different modules. So that's it was good"

Participant 9

"I think even people who haven't used a gym or haven't done exercise before, would be able to understand this, so yeah I think it's stand alone"

Participant 11

Regarding the technical architecture, most participants expressed the view that the platform was smooth running, easy to navigate and had high readability.

"It was smooth running, and it was easy to navigate within modules, I think. It is quite engaging. It is clearly laid out and is informative yeah, I think it is really good and useful"

Participant 4

Features participants found beneficial were; animated videos of the exercises, instructions given under the animated videos, the ability to download the PDF format of the complete list of exercises together with instructions and the ability to progress and regress the exercises from a large number of exercises.

"So, the biggest thing was videos, just watching it while doing it. It is all there, and if you have any problem you just go back and look at it. Initially I did refer to the videos even for simple exercises because I wanted to do it correctly".

Participant 1

"I kind of liked the way it was structured with 4 modules, it's kind of gave quite a nice sort of place to fit yourself against that. it was structured in that way it is easy to find the best exercises suit you and progress from there. And I found the PDF file was very helpful, I actually referred to videos only the first few times, after that I used the PDF file which I downloaded"

Participant 3

"There was more to it than I was expecting actually I was expecting maybe one module with some exercises on it but I really like that t..... you have you've got different levels for different areas of exercise which I found quite useful actually. It was really interesting to see how much you could actually do differently across the modules. depending on how you were focusing on kind of moving up"

Participant 10

Sub-theme 2: Feeling safe and reassured

All participants concurred that they felt reassured and safe knowing they are engaged in a reliable programme.

"Obviously there is a wealth of information out there on YouTube but you can spend half your time searching for things and there's always a question of whether or not if it's coming from a medically trained or professionally trained platform...so this provides confidence"

Participant 2

"Also, It makes you less anxious because you are doing something about your pain and doing something right and it is coming from a professional source"

Participant 1

Four participants stated that the exercises were simple, and two participants claimed they were familiar with some of the exercises. This simplicity and familiarity of the exercises had a positive effect on the use of the intervention.

"I liked the exercises they were simple and easy to follow, and overall it was low risk in so many ways in the sense that you know I certainly was not going to be worried about doing those exercises unsupervised either.."

Participant 8

Sub-theme 3: Convenience in accessing and engaging in the exercise programmes

Participants appreciated the convenience of using the intervention and discussed different aspects which they believed were the most useful. Furthermore, this subtheme links with other subthemes and themes as shown in the thematic map. Seven participants highlighted that having the opportunity to engage in a self-management programme from home or any place they want was very useful, especially during the period of study with COVID-19 restrictions, this suggests it was a very timely intervention. Additionally, it also fitted with their different lifestyles. Three participants claimed that having good accessibility to all components of the intervention through mobile phones and desktop/laptop computers was very convenient.

"I think it is really helpful, and very timely. Especially right now because people are not able to access to see a physio or a doctor, so if you would think of someone like me with a very troublesome pain definitely this would be very helpful to do it from home ..."

Participant 1

"this works quite nicely for me, I hate going to the gym, I hate going to ask other people to help, going to the doctors for me is a nightmare - I hate it. I'll go only if I'm like dying. so actually, something like this right puts the power back in your hands is I find really useful.

and it's like I said it works well on the laptop as well on mobile, so it works really well as a self-management tool for me"

Participant 10

"what made it nice is that you could just dip in and out when you had time to do so around your routine .so with me with two children it is quite hard to stick to set for myself. because they take my main priority and once, I get them sorted and then I have to do my exercises. what website provide me is a nice platform to just jump in and engage"

Participant 7

Additionally, participants confirmed that the flexibility of the exercise programmes was beneficial, and they felt it increased their BACK-to-FIT™ use. Three participants mentioned that they liked the fact that they could engage with the modules at their own pace and preference, while two participants highlighted the usefulness of the ability to do the exercise programmes anytime, anyplace without any special clothing or equipment. Participants also felt the programmes they followed were tailored to their needs.

"There were lots of stuff and information that I could take in and I can do it at my own pace. I also I could look through it all and then before I actually started it wasn't like some of the things where once you start the exercises you have to kind of carry on to next through you could do this on your own pace it was quite easy to follow."

Participant 5

" I also liked the simplicity of the movements and I don't need equipment or you don't need put into anything but you realise how much you can do just with your own body weight and just in your everyday environment. I think that way as well it is just easy access and it's so accessible for anybody. It was a good concept"

Participant 8

"this programme offers me a lot more exercises than I received from the chiropractor few months back, which I could kind of sort of tailored to suit my own needs. thorough these I was able to link them with some of my daily routines as well that I know that will help my back"

Participant 7

8.4.4.1.3 Theme 3: Benefits of BACK-to-FIT™

The third theme was created by merging four subthemes that describe several aspects of benefits participants experienced using BACK-to-FIT™.

Sub-theme 1: Perceived control of pain and readiness

It was interesting to note that despite current improvements in pain, five participants were anticipating pain flare-ups in future due to their work, and other activities they do or have done in the past. However, all five participants stated they felt ready to better self-manage flare-ups with exercise in future using BACK-to-FIT™ exercise. Furthermore, four participants (including one of the above out of four) claimed they feel like they have regained control of their LBP.

"it allows you to regain that control and to manage the flare-up so that's easier it's good"

Participant 2

"Yeah, I definitely have less back pain, ...like I said when if I ever like I spent a long-time work carrying heavy stuff around and I know that I will get back pain and then I made sure I did more exercises from the modules (BACK-to-FIT™) before and after so I know I won't be stiff and will stay more mobile. It was good because then I had the control of my pain and was able to stay ahead of it"

Participant 5

Sub-theme 2: Improvement in pain, stiffness and activity participation

Benefits stated by the participants after using the BACK-to-FIT™ intervention for 4-weeks included reduced pain levels, ability to sit for longer duration without pain, reduced stiffness, increased activity participation and engagement with usual activities and other activities such as yoga and dance classes.

"yes, I can confidently say my pain is definitely less, great times. And I have been active for the past 2 weeks than I have been for ages... As I said I also started my spin class too.."

Participant 6

"yes it's not a good thing , but now, I think I can sit for longer without getting pain.. that deep some nagging kind of pain not there anymore and I'm able to sit for a longer duration although I don't want to ..so then in general I feel more flexible and free like it's not stiff"

Participant 1

Sub-theme 3: Improved confidence and motivation

Using the intervention had improved confidence in two participants, and one of these two participants and another three mentioned that engaging in the programme also enhanced their motivation to continue the exercise. Some of the intervention characteristics that played a pivotal role in improving participants' confidence and motivation included the ability to progress and regress the exercise, the ability to select and continue exercise according to their preference and pace, ability to see the correct way of doing the exercise and awareness that they are engaged in a programme developed by professionals that is reliable. Accordingly, this subtheme was linked with the subthemes from "Strengths" and "Intervention Engagement", as shown in the thematic map.

"I have spent a lot of my life after taking that level of control and finding out motivation and confidence in exercise is a way forward to reducing pain and maintaining a healthy lifestyle. I think this programme gives it, specially through going up or down the levels of the exercises and the fact that I can see if I am doing them correctly gave me confidence"

Participant 2

Sub-theme 4: Enhanced awareness and understanding of LBP

Seven participants out of eleven claimed that the programme improved their understanding of LBP and what exercises to do. Although some have had previous experiences with exercises and self-management, they reported that BACK-to-FIT^{TM} provided more in-depth and LBP and exercise specific knowledge.

"yeah, I had some understanding I need to stay active and I need to keep moving and the bit… but this added a lot to that knowledge and I learned a lot of back specific exercises and also some new information in the second module"

Participant 11

Theme 4: Recommendations for improvements

The last theme was generated by combining two subthemes that covered further improvements in the intervention. Some participants revealed a few difficulties and problems they encountered while using the intervention and suggested addressing them in a future prototype. Furthermore, they also proposed new intervention functions and features to be considered to integrate with the following prototype of BACK-to-FIT™.

Sub-theme 1: Problems encountered in the current version

Three participants encountered some technical difficulties when using BACK-to-FIT™. One of the three participants had issues loading the website and stated it usually takes a bit longer than others and sometimes the website did not appear. Moreover, one participant could not access BACK-to-FIT™ intervention through their mobile but only through the computer. The other participant stated the pages' readability on the phone was less than when using the computer due to some differences in the page settings. Other than the technical difficulties, another two participants mentioned that they were uncertain which exercises to choose and when to progress and regress between levels of the exercises. Thus, they suggested more clarity to the instructions giving them more guidance towards selecting exercise programmes and progressing/regressing them.

"sometimes I was wondering whether should actually move on to the next level yet or not.. all the animations and the instructions given within the levels are quite clear. but what I couldn't easily differentiate is where I should stop these exercises, exactly when to go back a level and how much of breaks, I need to take in between the levels"

Participant 4

"Only thing is I had use the laptop as well to download the exercise plan because I couldn't seem to get the exercise bits to work on the phone , just couldn't download them. It could be just me..."

Participant 5

Sub-theme 2: Suggestions for further development

Participants also discussed several ideas on how this intervention could be further developed. Six participants suggested converting the intervention into a mobile app, so the accessibility and convenience of using the intervention would increase further.

"I use my phone for literally everything so having it as an app on you know on my phone will be amazing"

Participant 10

Three participants recommended that a narrated audio embedded in the animated exercise videos would be extremely helpful as the user would not have to look at the mobile or computer screen for instructions while doing the exercises.

"I think the videos did not have audio. It would be better, you know if it is there so I can just put it and then I just continue the exercise. I don't have to read the instructions while doing the exercise"

Participant 1

Three participants also proposed introducing more vigorous exercises to further progress into the active back module.

"It would be nice to add more exercise if you can at some level ..three or four more give you more levels up, ..more vigorous exercises … I suppose you can keep going on adding more and more. That's the difference in this programme"

Participant 9

Another two participants stated that they would prefer if the intervention could be more tailored with a personal login and an account or profile with a record of their engagement with the modules. They believed it would allow the user to track their progress.

"I think having a personal account, like necessarily….. like a you know like a couch to 5K where you go through the different levels till you get to 5K like that. Because there is recording things and logging that so that I don't have to kind of go back through and try to figure out which one I did last time, would probably be useful for me personally. I'm a bit lazy and that would make my life a bit easier. But it's easy enough to find different exercises on there I think it's just got to try to remember which programme it is following"

Participant 3

Furthermore, participants recommended making the intervention available to the public through the NHS while people wait to see a physiotherapist. Two participants confirmed that BACK-to-FIT^{TM} was more useful and user-friendly than their previous LBP self-management experience with NHS, where they only received a leaflet of exercise instructions with diagrams.

"I've have accessed NHS for many years due to back pain mostly to get an exercise leaflet and also gone to many physio, and it is a resources I would have liked to be provided at that

point when I was really suffering from back pain. So, if this is a programme that can be launched and offered extended out further then I think that would be great"

Participant 2

Overall, the participants'' use of BACK-to-FIT^{TM} was a positive experience. They commented that they understood its purpose and were able to distinguish the differences between this intervention and existing self-management resources for LBP. Also, they found the intervention very useful, convenient, and informative.

"I think it's very useful tool for people to have, to particularly if they're just starting out in the process of managing back pain, if they have not a great deal of knowledge about fitness and maintenance and experience with exercising and I think it's a really useful tool."

Participant 2

8.4.4.2 Normalisation process theory (NPT) analysis of BACK-to-FIT^{TM}

NPT analysis of the intervention was undertaken as outlined in Murray et al.'s (2010) NPT framework considering interview data. The NPT analysis undertaken for BACK-to-FIT^{TM} is shown below in Table 8.6. It does not only look at the early implementation but also evaluates beyond the initial stage to the point where the intervention could become embedded into routine practice or "normalise". Given that NPT analysis focuses on work that both individuals and groups do to enable an intervention to become normalised (Murray et al. 2010).

Table 8.8: Normalisation process theory analysis of BACK-to-FIT^{TM}

Questions considered	Evaluation of BACK-to-FIT^{TM} intervention
Coherence (i.e meaning and sense-making by participants)	
Is the intervention easy to describe?	Yes. It was easy to describe BACK-to-FIT^{TM} to the participants they clearly understood the purpose of using and how to use it.
Is it (BACK-to-FIT^{TM}) distinct from other interventions?	Yes, participants compared the BACK-to-FIT^{TM} intervention with their previous experiences of self-management and identified the differences

	between those and this intervention (section 8.4.4.1).
Does it have a clear purpose for all relevant participants?	Yes, the main aim was to improve exercise self-management in people with LBP. Participants understood the purpose of the intervention evidenced by individual interviews.
Do participants have a shared sense of its purpose?	There was no interaction between the participants of the study. However, participants have shared their experience with others known to them expressed they understood and value the intervention (section 8.4.4.1 Theme 1-subtheme 3)
Are the benefits likely to be valued by potential participants?	Yes, participants clearly articulated the benefits the BACK-to-FIT^{TM} intervention brough to them - evidenced by potential benefits questionnaires (section 8.4.3) and individual interviews (Theme 3 section 8.4.4.1)
Will it (BACK-to-FIT^{TM}) fit with the overall goals and activity of the organisation?	Promoting exercise and self-management is considered a key strategy for managing LBP and meet health service demands. Although it is very likely, given the lack of exploration of organisations' and healthcare professionals' opinions on this, it is premature to confirm if this will fit with the overall goals and activity of the respective organisations.
Cognitive participation (i.e commitment and engagement by participants)	
Are target user groups likely to think it is a good idea?	Yes, they think it is a very useful and a timely intervention (section 8.4.4.1 Theme 2)

Will they see the point of the intervention easily?	Yes, they clearly understand the purpose of the intervention as evidenced during the interviews. (section 8.4.4.1)
Will they be prepared to invest time, energy and work in it?	Yes, participants continuously used the intervention for four weeks and claims to continue using it (section 8.4.4.1).
Collective action (i.e. the work participants do to make the intervention function)	
How will the intervention affect the work of user groups?	BACK-to-FIT^{TM} is an intervention people with LBP can use by themselves. It has improved their PA level and helped them continue their daily activities (section 8.4.4.1 Theme 1, 2).
Will it promote or impede their work?	Yes, participants claimed that following up on the programme made it easier to engage in daily activities and jobs. It enhances exercise self-management in people with LBP (section 8.4.4.1 Theme 2)
What effect will it have on consultations?	It can potentially reduce the need for appointments to see a doctor or physiotherapist about their LBP. However, this has not been studied during this project and will need further research.
Will users require extensive training before they can use it?	A majority of the participants agreed the intervention was straightforward and did not require prior training. However, 2/11 suggested more guidance on selecting the appropriate exercises. Moreover, if the complexity of BACK-to-FIT$^{TM\ to}$ be increased in future iterative versions this will have to be reconsidered (section 8.4.4.1- Theme 4 subtheme 1).
How compatible is it with existing work practices?	Not known since this was not explored during this study and will need further research.

What impact will it have on the division of labour, resources, power, and responsibility between different professional groups?	Not known as this aspect of the use was not researched during this study and will need further research.
Will it fit with the overall goals and activity of the organisation?	Exercise and self-management are the key recommendations for managing LBP, and this intervention has promoted both elements in participants. However, to explore how BACK-to-FIT^{TM} fit within healthcare settings was not studied and warrants further research.
Reflexive monitoring (i.e. participants reflect on or appraise the intervention)	
How are users likely to perceive the intervention, once it has been in use for a while?	Participants mentioned they are going to continue using the intervention in future as needed. Even if the participants do not use it continuously, they are likely to return to use the intervention at times of pain recurrence.
Is it likely to be perceived as advantageous for patients or staff?	All participants claimed the intervention was beneficial (section 8.4.4.1 Theme 2). Potential advantages of implementing BACK-to-FIT^{TM} for staff of healthcare settings should be investigated in future research.
Will it be clear what effects the intervention has had?	Yes, after the intervention, participants had fewer symptoms, increased PA levels, improved exercise self-efficacy and better-coping strategies (section 8.4.4.1 Theme 2).
Can users/staff contribute feedback about the intervention once it is in use?	Feedback was obtained from all users in order to develop it further in an iterative version. Healthcare professionals' feedback however was not obtained.
Can the intervention be adapted or improved on the basis of experience?	Yes, as a digital intervention hosted on a website BACK-to-FIT^{TM} has an unlimited potential to modify or expand further according to the needs of broader user groups (section 8.4.4.1 Theme 4 – subtheme 2).

Analysing BACK-to-FIT^{TM} according to above NPT analysis ensured that all the elements of the NPT framework have been considered within the intervention. However, this analysis also highlights some key features to be attentive to during future development and large-scale evaluation within an organisational structure.

8.5 Discussion

8.5.1 Chapter overview and summary

This chapter presented details regarding the methods and results of the preliminary evaluation of BACK-to-FIT^{TM}. This discussion section will first summarise the findings; then the findings will be interpreted and discussed in line with previous literature. Next the study limitations, clinical implications and future research directions will be discussed, followed by a conclusion.

8.5.2 Summary of the findings

This preliminary evaluation study comprised of evaluation of twelve participants at baseline and after 4-week use of BACK-to-FIT^{TM}. Four of sixteen recruited participants (25%) dropped out before completing the 4-week follow up. Participants who completed the programme reported a mean age of 38.8 years and mean BMI value of 26.38. Two thirds of the sample (8) were employed in desk-based jobs. At the baseline, the sample had a mean LBP intensity of 4.16 on NPRS and reported a mean score of 15.33 for LBP related disability on ODI V2. Moreover, participants scored a mean of 37.5 on SSE scale for exercise self-efficacy and reported a mean level of PA equal to 1455 MET-minutes/week at the baseline. Overall, baseline and follow-up data comparison showed positive results across all measured health outcome measures. However, several factors limit the extrapolation of these findings. For example, compared to most of the existing studies published on digital SMIs for LBP, this sample comprised of significantly smaller numbers of participants and participants' mean age was lower (Amorim et al. 2016; Geraghty et al. 2018; Sandal et al. 2021). Furthermore, LBP was self-reported, and participants voluntarily enrolled for this study demonstrating a care-seeking behaviour. However, mean value for pain intensity and BMI of the participants at the baseline were comparable with existing studies with similar pain (Geraghty et al. 2018; Sandal et al. 2020) and BMI values (Amorim et al. 2016; Shebib et al. 2019; Hodges et al. 2021).

Participants of this study had a low level of LBP related disability according to ODI V2 scores and reported less disability compared to several other studies (Chhabra et al. 2018; Selter et al. 2018; Shebib et al. 2019). Whilst these data represent only twelve participants who engaged in the programme, reasons for dropouts were not assessed. Considering these facts, representativeness of the sample of this study appears low. Yet, overall purpose of this study was to establish a preliminary indication of usability, potential benefits and user experience of BACK-to-FIT^{TM} intervention, rather than measuring absolute effectiveness. Results of this study provided some insight into future iterations of the intervention as well as methodological considerations for future larger scale studies.

As the primary outcome of this study usability score measured with SUS, revealed a mean score of 81.87, which is considered an above-average score (Sauro 2011) falling between ‘good’ (72 points) and ‘excellent’ (85 points) (Bangor et al. 2009). The secondary research outcomes related to technological acceptance, potential health benefits and the user experience of the BACK-to-FIT^{TM} intervention. Regarding technology acceptance, more than 75% of the sample always agreed (> somewhat agree) on all of the measurement items across eight TAM3 constructs pointing to high rates of technology acceptance. The results of the descriptive statistical analysis of baseline and follow-up data showed improvements in pain intensity, LBP-related disability, exercise self-efficacy, moderate, vigorous and total levels of PA. The mean score for pain intensity of the sample measured using the NPRS was reduced by 1.89 points following four weeks of BACK-to-FIT^{TM}. ODI V2 total mean score also showed a reduction of 6.33 after the follow-up, revealing fewer levels of LBP-related disability among the participants. SEE score demonstrated an increase of 22.17, revealing the benefits of the intervention to enhance participants' exercise self-efficacy. Participants reported an increase in moderate and vigorous PA levels by 366 and 268 MET-minutes/week respectively while total level of PA also increased by 483 MET-minutes/week after using the intervention for four weeks.

The user experience of BACK-to-FIT^{TM} intervention was evaluated using a qualitative study that included individual semi-structured interviews. Four broad themes emerged from the thematic analysis of the interview data, these were intervention engagement, facilitators, benefits of the BACK-to-FIT^{TM} intervention and recommendations for its improvement. Whilst qualitative analysis revealed a positive user experience overall, some recommendations and feedback related to potential further Improvements to the BACK-to-FIT^{TM} intervention. Conducting an NPT analysis of interview data of the user experience was helpful in identifying already existing potentials of BACK-to-FIT^{TM} intervention if implemented on a larger scale. Most importantly participants disclosed several aspects for further modifications to the methods of delivery and application.

8.5.3 Usability

Many studies have evaluated the usability of LBP digital interventions on self-management, but only a few have used SUS to measure their intervention's usability (Irvine et al. 2015; Nordstoga et al. 2020). Nordstoga et al.'s (2020) selfBACK study, is a single-arm pilot study evaluating 43 users who used selfBACK intervention for six weeks with a similar baseline mean pain intensity (NPRS 4.1). selfBACK app has been designed to deliver tailored education and exercise related to LBP self-management and one of the very limited SMIs that are predominantly based on exercise. A comparison of the mean scores of Nordstoga et al.'s (2020) study evaluating the usability and acceptability of the selfBACK app showed lower SUS mean scores at stages 1 and 2 of their study compared to BACK-to-FIT^{TM} intervention. Whilst stage 1 SUS score for selfBACK was 64.7 (range 10 - 95), the iterated version tested at stage 2 had a score of 70.5 (range 45 – 95). Meanwhile, FitBack (Irvine et al. 2015), a self-management intervention predominantly based on a cognitive behavioural approach, obtained a mean SUS score of 78.6 (standard deviation of 15.7). Accordingly, BACK-to-FIT^{TM} reported a higher usability score than both selfBACK and FitBack interventions. FitBack score also falls between good and excellent categories (Bangor et al. 2009), thus more consistent with the SUS scores of BACK-to-FIT^{TM}. However, several differences between studies including less dropout rate (1.9%), sample size (n=199) follow up period (2 months) prevents any direct comparison of FitBack results with BACK-to-FIT^{TM} intervention. In addition to the above studies, considering overall literature not limiting to LBP and self-management, the average SUS score across 3500 surveys within 273 studies on different platforms (Web, mobile phones, TV, etc.) was 70, and the average score for web applications was 68.2 (Bangor et al. 2009).

Another digital LBP self-management intervention based on LBP education (Madill et al. 2019) assessed their interventions' usability to reveal a very high usability score (9.6/10). Nevertheless, this study has used a questionnaire designed by its authors to evaluate the usability of the intervention in which neither validity nor reliability had been tested, thus values remain incomparable. Findings of a systematic review evaluating the usability of arthritic pain self-managements applications (Bhattarai et al. 2018) have revealed a usability score of 3.2 out of 5 in an existing application (WebMD Pain Coach V1.3, 2016). Authors of the above review have used a validated 5-point Likert scale similar to SUS and a value of 3.2 is considered as moderate usability (Arnhold et al. 2014).

8.5.4 Technology Acceptance

As the first of the secondary research questions, users' acceptance of using technology in BACK-to-FIT™ intervention was assessed using a questionnaire based on the TAM3 model. Eight constructs related to technology acceptance were measured during this study and involved perceived usefulness, perceived ease of use, computer self-efficacy, perceptions of external control, computer anxiety, perceived enjoyment, subjective norm and behavioural intention. These constructs were selected from the original TAM3 questionnaire to suit the context of this study. All constructs reported mean scores higher than five out of seven highest possible scores. At the same time, all users agreed (somewhat, moderately or strongly) with all sixteen individual measurement items across the eight TAM3 constructs. The highest mean score for the computer anxiety construct denotes that participants were comfortable using BACK-to-FIT™ without fear or apprehension of using the technology. The subjective norm construct mean score was 5.04 and compared to other constructs, participants generally had a lower perception of people who were important to them thinking they should use the BACK-to-FIT™. Although there is no set benchmark or a cut-off point for TAM3 scores, multiple studies indicate that a mean score of 5 or above is a higher level of technology acceptance (Jamieson et al. 2015; Isernia et al. 2019). Accordingly, this study's results suggest high acceptance of using technology in BACK-to-FIT™ among participants. Although, generalisability is not the main intention of the acceptability studies, given the small sample size, limited use of descriptive statistics to describe the technology acceptance, significant drop out rate (25%) and the short duration of the follow up period, caution must be applied when interpreting these findings. For example, a separate study was conducted to explore the user acceptance of an unsuccessful multicomponent LBP intervention (Schaller and Froboese 2014) designed on the premise of telephone, web and face-to-face coaching. This aimed to create a healthy lifestyle in LBP patients but revealed poor acceptance of web coaching compared to face-to-face coaching (Dejonghe et al. 2020). Therefore, it is vital that results obtained in this study, which are related to the technology acceptance of the BACK-to-FIT™ intervention, be explored qualitatively as found in several other LBP self-management interventions (Jansen-Kosterink et al. 2019; Nordstoga et al. 2020). However, none of the existing digital interventions on LBP self-management have used TAM questionnaires to quantitatively evaluate the technology acceptance of their intervention, this therefore limits any direct comparison of BACK-to-FIT™ intervention results with the literature. According to Nordstoga et al. (2020) selfBACK study's mixed methods evaluation of acceptability mainly focused on the completion time of the baseline and follow-up questionnaires (Nordstoga et al. 2020) rather than acceptability of the intervention or technology acceptance. A qualitative exploration of acceptance of telemedicine services among patients with LBP, whiplash and chronic obstructive pulmonary disease (COPD) has established that acceptance depends on multiple factors that are not part of well-established theories which explain technology acceptance (Jansen-Kosterink et al. 2019). Furthermore, authors suggest that these factors are likely to be more specific such as a fit between the service configuration and daily life and personal motivation rather than general determinants like ease of use and perceived usefulness. Given this evidence and the limitations of this preliminary evaluation technology acceptance of BACK-to-FIT™ intervention clearly warrants further research, in particular a qualitative exploration of present findings.

8.5.5 Pain intensity

Although participants only had the opportunity to use the intervention for four weeks, a comparison of mean scores at baseline and four-week follow-up show improvements in almost all the outcome measures for potential health benefits. The reduction of 1.89 points on the NPRS indicates the potential effect of BACK-to-FIT™ in improving pain in patients with LBP. This mean reduction of 1.89 points was higher than previously reported levels in similar interventions which focused on LBP self-management. For example, selfBACK intervention (Sandal et al. 2020) reported a reduction of one point in VAS for pain intensity, while a retrospective study evaluating 180 users of the Kaia app for four weeks reported a reduction of 1.3 points on the NPRS. A recently published RCT of the selfBACK intervention compared 232 in the intervention group with 228 controls, it found a drop of 1.5 on NPRS in the intervention group compared with a drop of 1.0 in the control group (Sandal et al. 2021). The mean score changes on the NPRS revealed in the SupportBack trial (Geraghty et al. 2018) are also far below the value observed in this study. The SupportBack trial is a randomised controlled feasibility study which recruited 87 patients with LBP and used three arms: usual care, internet intervention plus usual care, and internet intervention plus a physiotherapist's telephone support. The most significant pain reduction between the baseline and the 3-month follow-up occurred in the intervention plus usual care group, which was 0.8. The IMPACT study (Amorim et al. 2019) compared the reduction in pain between the intervention and control group in their study of 68 patients with LBP, it revealed a change of 1.5 points improvement in NPRS at baseline and six months follow-up. Accordingly, the change in the pain intensity at baseline and follow-up in this study remains higher compared to all the studies mentioned above. However, it is premature to make a comparison of these results due to the differences in the study designs, sample characteristics and the content of the interventions. For instance, the IMPACT study consisted of a much older population (mean age 59.5) with a higher BMI value (28.9) and had a higher pain intensity at the baseline (5.4) compared with the participants of this study. Although selfBACK RCT (Sandal et al. 2021) and SupportBack trials reported similar baseline pain intensities, both studies had follow up results reported after 3 months whereas this study follow-up was limited to 4-weeks. Furthermore, all of the above studies recruited participants who had actively sought care through their healthcare practitioners prior to enrolling in the study. Though BACK-to-FIT™ participants were not actively seeking care at the time of the intervention their history of seeking help was not obtained. Similarly, a number of other characteristics including current use of pain medication and participants’ level of education were not considered, this makes any direct comparison of these results challenging.

Even though, the mean drop of pain intensity was higher than other studies, the mean change of score of this study did not meet the minimal clinically important difference (MCID) on the NPRS for LBP, which is reported to be 2 points (Childs et al. 2005). This could be explained by the limited period between the baseline and follow-up and the small sample size. Yet, seven out of the twelve users (58.3%) had a drop equal to or greater than 2 points on the NPRS. In addition to absolute MCID, a 30% improvement from the baseline is considered helpful in LBP outcome measures, including NPRS (Ostelo et al. 2008). In this study percentage drop of NPRS score was 45.43%. Despite these improvements there is a lack of robust evidence to support the effectiveness of the intervention in reducing pain levels due to the absence of a control group and also due to the short follow up period. Given that follow up was only 4 weeks, changes of pain intensity may have occurred as time passed, this leaves any further interpretation of the results impossible.

8.5.6 Disability

According to the findings of this evaluation study, participants showed improvements in the level of disability. This was measured using modified ODI (ODI V2), ODI V2 is a widely used instrument which measures the level of disability. The MCID for ODI V2 is reported as 10 points (Ostelo and de Vet 2005) while a 30% change from baseline is considered beneficial, this is similar to other LBP outcome measures (Ostelo et al. 2008).

Even though only a 6.33 change in the mean ODI score was observed amongst participants of BACK-to-FIT^{TM}, the percentage improvement from the baseline measurement of the score was 41.29%. Therefore, these results show the potential effects of BACK-to-FIT^{TM} in reducing the level of disability amongst people with LBP. Four users (33.33%) of the sample achieved a minimum change of 10 points in their ODI scores.

These findings largely agree with research evaluating other digital interventions for LBP self-management. A randomised controlled study (RCT) of Shebib et al. (2019) which evaluated the effects of a digital self-management programme for people with LBP reported MCID less than 10 points in the ODI score but observed improvements in the score higher than 30% from the baseline score. Regardless of the larger sample size (n=69) and the longer follow up duration Shebib et al.'s (2019) intervention reported baseline pain intensities (VAS 43.6/100) and low back pain disability (ODI – 19.7) broadly similar to this study. However, significant differences exist between the content of Shebib et al.'s (2019) intervention compared to BACK-to-FIT™, including integrated CBT elements, motion sensor-guided physical activities and unlimited access to personal coaching. Meanwhile, the levels observed in BACK-to-FIT™ evaluation are far below those observed by Chhabra et al. (2018) in their RCT, it compared chronic LBP patients using the Snapcare app with the controls for who had usual care including pain medication and advice on PA and exercise. They have observed changes of 31.93 and 11.50 on the ODI V2scores in the intervention and control groups, respectively, following the intervention for 12 weeks. Although the Snapcare app predominantly focused on improving the participants' PA level, similar to BACK-to-FIT™, the sample consisted of chronic LBP patients who had symptoms for more than 12 weeks. This explains the higher baseline ODI scores thus there is likely potential to detect a larger difference in the follow up. Moreover, both control and intervention groups' participants of the Snapcare study reported higher baseline pain intensities (7.3) compared to participants of the present study.

The most likely explanation for the low ODI score difference between the baseline and the follow-up in this study is the low ODI mean scores at the baseline which could be associated with participants' self-reported LBP. Although the percentage improvement in the scores shows promise for the outcome, caution needs to be exercised when interpreting the above discussed results given the small sample size, self-reported LBP, shorter follow up period and the absence of a control group.

8.5.7 Exercise self-efficacy

The present study's findings show that participants' self-efficacy to exercise was enhanced by 22.17 points after using the BACK-to-FITTM intervention. This marks an improvement of 59% from the baseline score and denotes a substantial improvement in exercise self-efficacy. No cut off points have been established to indicate a low, moderate or high SEE scores and a higher score (out of 100) denotes better exercise self-efficacy. Despite having a low mean pain intensity, participants reported only 37.5 as the baseline SEE score, but demonstrated surge at the follow up 59.6. Although SEE has been used widely to measure exercise self-efficacy in various study populations (McAuley et al. 2003), there has been a lack of similar studies measuring exercise self-efficacy in people with LBP using digital self-management solutions.

Alternatively, several LBP digital self-management studies including SupportBack (Geraghty et al. 2018) selfBACK (Nordstoga et al. 2020; Sandal et al. 2021) and PainCare (Yang et al. 2019) interventions have assessed participants' pain self-efficacy. Thus, the ability to compare the scores of this study is limited. Exercise self-efficacy is known as the most influential factor when planning for exercise (Shin et al. 2006). More than a 30% increase in the baseline scores in the SEE scale BACK-to-FIT™ indicates promising outcomes in improving exercise self-efficacy. Exercise self-efficacy outcomes are likely to influence motivation to exercise, and mobility-related behaviour (McAuley et al. 2003), and therefore, BACK-to-FIT™ is likely to enhance overall exercise engagement of people with LBP. Given the importance of exercise in LBP self-management, this lack of studies focusing on LBP exercise self-efficacy highlights a significant gap in LBP literature.

8.5.8 Physical activity

The levels of PA of the participants in this study also improved over the four weeks of using the intervention. At the baseline, the total level of PA as per IPAQ-SF results was 1455 metabolic equivalent minutes per week (MET-minutes/week). This value is the result of the total amount of time participants were actively engaging in moderate, vigorous activities or walking summed up to obtain a weekly total in minutes. This was an unexpected mean score, it exceeds the American Heart Association's recommendations of the minimum level of PA; approximately 450–750 MET/per week or moderate exercise for 30 min/day, five days a week (Haskell et al. 2007; Denay et al. 2020). Although it is difficult to be certain, these figures might suggest a potential overestimation of the level of PA by the participants which would question the reliability of the self-reported measure of PA, in this case, IPAQ-SF. However, if PA levels are overrated, whether it is only confined to baseline or present in both baseline and follow-up data remains unclear. Despite IPAQ being the most widely used self-reported measure assessing the level of PA (Lee et al. 2011), similar issues have been reported previously (Hallal et al. 2010). Authors of SupportBack trial (Geraghty et al. 2018) also suspected a similar overestimation of the PA levels reported in their trial with a median value of 2343 MET-minutes/week at the baseline. Adapting objective measures using technological devices such as pedometers and accelerometers could be a better method of overcoming this issue. The IMPACT trial (Amorim et al. 2019) used a combination of self-reported outcome measures and activity trackers to evaluate a PA intervention for people with chronic LBP that involves health coaching, a mobile health application, and a pedometer. However, the six-month follow-up results of the participants of the IMPACT trial showed an increase in walking and a decline in total, moderate and vigorous IPAQ values. The intervention group had improved walking compared to baseline by 112 MET-minutes/week. This group also showed an improvement of 183 MET-minutes/week against the control group at follow-up, while total moderate and vigorous activity levels declined compared to the baseline (12 and 48 MET-minutes/week, respectively) (Amorim et al. 2019). The above findings are contrary to the BACK-to-FIT™ study which showed improvement in moderate, vigorous and total PA levels of 366, 268 and 646 MET-minutes/week respectively. In contrast to IMPACT trial findings, a decline was seen in walking with a drop of 78 MET-minutes/week. It is possible that participants spent more time doing back-specific exercises, as shown in BACK-to-FIT™, rather than walking.

8.5.9 User Experience

Thematic analysis of the data revealed four overarching themes, these included intervention engagement, benefits of the intervention, facilitators, and recommendations for improvements. The themes broadly reflected those of previous studies in this area of research (Anderson et al., 2016; Svendsen et al., 2020). Based on the findings, BACK-to-FIT™ appeared to be an advantageous, convenient, and positive experience which helped the participants to be more active and improved their LBP self-management. Overall, the findings of this part of the study were consistent with quantitative findings and revealed good usability and technology acceptance.

8.5.9.1 Theme 1 – Intervention engagement

A decision was taken that BACK-to-FIT™ users should not be restrained in their use of the intervention. Users were therefore not given a strict protocol or recommended programmes to follow within the intervention, this would offer autonomy to the user to select and progress according to their individual needs. A document with general recommendations for exercise frequencies, sets and durations was available to download according to their desire. Hence, participants engaged with the intervention and exercise programmes in different ways according to their preferences and convenience, this was considered as a positive observation. Accordingly, some participants declared that they tended to use the application less often but continued exercises regularly. This is consistent with previous studies (Anderson et al. 2016; Geraghty et al. 2020), where participants tended to visit the application less often once they were familiar with the exercise programmes or once they achieved their goals. Transient engagement and less commitment to using the interventions over time is a common observation (Dennison et al. 2013). Hence adding more levels of exercises, as suggested by the participants during the interviews, might facilitate them to continue their engagement for a more extended period. However, if not designed sensibly this might also have the opposite effect on the intervention, some participants could be overwhelmed with the amount of information and content (Slater et al. 2016; Riis et al. 2018).

For most participants, having autonomy over the intervention helped them continue using BACK-to-FIT™ despite their busy lifestyles, it positively affected their engagement with the programme. These findings comply with recommendations in existing research to incorporate features that support self-regulation. As proposed in self-determination theory (Deci and Ryan 2000), this might allow participants to self-organise their experiences and behaviour, thus promoting the experience of autonomy. Furthermore, these results also support evidence from previous qualitative studies that indicate better engagement (Ahtinen et al. 2009), users' appreciation (Dennison et al. 2013), and effectiveness (Knittle et al. 2018) in PA interventions consisting of features with self-regulation. On the other hand, several participants indicated that they would like more guidance to be implemented in future versions when deciding on the exercise programmes that best suit them. These views are supported in similar studies exploring user experience of digital interventions related to LBP and PA. Geraghty et al. (2020) reported that the addition of physiotherapist support received via a telephone call provided reassurance and motivation for the participants in that group in comparison to the usual care group and usual care plus internet intervention group in their SupportBack trial. However, if implemented as a large-scale intervention accessible to the public, provision of ongoing and long-term support by a physiotherapist or a healthcare professional may not be feasible. Integrating a self-assessment tool that offer solutions such as giving the user an opportunity to contact a physiotherapist, as proposed by Geraghty et al. (2020), to overcome this barrier may provide an opportunity to personalise the intervention content according to the symptoms and clinical presentation of the individuals thus allowing better likelihood of successful LBP self-management.

8.5.9.2 Theme 2 – Facilitators

In contrast to previous findings from existing DHIs on LBP (Svendsen et al. 2020), participants of BACK-to-FIT™ reported smooth navigation between modules and easy access to all modules. Also, simple structure, user-friendly design and quality and clarity of information were the main facilitators. Existing literature emphasises the importance of the simplicity of the interventions to permit a better user experience, particularly in behavioural health interventions, to avoid any barriers to engagement (Baretta et al. 2019). However, a note of caution is due here since this sample represented young to middle-aged individuals with access to devices, likely to have substantial literacy. Views from this study's findings could have been different if the sample was comprised of older adults with less literacy. A lack of literacy and issues with accessing technology are identified as barriers to using interventions and these will reduce engagement (O'connor et al. 2016). Furthermore, it should be noted that one participant who completed the 4-week follow up did not participate in the interviews and four participants did not complete the follow-up programme at all. It is possible that interviewing these participants, who may different socio-demographic backgrounds. could re-balance above discussed findings.

Several BACK-to-FIT™ intervention functions received highly positive feedback. This included animated exercise videos, these were distinguished as a unique feature in BACK-to-FIT™ and were popular with all the participants interviewed. The ability to progress and regress the exercise, availability of instructions for each exercise, convenient access to exercise programmes and the simple exercises that could be followed from any location without specific equipment, were amongst the most popular features of the intervention. Although there is a plethora of health resources and applications on LBP self-management available, the quality and accuracy of the content of these interventions was reported to be poor (Machado et al. 2016). Whilst the interventions have failed to meet the users' needs (Costa et al. 2020), most have not been evaluated rigorously (Machado et al. 2016; Escriche-Escuder et al. 2020). Cost et al. (2020) assessed the most prominent and top 20 LBP websites identified in the search engines across Australia, the United States of America (USA), the United Kingdom and Canada using a 16-item validated scale, they identified that 55% of them rated poor or fair and only one rated as excellent. According to authors the 16-item scale used in the above is the product of another research project which identified information and presentation preferences of people with LBP when designing an online intervention (Nielsen et al. 2014). Machado et al. (2016) reported in their review of 61 identified mobile applications which offered CLBP self-management, none of them were in a trial to evaluate their effectiveness. Furthermore, authors concluded that the overall quality of these applications was low. Accordingly, clinical endorsement and the ability to trust the available online information seems essential to users of LBP digital interventions (O'connor et al. 2016; Svendsen et al. 2020). BACK-to-FIT™ users reported that they felt safe and reassured about the reliability of the content, knowing it was underpinned by research, theory and practice, thus they were more confident in using it. Furthermore, in contrast to the findings stated by Riis et al. (2018) where participants reported problems with understanding the content and finding the context irrelevant, BACK-to-FIT™ users found the content simple to understand and relevant. Although participants of this study did not have a strong preference for further information related to LBP, existing literature reported that additional information had been requested by LBP patients when designing LBP SMIs. This related to topics other than those covered within the BACK-to-FIT™ intervention (Nielsen et al. 2014; Slater et al. 2016; Riis et al. 2018). Some of these preferences include the necessity of definitive diagnosis, use of imaging such as scans and x-rays, having access to support groups and community groups. However, two participants suggested that they would benefit from having more instructions and guidance when selecting the most appropriate exercise to start the exercise programmes. Considering the above factors and the lack of user involvement in the initial development of this intervention, the requisite role of future research to explore opinions on BACK-to-FIT™ among a larger group of users is apparent.

8.5.9.3 Theme 3 – Benefits of BACK-to-FIT™ intervention

Most participants stated they had experienced less pain and engaged in exercise and other physical activities more easily than before as a result of using the BACK-to-FIT™ intervention. Engaging in exercise using BACK-to-FIT™ was perceived to have helped the participants regain control over their pain and improved their confidence and motivation to be active and exercise. This is consistent with Geraghty et al. (2020) findings, participants experienced reassurance, increased awareness of LBP self-management and enhanced motivation. However, contrary to SupportBack (Geraghty et al. 2020) participants who preferred walking and gentle back exercises, most of the participants in this study engaged in the Active back module that included back-specific vigorous exercises rather than the walking module. These discrepancies could be mainly attributed to a difference in the mean age of the two samples, SupportBack had a higher sample mean age in both interventional groups (54.5, 59.3) compared with this study (38.8). In addition, the participants in the Geraghty et al. (2020) study had pre-existing comorbidities and severity of LBP which they reported as barriers to using the intervention. BACK-to-FIT™ users had no other comorbidities and had lower disability, this could explain why the participants in those two studies preferred different modes of exercise.

In accordance with the existing views of the participants of LBP digital interventions (Nielsen et al. 2014; Costa et al. 2020), BACK-to-FIT™ users reported previous experience of failing to obtain desired LBP-related information. This demonstrates a mismatch between information needed and what is available to the public. Participants of this study believed they had enhanced their awareness and understanding of LBP and being active and had access to an array of important information.

BACK-to-FIT^{TM} was tailored to some extent by allowing the participants to select the best modules to fit with their individual needs. O'Connor et al. (2016) claims that tailoring DHIs to an individual's symptoms and functional limitations enhances engagement and thus may improve the effectiveness of the intervention. Individual preference for using tailored DHIs among healthy individuals and people with LBP was also supported (Baretta et al., 2019; Svendsen et al. 2020).

8.5.9.4 Theme 4 – Recommendations

A few technical problems were encountered by participants whilst using the intervention, these included slow loading of the web pages and less readability when using the mobile phone. Svendsen et al. (2020) reported similar findings in their review, they observed IT equipment related problems and difficulty accessing the interventions as common issues among the users of digital interventions in LBP self-management. Although it can be challenging to address potential individual technological glitches, it is important to understand that the level of tailoring discussed above would require stable connectivity and proficient use of technology. This needs to be considered carefully in further development. In this study suggestions for future development included a more tailored application with personal login and the ability to monitor the progress of the exercise programmes for the individual. Participants also suggested several features they would like to see included in a further developed version of the intervention, this included adding audio narration to the exercise videos and developing the intervention into a mobile app.

8.5.10 Normalisation process theory (NPT) framework informing future development

NPT analysis of the BACK-to-FIT^{TM} intervention was undertaken to ensure that what was proposed would be implementable long term (Murray et al. 2010). This is the first digital intervention focused on LBP exercise self-management to conduct an NPT analysis. Although BACK-to-FIT^{TM} functions as a standalone intervention at the moment; NPT analysis helped to observe the comprehensive picture of how it could be implemented on a larger scale or even at the organisational level if proven effective.

Whilst BACK-to-FIT^{TM} encompasses some elements of the NPT framework, the analysis revealed constructs with potential for improvement with future research. During the NPT analysis it was clear that it responded positively to a majority of the items of coherence, cognitive participation and reflexive monitoring constructs indicating a promising individual use of BACK-to-FIT^{TM} intervention. However, when it comes to collective action construct, a number of elements remain inconclusive and require further investigation before confirming the success of the BACK-to-FIT^{TM} intervention. For example, a broader analysis must evaluate how well this intervention could work, should this intervention be recommended by doctors, nurses and physiotherapists as a resource. Also, how well the intervention would fit with the goals of the organisation, how it will affect the existing practice by members of staff and the impact of the intervention on healthcare staff members' workload, labour and responsibility. If the general public endorses the intervention, this may reduce the burden on primary care, mainly by reducing the number of consultations with primary care health care workers including doctors and/or physiotherapists. But again, future research is warranted prior to confirming these benefits. However, it is evident from the literature that even when interventions are favourably perceived by the public, or the patients during evaluation using NPT, it does not guarantee a successful implementation in organisations or among healthcare providers (Farr et al., 2018). Therefore, further intervention analysis using the NPT framework is warranted before future implementation in collaboration with any settings and service providers.

8.5.11 Limitations

A number of limitations of this study can be identified. One of the main limitations of this evaluation study is the small sample size, this prevented using inferential statistics to compare the baseline and follow-up data and to confirm any significant differences in the outcome scores (Jones et al. 2003). Therefore, the improvements observed in all outcomes of health benefits remain statistically uncertain without knowing whether these improvements were random or were a true effect of the BACK-to-FIT^{TM} intervention. Furthermore, a lack of control group in this study also prevented confirming BACK-to-FIT^{TM} intervention's effects as it was not clear if these improvements were the result of time passing rather than due to engaging the intervention. Although this limits any comparison of the findings, evaluating effectiveness of the intervention was not the focus of this preliminary study thus addition of a control group was not essential. Also, participants of this sample had self-reported LBP and were not diagnosed by any healthcare professional. Whilst this could be a disadvantage, it also explains the reason why lower disability levels were reported at the baseline. However, early intervention to reduce pain and maintain the level of PA and exercise is highly recommended to prevent long-term LBP associated disability and reduce the recurrence of LBP (Kongsted et al. 2015; Buchbinder et al. 2018; NICE 2019). Therefore, it was expected that BACK-to-FIT^{TM} intervention would grant the opportunity to people with early, less disabling LBP to be active and proactive in their recovery instead of spending months waiting to be seen by a healthcare professional.

Another sample-related limitation is the characteristics of the participants (Bland 2015). All the study participants were between the ages of 25 – 50 and employed, thus limiting the generalisability of the results in younger and older individuals with LBP. However, this representation aligns with previously found associations of LBP as the most common cause of sick leave due to any musculoskeletal problem and high rates of disability among the working population (Buchbinder et al. 2018; Hartvigsen et al., 2018). Therefore, BACK-to-FIT^{TM} intervention has the potential to be adopted for use in the workplace, not only as an LBP self-management intervention but also as a LBP prevention measure.

Other than age, demographic factors such as ethnicity, economic status and educational attainment significantly influence the access and engagement of DHIs (O'connor et al, 2016). Being a small pilot study, these factors were not explored and were beyond the scope of this study. The small sample size of this study was not powerful enough to tackle this aspect and will be investigated further as part of a future evaluation plan. The study was advertised, and participants were recruited online, thus potentially reaching to regular users of the internet, computers and other electronic devices. Therefore, it is possible that users had good existing digital literacy, which is an advantage in using any digital intervention.

Whilst this may be seen as a disadvantage for the generalisability of the results of this study, developing digital interventions needs potential early adopters to even scale an intervention before it can be widened to other populations in need of such technologies (Labrique et al. 2020).

Overall, this preliminary evaluation has revealed promising outcomes over the four weeks, however it warrants more research to confirm these outcomes and also to explore potential implications of larger scale implementation among people with LBP as well as collaboration with healthcare professionals. Future research and clinical implications of BACK-to-FIT™ intervention are discussed later in this thesis, as a separate section in Chapter 9.

8.6 Conclusion

From this preliminary evaluation study, it appears that the BACK-to-FIT™ intervention developed in this PhD thesis has good to excellent usability, high technology acceptance and the potential to offer several health benefits. These include improvements in pain, disability, exercises self-efficacy and PA levels. User experience evaluated qualitatively at the end of 4 weeks of using the intervention also demonstrated promise with participants feeling reassured, reporting enhanced confidence and perceiving improvements in pain, disability and PA levels. Users engaged in various ways with the intervention and appeared to display an autonomous self-regulatory process supported by the convenient structure of the intervention.

As a preliminary study with a small sample, no control group and a short follow-up period, caution must be exercised when interpreting these preliminary results. Nevertheless, BACK-to-FIT™ offers positive data that can be utilised in future development and evaluation of the intervention. This is particularly useful for early intervention, targeting individuals not yet seeking medical help but, with early symptoms which they perceive as limiting their daily lives and function.

In comparison to the outcomes of this short follow-up study, it is evident that a majority of existing DHIs have failed to achieve overall superior outcomes in the long term, regardless of the technologies and the complex development processes utilised. Whilst the complex nature of multifactorial LBP could explain this, it warrants further exploration to understand how DHIs could be improved to meet the biopsychosocial needs of the individuals to achieve better outcomes.

Chapter 9: Overall Summary

9.1 Introduction

The overall aim of this thesis was to develop and explore the potential role of a novel digital intervention in facilitating optimum and tailored ESM in people with LBP. This process involved designing an evidence, theory, and practice-based intervention, producing the intervention and finally conducting a preliminary evaluation of the intervention. According to Hoddinott (2015), an intervention development study describes the rationale, decision-making processes, methods and findings from the idea or inception of the intervention until it is ready for formal feasibility, pilot or efficacy testing before a full trial or evaluation. This PhD thesis followed the MRC guidance (Craig et al. 2008) for developing complex interventions as the critical overlying framework. Although this study was planned and initiated before publishing the updated MRC guidance (Skivington et al. 2021), key recommendations and considerations advocated by the updated guidance were considered throughout the project. To the author's knowledge, this is the first study to develop a DHI to facilitate ESM in LBP according to MRC guidance and to use a rigorous development process supported by evidence, theory and practice. It is believed that the iterative process discussed in this thesis will help other researchers to develop effective digital resources for users.

In summary, the project consisted of three main phases: Phase 1 identified the evidence base and generated the first research question, this was answered by conducting a systematic review and a meta-analysis (Chapter 4). The second phase aimed to identify and/or develop a theory, consequently generating the second research question. Two studies were conducted to answer the second research question, these involved a focus group study (Chapter 5) as the first and a mixed methods survey (Chapter 6) as the second. The logical next step was intervention modelling, representing the study's phase 3 and consisting of two parts: Part 1 – Producing the intervention, a web application named BACK-to-FIT^{TM} (Chapter 7) and Part 2 – preliminary evaluation of BACK-to-FIT^{TM} (Chapter 8).
This penultimate chapter discusses the aims and the headline results of each phase. It then compares existing digital interventions with a focus on ESM in people with

LBP and finally, the chapter outlines the overall strengths and weaknesses of this study.

9.2 Phase 1

The preliminary literature review was conducted, the important question was to find out the value of the exercise components within LBP self-management. Accordingly, a systematic review and meta-analysis were conducted to answer the research question: "What is the effect of LBP self-management interventions with exercise added?”.

9.2.1 Aims

The aims of this systematic review and meta-analysis were as below.

- to estimate the effect of SMIs with exercise components on pain and disability at short-, intermediate- and long-term follow-up in patients with CLBP.

- to summarise the characteristics of the SMIs with exercise including content and mode of delivery.

9.2.2 Headline results

- There is low-quality evidence which suggests that SMIs with added exercise components have moderate but significant positive effects on both pain and disability in individuals with CLBP across short-term, intermediate and long-term periods compared to usual care.
- A, considerable heterogeneity was observed in both content and mode of delivery of SMIs reviewed.
- A majority of the existing SMIs are predominantly focused on the cognitive behavioural approach and had paid no or minimal attention to incorporating exercise and PA in their programmes.
- Most of the studies did not report details of exercise prescription such as frequency, intensity, or duration of the exercises.
- Tailoring of exercise to meet the needs of the individuals was not always considered within the studies that comprised exercise programmes. Few studies, that tailored their exercise programmes used different criteria to tailor

them including job type, self-reported outcome measures and physical assessment.

- SMIs were based on the premise of several cognitive-behavioural models including the model of chronic pain, chronic disease self-management model and cognitive behavioural approach.
- Whilst some of the SMIs employed face-to-face approaches, others were delivered using the internet.
- None of the studies involved users in the development process of their interventions or had pre-tested the interventions with users.

9.3 Phase 2

During this phase a focus group study with musculoskeletal physiotherapists and a survey with clinicians and researchers were conducted to answer the research question “what are the key components, as recommended by the expert clinicians, required within a digital exercise self-management intervention to encourage people with LBP to be physically active and exercise and how to tailor them?”

9.3.1 Aims

The aims of the two studies are shown below.

- To explore musculoskeletal physiotherapists’ practice and perspectives on the key components required in a self-management intervention to encourage people with LBP to be physically active and exercise
- To identify the key components of the assessment recommended by experts to tailor an ESM programme for people with LBP.

9.3.2 Headline results

9.3.2.1 Focus group study

- Thematic analysis of focus group findings revealed four overarching themes, these included 1) A holistic approach to the assessment 2) Exercise and PA based management 3) Education and awareness 4) Optimum ESM and digital interventions.

- All physiotherapists who participated in the study appeared to adopt an evidence-based approach and agreed with current guidelines for managing LBP.
- The importance of a holistic, individualised and biopsychosocial approach in the assessment and management of LBP patients was emphasised.
- Physiotherapists used both general and specific exercise approaches in managing their LBP patients.
- An inconsistency in the use of LBP classification systems to deliver more targeted exercises was noted among the physiotherapists.
- Whilst acknowledging the catalyst role a digital intervention could play in improving ESM, they also highlighted the importance of integrating exercise and education components within the intervention.
- Physiotherapists showed agreement in general, but some different viewpoints were also evident regarding the use of digital interventions in ESM for people with LBP.

9.3.2.2 Survey study

- Agreement of 80% or more was achieved using seventeen questions in the history taking component, these included six items from the LBP domain, one from general health, four questions in the work and lifestyle domain and six from the exercise and PA planning domain.
- Out of twenty-one tests in the physical assessment component, only five tests were identified by the participants as important when deciding on a self-management programme and achieved agreement of 80% or more. These included pain aggravating-easing factors, forward bending, sit to stand and lumbar spine ROM.
- Participants also suggested new items to be added in history taking and the physical assessment component. Among these were eight items in the history taking component and three tests in the physical assessment component.

9.4 Phase 3

During this phase, a prototype version of the intervention, BACK-to-FIT^{TM} web application, was developed and its outcomes were evaluated in a preliminary evaluation study to answer the third research question "What is the preliminary user experience, usability, acceptability, and potential health benefit of BACK-to-FIT^{TM}" Findings from both phases 1 and 2 informed the development of the BACK-to-FIT^{TM} design and its content. A range of intervention functions identified through literature and focus group discussions with physiotherapists in phase 2 were used appropriately when designing the application.

9.4.1 Aims

Aims of this phase were as below.

- To develop a prototype version of the intervention – BACK-to-FIT^{TM} intervention by integrating findings from phase 1 and 2.
- To obtain preliminary evidence of usability, technological acceptability, potential health benefits and overall user experience of the BACK-to-FIT^{TM} intervention.

9.4.2 Headline results

- Sixteen participants were recruited and twelve completed the 4-week follow-up and evaluation.
- The sample had a mean age of 38.8 years and a mean BMI value of 26.3. Most of the sample (66%) were employed in desk-based jobs.
- The baseline mean scores for pain intensity, disability, exercise self-efficacy and total level of PA were 4.1 (NPRS), 15.33 (ODI V2), 37.5, 1455 MET/minutes per week respectively.
- The quantitative investigation of the usability of the BACK-to-FIT ^{TM} intervention using SUS (Brooke 1996) showed an above-average mean score of 81.8/100. According to Bangor et al. (2009) this score falls within the good to excellent category.
- Evaluation of technology acceptance of BACK-to-FIT^{TM} using a questionnaire based on TAM3 demonstrated positive results across all eight constructs and

achieved mean scores > 5 (highest score possible =7). The highest mean score reported for computer anxiety (6.6) indicated that participants were comfortable using the internet and the lowest mean score reported for subjective norm (5.0) denoted a lesser perception on other people's thoughts on whether they should use BACK-to-FIT^{TM}.

- According to follow-up evaluation the mean pain intensity dropped by 1.89 points on the NPRS. This denoted a percentage drop of 45.43% compared with the baseline value.
- LBP related disability was dropped by 6.33 points on the ODI V2 at the end of the follow-up period compared with baseline and showed a percentage improvement of 41.29%.
- Self-efficacy was enhanced by 22.17 points compared with the baseline score and marked an improvement of 59%.
- Moderate, vigorous and total PA levels were also improved by 366, 268 and 483 MET-minutes/week respectively. However, the mean value for walking at the follow-up evaluation showed a slight decline by 152 MET-minutes/week compared to the baseline.
- Four broad themes emerged from the thematic analysis of the interview data related to the user experience of BACK-to-FIT^{TM}; intervention engagement, facilitators, benefits of the application and recommendations for further improvement. Whilst overall user experience was positive, users also provided feedback on the areas that needed further refinement. Conducting an NPT analysis of interview data of the user experience was helpful to identify already existing potentials of BACK-to-FIT^{TM} intervention if implemented on a larger scale and most importantly disclosed several aspects for further modifications in the methods of delivery and application.

9.5 Strengths and limitations

Overall, this project had several strengths.

Strengths:

- BACK-to-FIT^{TM} intervention was developed following a vigorous process and was informed by evidence, practice and theory. It was the first LBP self-management intervention to follow MRC guidelines in the development process conclusively.

- Furthermore, unlike most of the other existing digital interventions that focused on LBP self-management with a premise of CBT (Buhrman et al. 2004; Chiauzzi et al. 2010; Geraghty et al. 2018; Higgins et al. 2020) and LBP education (Madill et al. 2019; Hodges et al. 2020) the context of BACK-to-FIT^{TM} intervention was predominantly based on exercise and PA engagement but also included LBP education and several BCTs.
- Another key strength was the use of a mixed methods approach. This thesis answered several research questions during each phase, each of these questions demanded different methodological approaches. Therefore, a mixture of both qualitative and quantitative methods including quantitative questionnaires, mixed methods questionnaires, focus groups and individual interviews were used appropriately to better answer the research questions.
- Whilst a majority of existing LBP self-management digital interventions are available only in mobile apps and cannot be accessed without installing them on a device, BACK-to-FIT^{TM} was accessed by using either mobile devices or computers with the internet to gain immediate access to relevant advice and guidance.
- Another significant strength of this project was the use of NPT as a framework for individual interviews, the NPT analysis was conducted on the implementation of BACK-to-FIT^{TM}. None of the existing LBP self-management interventions have been analysed using the NPT to consider the normalizing of these interventions or their broader use in collaboration with others such as health professionals.

Whilst this project has many strengths, it also has several potential limitations.

Limitations:

- The overall stakeholder involvement in the development process was limited to healthcare professionals and researchers. Only physiotherapists were involved in the focus group study and the majority of the participants of the survey study were also physiotherapists. The scope of this study was limited by this, also it did not include end users to obtain their perspectives and explore their expectations of the intervention, as seen in some existing studies (Hodges et al. 2020). However, the above limitations have been reduced by considering the relevant literature extensively when using these data to determine the content of the BACK-to-FIT™ intervention.

- There is also limited use of the findings from the survey study in the overall design of the developed intervention. The rationale for the survey study in phase 2 was to investigate the capacity to tailor the ESM delivered through this intervention. Following the focus group study, it was apparent that a thorough assessment including subjective and objective elements would be the key contributing factor in tailoring exercise and self-management advice for people with NSLBP. Although the survey study in phase 2 produced some important findings related to LBP assessment, integrating an assessment tool was beyond the scope of this PhD study. However, although a self-assessment tool was not embedded in the intervention at this stage, some of the findings of this study implicitly contributed to the intervention content and the design. For example, the subjective assessment component revealed a high agreement on the importance of understanding 'access to exercise equipment and facilities. Accordingly, when designing the exercise programmes of the BACK-to-FIT™ intervention, an attempt was made to include exercises people can engage in with no or minimal use of special equipment.
- This project also has several methodological limitations, these include low response rate of the survey study, short follow up duration, the lack of a control group, the small sample size and the limited representativeness of the sample in the evaluation study.
- Furthermore, the frequency or the nature of the user engagement of the BACK-to-FIT™ intervention was not evaluated in the final study and this emerges as a key limitation of this project. Although it was planned originally to collect website usage statistics, this was not implemented due to a technical error that occurred during the setting up of the webpage. However, during individual interviews users were asked about their engagement how

often they visited the website. However, they were not instructed to keep a record of their website visits or the exercises they did.

- One of another the limitations in the intervention design included failure to reach people who did not have access to digital devices and the internet. Furthermore, despite gathering data relevant to tailoring the application with a potential self-assessment tool, it was not possible to develop this component at this stage to be included in the prototype version.
- Although a face-to-face data collection procedure was planned originally, due to the impact of COVID-19 pandemic and related restrictions, the last phase's data collection was executed online as opposed to using face-to-face methods. However, the overall impact of this on the project was minimal.

9.6 Future Recommendations

This project was a preliminary study which endeavoured to present a digital ESM intervention for people with LBP to help them exercise and be active. However, the BACK-to-FIT™ intervention would further benefit from multiple research and development processes in future as follows:

- Further research should be conducted to explore the other potential means of integrating a self-assessment into the intervention to deliver a more tailored programme.
- According to the new MRC guidance (Skivington et al. 2021) modification or the refinement of the intervention should be considered within each stage of developing and evaluation of a complex intervention. Accordingly, refinement of the BACK-to-FIT™ intervention should be considered in order to accommodate some of the suggestions made by users before proceeding to a scaled-up evaluation. Few examples for some of these modifications could be integrating a more personalised approach by having individual accounts they can login into, adding audio narration to exercise videos, converting the application to a mobile app.
- Following the development process of the MRC guidance (Craig et al. 2008; Skivington et al. 2021) which was used for this project, as the next step it would have been appropriate to conduct a pilot study aiming to assess the

feasibility, estimate the recruitment and retention rates and calculate appropriate sample sizes for a larger scale intervention evaluation study. It will be important to consider addressing the methodological limitations encountered during the preliminary evaluation study of this project.

- MRC guidance also advocates stakeholder involvement during each stage when developing and evaluating an intervention. Given this and also considering the findings of the NPT analysis of the BACK-to-FIT^{TM} intervention it is imperative to conduct research primarily focusing on the collective work construct of the NPT framework. If a decision is made to implement the intervention in collaboration with primary healthcare settings, in addition to assessing the feasibility and acceptability in a larger sample of the general public it will be essential to obtain feedback from primary care health professionals on how this intervention could work in their work setting and its effect on their work. Should this research be explored successfully it will give an indication of the feasibility of a larger scale implementation collaborating with the wider general population and healthcare professionals from primary healthcare settings.
- In addition, further research is crucial to explore the reasons behind the commonly seen poor outcomes of DHIs focused on LBP self-management and to understand individual, social and environmental barriers leading to poor exercise and PA engagement in people with LBP. This more comprehensive understanding will be instrumental when refining interventions like BACK-to-FIT^{TM} to deliver more tailored ESM solutions to people with LBP to help them to be active and exercise.

Chapter 10: Conclusion

There is ever increasing use of digital technologies including internet resources to support self-management of LBP. In hope to help themselves, many people with LBP use and search the internet daily to find appropriate LBP self-management advice and resources including appropriate exercise. Yet the available resources lack evidence and are built with little to no involvement from stakeholders, limiting its appropriateness and scale up potential. In addition, despite that PA and exercise tailored to individual needs and capabilities is recommended as the mainstay LBP self-management in clinical guidelines globally, LBP self-management tends to mostly include psychological support and pain education with exercise and physical activity recommended but otherwise left unaddressed. This points to a clear need for evidence based digitally enabled SMIs that help people with LBP access exercise tailored to their needs and capabilities, particularly given evidence of increasing prevalence and associated disability.

This PhD project's overall aim was therefore to develop evidence, theory and practice based digital intervention prototype to facilitate PA and ESM in people with LBP called BACK-to-FIT™.

The development process was based on MRC complex intervention development guidance and consisted of multiple studies including current evidence review to evaluate the effects of SMIs with exercise components added, focus groups with physiotherapists and survey with a wider group of stakeholders including clinicians, and research experts. To author's knowledge this is the first DHI focused on SMI in LBP that followed a rigorous development process according to the MRC complex intervention guidance.

Phase 1 systematic review and meta-analysis clearly demonstrated that despite the low-quality evidence, SMIs with exercise add value in reducing pain and disability of people with LBP.

Phase 2 was able to inform the development and design of BACK-to-FIT™ application by identifying key intervention functions and features required within the application and approaches to tailor them.

Phase 3 then used the information from the previous phases to develop an initial prototype designed to offer people with LBP structured exercise routines that can be modified by each individual user as their condition and exercise tolerance changes over time thus offering means of tailored ESM to promote ongoing engagement. The initial evaluation of the BACK-to-FIT^{TM} intervention demonstrated promising results in usability, technology acceptance and health benefits (pain, disability, exercise self-efficacy, level of PA).

Those promising early results merit further development and evaluation of the BACK-to-FIT^{TM} intervention either as a stand-alone platform or an adjunct to other SMIs. However, it needs to be acknowledged that this was a preliminary evaluation with a relatively small sample, no control group and relatively short follow-up period. Nevertheless, this was an important step in the BACK-to-FIT^{TM} development presenting opportunities for further development to maximise BACK-to-FIT^{TM} implementation and scale up. As the next step it is suggested to conduct multiple research projects with rigorous research methods to assess its feasibility and to complete the preparatory work for an extensive evaluation of the application. Additionally, further research should include deeper exploration of individual, social and environmental barriers, and opportunities for individuals with LBP to adopt exercise and PA behaviours in a range of settings including work, community and home setting. This will aid in the development of BACK-to-FIT^{TM} self-assessment tool and resources to deliver more targeted and individualised ESM solutions.

This PhD thesis adds important knowledge and learning to the evolving research and development of DHIs to support self-management of people with recurrent and long-term conditions. In particular, this thesis demonstrated that stakeholders can be successfully engaged in the process of development resulting in an early prototype demonstrating promise in empowering people to engage in PA and exercise.

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Appendix 1: Publication

Rathnayake, A.P., Sparkes, V., Sheeran, L., 2021. What is the effect of low back pain self-management interventions with exercise components added? A systematic review with meta-analysis. Musculoskeletal Science and Practice, 56, p.102469.

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Appendix 2: A summary of the existing DHIs focused on LBP self-management

Study / Intervention name	Platform	Study design	Sample	Intervention	Control	Assessment and follow up	Primary outcomes	Secondary outcomes	Results
Amorim et al, 2019 / IMPACT	Mobile app	Pilot RCT	>18 yrs, Chronic CLBP (> 12 weeks), discharged from physiotherapy but still symptomatic (at least 3/10 NRS)	n = 34, mean age = 59.5 , mean BMI = 28.9 PA & sedentary behaviour information booklet + advice to stay active + 1 face-to-face coaching session to develop tailored PA plan and 12 sessions over the phone + supported by an activity tracker (Fitbit), and mobile application to monitor participants' goals and physical activities	n = 28, mean age = 57.1 , mean BMI = 27.2 Standard care (PA information booklet and advice to stay active)	Baseline Weekly 6 months	Care seeking, pain levels and activity limitation, RMDQ, Assessment of feasibility	MVPA measured with IPAQ, PA data from accelerometer (Actigraph GT3X+), GAS	Positive trends towards reduced care seeking and activity limitation in the intervention group compared to control without any statistical significance. Intervention group significantly reported more walking and attained more goals compared to controls. No significant difference in PA data or IPAQ data. Participants were largely satisfied with the intervention.
Buhrman et al, 2004	Webpage	RCT	18-65 yrs Chronic (> months) back pain	n = 22, mean age = 43.5 A 6-week internet-based cognitive behavioural self-help treatment with telephone support including treatment consisted of education, cognitive skill acquisition, behavioural rehearsal, generalization and maintenance and exercises with individualized graded activity basis and structured information.	n = 29, mean age = 45.0 Waiting list	Pre-treatment Post-treatment 3 months	CSQ	MPI, PAIRS, HADS, pain diary,	Intervention group showed significant improvements in catastrophizing, control over pain and ability to decrease pain. No significant difference in MPI, PAIRS, HADS or pain intensity.
Chhabra et al, 2018 / Snapcare	Mobile app	RCT	Mechanical LBP > 12 weeks with or without radicular symptoms, > 18 yrs	n = 45 mean age = 41.4, mean BMI = 23.15 Usual medicine prescription + Snapcare App including daily activity goals (including back and aerobic exercises), aimed at motivating, promoting, and guiding the participants to increase their level of PA and exercise adherence.	n = 48, mean age = 41.0, mean BMI = 23.54 Usual prescription + recommended level of PA (including home exercises	12 weeks post intervention	NPRS, MODI	Daily PA, CSS (Current Symptom Score)	Both groups had reduced levels of pain and disability, Significant BGD for drop of disability in intervention group, No significant BGD for pain.
Chiauzzi et al, 2010 /	Interactive website	RCT	Back pain for at least 10 days each month for	n = 104, mean age = 47.3 2 weekly sessions across 4 weeks.	n = 105, mean age = 45.0	Baseline 4 weeks 3 months	ODQ, BPI, CPCI, PGIC, DASS, PSEQ, PCS, FABQ		Intervention group showed significantly lower stress, increased coping self-

PainACTION-Back			at least 3 consecutive months immediately prior to the study	Website is based on CBT and SM principles including 1) collaborative decision making 2) CBT to improve self-efficacy, manage thoughts and mood, set clinical goals, problem-solving, and prevent pain relapses; (3) motivational enhancement through tailored feedback; and (4) wellness activities to enhance good sleep, nutrition, stress management, and exercise practices. Tailored informatio interactive tools, personalized assessments, and articles.	Email of back pain guide	6-months			statements, greater use of social support and clinically significant differences in current pain, depression, anxiety, stress, and global ratings of improvement.
Geraghty et al, 2018 / SupportBack	Website	3 arm-randomised controlled feasibility trial	> 18 yrs, Current LBP (within last 2 weeks)	n = 29 Intervention + Physiotherapist support , mean age = 59.3 6 weekly sessions, including rationale for PA, goal setting options including automatically tailored exercise options, reviewing, and amending activity goals with automatic feedback, patient education topics on LBP and self-management. + 3 telephone calls (up to a total of 60 mins) by a physiotherapist to provide support and encouragement to participants to use the intervention.	n = 28 Usual care, mean age = 60.3 n = 30 Intervention + Usual care, mean age = 54.5	Baseline 3 months	Feasibility of the trial design (recruitment, adherence and retention	RMDQ, NRS, the number of troublesome days STarT Back tool, PCS, IPAQ-SF, TSK	Adherence to the intervention was higher in the physiotherapist-supported arm, compared to stand-alone internet intervention. Intervention + physiotherapist support arm also showed greater improvements in RMDQ, NRS, and the number of troublesome days compared to the other 2 groups.
Higgins et al, 2020 / Pain EASE	Website	Single arm feasibility and preliminary efficacy study	Moderate LBP (ie, NRS pain intensity scores of ≥4) for ≥3 months	n = 58, mean age = 50.9 CBT based website consisted of 10 pain coping skills modules including Pain education, Setting personal goals, Planning meaningful activities, PA, Relaxation, Developing healthy thinking patterns, Pacing and problem solving, Improving sleep, Effective communication AND Preparing for the future. Also included optional self-monitoring forms, progress tracking and resources section with links to education and skills about chronic pain and comorbid problems	-	Baseline 10 weeks	WHYMPI	POMS, NRS, MOS sleep scale, MFI, BDI, Feasibility Measures (Credibility, Satisfaction, and Usability) questions	Significant improvements noted post-intervention in pain interference (WHYMPI) score, BDI, and total mood disturbance. Majority were very or moderately satisfied with the programme. Pain interference

Hodges et al, 2021 / MyBackPain	Website	RCT	> 18 yrs, LBP of any duration, access to internet	n = 214, mean age= 48.1 , mean BMI =27.7 LBP resource with education elements on red flags, reassurance, staying active, unnecessary investigations, principles of management of LBP and disease knowledge	n = 226 Self-directed use of internet – visited LBP websites to seek information weekly recorded	1 month 3 months 6 months 12 months	Health Literacy Questionnaire,	Health Literacy Questionnaire, quality of treatment choices, VAS, RMDQ	Access to MyBackPain was not superior to unguided internet use on primary outcomes, No significant or consistent between group differences in secondary outcomes
Huber et al, 2017/ Kaia	Mobile app	Retrospective analysis	Users of the Pro version subscribed before March 2017	n = 180, mean age = 33.9 Comprises of Back pain-specific education physiotherapy/physical exercises, and mindfulness and relaxation techniques. Exercises and content were tailored according to the self-test results and allocated from a pool of 120 exercises based on an algorithm. A pool of 145 exercises is subdivided into 5 classes and within each class are ranked depending on exercise difficulty and strain.	-	Baseline 4 weeks 8 weeks 12 weeks	NRS		Substantial dropout over tim is noted. Results show a significant pain reduction over time through using the app; and an even better outcome for completers of th programme. Subgroup analysis of acute, subacute, or chronic classification revealed no significant main effect of group (*P*>.30) on the reduction of pain.
et al, 2015 / FitBack	Mobile/ web intervention	RCT	CLBP patients from public	n=199 An 8-week multiple-visit programme based on self-tailored cognitive-behavioural approach, designed aiming to encourage to adopt appropriate pain prevention behaviours + 8 program emails with content and prompt related to CLBP self-management. Instructional videos on specific strength and stretching exercises tailored by job type.	n=199 Usual care n = 199 alternative care group: (initial email + 8 reminder emails with d links to 6 websites about NLBP resources.	Baseline 2 months 4 months	Do you have low back pain now? (yes/no). MPI, Dartmouth CO-OP scale, WLQ, PAM, SOPA short version, Stanford Presenteeism scale, Prevention-Helping Behaviours questionnaire, Knowledge, self-efficacy and Catastrophizing of Pain questionnaires, behaviour intensions, User Satisfaction questionnaire, SUS, Understanding and Implementation Survey,		Intervention group showed greater improvement compared to the control group in every comparison of the critical physical, behavioural, and worksite outcome measures at 4-months and performed better than the alternative care group on current back pain, behaviour, and worksite outcomes at 4-months and greater improvement compared to both the control and alternative care groups at 4-months on patient activation, constructs of the TPB, and attitudes toward pain.

Madill et al, 2019 / Take Back Your Back	iPad app	Pilot study	At least moderate-severity CLBP every day or almost every day for three months, ≥60 yrs	n = 30, mean age = 75.2 An app to 1) efficiently screen for important CLBP conditions, 2) provide personalized patient education based in responses, and 3) facilitate meaningful, focused patient–provider communication regarding treatment targets and expectations.	-	Immediately following the use of the app	Usability and utility questionnaire designed for the study		App was rated highly for usability (9.6/10) and utility (8.9/10). 82.1% agreed app would help them communicate with their doctor and that it gave them useful information about potentially harmful or unnecessary interventions such as opioids and imaging. Participants were able to successfully use the application without assistance.
Krein et al, 2013	Pedometer + website	RCT	Back pain >3 months, self-reported sedentary lifestyle (<150 minutes of PA per week)	n = 111, mean age = 51.2, mean BMI = 30.6 Consisted of uploading pedometer, a website that provided automated goal setting and feedback with weekly email reminders, targeted messages, and educational materials, and an e-community. Website provided graphical and written feedback about the progress and motivational and informational messages. Also included back class materials and a video of specific strengthening and stretching exercises.	n = 118, mean age = 51.9 , mean BMI = 31.6 Usual care + pedometer only	6 months 12 months	RDQ, MOS	NRS, pedometer data for step-count, FABQ- PA subscale, Exercise Regularly Scale	A significant improvement in disability at 6 months in the intervention group but not at 1 months but showed lower scores compared to control. Improvements in pain, MOS and fear avoidance in PA but not statistically significant.
Pozo-Cruz et al, 2012	Website	RCT	18-64 yrs, Subacute NSLBP with or without pain radiating to 1 or both legs, > 6 weeks < 12 weeks, physically inactive office workers with minimum 6 hours work per day at a	n = 50, mean age = 46.8 engagement in the web-based program at work site for 11 minutes each day, 5 days a week for 9 months. Programme involved viewing 2-minute video of postural interventions, followed by a 7-minute video of the daily exercises, and finished with a repetition of the postural interventions. Each daily session included strength, flexibility, mobility, and stretching exercises	n = 50, mean age = 45.5 Standard care (all existing non–web-based interventions offered by the University of Extremadura's Preventive Medicine Service)	Baseline 9 months	RMDQ, EQ-5D-3L	Shirado-Ito lumbar and abdominal tes for trunk muscle endurance, number of episodes of LBP	Significant improvements in disability score (RMDQ), quality of life EQ-5D-3L and in the number of episodes of LBP were shown in the intervention group compared to the control group.

			computer workstation					
Rabbi et al, 2018 / MyBehaviorCBP	Mobile app	Pilot study	Chronic (> 6 months) back pain	n = 10 Automatically generates physical activity recommendations based on an individual's past behaviour using sensor data and self-reported physical activity logs. App comprised 2 modules including routine behaviour recognition and recommendation generation modules	-	Daily 5 weeks	App usage and Physical activity log, Daily evening survey, Exit survey to measure early-efficacy, and acceptability	Users found the app easier to adopt and recommendations were actualized more with an increase in approximately 5 minutes of further walking per day compared to the phase without the app. No significant reduction of pain.
Sandal et al, 2021/SELFBACK	Mobile app	RCT	> 18 yrs, NSLBP with 6 points or higher on RMDQ	n = 232, mean age = 48.3 Artificial intelligence based app with decision support system that provides weekly tailored self-management recommendations including Physical activity (number of steps strength and flexibility exercises), educational messages , general information about low back pain access to several tools (goal setting, mindfulness, pain relieving exercises and sleep reminders) that participants could use at their convenience	n = 229, mean age 46.7 Usual care	Baseline 6 weeks 3 months 6 months 9 months	RMDQ , FABQ, PSEQ, BIPQ, PSEQ	The percentage of participants with at least 4 points improvement in RMDQ was 52% in the intervention group and 39% in the control. But between group difference of pain-related disability was small and of uncertain clinical significance.
Schulz et al, 2007 / ONESELF	Website	Controlled trial	18 – 65 yrs, LBP > 3 months	n = 20, mean age = 45.4 Website consisted of tailored resources including : the library with educational material on the nature and management of CLBP, The gym with videos and description of exercises to be selected after discussion with the doctor / physiotherapist , a forum and chat-rooms, "the experts say that" and "The specialists answer that" with videos and electronic materials on topics proposed by health professionals on the basis of patients' frequently asked questions, "tell a story",	n = 15, mean age = 41.1 Usual care	Baseline 5 months	Validated questionnaire including revised RMS, NRS and in the intervention group perceived general and specific utility of the website and the level of comprehensibility of the information provided.	Intervention group suggested a positive trend towards a low intensity of back pain; an increase in physical activity; a reduction in both medical consultation and the use of painkillers, and a gain in declarative and procedural knowledge.

				where users can share their stories and comment on stories presented by other users.					
Shebib et al, 2019	App in a tablet computer	RCT	> 18 yrs, Chronic (> 6 weeks) NSLBP	n = 113, mean age = 43 mean BMI = 26 A 12-week digital care programme consisting of exercises, CBT, education articles, peer support discussions, activity and symptom tracking through a digital app. Exercises included sensor-guided physical therapy exercises and aerobic activities; 3 times per week.	n = 64, mean age = 43, mean BMI = 26 Usual care + 3 digital education articles	Baseline 12 weeks	MvK scale, ODI	VAS, Surgery interest	Pain and disability significantly improved, and surgery interest has reduced significantly in the intervention group compared to the control group.
Toelle et al, 2019/ Kaia	Mobile app	RCT	18 – 65 yrs, NSLBP with a mean pain intensity of ≥ 4 on NRS > 2 weeks	n = 53, mean age = 41 mean BMI = 24.4 Comprises of Back pain-specific education physiotherapy/physical exercises, and mindfulness and relaxation techniques. Exercises and content were tailored according to the self-test results and allocated from a pool of 120 exercises based on an algorithm. A pool of 145 exercises is subdivided into 5 classes and within each class are ranked depending on exercise difficulty and strain.	n = 48, mean age = 43, mean BMI = 25.4 6 weekly individual face-to-face physiotherapy sessions comprising tailored exercises and manual therapy.	Baseline 6 weeks 12 weeks	NRS	HFAQ ,GCPS VR-12, MQS Frequency of app use, number of completed sessions	Both groups improved significantly over the 12 weeks and significant low pain intensity in the intervention group compared to the control only at 12 weeks. No significant between group differences or correlations for other outcome measures
Yang et al, 2019 / Pain Care	Mobile app	RCT	≥18, with confirmed diagnosis of CLBP (>3 months)	n = 5, mean age = 35.0 Physiotherapy + Self-management programme through the app. Individualised exercises prescribed by the physiotherapist + Reminders (that can edit by subjects) for exercises for personalised time slots and pain diary sent via the app. Also the subjects could input the pain intensity, activity levels and remarks after each exercise and retrieve and share own data through a website.	n = 3, mean age = 50.3, Physiotherapy (manual therapy, electrophysical therapy, and traction) only	Pre-treatment 2 weeks 4 weeks	VAS, PSEQ, RMDQ, SF36		Intervention group showed significant improvements in PSEQ, RMDQ, SF36-Bodily Pain and SF36-Mental Health.

Appendix 3: The participant recruitment email - Phase 2: Focus group study

Email invitation for Focus groups

[redacted]

[redacted]

[redacted]

[redacted]

EXERCISE AND PHYSICAL ACTIVITY FOR LOW BACK PAIN SELF-MANAGEMENT

(PhD study by Akushla Rathnayake)

We are looking for qualified **Physiotherapists** to take part in a **focus group** about **low back pain self-management involving exercise and physical activity**.

Please find enclosed study information sheet for further details.

If you would like to participate please contact Akushla on SenarathA@cardiff.ac.uk / 07492404457

...

Reply | Reply all | Forward

Appendix 4: The participant information sheet - Phase 2: Focus group study

PARTICIPANT INFORMATION SHEET

Study Title:

Back-to-Fit™ : A web-based self-management for low back pain –

Phase II - Focus groups

Invitation paragraph

- This is an invitation to be involved in our study. A full description of the study aims, and its contents are described in detail in this sheet. Before you decide if you want to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information carefully.

Who is organizing and funding the research?

- This study is Phase II of the Back-to-Fit™, a web-based self-management for low back pain study, which is being conducted by Akushla Rathnayake, a PhD student at Cardiff University. This study is supervised by Dr Liba Sheeran and Dr Valerie Sparkes and funded by Cardiff University Biomechanics and Bioengineering Centre, Versus Arthritis. The data of this study could be used in the development of the exercise feature of the Back-to-Fit™ online intervention. Contact us if there is anything that is not clear or if you would like more information. Discuss it with others if you wish before you decide whether or not you wish to participate.

What is the purpose of this study?

- The aim of this study is to develop a self-management programme to help people with low back pain to be active and exercise. We wish to obtain your opinion and ideas about the plan for the self-assessment and exercise/activity prescription.
- This information will be used to inform the development of a new web-based intervention to facilitate self-management of low back pain.

The focus group will be conducted in English and therefore a willingness to use English in the focus groups will be required to participate. Once data is transcribed it will be sent back to you for confirmation.

What are the possible disadvantages and risks of taking part?

- There are no foreseeable risks involved in participating in these focus groups.

What are the possible benefits of taking part?

- You will receive no direct benefits from participating in this research study. However, your responses will be used to develop a new web-based self-management for low back pain which may benefit patients in the future.

Will my taking part in the study be kept confidential?

- The researchers will keep all study records, including the audio records, transcripts, and notes of your data, in a secure location. Research records will be labelled with the pseudonym. All electronic files containing identifiable information will be stored in a password protected personal computer to prevent access by unauthorized users. At the conclusion of this study, the research team may publish their findings, but the information will be presented in summary format, and you will not be identified in any publications or presentations. You can have a copy of the results if you request by email.
- Your personal information and the data that will be generated during the focus group discussions will be stored for 15 years and then will be destroyed in line with data protection procedures. Any information you provide will not be shared with anyone else.

What will happen if I don't carry on with the study?

- As mentioned above you have the right to withdraw at any point of this study. All the collected information will be erased and will not be used further.

What will happen to the results of the research study?

- During the focus group discussions, we would be exploring your ideas of a self-management programme with a plan for exercise and activity prescription to people with low back pain. Following the focus group discussions, the data will be analysed and the first prototype of Back-to-Fit™, a web-based self-management tool for people with low back pain will be developed. The aim of this intervention is to facilitate self-management of people with low back pain by increasing their exercise engagement and physical activity levels.
- The data will form part of my PhD thesis and the results of the study will be presented at scientific meetings and published in journals for healthcare professionals and computer scientists. You will not be identified in any report/publication, but we may use some of the comments that you provide us within our reports.

Who has reviewed this study?

- This study has been reviewed by the School of Healthcare Sciences Research Ethics Committee, Cardiff University.

What if there is a problem?

- If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact SenarathA@cardiff.ac.uk / 07492404457)
- If you remain unhappy and wish to complain formally, you can do this by contacting the School of Healthcare Sciences Director of Research Governance (Dr Kate Button buttonk@cardiff.ac.uk 02920687734).
- In the event that something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cardiff University, but you may have to pay your legal costs.

Thank you for your time.

Akushla Rathnayake

Appendix 5: Topic guide - Phase 2: Focus group study

Focus Group Topic Guide

- I'm Akushla and I am a 2nd year PhD student at School of Healthcare Sciences, Cardiff University. First, I would like to thank all of you for coming today. I know you all are very busy, and thanks for taking time to participate in this focus group. I hope you've had a chance to read the information sheet.

- The main purpose of this overall study is to design a web-based tool to facilitate self-management in people with low back pain to improve their PA and exercise engagement.

- During this phase of the study, we would like to explore your opinion and inputs on Low back pain self-management.

- When I mean LBP, during this focus group these would be patients with NSLBP without severe centrally sensitized chronic pain or any specific pathologies underlining LBP. such as fractures, tumours, infections etc

- This would be the group who would like to engage in PA and exercises at the same time not sure what to do how to do or whether it would be safe to do so. They might be afraid that their pain would be triggered by PA and exercises.

- If you are interested in receiving a copy of the results of the study, we can make it available to you at the end of the study.

- I would like to remind you a few housekeeping notes.

- Please note that this whole conversation would be audio recorded. And for the purpose of the clarity of the recording please make sure only one person talks at a time, loud and clear enough. Please feel free to engage in the discussion and share your experience with us.

- Also, it would be appreciated if you can silent your mobile phones and if anyone needs to answer the phone of course you can step outside and join us after.

- Along the conversation sometimes I might interrupt or push a little bit to finish the discussion on time.

- We have some refreshments on the desk. Please feel free to help yourselves while you talk.

Alright, to start the discussion Could you please introduce yourselves using your first names and describe your work settings and what type of low back pain patients do you typically see?

✓ E.g.: Age, Teens, Sports, Sedentary, Active

Assessment

My first question is about deciding on the best management approach for patients

1. If we rule out all the red flags and yellow flags and subjective questions, could you please tell me what are the key things you would assess?
2. How do you decide what to include in the treatment programme when you treat NSLBP patients?
3. In an ideal world if there is not any time or resource limitations what would your assessment look like? Is there anything you would do differently?
   - ✓ E.g.: motion capture, motor control etc.

Management

1. What would be typically included in a typical management programme for the patients with NSLBP and how do you decide the content?
   - ✓ E.g.: types of exercises, general walking, gym etc.
2. That mean how do you decide what exercise and PA approach is best for which patient?
   - ✓ is it by their age, physical capacity, does occupation, education level play role.?
   - ✓ what about patient preference opportunity (i.e., access to gym)
3. Do you prescribe exercises depending on how they move?
   - ✓ E.g.: how stiff they are or any patterns of movement or method of subgrouping them to decide the best exercises?
4. In an ideal world what would be the self-management for LBP patient look like? If there is no time or resource limitations is there anything you would like to add for the exercise and PA packages of your patients?

Exercise self-management strategies and use of technology

1. What are the strategies you use when prescribing them exercise self-management?
   - ✓ E.g.: pen and paper, apps videos
   - ✓ exercise portals
   - ✓ (ag apps, digital exercise platform physio-tools, phones or videos)
2. Do you use any form of technology for patients to help with their self-management?
   - ✓ Do you get them to monitor/ self-evaluate them? like motion tracers, apps fit bit Reminders, exercise portals with photos and videos
3. How do you think we can use technology or digital devices to facilitate exercise self-management?

Appendix 6: Topic guide - Phase 2: Focus group study: Pilot version

Title of Study: Back-to-Fit^{TM}: A web-based self-management for mechanical low back pain – Phase II

Focus group topic guide for Physiotherapists

These are topic guidelines with some example questions. Due to the inductive nature of the focus group, new topics and questions that arise will also be explored and discussed further.

- **Welcome**

Thank you for being part of this focus group. You have all read the information leaflet and will have a general idea of the purpose of the study. There are no right or wrong answers only differing points of view.

For the recording could each of you sate your pseudonym, which clinical setting you are working in and how many years have you been practicing as a musculoskeletal physiotherapist?

- **Statement of the ground rules of the focus group, and assurance of confidentiality**

Please make sure you identify yourself using the given pseudonym throughout this focus group discussion. While your views are highly valued, your personal details or the information you will discuss within this focus group will not be disclosed to any other parties. The researchers would like to remind participants to respect the privacy of your fellow participants and not repeat what is said in the focus group to others.

- **Topics to discuss**

Assessment

- What is your opinion with regards to key components of a LBP assessment when designing a self-management programme for your patients?
- What is your opinion regarding the proposed sub-grouping of patients according to their clinical presentation of low back pain? (These groups will be developed using the identified key subjective questions in the Phase 1)
- What do you think would be the most appropriate posture/ movement test/s to be performed by patients?

Management

- What do you tend to include in the management of your LBP patients?

- How do you decide what exercise and PA approach is best of which patient? (is it by their age, physical capacity, does occupation, education level play role, what about patient preference opportunity (i.e. access to gym)

Self-monitoring

- Do you tend to give patients some way of self-evaluation (e.g. reach test, forward bend slide test)
- if so, what instruction would you give (e.g. when to do these, for what purpose, what instructions, video or photo?
- Do you use any form of tech to get patients to self-monitor their PA and exercise goals (eg. Motion trackers, apps, exercise portals, video or photos to reminders)

Self-management exercise strategies

- How do you monitor adherence (e.g. do you get them to demonstrate what they did at home, do you use apps or digital platforms for people to access their ex's? If so which ones)
- Do you technologies to help people to stick to the programme and do the exercise well (ag apps, digital exercise platform physio-tools, phones or videos)
- How do you think we can use technology to help people to self-manage their LBP?

Appendix 7: Ethical approval letter - Phase 2: Focus group study and the survey

School of Healthcare Sciences
Head of School and Dean Professor David Whittaker

Ysgol Gwyddorau Gofal Iechyd
Pennaeth yr Ysgol a Deon Yr Athrawes David Whittaker

29 March 2019

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Prifysgol Caerdydd
Ty Dewi Sant
Mynydd Bychan
Caerdydd CF14 4XN

Akushla Rathnayake
School of Healthcare Sciences
Cardiff University

Dear Akushla

Back-to-Fit: A web-based self-management for mechanical low back pain

I am writing to inform you that the Chair of the Research Ethics Committee has, following consultation, approved your revised research proposal. The Committee will ratify this decision at its meeting on 9 April 2019.

Please note that if there are any major amendments to the project you will be required to submit a revised proposal form. You are advised to contact me if this situation arises. In addition, in line with the University requirements, the project will be monitored on an annual basis by the Committee and an annual monitoring form will be despatched to you in approximately 11 months' time. If the project is completed before this time you should contact me to obtain a form for completion.

Please do not hesitate to contact me if you have any questions.

Yours sincerely

Liz

Mrs Liz Harmer Griebel
Research Administration Manager

c.c. Liba Sheeran, Valerie Spakes

Appendix 8: The consent form – Phase 2: Focus group study

Subject Consent Form

Title of Study: Back-to-Fit™: A web-based self-management for low back pain – Phase II (Focus groups)

Name of Researcher: Akushla P.S Rathnayake

Please initial box

1. I confirm I have read and understood the participant information sheet version 2.0 dated 24/03/2019 for the above study and have had the opportunity to consider the information, to ask questions and to have these answered. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. ☐
3. I understand that all information about this focus group will be kept in a confidential way and destroyed once the study is completed. ☐
4. I understand that the responses of this study will be used to support other research in the future and may be shared anonymously with other researchers. ☐
5. I understand that the information I submit, including anonymised direct quotes, may be included in any resulting report. ☐
6. I understand that my participation will be audio recorded for accuracy and I consent to the use of this material as part of the project. ☐
7. I agree to take part in this study. ☐

Participant Signature:	Print Name:	Date:

By signing below, I indicate that the participant has read and, to the best of my knowledge, understands the details contained in this document and has been given a copy.

Researcher signature	Print Name:	Date:

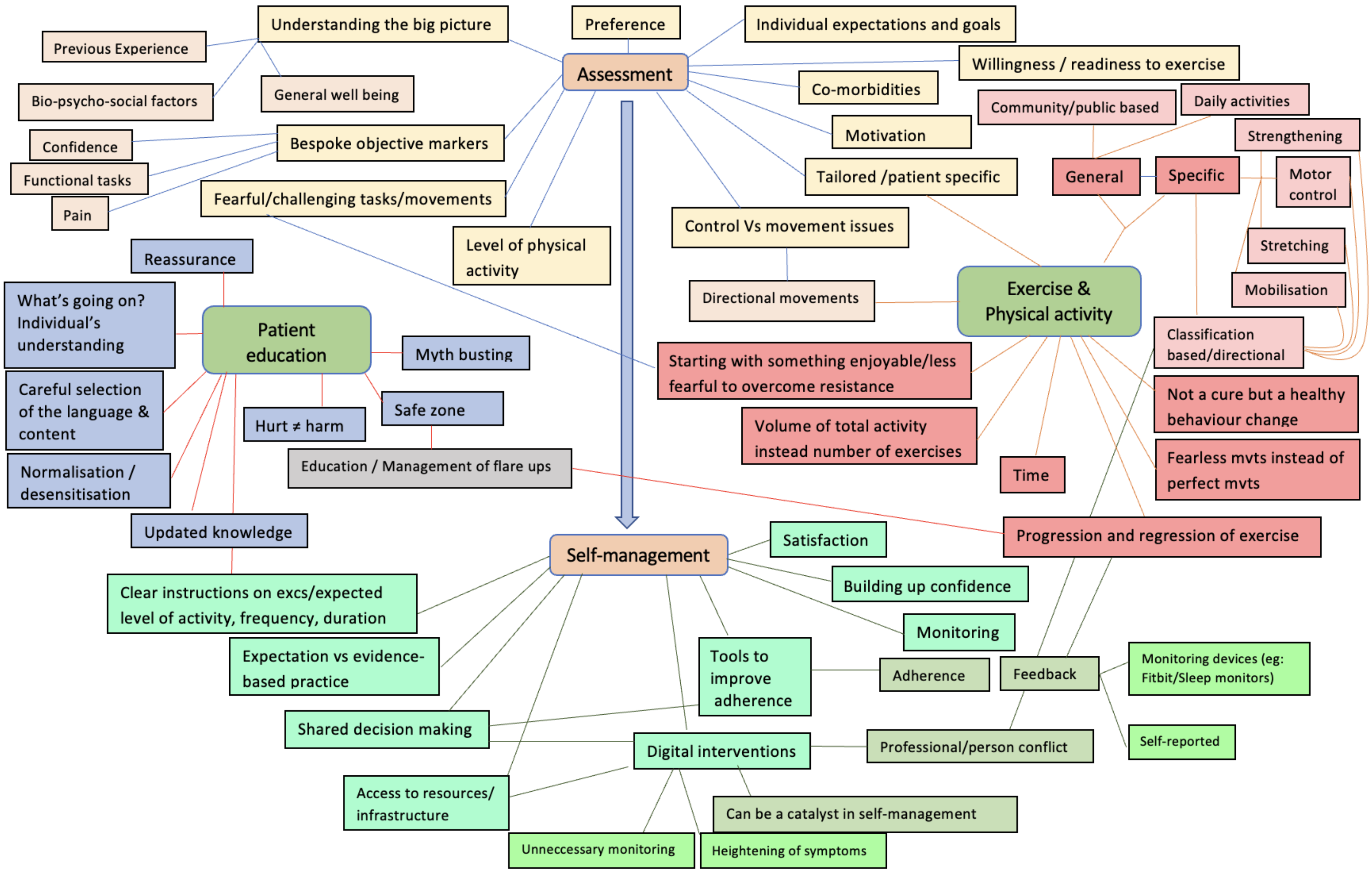
Appendix 9: Codes and themes generated in the data analysis – Phase 2: Focus group study

No.	Code	Focus group 1	Focus group 2	Focus group 3
1.	Functional tasks – gives more details to understand the big picture than random individual tests	7, 9, 24,37	2	15, 20
2.	Direction specific / pain patterns could be very useful in decision making	10,57	55, 56	
3.	More holistic assessment instead of just checking mvts			9
4.	Assessment – part of the parcel			26
5.	Certain approaches/ classification mainly to identify movement or control/stiffness issue and prescription of excs accordingly could be very effective in certain groups	10,57,71,78		
6.	Level of physical activity/ lifestyle	29, 70, 71	23	8
7.	Challenging/ fearful functional tasks as a marker and motivation to overcome fear and move	25	43	20
8.	Assessing and enhancing level of motivation	8, 10, 55, 57, 68		41, 42, 43, 133
9.	Readiness to exercise / willingness	8, 10, 68		8
10.	Biopsychosocial factors – understanding the big picture / being vigilant about the patient as a whole / general wellbeing, having more than one issue	8, 13,14,26,33, 36,39,84,112	25	4, ,45,58, 61, 73
11.	Might be individuals who'd gone through the whole cycle/ recurrence			68, 69
12.	Everyone has yellow flags			12
13.	Individual expectations / goal/ carrier specific expectations	32, 10,11,16,17,19, 57, 59, 69, 74	18, 19	8,14, 46, 47
14.	Time that can spend for the exercise is an important factor	11	124	
15.	What went wrong? Experience / BARRIERS	98		69, 72
16.	Pain factor matters	16		
17.	Education on flare ups and Safe Zone – feed back to manage flare ups according to the monitoring / feedback	96, 114,82,83,81,84	59, 60, 61, 62, 120	92, 94, 96, 100
18.	Individual's understanding – What's going on, agreement on what to achieve?	39,44,45,47,48		47
19.	Myth busting with Careful selection of language and updated/evidence-based information to enhance confidence	63, 64	102, 104	65, 86, 91, 102, 107, 108, 133, 137, 139
20.	A succinct but effective education component is a must	113, 126, 127		74, 75
21.	Preference / starting with something enjoyable and less fearful and progression	32, 54, 55, 56, 57, 59, 68,	17, 30	30, 43

22.	Gradual Desensitizing the fearful behaviour/reassurance to overcome the resistance and to motivate	34, 55, 61, 92	20, 24, 43, 45, 46, 47, 102, 104	15, 17, 104
23.	Gradual progression from a baseline strength and conditioning	61	24, 45	
24.	Focusing on total volume of PA/excs instead of reps/sets	54	124, 25	123
25.	Quantity vs quality of mvt – how free mvts are instead of how far can go			26, 107, 105
26.	Ax and Exs Must be tailored to individual's needs	57,69	22, 92	16,17,27, 55, 70
27.	A spectrum of exercises with general and specific excs & functional activities to tailor the programme	54, 57	24, 41, 48	9, 59, 60, 79, 89, 88
28.	Public, community based long term management		68,70	54
29.	Advice and clear instruction on what to achieve (intensity, duration) / agreement			32, 56
30.	Progression and regression of exercises			156
31.	Practical issues with technology / Infrastructure/ digital literacy	21		124, 125, 126, 127
32.	Careful use of technology - Unnecessary monitoring, evaluation Monitoring the function instead of pain	40,42,49,50,71, 93	11 85	97
33.	Digital/technological applications – might not be for all	29,19,40,103, 104	97	
34.	Digital technologies as a catalyst for SM	29,19,40	92, 99, 101, 102, 103	
35.	Way forward: Tailoring the management from the feedback / monitoring receive form patients through wearable tec/technology	31,37, 93,94,95,96,	12,13,14,15, 92	52, 137, 135, 136
36.	Use of technology to educate, normalize/desensitize or make resilient	51,52, 122, 121, 118,117, 116		84
37.	Technology as a part of a comprehensive assessment without overdoing	40	15,16	
38.	Tools to improve adherence -	88,89,90, 91,92,97, 115,	71	48, 88, 111, 114, 113, 115
39.	patient preference / shared decision making	131, 132	33,31,32,38, 30, 118	50, 65, 85,79, 88, 148, 150
40.	As a healthy behaviour change with updated info and reassurance / helpful beliefs	128, 123, 112, 120, 123,124	105, 102,120, 95, 97	34, 35, 77, 81, 82,83, 79, 92, 119, 120, 121, 142
41.	Coaching or signposting through journey instead of teaching a programme			36, 37, 39, 142
42.	Patient satisfaction / Conflict between patient expectation vs evidence-based practice			11, 17,24, 25, 73, 74

43.	Don't prefer classification or subgroups-based assessment or exercises		54	103
44.	Patients are confused with different opinions/ expectations			73, 76
45.	Professional-personal conflicts			130, 131, 129, 188
46.	evidence vs practice			103
47.	Time limitation -physios	36		44, ,45

Appendix 10: The thematic map – Phase 2: Focus group study



Assessment
Understanding the big picture
Preference
Individual expectations and goals
Previous Experience
Willingness / readiness to exercise
Bio-psycho-social factors
General well being
Co-morbidities
Community/public based
Daily activities
Confidence
Bespoke objective markers
Motivation
Strengthening
Functional tasks
Tailored /patient specific
General
Specific
Motor control
Pain
Fearful/challenging tasks/movements
Control Vs movement issues
Reassurance
Level of physical activity
Stretching
Directional movements
Exercise & Physical activity
Mobilisation
What's going on? Individual's understanding
Patient education
Myth busting
Classification based/directional
Starting with something enjoyable/less fearful to overcome resistance
Careful selection of the language & content
Safe zone
Not a cure but a healthy behaviour change
Hurt ≠ harm
Volume of total activity instead number of exercises
Education / Management of flare ups
Fearless mvts instead of perfect mvts
Normalisation / desensitisation
Time
Updated knowledge
Satisfaction
Progression and regression of exercise
Self-management
Clear instructions on excs/expected level of activity, frequency, duration
Building up confidence
Monitoring
Expectation vs evidence-based practice
Tools to improve adherence
Adherence
Feedback
Monitoring devices (eg: Fitbit/Sleep monitors)
Shared decision making
Digital interventions
Professional/person conflict
Self-reported
Access to resources/ infrastructure
Can be a catalyst in self-management
Unneccessary monitoring
Heightening of symptoms

Appendix 11: The online survey questionnaire - Phase 2: Survey study

Back-to-Fit : A web-based self-management for people with low back pain

Page 1: Back-to-Fit : A web-based self-management for people with low back pain

This PhD study aims to develop a digital tool to improve how people with nonspecific low back pain (NSLBP) engage with exercise self-management (ESM) at home. For this, we need to know what is typically considered important when designing a tailored ESM programme for someone with NSLBP.

For this first part of the study, we are seeking your opinion as a clinical and/or research expert, about the key components (subjective questions and physical tests) of NSLBP assessment which would help you to design a tailored and most appropriate exercise programme. This information will be used to inform the self-assessment feature within a digital tool called 'Back-to-Fit™ offering personalised self-management exercise solutions for people with NSLBP.

Full information about the study and what your participation would involve is in the Participant Information Sheet (version 2.0 24/03/2019) which you can *find here.*

If you are interested in taking part please press **next.**

.

Page 2: Participant Consent Form

To confirm agreement with each of the statements below, please answer the questions below.

1. I confirm I have read and understood the participant information sheet version 2.0 dated 24/03/2019 for the above study and have had the opportunity to consider the information, to ask questions and to have these answered. * *Required*

- Yes
- No

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. * *Required*

- Yes
- No

3. I understand that all identifiable information will be kept in a confidential way and destroyed once the study is completed. * *Required*

- Yes
- No

4. I understand that the responses of this survey will be used to support other research in the future, and may be shared anonymously with other researchers. * *Required*

- Yes
- No

5. I agree to take part in this study. * *Required*

- Yes
- No

Page 3: Demographics

1. What is your occupation? (*Tick all that applies)*

- ☐ Medical doctor
- ☐ Physiotherapist
- ☐ Researcher
- ☐ Nurse
- ☐ Psychologist
- ☐ Chiropractor
- ☐ Osteopath
- ☐ Other

If you selected Other, please specify:

Are you a member of the Society for Back Pain Research (SBPR) ? * *Required*

- ○ Yes
- ○ No

Are you a member of the Musculoskeletal Association of Chartered Physiotherapists (MACP) ? * *Required*

- ○ Yes
- ○ No

2. How many years qualified?

- ○ 0-5
- ○ 6-10
- ○ 11-20
- ○ 20+

3. What is your highest qualification obtained? *(Tick all that applies)*

- ☐ PhD
- ☐ MSc
- ☐ BSc
- ☐ MD
- ☐ Other

If you selected Other, please specify:

4. How many years you have been working with people with low back pain?

- ○ 0-5
- ○ 6-10
- ○ 11-20
- ○ 20+

5. What is your work setting? (*Tick all that applies)*

- ☐ Private
- ☐ University (Higher Education Institute)
- ☐ Sports Institute (E.g: National Governing Body)
- ☐ NHS
- ☐ Other

If you selected Other, please specify:

Page 4: Assessment of nonspecific low back pain for developing an exercise self-management programme

In this PhD research study we are interested in improving exercise engagement of people with NSLBP who exhibit a clear mechanical stimulus pain behaviour (i.e. well defined pain-provoking and pain-relieving postures, movements and activities), absence of dominant yellow flags (e.g. fear avoidance, anxiety, depression and catastrophizing etc.) and absence of red flags (features indicating serious pathology such as cauda equina lesion, fractures, malignancy etc) and no nerve root signs and symptoms with neurological deficit.

Below we include some of the typical screening questions and physical and movement tests that clinicians conduct to help to formulate a tailored exercise plan for a person with NSLBP. We would like you to rate your agreement according to its importance when developing a tailored exercise self-management programme for people with NSLBP. Please consider a full red and dominant yellow flag screen is complete.

Screening questionnaire

1. For this section on Low Back Pain history, please rate the degree of importance of the listed information to help you **to develop a tailored exercise self-management programme for NSLBP**?

Please rate your agreement with each statement using a 5 point scale with,

strongly disagree, disagree, agree nor disagree, agree and strongly agree

Low back pain

	strongly disagree	disagree	agree nor disagree	agree	strongly agree
Duration of the current episode of pain	○	○	○	○	○
Recurrence of symptoms	○	○	○	○	○
Mechanism of onset	○	○	○	○	○
Low back pain history since onset (i.e.: Improving/same/worse)	○	○	○	○	○
Severity of pain	○	○	○	○	○
Nature of pain (e.g. sharp, dull, aching)	○	○	○	○	○
Irritability (i.e.: how quick the pain comes on)	○	○	○	○	○
Aggravating and easing factors	○	○	○	○	○
24-hour low back pain behaviour	○	○	○	○	○
Sleep disturbances	○	○	○	○	○

Would you add anything to the list above? * *Required*

- Yes
- No

If Yes please specify

2. For this section on General Health, please rate the degree of importance of the listed information to help you **to develop a tailored exercise self-management programme for NSLBP?**

Please rate your agreement with each statement using a 5 point scale with,

General health

	strongly disagree	disagree	agree nor disagree	agree	strongly agree
Existing medical conditions or co-morbidities (e.g.: Hypertension, Diabetes, Fibromyalgia, Osteoarthritis, Asthma, Cardiovascular disease)					
Pain medications					
Height and weight					
Physical activity questionnaire data					
Patient's estimate of fitness level					

Would you add anything to the list above? * *Required*

- Yes
- No

If Yes please specify

3. For this section on Work and Lifestyle, please rate the degree of importance of the listed information to help you **to develop a tailored exercise self-management programme for NSLBP?**

Please rate your agreement with each statement using a 5 point scale with,

strongly disagree, disagree, agree nor disagree, agree and strongly agree.

Work and lifestyle

	strongly disagree	disagree	agree nor disagree	agree	strongly agree
Employment history and environment	○	○	○	○	○
Predominant daily activities on an average day	○	○	○	○	○
Current exercise/physical activity/leisure habits (e.g.: Type/ frequency and intensity of exercises/gym/sport activities)	○	○	○	○	○
Detailed information of domestic and social activities	○	○	○	○	○

Would you add anything to the list above? ✱ *Required*

○ Yes

○ No

If Yes please specify

4. For this section on Exercise/Activity programme planning, please rate the degree of importance of the listed information to help you **to develop a tailored exercise self-management programme for NSLBP**?

Please rate your agreement with each statement using a 5 point scale with,

strongly disagree, disagree, agree nor disagree, agree and strongly agree.

Exercise /Activity programme planning

	strongly disagree	disagree	agree nor disagree	agree	strongly agree
Individual functional and fitness goals	◌	◌	◌	◌	◌
The most preferred/ enjoyable mode of exercise/activity (e.g. swim, bike, walking, gym, outdoors)	◌	◌	◌	◌	◌
The preferred mode of motivational support (e.g. emails, texts, reminders)	◌	◌	◌	◌	◌
The preferred mode of supporting materials (online, video, audio, paper copies)	◌	◌	◌	◌	◌
The preferred mode of monitoring progress (exercise summaries, reports, pain monitoring options)	◌	◌	◌	◌	◌
Patient's access to health monitoring apps	◌	◌	◌	◌	◌
Access to local facilities (e.g. gym, social centre, walking group)	◌	◌	◌	◌	◌

Would you add anything to the list above? * *Required*

- ◌ Yes
- ◌ No

If Yes please specify

Page 5: Assessment of nonspecific low back pain for developing a self-management programme

Physical and movement screen

5. How much do you agree with the importance of the following movement and posture tests in helping you to develop a **tailored exercise self-management programme for NSLBP**?

Please rate your agreement with each test using a 5 point scale with,

strongly disagree, disagree, agree nor disagree, agree and strongly agree.

	strongly disagree	disagree	agree nor disagree	agree	strongly agree
Usual sitting posture	○	○	○	○	○
Upright sitting posture	○	○	○	○	○
Standing	○	○	○	○	○
Bending forward	○	○	○	○	○
Bending backward	○	○	○	○	○
Bending sideways	○	○	○	○	○
Lumbar spine Range of Motion	○	○	○	○	○
Thoracic spine Range of Motion	○	○	○	○	○
Hip Range of Motion	○	○	○	○	○
Speed of execution of tasks	○	○	○	○	○
Anterior/posterior pelvic tilt	○	○	○	○	○
Twisting	○	○	○	○	○
Sit to stand	○	○	○	○	○
Performing a lifting manoeuvre	○	○	○	○	○
Walking	○	○	○	○	○
Squatting	○	○	○	○	○
Walking downstairs	○	○	○	○	○
Walking upstairs	○	○	○	○	○
Pulling up a sock while seated	○	○	○	○	○
Any pain provoking tasks/movement	○	○	○	○	○
Any pain easing tasks/ movements	○	○	○	○	○

2. Are there any other posture/movement tests you would consider important to assess to help you develop a self-management exercise programme for NSLBP? * *Required*

○ Yes

○ No

If yes please specify

Page 6: The End

Thank you for taking part in the survey.

Appendix 12: The participant information sheet - Phase 2: Survey study

PARTICIPANT INFORMATION SHEET

Study Title:

Back-to-Fit™: A web-based self-management for low back pain – Phase I

Invitation paragraph

- This is an invitation to be involved in our study. A full description of the study aims and its contents are described in detail in this sheet. Before you decide if you want to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information carefully.

Who is organizing and funding the research? ‹‹

- This survey is Phase II of Back-to-Fit™, a web based self-management for low back pain, which is being conducted by Akushla Rathnayake, a PhD student at Cardiff University. This study is supervised by Dr. Liba Sheeran and Dr. Valerie Sparkes and funded by Versus Arthritis. The data from this study could be used in the development of a self assessment feature of the Back-to-Fit™ intervention. Contact us if there is anything that is not clear or if you would like more information. Discuss it with others if you wish, before you decide whether or not you wish to participate.

What is the purpose of this study?

- The aim of this survey is to identify the key subjective questions asked and main movement tests performed during the assessment of a patient with low back pain patients by specialised musculoskeletal clinicians.
- This information will be used to inform development of a new web-based intervention to facilitate self-management of low back pain.

Why have I been invited?

- You are being invited to join this study as you are an expert clinician with over 10 years' experience in the management of Low back pain and have a postgraduate qualification related to low back pain.

Do I have to take part?

- Taking part in this survey is completely voluntary. It is your choice to join this study or refuse.
- You will be asked to endorse a consent form within the survey. If you decide to take part, you are still free to withdraw at any time without giving a reason or prior notice. Should you decide not to take part, you do not have to provide a reason for such decision. All the information regarding this study is either described in this sheet or in the email sent to you.

What will I have to do?

- If you are happy to take part in the survey please complete the consent page to continue. It needs to be noted that you can withdraw at any point of the study. Your participation in this online survey will require you to answer questions including your demographic data and subjective and objective assessment of the low back patients. It will take approximately 10 minutes to complete the survey.

What are the possible disadvantages and risks of taking part?

- There are no foreseeable risks involved in participating in this survey.

What are the possible benefits of taking part?

You will receive no direct benefits from participating in this research study. However, your responses will be used to develop a new web-based self-management for low back pain which may benefit patients in the future.

Will my taking part in the study be kept confidential?

- All information that is collected during the course of the research including your survey answers will be kept strictly confidential. A Secure Sockets Layer (SSL) encrypted connection and a server would be used to circulate the survey link via OnlineSurveys.com where data will be stored in a password protected electronic format. Access to your name, email address, or IP address will be restricted to an authorised person only (principal investigator).
- OnlineSurveys.com does not store any of your personal data or will not be disclosed to any third parties. No one will be able to your answers, and no one will know whether or not you participated in the study.
- Your data will be stored for 15 years and then will be destroyed in line with data protection procedures. Any information you provide will not be shared with anyone else.

What will happen if I don't carry on with the study?

- As mentioned above you have the right to withdraw at any point of this study. All the collected information will be erased and will not be used further.

What will happen to the results of the research study?

- Analysed results of the survey responses obtained during this survey will be shared anonymously among the subjects of the Phase II of the study (which follows this Phase) to gain agreement to be used as the subjective assessment of the web intervention.

- This intervention will facilitate the self-management of patients with low back pain, in which they could identify the specific exercises according to their own movement dysfunction.

- The data will form part of my PhD thesis and the results of the study will be presented at scientific meetings and published in journals for healthcare professionals and computer scientists. You will not be identified in any report/publication but we may use some of the comments that you provide us with in our reports.

Who has reviewed this study?

- This study has been reviewed by the School of Healthcare Sciences Research Ethics Committee, Cardiff University.

What if there is a problem?

- If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (SenarathA@cardiff.ac.uk 07492404457) .
- If you remain unhappy and wish to complain formally, you can do this by contacting the School of Healthcare Sciences Director of Research Governance (Dr Kate Button buttonk@cardiff.ac.uk 02920687734).
- In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cardiff University but you may have to pay your legal costs.

Thank you for your time.

Akushla Rathnayake

Appendix 13: Downloadable summary of the exercise programmes - BACK-to-FIT™ intervention

BACK-to-FIT™ *let us help you to help yourself*

PROGRAMME 1
WORRIED BACK

LEVEL	EXERCISE NAME	FREQUENCY	REPETITIONS
1. Getting YOUR back FIT using a CHAIR			
-2 -1 0 1 2	Seated slump and sit up Seated back rotations Seated reach down Seated side bends Sit to stand	If you are sitting for longer than 1-2 hours try to do a few repetitions every hour. If not try 2-3 sets daily	2 - 5 reps
2. Getting YOUR back FIT using STAIRS			
-1 0 1	Step ups Step up and over Walking up and down a flight of stairs	3-5 times a week	Begin with one set of 5-8 repetitions. Repeat 2-3 times with 1-minute break in between.
3. Getting YOUR back FIT for WALKING			
-2 -1 0 1 2	Double heel raise (holding on) Single heel raise (holding on) Step up and over Wall Squat Body weight squats	3-5 times a week	Begin with one set of 8-10 repetitions. Repeat 2-3 times with 1-minute break in between.
4. Getting YOUR back into WALKING			
-1 0 1	Walking at your own pace Walking with a friend Walking with a backpack	3-5 times a week	Begin with 2-5 minute walks with a short 30 second stop repeated 3 times to make up 6-15 minute walk. Gradually increase the total time you walk each day up to 30-40 mins.

BACK-to-FIT™ *let us help you to help yourself*

PROGRAMME 2
ACTIVE BACK

LEVEL	EXERCISE NAME	FREQUENCY	REPETITIONS
1. GETTING YOUR BACK MOBILE			
-3 -2 -1 0 1 2 3	Knee rolling Seated Back Rotations Seated forward bend Standing forward & backward bend Standing rotations Standing side-bends Backward bend in prone	Repeat 2-3 sets daily	2 - 5 reps
2. Getting YOUR back STRONG using UPPER BODY exercises			
-2 -1 0 1 2	Biceps curls with weights Desk hold Desk superman Desk press Body weight triceps curls	3-5 times a week	Begin with one set of 8-10 repetitions. Repeat 2-3 times with 1-minute break in between.
3. Getting YOUR back STRONG using LOWER BODY exercises			
-3 -2 -1 0 1 2 3	Double leg bridge Mini squat Single leg bridge Wall squat Body weight squat Lunge Split squat	3-5 times a week	Begin with one set of 8-10 repetitions. Repeat 2-3 times with 1-minute break in between.
4. Getting YOUR back STRONG with WALKING			
-3 -2 -1 0 1 2	Double heel raise Single heel raise Step up and over Wall Squat Lunge Body weight squats	3-5 times a week	Begin with one set of 8-10 repetitions. Repeat 2-3 times with 1-minute break in between.
3	Walking progression	3-5 times a week	Begin with 2-5 minute walks with a short 30 second stop repeated 3 times to make up 6-15 minute walk. Gradually increase the total time you walk each day up to 30-40 mins.

Appendix 14: Self-screening for red flags and serious pathologies before the use of BACK-to-FIT^{TM} intervention

1. *Eligibility check list: Potential participants open link in the e-leaflet were linked to access eligibility check list:*

a) *"Are you over the age of 18?"*
b) *"Do you have access to internet and a computer/tablet or mobile phone?"*
c) *"Do you have low back pain within the last 4 weeks?"*
d) *"Are you pregnant or breast feeding?"*
e) *"Are you involved in any other back pain research?"*
f) *"Do you currently receive active medical/surgical treatments or physiotherapy for low back pain?"*

*Participants who answered **'yes'** to a, b, c and **'no'** to d, e, f above were proceeded to low back pain self-screen. Others were informed of the eligibility and thanked for their participating thus far.*

2. *Low back pain self-screen: formulated from the NICE guidance on clinical indicators of specific pathology or systemic illness self-screening tool included the following questions:*

a) *Is your low back pain constant and worsening for the past 4 weeks?*
b) *Did your low back pain start or got much worse following a fall?*
c) *Did your low back pain coincide with feeling unwell e.g. Fever, chills, night sweats (with no other explanation)?*
d) *Do you have altered or loss of sensation around your back passage or genitals (noticeable e.g. When wiping after going to the toilet)?*
e) *Are you experiencing any unexplained widespread weakness in one or both legs?*
f) *Do you have difficulty passing or controlling urine or faeces?*
g) *Did your low back pain coincide with any unexplained trouble walking (e.g. Limping, tripping, falling, feeling unsteady on your feet)?*

Answer 'no' proceeded to participant information sheet. Answer 'yes' to any of the above informed of that they were not eligible for the study and thanked for their participating thus far. Also, they were advised to seek medical advice if they still experience symptoms. Participant information sheet (PIS) was hosted by Online Surveys platform and detailed information on the nature, significance, implications and risks of the study and the right to withdraw at any time. Contact details for further information were supplied. PIS was formatted into sections that the participant was required to scroll through with an option at the end to print, download and/or save. After this the participants were required to tick 1 of 3 options (1) 'I read the information sheet and want to participate', (2) 'I read the information sheet but need to talk to someone before I decide to take part' (3) 'I don't want to participate'.

a) Option (1) (i) will take participant to the e-consent form (details below)

b) Option (2) will trigger automatic message to the participant, stating the principal investigator (AS) will call them to answer any questions (with preferred phone number). Those who verbally agree to participate will be given a link to access the e-consent form (detailed below).

c) Option (3) will invite the participants to state reasons for opting out (e.g. I don’t have time, I am managing my back pain well already, other) and a message ‘thank you for your interest and time this far’.

Appendix 15: Recruitment email and e–leaflet - Phase 3: Evaluation study

Read / Unread

Volunteers needed for Low Back Pain study

A [redacted]

[redacted] +42 others

Thu 15/04/2021 08:41

Dear All,

My Name is Akushla Senarath Rathnayake and I am a PhD candidate at School of Healthcare Sciences, Cardiff University. My study aims to develop and evaluate BACK-to-FIT^{TM} intervention, designed to help people with LBP to get active and exercise safely.
As a part of this study, I would like to invite **people with Low Back Pain to** participate in this original research project which involves completing an initial online questionnaire, using BACK-to-FIT^{TM} website for 4 weeks and giving your feedback through a follow-up survey and a short online interview.
Participants can take part in this study if they have had low back pain for more than 4 weeks that affects their function and ability to get active and exercising, are 18 years of age or older, can read and write English and have access to a device with an internet connection.
The initial online questionnaire takes approximately **10 minutes** to complete. Participants can access the online questionnaire via the link below.
https://cardiff.onlinesurveys.ac.uk/btf-pre-intervention
The participant Information Sheet of this survey is available via a link in the online questionnaire.
For further information or any queries, please do not hesitate to contact the researcher via SenarathA@cardiff.ac.uk
Thank you for your kind help in advance in distributing this research project.

Kind regards,
Akushla S Rathnayake

BACK-to-FIT^{TM}
Let us help you be active and exercise

Do You Have Back Pain?

Would you like some help to get active and exercise safely?

Join our study!

Who are we looking for ?

We want **people with Low Back Pain** to take part in an online study to evaluate BACK-to-FIT^{TM} intervention, designed to help people with LBP to get active and exercise safely.

You are eligible if you:

- ✓ Have had low back pain for more than 4 weeks that affects your function and ability to get active and exercising
- ✓ Are 18 years of age or older
- ✓ Can read and write English
- ✓ Have access to a device with internet connection

What does this study involve?

- ✓ Fill in online survey
- ✓ Get access to BACK-to-FIT^{TM} website for 4 weeks
- ✓ Give us your feedback through a follow up survey and **a short online interview**

To confirm your eligibility and participate in the study, go to:
For further information, please contact the main researcher: Akushla Rathnayake
- Email: SenarathA@cardiff.ac.uk
- Mobile: 07492404457

BIOMECHANICS & BIOENGINEERING RESEARCH CENTRE VERSUS ARTHRITIS

CARDIFF UNIVERSITY PRIFYSGOL CAERDYDD

Appendix 16: Eligibility check, self-screening, informed consent and baseline questionnaire

BACK-to-FIT : Pre-intervention Questionnaire

Your eligibility

Thank you for your interest.

! We first need to check whether you are eligible to take part in the study. Please answer the following questions with either Yes or No.

Are you over the age of 18? ✱ *Required*

- Yes
- No

Do you have access to the internet and a computer/tablet or mobile phone? ✱ *Required*

- Yes
- No

Have you had low back pain for more than 4 weeks that is affecting your ability to get active and exercising ? ✱ *Required*

- Yes
- No

Are you pregnant or breastfeeding? ✱ *Required*

- Yes
- No

Are you involved in any other back pain research? ✱ *Required*

- Yes
- No

Do you currently receive active medical/surgical treatments for low back pain? ✱ *Required*

- Yes
- No

Self-Screening

Have you experienced any of the following related to your low back pain?

1. *Low back pain started or got much worse following a fall.*
2. *Low back pain coincides with feeling unwell e.g. Fever, chills, night sweats (with no other explanation).*
3. *Altered or loss of sensation around your back passage or genitals (noticeable e.g. When wiping after going to the toilet).*
4. *Any unexplained widespread weakness in one or both legs?*
5. *Difficulty passing or controlling urine or faeces?*
6. *Low back pain coincides with any unexplained trouble walking (e.g. Limping, tripping, falling, feeling unsteady on your feet)?*

Select yes if you have experienced any of the above. ✱ *Required*

- Yes
- No

Participant Information Sheet

Great !!! As you fulfil the eligibility criteria, we would like to invite you to take part in our Cardiff University research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. You will have an opportunity to ask questions if you read anything that is not clear, or you would like further information.

The purpose of this study is to evaluate the usability, acceptability, potential health benefits and user experience of BACK-to-FIT™ intervention designed to help physical activity and exercise self-management in people with LBP.

You are invited to use the BACK-to-FIT intervention for 4 weeks and data will be collected before and after to the use of the intervention using online questionnaires and an online/telephone interview.

Full information about the study and what your participation would involve is in the Participant Information Sheet (version 1.1 12/09/2020) which you can ***find here.***

Please select one of the options below. ✱ *Required*

- ○ I read the information sheet and want to participate
- ○ I read the information sheet but need to talk to someone before I decide to take part
- ○ I don't want to participate

Further information

You can contact the principal investigator to obtain any further information related to this study.

Akushla Senarath Rathnayake

074 92404457; senarathA@cardiff.ac.uk

Alternatively please submit your contact details, so we can contact you to provide more information on the study and answer your questions.

Your name ✱ *Required*

Mobile/telephone number *Optional*

Email address *Optional*

E-consent form

Title of the research project: EVALUATION OF USABILITY, ACCEPTABILITY, PRELIMINARY HEALTH BENEFITS AND USER EXPERIENCE OF BACK-TO-FIT^{TM} DIGITAL PLATFORM.

Name of Chief/Principal Investigator: Akushla Senarath Rathnayake

Please confirm agreement with each of the statements below by selecting the correct answer.

I confirm that I have read the information sheet dated 12/09/2020 version 1.1 for the above research project. * *Required*

- Yes
- No

I confirm that I have understood the information sheet dated 12/09/2020 version 1.1 for the above research project and that I have had the opportunity to ask questions and that these have been answered satisfactorily. * *Required*

- Yes
- No

I understand that my participation is voluntary, and I am free to withdraw at any time without giving a reason and without any adverse consequences (e.g. to medical care or legal rights, if relevant). I understand that if I withdraw, information about me that has already been obtained may be kept by Cardiff University. * *Required*

- Yes
- No

I understand that data collected during the research project may be looked at by individuals from Cardiff University or from regulatory authorities, where it is relevant to my taking part in the research project. I give permission for these individuals to have access to my data. * *Required*

- Yes
- No

I understand who access to personal information will have provided, how the data will be stored and what will happen to the data at the end of the research project. * *Required*

- Yes
- No

I consent to being audio recorded/ video recorded/ for the purposes of the research project and I understand how it will be used in the research. * Required

- Yes
- No

I understand that anonymised excerpts and/or verbatim quotes from my [interview/questionnaire etc] may be used as part of the research publication. * Required

- Yes
- No

I understand how the findings and results of the research project will be written up and published. * Required

- Yes
- No

I agree to take part in this research project. * Required

- Yes
- No

Name

Contact number

email address

Pre-intervention Questionnaire

Thank you for agreeing to take part in this study.

Please answer the questions of the BACK-to-FIT pre-intervention questionnaire you will find in the next few pages.

Within 48 hours after submitting the answers you will be contacted by the main researcher to invite you to follow BACK-to-FIT online exercise platform with full access to all modules including exercises.

Please press next to begin.

Demographic Data

Age

Gender * Required

- Male
- Female
- Prefer not to say

Weight (Kg)

Height (cm)

Pain intensity

The numerical pain rating scale

Please indicate in the scale below the number between 0 and 10 that best describes your pain at this time. A zero (0) means 'no pain' and a ten (10) means 'the most severe pain'. * Required

Please don't select more than 1 answer(s) per row.

Please select at least 1 answer(s).

	0 (No pain)	1	2	3	4	5	6	7	8	9	10 (The most severe pain)
.											

Is this your first episode of low back pain? * Required

- Yes
- No

If no, how long have you had low back pain?

Self-Efficacy for Exercise (SEE) Scale

How confident are you right now that you could exercise three times per week for 20 minutes if:

Please don't select more than 1 answer(s) per row.

	0 (Not Confident)	1	2	3	4	5	6	7	8	9	10 (Very Confident)
The weather was bothering you	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
You were bored by the program or activity	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
You felt pain when exercising	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
You had to exercise alone	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
You did not enjoy it	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
You were too busy with other activities	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
You felt tired	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
You felt stressed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
You felt depressed	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

International Physical Activity Questionnaire

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?
✱ *Required*

If select, 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.** ✱ *Required*

If select, 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?

If select, 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

Oswestry Low Back Pain Disability Questionnaire

Please answer by selecting **ONE answer in each section** for the statement which best applies to you.

Pain intensity * *Required*

- I have no pain at the moment
- The pain is very mild at the moment
- The pain is moderate at the moment
- The pain is fairly severe at the moment
- The pain is very severe at the moment
- The pain is the worst imaginable at the moment

Personal care (washing, dressing etc) * *Required*

- I can look after myself normally without causing extra pain
- I can look after myself normally but it causes extra pain
- It is painful to look after myself and I am slow and careful
- I need some help but manage most of my personal care
- I need help every day in most aspects of self-care
- I do not get dressed, I wash with difficulty and stay in bed

Lifting * *Required*

- I can lift heavy weights without extra pain
- I can lift heavy weights but it gives extra pain
- Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eg. on a table
- Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- I can lift very light weights
- I cannot lift or carry anything at all

Walking * *Required*

- Pain does not prevent me walking any distance
- Pain prevents me from walking more than 1 mile
- Pain prevents me from walking more than 1/2 mile
- Pain prevents me from walking more than 100 yards
- I can only walk using a stick or crutches
- I am in bed most of the time

Sitting * *Required*

- I can sit in any chair as long as I like
- I can only sit in my favourite chair as long as I like
- Pain prevents me sitting more than one hour
- Pain prevents me from sitting more than 30 minutes
- Pain prevents me from sitting more than 10 minutes
- Pain prevents me from sitting at all

Standing * *Required*

- I can stand as long as I want without extra pain
- I can stand as long as I want but it gives me extra pain
- Pain prevents me from standing for more than 1 hour
- Pain prevents me from standing for more than 30 minutes
- Pain prevents me from standing for more than 10 minutes
- Pain prevents me from standing at all

Sleeping * *Required*

- My sleep is never disturbed by pain
- My sleep is occasionally disturbed by pain
- Because of pain I have less than 6 hours sleep
- Because of pain I have less than 4 hours sleep
- Because of pain I have less than 2 hours sleep
- Pain prevents me from sleeping at all

Sex life (if applicable) * *Required*

- My sex life is normal and causes no extra pain
- My sex life is normal but causes some extra pain
- My sex life is nearly normal but is very painful
- My sex life is severely restricted by pain
- My sex life is nearly absent because of pain
- Pain prevents any sex life at all

Social life * *Required*

- My social life is normal and gives me no extra pain
- My social life is normal but increases the degree of pain
- Pain has no significant effect on my social life apart from limiting my more energetic interests eg, sport
- Pain has restricted my social life and I do not go out as often
- Pain has restricted my social life to my home
- I have no social life because of pain

Travelling * *Required*

- I can travel anywhere without pain
- I can travel anywhere but it gives me extra pain
- Pain is bad but I manage journeys over two hours
- Pain restricts me to journeys of less than one hour
- Pain restricts me to short necessary journeys under 30 minutes
- Pain prevents me from travelling except to receive treatment

Appendix 17: The system usability scale items - Phase 3: Evaluation study

Page 3: Usability Scale

On a scale between Strongly Agree to Strongly Disagree, please rate the following statements according to your experience of BACK-to-FIT. ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select at least 10 answer(s).

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
I think that I would like to use BACK-to-FIT platform frequently.	☐	☐	☐	☐	☐
I found this programme unnecessarily complex.	☐	☐	☐	☐	☐
I thought this programme was easy to use.	☐	☐	☐	☐	☐
I think that I would need assistance to be able to use BACK-to-FIT programme.	☐	☐	☐	☐	☐
I found the various functions in this platform were well integrated.	☐	☐	☐	☐	☐
I thought there was too much inconsistency in this programme.	☐	☐	☐	☐	☐
I would imagine that most people would learn to use BACK-to-FIT platform very quickly.	☐	☐	☐	☐	☐
I found this programme very awkward to use.	☐	☐	☐	☐	☐
I felt very confident in using this platform.	☐	☐	☐	☐	☐
I needed to learn a lot of things before I could get going with BACK-to-FIT programme.	☐	☐	☐	☐	☐

Appendix 18: The system usability scale

System Usability Scale

	Strongly disagree				Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

Scoring SUS

SUS yields a single number representing a composite measure of the overall usability of the system being studied. Note that scores for individual items are not meaningful on their own.

To calculate the SUS score, first sum the score contributions from each item. Each item's score contribution will range from 0 to 4. For items 1,3,5,7,and 9 the score contribution is the scale position minus 1. For items 2,4,6,8 and 10, the contribution is 5 minus the scale position. Multiply the sum of the scores by 2.5 to obtain the overall value of SU.

SUS scores have a range of 0 to 100.

The following section gives an example of a scored SU scale.

Appendix 19: The technology acceptance measurement items - Phase 3: Evaluation study

Page 4: Technology Acceptance

How much do you agree or disagree with the following statements ? ✱ *Required*

Please don't select more than 1 answer(s) per row.

Please select at least 18 answer(s).

	Strongly Disagree	Moderately Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Moderately Agree	Strongly Agree
I believe that BACK-to-FIT is useful in helping me to be physically active and exercise to better self-manage my low back pain.	☐	☐	☐	☐	☐	☐	☐
Using BACK-to-FIT enhances my effectiveness in self-managing my back pain.	☐	☐	☐	☐	☐	☐	☐
I believe BACK-to-FIT is informative for planning my back pain self-management	☐	☐	☐	☐	☐	☐	☐
Using BACK-to-FIT improves my exercise and physical activity engagement.	☐	☐	☐	☐	☐	☐	☐
I find that interacting with BACK-to-FIT does not require a lot of mental effort.	☐	☐	☐	☐	☐	☐	☐
I find the BACK-to-FIT easy to use.	☐	☐	☐	☐	☐	☐	☐
I am comfortable with interaction and navigation of BACK-to-FIT.	☐	☐	☐	☐	☐	☐	☐
I am confident in using the BACK-to-FIT platform without any further manuals or instructions.	☐	☐	☐	☐	☐	☐	☐
I enjoy using smartphone apps and computers to help my physical activity.	☐	☐	☐	☐	☐	☐	☐
I am comfortable using internet.	☐	☐	☐	☐	☐	☐	☐
I have control over using BACK-to-FIT.	☐	☐	☐	☐	☐	☐	☐
I enjoy using online platforms and applications to help being active and exercise.	☐	☐	☐	☐	☐	☐	☐
The actual process of using BACK-to-FIT is pleasant.	☐	☐	☐	☐	☐	☐	☐
People who influence my behaviour think that I should use BACK-to-FIT.	☐	☐	☐	☐	☐	☐	☐
People who are important to me think that I should use BACK-to-FIT.	☐	☐	☐	☐	☐	☐	☐
I intend to use BACK-to-FIT to self-manage my back pain.	☐	☐	☐	☐	☐	☐	☐
I plan to use BACK-to-FIT in the next few months.	☐	☐	☐	☐	☐	☐	☐
I will strongly recommend others to use BACK-to-FIT.	☐	☐	☐	☐	☐	☐	☐

Appendix 20: Interview topic guide - Phase 3: Evaluation study

Interview guide questions

The following issues will then be addressed/explored:

Topic 1: Respond to the information and content presented, gain understanding of the role of BTF. (coherence)

What do you think about the information and content presented in BTF? Does it make sense ?

Probe:
- Do you distinguish BTF from currently available excs self-management tools? How?
- Do you agree/understand about the purpose and benefit of using BTF?
- Do you how BTF affects exercise self-management and tasks?
- Do you agree/understand the potential value benefits and importance of the intervention.

Topic 2: Are you open to the idea of an online LBP self management website? (cognitive participation)

Who/what drives you to use BTF for you to exercise? What do you think are the barriers and facilitators to use of an online tool as BTF?

Probe:
- Who do they engage with – family, friends, or health professionals?
- What role do they take themselves? What are participants' views about using an online tool?
- Willingness to use and continue BTF?

How did you use BTF during the last few weeks?– what are the benefits, drawbacks?

Probe:
- Were you able to use the website and its components in practice as you required?.
- Did you get enough support with regards to the intervention eg: material resources, advice and guidance?
- How confident are you in using BTF?
- Can barriers to use of internet resources be identified? Would it be compatible with current ways of LBP exercise self-management?
- Would there be concerns about the technology? What would make it attractive? What would put them off?

Topic 4:, **Can you determine how effective and useful the intervention is from the use of formal and/or informal evaluation methods?**

to provide evidence that the intervention is helpful (reflexive monitoring)

What features did you like **about BTF**
Probe:

- What do you do differently as a result of using BTF?
- In what ways do you think that BTF could be improved?
- Do you think it is worthwhile ?
- What components and/or actions about BTF would you change? Why?

Any further areas of discussion:

Do you have anything further to add from what we have discussed today?

Give thanks for participating.

Appendix 21: Ethical approval letter – Phase 3: Evaluation study

School of Healthcare Sciences
Ysgol y Gwyddorau Gofal Iechyd

Interim Head of School and Dean /Pennaeth yr Ysgol Dros Dro a Deon Professor David Whitaker

Cardiff University
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Prifysgol Caerdydd
Ty Eastgate
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Appendix 22: The participant information sheet – Phase 3: Evaluation study

PARTICIPANT INFORMATION SHEET

Evaluation of Usability, Acceptability, Preliminary Health Benefits and User Experience of Back-To-Fit™ Digital Platform.

You are being invited to take part in a research project. Before you decide whether or not to take part, it is important for you to understand why the research is being undertaken and what it will involve. Please take time to read the following information carefully and discuss it with others, if you wish.

Thank you for reading this.

1. What is the purpose of this research project?

This study is a part of the BACK-to-FIT™ study, a digital platform to improve physical activity and exercise self-management in people with LBP, which is being conducted by Akushla Senarath Rathnayake (AS), a PhD student at Cardiff University. This study is supervised by Dr Liba Sheeran and Dr Valerie Sparkes and funded by Versus Arthritis. Data from this study will be used in the preliminary evaluation of the BACK-to-FIT™ intervention.

2. Why have I been invited to take part?

This research study is the preliminary evaluation of usability (how easy is to use), acceptability (how well the intervention is delivered via the digital platform), potential health benefits and user experience of BACK-to-FIT™ intervention designed to help physical activity and exercise self-management in people with LBP.
You have been invited because you are an adult of 18 years or older and currently have low back pain and have had it for at least 4 weeks.

3. Do I have to take part?
No, your participation in this research project is entirely voluntary and it is up to you to decide whether or not to take part. If you decide to take part, we will discuss the research project with you and ask you to sign a e-consent form. If you decide not to take part, you do not have to explain your reasons and it will not affect your legal rights. If you are a student at Cardiff University, involvement in this research project will have no effect on your education or progression through a degree course.

You are free to withdraw your consent to participate in the research project at any time, without giving a reason, even after signing the consent form.

4. What will taking part involve?

- After deciding to take part in the study, you are required to complete the e-consent form hosted on an online survey platform.
- Following the endorsement of your e-consent to take part in the study you will be directed to an online survey which will consist of a baseline questionnaire including demographic data and self-reported outcome measures related to your low back pain. It will take approximately 10 minutes to complete the above survey.
- Upon the successful submission of the above online survey you will be contacted by the main researcher (AS) by email and provide you with the link and the log in details for the BACK-to-

FIT^{TM} intervention website. This will give you the options of 3 main modules including back pain education and exercise solutions and you will be asked to follow up the programmes and modules of your choice for 4 weeks to improve your exercise and physical activity.

- After 4 weeks you will be contacted by the main researcher (AS) to organize an interview of 20-30 minutes which will be done via zoom (online) or telephone, to explore your user experience with the BACK-to-FIT^{TM} intervention. This interview will be audio recorded and will be transcribed later for the analysis purposes.
- Also, you will be emailed a link to the post-intervention online survey which will include the same self-reported outcome measures and 2 additional short questionnaires exploring the usability and the acceptability of the intervention. It will take approximately 15 minutes to complete the survey.

5. Will I be paid for taking part?

No. You should understand that any data you give will be as a gift and you will not benefit financially in the future should this research project lead to the development of a new treatment/method/test/assessment.

6. What are the possible benefits of taking part?

No promise will be made that participation in this study will help participants to improve their back pain. Nevertheless, BACK-to-FIT^{TM} intervention offers evidence-based advice following current clinical guidelines with hope of empowering people with low back pain to improve their exercise and physical activity engagement and it is likely that participants may benefit following the exercise and education modules in the intervention. Also, information obtained from the study will help to improve development of the next prototype of the intervention in to an advanced and a bespoke version if successful.

7. What are the possible risks of taking part?

While it is not envisaged that this study will present any significant risks following issues have been considered:

- The self-screening questionnaire at the start of BACK-to-FIT^{TM} may indicate a more serious condition, and if this is the case you will be encouraged to consult your doctor. Low Back Pain self-screen formulated from the National institute for health and care excellence (NICE) guidance on clinical indicators of spinal pathology or systemic illness have been used. If you answer 'yes' to any of the screening questions you are not able to participate in the study and it is recommended that you seek medical advice. You can contact the research team anytime if you have any questions about the study.
- The study will hold sensitive information relating to your health. All data including online interview and survey data will be anonymised, fully encrypted, stored and back up on a secure web-based server operated from Cardiff University.
- If you have not been active for a while, there is a minimum risk of a flare up in your low back pain symptoms during the 4-week exercise programme of the intervention. However, necessary advice and guidance to manage your symptoms in case of an LBP flare up are given in the introduction and the patient education module. Additionally, you are encouraged to contact the main researcher (AS) whenever it is required to obtain further advice or guidance.

8. Will my taking part in this research project be kept confidential?
All information collected from you during the research project will be kept confidential and any personal information you provide will be managed in accordance with data protection legislation. Please see 'What will happen to my Personal Data?' (below) for further information.

9. What will happen to my Personal Data?

All information that is collected during the course of the research including your personal data will be kept strictly confidential. The procedures for handling, processing, storage and destruction of data will follow the Data Protection Act 2018. All the data will be anonymous and given a code, known only to the researcher. A Secure Sockets Layer (SSL) encrypted connection and a server would be used to circulate the survey link via OnlineSurveys.com where data will be stored in a password protected electronic format. Access to your name, email address, or IP address will be restricted to the principal investigator (AS) only. OnlineSurveys.com does not store any of your personal data or will not be disclosed to any third parties. No one else will be able to see your answers, and no one will know whether or not you participated in the study.

Cardiff University is the Data Controller and is committed to respecting and protecting your personal data in accordance with your expectations and Data Protection legislation. Further information about Data Protection, including:

- your rights
- the legal basis under which Cardiff University processes your personal data for research
- Cardiff University's Data Protection Policy
- how to contact the Cardiff University Data Protection Officer
- how to contact the Information Commissioner's Office

may be found at https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection

After a maximum 05-year period the research team will anonymise all the personal data it has collected from, or about, you in connection with this research project, with the exception of your e-consent forms. Your e-consent form will be retained for 15 years and may be accessed by members of the research team and, where necessary, by members of the University's governance and audit teams or by regulatory authorities. Anonymised information will be kept for a minimum of 05 years but may be published in support of the research project and/or retained indefinitely, where it is likely to have continuing value for research purposes.
If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

10. What happens to the data at the end of the research project?

Data from this study will be utilised to preliminary evaluate the BACK-to-FIT™ intervention and to further develop the second prototype of the intervention.
Additionally, data will form part of principal investigator's PhD thesis and the results of the study will be presented at scientific meetings and published in journals for healthcare professionals and computer scientists. You will not be identified in any report/publication, but we may use some of the comments that you provide us with in our reports.

11. What will happen to the results of the research project?
It is our intention to publish the results of this research project in academic journals and present findings at conferences. We intend to use verbatim quotes form your online interviews relevant to the publications. However, participants will be anonymised and will not be identified in any report, publication or presentation. A copy of the results would be available for you to obtain after completing the study.

12. What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the chief investigator who will do her best to answer your questions (Akushla Senarath Rathnayake; senarathA@cardiffa.ac.uk 07492404457) . If you remain unhappy and if you wish to complain, or have grounds for concerns about any aspect of the manner in which you have been approached or treated during the course of this research, please contact Dr Kate Button, Director of Research Governance, School of Healthcare Sciences (Dr Kate Button; buttonk@cardiff.ac.uk, 02920687734). If your complaint is not managed to your satisfaction, please contact Professor David Whitaker, Head of School, whitakerd@cardiff.ac.uk or 02920 874703.
If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for legal action, but you may have to pay for it.

13. Who is organising and funding this research project?
The research is organised by Akushla Senarath Rathnayake, Dr. Liba Sheeran and Prof. Valerie Sparkes, School of Healthcare Sciences in Cardiff University. The research is currently funded by Biomechanics and Bioengineering Research Centre Versus Arthritis, Cardiff University.

14. Who has reviewed this research project?
This research project has been reviewed and given a favourable opinion by the School of Healthcare Sciences Research Ethics Committee, Cardiff University.

15. Further information and contact details
Should you have any questions relating to this research project, you may contact us during normal working hours:

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074 92404457 ; senarathA@cardiff.ac.uk
School of Healthcare Sciences, College of Biomedical and Life Sciences
Cardiff University
Eastgate House, Newport Road, Cardiff
CF24 0AB

Thank you for considering to take part in this research project. If you decide to participate, you will be given a copy of the Participant Information Sheet and a e-consent form to keep for your records.