

# Validation And Evaluation of A Work-Based Individualised Digital Health Intervention (BACK-On-LINE<sup>™</sup>) to Support Self-Management of Low Back Pain

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## Abstract

**Background**: Low back pain (LBP) imposes physical, psychological and financial burdens on individuals, especially the working-age population. Self-management offering education, encouraging exercise and staying in work is recommended, but existing support is mainly provided within primary care settings. Digital health interventions developed for health self-management (DHSMIs) provides an opportunity for early intervention of LBP in the workplace. However, existing DHSMIs tend to be unidimensional focused on physical behaviours in work, providing generic LBP advice with minimal individualisation as recommended within clinical guidelines. BACK-on-LINE<sup>™</sup> (BOL) has been designed as an individualised DHSMI accessible to people with LBP in the workplace. It incorporates the previously developed BOL selfassessment to classify LBP into nociceptive and nociplastic pain subgroups by pain mechanisms and provides an individualised work-based intervention for LBP management. Therefore, this PhD project aimed to first synthesise and appraise existing evidence on DHSMIs, focused on individualised LBP self-management in the workplace. The technological feasibility, acceptability and potential benefits of using BOL for LBP across three different work settings was determined and, baseline data from this evaluation determined reliability and validity of the BOL self-assessment.

**Methods:** Based on the UK National Institute For Health And Care Research and Medical Research Council's complex intervention assessment framework, a three-phase mixed-methods research design was conducted. The systematic review (Phase 1) reviewed current DHSMI research on LBP self-management in the workplace, particularly individualised DHSMIs. Phase 2 established the cut-off points and assessed the reliability and validity of the BOL self-assessment in discriminating LBP subgroups among the working population. In Phase 3, technological feasibility, acceptability and potential benefits of applying BOL to assist LBP self-management in the workplace were evaluated through a comprehensive interpretation of the mixed data.

**Results:** The systematic review revealed a scarcity of DHSMIs for LBP selfmanagement in the workplace, and self-management of LBP was predominantly unidimensional, with only one study attempting individualisation. Phase 2 established the cut-off point (36 points) of BOL self-assessment for discriminating LBP subgroups in the working population. The BOL self-assessment demonstrated good test-retest reliability, internal consistency, construct and criterion validity. In Phase 3, BOL was found to be technologically feasible and acceptable in aspects such as usage (10.25 visits per participant), self-assessment and offering individualised feedback. There was a significant loss in follow-up, which may be attributed to the industrial shutdown and the shifted work focus of the involved NHS occupational health departments due to COVID-19. **Conclusion:** There is a lack of high-quality research on the DHSMI for LBP in the workplace, with further scarcity of individualised DHSMIs. Classifying LBP based on pain mechanisms is deemed useful and welcomed by BOL users. It is technologically feasible and acceptable to use BOL to support LBP self-management in the healthcare, education and transport industries. Enhancing adaptability and functionality were suggested areas by BOL participants for improving individualisation.

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## Abbreviation

Abbreviation	Term
AUC	Area Under The Curve
BOL	Back-On-Line <sup>™</sup>
CBT	Cognitive Behaviour Therapy
DHSMI	Digital Health Self-Management Intervention
GP	General Practitioners
НСР	Healthcare Professionals
ICC	Intraclass Correlation Coefficient
IPAQ-SF	The International Physical Activity Questionnaire- Short Form
LBP	Low Back Pain
MRC	Medical Research Council
MSD	Musculoskeletal Disorder
MSK	Musculoskeletal
NG	National Guideline
NHS	National Health Service
NICE	National Institute For Health And Care Excellence
NIHR	National Institute For Health And Care Research
NPRS	Numerical Pain Rating Scale
ODI	Oswestry Disability Index
ONS	Office For National Statistics
PROM	Patient-Reported Outcome Measure
RCT	Randomised Controlled Trial
RMDQ	Roland-Morris Disability Questionnaire
ROC	Receiver Operating Characteristic
RTW	Return To Work
SA	Sickness Absence
SBST	Start Back Screening Tool
SCT	Social Cognitive Theory
SD	Standard Deviation
SDT	Self-Determination Theory
SR	Systematic Review
U.S.	United States Of America
UK	United Kingdom

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#### 1. Chapter 1: Introduction

As a prevalent and disabling condition, low back pain (LBP) was estimated to affect over 60% of the adult population at some point in their lives (Ferreira et al. 2023). In the United Kingdom (UK), the one-year prevalence of LBP was reported as 30.79% (Palmer et al. 2000; Yu et al. 2022), indicating that one in three UK residents would be affected by LBP in one year. The results from a cross-sectional study including 15,272 UK residents showed that LBP particularly affected the working population aged 41-50 years old (Macfarlane et al. 2012). As the second most common cause of absenteeism in the working population, LBP has severely impaired the productivity of the UK workforce (Maniadakis and Gray 2000), with the highest rates of absenteeism found in the health services (4.2%) and education (3.0%) (Statistics 26 April 2023). Between 2021 and 2022, the Office for National Statistics (ONS) reported an all-time high 185.6 million workdays lost due to musculoskeletal disorders (MSD; with LBP most prevalent) accounting for around 23.4 million days. Of the total 477,000 cases of work-related MSD documented by the UK Health and Safety Executive (HSE) in 2022, 42.35% were attributed to back pain. The HSE annual report 2022 also stated that work-related health issues cost up to £11.2 billion, with MSD (LBP included) accounting for 27% of the total expenditure. Meanwhile, the prevalence of LBP in the general working population has resulted in high volume of healthcare demand, from consultations and diagnosis to rehabilitation services, thus further straining healthcare resources (Montgomery et al. 2017). MSD combined were reported to account for approximately 30% of general practitioner (GP) consultations (Margham 2011) which resulted in an annual expenditure of £4.76 billion to the National Health Service (NHS) (Greenhalgh et al. 2020). Furthermore, with healthcare being reported as the industry with the highest sickness absence (SA) rate by the ONS in 2023, the NHS was estimated to experience up to a £2.4 billion loss because of its own staff absenteeism due to LBP (Dixon et al. 2018). These enormous expenditures puts strain on the already overwhelmed NHS resulting in longer appointment waiting times and reduced availability of primary care for people with LBP (Cooper et al. 2008).

Given the complex and growing demands that LBP has placed on primary care services, the National Institute for Health and Care Excellence (NICE) updated the guidelines for LBP and sciatica management (NG 59), which promoted self-

management, keeping active and staying in work (National Guideline 2016). The selfmanagement of chronic diseases has been described as the capability of an individual to manage the symptoms, treatments, physical and psychological outcomes, and modifications of lifestyles (Kongsted et al. 2021). This traditional primary care paradigm, sometimes referred to as patient empowerment (Bodenheimer et al. 2002), encouraged patients to become their own health resources and take active responsibility for managing their health condition through reinforcing internal motivation (Baumann and Dang 2012; Du et al. 2017). However, the effectiveness of self-management was found to be affected by individuals' decision-making capacity to make the changes necessary to maintain their health status (Lorig and Holman 2003). This left some patients feeling isolated and overwhelmed, especially those with chronic conditions who have low self-management activation (Paukkonen et al. 2022). Also, the low-level self-management was found to be associated with higher healthcare utilisation and costs, poorer physical health and health-related quality of life (Barker et al. 2018; Choi et al. 2022).

Therefore, recent clinical self-management interventions has shifted from traditional self-management models, which placed the responsibility on individuals, towards supported self-management, where healthcare professionals (HCPs) play an active role and work with patients (Kang et al. 2024). Under this supported self-management model, HCPs break down individual goals into manageable steps based on the patient's capabilities through interventions such as peer support, self-management education, and health coaching, thereby assisting the patient in developing the ability to address the self-perceived most important issues, and eventually helping the patient successfully manage long-term conditions (Kang et al. 2024). For its potential to improve health outcomes, reduce healthcare utilisation, and enhance patient satisfaction, this supported self-management approach has been recognised as the best patient-centred care practice by NICE (NG 138)(NICE 2021). Whilst there is growing research in high quality self-management interventions for people with LBP in primary care (Dineen-Griffin et al. 2019), there is lack of research for LBP self-management in workplace.

"Working for a Healthier Tomorrow", was a pioneering report with respect to public health policy focused on occupational health (Black 2008). More organisations and

employers have recognised "the key role the workplace can play in promoting health and well-being" (Webber 2019, p. 15). The government and employers have proactively engaged to improve workplace health and well-being through employee education and training, flexible working arrangements and occupational health services (Waddell and Burton 2001). However, LBP-related self-management initiatives were still nested within primary care settings and typically become relevant only when working population seeks time off work (Gomes et al. 2022). There may be an opportunity to intervene earlier whilst people may be experiencing back problems in the workplace but are not yet at a stage where they need to take time off work (Vargas-Prada et al. 2016). As recommended by NICE on the management of longterm SA (NG 146), organisations should provide employees with SA lasting more than four weeks with early interventions such as rehabilitation, counselling, employee assistance programme or referrals to occupational health, thus assisting with return to work (RTW), reducing recurrent SA, and preventing people from progressing from short-term to long-term SA (NICE 2019a).

As an emerging intervention approach in the Internet era, digital health interventions to support self-management (DHSMIs) are being increasingly developed to provide health-related advice and educational information (Nicholl et al. 2017). Existing evidence suggests that DHSMIs have great potential in addressing the challenges in promoting LBP self-management (Nicholl et al. 2017; Geraghty et al. 2018; Cui et al. 2023). From the NHS perspective, these internet-based interventions are potentially low cost (Jiang et al. 2019) and compared to traditional face-to-face medical treatment, DHSMIs can be more easily accessed (Cui et al. 2023). Also, DHSMIs can flexibly function as the main instrument of the intervention or as a medium for remote healthcare to provide advice and resources based on evidence-based practice and guidelines (Barbosa et al. 2021). According to a recent systematic review (SR), several DHSMIs exist to support LBP in the workplace, including web-based education on positive thinking and meditation, virtual animated therapists providing sleep advice, and software for sitting postures reminders (Stratton et al. 2021). However, these interventions were found to produce small effect on work-related outcomes such as absenteeism and workability. Some DHSMIs adopted cognitive behavioural therapy (CBT) to address psychosocial factors in the workplace, such as SA-related stress (Weber et al. 2019) and depression (Billings et al. 2008), but similarly the impact of those interventions on work-related factors remains small (Moe-Byrne et al. 2022).

The key problem is that these interventions tend to address a single dimension within highly complex and multifactorial LBP disorder (Svensson et al. 2009), which is known to be maintained by range of bio-psycho-social factors (Richard 2013). This means that unidimensional interventions would likely bring benefits to only a discrete subset of people with LBP (Zaina et al. 2023). Another issue is that most of existing DHSMIs for LBP offer largely generic advice with limited attempts for stratification, considering individual characteristics (e.g. demographics, pain mechanism, and occupation), needs and capabilities of individuals with LBP (Hunter et al. 2023). As a recommended LBP management approach (National Guideline 2016), stratification in pain management refers to the process of categorising patients into distinct subgroups based on specific characteristics or risk factors, with the goal of individualising treatment approaches to individual's unique needs and capabilities (Delitto et al. 2021). Several stratification techniques and classification systems have been developed and validated in the context of pain management to provide evidence-based intervention, particularly for chronic pain conditions like LBP, such as pathological anatomy based (Petersen et al. 2017), treatment-based (Alrwaily et al. 2016), prognostic-based (Hill et al. 2008), movement-based (Sahrmann et al. 2017), pain mechanism-based (Smart et al. 2008). These approaches recognise the heterogeneity of pain conditions and individual characteristics and aim to improve treatment outcomes by providing more individualised interventions.

Consistent with this approach, BACK-on-LINE<sup>™</sup> (BOL) was developed by Alothman et al. (2017, 2019) and Sheeran et al. (2024) as a work-based individualised DHSMI to support the self-management of LBP in workplace. The conceptual goal was for users to self-categorise their LBP based on dominant pain mechanism derived from individual's account of their pain behaviour, and perceptions of LBP impact on their lifestyle and workability using the BOL self-assessment developed with expert consensus (Alothman et al. 2017). This then provided individualised guidance from recommended guidelines on pain, physical activity, exercise and sedentary behaviour reflecting their pain type and work profile (Sheeran 2024a,b). While preliminary evidence exists regarding the psychometric properties, reliability, and validity of the

BOL self-assessment for classifying pain subgroups, this evidence was based on a small sample population within primary care (not workplace) settings (Alothman et al. 2019). In addition, while previous studies have described the development phase of the BOL self-assessment (Alothman et al. 2017,2019) and the BOL self-management intervention (Sheeran 2024a,b), the technological feasibility, acceptability and potential benefits of the individualisation approach within the BOL self-management intervention have yet to be evaluated. Finally, to ensure the intervention development is informed by the most current and robust evidence base, a critical evaluation and synthesis of recent research on individualised digital health self-management interventions (DHSMIs) for LBP in workplace settings is needed to contextualise findings and guide evidence-informed enhancements. This PhD thesis has set out to answer to these research gaps adopting the Medical Research Council (MRC) framework for complex health intervention development and evaluation to promote the understanding and application of DHSMI for LBP in workplace settings (Skivington et al. 2021).

#### 1.1 Aims and objectives

Reflecting on the identified research gaps, the overarching aim of this PhD project is to advance the development of the BACK-on-LINE<sup>™</sup> (BOL) digital health self-management intervention (DHSMI) tailored specifically for workplace populations experiencing low back pain (LBP)

To address this aim, the thesis is structured into three distinct phases, each with specific objectives:

#### Phase 1. Systematic Review

**Objective:** To critically appraise and synthesise the most recent evidence on the effects of individualised DHSMIs for LBP self-management in workplace settings.

#### Phase 2. Psychometric Evaluation of the BOL Self-assessment

**Objective:** To establish the optimal cut-off point for the revised online version of the BOL self-assessment tool and evaluate its psychometric properties—including reliability and validity—in classifying nociceptive and nociplastic pain groups among working populations in industries with high LBP prevalence.

### Phase 3. Feasibility and Acceptability Study of BOL for LBP Self-management

**Objective:** To evaluate recruitment feasibility, technological feasibility, acceptability, and perceived benefits of the BOL DHSMI, accompanied by a qualitative exploration of user experiences within occupational settings.

#### 1.2 Thesis structure

This thesis is organised into eight chapters. <u>Chapter 1</u> introduces the study and outlines the thesis aims, which inform the structure of this thesis. <u>Chapter 2</u> follows with a comprehensive literature review, providing the background of this research. It critically evaluates the existing evidence on conventional approaches to managing LBP and examines the challenges associated with self-management in workplace settings. The chapter also reviews the use of DHSMIs for LBP self-management in workplace, identifies the limitations of current practices and emphasises the need for individualised approaches that underpin the aims of this PhD project. Next, it appraises previous developments of BOL and highlights its advantages in addressing these gaps which justifies the rationale for conducting this study.

<u>Chapter 3</u> outlines the research paradigms, justifies the adoption of a pragmatic research philosophy, and explains the convergent parallel mixed-methods design. It also introduces the NIHR/MRC framework for evaluating complex interventions, contextualising the BOL intervention, and presents its content and theoretical framework.

The study is conducted in three phases:

- Phase 1 (<u>Chapter 4</u>): A systematic review (SR) to synthesise evidence on the effects of DHSMIs on LBP in the workplace, focusing on individualised interventions. The SR assesses the quality of evidence, participant characteristics, outcome measures, and intervention effects, concluding with limitations and future recommendations.
- Phase 2 (<u>Chapter 5</u>): Methodology for determining the cut-off point and evaluating the psychometric properties of the BOL self-assessment. The chapter discusses

the reliability and validity of the BOL tool, comparing its performance with the SBST for classifying LBP pain mechanisms.

- Phase 3 (Chapters 6 and 7):
- <u>Chapter 6</u>: Quantitative analysis, detailing the research design, recruitment, data collection, and analysis of the BOL study. It presents descriptive statistics and evaluates the technological feasibility, acceptability, and potential benefits of BOL for LBP management.
- <u>Chapter 7</u>: Qualitative analysis of telephone interviews with BOL participants, exploring their feedback on BOL access, self-assessment, feedback modules, and perceptions of BOL's effectiveness in LBP self-management. Participant recommendations for future BOL development are also discussed.

<u>Chapter 8</u> concludes this thesis with a discussion of the main findings, contributions to knowledge, and implications for the application of BOL in occupational health. It also addresses the study's strengths, limitations, and recommendations for future development of BOL.

This thesis provides original contributions to knowledge by advancing the understanding and application of digital health self-management interventions (DHSMIs) for workplace low back pain (LBP) management. The first evidence synthesis of DHSMIs for LBP in the workplace contributes to the growing field of digital health interventions, with a particular focus on individualised, evidence-based approaches to managing LBP in the workplace. Second, this thesis validates the BOL self-assessment tool in classifying nociceptive and nociplastic pain subgroups in the working population, strengthening the evidence base of mechanism-based approaches for tailoring interventions to individuals with distinct LBP profiles. For the BOL, which is at the feasibility stage of the NIHR/MRC framework, this thesis provides an original contribution by demonstrating the feasibility of recruiting participants from multiple workplace settings and providing preliminary evidence of good technological feasibility and acceptability of the BOL intervention. The results of feasibility study offers practical insights into the future implementation stage of BOL in workplace settings and identifies strategies to improve engagement, accessibility, and retention in future large scale trails.

#### 2. Chapter 2: Literature review

#### 2.1 Introduction

This chapter reviews the impact of LBP on society, organisations, and individuals, the guidelines for managing LBP in primary care and occupational health settings and existing occupational health policies. Then, an in-depth examination of the evidence for the common practices for LBP management in the workplace is presented, with a focus on self-management. It then provides an insight into the DHSMIs developed to support LBP self-management in the workplace, followed by highlighting the importance of the classification approach in providing individualised LBP interventions. Lastly, to address the knowledge gaps and underlying limitations of current intervention practices in supporting self-management of LBP in the workplace, this chapter presents an overview of a work-based individualised DHSMI (BOL), bringing together previous development and the prospects for future development.

#### 2.2 Low back pain in the working population

#### 2.2.1 Prevalence of LBP

Low back pain has been recognised as one of the most prevalent health problems worldwide (Yang et al. 2016; Fatoye et al. 2019; Ferreira et al. 2023). In the recent Lancet series, LBP was defined as pain occurring between the lower rib margin and the creases of the buttocks, often accompanied by neurological symptoms in the lower limbs (Hartvigsen et al. 2018). The European guidelines for the prevention of LBP (Burton et al. 2004) outlined a similar definition of LBP as "pain and discomfort localised below the costal margins and above the inferior gluteal folds, with or without leg pain" (Burton et al. 2006, p. 140). It has been widely accepted in current literature that LBP is not a single medical condition but rather a multifactorial symptom, typically of an acute and self-limiting nature (O'Sullivan 2005). However, while acute pain symptoms may resolve over time, 6 - 8% population with LBP could experience persistent and recurrent pain even over 12 weeks (Nicol et al. 2023). Furthermore, two-thirds of individuals with LBP experience a recurrence of pain within 12 months (da Silva et al. 2019), thereby increasing the risk of disability (Vlaeyen et al. 2018). In the United Kingdom (UK), more than half of the LBP patients in primary care remained in persistent pain and disability three months after the initial consultation (Jones et al. 2006). Meanwhile, only 10-15% LBP cases were diagnosed with specific causes such

as vertebral fracture, malignancy, or infection (Hartvigsen et al. 2018). The remaining 85-90% of LBP is termed non-specific LBP, characterised by pain that is not attributed to any specific, identifiable pathological cause (Maher et al. 2017).

LBP has established itself as a ubiquitous issue affecting adults of all ages, with its prevalence spanning across different demographic, geographic, and socioeconomic backgrounds (Ferreira et al. 2023). Approximately 80% of the population, at some point in their lives, will experience LBP (Fatoye et al. 2019). In 2020, LBP impacted 619 million people worldwide, and was expected to reach 843 million by 2050 (Ferreira et al. 2023). The prevalence of LBP has been found to vary regionally, influenced by factors including culture, socioeconomics, and healthcare availability (Vlaeyen et al. 2018). In industrialised countries such as the UK, a cross-sectional study among adults aged over 25 years (n = 15,272) reported a 1-month LBP prevalence rate of 23.2% in the UK (Macfarlane et al. 2012). A national household survey of 2022 in the United States (U.S.) revealed an annual prevalence rate of 20.5% for LBP among adults (Yong et al. 2022). Likewise, Australia also faced a substantial burden of LBP, affecting 25.5% of the adult population (Kent and Keating 2005). The European Urban Health Indicators System project reported a higher average prevalence of LBP (44.6%) in 32 urban areas of 11 European countries, ranging from 33.4% to 67.7% (Ugwu and Pope 2023). This study was implemented in 2010, before Brexit, and therefore included the data of LBP prevalence in the UK. Compared with the 23.2% 1-month prevalence of LBP in the Macfarlane et al. study, this project reported a higher prevalence (37.1%) across all age groups (n= 6223) in the UK (Ugwu and Pope 2023). In this study across Europe, participants who self-reported having experienced at least one day of LBP in the past month were classified as individuals with LBP (Pope et al. 2017). It is important to stress that this data is based on a sample obtained from population-intensive cities, thus does not include rural and deprived areas (Pope et al. 2017). Therefore, the data collection method and the varying levels of healthcare, education, and economic status of the selected samples is likely to contribute to the high but varied prevalence of LBP even between European industrialised countries.

Not only in industrialised countries, LBP has reached a global pandemic scale and is now a leading cause of disability worldwide (Ferreira et al. 2023). This is the case despite data on LBP in low-middle income countries likely being underreported (Fatoye et al. 2023). Due to the scarcity of data on the prevalence of LBP in low-middle income countries, accurate estimates of LBP remained challenging (Morris et al. 2018). Although there is a lack of nationwide studies with large sample size, the available evidence indicates that the prevalence of LBP is higher in low-middle income countries (Sharma and McAuley 2022). A SR of studies assessing risk factors for LBP in Iranian workers over the past 15 years reported an annual prevalence of LBP of 48.8% (Mazloumi et al. 2020). Similarly, the annual prevalence of LBP among 296 office employees was reported as 55.4% in Ethiopia (Workneh and Mekonen 2021). Furthermore, in Bangladesh, 62% of industrial workers were reported to have LBP in a cross-sectional study (Chowdhury et al. 2023). Although there are some regional differences in the prevalence of LBP (Chen et al. 2022), the evidence from global studies indicate that high prevalence of LBP is a critical challenge particularly among the working-age populations, both in industrialised and low-middle income countries (Ferreira et al. 2023).

#### 2.2.2 Economical burden of LBP

As a major global public health challenge, the burden imposed by LBP cannot be overstated. Consequently, its impact extends beyond affecting individuals, but has a wider impact on healthcare systems, economies, and society (Fatoye et al. 2023). The direct costs associated with LBP, particularly on health resource consumption and government expenditure, are widely reported (Alonso-García and Sarría-Santamera 2020; Chen et al. 2022; Wang et al. 2022; Yong et al. 2022; Fatoye et al. 2023; Ferreira et al. 2023). From the 2019 Global Burden of Disease study, it was observed that LBP contributed to an estimated 63.7 million disability-adjusted life years (DALYs) globally (Wang et al. 2022). DALY was described as a statistical indicator representing the number of years of life lost due to the prevalence and mortality associated with a specific disease (Nolte et al. 2019). It is this disability associated with LBP that has become a significant driver of global healthcare expenditures (Wang et al. 2022).

An enormous financial burden stemming from LBP has also been reported in the UK, with an estimated £3.5 billion in direct medical costs (Zemedikun et al. 2023). It was estimated that approximately 9.5 million people experienced LBP in the UK in 2019 (Versus Arthritis, 2021), which contributed to £35.9 billion in healthcare expenditure in 2020 (Zemedikun et al. 2023). There are an estimated 1,600,000 people visiting the

outpatient departments of hospitals each year for treatment for LBP (Main et al. 2005). Previous research has stated that chronic pain conditions, including LBP, have resulted in 4.6 million GP consultations, equivalent to the full-time workload of 793 general practitioners (Smith et al. 2014). Furthermore, over half of LBP patients (56.5%) were referred to specialists or surgery (Hong et al. 2013). Meanwhile, previous research has indicated that over 29% individuals with LBP revisit their GP within three months (Croft et al. 1998). As of 2022, 62.8% of patients with LBP experienced waiting times exceeding 18 weeks before being referred to a physiotherapist (NHS 2023). During this prolonged waiting time, limited access to healthcare resources exacerbated patient anxiety (Kulkarni et al. 2021), which made acute LBP more likely to progress to chronicity and disability (Galbusera et al. 2021).

#### 2.2.3 Societal and organisational burden of LBP

Whilst all age groups from children to the elderly are affected, it is the working age population that is affected the most (Hartvigsen et al. 2018), with a significant proportion of affected individuals developing recurrent LBP problems (19.6%) (Bikbov et al. 2020).

The working population was found to have a 2.5 times higher prevalence of LBP than the non-working population (95% Confidence Interval(CI): 1.21 - 4.10)(Hartvigsen et al. 2018). A National Health Interview Survey reported that the prevalence of LBP among all working population in the U.S. was 25.7% (Yang et al. 2016). According to data from the Sixth European Working Conditions Survey (2015), the prevalence of LBP among 1,623 employees and self-employed people in the UK was 35% (Rizzello et al. 2019). Whereas in low-middle income countries, the point prevalence of LBP among the working population also reached 39% (Morris et al. 2018). The prevalence of LBP also varies between occupations. Office workers were reported with annual LBP prevalence ranging from 18% to 38% (Janwantanakul et al. 2011; Mehrdad et al. 2016). In transport workers, the annual prevalence of LBP has been reported to be even higher, at 55.4% (Workneh and Mekonen 2021). Likewise, high annual prevalence of LBP was reported among HCPs, including dentists (88.9%), physicians (73.2%) and nurses (72.9%) (Alnaami et al. 2019).

The high prevalence of LBP, combined with the significant burden it imposes, has led to substantial social and economic impacts on the working-age population. The burden of LBP on working populations is associated with inability to work, leading to indirect costs incurred through lost workdays in SA and decreased productivity, which pose substantial financial burdens on individuals, businesses, and governments. According to the UK ONS, MSD related to LBP and neck pain were the second most common cause of SA, accounting for 23.4 million days lost in 2022. In the UK, 12.5% of the unemployed cited LBP as a reason for not working, with 135,000 LBP individuals applying for Disability Living Allowance (Main et al. 2005), with only 10% on incapacity benefits returning to work (Main et al. 2005). In addition, people who have received social benefits for for LBP for more than six months were likely to continue to receive benefits after five years (Main et al. 2005). From a study of the working population in Jersey, UK, LBP patients with SA over six months represented only 3% of the study sample but contributed to 33% of the benefit claims (Watson et al. 1998). Similarly, it also accounted for 1.49 billion lost workdays annually in U.S. industries, of which 1.08 million were attributed to work-related LBP (Freburger et al. 2009). The productivity losses stemming from LBP accounted for \$1.738 billion in social costs in U.S. (Carregaro et al. 2020), which included benefits for people unable to work due to LBP and additional costs incurred due to the entitlement to these benefits.

#### 2.2.4 Impact of LBP on individuals

Apart from imposing both direct and indirect financial challenges on governments and organisations, LBP also has several impacts on individuals. Typically, one of the common symptoms of LBP in individuals is pain associated with a significant loss of physical function (Weiner 2007), ranging from inability to perform simple daily tasks like bending to tie shoelaces to more physically demanding activities such as heavy lifting and gardening (Ge et al. 2022). This status of impaired functionality, as one dimension of disability associated with LBP, would prevent individuals from engaging in daily activities in their preferred way (Grabovac and Dorner 2019), thus provoking feelings of frustration, isolation, and an overall decrease in life satisfaction (Bailly et al. 2015). The sustained discomfort and uncertainty about recovery may further exacerbate pre-existing stress levels, eroding individuals' self-esteem and sense of control over life (Mathew et al. 2013). Findings of qualitative research indicated that individuals with LBP may withdraw from social activities and interpersonal

relationships with partners, family, and friends due to pain and concerns about exacerbation of conditions (Snelgrove and Liossi 2009). This decreased social engagement was revealed to be associated with deeper sense of isolation and loneliness in individuals with LBP (Smith et al. 2019), which would further worsen the pressure and burden on their family members (Meints and Edwards 2018).

For the working population with LBP, along with changed physical activities and lifestyles, there is also a huge challenge in adjusting to the unpredictable nature of pain in the workplace (Bunzli et al. 2015). Previous research revealed that employees with insufficient LBP preparation, especially psychological adjustment, would generate lower satisfaction with the working environment when responding to a normal workload (Hoogendoorn et al. 2000). This challenge of coping with LBP in the workplace can result in reduced concentration and productivity for employees (Manchikanti et al. 2014; Grabovac and Dorner 2019). It was reported that the low satisfaction within the workplace, associated with LBP, would further increase the risk of developing chronic pain and even disability (Williams et al. 1998). In contrast, a prospective study showed that employees with higher job satisfaction were more likely to return to work after SA for LBP (Odds Ratio (OR) = 1.26; 95% CI 1.11-1.44) (Van Der Giezen et al. 2000). Meanwhile, the perception of individual's inability to fully contribute to the workplace could also bring a significant loss of self-esteem (Gómez-Jorge and Díaz-Garrido 2023), thus leading to emotional distress that may extend outside the workplace and permeate all aspects of the employee's personal life. Concerns arising from this were reported to be particularly common among younger workers, who tend to perceive LBP as a threat to their careers (Busch 2005). While in other age groups, the fear of potential unemployment and the associated economic deprivation, as well as concerns about future well-being, also heightened job insecurity (Yang et al. 2016). An increasing body of research found that the physiological vulnerability resulting from LBP could be even more severe and, in some cases, lead to further negative effects, including insomnia (Generaal et al. 2017), depression (Wong et al. 2022), and anxiety (Ferrie et al. 2002). Uncertainty over the ability to manage pain and fear of pain recurrence could also create anxiety and lead to avoidance behaviours (Wertli et al. 2014). The fear of worsening work-related symptoms further intensify the emotional distress and resulting in both physical and emotional painfulness (Bunzli et al. 2017; Vignoli et al. 2017).

#### 2.3 Guidelines for managing LBP in occupational health settings

This section provides a review of the current guidelines and policies on LBP management in both primary care and occupational health settings. It explores the essential strategies for LBP management, highlighting the importance of early intervention, evidence-based treatments, and the promotion of staying active and returning to work.

#### 2.3.1 Clinical practice guidelines for the management of LBP

Clinical guidelines from 11 countries, including the UK (National Guideline 2016), U.S. (Qaseem et al. 2017) and Australia (Innovation 2016), recommended different types of exercise including supervised exercise, motor control exercises, yoga, and functional exercise for LBP (Chenot et al. 2017; Qaseem et al. 2017; Stochkendahl et al. 2018). Also, most of the guidelines considered psychosocial factors in the management of LBP and prioritised a multidisciplinary approach (Oliveira et al. 2018b). Some guidelines underlined the importance of self-management and encouraging people with LBP to stay active and return to normal activities (Pohjolainen et al. 2015; National Guideline 2016; Chenot et al. 2017).

The NICE guidelines on LBP and sciatica (NG59) recommended non-pharmacological treatment methods, emphasising self-management, exercise, and cognitive behavioural approaches to improve pain, quality of life and overall health status. It particularly noted that intervention should be individualised to personal needs, preferences, and capabilities (National Guideline 2016).

Another important feature of the NICE guidelines was the Return to Work (RTW) programme (NG 146) (NICE 2019b), which recognised the importance of workplace factors in the management of LBPs. The RTW programme was designed to promote the return of employees with LBP to paid jobs through combined physical and psychological programmes after SA. While it shared similarities with the clinical application of multidisciplinary rehabilitation, which typically included multimodal exercise, manual therapy, cognitive-behavioural therapy (CBT), and education (Kamper et al. 2015), the RTW programme focuses more on retaining or regaining ability to participate in work activities. This programme suggested that employees with

LBP should be provided with individualised workplace intervention to help them stay in work or return to work promptly (NICE 2019b). Furthermore, the guideline advised healthcare practitioners to consider the impact of work-related psychosocial risk factors on the onset and persistence of LBP. For employees who lost their jobs due to pain-related SA, returning to work was expected to improve pain and quality of life by addressing work-family imbalances and job instability (Yang et al. 2016). By implementing these recommendations in the workplace, employers and healthcare practitioners may support employees with LBP to better manage their condition whilst staying in work.

#### 2.3.2 Occupational health guidelines

Occupational health is a key branch of healthcare dedicated to the prevention and management of work-related health problems (Sparks et al. 2001). Of all the occupational health problems, LBP was recognised as the most common but challenging issue in the workplace (Waddell and Burton 2001). According to a survey conducted in 2000, nearly half of adults in the UK reported having experienced LBP that lasted for at least 24 hours at some point in a year (Palmer et al. 2000). The disability (Bartys et al. 2017), reduced productivity (Carregaro et al. 2020), and associated costs (Gaskin and Richard 2012) caused by LBP affected both companies and individuals.

In the UK, the well-being of the working population has been regarded as fundamental to the health of society (Waddell and Burton 2006). In March 2000, the UK Faculty of Occupational Medicine introduced the original national occupational health guidelines for LBP, making it the world's first evidence-based occupational guideline for LBP (Waddell and Burton 2001). This guideline reflected on Waddell's concept of Biopsychosocial Model (BPS) (Waddell 1987), for the management of LBP in the occupational setting. This guideline recommended identifying potential psychosocial disorders and risk factors of LBP in occupational settings beyond screening for "red flags" and neurological indicators (Waddell and Burton 2001, p. 127). Also, this guideline suggested staying active with LBP and implementing multidisciplinary interventions to prevent the development of chronic pain and disability. Moreover, the guidelines emphasised the necessity for communication, collaboration, and goal

setting between employees with LBP, occupational health departments, employers, and healthcare professionals in primary care (Waddell and Burton 2001).

This guideline marked an advancement in occupational health, recognising the multifaceted nature of LBP and the necessity for a holistic management strategy. Complementing this approach, the Health and Safety Executive (HSE) plays a crucial role in enforcing workplace health and safety regulations. The HSE has implemented various regulations and policies to reduce the risk of work-related LBP and promote the health and safety of workers, such as the Manual Handling Operations Regulations (Health and Safety Executive 2018) and Display Screen Equipment (Health and Safety Executive 2019). These regulations stated that the employer is under an obligation to protect workers from performing tasks with a risk of LBP. Apart from assessing the risks associated with manual handling tasks that may contribute to LBP, employers were required to provide a safe working environment with appropriate training, workstation setup and regular breaks to prevent LBP in the workplace (Health and Safety Executive 2021).

While the HSE devoted its efforts to promote a proactive approach by raising awareness among employers and employees about the importance of early intervention and prevention strategies, the diverse safety cultures between organisations and the lack of commitment from senior management brought significant challenges for implementation (Biron et al. 2010). As evolving technology changed many structures of industries, another challenge for the HSE was to keep up with the development in LBP risk assessment and management programmes to meet the needs of changing and different industries. Also, employees' negative attitudes towards workplace interventions and resistance of behavioural change were also huge obstacles in the advancement of HSE policies and regulations (Mareš 2018). To overcome these challenges, previous research suggested system-wide policy changes to shift resources from unnecessary care to support the approaches recommended in the mainstream LBP guidelines (Traeger et al. 2019). As advocated by HSE, it is vital to progress a certain level of awareness across the whole spectrum of the industry to spark organisational change and employee engagement (Duryan et al. 2020).

#### 2.4 Managing LBP in the workplace

Over the past two decades, multiple occupational health interventions and strategies have been developed by organisations and companies based on existing clinical and occupational guidelines for SA (van Vilsteren et al. 2015), disability (Russo et al. 2021) and socio-economic factors (Poulain et al. 2010). Given the nature of different occupations, interventions have been designed to address an array of goals, including prevention and management of LBP, improving disability, reducing SA and facilitating returning to work (Poulain et al. 2010; Fisker et al. 2022; Turesson et al. 2022). Following the NICE guidelines on LBP, this study focussed on research to achieve the above goals through non-pharmacological workplace interventions. This section below critically reviews research literature centred around delivering education, ergonomic, exercise, and multidisciplinary interventions to support LBP management in the workplace.

#### 2.4.1 Education

In accordance with the promotion of 'Safety management and risk education in the workplace' (Waddell and Burton 2001), educational interventions in the form of pamphlets (Hazard et al. 2000), booklets (Rantonen et al. 2014) or other written materials containing health information related to LBP have been introduced into many large organisations for its established cost-effectiveness (Marshall et al. 2003). Previous workplace educational interventions for the management of LBP was reported to include LBP-related anatomy information (spinal structure, causes of LBP, types of pain) (Brox et al. 2008), ergonomic skills on work-related movements (sitting, handling, lifting) (Verbeek et al. 2011), behavioural-cognitive techniques for occupational mental health (stress, phobias) (Brox et al. 2008), and lifestyle advice (staying active, return to work) (Ainpradub et al. 2016).

Education interventions have been widely used and have demonstrated effectiveness in improving treatment adherence, exercise self-efficacy, and knowledge in clinical LBP patients (Barbari et al. 2020; Correia et al. 2023). However, the effectiveness of the education intervention for LBP management in the workplace varies across studies. A SR reported that education intervention, when used as a single preventive approach, was generally ineffective in preventing or reducing LBP in the working population (Maher 2000). Similarly, a SR by Tveito et al.(2004) found that single education intervention did not demonstrate a significant effect on SA due to LBP (Tveito et al. 2004). However, the evidence for both reviews was based on a small number of studies (n=6) and there was overlap in the inclusion of studies. Also, the methodological quality of the included RCTs was only low to moderate. Therefore, the evidence from these two SRs should be interpreted with caution. More recent studies, instead, have shown that education intervention alone seems to improve SA in the workplace. A workplace education intervention focused on mental health of firefighters was reported to have a significant effect on SA, with a reduction of 6.45 hours per employee in 6 months (Milligan-Saville et al. 2017). It was consistent with findings from another RCT in Norway, whereby government officials who received the educational intervention for LBP reported an average of 4.4 days reduction in SA over six months (Ree et al. 2016). However, it was not clarified in Ree et al.'s study whether these SA days were due to LBP. Meanwhile, participants in this study reported a high baseline SA of 8.58 days per three-month period (Ree et al. 2016), while this figure was only 1.09 days in the other study targeting firefighters (Milligan-Saville et al. 2017). Meanwhile, both control and intervention groups returned to baseline SA levels six months after the intervention (Milligan-Saville et al. 2017). This is consistent with findings from a previous review that educational intervention was not associated with long-term effects on LBP pain, disability, absenteeism, and quality of life (Ainpradub et al. 2016). These findings indicate that the effects of education intervention are likely to be short-term, due to obtained behaviours and knowledge would fade over time (Steffens et al. 2016).

Maher et al. (2000) stated that education may be a valuable component when combined with other interventions such as exercise programmes and ergonomic modifications (Maher 2000). Although the effectiveness of the education intervention remains inconsistent, the good compatibility with different research objectives has allowed educational interventions to be used in combination with other workplace interventions to improve knowledge of prevention and management of LBP for behavioural change (Chaléat-Valayer et al. 2016; Huang et al. 2020; Russo et al. 2021). Meanwhile, some researchers have recognised that education interventions were usually delivered in a standardised format without considering individual needs, learning abilities, occupation characteristics and LBP risk factors (Schapira et al. 2017). Thus, Ricci et al. (2022) proposed a patient-centred communication model to

individualise patient education intervention (Ricci et al. 2022). The recent SR also reported that interventions with individualised education components demonstrated similar or better outcomes than non-individualised interventions for pain and disability in LBP, but still without long-term effects (Chys et al. 2022).

#### 2.4.2 Ergonomic intervention

As an applied science concerned with modifying systems to enhance health, performance and effectiveness (Tricker and Tricker 1999), ergonomics has been applied to fit the need to improve safety and productivity in the working place (Dul and Neumann 2009). In previous research, ergonomic interventions in the workplace included modifying the physical working environment to improve posture during working (Dutta et al. 2014; Lee et al. 2021a), applying ergonomics education to expand knowledge and skills on work-related movements (Denadai et al. 2021), and utilising machines and supportive equipment to perform repetitive physical tasks (Bataller-Cervero et al. 2019). In previous studies on occupational health, sedentary behaviour (Motuma et al. 2021), poor manual handling (Landry et al. 2008), and awkward postures (Kripa and Kaur 2021) have been identified as common risks for LBP in the workplace. In addition, the lower back is particularly susceptible to strains and injuries due to poor posture, repetitive tasks and prolonged sitting (Al-Otaibi 2015), making it a prime target for ergonomic interventions to mitigate these risks. Therefore, workplace ergonomic interventions developed to modify these LBP risk factors have long been considered one of the most comprehensive approaches for improving the work settings (Williams et al. 2007).

Some studies have attempted to improve the effectiveness of education interventions through the application of ergonomic advice or the aid of ergonomic equipment, but the evidence was still inconsistent across studies. A SR reported high quality evidence to support that ergonomic interventions combined with education can reduce absenteeism in health care workers (Bos et al. 2006). But this evidence needs to be approached carefully, as four of the studies in this review that reported a reduction in MSDs also included exercise interventions. Also, due to the heterogeneity of intervention content and design, there was a lack of clear evidence to support which kind of ergonomic intervention combined with education can improve LBP symptoms and absenteeism. While in a recent RCT, 315 workers with LBP from a Japanese

machinery factory received a participatory ergonomics programme with provision of ergonomic training and ergonomic action checklists (Kajiki et al. 2017). Through educating employees on the MSK mechanism and encouraging them to use the ergonomics action checklist during work, the awareness of the importance of work posture was found to be improved after ergonomic training sessions. Contrast to findings in the previous SR (Bos et al. 2006), no significant difference was observed in pain and work efficiency between the intervention group and the control group which used the same ergonomics action checklist without attending education sessions after 10 months (Kajiki et al. 2017). The results of this RCT suggest that the addition of ergonomic interventions still did not enhance the long-term effects of educational interventions for managing LBP in the workplace. However, this study did not report any blinding or control measures for contact between participants, and the outcome measures mainly focused on the cases of improved work posture and ergonomic tool use.

In addition, similar results were observed in a RCT on nurses with LBP (Hartvigsen et al. 2005). No significant difference was found in the number of days and episodes of experiencing LBP at follow-up between the intervention group which received weekly education intervention on body mechanics and ergonomic techniques for patient transfers and weightlifting, with the control group which only received one three-hour instruction session (Hartvigsen et al. 2005). As this study did not evaluate the level of ergonomic knowledge and skills before and after the intervention, it is unclear whether the participants were successfully equipped with the intervention content. Also, a previous study has identified the risk factors for LBP in the nurse population as long working hours and frequent patient lifting (Byrns et al. 2004). But this study did not report on whether there were differences in the workload of the nurses between the two groups during intervention.

Ergonomic equipment is widely used for LBP management in the workplace, of which the most used is the sit-to-stand workstation (SSW) and is seen to be beneficial in reducing pain (Ognibene et al. 2016; Agarwal et al. 2018). In a meta-analysis, the use of SSW significantly reduced LBP in office workers, with a standardised mean difference (SMD) of -0.23 (95% CI: -0.437, -0.023) on the 10-point visual analogue scale (VAS) (Agarwal et al. 2018). However, the pain reduction did not meet than the 2-point minimal clinically important difference (MCIC) for LBP using VAS (Ostelo and de Vet 2005). In a study involving university employees with LBP and self-reported sedentary behaviour over 6 hours per day, the introduction of SSW resulted in a significant reduction in the group of worst pain levels compared to the use of a traditional desk over a 3-month period (Ognibene et al. 2016). But no significant differences were observed in overall pain intensity or disability before and after the intervention (Ognibene et al. 2016). Considering this study did not adopt a control design, and more than half of the participants (n=25) received at least one LBP treatment or surgery during the intervention, this could have confounded the results.

Although SSW appear to reduce pain intensity, the effectiveness in promoting work performance is limited. A SR reported that SSW can reduce sedentary behaviours by allowing employees to switch between sitting and standing postures throughout the workday (Torbeyns et al. 2014). But other than reduced sitting time, no improvement in work performance was identified (Torbeyns et al. 2014). A RCT reported that 35 office workers experienced a significant increase in perceived work vigour after using SSW in the office for 4 weeks (Ma et al. 2021). Although Ma et al. (2021) believed that the freely available use of SSW could reduce workplace anxiety and thus enhance performance, no significant improvement in work dedication and concentration was found (Ma et al. 2021). A RCT further pointed out that frequent postural changes produced by office workers using SSW could raise the alertness of nearby co-workers, which in turn result in decreased concentration at work (EF Graves et al. 2015), which was supported by the results of a Cochrane meta-analysis. Compared to normal sitting desks in the office, although SSW reduced sitting time by an average of 57 minutes per day over 3 to 12 months intervention, it also resulted in an average loss of 100 minutes of working time per working day (Shrestha et al. 2016).

Other ergonomic equipment aimed at preventing awkward postures and reduce LBP, including lumbar supports (Bataller-Cervero et al. 2019) and wearable motion capture devices (Lind et al. 2023), are increasingly popular in workplaces (Torbeyns et al. 2014; Agarwal et al. 2018). But the Cochrane review concluded that there was a lack of consistent evidence on the effectiveness of ergonomic interventions on sedentary time and long-term MSDs (Parry et al. 2019). In addition, some ergonomic equipment can produce further harm on working populations with LBP, for example, back belts and

weightlifting aids as they appear to be ineffective in reducing the incidence of LBP in occupations involving heavy lifting tasks (Lahad et al. 1994). Instead, an increased risk of injury was reported among the 642 baggage handlers at airlines using these aids (Reddell et al. 1992). Based on these findings, the National Institute for Occupational Safety and Health discouraged the use of lumbar supports for uninjured workers (Van Poppel et al. 1998).

#### 2.4.3 Exercise intervention

In most clinical guidelines for LBP, exercise is recommended as first-line treatment for pain relief, preventing recurrence and disability (Oliveira et al. 2018b). Occupational guidelines also reported exercise as a key aspect for promoting workplace well-being and enhancing quality of life (Black 2008). The effectiveness of exercise interventions on LBP has been reported in previous SRs of clinical interventions (Gordon and Bloxham 2016; Babatunde et al. 2017). A review concluded exercise intervention as a safe and effective first-line routine treatment in primary care for LBP (Foster et al. 2018). In addition, a Cochrane review reported that exercise interventions including strength training, Pilates, stretching and aerobic exercise were more effective in the treatment of LBP than single education intervention or usual care (Hayden et al. 2021).

Although exercise interventions have demonstrated effectiveness in managing LBP in primary care, the effectiveness in the workplace was inconsistent across studies. A SR analysing the effectiveness of exercise interventions, demonstrated that short exercise sessions (10-15 minutes) during the working day (3-5 days), including stretching, aerobic exercise and postural stability training, can reduce the LBP symptoms and improve the quality of life of office workers (Gobbo et al. 2019). However, the exercise interventions in this review were combined with education, ergonomic adaptations and electrical stimulation. Besides, this review included studies in the home setting. Therefore, evidence from this review is insufficient to support the effectiveness of exercise interventions consisting of strength, flexibility, and relaxation training were reported not to reduce pain intensity and the incidence of LBP (Maciel et al. 2018). But the included exercise intervention studies to prevent LBP in the workplace were reported to be of low methodological quality. Also, this review was conducted based on search findings from a single electronic database with significant heterogeneity in terms of the

occupations of participants, type and intensity of LBP ( $I^2 = 93\%$ ) (Maciel et al. 2018). In contrast to the findings of Maciel et al, another overview of SRs on occupational interventions for the prevention of LBP reported that there was moderate to high quality of evidence supporting the effectiveness of exercise interventions (stretching, flexibility, endurance exercises) in preventing the occurrence of LBP in the workplace for 12 months (Sowah et al. 2018). Given the discrepancies in methodology and inclusion criteria between SRs, this review is highly heterogeneous thus lacking a categorisation and description of the study interventions and sample characteristics. Meanwhile, the same individual study may be included in different SRs, and potential duplication of data may misrepresent the evidence base.

Although clinical guidelines have identified exercise interventions as recommended treatments in primary care, there is a lack of consensus on which specific type of exercise interventions is most effective for LBP (Bell and Burnett 2009). A review identified that muscle strength training and stability exercise was most effective in reducing pain associated with LBP, whereas aerobic and mixed exercise (yoga, Pilates) did not show an intervention effect (Searle et al. 2015). However, this conclusion was not supported by other studies. A meta-analysis reported that Pilates training was the most effective treatment for improving LBP (Owen et al. 2019). Considering this result was generated from 89 qualitative studies, the limited power of statistical analysis may weaken the trustworthiness of the evidence. Contrary to the conclusions of Owen et al, in another overview of 45 SRs on existing exercise interventions for LBP, there was no significant difference between the effects of different exercise interventions, including aerobic training, motor control, resistance training, and Pilates, on pain and disability of LBP (Grooten et al. 2022). The controversy was also present in research on exercise interventions in the workplace. Although previous studies have claimed that exercise interventions are effective in reducing LBP symptoms in office-based white-collar workers (Gobbo et al. 2019), the mixed control group settings included in the study (ergonomics, education, usual care, no exercise) prevented further quantification of each component's effectiveness. All the per-mentioned reviews of exercise interventions for LBP had the issue of failing to compare effectiveness between studies due to the high heterogeneity of experimental designs of the included studies and therefore were unable to specify the effective components of the exercise interventions. The evidence of effectiveness demonstrated by Pilates, which combines

strength, stretching and muscle control, has also directed to a point that a particular type of exercise training is unlikely to be the single best treatment for LBP (Powell et al. 2011; Owen et al. 2019).

In the absence of evidence on the most effective type of exercise for LBP, some studies have begun to explore the optimal design for a single exercise intervention. In a 12-week exercise intervention study of male employees with LBP, a progressive exercise programme with high-intensity strength training significantly increased lumbar muscle strength. However, the high-intensity strength training did not provide better improvement in fear of movement than low-intensity strength training (Helmhout et al. 2004). However, only males were included and therefore the data cannot be generalised to females. Moreover, due to the lack of the placebo group with no exercise, it is uncertain whether the improvement in LBP observed in the low-intensity exercise intervention group resulted from a potential Hawthorne effect (Shephard 1996).

In contrast, in another 12-week exercise intervention experiment, high-intensity exercise training (muscle strength, endurance, and cardiorespiratory exercise) provided greater improvements in disability and exercise performance among nurses (69% female) with LBP than moderate-intensity exercise training of the same type of exercise (Verbrugghe et al. 2019). Surprisingly, no significant increase in muscle strength was observed compared to the Helmhout et al.'s experiment, which both involved high-intensity exercise intervention. Considering the discrepancy in the standards for exercise intensity between the two studies, and the variation in physiological responses to exercise interventions by gender (Ansdell et al. 2020), the potential benefit of increasing the intensity of an exercise intervention to improve LBP remains unclear.

Apart from exercise intervention content and design, some occupational and personal factors in the working environment also appear to affect exercise intervention effectiveness. In a study conducted on government administrative offices with LBP, only 48% of the participants self-reported the completion of low intensity stretching exercises three times a week in eight months. Those who did not complete the exercise reported feeling embarrassed about exercising in public with their colleagues

and were reluctant to spend their lunch breaks exercising (Macedo et al. 2011). In occupations requiring more collaborative work (firefighters), it was the lack of peer support for completing the exercise together as the biggest individual reported barrier. However, it is notable that the final completion rate for this exercise intervention, which focuses on strength training, was only 67%. One potential occupational factor contributing to this low completion rate was reported as the lack of time due to responding to emergency work (Mayer et al. 2013). Among healthcare professionals (nurses) with similar work schedules, only 53% of those with mild LBP (VAS = 3.7) were found to be able to complete a combination of stretching and core training exercises 1-2 times for 8 weeks (Taulaniemi et al. 2020). However, the issue of emergency work may not be the only factor, as 10% of the participants who were available and supervised still did not participate in any exercise at all (Taulaniemi et al. 2020). It is worth noting that the participants included in this study had a low education level (35.1% secondary education and below), which was found to be associated with low exercise self-efficacy, self-regulation behaviours, and exercise adherence in people with LBP (Rhodes et al. 2017). In an exercise intervention study that involved local councils, bus companies, universities, and hospitals in the UK, increased physical activity levels were found only among the most engaged council working participants. In the absence of organisational promotion, management and supervision, only 15 % of employees responded to the exercise intervention in the workplace (Lawton et al. 2014). This evidence demonstrated that inadequate organisational support for the time and resources required for exercise participation by people with LBP may also obstruct the implementation of exercise interventions in the workplace (Garne-Dalgaard et al. 2019).

### 2.4.4 Multidisciplinary intervention

Rasmussen et al. (2013) and Steinmetz et al. (2022) concluded that a single intervention is not sufficient for managing LBP in the complex working environment, Thus, a multidisciplinary rehabilitation programme is preferable to manage the rehabilitation needs of individuals who are significantly impacted by LBP (Kamper et al. 2014). This intervention typically involves the collaboration of healthcare professionals with different expertise, including education, physiotherapy, and psychology (Guzmán et al. 2001; Scascighini et al. 2008; Kamper et al. 2014). The multidisciplinary intervention is deemed to promote functional recovery, pain

management strategies and overall health improvement from the BPS perspective (Norlund et al. 2009).

The effectiveness of multidisciplinary intervention in improving LBP has been reported in the previous systematic review (Marin et al. 2017). However, this evidence was based on a limited number of low-quality RCTs (n = 3) with a high risk of bias. Another 12-week multidisciplinary workplace intervention consisting of participatory ergonomics, physical and cognitive behavioural training was also reported to be effective in reducing pain duration and intensity among LBP nurses working in elderly care (Rasmussen et al. 2015). The 3-month multidisciplinary intervention reduced the number of days experiencing LBP by 0.8 days and the intensity of pain by 0.4 on a 10point VAS (Rasmussen et al. 2015). Similarly, in a 6-month RCT conducted with nurses, the multidisciplinary intervention was also effective in reducing pain intensity by raising self-efficacy and emphasising self-regulation (Shojaei et al. 2017). But in this study, the mean value of baseline pain intensity measured using a 10-mm VAS was 1.97 with a standard deviation (SD) of 5.01. The large SD value in this study represents a high variability of the baseline pain intensity, suggesting that the mean may not be a good description of the central tendency of the pain intensity, whereas other metrics such as the median may be more appropriate.

However, the evidence for multidisciplinary intervention on work-related factors in people with LBP is inconsistent. In a RCT conducted with 770 employees with LBP, participants in the intervention group received an early multidisciplinary intervention to reduce SA due to LBP from a multidisciplinary team which consisted of a psychologist, ergonomist, occupational physician, case manager and coordinator who facilitated communication between departments. However, the 12-week multidisciplinary intervention did not demonstrate better improvements in absenteeism compared to the usual care (Fisker et al. 2022). A possible explanation may be that the usual care component also contained treatments focusing on BPS factors, which blurred the actual differences between the treatments received by the intervention and control group.

In another 4-week short-term multidisciplinary intervention study, no significant difference in SA rates was observed between employees with LBP who received

multidisciplinary interventions (16.6%) and brief physiotherapy (18.8%) after two years (Jensen et al. 2012). Also, no significant difference was observed in the rate of RTW between the two groups at 1-year follow-up (66% and 61%). It should be noted that 42% of participants who requested SA in the first year continued to request SA in the second year. All the participants who applied for SA for LBP received SA benefits or social welfare and 83 of them claimed for work-related injuries (Jensen et al. 2012). However, in Jensen et al.'s study, it was found that multidisciplinary interventions were effective for a particular one-third of participants who self-reported experiencing a perceived risk of unemployment (Jensen et al. 2012). This highlights the importance of targeting interventions to specific factors (e.g., demographic, psychosocial and occupational factors) to increase the effectiveness of multidisciplinary intervention for people with LBP. This point was supported by a recent SR which concluded that multidisciplinary interventions demonstrated enhanced work-related outcomes among people with LBP under 50 years old with severe disability (Oswestry Disability Index (ODI) >22 points) (Bernaers et al. 2023). Developing classification models to find the subgroups of LBP which would benefit most from individualised multidisciplinary interventions appear to improve the effectiveness of multidisciplinary interventions for working population with LBP.

However, the implementation of multidisciplinary workplace interventions face barriers due to the prolonged duration of team meetings for coordination and decision-making resulting in unsatisfactory timescales and continuity of interventions (Kamper et al. 2015). Also, the access to treatment has usually been limited to specialised medical centres making access not available to all (Syed et al. 2013; Marin et al. 2017). In addition the intensive treatment scheduling represented an overwhelmingly combination of financial and time burdens for employees with LBP (Kamper et al. 2015). Even the intervention programmes are well-organised, working populations with LBP sometimes might be unable to attend due to work schedule conflicts, further complicating the difficult task of coordinating multidisciplinary collaboration (Kamper et al. 2015). Therefore, there is a need to seek more convenient solutions for LBP management in the workplace.

#### 2.4.5 Individualised workplace interventions for LBP

Evidence from previous sections has demonstrated that education (Ree et al. 2016), exercise (Tersa-Miralles et al. 2022), and ergonomic interventions (Lee et al. 2021b) could contribute to prevention and management of LBP in the workplace, but the evidence was inconsistent between studies (Proper and van Oostrom 2019; Sundstrup et al. 2020; Russo et al. 2021). The lack of evidence from single-intervention studies has led researchers to realise that a combination of BPS factors contributes to LBP in the workplace (Otero-Ketterer et al. 2022). Also, findings from multidisciplinary interventions revealed the existence of LBP subgroups that could benefit most from specific interventions (Jensen et al. 2012). As a result, several studies suggested that individualised interventions could be developed to address the specific needs and risk factors of the LBP population (IJzelenberg et al. 2007; Jay et al. 2015; Serra et al. 2019; Bernaers et al. 2023).

Although workplaces have designed conventional intervention to be more individualised, it does not seem to be embraced by the LBP participants. In a previous RCT on chronic musculoskeletal (MSK) pain among laboratory technicians, a screening questionnaire was designed to assess the stress and pain of participants (Jay et al. 2015). Individualised cognitive-behavioural education interventions were provided based on the participants' stress levels. Participants also received resistance and motor control training supervised by a physical training instructor based on participants' pain intensity. Participants who received the 10-week individualised intervention reported significantly reduced pain intensity compared to the control group, which received only reminders emails to exercise and rest. But no significant reduction was observed in stress levels as the attendance rate for cognitive-behavioural education in this study was only 47.5% (Jay et al. 2015). Also, participants in this experiment were all female, which limited the generalisability of the findings (Jay et al. 2015). While in another large-scale RCT (n=489) with predominantly male participants (97.1%), individualised workplace intervention including occupation-based pain education, ergonomic adjustments, and on-site physiotherapy did not report better outcomes than usual care (physiotherapy) on pain, SA, mental health and quality of life after 12 months (IJzelenberg et al. 2007). Both groups were provided with physiotherapy, but only 4 participants in the intervention group attended physiotherapy

in the workplace over the 6-month period. While in the control group, 20 participants attended physiotherapy in hospital (IJzelenberg et al. 2007).

In another study, 257 nurses with MSK pain (including LBP) were asked to complete a pre-designed and validated self-assessment (Serra et al. 2019). By analysing the answers to the self-assessment regarding pain, function impairment, quality of life, fear of movement, anxiety, and mood disorders related to LBP, the participants were grouped into different MSK risk groups for individualised workplace interventions. Lowrisk participants only received education about their health beliefs, while medium and high-risk patients received 12 weeks of individualised interventions, including participatory ergonomics, lifestyle interventions (healthy diet, mindfulness of stress, and outdoor exercise), CBT, and rehabilitation consultations. However, apart from the initial good engagement in participatory ergonomics (95.8%), completion rates for lifestyle (4.7% - 32%) and rehabilitation consultation (38.5%) were both low (Soler-Font et al. 2021). One potential explanation was the costs associated with the individualised workplace interventions (mean = €367) were much higher than the single workplace interventions (mean = €38) (Soler-Font et al. 2024). Another barrier to the completion identified in the follow-up was participants lack understanding of the complex intervention design (Soler-Font et al. 2021). With such issue existing among the nurses with healthcare background, it could be more difficult to implement in other populations with low health literacy (Keyworth et al. 2019).

# 2.4.6 Summary of the workplace interventions

Conventional workplace LBP interventions vary in the design, content, and effectiveness. The following summaries the main benefits and limitations to consider for these interventions:

## 1. Education interventions

*Benefit:* Established cost-effectiveness (Marshall et al. 2003); improved treatment adherence, exercise self-efficacy, and knowledge in clinical LBP patients (Barbari et al. 2020; Correia et al. 2023)

*Limitation*: Short-term effects as a standalone approach (Steffens et al. 2016; Chys et al. 2022); often standardised content which lacks individualisation based on learning needs and occupational factors (Schapira et al. 2017)

# 2. Ergonomic Interventions

*Benefit:* Effective in reducing sedentary behaviours (Torbeyns et al. 2014) *Limitation*: Decreased work concentration due to frequent postural changes limits widespread adoption (EF Graves et al. 2015)

# 3. Exercise Interventions

*Benefit:* Comparable cost-effectiveness to educational interventions (Lin et al. 2011); recognised as essential for LBP prevention and management (Foster et al. 2018) *Limitation*: Adherence in workplace settings (Taulaniemi et al. 2020)

# 4. Multidisciplinary Interventions

*Benefit:* Effective in reducing pain duration and intensity (Rasmussen et al. 2015); consistent with BPS perspective (Norlund et al. 2009); preferable to a unidimensional intervention (Fisker et al. 2022)

*Limitation*: No significant improvement in work-related outcomes compared to usual care (Marin et al. 2017); cost and time constraints for working populations (Kamper et al. 2015); low participant engagement (Soler-Font et al. 2024).

# 5. Individualised Approaches

*Benefit:* Address the specific needs and risk factors of the LBP population (IJzelenberg et al. 2007; Jay et al. 2015; Serra et al. 2019; Bernaers et al. 2023) *Limitation*: Complex intervention design may result in the increased cost and low engagement (Soler-Font et al. 2024)

Therefore, There is a need for more accessible, flexible and cost-effective solutions for delivering individualised workplace interventions for LBP (Crawford et al. 2020).

# 2.5 Self-management of LBP

The current clinical guidelines, advise that LBP is primarily managed in primary care through medical interventions, education, physiotherapy and lifestyle changes (Oliveira et al. 2018b). However, 5-10% of population with LBP will progress into persistent LBP, or disability (Meucci et al. 2015) and many will experience recurrence after 12 months (Hayden et al. 2010). Thus to address the combined medical and

socio-economic burden of long-term care for LBP (<u>Section 2.2</u>), self-management was proposed as a solution (Lorig and Holman 2003). By providing people with empowerment and autonomy (Scambler 2016), the self-management approach proposed to encourage individuals to take ownership of their LBP (Barlow et al. 2002), to make informed decisions, to engage with healthcare professionals and to adopt strategies to improve their health (Kongsted et al. 2021).

As a patient-centred approach, self-management was defined as "the ability of an individual to manage the symptoms, treatments, physical and psychological consequences, and lifestyle changes inherent in chronic disease" (Barlow et al. 2002, p. 178). This ability is closely associated to another concept known as self-efficacy, which refers to the confidence that an individual is capable of planning and performing actions to achieve a desired outcome (Bandura 1977). Past research has shown that patients with chronic conditions of low self-efficacy tended to be accompanied by severe pain levels, functional impairment, and emotional distress (Jackson et al. 2014), whereas patients with higher self-efficacy reported a higher quality of life in primary care (Peters et al. 2019). Reviews also noted that high self-efficacy is associated with improved treatment adherence (Farley 2020) and reduced healthcare utilisation (Lorig et al. 2001). Self-management can enhance self-efficacy and optimise treatment outcomes for patients with chronic diseases like LBP (Peters et al. 2019). Thus, the concept of self-management has been recommended by most of the clinical and occupational guidelines to encourage people with LBP to proactively cope with pain, continue moving and stay in work (Burton et al. 2004; O'Connell et al. 2016). The NICE guidelines also recommended self-management as a key option for all pathway of the LBP management, "providing people with advice and information tailored to their needs and abilities to help them self-manage their LBP" (National Guideline 2016, p. 7).

Despite the increasing acceptance of self-management as an approach, there are challenges in providing effective self-management in people with LBP (Liddle et al. 2007). A previous review demonstrated moderate-quality evidence that self-management can improve disability and pain in both short and long-term LBP, but the effect is very small (Oliveira et al. 2012). In this review, the specific components of self-management in the included studies were heterogeneous and lacked specific

descriptions. In the absence of evidence on the design of optimal LBP selfmanagement interventions, it was uncertain whether any studies included ineffective self-management components. Although there was a high level of heterogeneity in the design of the control groups of the included studies (physiotherapy, exercise, education, and acupuncture), they were similar to the approaches commonly utilised in primary care (Oliveira et al. 2012). Therefore, the small intervention effects indicated that self-management of LBP was not significantly superior to other clinical interventions on pain and disability. Meanwhile, findings from a qualitative study further illustrated the challenges limiting the self-management of LBP (Devan et al. 2018). In the absence of knowledge of pain, patients were found to attempt to self-resolve their LBP without consulting a healthcare professional (Fu et al. 2016). People with LBP thereby underestimated the severity of their pain and subsequently delayed seeking specialised medical care for potentially serious conditions (Ahern et al. 2019). Patients who visited primary care without the understanding of the contributing factors still focus on relieving symptoms on a single aspect (Fu et al. 2016), without realising the holistic management of the BPS factors of LBP (Kamper et al. 2015). Also, with a lack of communication with healthcare professionals, people with LBP felt that the selfmanagement advice offered by primary care did not match their individual needs, preferences and lifestyles, further reducing motivation for self-management (May 2007). Therefore, future research needs to refine self-management by incorporating comprehensive and individualised approaches that align with patients' needs, preferences, and lifestyles to improve the effectiveness of self-management for LBP.

### 2.5.1 Challenges of LBP self-management in the workplace

The heavy burdens of LBP on organisations (Section 2.2.3) have raised the awareness of employers on the importance of promoting proactive health management in the workplace to prevent LBP from progressing to the point that employees seek SA (Shaw et al. 2012). In previous studies, LBP-related medical costs and work claims have been reported as direct economic costs (Carroll et al. 2010). While indirect cost from LBP-related absenteeism and reduced productivity was often calculated in estimated numbers (van Duijn et al. 2010). The lack of clear evidence of the financial benefits frustrated organisations from embedding self-management of LBP for employees into the long-term management of workplace wellness (Loisel et al. 2005; Kongsted et al. 2021). In addition, in organisations with an occupation health

department, the provided onsite support may not always meet the needs of individual employee. This contributed to the ambivalence of employees towards self-management through the occupational health department in the workplace with the concern that it lacked the necessary skills to co-operate and guide self-management (Bosma et al. 2021).

Research has also identified that the absence of long-term support for workplace selfmanagement in some organisations is associated with lack of sustained engagement and low adherence from employees (Shaw et al. 2022). Transitioning from the passive treatment to active self-management model can be challenging and even counterintuitive for people who rely on treatment from healthcare professionals (Shipton 2018). From the qualitative findings, some employees with LBP stated their preference for instant symptom relief through medical interventions, as this minimised disruption to their work (Liedberg et al. 2021). This preferred approach and passive attitudes towards self-management of pain may lead to scepticism, resistance and low self-efficacy (Grant et al. 2019a; Caneiro et al. 2021). In previous research, selfefficacy has been recognised as important determinant for intervention adherence and highly correlated with the effectiveness of self-management interventions (Farrell et al. 2004; Lunenburg 2011; Jackson et al. 2014). Moreover, a recent cross-sectional study revealed that the stigma associated with LBP may prevent individuals from requesting appropriate workplace accommodations (Harada et al. 2023). In the focus group with LBP population in the workplace, participants expressed that they experienced negative reactions, scepticism and even criticism from co-workers if LBP prevented them from completing normal tasks (Ree et al. 2019). Stereotypes of LBP and disability from co-workers and line managers also led to people with LBP hiding their condition due to perceptions of unfairness, fear of job insecurity and discrimination, which further obstructed participation in self-management (Blake et al. 2021).

To overcome the challenges of implementing LBP self-management in the workplace, there is a need to develop a cost-effective and evidence-based solution to support organisations with limited resources. In addition, there is a need to provide people with LBP with more convenient access to professional support and guidance in selfmanagement without having to pay multiple visits to workplace occupational health and primary care services. More importantly, it is necessary to address the barriers that employees face when engaging in self-management and search for a more individualised and user-friendly form.

### 2.6 The use of DHSMIs for LBP in the workplace

Developments in digital technology are increasingly used across all aspects of daily life, and healthcare is no exception (Turesson et al. 2022). As a rapidly evolving area in healthcare, digital health is changing the way people manage their health (Abernethy et al. 2022; Rintala et al. 2022). Digital technologies, such as websites, mobile applications (APP), and wearable devices have been utilised to deliver healthrelated information, communication with medical professionals, or interactive interventions for various health conditions (WHO 2018). These interventions developed to improve health outcomes, enhance patient engagement, and provide accessible and scalable solutions for health care delivery were recognised as Digital Health Interventions (DHSMIs) (Bashi et al. 2020; Hewitt et al. 2020). Benefiting from the scalability of digital technology, the DHSMIs for self-management can be implemented in a large sample size (Nicholl et al. 2017). Also, compared to standard care, self-management DHSMIs were reported to save office workers up to €500 for every LBP recurrence (del Pozo-Cruz et al. 2012a). The underlying resonance between the flexibility of digital technology and the multifaceted nature of LBP has led to DHSMIs being seen as a promising approach to addressing the prevention and management of LBP in the workplace (Howarth et al. 2018). Many organisations have started to support the health and well-being of their workforce by accessing these DHSMIs through any internet-enabled device at the workplace (Mills et al. 2007).

But with the development of DHSMIs, the boundaries between this concept and telemedicine were blurred, which sometimes led to a misguided opinion viewing DHSMIs as simply shifting the location of health management from physical healthcare facilities to virtual settings (Giansanti 2023). To avoid conceptual confusion, the Digital Therapeutics Alliance defined DHSMIs as "delivering evidence-based therapeutic interventions to patients driven by software to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimise patient care and health outcomes" (Dang et al. 2020, p. 2208). The terminology of DHSMI used in this study is consistent with previous research and reviews, which was defined as any intervention delivered

through a computer, mobile phone, or handheld device, including web-based or desktop computer programs or mobile applications that provide self-management information or materials (McLean et al. 2016b). The central focus of DHSMIs in the workplace was to support individuals staying in work by self-managing LBP without relying on direct input from healthcare services and medical treatment (Stratton et al. 2021). Based on this core objective, this section reviews DHSMIs with different functions that have been developed for LBP self-management in the workplace.

### 2.6.1 Activity monitoring

In many occupations, sitting is a common activity (Lis et al. 2007). A SR reported consistent findings that sedentary behaviour is a major risk factor of LBP in the workplace (Dzakpasu et al. 2021; Mahdavi et al. 2021). Awkward postures associated with sedentary behaviours were also considered to contribute to muscle stiffness and discomfort in the lower back (Barthelme et al. 2021). Workplace interventions aimed at reducing sedentary behaviour, including exercise interventions (Vitoulas et al. 2022) and ergonomic adjustments (Agarwal et al. 2018), have been reported to be effective in reducing the incidence of LBP, indicating that sedentary behaviour may be a modifiable risk factor of LBP in the workplace. Meanwhile, DHSMIs utilising computer software, mobile applications, and wearable technologies were found to reduce daily sitting time by 41.28 minutes (95% CI: 21.58, 60.99) among working population (Stephenson et al. 2017). Based on the effectiveness of DHSMIs in reducing sedentary time, some studies have looked to improve LBP in the workplace through DHSMIs that target sedentary behaviours.

The DHSMI 'Welbot', a desktop software, was developed aiming at reducing sedentary behaviour and improving workplace wellbeing (MacDonald et al. 2020). Welbot was designed to recommend customised short (1-5 minutes) stretching exercises, breaks from screen and positive thinking based on the activity level of the user over the past week. 80 employees from four UK companies with MSDs (LBP included) downloaded Welbot on their working computers and received healthcare promotion from Welbot. Prompted content from Welbot was presented in text and images to explain the rationale for the nudge and on how to complete the recommended content to the participants. It significantly increased the standing time (10%) and sit-stand transitions (once per hour) within 4 weeks but reported a significant decline in work engagement.

Participants stated at the 6-month follow-up that they could not choose the time of the intervention to fit their work schedules and had to interrupt work to comply with the tasks from Welbot, which led to a 40% drop-out at the first month. In addition, no significant improvement in pain was found by using Welbot. Considering that the baseline pain intensity was only mild (Mean = 2.16, SD = 2.00, 10 - point VAS), the change in pain may thus not have been substantial.

Instead of using self-reported data, some DHSMIs studies selected wearable technology to provide more individualised self-management by capturing employee activity and posture. In a RCT based on Cognitive Behavioural Theory (Kaplan 1990), 27 participants with more than 20 hours of desk work per week received workplace self-management for 6 months (Gibbs et al. 2018). Participants in the intervention group received education on the risks of sedentary behaviour for health and were encouraged to use SSW in the workplace for frequent posture changes (every 30 minutes) and standing in the office (2-4 hours per day). People with LBP in the intervention group also received monthly teleconference and were asked to set personal goals and strategies for self-management of sedentary behaviour. An electronic wristband detected activity status of the individual, alerting the participant to move if they had not moved for more than 30 minutes. Participants could modify the prompting time according to their preferences. Compared to the control group, which did not receive any intervention, people with LBP in the intervention group significantly reduced their sitting time by 35%, which was 1.5 hours less per day than in the control group (Gibbs et al. 2018). Significant improvement was observed in the disability (MD of ODI = 8.0, p=0.001) but not in pain intensity (Gibbs et al. 2018). In this study, participants classified as too mild or acute pain (n=86) were excluded from the intervention. But the study did not reveal information on the criteria of pain intensity for exclusion. The lack of inclusion of severe LBP may contribute to an underestimated intervention effect on pain intensity.

Apart from monitoring sedentary behaviour, DHSMIs were designed to monitor specific postures during work activities and provide corresponding feedback. A DHSMI called BackUp, based on behavioural intervention theory, used smart clothing equipped with an inertial measurement unit to track spinal posture in nurses with LBP (Bootsman et al. 2019). By monitoring spinal activity based on a predetermined model of work

activity (desk work and caring for patients), BackUp can generate an audio alert when poor posture is recognised for more than 1.5 seconds. The mobile application connected to BackUp would then record the activity and send feedback to explain the reason for the alert and providing education on correct posture. Compared to participants who worked normally, those who received feedback from the BackUp reduced bad posture by 6.46 times per day (Bootsman et al. 2019). However, in the follow-up interviews, participants reported that they would become irritated and ignore the repetitive alert when they did not know how to complete a particular task in the correct posture (Bootsman et al. 2019). In addition, the audio notification of the poor posture also attracted extra attention from colleagues and patients (Bootsman et al. 2019), which may lead to negative social impacts for employees facing LBP stigma in the workplace (Notcutt and Gibbs 2010).

### 2.6.2 Communication

The ability to overcome barriers was recognised to be fundamental for people with LBP returning to work through self-management (Kawi 2014). However, when this ability is insufficient, there can be a mismatch between the individual's efforts to self-manage LBP and the expectations from the employers (Grant et al. 2019b), which would exacerbate stress and even silence from the employee (Milliken et al. 2003). Meanwhile, the communication between employee and employer on LBP was sometimes directly replaced by application for SA. To address this issue, workplace DHSMIs focusing on communication have been proposed to facilitate information exchange, connectivity and collaboration when managing LBP in the workplace (Turesson et al. 2022; Svanholm et al. 2023).

Recently, a DHSMI was developed for Sustainable Worker Digital Support for Persons with Chronic Pain and their Employers (SWEPPE) (Turesson et al. 2022). Participants were able to set personal RTW goals through the SWEPPE mobile application. By completing a daily self-assessment, employees with chronic pain (LBP, neck pain, neuropathic pain and myofibromyalgia) can self-monitor their pain status and access multi-media information from a pre-developed knowledge database on BPS factors (pain, physical activity, balance of daily living, sleep and workplace adaptations). Meanwhile, employees had the opportunity to leave questions within the application and receive written responses from a team of health coaches consisting of physical

therapists, occupational therapists, psychologists and physicians. Furthermore, employees with chronic pain can authorise their employer to access their personal database of planned activities, work capacity, and progress towards goals within SWEPPE. Within the shared information, employees can report specific needs of support to their employers.

However, feedback from employees and employers on the communication function was not encouraging. Participating employees were neutral about the usefulness of sharing information with their employer with an average score of 53.5 points (Turesson et al. 2022) using the 100-point System Usability Scale (SUS) (Over 70 = good usability) (Lewis and Sauro 2018). Self-management strategy developed by employees were given the lowest usability ratings by employers (Mean SUS = 46 points) (Turesson et al. 2022). In this study, one employee raised eight requests for support from their employers, which was described as a lack of a sense of boundaries by the employers (Svanholm et al. 2023). Thus, 25% of participated employers stated that SWEPPE was not supportive at all (Svanholm et al. 2023). There was also disagreement on the perceived usefulness of SWEPPE intervention between employees and employers. Participating employees considered all the contents of SWEPPE to be relevant and 57% of them wished to keep using it after intervention (Turesson et al. 2022). However, employers expressed concerns about the long-term use of SWEPPE, especially when the time required to produce effective outcomes on LBP remained unknown (Svanholm et al. 2023).

Although SWEPPE demonstrated the technological feasibility of bridging employeeemployer communication (Turesson et al. 2022), current evidence could only support that it may improve employers' understanding of the pain conditions of their employees. Current evidence did not support that DHSMIs centred on communication functions facilitates the provision of appropriate support for LBP by employers. Moreover, findings indicated that the quality of communication provided by DHSMIs in the workplace may be highly dependent on the relationship between the employee and the employer, as well as the employee's personal attitudes towards chronic pain (Svanholm et al. 2023). Meanwhile, the unprecedented COVID-19 pandemic placed significant limitations on face-to-face communication in the workplace (Baek et al. 2021) and worsened feelings of isolation among people with LBP (Rauschenberg et al. 2021). These limitations created new challenges and demands for DHSMIs in the workplace, requiring more innovative approaches to maintain good self-motivation in the LBP self-management.

### 2.6.3 Interactive DHSMIs

The development of digital technologies has facilitated a convergence between different disciplines, which provided the fundamental knowledge and tools to develop DHSMIs with interactive functions. Various types of interactive technologies, including online websites, mobile applications, telehealth services, artificial intelligence (AI) and virtual reality (VR) have been used as mediums for interactive DHSMIs. The usercentred design featured in interactive DHSMIs requires a direct involvement from the user, such as entering data, responding to prompts, or interacting with multimedia content (Bailey et al. 2010). Users could receive immediate health-related feedback based on their inputs, such as visualised data and responsive reminders (McLean et al. 2016b). Interactive features such as setting personal goals, progress tracking and real-time conversations based on feedback mechanisms have also been developed to increase patient engagement, motivation and adherence to DHSMIs (Riva et al. 2014; Rabbi et al. 2015). DHSMIs with interactive features has been found to increase user engagement with digital interventions, improve adherence to health advice and promote confidence in self-management of chronic conditions (Murray et al. 2004; McLean et al. 2016b).

Interactive DHSMIs have demonstrated promising results on addressing multidimensional factors of LBP in previous studies. In a previous SR of DHSMIs for self-management of LBP, web-based interactive DHSMIs to support LBP self-management in clinical settings demonstrated improvements in disability, pain intensity, quality of life, and psychosocial factors (Nicholl et al. 2017). DHSMIs in the included six RCTs and three RCT protocols reported interactive features including visualised graphs on health status, web forum discussions with healthcare professionals, and simulated conversations (Nicholl et al. 2017). These included interactive DHSMIs were designed to provide individualised exercise programmes and education materials using pre-programmed algorithms to analyse data input from participants. Due to the high heterogeneity in the design of included interactive DHSMIs, it was unable to calculate the size of the effectiveness. Also, these interactive

DHSMIs were reported to provide LBP self-management individualised to gender, occupation type, and obstruction level of LBP to daily life (Nicholl et al. 2017). However, as the studies included in this SR were mainly clinical trials conducted on mixed populations (non-working included), it is not clear whether evidence from this review could be applied to interactive DHSMIs for LBP self-management in the workplace.

Beyond interactive DHSMIs based on web and mobile apps, an artificial intelligence (AI) driven chatbot was developed to send daily conversations to engineers and office workers in a manufacturing company with MSK conditions (including LBP) at a fixed time over 12 weeks, which achieved a high intervention retention rate of 92% (Anan et al. 2021). Comparing to the control group with usual care, patients who used AI-based interactive DHSMI were 6.36 times more likely to not have severe LBP after intervention (95% CI: 2.57-15.73) (Anan et al. 2021). Although the study reported that the AI-assisted DHSMI reduced MSK pain in 44 participants, it did not report data on pain intensity scores for each group before and after the intervention. Also, the study lacked a description of the exercise intervention components included in the DHSMI, making it unclear whether there were differences between the intervention and control groups in terms of the exercise intervention components they received. Besides, it also included participants with shoulder and neck pain, making it uncertain whether the findings of this study can be applied to the working population only with LBP.

Virtual Reality (VR) technology has also provided opportunities for a new era of dynamic interventions for LBP. Based on an embodied model of pain psychology, VR enabled participants to immersively interact with the simulated 3D world (Malloy and Milling 2010). After COVID-19, home-based working, also known as fluid workplace, has gradually become a common practice (Kong et al. 2022), bringing new opportunities for VR which requires a secure and private space (Torous et al. 2021). It has been used to design and develop interactive, user-friendly, and adaptable digital health solutions, especially in addressing psychological factors of pain (Baniasadi et al. 2020). A recent meta-analysis reported that interactive VR-based DHSMIs significantly reduced pain intensity (SMD = -1.92; 95% CI = -2.73, -1.11) and fear of movement (MD = -8.96; 95% CI = -17.52, -0.40) compared with other pain interventions in the adult population with LBP (Brea-Gómez et al. 2021). This finding was supported by another recent RCT using VR technology, which reported to adopt

pain psychology theories for reducing fear and pain avoidance behaviours (Eccleston et al. 2022). During the use of VR, the virtual mentor integrated educational content by explaining rationale, setting goals, and behaviour reinforcement to encourage working population with LBP in completing different kinds of activities through immersive simulated scenarios (Eccleston et al. 2022). Compared to standard care and VR without educational content, VR combining cognitive behavioural education further improved fear of movement in patients with LBP after a 9-week intervention (Eccleston et al. 2022). Similarly, another VR intervention combining cognitive behavioural education, positive thinking, and pain neuroscience education also reported significant improvements in LBP intensity and pain interference of people with LBP (Garcia et al. 2021). Existing evidence has demonstrated that VR is effective in reducing pain intensity and kinesiophobia in patients with LBP (Brea-Gómez et al. 2021). While working age populations were included in the above studies, all studies were RCTs in clinical settings. Therefore, more research evidence is needed to demonstrate the effectiveness of virtual reality technology for improve LBP in the workplace.

Meanwhile, both referred RCTs using VR reported safety issues and adverse events. During the 5-month trial period, Eccleston et al. reported 28 device defects and 140 adverse events (Eccleston et al. 2022). The study conducted by Laura et al. (2021) also reported 12 adverse events mainly for nausea and motion sickness (Garcia et al. 2021). As VR requires specific equipment (e.g. headset) to visualise 3D scenes, the visual impairment and postural stability issues caused by dizziness have been raised since VR was introduced, but remain unresolved (Nichols and Patel 2002). Meanwhile, the space and cost required for VR equipment further limited the widespread application in the workplace (Naylor et al. 2019). For some occupations, such as transport, it is difficult to provide the required space and safe environment for VR in the workplace. Although previous studies have shown that the cost of VR for managing LBP can be comparable to the cost of routine physiotherapy, however, this evidence is based on the condition that VR equipment in a clinical setting can be reused by many patients (Fatoye et al. 2022). For general businesses, VR represents a considerable cost such as the equipment and there are challenges providing employees with work-based and individualised VR programmes.

#### 2.6.4 Individualised DHSMIs in supporting LBP self-management

From the findings presented above, DHSMIs for the self-management of LBP commonly appear to be composed of several components, such as educational materials about LBP (Aliakbari et al. 2020), exercise programmes (Jorvand et al. 2020), and pain management strategies (Huber et al. 2017). The main purpose of these interventions was to empower individuals to take an active role in the management of their LBP (Calvillo et al. 2015). But those DHSMIs developed for LBP selfmanagement in the workplace were often reported to have low participant engagement and retention rates (Taulaniemi et al. 2020; Tersa-Miralles et al. 2022). These findings indicate that those self-management DHSMIs may not have empowered the working population to manage their LBP in their preferred way. Therefore, that there is a need to individualise the design of evidence-based LBP self-management to the patient's needs and abilities (Maher et al. 2017). This direct connection to personal information was believed to increase user's perceived relevance to the content of the intervention (Petty et al. 1986). According to the Elaboration Likelihood Model, perceiving information as personally relevant would enhance their motivation to process the provided information (Petty and Cacioppo 1979). Following this recommendation, interactive DHSMIs, especially those which could generate individualised intervention contents based on contributions and responses from users within the programme, have become more favoured in the management of LBP (Chys et al. 2022). The sense of autonomy and privacy derived from self-paced adjustment was also highly accepted by working population suffering from mental disorders in the workplace (Moe-Byrne et al. 2022).

Irvine et al. (2015) developed an individualised DHSMI, FitBack, to help users build customised strategies to manage and prevent LBP (Irvine et al. 2015). Based on the CBT, Theory of Planned Behaviour (TPB) and Social Cognitive Theory (SCT), FitBack provided pain and activity self-monitoring tools as well as individualised text and video content to people with LBP. These intervention components containing knowledge of pain perception, exercise and stretching, and ergonomic education were developed by an expert team of orthopaedic surgeons, physiotherapists and pain psychologists based on the recommendations of the American Pain Society. FitBack provided individualised intervention content based on the user's type of work and activity, such as sedentary behaviours, prolonged standing, drivers, and weightlifting jobs. Users

could customise their daily LBP self-management activities from four categories (rest, positive thinking, stretching, and exercise). These self-management components were presented in the form of pre-recorded instructional videos on various topics (e.g. pain fear management, medication management, and the benefits of staying active). Also, the FitBack intervention encouraged users to record their daily pain and selfmanagement, with trend being demonstrated in visual charts (7-day and 30-day). A weekly email was sent to direct users to the recommended intervention and remind them to maintain self-monitoring and self-management. Over the 16-week intervention, the intervention group receiving FitBack reported significant improvements in pain, behaviour, and workplace outcomes than the alternative care group with general LBP online resources and the control group without any intervention (Irvine et al. 2015). Utilisation of the different components was reported as 67.8% - 86%, demonstrating an overall good system usability (Mean of SUS = 78.6; SD = 15.7) (Irvine et al. 2015). But no significant improvements in productivity and the presenteeism were found at the 8-week follow-up (Irvine et al. 2015). In this study, 27.6% of the population was not in full-time working which may muddle criteria for presenteeism. Also, 94.6% of the patients reported mild to moderate pain and more than half (52.3%) were not experiencing LBP during intervention (Irvine et al. 2015). Improvements found at the 16-week follow-up further suggest that DHSMI for LBP self-management may require a longer intervention period in the workplace.

Another AI-based individualised DHSMI for LBP self-management, selfBACK, was developed based on evidence and clinical decision-making (Mork and Bach 2018). It collects baseline information on patient demographics, pain perception, psychological aspects of pain, life and work habits, and self-efficacy to create a case of patient information. Similar cases in the existing database were searched for matches and the clinical treatment plan of the most similar case was used as the initial plan for the patient. Educational material on self-management and recommended exercises individualised to the patient's personal goals are provided in the selfBACK. Daily steps and inactivity time of the patients is collected through a wearable device (pedometer wristband) to analyse the patients' exercise capacity and adherence to the recommended intervention content and recorded as an activity log. At the end of the first week, the LBP self-management plan was updated by comprehensively analysing the patient's pain and activity characteristics, exercise characteristics and preference

for self-management content. Plans with good adherence and intervention outcomes are recorded as new cases and added to the original database. The built-in logic algorithm is continuously optimised by learning from these cases to provide the most appropriate self-management plan for future LBP patients.

This Al-based selfBACK has been tested in a clinical setting (Sandal et al. 2020; Sandal et al. 2021). During a 6-week pilot study, 51 patients accessed selfBACK at an average of 65 times with an average of 134 minutes total app using time. With an average of 6 minutes usage per person per day, selfBACK's individualised weekly selfmanagement plan reported high completion rates. The pilot study reported 100 % completion of exercise recommendations, 130% completion of step goals and more than half of educational materials being read. In the subsequent RCT with 371 participants, selfBACK significantly improved pain intensity, disability, self-efficacy and work capacity over the 9-month intervention (Sandal et al. 2021). As an addition to clinical decision-making and standard care, selfBACK has demonstrated its value. But empathy, compassion, and judgement in complex decision-making are characteristics difficult for AI to demonstrate (Rowe et al. 2022), which may explain why the benefits of selfBACK over standard care were not statistically significant. Meanwhile, although both studies reported improvements in long-term disability and work ability, the participants were not all working populations (60% full-time employed) (Sandal et al. 2020; Sandal et al. 2021). Also, both studies were conducted in clinical settings, it was unknown whether the effectiveness of selfBACK could be generalisable in the occupational settings and working populations.

## 2.6.5 Summary of workplace DHSMI practice for LBP self-management

DHSMIs with activity monitoring functions are effective in reducing sedentary hours in the workplace (Stephenson et al. 2017), but the effectiveness in improving pain and disability was inconsistent. The constant feedback notifications and frequent position changes were also found to reduce work concentration and disrupt work routines (Bootsman et al. 2019; Carter et al. 2020; MacDonald et al. 2020). For DHSMIs designed to enhance workplace communication and collaboration, the challenges of reconciling expectations, efforts and personal requirements between employees and employers made it difficult to reach a shared understanding (Grant et al. 2019b; Turesson et al. 2022). But promoting DHSMIs at an organisational level allowed

employers to reflect on the obstacles faced by employees when managing LBP in the workplace, which reinforced empathy and communication of LBP-related needs (Blake et al. 2021). Based on predefined models or AI, interactive DHSMIs have demonstrated its potential in providing individualised LBP self-management by matching evidence-based information with demographic characteristics, risk factors identified in the self-assessment and individual preference (Chiauzzi et al. 2010; Irvine et al. 2015; Sandal et al. 2021; Turesson et al. 2022), but limited interactive DHSMIs contained work-based components. In addition, the insufficient relevance of the content and ability to address individual needs further limited the effectiveness of DHSMIs on LBP in the workplace (Howarth et al. 2018; Stratton et al. 2021; Moe-Byrne et al. 2022). To address this issue, identifying subgroups of LBP under specific classification methods to provide effective and individualised interventions seems to be a promising approach (Hebert et al. 2011). **Figure 2-1** summarises the effects and challenges of existing DHSMIs of different functions for workplace LBP management.

**Figure 2-1**. Summary of the effect and challenge of different types of digital health self-management interventions (DHSMIs) for low back pain management in workplace.

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- Effective in reducing sedentary hours in the workplace
- Inconsistent effectiveness in improving pain and disability
   Frequent feedback and position changes can disrupt work





- Promoting at an organisational level enhances empathy and communication regarding LBP-related needs.
- Difficult to align expectations, efforts, and personal requirements between employees and employers.

#### Interactive DHSMIs



- User-friendly solution to addressing psychological factors of pain
- Limited work-based components
- **Safety concerns**

concentration

### Existing Individualised DHSMIs



- Evidence-based content matched with user characteristics and preferences
- Limited number of existing individualised DHSMIs
- Centred on clinical studies

### 2.7 Pain classification for better individualised management

It is widely established in research that LBP disorders are essentially multifactorial in terms of pathoanatomical, physical, neurophysiological, and social factors (Fairbank et al. 2011; Karayannis et al. 2012). However, the underlying contributing factors that cause the condition and the extent to which they predominate among individuals were different. It has become an important priority to accurately classify subgroups and deliver treatment for the underlying mechanisms of the LBP and NICE recommended the use of risk assessment tools for stratified primary care (National Guideline 2016). By identifying specific risk factors through the classification system, healthcare providers were able to predict the progression of LBP and its impact on daily activities, thus informing better decisions of evidence-based interventions. This section provides the description of current LBP classification models.

## 2.7.1 An overview of LBP classification models

Aligned with recommendations from the NICE advocacy, numerous classification systems and models have emerged over the years in the field of LBP to identify pain pathways and underlying mechanisms (Steinmetz 2022). These well-studied models can be broadly categorised into three main directions: location of symptoms, sources of mechanical inputs and pain mechanism (Riley et al. 2021). Among these, six classification models have been widely accepted and validated by the LBP research, including the Pathoanatomic Based Classification (PBC) (Petersen et al. 2003), McKenzie's Mechanical Diagnosis and Therapy (MDT) classification model (Lam et al. 2018), Sahrmann's Movement System Impairment (MSI) model (Sahrmann et al. 2017), Multi-dimensional Classification System (MDCS) (O'Sullivan 2005), Treatment-Based Classification (TBC) (Alrwaily et al. 2016) and Pain Mechanism-Based Classification (PMC) (Woolf et al. 1998). These models provided rigorous frameworks for understanding and classifying different subgroups of LBP, aiming at more targeted and effective treatments.

# 2.7.1.1 Pathoanatomic based classification (PBC)

Pathoanatomic Based Classification (PBC) has been developed for diagnostic use in primary care settings for people with LBP through a combination of medical imaging and orthopaedic tests. A clinically homogeneous subgroup of patients with LBP was identified by a presumed 12-category hierarchy structure of symptoms. The PBC first considers possible structural issues with the disc in combination with orthopaedic imaging. For the LBP that does not meet the criteria for being affected by mechanical loading, further consideration will be given to dominant leg pain, such as entrapment neuropathies, spinal stenosis and abnormal pain syndromes. If the patient did not meet the symptom descriptions in the 11 broad categories above but still presented significant pain above the hip that was disproportionate to the physical illness, further consideration was made for associated cognitive and affective disturbances.

The PBC system demonstrated good inter-tester reliability, with an overall agreement rate of 72% for each of the subgroups classified in the PBC system and kappa coefficients ranging from 0.44 to 1.00 (Petersen et al. 2004). The most significant advantage of this systematic classification would be that the therapist could choose the most effective treatment for the individual patient based on the diagnosis (Petersen et al. 2003). Personalised LBP physiotherapy based on the PBC model demonstrated superior outcomes compared to the application of other guidelines or individually recommended LBP treatments (Ford et al. 2016). In a 10-week controlled study, significant improvements in pain (MD = 1.3) and disability (MD = 4.7) were observed (Ford et al. 2016). This evidence indicated that the PBC model can consistently be applied by different healthcare professionals, leading to reliable LBP diagnoses. However, apart from these two studies, no other evidence supports this classification.

The PBC approach has limitations as it may exhibit discrepancies across medical specialities and may not be generally accepted or standardised (Brady 2017). Additionally it neglects other important factors, including patient-reported outcomes and psychosocial factors (Karayannis et al. 2012) and fails to consider the BPS nature of LBP accepted in contemporary literature (Waddell 1987). Consequently, there have been calls for a multidimensional approach that combines PBC with other classification systems to provide a more comprehensive understanding of diseases and conditions (Richard 2013; Neelapala et al. 2019).

Also, the NICE guidelines do not recommend routine radiological imaging for the diagnosis of LBP in adults (National Guideline 2016). The NICE guidelines recommend considering imaging only in specific clinical scenarios, such as when there

are red flags or clinical suspicion of a serious underlying condition, or when imaging is likely to influence management decisions (National Guideline 2016). The NICE guidelines emphasised that most cases of LBP do not have a specific underlying cause that can be identified through imaging (National Guideline 2016). One of the reasons for not recommending routine radiology is that imaging findings, such as degenerative changes or disc herniation, are common in asymptomatic individuals and may not necessarily correlate with the presence or severity of symptoms (National Guideline 2016). Therefore, imaging findings alone may not provide useful information for guiding treatment decisions or predicting outcomes (O'Connell et al. 2016). Besides the NICE guidelines, Canadian (Group 2015) and Australian (Innovation 2016) clinical guidelines on LBP also highlight the potential harms of unnecessary imaging, including exposure to ionizing radiation, false-positive findings that can lead to unnecessary interventions, and increased healthcare costs (Hall et al. 2021).

## 2.7.1.2 Mechanical diagnosis and treatment (MDT)

The MDT classification model developed by McKenzie (McKenzie and May 2003) was a well-recognised approach to the assessment and treatment of MSD (Lam et al. 2018; Namnaqani et al. 2019). MDT focused on the assessment and treatment of spinal disorders, exploring whether LBP symptoms could be exacerbated or reduced by repetitive lumbar spine movements or postures in specific directions (McKenzie and May 2003). Patients were classified into three categories by their response to specific exercise, posture, and loading strategies: derangement, dysfunction, and postural syndromes (Hefford 2008). Derangement syndromes typically involve repetitive mechanical displacement of spinal (disc) structures, whereas dysfunction syndromes focus on restoring the normal range of motion. Postural syndromes emphasise the correction of poor postural habits to reduce postural stress. The MDT model adopted a staged assessment process to categorise and individualise exercises and treatments for these conditions, with particular emphasis on self-management (Werneke and Hart 2004).

The MDT classification model has previously been shown to have moderate to good inter-rater reliability in spinal MSK assessments (kappa values = 0.6 - 0.84) (Razmjou et al. 2000; Kilpikoski et al. 2002; Clare et al. 2005) and excellent reliability when classifying mechanical LBP patients, with an overall agreement of 82% (van Helvoirt

et al. 2025). This acceptable inter-rater reliability was observed in both novice and experienced assessors (Willis et al. 2017). Recent studies have shown a significant improvement in pain intensity (MD = -1.00, 95% CI: -2.09 - -0.01) when applying MDT (Garcia et al. 2018). In the treatment of people with LBP, MDT interventions combined with personalised information and guidance were more effective in improving disability (MD = 1.5, 95% CI: 0.2 - 2.9) than general manual therapy (Petersen et al. 2011).

However, the effectiveness of MDT interventions in people with LBP has been controversial. Previous reviews argued that interventions following the MDT model did not surpass stand-alone manual therapy, exercise, or education in resolving pain or disability among people with acute (Lam et al. 2018) and chronic LBP (Sanchis-Sanchez et al. 2021). The conflicts between the evidence were thought to be due to the experimental intervention design not adhering to the core principles of MDT classification (Halliday et al. 2019). In a SR, MDT studies that were considered to follow core principles exhibited better improvements in pain and disability compared to studies that claimed to follow the MDT model (Halliday et al. 2019). Also, despite the high availability of practitioners trained by the MDT, there may be discrepancies towards the attitudes of using the MDT classification model amongst them. A lack of confidence was reported for some healthcare practitioners who rarely use the MDT classification model when treating spine-related extremity conditions (Takasaki et al. 2015). Therefore, further research was needed to investigate whether LBP interventions applying the MDT would be more effective than other rehabilitation interventions (Lam et al. 2018).

## 2.7.1.3 Movement system impairment (MSI) model

The MSI model, developed by Sahrmann (Sahrmann et al. 2017), provided a MSK assessment and treatment approach that emphasised the relationship between movement impairments and pain or dysfunction. The MSI model was centred on the concepts of the kinesiopathological model, which places priority on identifying and resolving movement disorders rather than a specific pathoanatomical diagnosis (Sahrmann et al. 2017). Based on observed specific movement disorders in patients, it has been categorised into flexion and extension syndromes targeting hypermobility of the lumbar spine and hips and micro-instability caused by repetition of joint movements (Azevedo et al. 2018). A key concept of this model was that repetitive

motion and sustained alignment that deviated from optimal kinematic criteria may contribute to the development and progression of LBP (Hoffman et al. 2010). As a result, the MSI model identified faulty movement patterns and deviations from optimal alignment through a comprehensive assessment of the patient's movement patterns, posture, and muscle imbalances (Sahrmann et al. 2017). Thus, treatment was based on the correction of impaired movement and alignment leading to tissue irritation, as well as the correction of tissue adaptations, including relative stiffness, muscle weakness and neuromuscular activation patterns (Sahrmann et al. 2017). The principal treatment instruments responded to the restoration of proper biomechanics and muscular balance by correcting movement disorders and avoiding extreme lumbar spine motion through individualised exercise movements and manipulation, as well as education (Azevedo et al. 2018).

A broad range of studies have demonstrated that the MSI model can provide an accurate and consistent diagnosis when classifying people with LBP with movement disorders (Trudelle-Jackson et al. 2008; Harris-Hayes and Van Dillen 2009; Henry et al. 2013; Kajbafvala et al. 2020). Kappa values for inter-rater reliability of different subgroups ranged from 0.61 to 0.81, demonstrating good reliability (Trudelle-Jackson et al. 2008; Harris-Hayes and Van Dillen 2009; Henry et al. 2013). Treatment based on the MSI model was considered effective in improving outcomes in patients with MSD in previous research (Caldwell et al. 2007; Sahrmann et al. 2017). However, evidence from recent RCTs suggested that LBP treatment based on the MSI model did not significantly differ from those unmatched interventions in improving LBP pain and disability (Henry et al. 2014; Azevedo et al. 2018; Azevedo et al. 2020), only exhibiting a noticeable increase in exercise adherence (Van Dillen et al. 2016). In addition, this theory assumes that all LBP derives from impaired movement caused by biomechanical changes. The unidimensional design does not address the fact that abnormal movement patterns are the result of interactions between the individual, environment, and task (Ludewig et al. 2017).

### 2.7.1.4 Treatment based classification (TBC)

The TBC system developed by Delitto et al. (1995) was based on discriminating between subgroups of patients with LBP based on clinical observations of responses to specific interventions. The TBC system was designed to determine the most

effective treatments for each subgroup through a three-level clinical decision-making process. The first level of TBC decides which patients can be treated primarily by physiotherapists based on the severity of LBP and its impact on daily life. The second level of decision-making classified LBP into three stages based on the response of patients to specific clinical tests and measures. Treatments in the TBC system involved interventions that have been shown to be effective for the subgroup, including manipulation, specific exercises, stabilisation and traction. At Level 3, TBC facilitated more targeted and personalised treatment approaches by supporting clinicians in the final classification of patients based on their clinical presentation and response to specific interventions in the previous level.

Although clinicians could then individualise interventions to meet the specific needs of each patient, the TBC system at that point lacked clear definitions of conceptual terms and diagnostic criteria, resulting in a categorisation of LBP as acute, subacute and chronic to correspond to the Level 2 decision-making staging in practice (Karayannis et al. 2012). In 2015, TBC system was updated with respect to its classification criteria and replaced the original three levels of clinical decision-making with a 2-level classification structure for health care providers and rehabilitation providers (Alrwaily et al. 2016). Patients with LBP on their initial visit were stratified into medical management, rehabilitation management, or self-care management by screening for severe pathology and "Red flags" (Verhagen et al. 2016). For those patients with LBP who require further rehabilitation, an assessment of pain intensity, disability status, clinical status, and psychosocial status was used to provide matched symptom modification, movement control, or function improvement (Alrwaily et al. 2016). In comparison to other criteria, the major distinction of TBC was the identification of two subgroups of LBP that were not suitable for rehabilitation management, defined as patients with underlying severe disease or sensitisation syndrome red flags and patients suitable for self-management of LBP (Alrwaily et al. 2016).

The TBC system has demonstrated moderate reliability in classifying people with LBP, with an overall agreement of 75.5% (kappa value = 0.57; 95% CI: 0.55 - 0.69) (Henry et al. 2012). Nearly the same results appeared in another validation study, with an overall agreement of 76% (kappa = 0.60; 95% CI: 0.56 - 0.64) in classifying 123 people with LBP (Fritz et al. 2006). 60.8% of people with LBP who received treatment based

on the TBC system improved pain outcomes and reduced visits for medical care (Childs et al. 2004). The interpretation of the effectiveness of LBP interventions adopting the TBC system was confounded by the multiple intervention components including spinal manipulation, stabilisation and traction (Bastos et al. 2022). Similar findings were reported in other studies, where analysing different TBC subgroups as homogeneous groups was found only to reflect the self-healing nature of LBP, not representing the effectiveness of TBC-based interventions (Ganesh et al. 2019). Existing studies rarely investigated the effectiveness of interventions in TBC subgroups separately, adding to this uncertainty (Bastos et al. 2022). However, this model does not consider the highly varied nature of those requiring rehabilitation self-management including those at risk of highly disabling LBP. Therefore, a major recommendation over years has been to utilise additional stratification to help allocate appropriate treatment and reduce inefficient variability in treatment (Karayannis et al. 2012).

### 2.7.1.5 Multi-dimensional classification system (MDCS)

A mechanism-based classification system described by O'Sullivan (O'Sullivan 2005) to understand and treat LBP was derived from the underlying mechanisms of pain and disability (Bogduk 1995,2004; Waddell 2004; Woby et al. 2004). It aimed to identify mechanisms for the presence of movement and control impairments pain associated with disabling LBP through a comprehensive assessment of the biomechanical and psychosocial factors (O'Sullivan 2005). As well as the identification of LBP red flags, the MDCS further indicated that a subset of psychological factors, such as anxiety, hypervigilance, fear, and stress, were predominant factors of altered central pain processing among LBP (O'Sullivan 2005). This neurological alteration in cortical mapping might exacerbate control dysfunction, triggering people with LBP to develop a pain "memory" and become centrally sensitised to recurrence (Ji et al. 2003, p. 700) and people with LBP may adopt maladaptive coping strategies (Linton and Shaw 2011).

Taking this into account, the MDCS classification system has individualised treatments to address specific mechanisms involved in people with LBP, such as improving movement control or reducing sensitisation through graded exposure and cognitivebehavioural strategies (O'Sullivan 2005). This therapeutic approach also addressed the psychosocial factors contributing to the pain, such as emotional and social contributions. It assumed that interventions based on a BPS model could evoke selfawareness in patients of their deficits due to dysfunction (O'Sullivan 2005). At the same time, explaining the dysfunction to patients using understandable terminology could relieve the potential fear and anxiety associated with dysfunction in people with LBP with LBP (Nielsen et al. 2014). Continuing to further improve patient perceptions related to pain and reducing fear avoidance through education would boost the internal motivation of people with LBP to participate in home exercise (Freudenreich et al. 2010). In theory, it will also improve patients' engagement in rehabilitation activities toward improvement of their prognosis (Delitto et al. 2012).

The MDCS was found effective in discriminating differences in postural control among LBP subgroups (Seraj et al. 2019). Based on MDCS, the existence of spinal postures causing dysfunction of lumbar muscle control was found among workers with LBP (O'Sullivan et al. 2006). In clinical use, the MDCS has shown moderate to excellent reliability in identifying and classifying LBP (kappa values = 0.61 - 0.82) (Dankaerts et al. 2006; Fersum et al. 2009). However, the reliability of MDCS was considered to depend on the level of training of the user (Karayannis et al. 2012), especially when clinical experts used the MDCS to classify LBP (kappa coefficient 0.96; 97% agreement) (Dankaerts et al. 2006).

Based on the MDCS, classification-based Cognitive Functional Therapy (CFT) has been reported in previous research to effectively relieve pain, reduce fear-avoidance beliefs, and minimise functional impairments (Meziat Filho 2016). When compared with subgroups classified by MDCS receiving exercise and manual therapy, better outcomes were observed in reduced pain and disability among those receiving CFT (Vibe Fersum et al. 2013b). Similar practices in the NHS physiotherapy services also had comparable efficacy, with 75% of people with LBP reporting improvements in disability and pain (Newton et al. 2014). However, it is important to be cautious about the effectiveness of MDCS, especially from RCTs that adopted usual care for the control group where the volume of care is not equal. In an RCT that compared the intervention group receiving stratified care through MDCS (n=238) and the control group received usual care (n=237), the usual care consisted of minimal input with only 3 control participants receiving in person physiotherapy (Konstantinou et al. 2020). A recent review also noted that MDCS-based CFT did not differ from core training

exercises and manipulative therapy in improving pain and disability in patients with LBP and lacked medium- to long-term effects (Devonshire et al. 2023). In addition, to be able to deliver this form of management, clinicians need to have at least 4 years of clinical experience (Vibe Fersum et al. 2019) and undergo over 100 hours of training (Castro et al. 2022). Also, patients need to visit the therapist up to 8 times to achieve significant outcomes (Vibe Fersum et al. 2013a). Therefore, there is currently insufficient evidence to support the use of MDCS as a more effective approach for LBP treatment than routine care in the clinic. The high requirement for therapist capability to use MDCS also limits its further application.

### 2.7.1.6 Pain mechanism-based classification (PMC)

Following intensive research into the molecular, cellular and system mechanisms of nociception and pain, a consensus was reached by a group of independent basic scientists, physiotherapists and clinicians to develop a Mechanism-Based Classification of pain (PMC) (Woolf et al. 1998). To summarise, PMC was based on the fact of the generation, transmission, modulation and perception of pain being determined by the interaction of the peripheral and central nervous systems (Smart et al. 2008). Through the processing and modulation of motor, neuroendocrine and immune systems, the injury perception system would determine the sensory, cognitive and emotional experience of pain (Smart et al. 2008). This PMC approach treated pain as a disease and clinical entity and considered the modulation of peripheral nociception, neurogenic contributions, and psychological influences underlying the unpredictability and complexity of the clinical manifestations of pain (Woolf 2004).

One aspect of PMC was the identification of symptoms and signs of central sensitisation in patients with LBP (Smart et al. 2012b). Central sensitisation was defined as an increased sensitivity of the central nervous system to pain stimulation, leading to amplified pain responses (Latremoliere and Woolf 2009). This phenomenon has been observed in various MSK pain conditions and was characterised by symptoms such as hyperalgesia and allodynia (Jensen and Finnerup 2014). The identification of these symptoms and signs could help clinicians determine the presence of central sensitisation and allow for the selection of individualised treatment and rehabilitation programs for subgroups of patients with chronic MSK pain (Riley et al. 2021).

The PMC also considered symptoms and signs of peripheral neuropathic pain in patients with LBP (Smart et al. 2012b). Peripheral neuropathic pain was believed to be caused by damage or dysfunction of the peripheral nerves and characterised by symptoms such as shooting or burning pain, numbness, and tingling (Smart et al. 2012b). As a summary of the PMC, the International Association for the Study of Pain (IASP) identified three main pain mechanism categories or phenotypes: nociceptive, neuropathic, and nociplastic (Pain 2020). To discriminate between different mechanisms of MSK pain, a Delphi study in 2022 reached an expert consensus of primary features and assessment findings (Shraim et al. 2022). It also highlighted the challenges in classifying MSK pain based on underlying pain mechanisms and called for more expert consensus in this area (Shraim et al. 2022).

Based on the PMC, nociceptive pain refers to pain contributed by the activation of nociceptors in response to non-neural tissue damage or inflammation (Merskey 1986). Nociceptors are specialised sensory receptors that detect thermal, mechanical, and chemical stimuli, and transmit signals to the brain, resulting in the perception of pain (Millan 1999). This type of pain is often described as a sharp, throbbing, or aching sensation (Kidd 2012) and is usually localised to the site of injury or inflammation (Catley et al. 2019). Nociceptive pain serves as an advantageous and protective mechanism that alerts the body to potential harm and promoting healing (Inquimbert and Scholz 2012; Catley et al. 2019). It is often associated with a predictable pattern of pain that is proportional to the severity of the underlying tissue damage (Freynhagen et al. 2019).

Neuropathic pain arises from damage or dysfunction of the nervous system itself (Treede et al. 2008). The exact mechanisms underlying neuropathic pain are complex and not fully understood (Campbell and Meyer 2006). It is believed to involve dysfunction or damage to the nervous system, leading to abnormal processing of pain signals (Campbell and Meyer 2006). Unlike nociceptive pain, it is often characterised by abnormal sensations such as burning, tingling, or shooting pain (Finnerup et al. 2016). Diagnosing neuropathic pain can be challenging, as there are no specific tests or biomarkers available (Freynhagen and Baron 2009; Baron et al. 2016; Finnerup et al.

al. 2016). Clinicians rely on a combination of patient history, physical examination, and screening tools to make a diagnosis (Baron et al. 2016).

Nociplastic pain is a relatively new concept that refers to pain that arises from altered nociceptive processing in the absence of ongoing tissue damage or inflammation (Fitzcharles et al. 2021). Unlike nociceptive and neuropathic pain, nociplastic pain is not directly related to specific tissue damage or nerve dysfunction. It is thought to involve changes of pain signals processing in the central nervous system, leading to increased sensitivity to pain signals (Fitzcharles et al. 2021). The concept of nociplastic pain has been proposed to better understand and classify certain chronic pain conditions that do not fit neatly into the categories of nociceptive or neuropathic pain syndromes, such as fibromyalgia, complex regional pain syndrome, irritable bowel syndrome, and LBP were considered to be explained by the definition of nociplastic pain (Treede et al. 2019; Nijs et al. 2021). In 2021, the IASP proposed a clinical criteria and grading system to classify nociplastic pain (Kosek et al. 2021). Participants who fulfilled the requirements of the first and fourth section of the criteria were considered to as probable nociplastic pain (Kosek et al. 2021).

- 1. Pain duration over 3 months
- 2. Regional rather than discrete distribution
- 3. The pain cannot entirely be explained by nociceptive or neuropathic mechanisms
- 4. Clinical signs or history of pain hypersensitivity and comorbidities

However, it is important to note that the three types of pain (nociceptive, neuropathic and nociplastic pain) can coexist and overlap in some cases (Freynhagen et al. 2019; Bułdyś et al. 2023). For example, osteoarthritis involving multiple mechanisms was reported to likely involve a mixture of these three pain mechanisms (Bailly et al. 2020). Considering that the current definition and diagnostic criteria for the three types of pain are still developing (Finnerup et al. 2016; Fitzcharles et al. 2021) and the clinical diagnosis may be influenced by the selection of the measurement questionnaires (Bailly et al. 2020; Bonezzi et al. 2020), it is difficult to identify the extent of overlap between the three types of pain.

The reliability and validity of clinicians using PMC have been investigated in several studies. In patients with neck pain, PMC demonstrated good reliability in identifying primary mechanism classifications (kappa = 0.84, 95% CI: 0.65 - 1.00) (Dewitte et al. 2019). The study also found moderate to substantial agreement among clinicians in classifying patients based on mechanisms-based criteria, suggesting that PMC can be a reliable tool applied in clinical practice (Dewitte et al. 2019). In another study of 40 patients with LBP, the PMC demonstrated good reliability (kappa = 0.77; 95% CI: 0.57-0.96; agreement = 87.5%), with 95% of items on the clinical criteria checklist considered clinically acceptable (Smart et al. 2010). The PMC subgroups of LBP was identified as having a high classification accuracy and was effective in identifying patients with LBP with central sensitisation (sensitivity 91.8%, specificity 97.7%) (Smart et al. 2012a). In an early experiment of exercise intervention, patients with idiopathic neck pain showed a 47% reduced pain after 6-weeks exercise intervention (Falla et al. 2004). The same exercise intervention reduced neck pain intensity by 37% in patients who manifested neuropathic pain characteristics of underlying peripheral sensitisation, whereas it only reduced pain intensity by 16% in patients who presented abnormal central pain processing mechanisms (Jull et al. 2007). This suggests that a single intervention cannot fully meet the needs of patients with different chronic pain phenotypes and that additional individualised treatment strategies are required (Falla and Hodges 2017). In a recent RCT with patients with chronic spinal pain (47% LBP), an PMC-based pain neuroscience education with cognition-targeted motor control training demonstrated better intervention outcomes (pain intensity, central sensitisation symptoms and disability) than the treatment with general education and exercises (Malfliet et al. 2018). The PMC-based neurological intervention for spinal pain retained 63.4% of the intervention effect at the 12-month follow-up (Malfliet et al. 2018). Although this study demonstrated better outcomes for PMC-based interventions than general treatment, it did not report whether the assessors differed from the trainers. In particular, the study included four different data collections without detailed descriptions of blinding, which could introduce potential detection bias.

In addition, there is a strong evidence on the existence of specific subgroups in chronic pain with poor treatment outcomes, higher pain intensity and risk of disability that match the description of PMC, including multiple sclerosis (Truini et al. 2013),

myofibromyalgia (López-Solà et al. 2017), osteoarthritis (Murphy et al. 2023a), LBP (Roussel et al. 2013), and cancer pain (Caraceni and Shkodra 2019). Although a number of studies have proposed treatment models for selecting interventions that might provide optimal outcomes (Kongsted et al. 2020; Steinmetz 2022), there is no firm evidence to support these models (Steinmetz 2022). Only a clinical case report documented that PMC-based treatment improved the ODI score in a patient with LBP (Hensley and Courtney 2014). Consistent with this finding, it is critical to recognise that the clinical criteria and grading systems for PMC in MSK pain are based on clinical experts consensus (Steinmetz 2022), the exploration of allocating optimal interventions for LBP subgroups is still in the early stage of mechanisms validation (Chimenti et al. 2018).

Meanwhile, there remains a debate over the consensus of the IASP pain classification (Kosek et al. 2016; Hoegh et al. 2022; Russo et al. 2022), and this controversy has also limited the group design of RCTs to some extent (Shraim et al. 2022). However, it is undeniable that more studies have started preliminary attempts by identifying PMC related mechanisms that could be targeted by existing interventions (Chimenti et al. 2018). Carlo et al. (2023) proposed an RCT centred on manipulative therapy, which attempted to phenotype LBP by using standardised measures of anxiety, depression, pain catastrophising, central sensitisation, and pain sensitivity (Gevers-Montoro et al. 2023). In another RCT protocol (Mackey et al. 2022), it was proposed to investigate the effectiveness providing individualised interventions based on PMC for LBP using CBT, mindfulness-based stress reduction and electroacupuncture. These findings highlighted the growing research interest in using PMC to deliver effective individualised interventions for people with LBP.

## 2.7.2 Summary of current LBP classification models

This section demonstrates evidence of utilising LBP classification models in improving intervention outcomes on pain intensity and associated disabilities and enhancing diagnostic accuracy (O'Sullivan 2005; Karayannis et al. 2012; Ford et al. 2016; Meziat Filho 2016; Garcia et al. 2018). Most LBP classification models are exclusively used by clinicians and the validity of these models was highly likely to depend on the capabilities of clinical practitioners in decision-making (Friedberg et al. 2013; Devonshire et al. 2023). To date however, there are no classification systems that can

be accessed by LBP populations themselves before entering the health system. Thus, one potential solution to address this issue is to develop classification models that can be used by LBP populations at the point of need, including the workplace given that most people with LBP are of working age and the burden LBP brings on a person in work (Ferreira et al. 2023). This approach not only offers an opportunity for improved patient outcomes but could also help conserve healthcare resources (Hill and Fritz 2011; Kolski et al. 2016).

As a promising classification model increasingly endorsed by the IASP, PMC advocates for a more holistic understanding of pain that incorporates biological, psychological, and social factors (Nijs et al. 2021; Nijs et al. 2023a; Nijs et al. 2024). It has become an increasingly recognised method to help develop individualised interventions by pain mechanism subgroups for patients with persistent MSK pain (Shraim et al. 2021). A patient-facing PMC model has been developed by Alothman et al. (2017), offering a timely and accessible tool for early LBP classification and supporting self-management in environments such as the workplace, where early action is critical (Nicholas et al. 2011; Vargas-Prada et al. 2016). This model and its implications are further discussed in the following section.

2.8 BACK-on-LINE<sup>™</sup> self-assessment a novel PMC based classification model DHSMI for individualised self-management of LBP in the workplace

BACK-on-LINE<sup>™</sup> (BOL) is emerging as a pioneering digital solution, representing a paradigm change in LBP self-management in the workplace. Based on the PMC model (Smart et al. 2012a), BOL classifies the subgroups of LBP and provide individualised intervention to patient's unique pain contributors. BOL aims to empower people with LBP across diverse occupational settings by actively engaging them on their LBP care journey through restoring autonomy and control over their condition.

This section aims to provide a comprehensive overview of BOL, summarising development and previous validation of this novel DHSMI. This section also assesses the available evidence for BOL and makes recommendations for its further development undertaken by this PhD project.

#### 2.8.1 BACK-on-LINE<sup>™</sup> self-assessment (Alothman et al. 2017,2019)

Following the PMC model recognised by IASP for MSD (Chimenti et al. 2018), BOL self-assessment aimed to subgroup LBP people by their own pain mechanism (Alothman et al. 2017). Under the PMC model, neuropathic pain is characterised by pain arising from a lesion or disease affecting the somatosensory system (Campbell and Meyer 2006), while nociplastic pain is pain that arises from altered nociception without evidence of ongoing tissue damage or inflammation (Nijs et al. 2021). Despite the refinement of definitions, the identification of neuropathic pain was still based on indirect inference using history examination and questionnaire (Chimenti et al. 2018). But a previous SR found that questionnaire used for identifying neuropathic pain lack comprehensive report of its development and measurement properties (Mathieson et al. 2015). Also, these questionnaires were developed in different languages, but their translated versions reported weak cross-cultural validity (Mathieson et al. 2015). Besides, due to the overlap in characteristics and clinical thresholds between nociplastic and neuropathic pain, some researchers started to question the existence of nociplastic pain (Shala 2022; Toda 2022). Furthermore, the IASP consensus suggested that nociplastic pain need to present pain characteristics distinct from nociceptive and neuropathic pain (Section 2.7.1.6). But the recent Lancet study argued this diagnostic method, which determines pain mechanisms by excluding other conditions, is highly prone to misdiagnosis of nociplastic pain (Fitzcharles et al. 2021).

Therefore, the decision to merge neuropathic and nociplastic pain into a single category in this study was based on the recognition that both conditions involve changes in sensory processing and central sensitisation (Roussel et al. 2013; Nijs et al. 2021; Fernández-de-Las-Peñas et al. 2022). By merging these two categories, this study aimed to capture the shared underlying mechanisms and clinical features of these pain conditions. Also, it can help better understand the overlapping features and mechanisms of these pain conditions (Nijs et al. 2021), and organise more targeted and effective treatment approaches. On the other hand, nociceptive pain is defined as pain that arises from actual damage to non-neural tissue and is associated with the activation of nociceptors (Thai and Fainsinger 2011). It was believed to be distinct from neuropathic and nociplastic pain as being directly related to tissue damage or inflammation (Fitzcharles et al. 2021). Grouping nociceptive pain as a separate

category allows for a clear distinction between pain resulting from tissue damage and pain arising from altered sensory processing or central sensitisation.

The merging of neuropathic and nociplastic pain into a single category while grouping nociceptive pain as a separate category was also proposed to improve the understanding of different pain mechanisms and facilitate targeted treatment approaches (Axén et al. 2011), which may also help identify overarching trends or associations of pain categories (Östergren et al. 2005). In the absence of data on the potential distribution of LBP subgroups in the target working population, this merging may prevent unstable clustering due to data sparsity (Fairbank et al. 2011). However, it is important to note that although merging may improve the clarity of the analysis, it could mask differences between pain types and lead to the loss of specific information (Williamson et al. 2022). Therefore, after determining the reliability and validity of the BOL self-assessment in classifying pain subgroups in the working population, further differentiation between neuropathic and nociplastic LBP will be achieved through future large-scale trials.

Based on the NICE guidelines, imaging is not recommended as a regular diagnosing approach for LBP in non-specialist settings, unless the imaging results would alter the management of LBP (National Guideline 2016). Instead, NICE guidelines recommended stratification at first contact with people with LBP, thus providing the individualised LBP management (National Guideline 2016). Of the tools designed for LBP stratification, the STarT Back Screening Tool (SBST) (Hill et al. 2008) was recommended by NICE guidelines as a risk stratification tool for LBP for primary care in the UK (National Guideline 2016). By identifying patients with a poor prognosis for LBP, SBST can assist practitioners to consider individual patient factors and provide an individualised treatment plan (National Guideline 2016).

The SBST is a 9-item questionnaire for identifying multiple predictors of persistent disabling LBP (Hill et al. 2008), containing questions on modifiable physical (items 1-4) and psychosocial (items 5-9) risk factors. Eight items were answered using a dichotomous response format ('agree' or 'disagree'), and the last item was on a Likert scale (5 categories). Items 1-4 were related to referred leg pain, disability and comorbid shoulder or neck pain, while the other five items made up the psychosocial

subscale, addressing psychosocial aspects related to fear, depression, catastrophising, worry and anxiety (Hill et al. 2008). The total score ranges from 0 to 9, and patients with LBP are classified as being at low, medium or high risk if they present with a poor prognosis in terms of disability. Patients were classified as low risk if the sum of the total scores was less than 4. Patients were classified into the moderate risk group if the total score was higher than 3 and the sum of item 5-9 scores was less than 4. If the total score was higher than 3 and the sum of items 5-9 was equal to or greater than 4, the patient was classified as high risk of presenting a poor prognosis. As an LBP stratification tool, the psychometric properties of the SBST (e.g., validity, reliability, cross-cultural validity) have been tested in various studies (Bruyère et al. 2014; Luan et al. 2014; Pilz et al. 2017). The test-retest reliability of SBST has been reported as excellent, with an intraclass correlation coefficient (ICC) of 0.90 (95% CI: 0.81–0.95) (Bruyère et al. 2014). The Cronbach's alpha coefficient ( $\alpha$ ) was reported as 0.73, showing a satisfactory internal consistency for the psychological subscale (Bruyère et al. 2014). High correlation (r=0.74) between SBST, Roland-Morris Disability Questionnaire (RMDQ) and Örebro Musculoskeletal Pain Questionnaire (ÖMPQ) were also observed (Fuhro et al. 2016).

The reason for Alothman et al. (2019) selecting SBST as a reference standard is because SBST also considers physiological, psychosocial and psychological risk factors, which is consistent with the BPS model underlying the BOL self-assessment. Also, the low and medium risk groups stratified by SBST typically experienced a low pain intensity and less interference from psychosocial factors (Hill et al. 2010b). Patients classified as low and medium risk by SBST would usually receive minimal interventions, including being informed of the promising prognosis of their condition, receiving advice on, being encouraged to stay active, receiving exercise and manipulation to resolve physical impairments, or taking simple medication for pain relief (Hill et al. 2010b). This to some extent matches with the characteristics of the nociceptive pain subgroup and the recommended treatment plans (Chimenti et al. 2018). While high-risk group of SBST tended to be associated with higher pain intensity and remarkable psychosocial factors interfering and required to receive CBT, multidisciplinary interventions and intensive exercise interventions (Hill et al. 2010b), which would be more consistent with the characteristics and treatment plans for the neuropathic and nociplastic pain subgroups (Chimenti et al. 2018). Therefore,

Alothman et al. (2019) calculated the cut-off point of the BOL self-assessment for discriminating pain subgroups (42 points) using the SBST as the gold standard to reflect the differences in pain mechanisms between LBP populations (Alothman et al. 2019). Also, using a widely validated scale or tool (SBST) as a reference was believed to ensure that the classification basis is evidence-based, thereby helping to enhance the reliability and validity of the new tool (Boateng et al. 2018).

#### 2.8.2 BACK-on-LINE<sup>™</sup> intervention (Sheeran 2024a,b)

With Alothman's fundamental work on the BOL assessment, the primary investigator of BOL, Doctor Liba Sheeran, worked with a technical team led by Jeffery Morgan and developed BOL intervention (Sheeran 2024b). The BOL intervention was designed as a multi-component, interactive, web-based DHSMI to provide accessible information, guidance, and individualised support for population with LBP in the workplace (Sheeran 2024a). The aim of the BOL intervention was to assist individuals with LBP to maintain or restore work participation by regaining self-management autonomy and increasing exercise self-efficacy through self-regulation procedures (self-monitoring and feedback) using highly accessible and individualised resources (Sheeran 2024a).

The current version of the BOL self-assessment was further optimised based on the Alothman et al.'s study and eventually set as 42 items (36 scoreable items) to obtain individual pain perceptions and the impact of LBP on work and family, personal and social life, exercise habits and physical activities. Responses were scored following the scoring rules established in the previous BOL development with slightly refinement (Alothman et al. 2017). Based on the model generated from expert consensus (Alothman et al. 2017), BOL intervention was developed with modules and toolkits for individualised LBP self-management and featured with a pre-programmed library of recommended reading materials to provide individualised feedback on factors contributing to individual's own LBP, sedentary behaviour, and physical activity level (Sheeran 2024a). Corresponding to the three sections in the feedback, the BOL grouped the LBP population based on the pain mechanism (Smart et al. 2012a), daily continuous sedentary/standing time (Dunning et al. 2018) and the International Physical Activity Questionnaire (IPAQ) classifications (Craig et al. 2003) to provided interventions individualised to the characteristics of the subgroups (**Figure 2-2**).

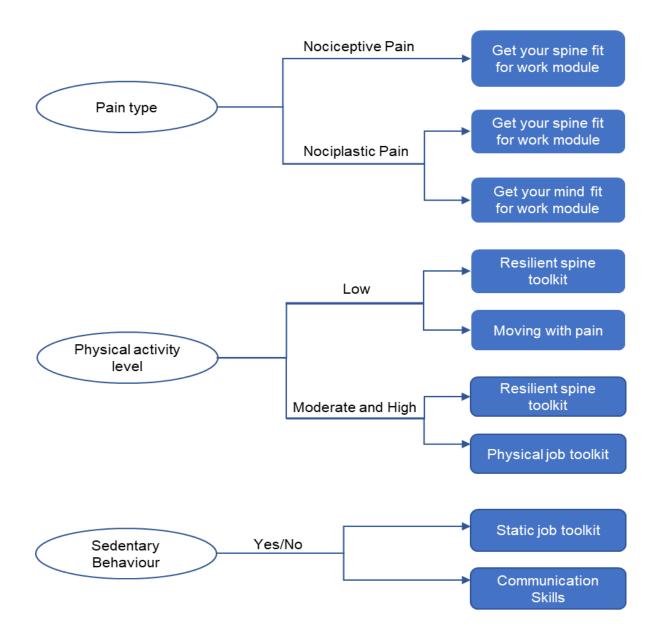
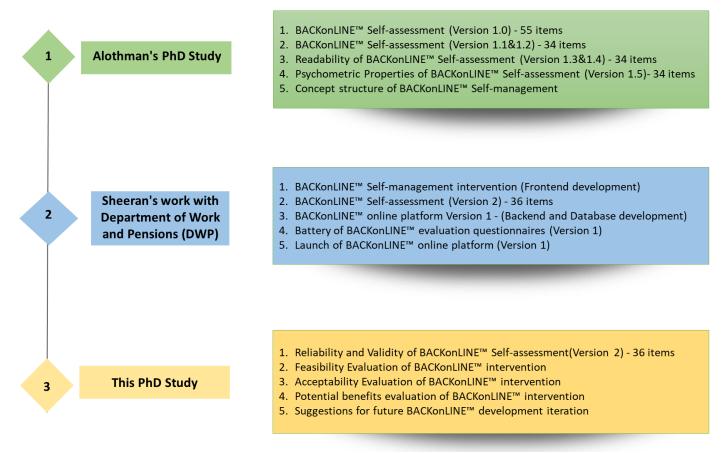
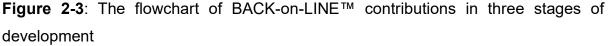


Figure 2-2. The individualisation process of the BACK-on-LINE<sup>™</sup> intervention.

In 2019, a mixed methods BOL study was conducted to explore the feasibility and acceptability of providing BOL to support LBP self-management industries with high LBP prevalence (healthcare and transport). The study design of this BOL study is described in <u>Chapter 3</u>, and the methods and results of the study are presented in <u>Chapter 6</u>. Figure 2-3 summarises the contributions of Alothman, Sheeran et al. and from this thesis to the development of BOL. The detailed contribution description is presented in <u>Appendix 3</u>.





#### 2.8.3 Appraisal of previous development

In the previous development by Alothman et al. (2019), the BOL self-assessment has demonstrated good face and content validity (Alothman et al. 2019). The BOL self-assessment exhibited excellent internal consistency (Cronbach's alpha = 0.87 - 0.90) and test-retest reliability (Intraclass Correlation Coefficient (ICC) = 0.92, 95% CI = 0.83-0.95) (Alothman et al. 2019). Different BOL domains also exhibited good construct validity when compared to other validated questionnaires with similar structures or outcome measures. The Pain Behaviour domain was reported with acceptable convergent validity with the Visual Analogue Scale of Pain (VAS) (Carlsson 1983), Oswestry LBP Disability Index (ODI)(Fairbank and Pynsent 2000), and SBST (Hill et al. 2008) (correlation coefficient r = 0.50 - 0.60)(Alothman et al. 2019). The Impact of LBP on Work and Life domains demonstrated similar convergent validity with SBST, Tampa Scale for Kinesiophobia (TSK)(Roelofs et al. 2004), and Pain Anxiety Symptoms Scale short form (PASS 20)(McCracken and Dhingra 2002) (r = 0.50 - 0.60)

(Alothman et al. 2019). Also, the Pain Perception domain exhibited comparable convergent validity with SBST, TSK, and PASS 20 (r = 0.44 - 0.60) (Alothman et al. 2019).

Alothman et al.'s study provided preliminary evidence of the validity and reliability of the BOL self-assessment. However, this evidence was based on a pilot study with a small sample size (n = 35), which may contribute to insufficient statistical power (Button et al. 2013), thus limiting the ability to accurately detect significant differences or associations (Serdar et al. 2021). Although previous development provided a critical basis for the readability, reliability and construct validity of the BOL self-assessment, there was an inadequate description of the characteristics of identified LBP subgroups in previous BOL research. Therefore, it is unclear whether there are significant differences between the LBP subgroups discriminated by the BOL self-assessment. Also, the pilot study of BOL was conducted among mixed population (working population and student) in a non-working environment (laboratory and home). Findings may lack generalisability to a broader occupational setting and working population. Therefore, future research is needed to further validate the reliability and validity of the BOL self-assessment in larger sample sizes of working populations in the workplace.

#### 2.9 Summary

As research and clinical practice advances in the understanding of LBP, patientcentred, individualised treatment plans and self-management have become the new paradigm for LBP management (Kongsted et al. 2021). The emergence of DHSMIs has provided potentially cost-effective, evidence-based solutions to the challenges experienced in self-management of LBP (Hewitt et al. 2020). These ongoing studies of DHSMIs for LBP self-management have demonstrated potential benefits in pain, disability, physical activity levels, mental health, and work ability (Proper and van Oostrom 2019; Lewkowicz et al. 2021; Moe-Byrne et al. 2022). The multifactorial nature of LBP resulted in DHSMI studies with widely varying intervention objectives and target populations (Nicholl et al. 2017). Due to the significant heterogeneity in design, intervention content, and individualising methods between studies, it is challenging to determine the effective components of DHSMI for LBP (Howarth et al. 2018). There has been continued reporting of DHSMIs for LBP self-management, however, the evidence for its effectiveness in assisting with workplace LBP issues was still limited (Russo et al. 2021). However, given the rapid development of digital intervention research, there is a need for a new synthesis of the current evidence on the effectiveness of DHSMIs used for the self-management of LBP in the workplace, particularly those of individualised DHSMIs.

When integrating digital technology into workplace LBP management, there was a lack of theory adaptation to integrate with existing evidence-based interventions (Stephenson et al. 2020). Meanwhile, current individualised DHSMIs typically treat LBP as a homogenous condition without considering the potential pain mechanisms of LBP (Shraim et al. 2022). This limitation would result in insufficiently individualised DHSMIs with only generic advice being offered (Lewkowicz et al. 2021). At the same time, available DHSMIs for LBP often focus on unidimensional factors of LBP, with limited application of a BPS model to form a comprehensive overview of the conditions in individuals (Ahmadvand et al. 2018). In contrast, BOL addressed these limitations by using a multidimensional self-assessment that addresses biological, psychological, and social factors, with the aim of providing individualised interventions to people with LBP based on their underlying pain mechanisms. Hence, it is necessary to first validate whether the BOL self-assessment can effectively subgroup people with LBP based on the pain mechanisms in the workplace. Following the establishment of the validity and reliability of the BOL self-assessment, it needs to explore whether the BOL would be technologically feasible and acceptable in supporting the self-management of LBP in the workplace. Also, the current evidence base for BOL did not include data on potential benefits for LBP. Thus, prior to conducting a large-scale RCT exploring the effectiveness of the BOL intervention for LBP in the workplace, pilot trials are needed to help optimise the experimental design and the structure and content of the intervention in future iterations of BOL development.

## 3. Chapter 3: Methodology

#### 3.1 Introduction

As a researcher, it is important to follow a rigorous and systematic approach to ensure that the results of the study are accurate and reliable (Creswell and Creswell 2017). To achieve this, the chapter starts with the fundamental philosophical assumptions and explains the rationale for adopting a pragmatic philosophy. This philosophy basis provides a flexible framework for the use of mixed methods, consistent with the objectives of this study. Following this, the chapter describes the methods of data collection and analysis for each part of the study, detailing the rationale for the selection of these methods. Based on the framework for developing and evaluating complex interventions from Medical Research Council (MRC) and National Institute for Health And Care Research (NIHR) (Skivington et al. 2021), this chapter summarises the current stage of the BOL development. Finally, the chapter concludes by presenting the content of the BOL intervention and the underlying theories that inform its design. By integrating these elements, the chapter provides a cohesive overview of the research process and the development of the mixed methods BOL study.

#### 3.2 Philosophical assumption

In this section, the foundational philosophical principles that underpin this PhD project are presented. By exploring the concept of methodology and key areas such as ontology and epistemology, this section outlines the research paradigm that shapes the approach to understanding, investigating and generating knowledge in this study. These philosophical perspectives guide the exploration of the phenomena under study and inform the selection of methods and interpretations of findings.

#### 3.2.1 Concept of methodology

Methodology is a fundamental concept of research, which is a systematic framework that guides research in how it is planned, conducted and analysed (Creswell and Creswell 2017). Specifically, it is not just a demonstration of practical research methods but provides a comprehensive framework for understanding how knowledge is generated, validated and interpreted in a particular context (Crotty 1998). The core

of methodology is the careful selection and justification of research methods, data collection and analysis techniques that are appropriate to the objectives and philosophical underpinnings of the research (Creswell and Poth 2016). It bridges the gap between theoretical concepts and practical research execution which ensures coherence and rigour throughout the research process (Crotty 1998). By clarifying the rationale behind the selection of methodology, it also provides transparency to the research and allows other researchers to critically appraise the methodology of research (Creswell and Creswell 2017). Methodology also involves critical reflection on the ontological and epistemological positions of the researcher, recognising how these philosophical perspectives influence the selection of methodology and the interpretation of research findings (Crotty 1998). For the development of DHSMIs for the self-management of LBP in the workplace, the researcher's ontological and epistemological standpoint plays a crucial role. It influences how the complexity of LBP is understood, how the effects of DHSMIs are measured, and how the different needs of the target population are conceptualised.

#### 3.2.2 Ontology and epistemology

Philosophical perspectives were recognised for their influence on how we conceptualise the constitution of knowledge and approach the study of phenomena (Weaver and Olson 2006). They often lead to deep philosophical reflection leading to questions such as: what exists? What is the nature of truth? How do we know what we know? These questions require us to reevaluate our assumptions about the world and our place in it. Within the realm of research methodology, ontology and epistemology formed the bedrock upon which we construct our understanding of the world (Misselbrook 2024). As an important part of research methodology design, understanding these two concepts and distinguishing between them could be helpful in positioning ourselves in the healthcare research methodology and selecting appropriate research methods (Hathcoat et al. 2019).

Epistemology, derived from the Greek word 'episteme,' stands for the theory of knowledge with regard to what knowledge is and how it is acquired. It is considered a branch of philosophy that examines the nature of knowledge and the process of obtaining and validating knowledge (Gall et al. 1996). Essentially, epistemology focuses on the nature and form of knowledge and how it can be transmitted to others

(Cohen et al. 2007). In other words, the epistemological perspective delves into what is known and the mechanisms through which this knowledge is obtained. In comparison, the ontological view is oriented towards the study of facts and what exists in reality (Crotty 1998). The main focus is on the nature of reality and the way in which knowledge about the world shapes reality (Crotty 1998). Ontology is concerned with what constitutes reality, what the real world is, and what we can know about it (Denzin and Lincoln 2011) and assumes that there is a single reality that can be studied existing in the world (Al-Ababneh 2020).

The beliefs, values and techniques shared by particular researchers about the direction of the research are considered to form the concept of paradigm (Scott and Usher 1996). The term paradigm has been defined as a set of fundamental beliefs addressing the essential nature of the social world principles (Guba and Lincoln 1994). Previous researchers believed that references to paradigms should be used as epistemological or methodological viewpoints (Ruhl 1995; Gilgun 2005). The adoption of certain ontological beliefs can affect the development of specific epistemological assumptions. Thereby, the researcher needs to be in "a position of objective detachment" to be able to discover "how things really are" and "how things really work", thus helping to validate the specific truths that are assumed verifiable in the research (Guba and Lincoln 1994, p. 109). Building on the foundational concepts of ontology and epistemology, philosophical assumptions have shaped the understanding of researchers about the world and the objectives of their research (Scotland 2012). Having different research paradigms would lead to different research questions and methodology selection (Kivunja and Kuyini 2017).

#### 3.2.3 Overview of research paradigms

Positivism has been widely used in healthcare research for its focus on objectivity and quantification (Tashakkori and Teddlie 1998). Positivism emphasises understanding and explaining phenomena through empirical evidence, scientific method and quantitative data (Park et al. 2020b). Positivist healthcare researchers often use experimental designs, surveys, and statistical analyses to test hypotheses and establish causal relationships (Crossan 2003). Common positivist research includes designing RCTs to assess the effect of DHSMI on LBP patients (Sandal et al. 2021) and conducting epidemiological studies that use large datasets to identify risk factors

for LBP in the working population, then use statistical methods to quantify the associations between these variables (Yang et al. 2023). However, criticisms have argued that positivist approaches in healthcare research simplifies complex health issues which ignores important contextual factors (Clark 1998). For example, while an RCT demonstrates the effectiveness of DHSMI in LBP patients under controlled conditions, it may not fully reflect the performance of DHSMI in the context of the real world, where adherence to DHSMI (Lin et al. 2018), lifestyle factors (Briggs et al. 2011) and working environment (Mochari-Greenberger et al. 2020) may influence the effects. Meanwhile, positivist research also has limitations in investigating the subjective experience thus may not sufficiently capture the multifaceted nature of the LBP.

Compared to positivism, constructivism assumes that knowledge and reality are socially constructed rather than objectively existing external truths (Schwandt 1996). Therefore, constructivism in healthcare research tends to construct meaning by understanding how patients, healthcare providers, and other stakeholders experience health, illness, and healthcare (Thomas et al. 2014). Qualitative interviews, observational studies, and focus groups are common methods used to investigate how LBP populations understand symptoms and DHSMI interventions (Svendsen et al. 2020). This methodology reveals nuanced understandings that cannot be captured by positivism research. Constructivist research typically uses descriptive analyses to reveal the internal relationships and patterns of phenomena (Cupchik 2001), but is insufficient in explaining the causality and developmental processes of these relationships. Meanwhile, due to the small sample sizes normally and focus on subjective experiences, it has limited the generalisability of the findings of constructivist studies (Boykin and Schoenhofer 1991). In addition, potential biases in data collection and interpretation by researchers may also affect the credibility of the results (Burns et al. 2022). Despite these limitations, constructivism research provides rich contextual insights and is therefore considered to have the potential to complement other research paradigms (Shannon-Baker 2016).

Unlike positivism and constructivism, the transformative paradigm believes that knowledge is not neutral and can be influenced by human interest (Jackson et al. 2018). In other words, knowledge reflects power and relationships in society and the purpose of knowledge construction is to help people improve society (Mertens 2008).

The transformative paradigm believes that knowledge creation should be embedded with efforts to improve social conditioning and challenge oppressive structures (Mertens 2008). Thus, transformative paradigm research often employs participatory research (Whitaker et al. 2021) and mixed method approaches (Jackson et al. 2018) to capture the complexity of the problem and amplify marginalised voices to ensure that participant perspectives and experiences are at the centre of the research design. In healthcare, transformative paradigm research tends to consider the ethical implications of research, emphasising reflexivity and stakeholder engagement (Jackson et al. 2018). These include, for example, the emphasis on collaboration between patients and healthcare providers in digital health research (Wannheden et al. 2022), the ethics of online healthcare (Solimini et al. 2021), and the issue of the digital divide (Nguyen et al. 2023). While the transformative paradigm provides a powerful framework for addressing social injustice and empowering marginalised groups (Mertens 2008), the focus on social change can lead to biased research design and interpretation (Hammersley and Gomm 1997).

For the complex health issue of LBP in the workplace, pragmatism has emerged as a valuable paradigm in healthcare research, providing a flexible and context-based framework (Poradzisz and Florczak 2019). Pragmatism, a theory of inquiry conceptualised by epistemology (Dewey 2018), prioritises pragmatics, relevance, and real-world applicability in research over traditional philosophical debates about the nature of truth and reality (Long et al. 2018). Pragmatists believe that the truth lies in its practical effect and application, rather than its compliance with abstract standards of truth (Patton 2014). They also view knowledge as dynamic and constantly evolving (Kelly and Cordeiro 2020), which means different research methods and approaches may be required to address different research questions and contexts (Long et al. 2018). However, the flexibility of pragmatism requires that researchers must ensure that the different methods used are systematic and transparent to avoid leading to a lack of methodological rigour (Hesse-Biber 2010).

The decision to adopt a pragmatic approach in this study was primarily due to the complexity of LBP management in the workplace and the multifactorial nature of LBP. Pragmatism prioritises practical results and real-world applicability, which fits well with the goal of developing LBP interventions that can be used in the workplace. The

flexible and context-based framework provided by pragmatism allows researchers to focus on the use of methods that best answer the research question, rather than strictly following a single methodological tradition (Allemang et al. 2022). For LBP research, pragmatism allows researchers to integrate objective measures of patient functionality with the subjective experience of pain and the psychosocial impact of LBP through a combination of quantitative and qualitative methods, which matches the widely accepted BPS model of LBP (Gatchel et al. 2007). In addition, the pragmatist view of knowledge as dynamic and evolving is consistent with the concept of DHSMI design which requires iterative development and continuous upgrades (Fernandez et al. 2019). Furthermore, the flexibility of pragmatism allows LBP participants and other stakeholders to be involved in the design of the intervention, thereby contributing to its relevance to their actual needs (Gélinas-Bronsard et al. 2019).

#### 3.3 Convergent mixed methods approach

The debate between quantitative and qualitative research has been a long-standing discussion in the research (Bryman 1984). Proponents of quantitative research have argued that surveys, experiments and statistical analyses can provide objective and generalisable findings (Creswell and Creswell 2017). By accurately measuring and quantifying variables, the reality can be revealed by exploring the causation between variables and conducting hypothesis testing (Castellan 2010). Therefore, quantitative research has typically been associated with positivism, which emphasises objectivity and the discovery of universal truths (Park et al. 2020a). Conversely, qualitative research methods such as interviews, observation and ethnography enable researchers to explore the subjective experiences, meanings and social contexts of individuals and groups (Lewis 2015). The capacity of qualitative research to capture rich and in-depth insights into complex phenomena is particularly useful for researching topics that are challenging to quantify or would require a deeper understanding of human behaviour and social interactions (Rahman 2020). Similarly, qualitative research is often associated with interpretivism, which emphasises understanding social phenomena from the perspective of the participants (Goldkuhl 2012).

The debate between quantitative and qualitative research has not been about choosing one method over the other but about recognising their complementary features and the value of using mixed methods (Liu 2022). Over time, researchers have recognised that for some research questions, mixed methods can lead to more robust and insightful findings than either qualitative or quantitative methods alone (Miles and Huberman 1994; Krantz 1995; Borrego et al. 2009). This design provides researchers with the ability to utilise the strengths of both qualitative and quantitative methods to gain a more comprehensive understanding of the research topic (Creswell and Creswell 2017). It also allows for the exploration of unexpected or contradictory findings that may occur with different methods (Fry et al. 1981). Researchers can select one method to interpret or combine results obtained from another method, thereby creating a more nuanced interpretation of the data (Halcomb and Hickman 2015). Furthermore, this method allows researchers to triangulate findings by collecting and analysing multiple sources of information (Jick 1979). This triangulation enhances the validity and reliability of the findings by cross-validating and verifying the findings obtained from different methods, providing a more detailed explanation of complex phenomena (Gelo et al. 2008). At the same time, researchers using mixed methods can also employ transformative designs that overcome the limiting positions of each method (Moffatt et al. 2006) and generate new insights and theories that transcend the individual methods (Harrison et al. 2020). Thus, the BOL study adopted a mixed methods approach, a methodology that integrates both quantitative and qualitative research components to provide a comprehensive analysis. This approach was chosen to leverage the strengths of both data types and to allow for a more nuanced understanding of the research questions.

Of the different mixed-methods research designs, this pragmatic PhD project used a convergent design (Creswell and Creswell 2017) to obtain different but complementary data on the BOL intervention to comprehensively evaluate the technological feasibility, acceptability, and potential benefits of BOL. This design allows for a combination of the strengths of quantitative methods in reflecting overall trends in the sample with the power of qualitative methods to depict details (Liu 2022). In a convergent mixed-methods study, the two types of data are usually of equal importance, and the research conducted by one method is not dependent on the results of the other, so qualitative and quantitative data collection are conducted in parallel (Creswell and Clark 2017). After the completion of data collection, the data were first analysed separately using the appropriate analysis methods for quantitative and qualitative data to fully explore

each dataset (Creswell and Clark 2017). In this PhD project, a narrative integration was used to combine the findings from the two datasets, exploring how the different types of data complemented, integrated or diverged from each other to develop a more comprehensive understanding (Doran et al. 2022). Specifically, in the quantitative phase of this study, the researchers statistically analysed the quantitative data collected using the electronic questionnaire to initially assess the technological feasibility of the BOL recruitment and intervention, the technology acceptance of the BOL intervention, and the associated potential benefits. In the qualitative phase participants' experiences of using BOL to self-manage LBP in the workplace were explored through interviews to gather feedback on their access to BOL, the content of the intervention, perceived usefulness, and suggestions for future development. If the qualitative phase could be used to investigate these discoveries more deeply and provide a more detailed and holistic understanding (Ivankova et al. 2006).

The quantitative component of the study involved using the online BOL platform to collect participant demographic characteristics, responses on the BOL self-assessment and a series of other measurement instruments (described in <u>Chapter 6</u>) at baseline and 4-week follow-up. The quantitative data used in this study was obtained from the database of this BOL platform in the form of downloadable Excel spreadsheets. After data collection, a descriptive analysis was conducted on intervention recruitment and BOL usage data to demonstrate the technological feasibility of the BOL intervention. Exploratory analyses of data on participants' individual health, work, and healthcare resources usage, and scores on other measurement instruments were conducted to explore the potential benefits of the BOL intervention. All quantitative data was analysed using Stata software (14, Stata Corp LLC, College Station, Texas, U.S.).

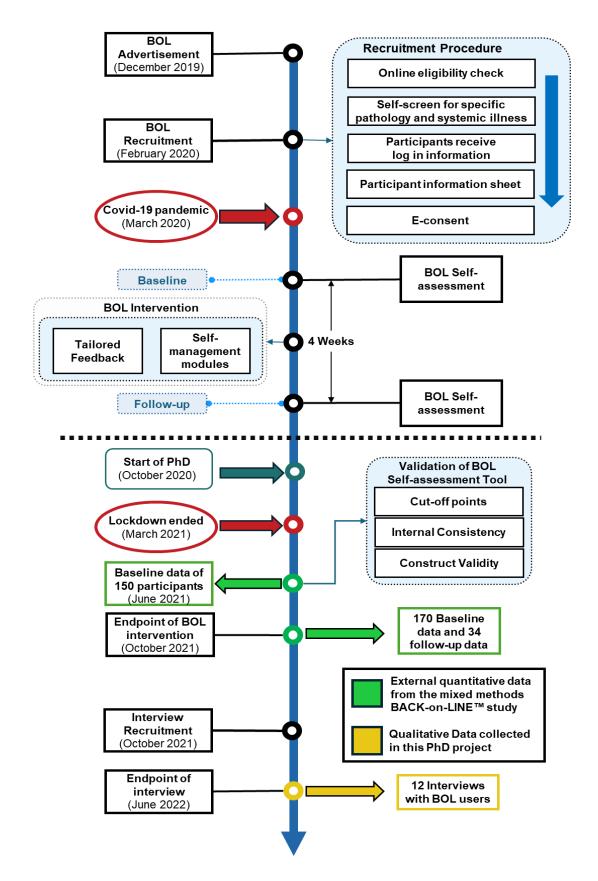
Concurrently, the qualitative component comprised semi-structured telephone interviews and the reflexive thematic analysis. Interviews constituted one of the key sources for qualitative data collection (Jamshed 2014). With the flexibility and adaptability of interviews (Pathak and Intratat 2012; Ruslin et al. 2022), it allowed the researcher to develop more complex questions regarding the study participants (Adeoye-Olatunde and Olenik 2021), thereby yielding more extensive qualitative data

(Dilshad and Latif 2013). For studies seeking in-depth exploration of participants' thoughts, feelings and beliefs about specific topics in research, semi-structured interviews were recognised as useful qualitative techniques (DeJonckheere and Vaughn 2019). This type of interview also permitted interviews to be conducted in a flexible and innovative approach, facilitating an exploration of individuals' cognitive and conceptual models of health behaviour (Renner 2001). Semi-structured interviews allowed the researcher to develop a deeper understanding of the experiences, perceptions and motivations of the participants (Ruslin et al. 2022). Participants were free to express themselves, providing detailed and context-rich responses that may not have been possible in a structured form of interview (Yilmaz 2013). While a set of predetermined questions existed, the interviewer could still reframe the conversation to delve deeper into relevant themes based on the respondents' answers. This flexibility enabled more comfortable and natural communication. Participants were more likely to provide candid responses, as they perceived their viewpoints to be valued, thus yielding more reliable data reflecting their own experiences (DeJonckheere and Vaughn 2019). Due to travel restrictions caused by the COVID-19 pandemic, a telephone interview was selected for this study (Carr and Worth 2001). With advances in technology, data generated from telephone interviews are considered to have comparable quality to face-to-face interviews (Carr and Worth 2001).

After conducting semi-structured telephone interviews, the collected data were systematically analysed using Reflexive Thematic Analysis (RTA). RTA proposed by Braun and Clarke (2006) embraces the essence of the qualitative paradigm centred on researcher subjectivity with a flexible coding process (Byrne 2022). Braun and Clarke believed that coding of qualitative data should evolve as the researcher interacts with the data and reflects on their own biases (Braun and Clarke 2023). The benefit of this process is that it encourages the researcher to engage deeply in the iterative process of data, coding and themes, thereby generating a richer and insightful analysis. Also, the flexibility of the RTA allowed the researcher to individualise the method of analysis (inductive, deductive and hybrid) to the specific research objectives and context of the interviews (Proudfoot 2023), which fits this pragmatic, mixed-methods study.

Meanwhile, unlike traditional thematic analysis which seeks to be objective and transparent, minimising the influence of the researcher on the analysis, RTA presents itself as a flexible qualitative research methodology which places the researcher's reflexivity at its core and acknowledges its influence on the analysis (Braun and Clarke 2021a). Braun and Clarke suggested that themes arise in an active process through the researcher's interpretive engagement with the data, rather than emerging passively or being discovered in the data (Braun and Clarke 2006). This approach encouraged researchers to be responsible for their own analytical decisions and to clearly represent their reasoning (Braun and Clarke 2019). By explicitly acknowledging and critically reviewing as to how one's own experience, knowledge, and social position influence the analysis, researchers can be more transparent in explaining how themes were constructed (Byrne 2022). Also, the reflexive nature of RTA could further enhance the pragmatic researchers' capacity to maintain equilibrium in the flexible analysis process (Ramanadhan et al. 2021).

The converging of those methodologies allowed for the simultaneous collection and analysis of both data types, facilitating a richer interpretation of the findings (Creswell and Creswell 2017). It is important to note that this PhD project utilised data from this mixed methods BOL study collected during the COVID-19 pandemic to evaluate technological and recruitment feasibility, acceptability, and potential benefits of BOL. Participants in Phase 3 of this BOL project were recruited from the LBP populations who participated in the mixed methods BOL study. **Figure 3-1** below illustrates the connection and delineation between this PhD project and the mixed methods BOL study.



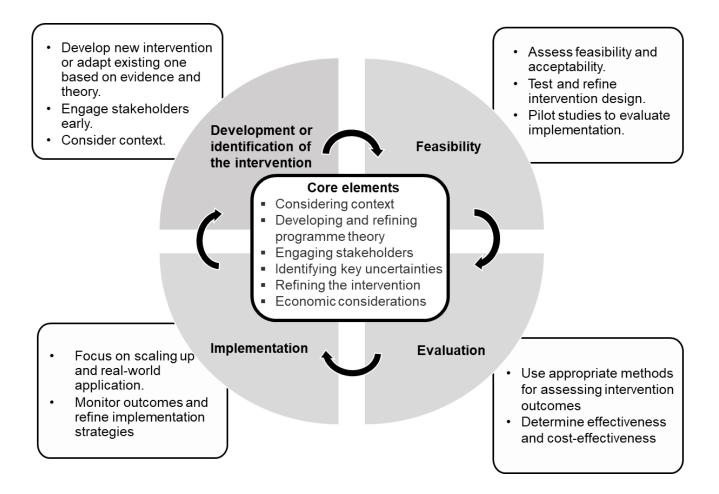
**Figure 3-1**. Flowchart illustrating the delineation between the data collection phase (conducted prior to this PhD) and data analysis phase (conducted as part of this PhD project) of the mixed methods BACK-on-LINE<sup>™</sup> study.

#### 3.4 BACK-on-LINE<sup>™</sup> intervention development

The BACK-on-LINE<sup>™</sup> (BOL) intervention is conceptualised as a complex intervention due to its multiple interacting components, the behavioral changes it targets, and its dependence on contextual factors (Campbell et al. 2007). It integrates self-assessment, individualised feedback, behavioral support, exercises, and occupational health guidance to address LBP in workplace settings. The complexity of BOL is further reflected in its individualised approach, as it classifies pain mechanisms and adapts self-management recommendations accordingly, leading to variability in user experiences and responses. This individualised approach, while improving relevance, complicates evaluation compared to standardised interventions (Craig et al. 2008).The digital format of DHSMIs introduces further complexities related to user engagement, adherence, and technological feasibility. In addition, the effectiveness of DHSMIs depends on interactions between these components and the workplace environment, which reinforces the BOL's classification as a complex intervention.

The NIHR and MRC previously updated its framework for developing and evaluating complex interventions (Skivington et al. 2021), which provided researchers committed to developing complex healthcare interventions with a structured approach for designing, testing, implementing, and evaluating. The decision to develop the BOL intervention following the NIHR/MRC framework was driven not only by its well-established role in guiding the development and evaluation of complex health interventions, but also by the need for a structured approach to designing DHSMIs for LBP, given its multifactorial nature.

The NIHR/MRC framework outlines four main iterative phases for DHSMI development: development or identification of the intervention, feasibility, evaluation, and implementation. **Figure 3-2** provided from Skivington et al. (2021) illustrates these phases.

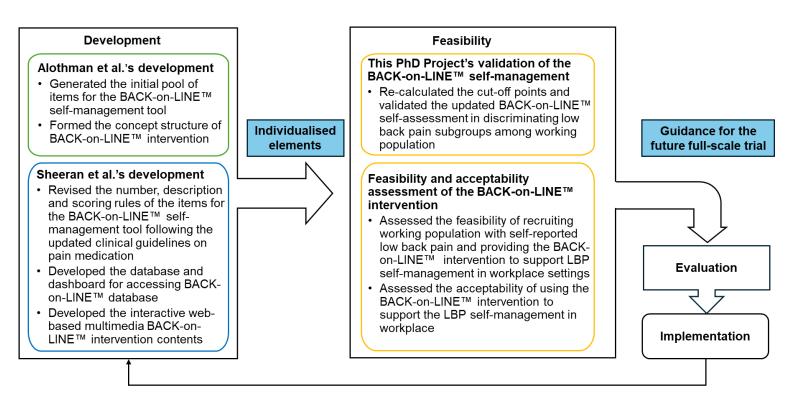


**Figure 3-2**. The four main iterative phases of the National Institute For Health And Care Research/Medical Research Council framework for developing and evaluating complex interventions (from Skivington et al. 2021)

The interpretation of the NIHR/MRC framework involved critically assessing which elements were most applicable to the context of BOL, considering its focus on workplace self-management. Key aspects such as the theoretical grounding, feasibility testing, consideration of implementation challenges, and iterative refinement were deemed highly relevant. As illustrated in **Figure 3-2**, the development phase of a complex intervention focuses on establishing the evidence base by understanding the research context and reviewing the evidence from published studies. As stated in <u>Section 2.8.1</u>, Alothman et al. (2017) generated the initial pool of items for the BOL self-assessment in the development phase by synthesising existing LBP-related questionnaires, with consideration of the BPS model and workplace factors. Building on the concept structure of the BOL intervention established through expert consensus

and stakeholder recommendations (employees) (Alothman et al. 2017), Sheeran et al. (2024) further developed the theoretical framework for the BOL intervention using existing behaviour change theories. The development of the BOL intervention was achieved by collaborating with other stakeholders, including healthcare professionals, software engineers, and employers (Sheeran 2024b). The co-creation with stakeholders established the individualisation as the core function of the BOL intervention outcomes (Sheeran 2024b). The next section (Section 3.5) provides a clear description of the theoretical framework underpinning the BOL intervention and explains how the various components of BOL interact to facilitate LBP self-management.

Alothman and Sheeran et al. refined the BOL intervention's conceptual structure using existing theories and relevant stakeholder input, ensuring that it is grounded in a robust theoretical foundation. This aligns with the development phase of the NIHR/MRC framework, which focuses on identifying the intervention's key components, mechanisms of action, and theoretical underpinnings. Based on this, this PhD project examines how the individualised elements of the BOL function in practice, particularly in workplace settings. It explores key feasibility considerations such as engagement, adherence, and potential benefits. This phase is essential for refining the intervention before progressing to more rigorous trials or broader implementation. It focuses on evaluating the technological feasibility of recruiting LBP population and delivering the BOL intervention within workplace settings. Also, this phase evaluates the feasibility of the BOL data collection procedure, and the validity of the instruments used for outcome measurement to refine the design and methods in preparation for future larger-scale BOL studies. In addition, this PhD project identifies and resolves issues encountered during the mixed methods BOL cohort study, helping to improve the design and implementation for future BOL studies. This aligns with the feasibility phase of the MRC framework, which focuses on testing the practicality of intervention procedures, recruitment, retention, and engagement strategies, as well as assessing measurement tools before proceeding to larger-scale evaluations. Figure 3-3 summarises how the NIHR/MRC framework has shaped the previous developments of BOL and guided this PhD project.



**Figure 3-3**. Flowchart illustrating the development process of BACK-on-LINE<sup>™</sup> following the National Institute For Health And Care Research/Medical Research Council framework for developing and evaluating complex interventions (from Skivington et al. 2021)

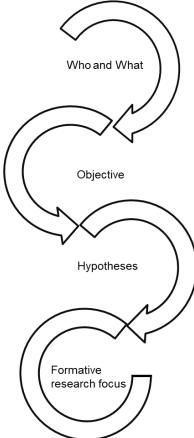
For the subsequent evaluation phase of BOL development, the main focus is to select the appropriate study design, outcome measures, sample size and address potential sources of bias and conduct large-scale BOL studies to determine effectiveness and cost-effectiveness of BOL intervention for LBP in the workplace. The recruitment and retention data collected in the feasibility phase would help to determine the optimal sample size with adequate statistical power. Also, the potential benefits observed in the feasibility phase could be used to determine the anticipated outcomes and appropriate measurements. More importantly, this phase needs to identify factors of the intervention process that may influence outcomes, thus determining how the BOL intervention produced the intended intervention effect and why it did not.

Although the implementation phase is the last of the four phases to be presented sequentially, the process of developing complex interventions is iterative rather than linear. The implementation phase of BOL development needs to focus on translating existing evidence into practice, including dissemination of BOL intervention results to

relevant stakeholders, monitoring the implementation process in the workplace settings, and evaluating LBP-related outcomes over time. Thus, researchers of the BOL intervention may need to shift back and forth between phases as new technologies becomes available or to adjust the BOL intervention for different workplace settings or populations.

## 3.5 BACK-on-LINE™ intervention and its theoretical framework

In the previous BOL development, Alothman et al. (2017) summarised findings from existing pain research to establish the use of the BPS and the pain mechanism-based classification (PMC) model as the theoretical framework to recognise the key roles of cognitive, psychological, and environmental elements in the complex pain experience. Based on this theoretical framework, Alothman et al. (2017) identified four domains of BOL self-assessment based on the BPS model and established the items of the four domains of BOL self-assessment based on the expert consensus from the first round of the E-Delphi study (Alothman et al. 2017). In addition, based on the PMC model and the expert consensus from the second round of the E-Delphi study, the themes of the intervention content for the different BOL subgroups were identified (Alothman et al. 2017).



Target population: low back pain population in the workplace
Target behaviour: monitoring and self-managing low back pain in the workplace

 To develop a self-assessment and self-management online tool (Back-on-Line <sup>™</sup>) and provide targeted and individualised treatment for people with low back pain before entering the healthcare system

- Individualised support: classifying by individual pain mechanism and providing self-management support by biopsychosocial factors of low back pain.
  Promote self-efficacy: empowering BOL users take responsibility of managing
- their condition. Encourage routine use: integrating BOL into daily routine to help BOL users
- Encourage routine use: integrating BOL into daily routine to help BOL users continuously monitor and adjust their pain management strategies for better outcomes.
- Simplify consistency: ensuring the user-friendly process to promote consistent use and sustained LBP management.
- Consensus between international physiotherapists on the BACK-on-LINE<sup>™</sup> self-assessment items and intervention self-management techniques
   Potential mode of delivery for BACKonLINE<sup>™</sup>

**Figure 3-4**. The development process of the theoretical framework of Alothman et al. (2017) to develop the BACK-on-LINE<sup>™</sup>

Overall, the theoretical framework of Alothman et al. (2017) emphasised the key role of the BPS model in identifying cognitive, psychological and environmental elements in the complex pain experiences. In addition, education (pain, sleep hygiene, mindfulness, and medication use) and exercise were identified as intervention components for different BOL subgroups under the PMC model. However, Alothman et al. (2017) did not specify the process and how to develop the BOL intervention components. Also, the theories used for BOL intervention development and the underlying mechanisms of the theories were not clearly described.

In the subsequent BOL development, Sheeran et al. (2024) adopted a theory-based design approach centred on user behaviour change, using Alothman et al.'s theoretical framework as the basis and established the theoretical framework for BOL intervention development to help understand the complex interactions between the factors that influence self-management behaviours in LBP populations (Sheeran 2024a,b). As a patient-centred approach, self-management was defined as "the ability of an individual to manage the symptoms, treatments, physical and psychological consequences, and lifestyle changes inherent in chronic disease" (Barlow et al. 2002, p. 178). An effective self-management not only involves adherence to healthcare advice but also requires the development of skills such as goal setting, problem-solving and decision-making (Grady and Gough 2014). Key prerequisites for effective self-management include a clear understanding of the health status, the availability of relevant resources and support, and the individual's motivation and confidence in their ability to manage their health (Nagelkerk et al. 2006; Pearson et al. 2007). Thus, Social Cognitive Theory (SCT), Self-Determination Theory (SDT) and the COM-B model were incorporated into BOL intervention development to provide valuable frameworks for understanding and enhancing self-management behaviours (Bandura 2002; Deci and Ryan 2008; Michie et al. 2011).

Developed by Bandura (1999), SCT emphasises the role of observational learning, imitation and modelling in behavioural change (Bandura 1999). At the heart of SCT is the concept of self-efficacy, which is the belief in one's own ability to perform a

particular task (Bandura 1999). According to Bandura, self-efficacy is influenced by four main sources: mastery experience, social modelling, social persuasion, and physiological and emotional states (Bandura 1999). These elements are critical to empowering individuals to take control of their own health. In terms of self-management, the SCT suggests that individuals can improve their self-efficacy by observing people who are successfully managing their condition, receiving encouragement and constructive feedback, and experiencing personal success in managing their own symptoms (Islam et al. 2023). This theory also emphasises the importance of providing individuals with opportunities to practice and refine their self-management skills in a supportive environment (Lent et al. 2017).

Self-Determination Theory (SDT) was developed by Ryan and Deci which focuses on the psychological needs that motivate human behaviour: autonomy, competence and relatedness (Deci and Ryan 2008). Autonomy refers to the need to feel in control of one's behaviour and goals. Competence refers to the need to perform tasks and acquire different skills, and relatedness refers to the need to feel connected to others (Deci and Ryan 2008). SDT proposes that when these needs are met, individuals are more likely to be motivated and engage in behaviours that promote health and wellbeing (Deci and Ryan 2008). In the area of self-management, the SDT suggests that interventions should provide individuals with options for how and when to engage in self-management activities, opportunities to build and demonstrate competence, and develop supportive relationships with healthcare providers (Patrick and Williams 2012).

The COM-B model developed by Michie et al. (2011) is a framework for understanding and developing behaviour change interventions (Michie et al. 2011). It considers that behaviour (B) as a result of three interacting components: Capability (C), Opportunity (O), and Motivation (M). In this model, capability refers to an individual's psychological and physical capacity to engage in the behaviour, such as ability of comprehension and reasoning. Opportunity encompasses physical opportunity from the environment and external factors that facilitate the behaviour, such as cultural and social influences. As motivation is influenced by ability and opportunity, it includes not only the motivation that arises automatically from learning and emotions but also the motivation generated during individual's active reflection process. Due to the causal relationship between elements, the COM-B model is often used to determine what needs to be changed to achieve the desired behaviour (Murphy et al. 2023b). In addition, the COM-B model can be used to help identify the functions required for interventions to achieve targeted behavioural change through a broader behavioural change wheel (Michie et al. 2011).

Using the COM-B model, the BOL first creates the physical opportunity by involving users completing the BOL self-assessment to facilitate engagement with the intervention. Based on the responses in the self-assessment, the BOL then reinforces reflective motivation by providing individualised feedback. For example, based on the physical activity level and daily sitting hours, the BOL provides feedback which contains congratulations to the users on their current level of physical activity as positive reinforcement or reminds users of their sedentary behaviour and highlights the benefits of staying active to stimulate motivation. Then, by assessing user's capability, opportunity and motivation for LBP self-management in the workplace, the BOL adjusts the recommendations to provide individualised interventions to promote the self-management behaviour. For example, for users with a low physical activity level, BOL provides the users with exercise instructions for spinal resilience and educational advice to encourage moving with pain to improve the physical and psychological capability. In addition, to increase users' automatic motivation, BOL designed work-based intervention components to help LBP population develop selfmanagement behaviour in the workplace and integrate self-management into work routine.

The development of the specific BOL intervention components was also guided by the SDT and SCT. The BOL intervention consists of embedded videos demonstrating exercises to relieve LBP and enhance resilience for spinal health in the workplace, thus providing clear modelling for the working population. This approach is consistent with Bandura's emphasis on social modelling as a key contributor to self-efficacy (Mobley and Sandovel 2008). At the same time, the whiteboard videos in the BOL intervention utilised social persuasion, using images of people from different occupations to convey messages of confirmation and reassurance (Appendix 4), further boosting the working population's confidence in their ability to manage their condition (Devan et al. 2021; Occa and Morgan 2022). Meanwhile, following the emphasis of SDT on user autonomy, BOL allows users to choose how and when to access the BOL platform and which resources to access. This flexibility ensures that

LBP people in the workplace are able to take control of their self-management journeys based on their work schedules, thus enhancing their internal motivation (de Vries et al. 2011). As well as empowering users to take control of their interactions with BOL to enhance internal motivation in managing their own conditions (Hunter et al. 2023), the BOL intervention also encourages users to create supportive and encouraging environments in both families and workplaces thus enhancing the relatedness with others (Deci and Ryan 2008). With tips and techniques related to communication skills, daily activities and work, the BOL intervention was designed to provide more effective ways for the LBP population to communicate and manage back problems at work and home (Appendix 4). By addressing self-efficacy, internal motivation, and relatedness, the BOL intervention aims to facilitate users' continuing interaction with BOL and sustainable self-management behaviours in the long term (Linge et al. 2021).

Sheeran et al. (2024) developed BOL as an interactive, work-based DHSMI to provide accessible information, tools and individualised support for people with LBP in the workplace. In general, the purpose of the BOL intervention was to assist LBP populations to increase their self-efficacy, thereby maintaining or restoring work participation and overall physical functioning. With the theoretical framework, the two main self-management modules of BOL intervention were featured with a pre-programmed library of highly accessible and individualised resources on education materials and exercise recommendations (<u>Appendix 4</u>). Table 3-1 provides a summary of overall process of the BOL intervention.

Week	Module	Content		
Week	Introduction	<ol> <li>Background knowledge of LBP in multimedia displays, including the prevalence of LBP, high-risk occupations, causes of LBP in the workplace, and modifiable lifestyle factors contributing to LBP.</li> <li>What is BACK-on-LINE<sup>TM</sup> (BOL)</li> <li>How BOL works</li> </ol>		
	BOL self- assessment questionnaires (46 questions)	<ol> <li>About me (e.g. Age, occupation, employer)</li> <li>My LBP (e.g. Pain duration, intensity, frequency)</li> <li>How my LBP impacts my work</li> <li>How my LBP impacts my lifestyle, family and social life</li> <li>How my LBP impacts me personally</li> <li>My exercise habits</li> </ol>		
	Feedback page	Based on the BOL self-assessment numerical score, individualised feedback containing relevant materials was provided within the three domains:		

Table 3-1. Summary of BACK-on-LINE<sup>™</sup> 4 weeks intervention

		1. Contributing factors (physical, psychological, combination					
		of both)					
		<ol><li>Sedentary behaviour (&gt;5 hours/day of continual</li></ol>					
		sitting/standing)					
		3. Physical activity levels (<150 minutes/week)					
	Self-management	Participants were given unlimited access to all BOL materials					
Week		with links to resources recommended specifically to them. The					
		module included content in the form of videos, activities, and					
		quizzes on:					
	<i>Module 1</i> : Getting your spine fit for work	1. Explain pain (physical overload story)					
		2. Posture and movement Toolkit					
2&3		3. Manual Handling Toolkit					
		4. Resilient Spine Toolkit					
	<i>Module 2</i> : Getting your mind fit for work	1. Explain pain (psychological overload story)					
		2. Active pain control Toolkit					
		3. Physical activity Toolkit					
		4. Resilient mind Toolkit					
	Self-reflection	Participants completed the follow-up self-assessment and					
		reflected on feedback received from their self-management					
Maak		modules. Reflection included the account of:					
Week 4		1. Informativeness and relevance of the provided advice					
4		2. Awareness and understanding of the information					
		3. Acquired knowledge to help modify pain behaviours					
		4. Confidence and ability to manage LBP					

## 3.6 Chapter Summary

This chapter illustrates the reasons for choosing pragmatism and adopting a mixed methods approach for this study. By demonstrating the NIHR/MRC framework for complex intervention development and evaluation (Skivington et al. 2021), this PhD project clarifies its position in BOL development. Also, this chapter demonstrates how the technological feasibility, acceptability, and potential benefits of the BOL intervention can be assessed through a mixed methods approach (Creswell and Creswell 2017). The chapter describes the theoretical framework of the BOL intervention and its application in practice. As described in the NIHR/MRC framework , the development of DHSMI is a dynamic and iterative process. In the next chapter, a systematic review (SR) is presented to comprehensively synthesise the effects of current DHSMIs for LBP self-management in the workplace, focussing on the individualisation of DHSMIs, and to appraise the quality of the evidence.

# 4. Chapter 4: Phase 1 - A systematic review of the effects of DHSMIs on low back pain in the workplace

#### 4.1 Introduction

As discussed in the literature review (<u>Chapter 2</u>), LBP continues to pose a severe burden on individuals, organisations and the government, with significant direct and indirect costs associated with LBP (Baumeister et al. 2012). For the working populations, the disability (Wami et al. 2019), decreased quality of life (Ge et al. 2022), and impaired relationships (Grabovac and Dorner 2019) caused by LBP severely affected life and work. The associated family-work imbalance (Kesiena et al. 2022), hostile work environment (Yang et al. 2016) and perceptions of job insecurity (Yang et al. 2023) further contributed to psychosocial stress, anxiety (Vinstrup et al. 2020) and depression (Lewis and Battaglia 2019). Employee sickness absence (SA), reduced productivity, lower job satisfaction and the risk of disability litigation stemming from the multifaceted nature of the LBP further aggravated the damage to the workplace (Wasiak et al. 2006; Heneweer et al. 2011; Carregaro et al. 2020).

A variety of workplace interventions have been developed to support people with LBP, including ergonomic interventions (Sundstrup et al. 2020), exercise (Jakobsen et al. 2015) and worksite training (Járomi et al. 2018). However, these interventions were generally developed to address a unidimensional factor or LBP and lacked adaptation to different occupational environments, which led to obstacles to implementation by managers and the utilisation of employees (Carolan and de Visser 2018). Multidisciplinary interventions consisting of ergonomic modifications, exercise programmes, cognitive-behavioural interventions, and education contents were developed to address multidimensional aspects of LBP (Soler-Font et al. 2021). However, the delivery of multidisciplinary interventions across a wide range of populations faced organisational and financial limitations. Factors such as scheduling issues, time constraints, interruptions in the workflow, and the burden of healthcare costs obstructed the final implementation (Rojatz et al. 2017; Garne-Dalgaard et al. 2019). Meanwhile, reliance on LBP treatment through health services and the associated long waiting times for accessing management for LBP was found to result in decreased awareness of pain management and self-efficacy (Cabak et al. 2015).

As a paradigm change in LBP management (Kongsted et al. 2021), the mainstream clinical guidelines recommended self-management as first-line of treatment for LBP (Oliveira et al. 2018b). Promoting workplace self-management was deemed to empower people to make informed decisions for self-care of LBP, to help people with LBP maintain productivity, and to improve self-efficacy and facilitate a sustainable return to work (Hutting et al. 2015; Kongsted et al. 2021; Tousignant-Laflamme et al. 2023). Following these evidence-based guidelines, patient-centred workplace interventions that support self-management have been developed with some demonstrating the effectiveness in improving pain, disability and other clinical outcomes in people with LBP (Russo et al. 2021; Dunleavy et al. 2022) including recovery of work ability (Liedberg et al. 2021). Meanwhile, the complexity of LBP has resulted in the realisation that a one-size-fits-all intervention or a simple stack of evidence-based contents may not adequately meet the unique needs of people for LBP self-management (Foster 2011). Therefore, the NICE guidelines on LBP recommended providing people with advice and information individualised to their needs and abilities to help them better self-manage (National Guideline 2016). Similarly, it has been recommended that research is designed to demonstrate evidence-based LBP self-management approaches based on an individual's need and the ability to improve intervention outcomes (Maher et al. 2017).

With advances in modern technology and access to internet, digital health interventions have been developed to provide self-management information and materials through computer, mobile phone, or other handheld device in the form of web page, computer programme or mobile application (McLean et al. 2016a). For its accessibility, convenience, reduced costs and improved patient experience, digital health self-management intervention (DHSMI) has been described as a promising solution to transform the way people monitor and manage their health (Michie et al. 2017). In recent years, DHSMIs have been increasingly used in self-management of LBP and reported improvements in pain intensity and functional levels of LBP patients (Lewkowicz et al. 2021). Hewitt et al. (2020) reported positive outcomes of DHSMIs on the pain and functional impairment of MSDs, including LBP (Hewitt et al. 2020). However, this evidence was based on DHSMIs used in clinical settings, including primary and secondary care. As described in the literature review (Section 2.4), existing reviews of workplace interventions have been largely on the effectiveness of

non-digital interventions for LBP (Maher 2000; Tveito et al. 2004; Williams et al. 2007; Coury et al. 2009; van Vilsteren et al. 2015; Vargas-Prada et al. 2016; Maciel et al. 2018; Sundstrup et al. 2020; Russo et al. 2021), focussed on mental health and lifestyle in the workplace (Howarth et al. 2018; Proper and van Oostrom 2019; Stratton et al. 2021). To the best of current knowledge, there have been no systematic reviews of DHSMIs for LBP in the workplace.

In the previous SR of DHSMIs for LBP, the complexity of LBP self-management has resulted in a high degree of discrepancy between studies in terms of objectives, participant characteristics, and intervention content (Nicholl et al. 2017). Apart from this, six included RCTs demonstrated moderate to high risk of bias and only two studies reported that the content of the DHSMI was based on evidence or clinical guidelines (Nicholl et al. 2017). In a recent SR, Lewkowicz et al. (2021) further reported positive effects of DHSMIs on pain, disability, and overall benefits to participants engagement (Lewkowicz et al. 2021). However, the heterogeneity of the study design made it difficult for both SRs to compare intervention outcomes between studies and generate clear conclusion of the effects of DHSMIs on LBP (Nicholl et al. 2017; Lewkowicz et al. 2021).

Also, the definition of individualising was very ambiguous between previous SRs. In the SR by Nicholl et al. (2017), DHSMIs which provide intervention content targeted at demographic or clinical characteristics (such as gender, occupation type, impact of pain on daily life) were defined as individualised DHSMIs (Nicholl et al. 2017). However, this definition may not fully describe individualisation as it does not capture the LBPrelated BPS factors, nor does it consider the individual needs. While in Lewkowicz et al.'s SR, DHSMIs focused on meeting participant's needs and preferences were identified as individualising, such as providing education sessions and advice based on individual's self-management objectives and delivering reminders according to individual's preference (Lewkowicz et al. 2021). Although individual needs were considered, none of the DHSMIs were individualised using validated classification models like the pain mechanism-based classification (PMC) model.

In addition to the inconsistency in the definition of individualising, there was a lack of reporting of the theoretical models or algorithms used for individualising in the previous

SRs. None of the SRs has reviewed on the reliability and validity of the model or algorithms used in these individualised DHSMIs for identifying LBP subgroups. In addition, as outlined in the literature review (Section 2.6.4), some work-based DHSMIs for LBP were developed with individualised features, but there has been no review to examine the individualising methods and the underlying classification models in these work-based DHSMIs.

## 4.2 Review question, aim and objectives

Therefore, the aim of Phase 1 of this thesis was to comprehensively review the level of evidence on DHSMIs for LBP in the workplace, with specific focus on individualising. More specifically, this SR aimed to address the question:

# What are the effects of work-based DHSMIs on LBP and does individualisation matter?

Primary objective of this SR was to examine the effects of work-based DHSMIs on LBP. Secondary objective was to map the key characteristics of the work-based DHSMIs including the key components, underpinning theories, and individualised approaches.

#### 4.3 Methods

This SR was designed and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Page et al. 2021). The comprehensive protocol for this SR was registered in the database of the PROSPERO (ID: CRD42023435184) on 15 June 2023.

#### 4.3.1 Literature search

For this review, a three-step search strategy was developed to identify studies published in English up to February 2023. An initial search of MEDLINE for DHSMIs was piloted first. The wording in the titles and abstracts of qualifying studies was analysed to optimise the search terms. A comprehensive search using the modified keywords searching strategy was conducted in the following electronic bibliographic databases: PubMed, MEDLINE, EMBASE, CINAHL, the Cochrane Library (Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Methodology Register) and Web of Science. In addition, the

included studies and reference lists in the previously published relevant reviews were checked. An additional search on unpublished theses, conference papers and unpublished trial registrations was also conducted, contributing to a balanced overview of the available evidence.

Following discussion with the review team, the search terms selected for reference were grouped into four concepts: (1) low back pain, (2) digital health interventions, (3) workplace, and (4) self-management. The keywords used in this database search of this SR are presented in the **Table 4-1**.

Search category 1		Search category 2		Search category 3		Search category 4
Low Back Pain	AND	Digital health interventions	AND	Workplace	AND	Self- management
Back pain		Internet Intervention		Occupational Wellbeing		Self-care
Back ache		Online Intervention		Occupational Wellness		Self-help
Spinal pain		Web-Based Intervention		Occupational Safety		Self- administration
		Internet Based Intervention		Occupational setting		Self-control
		mHealth		Working Conditions		Self-evaluation
		eHealth		Working Environment		Self- assessment
		Digital Health		Work Activities		
		Mobile Health		Employee		
		Digital Devices		Worker		
		Computer programme		Workplace		
		Laptop		Factory		
		Handheld Device		Company		
		Mobile Device		Office		
		Smartphone		Warehouse		
		Mobile phone		Industry		

Table 4-1. Keywords search strategy for data-bases

Digital Platform	
Online Application	
Арр	
Mobile App	
mobile application	
Software	

Search terms were adapted to other bibliographic databases and used in conjunction with database-specific controlled trial filters. The full search strategy used in all databases for the search terms including specifications on the use of headings, keywords or abstract screening was detailed in <u>Appendix 5</u>.

# 4.3.2 Eligibility criteria

Following the recommendations of the Cochrane Handbook for systematic reviews, the Population, Intervention, Comparison, and Outcome (PICO) framework was used to define the criteria of studies for inclusion (McKenzie et al. 2019).

**P** (Population): Studies examining working populations with LBP were included in this review. LBP is defined as pain occurring between the lower rib margin and the creases of the buttocks accompanied with neurological symptoms in the lower limbs (Hartvigsen et al. 2018), without red flags of serious spinal pathology or systemic illness (National Guideline 2016). The working population is defined as people of working age (between 18 and 64 years old) in employment (full-time, part-time, self-employed) (Luciano and Meara 2014).

I (Intervention): The definition of DHSMI is consistent with the previous review as any intervention delivered through a computer, mobile phone, or handheld device, including web-based or desktop computer programs or mobile applications that provide self-management information or materials (McLean et al. 2016a). Self-management information or materials must work without the need for direct feedback from healthcare professionals as individual support. Individualisation is defined as an automated process that generates relevant information or feedback through the

application of classification models to process user inputs (Moe-Byrne et al. 2022). Studies involving DHSMIs delivered as part of medical treatments (e.g., pharmacological treatments, surgical treatments), without pre-designed intervention contents, or used only as a data collection tool will be excluded.

**C (Comparison):** Studies with a control group receiving usual care, non-digital selfmanagement interventions or non-individualised DHSMI were considered eligible for the review.

**O** (**Outcome**): Consistent with previous SRs on LBP (Du et al. 2017; Hewitt et al. 2020), studies using pain intensity and disability level measured by validated measuring instruments as primary outcomes were included.

**Secondary outcomes:** Considering the specificity of LBP management in the workplace, studies reporting outcomes on work (SA, productivity), quality of life, physical performance, and psychosocial (stress, anxiety, depression) factors as secondary outcomes were included.

Study design: RCTs with full text available and published in English were included.

# 4.3.3 Screening and selection

The titles and abstracts of studies retrieved using the search strategy were screened by the main review author (MC) to identify studies eligible for inclusion criteria. To reduce the risk of bias, a second review author (LS) independently screened 10% of titles and abstracts. The full text of these potentially eligible studies was assessed independently by a pair of review authors (MC, LS). Any disagreement between the two review authors regarding the eligibility of a particular study was mediated through a full-text screening with a third reviewer (VS).

# 4.3.4 Study quality appraisal

For the eligible papers, prior to inclusion in the review, two review authors (MC, LS) independently assessed the risk of bias by considering the following characteristics, as recommended by the Cochrane Collaboration: sequence generation, allocation concealment, randomisation procedure, blinding of participants, personnel and

outcome assessors, management of incomplete outcome data, selective reporting of results, and other risks of bias identified by the review panel (Higgins et al. 2011). Disagreements between review authors about the risk of bias for a particular study were resolved through discussion. Unresolved disagreements about the risk of bias were referred to a third reviewer (VS).

#### 4.3.5 Data extraction

All identified papers from the searched databases were uploaded to Rayyan, an integrated online web tool for conducting SR (Ouzzani et al. 2016). The titles and abstracts of studies retrieved using the search strategy were independently screened by the two review authors (MC, LS) to identify studies that are potentially eligible for inclusion (**Appendix 6**). Any discrepancy between the two reviewers regarding the eligibility of a particular study was mediated through a full-text screening with a third reviewer (VS). Duplicates were identified using Rayyan's built-in Al duplicate detection tool, and all suggested duplicates were screened by a review author (MC) to ensure correctness. Details of the number of references retrieved, full-text papers obtained, articles included and excluded, and the reasons for exclusion were produced using the Rayyan embedded labelling function (**Figure 4-1**).

Due to the substantial heterogeneity of the intervention content, control group settings, and outcome measures between the included studies, conducting a meta-analysis may lead to misguided conclusions (Cote et al. 2018). Studies in this review presented a moderate to high risk of bias, where conducting a meta-analysis could produce biased and unreliable summary estimates (Impellizzeri and Bizzini 2012). Given these limitations, conducting a meta-analysis in this review was not appropriate. Therefore, descriptive tables were populated using the data from the original paper, accompanied by a narrative synthesis (Campbell et al. 2020) presenting details of the characteristics of included studies (e.g., author, date of publication, country, population demographic characteristics) and used DHSMIs (e.g., intervention duration, contents, applied theories, methods of individualising). Effects of DHSMIs on the primary outcomes (pain and disability) and secondary outcomes (work-related, quality of life, physical performance and psychosocial factors) were extracted using an Excel spreadsheet. One review author (MC) extracted and documented the data with another review

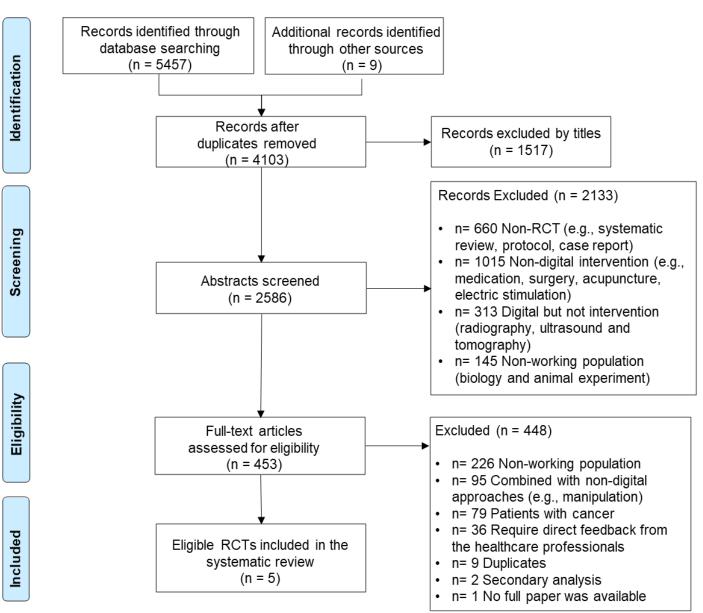
author (LS) checked the completeness and accuracy of the data entry. Disagreements were referred to a third reviewer (VS) for resolution.

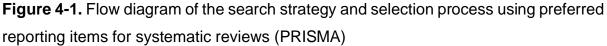
# 4.4 Results

# 4.4.1 Study selection

An initial search of six major databases identified a total of 5457 articles. After retrieving nine additional studies from other sources and removing duplicates, 4103 records were identified and exported to Rayyan. After screening for titles, 1517 irrelevant articles were excluded. 2133 articles were excluded through the process of abstract screening with 453 remaining for full-text review. For a thorough and comprehensive review, the reference list of the included articles was searched. No other relevant articles were identified to meet the criteria of this SR, which may indicate the lack of research in DHSMIs for self-management of LBP in the workplace. There were no disagreement raised between the pair of review authors (MC, LS) during the screening, quality appraisal and data extraction procedures.

Overall, 5 articles met the eligibility criteria and were included in this review (**Table 4-2**). For one study, the study sample included both university students and retired employees. This was retained due to the small sample size of the non-working population (n=6) and the limited number of studies in this area. The PRISMA flowchart (**Figure 4-1**) provided an overview of the selection procedure.





# 4.4.2 Quality appraisal

The Cochrane Collaboration's Risk of Bias tool was used to assess the risk of bias in 5 included trials (**Figure 4-2**). Computer-generated random sequences were used in 4 trials (del Pozo-Cruz et al. 2012a; Almhdawi et al. 2020; Cimarras-Otal et al. 2020; Anan et al. 2021), and one trial did not describe the method of sequence generation (Irvine et al. 2015). For selection bias, one trial did not report the details of allocation concealment (Irvine et al. 2015). Two trials developed automated data collection using electronic questionnaires (Irvine et al. 2015; Anan et al. 2021) and two trials reported evaluators blinding (Almhdawi et al. 2020; Cimarras-Otal et al. 2020), which

contributed to a low risk of detection bias. One study did not blind participants and used subjective self-assessment (Anan et al. 2021), which presented a high risk of detection bias. For performance bias, 2 trials reported using a rigorous double-blind design (participants and researchers) (Almhdawi et al. 2020; Cimarras-Otal et al. 2020) and one trial reported using a single-blind design (researchers). One trial presented insufficient information on the blinding design (Irvine et al. 2015). For attrition bias, one study detected recruitment frauds, where participants provided fake personal information to participate in the study for financial incentives and did not report reasons for participant dropout (Irvine et al. 2015). A high risk of attrition bias was identified in one trial due to the high dropout rate (55%) (Cimarras-Otal et al. 2020). One trial reported the baseline data of intervention and control groups as means and SD but reported follow-up results as proportion of improvement, which indicated a high risk of reporting bias (del Pozo-Cruz et al. 2012a). For other bias, four trials were funded by independent research grants with a low risk of funding bias (del Pozo-Cruz et al. 2012a; Almhdawi et al. 2020; Cimarras-Otal et al. 2020; Anan et al. 2021). One trial was funded by a healthcare technology company which developed the DHSMI used in the trial, resulting in a high funding bias (Irvine et al. 2015). Based on the outcomes assessed above, the studies included in this SR demonstrated moderate risk of bias.

Key ♣ Low risk of bias ■ High risk of bias ? Unclear risk of bias	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of outcome assessment (detection bias)	Blinding of participants and researchers (performance bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Del Pozo-Cruz et al, 2012	+	+	+	•	+	-	+
Almhdawi et al, 2020	+	+	+	+	+	+	+
Anan et al, 2021	+	+	-		+	+	+
Cimarras-Otal et al, 2020	+	÷	+	+		+	+
Irvine et al, 2015	?	?	+	?	?	+	•

Figure 4-2. Risk assessment of bias in the included studies

# 4.4.3 Characteristics of eligible studies

Of the five studies identified, the author of one study published three papers, one RCT (del Pozo-Cruz et al. 2012a) and two data reanalysis (del Pozo-Cruz et al. 2012b; del Pozo-Cruz et al. 2013) based on the initial trial. The study populations and interventions were the same, but each publication reported separate outcomes. Therefore, data from these studies were extracted and combined to avoid duplication of results from participants, and therefore only 5 separate RCTs were included in the data extraction and results tables (**Table 4-2**).

Of the five included studies published between 2015-2021, two were based in Spain (del Pozo-Cruz et al. 2012a; Cimarras-Otal et al. 2020), one in the U.S. (Irvine et al. 2015), and the remaining two studies were based in Japan (Anan et al. 2021) and Jordan (Almhdawi et al. 2020). The duration of the included trials ranged from 6 weeks to 9 months.

# **Participant characteristics**

A total of 840 participants were enrolled in the five RCTs, with 322 allocated to the intervention group and 518 to the control group. Study sample size ranged from 18 to 398 participants. Out of the 5 included RCTs, 3 studies reported a power calculation to determine the required sample size and all recruited adequate number of participants with a statistical power of 0.80 (del Pozo-Cruz et al. 2012a; Almhdawi et al. 2020; Cimarras-Otal et al. 2020). Of these, 2 studies reviewed the literature (del Pozo-Cruz et al. 2012a; Cimarras-Otal et al. 2020), and one conducted a pilot study to help define the effect size (Almhdawi et al. 2020). Slightly more than half of the included participants were female (56.3%), with the proportion varying from 18.7% to 88.6% across studies. Only one study reported on demographic characteristics on ethnicity, educational levels and income status of the study population (Irvine et al. 2015). The mean age of participants in the four studies ranged from 40.48 to 46.83 years old (del Pozo-Cruz et al. 2012a; Almhdawi et al. 2020; Cimarras-Otal et al. 2020; Anan et al. 2021), with the exception of one study that did not report such data (Irvine et al. 2025).

The age eligibility criteria for all five studies was between 18 and 65 years of age, and 95.5% to 100% of the population was employed (del Pozo-Cruz et al. 2012a; Irvine et al. 2015; Almhdawi et al. 2020; Cimarras-Otal et al. 2020; Anan et al. 2021). All studies were conducted in a working environment, with three of the trials conducted in office settings (del Pozo-Cruz et al. 2012a; Irvine et al. 2015; Almhdawi et al. 2020) and two in manufacturing factory settings (Cimarras-Otal et al. 2020; Anan et al. 2021). The average number of days off work per year due to LBP in three studies ranged from 3.10 to 12.12 days (Irvine et al. 2015; Almhdawi et al. 2020; Cimarras-Otal et al. 2020; Cimarras-Otal et al. 2020). For the eligibility criteria of LBP, one trial reported having participants with subacute LBP (del Pozo-Cruz et al. 2012a), and two trials reported having participants with LBP

(Almhdawi et al. 2020; Cimarras-Otal et al. 2020). The other two trials included participants with LBP (Irvine et al. 2015) and LBP with significant MSK symptoms (Anan et al. 2021)

# Table 4-2. Study and participant characteristics

Author, Country, Year	Participants	Female (%)	Employment Status (%)	Sickness absence*, Mean (SD	Follow ) <sup>up</sup>	Intervention	Control	Main outcome	Measuring instrument
Cruz et al, Spain, 2012	90 University office workers with subacute low back pain lasting 6 weeks to 12 weeks; IG: n=44 (mean age: 46.83±9.13) CG: n=46 (mean age: 45.50±7.02)	IG=84.8 CG=88.6	Full-time Employed (100%)	N/R	9	Daily email reminders during weekdays containing a link to the online sessions with pre-recorded exercise video demonstrations and postural education material	Standard preventive occupational care and medication	<ul> <li>(1) Pain intensity</li> <li>(2) Risk of chronicity↓</li> <li>(3) Functional disability</li> <li>(4) Quality of Life</li> <li>(5) Back trunk muscle endurance</li> </ul>	<ol> <li>Visual analogue scale (VAS)</li> <li>Keele STarT Back Screening Tool (SBST)</li> <li>Roland Morris Disability Questionnaire (RMDQ)</li> <li>The European Quality of Life Questionnaire-5 dimensions-3 levels (EQ-5D-3L)</li> <li>The Shiradolto lumbar and abdominal tests</li> </ol>
Almhdawi et al, Jordan, 2020	41 Governmental office workers with chronic low back pain lasting over 3 months; IG: n=21 (mean age: 40.48±7.22) CG: n=20 (mean age: 41.70±6.35)	IG=66.7 CG=40.0	Full-time Employed (100%)	IG=4.14 (7.60) CG=3.30 (6.47)	6 weeks	Mobile application "Relieve my back" consisted of general advice and instruction, office-based stretching exercises for lower back and abdominal muscles, and four daily phone notifications promoting walk break, right posture and exercise.	with general nutrition advice not	(5) Physical activity	<ol> <li>Visual Analogue Scale (VAS, 11 point)</li> <li>Oswestry</li> <li>Disability Index questionnaire</li> <li>(ODI)</li> <li>The 12-item</li> <li>Short-Form Health</li> <li>Survey (SE-12)</li> </ol>

(6) Depression Anxiety Stress Scale (DASS)

Anan et al, Japan 2021	94 manufacture company engineers with remarkable musculoskeletal symptoms who reported to have frequently or almost always low back pain; IG: n=48 (mean age: 41.8±8.7) CG: n=46 (mean age: 42.4±8.0)	G=18.7 CG=28.3	Full-time Employed (100%)	N/R	12 weeks	and tips on improving	Daily 3 minutes exercises to prevent stiff shoulders and low back pain during break time.	<ol> <li>Pain intensity</li> <li>Improvement of pain symptoms</li> </ol>	<ul> <li>(1) Subjective 5- point assessment scale</li> <li>(2) Battery of questionnaires designed for this study</li> </ul>
Cimarras Otal et al, Spain, 2020	18 Assembly line workers with chronic low back pain; IG=10 (mean age: 42.25±7.28) CG=8 (mean age: 42.20±5.59)	IG=20.0 CG=50.0	Full-time Employed (100%)	IG=3.8 (12.01) CG=12.12 (34.29)		recommended by the American College of Sport Medicine (ACSM) and exercise adapted to the movement pattern		<ul> <li>(1) Pain intensity and interference</li> <li>(2) Functional disability</li> <li>(3) Spine Function</li> </ul>	<ol> <li>Brief Pain</li> <li>Inventory - Short</li> <li>Form (BPI-SF)</li> <li>Oswestry</li> <li>Disability Index</li> <li>questionnaire</li> <li>(ODI)</li> <li>The flexion</li> <li>relaxation (F/R) test</li> <li>measuring</li> <li>kinematic</li> <li>parameters (angle</li> <li>and flexion or</li> </ol>

bending speed)

Irvine et al, United States, 2015597 Employees from four companies (trucking, manufacturing, technology, and a IG=58.3 corporate headquarters) with 1=58.8 Iow back pain; CG IG=199 (mean age: 2=62.8 N/R) CG 1=199 (mean age: N/R) CG 2=199 (mean age: N/R)Employed IG=95.5% CG 1=96.0% CG 2=96.5%N/R CG 1=199 (mean age: N/R) CG 2=199 (mean age: N/R)CG 1	A web-based online program "FitBack" with self-monitoring tool to track pain levels, self- care activity picker ontaining text articles and videos on pain, 4 pain management, months ergonomics and job type, and weekly exercises based on the severcises based on the pain self-care providing general back pain. CG 2 exercises based on the pain self-care to return to the program.	Pain outcomes equency, ensity, and ration) Pain efferences Functionality d Quality of Life Productivity Presenteeism Planner haviour (Self- tixation, haviour entions, self- icacy, attitudes vard pain and in tastrophising)(1) Battery of questionnaires designed for this study (2) Adapted scale from Multidimensional Pain Inventory Interference Scale of the Brief Pain Inventory (3) The 9-item Dartmouth CO-OP scale (4) The 4-item Work Limitations Questionnaire (WLQ) (5) The 6-item Stanford Presenteeism scale Battery of questionnaires designed for this study (6) Battery of questionnaires designed for this study
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\* N/R: Not reported; IG: Intervention group; CG: Control group; Sickness absence: sick leave days due to low back pain from last year

#### 4.4.4 Characteristics of DHSMIs

Five different DHSMIs were identified in the five included trials, with the key characteristics of the included interventions summarised in **Table 4-3** below. Trials conducted after 2020 all developed DHSMIs in the form of mobile application (Almhdawi et al. 2020; Cimarras-Otal et al. 2020; Anan et al. 2021), while two previous trials developed DHSMIs as online website platforms (del Pozo-Cruz et al. 2012a; Irvine et al. 2015). Two trials used electronic self-assessment questionnaires for automated data collection but did not report encryption measures for data security (Irvine et al. 2015; Anan et al. 2021). Two trials collected data through paper based self-assessment questionnaires or measurement by the researcher but also did not report on data storage (del Pozo-Cruz et al. 2012a; Almhdawi et al. 2020). One study lacked a detailed description of the data collection process (Cimarras-Otal et al. 2020).

#### Intervention content

All five trials reported on the intervention content, three of which briefly described the intervention in the methods section (Irvine et al. 2015; Cimarras-Otal et al. 2020; Anan et al. 2021), and two described the details of the intervention (del Pozo-Cruz et al. 2012a; Almhdawi et al. 2020). After searching the appendices, other trials by the original authors, and further studies using the same DHSMI presented in the included trials of this review, no further detailed descriptions of the design and development process of the DHSMIs were found. Exercise and education formed the key two components of the interventions reviewed.

#### <u>Exercise</u>

Exercise was included in interventions of all five trials. Two studies presented prerecorded exercise videos (del Pozo-Cruz et al. 2012a; Irvine et al. 2015), and two presented as images combined with text (Almhdawi et al. 2020; Anan et al. 2021) One study did not report the method of demonstrating the exercise intervention (Cimarras-Otal et al. 2020). Of the four DHSMIs that included strengthening exercises for key muscle groups (abdominal, lumbar, hip and thigh), three were based on work activities (Almhdawi et al. 2020; Cimarras-Otal et al. 2020) or type of occupation (Irvine et al. 2015).The DHSMIs of the five trials all included both static and dynamic stretching exercises, and two of the trials were designed based on work activities (Cimarras-Otal et al. 2020) and occupation types (Irvine et al. 2015). Two trials reported using an evidence-based exercise intervention component (Almhdawi et al. 2020; Cimarras-Otal et al. 2020), and one of these was developed based on exercise recommendations from the American College of Sport Medicine (ACSM) (Cimarras-Otal et al. 2020).

#### Education

The education component covered a wide range of factors, including sitting posture (del Pozo-Cruz et al. 2012a; Almhdawi et al. 2020; Anan et al. 2021), physical mechanics related to work activities (Almhdawi et al. 2020), ergonomics of the work environment (del Pozo-Cruz et al. 2012a; Almhdawi et al. 2020), pain anatomy and physiology (Irvine et al. 2015; Almhdawi et al. 2020; Anan et al. 2021), lifestyle (Irvine et al. 2015; Almhdawi et al. 2020), exercise (Irvine et al. 2015; Almhdawi et al. 2020), cognitive and behavioural strategies (Irvine et al. 2015; Anan et al. 2021), and pain prevention (Irvine et al. 2015; Almhdawi et al. 2020). Pre-recorded videos of advice on pain, pain management, posture and workplace ergonomics were used in two studies (del Pozo-Cruz et al. 2012a; Irvine et al. 2015), two studies described the education intervention content in the form of text for daily activities to improve pain symptoms, body mechanics and mindfulness (Almhdawi et al. 2020; Anan et al. 2021), with one DHSMI developed with evidence-based information based on European clinical guidelines on LBP (Almhdawi et al. 2020).

#### Individualisation

The DHSMIs in the two trials were reported to allow participants to explore and select self-management content based on their individual needs and preferences (Irvine et al. 2015; Anan et al. 2021). In the study by Anan et al. (2021), an AI-assisted chatbot provided participants with preset exercise interventions at a fixed time each day. Participants could select preferred exercise interventions from a list and choose the time to receive the intervention messages (Anan et al. 2021). However, Anan et al. did not state whether their DHSMI categorised the LBP population to provide an intervention content specifically targeting the type of LBP or its dominant mechanisms. It remains uncertain whether the DHSMI was individualised based on the limited description provided in the Anan et al.'s trial.

In the trial of Irvine et al, an individualised DHSMI (Fitback) was developed for the selfmanagement of LBP in the workplace (Irvine et al. 2015). Fitback was designed to classify the LBP population as sitters, drivers, lifters and standers based on the primary work activity during the day. Using this classification model, Fitback was reported to match exercises and education materials to classified job types. Irvine et al.'s trial described the use of Social Cognitive Theory (SCT) and Theory of Planned Behaviour (TPB) as theoretical frameworks underpinning the classification model of the DHSMI (Fitback) and provided a self-monitoring feature based on the theory aimed at promoting self-management behaviours (Irvine et al. 2015). Participants were allowed to select preferred intervention content from four recommended modules (rest, positive thinking, health literacy, exercise) and report additional self-management activities apart from the recommended contents. Irvine et al.(2015) only described that Fitback classified job types based on self-reported data from participants, without disclosure of the details of the logic model or algorithms used for classification. A search of research on Fitback and other studies by the original authors did not identify any other description of the development process of Fitback or validation of the reliability, accuracy, and overall effectiveness of the classification model. The characteristics of the DHSMIs utilised in these five trials were described in Table 4-3.

Author, Country, Year	Mode of delivery	Data Collection	Theoretical framework	Classification model	Methods of individualising	Intervention content
Del Pozo- Cruz et al, Spain, 2012	Website	Paper-based self- assessment questionnaires collected by researcher	N/R	N/R	N/R	<ol> <li>Exercise: 7-minute video of the daily strengthening, flexibility, mobility, and stretching exercise video demonstration on the main postural stability muscles (abdominal, lumbar, hip, and thigh muscles).</li> <li>Education: 2-minute video of advice on sitting posture, modifying working environment and choosing proper ergonomic equipment.</li> <li>Exercise: Weekly 3-4 sessions of</li> </ol>
Almhdawi et al, Jordan, 2020	Mobile Application	Paper-based self- assessment questionnaires collected by researcher	N/R	N/R	N/R	<ul> <li>20 minutes office-based stretching exercises and home-based strengthening exercises.</li> <li>2. Education: Evidence-based information recommended by European clinical guidelines on:</li> <li>Facts about your back</li> <li>Staying active/ active rest</li> <li>How to manage low back pain when having severe pain</li> <li>Managing pain medically</li> <li>Things you do that increase/decrease your low back pain</li> <li>When to seek a physician (Red flags)</li> <li>The importance of exercise</li> <li>Improper body mechanics: wrong lifting</li> <li>Proper body mechanics: correct</li> </ul>

# **Table 4-3.** Description of characteristics of digital health intervention in selected trials.

liftingErgonomic workstation: correct body posture while working on a desk

Anan et al Japan, 2021	BIIDON	Electronic self- assessment questionnaires collected using online automated system	N/R	N/R	<ol> <li>Users can choose their preferred exercise from a list of daily recommended exercises provided by the Al-assisted chatbot.</li> <li>User can choose time for receiving daily notifications by responding to the message sent by the Al-assisted chatbot.</li> </ol>	
Cimarras- Otal et al, Spain, 2020	Mobile Application	N/R	N/R	N/R	N/R	<ol> <li>Exercise: Exercises designed based on 6 patterns of movement during work: Displacement in the workplace; Cervical movement; Spinal movement; Handle loads; Range of shoulder movement; Use of tools. The series of exercises progressed with 3 levels: starting level (first 3 weeks), average level (4th and 5th weeks) and advanced level (7th and 8th weeks).</li> <li>Education: N/R</li> </ol>

Irvine et al, United Website States, 2015	Electronic self- assessment questionnaires collected using online automated system	Social cognitive theory; Theor of Planned Behaviour	<ul> <li>ythe day</li> <li>Standers: stand most of the day</li> <li>Drivers: drive most of the day</li> <li>Lifters: do a</li> </ul>	low back pain. 2. Self-monitoring: users can record daily pain intensity to produce a 7- f day and 30-day graph of individual pain level. 3. Diary Functions: Users	<ol> <li>Exercise: Instructional videos on specific strength and stretching exercises individualised by job type (sitter, stander, driver, lifter).</li> <li>Education: 30 brief (1-4 minute) videos on general aspects of pain and pain management, cognitive and behavioural strategies to manage and prevent pain.</li> </ol>
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\* N/R: Not reported; AI: artificial intelligence

#### 4.4.5 Effects of interventions

All the included trials were designed with a control group and included different types of management, with one trial featuring two control groups (Irvine et al. 2015). Of the six control groups from the five included studies, two control groups were designed with general exercise (Cimarras-Otal et al. 2020; Anan et al. 2021). The other four control group settings varied from general advice unrelated to LBP (Almhdawi et al. 2020), non-individualised advice for self-management of LBP (Irvine et al. 2015), standard occupational care (del Pozo-Cruz et al. 2012a), and no intervention (Irvine et al. 2020; Cimarras-Otal et al. 2020; Anan et al. 2021). Three trials included a short-term follow-up (6 - 12 weeks) (Almhdawi et al. 2020; Cimarras-Otal et al. 2020; Anan et al. 2021) and two had a mid-term follow-up (4 - 9 months)(del Pozo-Cruz et al. 2012a; Irvine et al. 2015). Within the selected five trials, the primary outcome measures were found to involve pain intensity, LBP-related disability, risk of chronicity, physical performance, psychosocial outcomes and work performance. The number of primary outcomes ranged from 1 to 5 across studies.

# Pain intensity

Three of the five RCTs used visual analogue scales (VAS) of different lengths to measure pain intensity (del Pozo-Cruz et al. 2012a; Almhdawi et al. 2020) (Anan et al. 2021). All five trials reported a positive effect of DHSMIs on intensity of LBP, with three reporting that DHSMIs significantly reduced short-term (6 weeks to 4 months) intensity of LBP in the workplace (MD between groups= -3.34 - -0.26) (Irvine et al. 2015; Almhdawi et al. 2020; Anan et al. 2021). Irvine et al. (2015) reported that the DHSMI individualised by job type demonstrated only a small intervention effect on pain intensity compared to the non-individualised DHSMI (effect size = 0.043, p=0.002) (Irvine et al. 2015), but did not report the measurement tool used for assessing pain intensity in the trial.

# <u>Disability</u>

LBP-related disability was identified as the primary outcome in three of the five studies. Of the three studies, one used the Roland-Morris Disability Questionnaire (RMDQ) (del Pozo-Cruz et al. 2012a), and two RCTs used the ODI as a measurement tool (Almhdawi et al. 2020; Cimarras-Otal et al. 2020). Del Pozo-Cruz et al. (2012) reported that after using DHSMI to self-manage LBP in the workplace for 9 months, participants showed a significant reduction in RMDQ scores compared to those who received standard occupational care (MD between groups = -7.36, 95% CI: -8.41, -6.31); p<0.001)(del Pozo-Cruz et al. 2012a). The results of the trial by Cimarras-Otal et al. (2020) also showed that participants using a DHSMI containing work-based exercises for 8 weeks had a better improvement in the ODI scores compared to those who used a placebo DHSMI and performed the exercises recommended by the ACSM guidelines (MD between groups = -6.10, 95% CI: -13.01, 0.81) (Cimarras-Otal et al. 2020). The trial conducted by Irvine et al. did not measure the intervention effect of individualised DHSMI on disability.

# Risk of chronicity

Only one study reported using the SBST as the measurement tool for the risk of chronic LBP (del Pozo-Cruz et al. 2012a). Del Pozo-Cruz et al. (2012) reported a significant increase in the proportion of participants at low risk of chronicity (37%, p= 0.005) after 9 months of using a DHSMI for LBP self-management in the workplace, compared to those receiving standard occupational care (del Pozo-Cruz et al. 2012a).

# Quality of life

Three trials reported on the short-term effects of DHSMIs on quality of life using the Dartmouth Collaborative Primary Care Information Project (CO-OP) (Irvine et al. 2015), the 12-Item Short Form Health Survey (SF-12) (Almhdawi et al. 2020), and the European Quality of Life 5 Dimensions 3 (EQ-5D-3L) (del Pozo-Cruz et al. 2012a). The Almhdawi et al. (2020) reported positive effects on the physical health-related quality of life (Almhdawi et al. 2020). Irvine et al. (2015) reported that DHSMI individualised by job type resulted in enhanced improvement of quality of life for the LBP population in the workplace than the non-individualised DHSMI (effect size = 0.029, p= 0.003)(Irvine et al. 2015).

# Physical Performance

Three trials assessed the effects of self-management DHSMIs in the workplace on physical performance, with two trials measured by researchers in a laboratory setting reporting significant improvements in core lumbar muscle group endurance (del Pozo-Cruz et al. 2012a) and spinal mechanical function (Cimarras-Otal et al. 2020). The study by Almhdawi et al. (2020) used the International Physical Activity Questionnaire (IPAQ) as measurement of physical activity level which did not find significant

differences between the groups (Almhdawi et al. 2020). It is worth noting that Almhdawi et al. (2020) reported the results of physical activity level in the form of total metabolic equivalents instead of the categorical levels recommended by IPAQ (low, middle, high) (Craig et al. 2003). Also, Almhdawi et al. (2020) did not specify whether the IPAQ used in the study was a short form or long form (Almhdawi et al. 2020).

# Psychosocial Outcomes

Two studies reported the effects of self-management DHSMIs in the workplace on different LBP-related psychosocial factors, such as sleep quality, depression, anxiety, stress and pain catastrophising (Irvine et al. 2015; Almhdawi et al. 2020). In the trial by Almhdawi et al, no group differences were reported between the work-based DHSMI and the placebo version, which only contained five online educational sections of proper nutrition information for LBP (Almhdawi et al. 2020). Irvine et al. (2015) reported significant benefits of DHSMI individualised by job type in the sense of responsibility for pain management, attitudes toward pain, and prevention-helping behaviours for LBP assessed using the adapted version of Patient Activation Measure (PAM), Survey of Pain Attitudes-Short Form (SOPA-SF), and originally developed scales with good reliability (Cronbach alpha = 0.90 - 0.93)(Irvine et al. 2015). But no significant effect of individualised DHSMI on pain catastrophising was found when compared to the non-individualised DHSMI, as measure by the adapted Tampa Scale for Kinesiophobia (TSK) (Irvine et al. 2015).

# Work performance

Only one trial reported on the effect of DHSMIs on work productivity and presenteeism measured by an adapted version of the 4-item Work Limitations Questionnaire (WLQ) and the 6-item Stanford Presenteeism scale (SPS-6) (Irvine et al. 2015). However, the trial conducted by Irvine et al. (2015) did not report greater improvement in work performance for participants with LBP using the DHSMI individualised by job type compared to those using a non-individualised DHSMI (Irvine et al. 2015).

Table 4-4.         Synthesis of outcome measures	and main results from included trials.
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Author, country, year	Pain intensity	Functional disability	Risk of chronicity	Quality of life	Physical performance	Psychosocial outcomes	Work performance
	etMeasure: <b>100-mm</b> VAS Outcome: N/R	Measure: <b>RMDQ</b> Outcome: ↓↓↓	Measure: SBST Outcome: ↓	Measure: <b>EQ- 5D-3L</b> Outcome: <b>N/R</b>	Measure: The Shiradolto lumbar and abdominal tests Outcome: ↓↓↓	N/R	N/R
Almhdawi et al, Jordan, 2020	Measure: <b>11-point</b> <b>VAS</b> Outcome: ↓↓↓	Measure: <b>ODI</b> Outcome: ↓↓	N/R	Measure: <b>SF-12</b> Outcome: <b>X</b>	Measure: IPAQ Outcome: X	Measure: <b>DASS, PSQI</b> Outcome: <b>X, X</b>	N/R
Anan et al, Japan, 2021	Measure: <b>5-point</b> VAS Outcome: ↓↓↓	N/R	N/R	N/R	N/R	N/R	N/R
Cimarras-Otal e al, Spain, 2020	t Measure: <b>BPI-SF</b> Outcome: <b>X</b>	Measure: <b>ODI</b> Outcome: <b>X</b>	N/R	N/R	Measure: <b>FER</b> Outcome: ↓	N/R	N/R
Irvine et al, United States, 2015	Measure: <b>Original</b> <b>questionnaire</b> CG1 Outcome: <b>X</b> CG2 Outcome: ↓	N/R	N/R	Measure: Dartmouth COOP CG1 Outcome: ↓ CG2 Outcome: ↓↓	N/R	Measure: <b>PAM-SF, Original</b> <b>questionnaires, SOPA-SF,</b> <b>TSK</b> CG1 Outcome: ↓↓, ↓↓↓, ↓↓↓, X CG2 Outcome: ↓↓, ↓↓↓, ↓↓	

**N/R**: Not reported; **X**: Effects not statistically significant ;  $\downarrow$  : p<0.05;  $\downarrow\downarrow$ : p<0.01;  $\downarrow\downarrow\downarrow$ : p<0.001

VAS: Visual Analogue Scale; RMDQ: Roland-Morris Disability Questionnaire; SBST: STarT Back Screening Tool; EQ-5D-3L: European Quality of Life 5 Dimensions 3 Level Version; ODI: Oswestry Disability Index; SF-12: The 12-Item Short Form Health Survey; IPAQ: The International Physical Activity Questionnaires; DASS: The Depression, Anxiety and Stress Scale; PSQI: Pittsburgh Sleep Quality Index; BPI-SF: Brief Pain Inventory - Short Form; FER: Angle, bending speed, and flexionextension ratio; Dartmouth COOP: The Dartmouth Primary Care Cooperative Functional Assessment Charts; PAM-SF: The Patient Activation Measure-Short Form; TSK: Tampa Scale of Kinesiophobia; SOPA-SF: the Survey of Pain Attitudes- Short Form; WLQ: The 4-item Work Limitations Questionnaire; SPS-6: The 6-item Stanford Presenteeism scale

#### 4.5 Discussion

The aim of this SR is to examine the effects of work-based DHSMIs on LBP and to map the components of work-based DHSMIs, underlying theories and individualisation approaches. Different work-based DHSMIs for LBP from five RCTs were identified through the database search. These DHSMIs were developed based on webpages (del Pozo-Cruz et al. 2012a; Irvine et al. 2015) and mobile applications (Almhdawi et al. 2020; Cimarras-Otal et al. 2020; Anan et al. 2021). The main intervention components of the DHSMIs were exercise instruction focusing on stretching and strengthening and educational interventions covering a wide range of BPS factors demonstrated in text, image and animation. Three DHSMIs were designed with workbased intervention components. Most of the DHSMIs included in this review (n=4) were designed with work-related intervention content, such as exercise interventions based on the working environment (Almhdawi et al. 2020) and work activities (Irvine et al. 2015; Cimarras-Otal et al. 2020), as well as workplace ergonomics education (del Pozo-Cruz et al. 2012a). One study referred to Social Cognitive Theory and Theory of Planned Behaviour as the theoretical framework for the DHSMI and was individualised by classifying the main type of daily work activities (Irvine et al. 2015). Of the included studies, positive effects of DHSMIs were observed on short to middle term pain intensity, disability, and physical performance. In the following sections, the main findings for each study objective are summarised and discussed with other literature.

# 4.5.1 Effect of DHSMI on LBP in the workplace

Given the scarcity of DHSMIs for LBP in the workplace, reviews used for comparisons in this section mainly examined DHSMIs used for MSK conditions (LBP included) or LBP in a mixed setting (clinical, home, and workplace). Although these conclusions may not be completely applicable to DHSMIs for self-management of LBP in the workplace, considering that both working populations and self-management were included in these reviews, the comparison still provides some valuable insights.

Findings in this review indicate that DHSMIs have positive outcomes on pain intensity, disability, and physical performance of LBP populations in the workplace. This finding is consistent with the results in previous SRs on DHSMIs used for MSK conditions (Garg et al. 2016; Hewitt et al. 2020; de Oliveira Lima et al. 2021; Lewkowicz et al.

2021; Valentijn et al. 2022). A meta-analysis by Rathnayak et al. (2021) reported that self-management combining exercise and education had positive effects on pain and disability in patients with LBP (Rathnayake et al. 2021). In this review, similar effects on LBP pain and disability were observed in three included studies using DHSMIs that included both education and exercise intervention components (Irvine et al. 2015; Almhdawi et al. 2020; Anan et al. 2021). Previous SR suggested that improvements in pain intensity and disability may be due to the inclusion of education materials in DHSMIs that enhanced the awareness among LBP populations of their MSK condition (Hewitt et al. 2020). This seems to be supported by the findings in this review, where no significant improvements in pain and disability were observed in studies of DHSMIs that only included exercises (Cimarras-Otal et al. 2020). A SR by Gordon et al. (2016) showed that exercise interventions only (stretching and strengthening exercise) have limited effects on LBP, and were even ineffective for acute LBP (Gordon and Bloxham 2016). These findings echo previous research calling for a multi-dimensional approach to treating LBP from physical, psychological and social perspectives (Kamper et al. 2015).

However, previous SRs of DHSMIs used for chronic MSK pain noted that while DHSMIs can improve knowledge for supporting self-management behaviours, there is a lack of evidence of the effect on psychosocial factors (Garg et al. 2016; Cottrell et al. 2017; Slattery et al. 2019). Similarly, in this review, while the included studies reported consistent evidence of DHSMIs on physical performance of people with LBP in the workplace, the evidence on the effects of DHSMIs on psychosocial factors was conflicted. Two trials in this review examined the effects of DHSMIs on psychosocial factors in workplace LBP populations, one of which did not observe significant effects of DHSMIs in improving depression, anxiety, and stress (Almhdawi et al. 2020). Although another trial reported improved self-management motivation and pain attitude, it did not find the effect of DHSMI on pain catastrophising in LBP population in the workplace (Irvine et al. 2015). It should also be mentioned that these data were collected using both original and adapted questionnaires developed by Irvine et al. (2015), but the details of these questionnaires and their reliability and validity results were not fully disclosed.

Results from a recent SR showed that pain catastrophising, depression, anxiety, stress, and sleep quality were key determinants of quality of life for people with LBP (Agnus Tom et al. 2022). This finding provides a potential explanation for the lack of consistent effects of DHSMIs on the quality of life of LBP population in the workplace in this review. Psychosocial factors of LBP are complex and multifaceted, involving emotional, cognitive and social dimensions (Ho et al. 2022). Current DHSMIs providing general intervention content in self-management of LBP may not fully address these complexities, thus leading to mixed results in terms of their effects. Lewkowicz et al.'s systematic review also found that while some DHSMIs offer individualised feedback and decision-making support, the limited scope and quality of these support systems may have reduced user engagement, which in turn contributed to the limited impact on psychosocial outcomes (Lewkowicz et al. 2021).

#### 4.5.2 Individualisation

The NICE guidelines (National Guideline 2016) and Maher et al. (2017) have emphasised the need to provide individualised LBP self-management. There is also growing evidence suggesting that individualised DHSMIs are more likely to produce optimal outcomes for LBP, resulting in increased self-efficacy and adherence to LBP self-management (Sandal et al. 2021; Chys et al. 2022; Cui et al. 2023). However, the reviewed studies did not demonstrate that individualisation had any significant additional effect on LBP management. This may be partly due to the limited number of studies employing individualised approaches. Also, DHSMIs which employed individualised approaches used unsophisticated methods such as classification by job type (Irvine et al. 2015) or provided unresponsive feedback using the chatbot (Anan et al. 2021). Other than classification on job types, no studies classified LBP based on dominant mechanisms underlying the pain disorder to better target self-management. Similar findings were observed in the previously SR by Lewkowicz et al. (2021) in which DHSMIs for LBP in clinical settings were individualised by physical activity level (Chhabra et al. 2018) and case-based reasoning (Sandal et al. 2020). Without individualising intervention content based on the dominant pain mechanisms, DHSMIs for LBP remain generic, potentially overlooking important BPS factors contributing to LBP. This generalisation may prevent DHSMIs from adequately addressing the complexity and multifactorial nature of LBP, thereby limiting its effect on pain and function improvement, particularly in the workplace. Given the complexity of LBP,

future research should focus on integrating LBP classification systems to better individualise management strategies to the underlying mechanisms.

In addition, there has been insufficient clarity on the definition of individualising. The lack of a clear definition and consistent guidelines on what constitutes individualisation further complicates the issue. In a previous meta-analysis of DHSMIs for chronic pain (6 RCTs on LBP), Martorella et al. (2017) reported that DHSMIs did not have significant improvement in primary LBP outcomes (pain and disability) compared to nonindividualised DHSMIs (Martorella et al. 2017). It is worth noting that DHSMIs which only included feedback features were considered as individualisation in this metaanalysis, which may influence the effects of the individualised DHSMIs on LBP. This finding indicates that discrepancies in the definition of individualisation may point to distinctly contrasting effects of DHSMIs on LBP, which could thereby discouraging future development of individualised DHSMIs on LBP. Unlike the DHSMI in this and previous SRs, the BOL not only provided feedback based on individual's response but also recognised the need of LBP populations. Compared to the unsophisticated individualised approach of the DHSMI in this SR, the BOL provides an adaptive and functional model of workplace self-management based on pain mechanisms, physical activity levels and sedentary behaviours. This allows for the provision of individualised interventions that better match the individual's specific pain profile. Future research should focus on integrating LBP classification systems to better tailor management strategies to the underlying mechanisms. In addition, DHSMI should focus on enhancing functionality to improve responsiveness to pain characteristics, job types, and user activities to become more dynamic and individualised.

#### 4.5.3 Intervention content and development pathway

The interventions in the reviewed studies included content of education material and exercise which is largely in accordance with contemporary clinical guidelines for LBP self-management (National Guideline 2016). However, only two of the included trials reported that the intervention content was developed in an evidence-based approach (Almhdawi et al. 2020; Cimarras-Otal et al. 2020). Current clinical guidelines state staying active and having at least one type of exercise for LBP self-management (Oliveira et al. 2018b). But none of the guidelines explicitly describe the type, frequency, and intensity of exercise for self-management (Comachio et al. 2024). The lack of

guidance on exercise and education content has been repeatedly raised, highlighting the lack of description of the content of DHSMIs for LBP self-management and discrepancies of intervention content in published literature (Nicholl et al. 2017; Hewitt et al. 2020). Future research should focus on describing and standardising intervention content, ensuring that contents are clearly defined and evidence-based to improve the consistency and effectiveness of DHSMIs for LBP.

The lack of detailed descriptions has further limited the ability to assess the effectiveness of DHSMIs on LBP. The studies included in this SR were also observed to be included in other meta-analyses examining the effectiveness of DHSMIs on LBP (Du et al. 2020; Hong et al. 2024). A common issue in these meta-analyses was the treatment of DHSMIs as a uniform concept, referring to them broadly as software or e-health tools for LBP self-management. This approach overlooked the significant variation in the content of the interventions ( $I^2 = 89.6\%$ ) (Hong et al. 2024). As a result, the substantial heterogeneity between studies made it difficult for these meta-analyses to pinpoint the specific components of DHSMIs that were effective for LBP. This finding also reflected the lack of a standardised framework for the development of DHSMIs for LBP self-management (Kongsted et al. 2021).

In addition, theories are rarely used in the DHSMIs included in this SR with a single study referring to the SCT and TPB (Irvine et al. 2015). There has been even more scarcity of research describing the process of development and the theoretical frameworks used in general DHSMIs for LBP (Svendsen et al. 2022b). Theories offer a structured framework for understanding behaviour and are instrumental in guiding the development of interventions (Michie et al. 2017; Fernandez et al. 2019). Without an appropriate theoretical underpinning, DHSMIs are likely to be constructed on untested assumptions and may not effectively address the underlying mechanisms that drive health behaviour change (Davis et al. 2015). Due to the lack of theoretical underpinning, there is inconsistency of selected outcome measures across studies in this SR. Also, none of the studies in this SR clarified whether the selected outcome measures can explain the underlying intervention mechanisms. This has also made it difficult for this SR, including previous SRs on DHSMIs for LBP, to assess what aspects of DHSMIs are effective (Nicholl et al. 2017; Lewkowicz et al. 2021).

Several theories and frameworks could be applied to the development of DHSMIs for LBP. Apart from the SCT and SDT referenced in the previous chapter (Section 3.5), the TPB selected in the Fitback developed by Irvine et al. (2015) provides useful insights. TPB focuses on the intention to perform a behaviour based on attitudes, subjective norms, and perceived behavioural control, which can be critical in designing interventions aimed at improving adherence to the DHSMIs (Bosnjak et al. 2020). However, the TPB's focus on rational reasoning excludes the unconscious influences on behaviour (Sheeran et al. 2013). This has resulted in variability in individual behaviour, such as the abandonment of an action after forming an intention, that cannot be explained by TPB (Sniehotta et al. 2014). Another widely used theory, the Health Belief Model (HBM), considers the variability of individual behaviour (Jones et al. 2015). By capturing an individual's perceived susceptibility and severity of the condition, as well as perceptions of the benefits of and barriers to interventions, the HBM has been used in DHSMIs aiming to enhance self-efficacy and likelihood of individuals to actively engage in disease management and prevention (Nematzad et al. 2023; Paganin et al. 2023).

Apart from the theories, the Behaviour Change Wheel (BCW) based on the COM-B model is also widely used in the development of DHSMIs (Beleigoli et al. 2018). The BCW offers a comprehensive framework that connects behaviour diagnosis with appropriate intervention functions and implementation policies (Michie et al. 2011). However, the BCW shifted primary focus on healthcare professionals and system-level changes in the intervention development (Faija et al. 2021). Compared to the BCW, intervention mapping (IM) emphasises the involvement of stakeholders, including patients (Fernandez et al. 2019). IM has been used as a structured framework to develop DHSMI for LBP through an iterative six-step process, focusing on the use of behavioural theories and empirical evidence (Svendsen et al. 2022b). Future research should focus on improving the quality of DHSMIs by following appropriate intervention development and theoretical frameworks. Quality research also need improve transparency in the reporting of both the intervention development process and the theoretical models applied. In this way, future DHSMIs can be developed systematically, providing with a clear pathway of the mechanisms of action. By following these practices, researchers can effectively conduct comparisons of DHSMIs and investigate the contexts in which different intervention components are effective,

scalable, and adaptable, thereby making a more substantial contribution to the selfmanagement of LBP.

#### 4.5.4 Strengths and limitations

The strength of this SR is that it provides the first synthesis of the effects and intervention content of DHSMIs used for LBP in the workplace, with a particular focus on individualisation. However, there are some limitations of this study that must be recognised. First, it is important to acknowledge the paucity of existing research on DHSMIs for LBP in the workplace. The scarcity of eligible studies and discrepancies of outcome measures between studies made it difficult to conduct a meta-analysis. Only one study developed DHSMI that provided individualised LBP intervention. However, neither the questionnaire used for the outcome measures nor the classification model to provide individualised intervention content was validated. Meanwhile, due to the lack of description, it is unclear how these DHSMIs were developed and who developed them. The involvement of stakeholders has been identified as crucial in ensuring that DHSMIs are individualised to the needs and preferences of users, and increasing the feasibility of successful implementation (Heijsters et al. 2022; Oberschmidt et al. 2024). Finally, although included studies reported on intervention content based on work activities or working environment, the intervention content remained generic and lacked specificity due to the limited underpinning theoretical basis, which is difficult to address the complexity of LBP selfmanagement in the workplace.

#### 4.5.5 Summary of recommendations

As shown in this SR, there has been limited report of the development process and use of evidence-based intervention components in the DHSMIs for LBP in the workplace. The National Institute For Health And Care Research and Medical Research Council (NIHR/MRC) has provided instructive guidance for developing and evaluating complex interventions, proposing a framework with four phases: development, feasibility/piloting, evaluation, and implementation (Skivington et al. 2021). The NIHR/MRC recommended approaching complex intervention development as a dynamic and iterative process that combines existing evidence, theory, and stakeholder perspectives. Future DHSMIs for LBP in the workplace should follow the

NIHR/MRC's framework to enhance the feasibility, acceptability and effectiveness of DHSMIs through a standardised development process.

Person-centred care model requires DHSMIs to better meet the unique needs of the LBP population (Themelis and Tang 2023). Although individualisation has been identified as an important factor in promoting engagement and adherence to the use of DHSMIs for LBP (Svendsen et al. 2020), none of the studies included in this SR examined the validity and reliability of the classification model used in these DHSMIs. To improve the quality of individualisation in DHSMIs for LBP, future research should prioritise the validation of classification models to ensure the reliability and validity across different occupations and working environments. Also, the development and validation process of the classification models need to be clearly documented to increase the credibility of the model.

Furthermore, as suggested by the NIHR/MRC, evaluation is an important part of the process of developing complex interventions. However, there has yet to be reported a clear model or framework to guide the evaluation of DHSMIs for LBP in the workplace. Therefore, it is necessary to develop a model to better inform the evaluation of workbased DHSMIs for LBP. Firstly, it needs to identify the work-related metrics in LBP self-management (e.g. absenteeism, work capacity and self-efficacy) and the outcome measures used for these target outcomes. Also, it needs to explore the theoretical framework used by the DHSMIs to better explain the anticipated effectiveness of DHSMIs on an individual's ability to perform and sustain work activities with LBP.

# 4.6 Conclusions

This review presents moderate quality of evidence supporting short to middle term (6 weeks - 9 months) positive effects of DHSMIs on pain intensity, disability, and physical performance for people with LBP in the workplace. However, the small number of included studies limits the generalisability of the findings. More high quality RCTs of DHSMIs for LBP in the workplace are needed in the future to strengthen the evidence base. A critical knowledge gap identified in this SR is the lack of individualisation in DHSMIs for LBP in the workplace. Only one of the five included studies used individualised DHSMI for LBP in the workplace, but it did not demonstrate any significant additional effect on LBP. Furthermore, the reviewed studies generally

provide insufficient descriptions of the intervention development process and its content. Theoretical application is also insufficient, with only one study referencing SDT and SCT as frameworks guiding the intervention design. Future research needs to follow the NIHR/MRC framework for complex intervention development and evaluation, with clear intervention development process pathway, detailed descriptions of intervention content, and appropriate application and interpretation of relevant theoretical frameworks.

To address the gaps identified in this SR, the BACK-on-LINE<sup>™</sup> (BOL) self-assessment offers a potential solution by introducing individualisation into DHSMIs. BOL enables individualised interventions by incorporating a self-assessment tool designed to classify LBP based on the PMC model. This BOL self-assessment holds the potential to help identify the dominant pain mechanism of individuals and support more individualised LBP management. Validation of this tool would be a step towards enhancing individualised DHSMIs for LBP in the workplace, potentially leading to more effective and targeted self-management approaches. The next chapter presents the validation results of the classification model used by BOL self-assessment to provide individualised LBP self-management in the workplace.

# 5. Chapter 5: Phase 2 – Determination of the cut-off point and evaluation of the psychometrics properties of the BACK-on-LINE<sup>™</sup> self-assessment in the workplace LBP population

#### 5.1 Introduction

Based on the pain mechanism-based classification (PMC) model for pain (Smart et al. 2008; Smart et al. 2010; Smart et al. 2012a), Alothman et al. (2017) developed the initial BOL self-assessment (Alothman et al. 2017). Although NICE guidance highlighted the importance of providing individualised self-management for working populations with LBP (National Guideline 2016), findings from the previous chapter's SR revealed that there is limited research on DHSMIs used for LBP in the workplace. Only one study was identified to tailor self-management on dominant work activity of the participant's job (Irvine et al. 2015), highlighting the need for developing tools that could offer self-management individualised to the underlying LBP disorder.

The literature review in Chapter 2 has explored a rage of classification models used for LBP including the contemporary PMC model to offer self-management individualised to dominant pain mechanism underlying the LBP disorder. International Association for the Study of Pain (IASP) published the clinical criteria and classification of pain based on dominant mechanisms for nociplastic pain (NP) (Kosek et al. 2021). Since then a range of 32 questionnaires, scales, and tools, including the Numerical Pain Rating Scales (NPRS), STarTBack Screening Tool (SBST), and Örebro Musculoskeletal Pain Screening Questionnaire (ÖMPSQ), have been recommended to differentiate between pain mechanisms (Bułdyś et al. 2023). A recent study published in Nature further suggested that Quantitative Sensory Testing (QST), which assesses perceptual responses to physical stimuli, remains to be the primary approach for evaluating pain mechanisms (Kaplan et al. 2024). While quantitative pain assessment offers advantages, using these resource-intensive methods for all pain patients may not be the most efficient use of healthcare resources. Therefore, combining tools like the PainDETECT Questionnaire (PD-Q), Douleur Neuropathique 4 Questions (DN4), and Central Sensitisation Inventory (CSI), along with assessments of non-pain features such as depression, anxiety, and sleep disorders, has been proposed as an effective approach for pain phenotyping (Kaplan et al. 2024).

However, a significant challenge remains that no single questionnaire, scale, or tool can identify all pain mechanisms. Most are only capable of distinguishing between two pain mechanisms (Shraim et al. 2021). While the IASP continues to work on determining which tools or combinations of assessments are most effective in discriminating between different pain mechanisms (Shraim et al. 2022), combining tools with numerous items could impose a significant burden on patients.

The BOL self-assessment represents the first attempt to develop a self-administered pain classification tool specifically designed for people with LBP to gain early access to individualised self-management. The BOL domains include items that measure pain intensity, location, and sensation, like the IASP-endorsed PD-Q and DN4 (Bouhassira et al. 2005; Freynhagen et al. 2006), as well as symptoms of central sensitisation, akin to those assessed by the CSI (Neblett et al. 2013).

First iteration of the BOL self-assessment was developed by Alothman et al. (2017) to distinguish between nociceptive pain (NC) and nociplastic pain (NP) origin. This was followed by a calculation of a cut-off point in the small sample LBP population from mixed settings against the NICE-recommended SBST (Alothman et al. 2019). In addition, Alothman et al. (2019) conducted an initial evaluation of the psychometric properties of the BOL self-assessment and reported good internal consistency, test-retest reliability, and construct validity (Alothman et al. 2019). In the subsequent development, Sheeran et al. (2024) optimised the descriptions and the scoring rules for items related to pain medication following the updated NICE guidelines on LBP and produced an online version (Sheeran 2024a,b). This necessitated a recalculation of the BOL self-assessment can produce accurate scores and appropriate classification of the pain.

In healthcare research, the psychometric properties of measurement instrument are crucial as they reflect whether the instrument accurately and consistently measures what it is intended to measure (Swan et al. 2023). According to the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) categories, the main psychometric properties include reliability, validity, and responsiveness (Mokkink et al. 2016). Where reliability refers to the consistency or stability of the

measurement instrument which can be assessed in different ways including internal consistency, test-retest reliability and measurement error (Mokkink et al. 2016). While validity refers to the extent to which an instrument can measure what it is intended to measure, including content validity, construct validity and criterion validity (Mokkink et al. 2016). Measurement instruments developed to measure changes in LBP-related outcomes over certain period needs to assess responsiveness to measure the degree of change in the construct over time (Mokkink et al. 2016). It was considered as a form of longitudinal validity of the measurement instrument, representing the extent to which an instrument can measure the expected direction or magnitude of change in measurement outcomes (Mokkink et al. 2021).

Therefore, the aim of the phase 2 of this PhD project was to 1) establish the cut-off point for the next version of BOL self-assessment to accurately classify NC and NP subgroups and 2) evaluate the reliability, construct validity, and criterion validity of the BOL self-assessment in LBP populations from range of work settings.

Following the recommendations of COSMIN, a hypothesis testing approach was used to assess two types of construct validity, (i) convergent validity (expected relationships with other validated measurement instruments of similar constructs) and (ii) knowngroups validity (expected differences between identified groups) (Mokkink et al. 2019). According to the COSMIN taxonomy (Mokkink et al. 2019), the specific objectives are: 1. To calculate the cut-off point of the BOL self-assessment for classifying NC and NP subgroups of participants with LBP;

2. To assess the diagnostic accuracy (sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (LR+) and negative likelihood ratio (LR-)) of the new cut-off point;

3. To assess the internal consistency by measuring the degree of correlation between the domains of the BOL self-assessment;

4. To assess test-retest reliability by measuring the stability of scores obtained by the same individual on the BOL baseline and follow-up self-assessments;

5. To assess the convergent validity by measuring the degree of correlation with other validated measurement instruments measuring similar dimensions;

6. To assess the known-groups validity by calculating the effect sizes of difference in LBP-related measurements between the BOL subgroups;

7. To assess the criterion validity by examining the ability of the BOL self-assessment in discriminating LBP populations at a high risk of disabling LBP under established criteria.

#### 5.2 Methods

#### 5.2.1 Dataset

The dataset used for the validation of the BOL self-assessment was derived from a single-arm prospective BOL cohort study conducted prior to this PhD project to explore the feasibility and acceptability of providing BOL intervention to support LBP self-management in workplace associated with a high prevalence of LBP (healthcare, transport, education), the results of which are reported in <u>Chapter 7</u>. Part of the data used in the Phase 3 was used for the Phase 2 evaluation in this chapter, which allowed recalculation of the cut-off point of the BOL self-assessment with a sufficient sample and evaluation of its psychometric properties in the working environment. This would help to validate whether the BOL self-assessment can accurately and consistently assess the multidimensional factors within the classification model applied. It would also provide an evidence base for the trustworthiness of the results obtained from the BOL self-assessment.

Overall, the dataset used in this chapter included 136 working adults (aged over 18 years old) that participated in the BOL cohort study between February 2020 and June 2021 with self-reported LBP affecting their ability to work. Details of the study design, recruitment process, eligibility criteria and procedures were described in the next chapter (Section 7.3). This dataset collected participants' responses to the BOL self-assessment and a series of outcome measures at baseline and 4-week follow-up. It included demographic data and potential benefits of BOL on individual health. The following sections describe domain settings of the BOL self-assessment and detail the measurement instruments used to collect these data.

#### 5.2.2 BOL self-assessment

As the core component of the BOL, the BOL self-assessment was developed to classify LBP subgroups based on individual's own pain mechanism. The BOL self-assessment was developed based on 21 previous developed questionnaires and tools for LBP, through an iterative development process that involved two rounds of E-Delphi

studies (Alothman et al. 2017,2019). A modified version of the E-Delphi technique was used to allow both UK and international physiotherapists with diverse research expertise and work experience to participate in the BOL self-assessment development at their convenience and regardless of geographical constraints (Alothman et al. 2017). Consensus levels were set prior to the start of the study, with rules and guidelines clearly explained to participants. Experts (n=38) rated the perceived importance of each item on a 7-point Likert scale and made suggestions for new items to be included in the self-assessment. After the Delphi studies, Alothman et al. (2017) refined the BOL self-assessment and adopted suggestions from the Plain English Campaign by using short sentences and single-word answers, which scored 92.2 on the Flesch Reading Ease readability assessment indicating excellent readability and comprehension (Alothman et al. 2017).

Recognising the multifaceted nature of LBP and the need to assess a broad range of factors to determine the optimal intervention, the BOL self-assessment contains 34 items covering four domains:

- Pain Behaviour Domain (PB, Biological Factors): This domain explored the type and magnitude of nociception, behaviours related to pain expression and management and physical activity.
- 2) Impact of LBP on Work Domain (PW, Social Factors): This domain assessed how LBP affects an individual's ability to work and employment status, emphasising the work-related aspects of LBP.
- Impact of LBP on Life Domain (PL, Social Factors): This domain investigated how LBP impacts an individual's overall life, including their daily activities and family support.
- Perception of LBP Domain (PP, Psychological Factors): This domain focused on how individuals perceive their LBP, exploring the beliefs, attitudes, and pain self-efficacy.

The response options and scoring rules are identical in the PL and PP domains where agree is being scored as two points, neutral as one point, and disagree as zero point. The other two domains (PB and PW) have varied response options and scoring rules. Individual items were scored from 0 to 3 points to reflect the severity and impact of

LBP. The items and specific scoring rules for the BOL self-assessment are displayed in <u>Appendix 1</u>.

# 5.2.3 Measurement instruments

The BOL self-assessment assessed four key domains: pain behaviour (PB), impact on work (PW), impact on life (PL), and perception of LBP (PP). These domains share similar constructs with the measurement instruments used at baseline and 4-week follow-up to measure the potential health benefits of BOL. Both the SBST and BOL self-assessment focus on the influence of psychosocial factors on LBP. While the Numerical Pain Rating Scale (NPRS) measures pain intensity to quantify the biological impact of LBP (PB) and the Roland-Morris Disability Questionnaire (RMDQ) evaluated disability and its impact on daily activities (PL).

# SBST

The SBST is a validated tool consisting of 9 items assessing physical and psychosocial risk factors for categorising patients with LBP as having a low, medium or high risk of developing persistent disabling LBP (Hill et al. 2008). The NICE guidelines have recommended the SBST as a LBP stratification tool in primary care to guide clinicians in providing individualised treatments to patients (National Guideline 2016). Alothman et al. (2019) used the SBST as a reference and calculated the initial cut-off point for the BOL self-assessment. The detailed content and results of the reliability and validity testing of the SBST, as well as the reasons for choosing the SBST as the gold standard for the BOL self-assessment, are described in Chapter 2 (Section 2.8.1). Both the SBST and the BOL self-assessment considered physical, psychosocial and psychological risk factors (pain, disability, fear avoidance, anxiety, depression).

# NPRS

Pain intensity was assessed by a single-item 11-point instrument for pain intensity assessment (Kahl and Cleland 2005), ranging from 0 (no pain at all) to 10 (the worst imaginable pain). Excellent test-retest reliability (Intraclass Correlation Coefficient (ICC) = 0.95-0.97) has been reported in patients with musculoskeletal pain (Alghadir et al. 2018). While a universally accepted cut-off point may be missing, a 3-class classification (Mild, Moderate or Severe pain) in clinical practice using cut-off values of 4, 7 for patients with musculoskeletal pain seems most appropriate (Boonstra et al.

2016). Comparison with the NPRS, which has been recognised as a reliable measure of pain intensity (Haefeli and Elfering 2006), would be helpful in evaluating whether the BOL self-assessment can provide an accurate and consistent assessment of pain.

# RMDQ

The RMDQ has been commonly used to assess disability caused by LBP (Ostelo and de Vet 2005; Jenks et al. 2022). It is a 24-item questionnaire scored on a scale of 0 to 24, where higher scores indicate more severe disability (Roland and Morris 1983). Previous studies have demonstrated the excellent test-retest reliability (ICC = 0.91) (Brouwer et al. 2004) and internal consistency (Cronbach's  $\alpha$  = 0.89) (Jenks et al. 2022) of RMDQ in LBP populations. Good convergent validity (Pearson's correlation coefficient r= 0.544) and concurrent validity (r=0.811) were also reported (Scharovsky et al. 2008; Kim and Lim 2011). The RMDQ contains 24 items on daily activities to measure of the level of LBP-related disability. The BOL self-assessment also contains items in the PB and Impact of LBP on Life (PL) domain measuring the impact of LBP on physical activities and daily lives.

# 5.2.4 Data collection

Data from all participants were collected using a custom developed online platform that included online version of all measured outcomes as well as BOL self-assessment. Participants accessed the online platform via a secure link using a unique 8-digit ID provided at enrolment. All the data were automatically stored in the form of encrypted, downloadable Excel sheets in the secure backend of the online platform. The researcher (MC) assessed and downloaded the data using an encrypted device authorised by Cardiff University.

# 5.2.5 Data analysis

Descriptive analyses were performed for baseline characteristics with continuous variables presented as mean value and SD, and categorical variables as numbers and frequencies (%). All statistical analyses were computed using the SPSS version 27.0 for Windows (IBM Corp., New York, NY) with a significance level of 5%. Sections below describe the data analysis process to answer to all 7 objectives described above related to (i) the BOL self-assessment cut-off point to distinguish between NC and NP pain types, (ii) diagnostic accuracy of the cut-off point, (iii) internal consistency across

the BOL self-assessment domains (iv) test re-test reliability (v) convergent validity of the BOL self-assessment with other similar measurement instruments (vi) known groups validity in distinguishing between NC and NP pain types and (vii) criterion validity for determining high risk of pain intensity, pain duration, disability, and absenteeism.

#### 5.2.5.1 Cut-off point and diagnostic accuracy

Following the previous BOL development, the high-risk group classified by the SBST served as the standard reference for categorising the NP group (Alothman et al. 2019). Receiver operating characteristic (ROC) curve (Park et al. 2004) was plotted to demonstrate the relationship between sensitivity and 1-specificity for different cut-off points of the BOL self-assessment using SBST as the reference standard. The point in the ROC curve closest to the upper left corner was considered to have the highest true positive rate (Carter et al. 2016). The Youden index (sensitivity + specificity - 1) (Youden 1950), which was considered to provide a balance between sensitivity and specificity (Akobeng 2007), was calculated to help identify the optimal cut-off point. The cut-off point for the BOL self-assessment was determined by combining the results of the ROC curve and the Youden index.

The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (LR+) and negative likelihood ratio (LR-) were calculated to assess the accuracy of the BOL self-assessment in classifying the LBP population by pain mechanism based on the new cut-off point. Sensitivity reflects the ability of the BOL self-assessment to correctly identify individuals with NP (true positives), while specificity measures its accuracy in identifying those with NC (true negatives) (Šimundić 2009). PPV represents the probability of individuals classified as NP by the BOL self-assessment truly has NP, and NPV indicates the likelihood that those classified as NC by the BOL self-assessment do not have NP (Parikh et al. 2008). The likelihood ratio (LR) refers to the ratio of the probability of obtaining a particular screening test result in individuals with the disease to the probability of obtaining the same result in individuals without the disease (Šimundić 2009). For the BOL self-assessment, a positive LR (LR+) indicates how much more likely a positive result (NP) is to occur in individuals with NP, while a negative LR (LR-) indicates how much less likely a negative result (NC) is in individuals without NP (Šimundić 2009). These

diagnostic metrics have been widely used to assess the accuracy of cut-off point for clinical measurement instruments (Faizi and Alvi 2023). The calculation methods for the diagnostic metrics are described in **Table 5-1** (Stehman 1997).

<b>Table 5-1.</b> A confusion matrix summarising the diagnostic metrics for the evaluation
of the cut-off point of BACK-on-LINE™ self-assessment.

	Reference standard positive <sup>a</sup>	Reference standard negative <sup>b</sup>	
BOL* positive <sup>c</sup>	True positive (TP)	False positive (FP)	Positive predictive value (PPV) $\frac{TP}{TP + FP}$
BOL negative <sup>d</sup>	False negative (FN)	True negative (TN)	Negative predictive value (NPV) $\frac{TN}{FN + TN}$
	Sensitivity $\frac{TP}{TP + FN}$	Specificity $\frac{TN}{FP + TN}$	Positive likelihood ratio (LR+) Sensitivity 1 – specificity Negative likelihood ratio (LR+) 1 – Sensitivity Specificity

**a**: High risk group classified by STarT Back Screening Tool

b: Low risk and medium risk group classified by STarT Back Screening Tool

c: Nociplastic pain group classified by BACK-on-LINE™ Self-assessment

d: Nociceptive pain group classified by BACK-on-LINE™ Self-assessment

\*BOL: BACK-on-LINE™

Following the criteria of previous studies, the sensitivity and specificity values of 0.8 - 1.0 is considered as high, 0.70 - 0.79 as moderate and below 0.70 as low (White et al. 2023). PPV and NPV are heavily influenced by the prevalence of disease in the population examined, and therefore there is no fixed standard for PPV and NPV (Šimundić 2009). PPV and NPV, when reported along with other diagnostic accuracy metrics such as sensitivity, specificity, and likelihood ratios, can provide a more comprehensive picture of the BOL self-assessment's performance (Poddubnyy et al. 2018). The criteria for likelihood ratios is summarised in **Table 5-2** which is consistent with previous clinical research (Berkman et al. 2015; Sleijser-Koehorst et al. 2021).

Positive likelihood ratios (LR+)	Negative likelihood ratios (LR-)	Test efficiency
> 10	< 0.1	High
5 - 10	0.1 - 0.19	Moderate
2 - 4.9	0.2 - 0.49	Weak
< 2	0.5 - 1.0	Insufficient

Table 5-2. Summary of criteria for likelihood ratios

## 5.2.5.2 Reliability

## Internal Consistency

Internal consistency refers to the degree of correlation between items designed to measure the same underlying concept or construct (Tavakol and Dennick 2011). The Cronbach's coefficient alpha ( $\alpha$ ) was used to describe the extent of intercorrelation between different domains of the BOL self-assessment (Tavakol and Dennick 2011). **Table 5-3** represents a reliability matrix anchored in classical test theory was adapted to judge the adequacy of internal consistency coefficients ( $\alpha$ ) considering sample size (Ponterotto and Ruckdeschel 2007). The domain-total correlations were also calculated using Pearson's correlation coefficient to assess how well each domain contributes to the overall construct measured by the BOL self-assessment. The correlation coefficient (r) was interpreted in line with the established criteria (< 0.49= week, 0.5 - 0.69= moderate, above 0.70 = strong) (Chan 2003).

ltem	Poting	Sample size			
nem	Rating	N < 100	N = 100 - 300	N>300	
≤ 6	Excellent	0.75	0.80	0.85	
	Good	0.70	0.75	0.80	
	Moderate	0.65	0.70	0.75	
	Acceptable	0.60	0.65	0.70	
7 - 11	Excellent	0.80	0.85	0.90	
	Good	0.75	0.80	0.85	
	Moderate	0.70	0.75	0.80	
	Acceptable	0.65	0.70	0.75	
≥ 12	Excellent	0.85	0.90	0.95	
	Good	0.80	0.85	0.90	
	Moderate	0.75	0.80	0.85	
_	Acceptable	0.70	0.75	0.80	

**Table 5-3.** Matrix for evaluating the adequacy of internal consistency coefficients of measures adapted from Ponterotto and Ruckdeschel (2007)

\*Internal consistency coefficients below the acceptable rating are considered unsatisfactory.

## Test-retest reliability

Test-retest reliability represents the consistency of a measurement instrument in producing the same results when measured multiple times on the same individual under the same condition (Fleiss 2011), which helps to determine stability and reproducibility in obtaining scores over time (Berchtold 2016). Having good test-retest reliability means that the results obtained from the measurement instrument are representative and less likely to be subject to measurement error or random fluctuations (Matheson 2019). At the 4-week follow-up, participants were asked: "Is your LBP getting better, staying the same or getting worse?". The baseline and 4-week follow-up data of participants who reported no change in LBP over the past 4 weeks were used to assess the test-retest reliability of the BOL self-assessment. As a widely used reliability index in test-retest analysis (Koo and Li 2016), intraclass correlation coefficient (ICC) was selected to assess the agreement between baseline and 4-week follow-up scores. ICC estimates and their 95% confident intervals were calculated based on single measurement, absolute-agreement, 2-way mixed-effects model (Koo and Li 2016). Following previous validation studies of health-related measurement instruments, ICC values between 0.5 and 0.74 is interpretated as low reliability, 0.75 -0.89 as moderate, and above 0.9 as high reliability (Bobak et al. 2018).

## 5.2.5.3 Validity

## Convergent validity

Convergent validity of the BOL self-assessment was assessed by correlations with other measures measuring similar constructs. Given the multi-factorial representation of biomedical, psychological, and psychosocial risk factors (Hill et al. 2008), SBST was selected as a reference standard to measure convergent validity of the BOL self-assessment tool (Hill et al. 2008). The convergent validity of the PB domain (the biological impact of LBP) was assessed using NPRS with PL domain (the impact of LBP on lifestyle) using RMDQ. Pearson's correlation coefficient was calculated to measure the degree of association with the correlation coefficient (r) interpreted in line with the established criteria (< 0.49= week, 0.5 - 0.69= moderate, above 0.70 = strong) (Chan 2003).

# Known-groups validity

This type of construct validity refers to an instrument's ability to discriminate differences between identified relevant groups (Davidson 2014). The BOL selfassessment classifies participants into NC and NP groups based on their total scores. The characteristics and differences between these two pain mechanisms are described in Chapter 2 (Section 2.8.1). NP is considered to arise from altered central nervous system nociception, commonly associated with central sensitisation (Nijs et al. 2023b). This may result in increased sensitivity and response to stimuli that do not normally cause pain, provoking greater pain intensity (Woolf 2011). Also, NP is often accompanied by other symptoms such as fatigue, sleep deprivation and depression (Galli 2023). These associated conditions may increase disability and reduce quality of life (Agnus Tom et al. 2022; Ge et al. 2022). In addition, as a result of complex interactions of biological, psychological and social factors, NP was reported to have a poor response to painkillers and common treatments that are effective for NC (Bułdyś et al. 2023), which requires multidisciplinary interventions or individualised treatment (Fitzcharles et al. 2021). In contrast, NC is considered to arise from activation of peripheral nociceptors as a protective response to actual damage or inflammation of body tissues (Inquimbert and Scholz 2012). NC generally manifests as severe and acute, with identifiable cause and location of the pain (Baliki and Apkarian 2015). Although NC can progress to chronicity and currently it is difficult to predict which populations might experience this transition (Apkarian et al. 2013), NC usually resolves with recovery and responds well to anti-inflammatory medications (Inquimbert and Scholz 2012). Therefore, it was hypothesised that the NP group categorised by the BOL self-assessment would have higher pain intensity, level of disability and risk of chronicity than the NC group.

The known-groups validity was assessed by calculating effect sizes for differences between NC and NP groups. A Shapiro-Wilk test was first performed to identify whether the score of RMDQ and BOL self-assessment were normally distributed (Shapiro and Wilk 1965). Differences on the scores of RMDQ and BOL self-assessment between the two groups were examined by t-test or nonparametric Wilcoxon Signed Rank test based on the normality of the data (King and Eckersley 2019). A chi-square test was calculated to compare the differences between the two groups in terms of SBST and NPRS score distribution (Pearson 1900).

Effect sizes for mean differences of the RMDQ and BOL self-assessment scores were quantified by calculating Cohen's d (Cohen 2013), while Cramer's V was calculated for the SBST and NPRS score (Rea and Parker 2014). Consistent with previous studies, the Cohen's d between 0.2 - 0.5 is interpretated as low, 0.5 - 0.8 as moderate, and above 0.8 as large (Eton et al. 2020). A Cramer's V between 0.07 - 0.21 is considered as low, between 0.21 to 0.35 as moderate and above 0.35 as high when the degree of freedom = 2 (Kim 2017).

#### Criterion validity

The BOL self-assessment aims to classify individuals with LBP in the workplace according to pain mechanisms into NC and NP phenotypes, each associated with specific levels of pain, disability, and prognosis (Alothman et al. 2017,2019). Widely accepted LBP questionnaires used to measure pain intensity, disability, and prognostic risk of developing highly disabling LBP include the NPRS, where high pain intensity is defined as a score of ≥7 (Boonstra et al. 2016). The RMDQ defines high disability as a score of ≥14 (Roland and Morris 1983). The SBST indicates a high risk of highly disabling LBP with a score of  $\geq$ 4 (Hill et al. 2008). In addition, for the working population, long term SA due to LBP (SA days  $\geq$  4 weeks) was also considered as a significant risk factor for many negative outcomes (Côté et al. 2008). The area under ROC curve (AUC) and 95% CI was calculated to describe the ability of the BOL self-assessment to correctly discriminate LBP population at high risk of disabling LBP under specific conditions (Fangyu and Hua 2018). Furthermore, as the 'gold standard' of the BOL self-assessment, the AUC and 95% CI of the SBST under these criteria were also calculated. In clinical research, an AUC of 0.60 to 0.69 was considered as low level of discrimination, 0.70-0.79 as moderate, and above 0.80 as high discrimination (Mandrekar 2010). The non-parametric DeLong's test was used to compare the ability to discriminate high-risk LBP populations in the workplace between the BOL selfassessment and the SBST (DeLong et al. 1988).

## 5.2.6 Ethical consideration

As the source of the dataset used in this study, the mixed-methods BOL study received ethical approval from the Research Ethics Committee of Cardiff University School of Healthcare and the NHS (<u>Section 7.3.3</u>). All data handling complied with the General Data Protection Regulation (GDPR) and the consent agreements to maintain

confidentiality and security. All identifiable data was stored separately from the research data and linked using a unique 8-digit identifier. Participant data was anonymised using the 8-digit identifier. All data was encrypted and securely stored on the Advanced Research Computing at Cardiff (ARCCA) server managed by Cardiff University.

# 5.3 Results

Data of 136 participants (36 males, 99 females; mean age = 42.6 years, SD = 10.0) who completed the baseline BOL self-assessment, NPRS, RMDQ and SBST were used in this study. Follow up data of 21 participants who completed the BOL self-assessment after receiving the BOL intervention for 4 weeks were used to assess the test-retest reliability. **Table 5-4** provides descriptive statistics for the study sample. In brief, of the participants, 31.6% (n = 43) reported experiencing LBP within the last 3 months, and 37% (n = 50) reported experiencing LBP for more than 6 months in the current episode. Although half of the participants had sickness absence due to LBP, most (84.6%) remained in the same job.

Table 5-4. Characteristics of participants in the study sample (n = 136) and scores
on selected measurement instruments at baseline

on selected measurement instruments at baseline	
Pain duration, <i>n</i> (%)	
0 - 7 days	25 (18.4)
8 - 14 days	15 (11.0)
15 days to 1 month	10 (7.3)
1 - 3 months	22 (16.2)
3 - 6 months	14 (10.3)
Over 6 months	50 (36.8)
Pain free periods, <i>n</i> (%)	
0 - 3 months	43 (31.6)
4 - 6 months	14 (10.3)
7 - 12 months	18 (13.3)
1 - 10 years	40 (29.4)
Over 10 years	21 (15.4)
Role change linked to LBP, <i>n</i> (%)	
Remained in the same role	115 (84.6)
Remained in the same role >= 13 weeks	8 (5.9)
Moved to a new role	3 (2.2)
Moved to a new role >= 13 weeks	6 (4.4)
Left job but able to return to work	1 (0.7)
Other	3 (2.2)
Sickness absence due to LBP, <i>n</i> (%)	
Never had time off	71 (52.2)
Less than 1 week	22 (16.2)

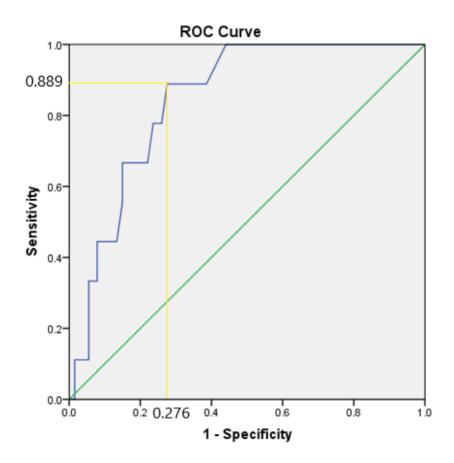
1 - 2 weeks 2 - 4 weeks 4 - 6 weeks 6 - 8 weeks	11 (8.1) 11 (8.1) 5 (3.7) 5 (3.7)
2 - 6 months	8 (5.8)
More than 6 months	3 (2.2)
BOL self-assessment (points), mean (SD)	
PB	19.8 (9.2)
PW	2.1 (1.5)
PL	2.8 (2.1)
PP	7.2 (2.7)
Total	31.9 (12.6)
RMDQ (points), mean (SD)	6.2 (5.0)
NPRS (points), <i>n</i> (%)	
0 - 3	38 (27.9)
4 - 6	67 (49.3)
7 - 10	31 (22.8)
SBST, n (%)	
Low Risk	85 (62.5)
Medium Risk	42 (30.9)
High Risk	9 (6.6)

**SD**: Standard Deviation; **LBP**: Low Back Pain; **BOL**: BACKonLINE<sup>™</sup>; **PB**: Pain Behaviour; **PL**: Impact of LBP On Lifestyle; **PW**: Impact of LBP On Work; **PP**: Pain Perception; **SBST**: STarT Back Screening Tool; **RMDQ**: Roland Morris Disability Questionnaire; **NPRS**: Numeric Pain Rating Scale

## 5.3.1 BACK-on-LINE™ self-assessment cut-off point

Nine participants diagnosed with high-risk LBP by SBST had a mean BOL selfassessment score of 46.2 points (SD=10.5). Participants classified as low-risk (n=85) and medium-risk (n=42) by SBST had mean BOL scores of 25.8 (SD=8.2) and 41.2 points (SD=12.2), respectively.

The optimal cut-off point for the BOL self-assessment was determined in the ROC curve analysis. The point closest to the upper left corner was identified with a sensitivity of 0.889 and a specificity of 0.724 (Figure 5-1).



**Figure 5-1.** Receiver Operating Characteristic curve of different cut-off points for the BACK-on-LINE<sup>™</sup> self-assessment using the STarT Back Screening Tool as reference standard.

BOL: BACK-on-LINE™; ROC: Receiver Operating Characteristic

\*Blue Line: shows the performance of BOL self-assessment at varied classification cut-off points, plotting the sensitivity (true positive rate) versus 1-specificity (false positive rate); **Green Line**: represents the visual reference line of no-discrimination, where the classifier has no predictive power and equivalent to random guessing; **Yellow Line**: marks the closet point to the left corner of the ROC curve, which represents a cut-off point with ideal accuracy in correctly identifying positive cases.

**Table 5-5** presents the sensitivity, specificity, PPV, NPV, LR+ and LR- of various BOL self-assessment cut-off points for subgrouping LBP. The score of 35.5, with the highest Youden index (J = 0.613), showed the same sensitivity and specificity of the closest point on the ROC curve, indicating that 35.5 is the optimal cut-off point for the BOL self-assessment in the working population with LBP.

Cut-off point	Sensitivity	Specificity	PPV (%)	NPV (%)	LR+	LR-	Youden Index
31.5	0.889	0.614	14	98.7	2.3	0.2	0.503
32.5	0.889	0.654	15.4	97.6	2.6	0.2	0.542
33.5	0.889	0.685	16.7	98.9	2.8	0.2	0.574
34.5	0.889	0.717	18.2	98.9	3.1	0.2	0.605
35.5	0.889	0.724	18.6	98.9	3.2	0.2	0.613
36.5	0.778	0.74	17.5	97.9	3.0	0.3	0.518
37.5	0.778	0.764	18.9	98	3.3	0.3	0.542
38.5	0.667	0.78	17.6	97.1	3.0	0.4	0.446
39.5	0.667	0.819	20.7	97.2	3.7	0.4	0.486
41	0.667	0.843	23.1	97.3	4.2	0.4	0.509
42.5	0.667	0.85	24	97.3	4.4	0.4	0.517
43.5	0.556	0.85	20.8	96.4	3.7	0.5	0.406
44.5	0.444	0.866	19.1	95.7	3.3	0.6	0.311
46	0.444	0.882	21.1	95.7	3.8	0.6	0.326
47.5	0.444	0.89	22.2	95.8	4.0	0.6	0.334
48.5	0.444	0.913	26.7	95.9	5.1	0.6	0.358
50	0.444	0.921	28.6	95.9	5.6	0.6	0.366
51.5	0.333	0.921	23.1	95.1	4.2	0.7	0.255
52.5	0.333	0.937	27.3	95.2	5.3	0.7	0.27
54	0.333	0.945	30	95.2	6.1	0.7	0.278
56	0.111	0.945	12.5	93.8	2.0	0.9	0.056
58	0.111	0.953	14.3	93.8	2.4	0.9	0.064
59.5	0.111	0.961	16.7	93.9	2.8	0.9	0.072
61	0.111	0.969	20	93.9	3.6	0.9	0.08
62.5	0.111	0.984	33.3	94	6.9	0.9	0.095

**Table 5-5.** Diagnostic metrics for different cut-off points of the BACK-on-LINE<sup>™</sup> self-assessment

**PPV**: positive predictive value; **NPR**: negative predictive value; **LR+**: positive likelihood ratio; **LR-**: negative likelihood ratio

\*The score of 35.5, marked in red, exhibited the highest Youden Index, representing an optimal BOL selfassessment cut-off point.

The cut-off point 35.5 of the BOL self-assessment showed high sensitivity (0.889) and moderate specificity (0.724). The NPV suggests that there is a 98.9% chance that those classified as NC do not have NP. Individuals with NP are 3.2 times more likely to be classified as NP by the BOL self-assessment at the cut-off point of 35.5 compared to those without NP. The LR+ and LR- of the cut-off point 35.5 fall within the range of 2-5 (LR+) and 0.2 - 0.49 (LR-), indicating weak but important test efficiency for the BOL self-assessment.

Given the integer nature of the BOL score, the final cut-off point was set at 36 points to avoid conflicts with the statistically optimal value. Thus, participants with a BOL self-assessment score below 36 were classified as having NC, while those with scores of 36 or higher were classified as having NP.

# 5.3.2 Reliability

# 5.3.2.1 Internal consistency

Following the matrix for estimating the adequacy of the internal consistency coefficients (**Table 5-3**), the BOL self-assessment with 34 scorable items achieved moderate internal consistency (Cronbach's alpha ( $\alpha$ ) = 0.83) with a sample with 136. The subscales of PB, PP and PL exhibited moderate to strong domain-total correlations, while PW presented less satisfactory results (**Table 5-6**).

Table 5-6. Internal consistency and domain-total correlations of	the BACK-on-LINE™ self-
assessment	

Category	Number of items	Domain-Total Correlation(r)	Cronbach's Alpha(α)	Rating
PB	18	0.96		
PW	6	0.31		
PL	3	0.64		
PP	7	0.75		
BOL self-assessment total	34		0.83	Moderate

**BOL**: BACK-on-LINE<sup>™</sup>; **PB**: Pain Behaviour; **PL**: Impact of LBP On Lifestyle; **PW**: Impact of LBP On Work; **PP**: Pain Perception

\*Cronbach's alpha rating according to the matrix proposed by Ponterotto and Ruckdeschel (2007)

\*All domain-total correlations are statistically significant (p<0.001)

# 5.3.2.2 Test-Retest Reliability

The BOL self-assessment had moderate test-retest reliability (stability) with an ICC of 0.88 (95% CI: 0.78-0.94) over a 4-week interval. Of the four domains, the PB had a high stability (ICC = 0.91, 95% CI: 0.83-0.95). The PL (ICC = 0.56, 95% CI: 0.28-0.76) and PP (ICC = 0.63, 95% CI: 0.38-0.80) domains demonstrated moderate stability. Low stability was observed in the PW domain (ICC = 0.41, 95% CI: 0.08-0.65).

# 5.3.3 Validity

# 5.3.3.1 Convergent validity

The results of the correlation analysis for convergent validity is detailed in **Table 5-7**. The results showed a moderately strong correlation between the BOL self-assessment and SBST with statistical significance (r=0.67, p< 0.001). The PB domain demonstrated a slightly weak but significant correlation with the NPRS (r=0.47, p< 0.001). PL domain measuring the impact of LBP on lifestyle had a significant moderate correlation (r = 0.59; p<0.001) with the RMDQ.

Table 5-7. Correlations between the BACK-on-LINE <sup>™</sup> self-assessment and other
validated measurement instruments measuring similar dimensions

	NPRS	RMDQ	SBST
PB	0.46***	0.56***	0.58***
PW	- 0.01	0.10	0.18*
PL	0.38***	0.59***	0.55***
PP	0.31***	0.44***	0.60***
BOL self-assessment total	0.47***	0.61***	0.67***

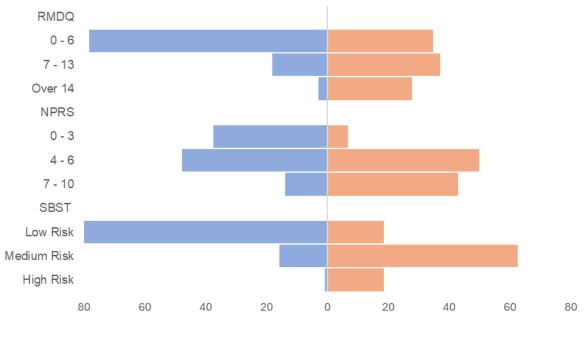
\*\*\* p < 0.001; \*\* p < 0.01; \* p< 0.05.

**BOL**: BACKonLINE<sup>™</sup>; **PB**: Pain Behaviour; **PL**: Impact of LBP On Lifestyle; **PW**: Impact of LBP On Work; **PP**: Pain Perception; **SBST**: STarT Back Screening Tool; **RMDQ**: Roland Morris Disability Questionnaire; **NPRS**: Numeric Pain Rating Scale

## 5.3.3.2 Known-groups validity

93 (68.4%) participants in this study were categorised in the NC group and 43 in the NP group (31.6%) using the new cut-off point (36 points). The mean total score of BOL self-assessment in the NP group is nearly twice that of the NC group (46.8 and 25.0, p<0.001) (**Table 5-8**).

As the RMDQ scores does not conform to a normal distribution (Appendix 7), a Wilcoxon Signed Rank test was conducted to compare the level of disability between the NC and NP groups classified by the BOL self-assessment. The NP group shows significantly higher RMDQ scores (9.93  $\pm$  5.88) than the NC group (4.47  $\pm$  3.45; p < 0.001). A chi-square test of the NPRS and SBST scores in the NC and NP groups showed significant differences in the distribution of pain intensity and LBP risk between the two groups (p<0.001) (**Table 5-8**). **Figure 5-2** demonstrates the differences in the distribution of the Back-on-Line<sup>TM</sup> subgroups in terms of pain intensity, disability, and risk of chronicity.



Nociceptive Pain

**Figure 5-2.** Comparison of distribution of pain intensity, disability, and risk of chronicity in Back-on-Line<sup>™</sup> subgroups.

**NPRS**: Numerical Pain Rating Scale; **SBST**: STarT Back Screening Tool; **RMDQ**: Roland Morris Disability Questionnaire

Effect size analyses indicated that the BOL self-assessment had high known group validity for discriminating the subgroup scores of PB, PL, PP domains, overall BOL self-assessment and RMDQ. **Table 5-8** presents the results of the t-test, non-parametric test and chi-square test conducted to determine the known-groups validity.

	Nociceptive Pain		Nociplastic Pain		Z	p- value	Effect size
Variables	n= 93		n= 43				
	Μ	SD	М	SD	-	Value	Cohen's d
RMDQ score	4.47	3.45	9.93	5.88	5.59	<0.001	1.25
PB score	14.92	4.44	30.42	7.71	8.98	<0.001	2.73
PW score BOL self-	1.87	1.39	2.51	1.56	2.4	0.017	0.44
assessment total score	25	6.28	46.81	9.43	9.36	<0.001	2.94
					t	p- value	
PP score	6.05	2.3	9.63	1.81	8.96	<0.001	1.65
PL score	2.15	1.89	4.26	1.67	6.27	<0.001	1.16
	Ν	% in column	Ν	% in column	<b>x</b> <sup>2</sup>	p- value	Cramer's V
SBST					53.77	<0.001	0.63
Low Risk	77	82.8	8	18.6			
Medium Risk	15	16.13	27	62.79			
High Risk	1	1.08	8	18.60			
NPRS					19.96	<0.001	0.38
0 - 3	35	37.63	3	6.98			
4 - 6	45	48.39	22	51.16			
7 - 10	13	13.98	18	41.86			

**Table 5-8.** Differences in self-assessment score, pain intensity, disability and risk of chronicity between low back pain subgroups classified by BACK-on-LINE<sup>™</sup> self-assessment

M: mean; SD: standard deviation; t: t test value; z: Wilcoxon Signed Rank test value; X<sup>2</sup>: chi-square test value; N: number; PB: Pain Behaviour; PL: Impact of LBP On Lifestyle; PW: Impact of LBP On Work; PP: Pain Perception; BOL: BACKonLINE™; SBST: STarT Back Screening Tool; RMDQ: Roland Morris Disability Questionnaire; NPRS: Numeric Pain Rating Scale

# 5.3.3.3 Criterion validity

The BOL self-assessment demonstrated moderately strong criterion validity in discriminating high-risk LBP individuals based on the disability level (AUC = 0.77, 95% CI: 0.66-0.88) and SA (AUC = 0.71, 95% CI: 0.60-0.82). The criterion validity in discriminating high-risk LBP individuals based on the pain intensity (AUC=0.67, 95% CI: 0.57-0.77) and pain duration (AUC=0.68, 95% CI: 0.59-0.76) was also close to moderate.

Compared to the reference standard (SBST), the BOL self-assessment BOL was better in discriminating high risk LBP individuals in the workplace on selected criteria. A significant difference was observed between BOL self-assessment and SBST in discriminating high-risk participants with severer pain intensity (AUCs=0.67 and 0.54, p=0.017) and disability (AUCs=0.77 and 0.54, p<0.001), longer pain duration (AUCs=0.68 and 0.53, p<0.001) and SA from work (AUCs=0.71 and 0.52, p=0.016).

#### 5.4 Discussion

#### 5.4.1 Summary of findings

The results of this study established a cut-off point of 36 for the BOL self-assessment to classify subgroups of LBP in workplace based on dominant pain mechanism. The new cut-off point showed high sensitivity (0.889) and moderate specificity (0.724) against SBST as a reference standard.

The BOL self-assessment demonstrated a moderate internal consistency (Cronbach's alpha ( $\alpha$ ) = 0.83) and test-retest reliability over a 4-week interval (ICC= 0.88, 95% CI: 0.78-0.94), confirming moderate reliability of the BOL self-assessment. Moderate correlations were found between the BOL self-assessment and other validated measurement instruments measuring similar LBP dimensions, such as SBST (r=0.67, p<0.001), suggesting moderate construct validity of the BOL self-assessment. In addition, the significant differences in NPRS, RMDQ, and SBST scores were observed in subgroups based on the new cut-off point, demonstrating a high known-groups validity of the BOL self-assessment to discriminate between NC and NP subgroups in the workplace LBP population. Finally, BOL self-assessment demonstrated moderate criterion validity and was superior to the SBST in discriminating high-risk disabling LBP populations from workplace by pain intensity (NPRS ≥7; AUCs=0.67 and 0.54, p=0.017), pain duration (≥6 months; AUCs=0.68 and 0.53, p<0.001), disability (RMDQ ≥14; AUCs=0.77 and 0.54, p<0.001) and SA from work (≥4 weeks; AUCs=0.71 and 0.52, p=0.016).

#### 5.4.2 Cut-off point

In this study, the Youden Index and the ROC curve was used to determine the new cut-off point (36 points) for the BOL self-assessment to discriminate between LBP subgroups in the working population (Youden 1950; Zweig and Campbell 1993). A variety of methods for determining the optimal cut-off point have been reported in previous studies (Tustumi 2022). The most popular approach was to identify the point on the ROC curve with the shortest distance from the upper-left corner of the unit

square (Zweig and Campbell 1993). Whilst this approach was used alone to determine the previous cut-off point for the BOL self-assessment in the study by Alothman et al. (2019), the reason for using the Youden index in this study is because it provides a clear criterion for selecting the optimal cut-off point by maximising overall diagnostic effectiveness of statistically highest sensitivity (identifying all true-positive cases) and specificity (no false-positive cases were found) (Luo and Xiong 2013; Monaghan et al. 2021). Also, using the Youden Index as a standardised method for determining cut-off points would promote consistency in future BOL studies as well as comparisons between studies using the BOL self-assessment for diagnostic testing (Reibnegger and Schrabmair 2014).

Using the new cut-off point, the BOL self-assessment correctly captured a large proportion of true positives (sensitivity = 0.889), indicating that the BOL self-assessment is moderately effective in identifying individuals with NP (true positive). However, the PPV showed that individuals classified as NP by the BOL self-assessment only had an 18.6% probability of having NP. It is important to note that the value of PPV is significantly affected by the prevalence of the condition in the population being tested (Parikh et al. 2008). In populations with a low prevalence, even tests with high sensitivity and specificity may have lower PPV values (Parikh et al. 2008). A recent review estimated that the prevalence of NP in the general LBP population is between 5-15% (Fitzcharles et al. 2021). In this study, the high-risk group of SBST was selected as true positives (NP). Only 9 individuals were classified as high-risk LBP by SBST, suggesting that the prevalence of NP in this sample was only 6.7% (9/136). The low prevalence of NP in the sample used for this study explains why the the BOL self-assessment has a low PPV value, despite having a sensitivity close to the excellent clinical test standard (90%) (White et al. 2023).

For the other metrics of the new cut-off point, the high NPV (98.9%) indicates that individuals classified as NC by the BOL self-assessment are highly likely to be free of NP. The low LR- (0.2) also suggests that the negative test result of the BOL self-assessment (NC) significantly decreases the probability of having NP, reinforcing the test efficiency of the BOL self-assessment in ruling out the condition of NC. In addition, the moderate specificity (0.724) indicates that there may be a small proportion of individuals incorrectly classified as NP (false positives) in this study. These results

collectively suggest that the current BOL self-assessment has better diagnostic performance in ruling out individuals with NC (true negatives) than in identifying those with NP (true positives) using the new cut-off point. This finding is consistent with the grouping approach used in the current BOL self-assessment, which combines neuropathic and nociplastic pain into one NP group considering their shared characteristic of pain hypersensitivity (Nijs et al. 2021). However, as the understanding of pain mechanisms deepens, the binary categorisation of NC and NP may no longer be applicable for the BOL self-assessment in the future when the differences between different pain mechanisms are clarified. Therefore, future studies of BOL should further optimise the grouping of neuropathic and nociplastic pain based on the existing good diagnostic performance of the BOL self-assessment on ruling out NC, to further enhance the individualisation of BOL.

In this study, given the absence of a 'gold standard' for NP diagnosis to date (Foubert et al. 2023), the extensively validated SBST was selected as the reference standard as Alothman et al. (2019). Although the SBST has been listed as one of the most common measures for NP, there is no clear consensus on the gold standard to assess NP (Bułdyś et al. 2023). Therefore, the diagnostic accuracy results of the BOL self-assessment under the new cut-off point might change with the future establishment of a gold standard for NP measurement. In addition, the results of this study reflect the accuracy of the BOL self-assessment in categorising LBP populations from specific workplaces under the new cut-off point, with some diagnostic metrics influenced by the prevalence of NP (Parikh et al. 2008). Therefore, future BOL studies need to investigate how varying NP prevalence in different work settings and LBP populations may affect the diagnostic performance of the BOL self-assessment.

#### 5.4.3 Reliability

In the study, the BOL self-assessment reported a moderate internal consistency (Cronbach's alpha = 0.83). For measurement instruments with multidomain design, the moderate internal consistency indicates that there is good correlation between the domains of the measure, whereby the domains collectively measure the same concept or construct (Mokkink et al. 2019). It also indicates that the structure of the BOL self-assessment is well-designed, with no significant redundancy or deviation (McCrae et al. 2011). The internal consistency results of this study are comparable to other

multidimensional LBP assessment tools such as SBST, ODI and RMDQ, with Cronbach's alpha reported ranging from 0.79 to 0.89 in LBP populations (Hill et al. 2008; Jenks et al. 2022; Koivunen et al. 2024).

Inconsistent with the moderate to strong correlations with the overall construct of the BOL self-assessment of other subdomains, there was low domain-total correlation in the PW domain (r =0.31). Items in the PW domain was designed to measure various aspects of LBP in the workplace, including perceived cause, workplace support, work status, duration of SA, and likelihood of returning to work. Although these factors are related to LBP in the workplace, they involve different constructs (physical, organisational and psychosocial). Therefore, there may not be strong correlations between an individual's responses to these questions, resulting in the low domain-total correlation of PW. For example, the participants may agree that their job contribute to their LBP, but still receive support from their line managers. In addition, previous research has highlighted that participants may alter their answers to certain questions based on their perceived social desirability, which in turn leads to response bias (Bergen and Labonté 2020). Individuals may under-report the impact of LBP on their work to avoid issues with stigma and job insecurity (Penn et al. 2020; Yang et al. 2023). Thus, the low domain-total correlation of the PW domain found in this study suggests that the work-related factors of LBP may be a complex domain with challenges to accurately measure the impact of LBP.

The BOL self-assessment also demonstrated a moderate test-retest reliability (ICC = 0.88; 95% CI: 0.78-0.94), with PB domain assessing biological factors of LBP (e.g. pain intensity, duration, and location) demonstrating excellent test-retest reliability (ICC = 0.91, 95% CI: 0.83-0.95) across the four-week interval. These results are in agreement with previous psychometric evaluations of the BOL self-assessment by Alothman et al. (2019), which reported an excellent four-week test-retest reliability of PB domain in a small sample of mixed populations with LBP (ICC = 0.91, 95% CI: 0.81-0.95).Our results are comparable to the test-retest reliability of other validated measurement instruments for pain including the Brief Pain Inventory (BPI) reporting similar ICC ranging from 0.84 to 0.90 over a one-week interval (Jelsness-Jørgensen et al. 2016), and the McGill Pain Questionnaire (MPQ) of excellent test-retest reliability over a five-day interval (ICC = 0.96) (Grafton et al. 2005). For people with chronic MSK

pain, pain experiences tend to remain relatively stable over short periods (less than four weeks) (Øverås et al. 2022). However, measurement instrument like the NPRS, which assesses single dimension (pain intensity), has been reported to have variable test-retest reliability (ICC = 0.67-0.96) in LBP populations (Stratford and Spadoni 2001). This highlights the limitations of single-dimensional measures in capturing the full complexity of pain experiences. The use of multidimensional assessment methods, particularly those incorporating subjective sensory and affective descriptions, is crucial as it allows participants to consistently describe pain characteristics even when there are slight variations in pain intensity (Wideman et al. 2019). By capturing a broader range of pain dimensions, these methods would provide a more comprehensive and reliable assessment of pain, thereby addressing the inconsistencies seen with single-dimensional measures (Fillingim et al. 2016).

It was noted that the PW domain showed the lowest test-retest reliability (ICC = 0.41) and the total score (mean= 2.07, SD= 1.47). Similarly, Sarallah et al. (2016) developed a multidisciplinary questionnaire to measure work-related LBP (Sarallah et al. 2016). However, the test-retest reliability of this guestionnaire at 2-week intervals among 452 healthcare workers was reported to be low (ICC<0.5) (Sarallah et al. 2016). The low test-retest reliability for measurement instruments designed with work-related domains highlights the complexity of LBP in the workplace. As a complex and multifaceted experience, pain can be influenced not only by physical factors but also by psychological and cognitive processes (Craig and MacKenzie 2021). Compared to assessing biological factors of the LBP, the measurement of psychosocial and workrelated factors can be more challenging as it involves various aspects of the workplace (e.g., working environment, job satisfaction, and organisational support). These psychosocial factors are associated with individual behavioural constructs such as self-efficacy (Edwards et al. 2016), pain beliefs (Fors et al. 2022) and emotional resilience (Hemington et al. 2017). Meanwhile, these individual behavioural factors are more susceptible to external factors and may vary by week or even by day (Rodriguesde-Souza et al. 2016), making it difficult to obtain consistent measurements over time. Many people with LBP continue working despite their conditions due to financial pressures, concerns of job security and the fear of facing disbelief from coworkers (Froud et al. 2014). These external psychosocial factors further complicate how individuals perceive and report their work-related challenges with LBP (Froud et al.

2014). Thus, the PW domain may not have been sensitive enough due to the complexity of LBP in the workplace. Therefore, future BOL studies should consider the variability in these work-related LBP factors and aim to improve the stability of PW domain in capturing the experiences of individuals managing LBP in the workplace.

#### 5.4.4 Validity

In this study, SBST was used as criterion measure to establish the cut-off point. As described in Chapter 2, definitions and diagnostic criteria for different pain mechanisms are still being explored with several existing measurement instruments designed for identifying pain characteristics (Bułdyś et al. 2023). However, those measurement instruments only consider a single dimension of LBP. Of the validated multi-domain measurement instruments, SBST was therefore selected as framed withing the BPS model, designed for LBP populations and utilised in cut-off point calculation of the previous BOL self-assessment version by Alothman et al. (2019). In this study, the BOL self-assessment demonstrated good convergent validity with the SBST (r =0.67, p<0.001). There were also significant correlations between all subdomains of the BOL self-assessment and the SBST (r=0.18 - 0.60). These results demonstrate the capacity of the BOL self-assessment in capturing the psychological and social factors that contribute to LBP.

In addition, the BOL self-assessment demonstrated moderate convergent validity with other LBP measurement instruments assessing similar constructs, such as the NPRS and RMDQ (r = 0.47-0.61, p<0.001). The specific BOL subdomains also demonstrated the highest correlations with instruments assessing the same dimensions, including the PB domain with the NPRS (biological factors; r = 0.46, p<0.001) and the PL domain with the RMDQ (impact of LBP on lifestyle; r= 0.59, p<0.001), indicating that the BOL self-assessment can effectively capture the same dimensions as respective well-validated instruments. It was noted that there was no significant correlation between the PW domain with NPRS and RMDQ in this study. Whilst PB and PL domains consider biological and psychosocial factors, the PW domain was designed to assess the organisational impact of LBP, focusing on how it affects the working environment and individual's functionality. Thus, the lack of correlation indicates that the PW domain RMDQ that focused on pain intensity and functional limitations. Also, the significant

correlations of the overall BOL self-assessment with NPRS, RMDQ and SBST further suggest that the PW domain should not be considered as a discrete construct, but as an integrated concept within the whole structure. Therefore, the results of the psychometric validation of PW domain should be viewed as a reflection of the complexity of LBP in the workplace and the interactions of various factors in the development and progression of LBP.

The LBP subgroups classified using the new cut-off point also showed high knowngroups validity to effectively discriminate the NC and NP groups in the scores of BOL self-assessment, RMDQ and SBST. Low discrimination was observed in the scores of PW domain and the NPRS. As previously described, personal preferences and psychosocial factors play significant roles in determining work-related LBP outcomes beyond the pain mechanism (Froud et al. 2014). In addition, studies have shown that external workplace factors like job demands, physical workload, and workplace support can also affect LBP outcomes (Keyaerts et al. 2022; Bezzina et al. 2023), but these work-related factors are not always associated with pain mechanisms. Thus, the low but significant known-groups validity in the PW domain further indicates the complexity and multifactorial nature of LBP. Meanwhile, the low discrimination of NPRS scores by the BOL self-assessment reflects that unidimensional measures, such as NPRS, may not effectively capture the complexities of LBP, particularly the psychosocial dimensions that contribute to different pain mechanisms (Dansie and Turk 2013). Also, recent research has shown that the overlap exists between different pain mechanisms (Johnston et al. 2023). Individuals with either NC or NP may report similar levels of intensity (Bułdyś et al. 2023), making it difficult to distinguish between the pain mechanisms based on pain intensity alone.

In addition to the moderate convergent validity and high known-groups validity, the BOL self-assessment also demonstrated a moderate criterion validity (AUC = 0.68-0.77) in discriminating individuals with high risk of disabling LBP based on factors such as pain intensity, duration, disability level, and SA. Previous studies have shown that pain intensity, duration, and baseline disability level are associated with the development of disabling LBP (Stevans et al. 2021; Yoo and Kim 2024). Recent research further indicates that negative work-related factors combined with long SA are associated with increased risk of disabling LBP (d'Errico et al. 2022). The

moderate criterion validity suggests that the BOL self-assessment is reasonably effective at discriminating those likely to experience severe functional impairment and disruption of work ability. For the workplace LBP management, the results suggest that the BOL self-assessment could be used as a useful tool for early identification of individuals at risk of disabling LBP as recommended by NICE (NICE 2019a), to allow for individualised interventions at an early stage, potentially reducing the burden of long-term disability and SA (Fisker et al. 2022). However, it is important to note that as the data were collected concurrently, the analysis can only reflect the BOL self-assessment's ability to discriminate individuals with associated risk factors of disabling LBP at the time of assessment, rather than predicting those would have disabling LBP in the future. Therefore, although the BOL self-assessment presents the potential to be an early screening tool for future workplace LBP management, the available evidence is insufficient. Future studies are needed to further explore the predictive validity of the BOL self-assessment for disabling LBP in the workplace.

Interestingly, it was observed that the BOL self-assessment (AUC = 0.68-0.77) performed better than the reference standard SBST (AUC = 0.52-0.54), especially when identifying LBP population with longer SA from work (AUCs=0.71 and 0.52, p=0.016). One possible explanation for this is that BOL captures a wider spectrum of LBP factors, particularly those related to work and employment, while the SBST focuses on classifying the risk of chronicity and disability based on pain and psychosocial factors (Hill et al. 2008). The BOL self-assessment was developed with the PW domain which assesses on how LBP impacts an individual's ability to work and employment status. SBST, while effective in clinical settings, was not specifically designed for workplace with less focus on work-related constructs (Unsgaard-Tøndel et al. 2021). In addition, the sample used in this study were from the workplace where the LBP may be attributed to a variety of work-related factors, such as workplace stress and job insecurity due to LBP (Mathew et al. 2013). The difference in sample source may explain why the SBST showed high criterion validity in a clinical sample (AUC=0.885, 95% CI: 0.818-952) (Hill et al. 2010a) but low criterion validity in the working population, under the same criteria of SA for more than 4 weeks for high-risk disabling LBP. Therefore, the better performance of the BOL self-assessment indicates it may be more likely to discriminate those at high risk of disabling LBP but remaining

in employment than those who have received primary care, to whom the SBST would be more applicable (Medeiros et al. 2021).

## 5.4.5 Strengths and limitations

The main strengths of this study was the large sample of participants (n=136) obtained across diverse occupational settings, which enhanced external and internal validity of the results. The new cut-off point of the BOL self-assessment showed a high sensitivity (0.889) and moderate specificity (0.724). Using this new cut-off point, the BOL self-assessment showed moderate internal consistency (Cronbach's alpha ( $\alpha$ ) = 0.83) and stability (ICC =0.88, 95% CI: 0.78-0.94) over a 4-week period. It also demonstrated moderately strong convergent validity (r =0.47-0.67) in measuring relevant constructs within the LBP population and high known-groups ability in discriminating the scores of pain subgroups. Furthermore, discrimination of high-risk disabling LBP individuals based on pain intensity (NPRS  $\geq$ 7), duration ( $\geq$ 6 months), disability level (RMDQ  $\geq$ 14) and SA ( $\geq$ 4 weeks) showed moderate criterion validity outperforming the reference standard SBST.

However, there are also several limitations of this study. Firstly, as with other patient reported outcome measures (PROMs), the tool may suffer from self-report bias (Althubaiti 2016), related to potential personal social desirability or external factors of the workplace (Latkin et al. 2017). To limit this bias, participants were informed that their participation would remain confidential from the employers and that no individual data would be shared, offering a good level of confidence to reduce this form of bias (Larson 2019). In addition, the similarity of the results between multiple data sources suggests that the sample included in this study might be unlikely to be subject to social desirability bias (Althubaiti 2016).

Secondly, face validity or responsiveness has not been assessed in this study. Face validity has been widely used as a measure to ensure that an instrument comprehensively covers all relevant dimensions (Lavrakas 2008). As a non-statistical type of validity (Anastasi and Urbina 1997), it is often used for measurement instrument validation on a starting point. In previous research, Alothman et al. (2017) reported good face validity of the BOL self-assessment through two rounds of expert Delphi studies with participant opinions (Alothman et al. 2017). Compared to the

previous version (detailed in the <u>Appendix 2</u>), although there have been some changes in number of items and scores of some items, the domain settings and the dimensions have not changed thus maintaining the original good face validity.

In addition, the PW domain reported low test-retest reliability (ICC =0.41, 95% CI: 0.08-0.65) and known-groups validity (Cohen's d =0.44) in this study. As discussed, the low stability and subgroups score discrimination of the PW domain reflected the complexity of work-related LBP and the challenge of capturing characteristics of this construct (Sarallah et al. 2016; Serranheira et al. 2020). Optimisation or the inclusion of more work-related items could be considered to better reflect the actual difficulties experienced by people in the work environment because of LBP. Besides, qualitative studies (e.g., interviews with BOL participants) could also provide deeper insights into the PW domain, thus helping to optimise and improve the assessment tool (Busetto et al. 2020).

A potential limitation of the BOL self-assessment tool was the focus on only two pain mechanisms, nociceptive (NP) and nociplastic (NC) pain, without including neuropathic pain as a separate subset. This decision was influenced by the specific context of the workplace setting. In occupational setting, individuals with neuropathic pain, typically characterised by high-intensity pain, are more likely to seek medical help are likely unable to participate in work thus would be unsuitable to self-manage. Therefore, focusing on NC and NP pain types was considered more relevant for the working population targeted by the BOL intervention whilst in workplace. Further, Nijs et al. (2023) propose that pain mechanisms often coexist as a mixture of nociceptive, neuropathic, and/or nociplastic pain. It could be suggested that as the neuropathic pain subsides, other pain mechanisms, such as NP or NC pain may persist as the person resumes work thus continuing to offer relevance (Nijs et al. 2023b). Nevertheless, recent research, such as Bittencourt et al. (2022), using the PainDETECT questionnaire (PD-Q), has demonstrated that individuals with neuropathic pain tend to have higher pain intensity than those with NP (Bittencourt et al. 2022). The findings from Bittencourt et al.'s study suggest that distinguishing between these pain mechanisms could provide more nuanced insights into LBP management potentially highlighting the need for and importance of refining pain classification in future research.

## 5.5 Conclusion

Overall, the new cut-off point of the BOL self-assessment demonstrated a good diagnostic accuracy with high sensitivity (0.889) and NPV (98.9%). The BOL selfassessment demonstrated good reliability in assessing LBP populations in the workplace, with moderate internal consistency (Cronbach's  $\alpha$  = 0.83) and test-retest reliability (ICC = 0.88, 95% CI: 0.78-0.94) over a 4-week interval. The subdomains and the overall BOL self-assessment was significantly correlated with other measurement instruments assessing similar constructs (NPRS, RMDQ, SBST), indicating a moderate convergent validity. This study showed a high known-groups validity of the BOL self-assessment at a cut-off point of 36, effectively discriminating between LBP populations by pain mechanisms. This study also detected moderately sufficient criterion validity of the BOL self-assessment for identifying high-risk disabling LBP populations with high levels of pain intensity and disability, long-term pain duration and SA. Interestingly, the BOL self-assessment was better at identifying high-risk disabling LBP populations from workplace than the SBST. The evidence in this chapter shows that the BOL self-assessment is a reliable and valid tool in the LBP population from workplace.

The next chapter examines the technological feasibility, acceptability, and potential benefits of delivering individualised self-management through the BACK-on-LINE<sup>™</sup> intervention (DHSMI). This intervention includes an embedded BOL self-assessment to enhance individualisation.

# 6. Chapter 6: Phase 3 - Technological feasibility, acceptability and potential benefit of BACK-on-LINE<sup>™</sup>

## 6.1 Introduction

In the SR of Chapter 5, it was found that there is a limited number of studies that report individualised DHSMIs to support LBP self-management in the workplace. In addition, existing DHSMIs for LBP self-management lack the application of theories when providing individualised support. Also, current DHSMIs were extremely heterogeneous in terms of the intervention design, population characteristics and objectives. Although these DHSMIs were claimed to be developed for working populations or occupational settings, work-related intervention outcomes have rarely been evaluated. These findings indicate that current DHSMIs supporting LBP self-management in the workplace lack a standardised framework for design and evaluation. Therefore, this PhD project followed the NIHR/MRC framework for the design and evaluation of complex interventions proposed by Skivington et al. (2021). The NIHR/MRC framework suggested that DHSMIs need to be developed or identified, feasibilitytested, evaluated, and implemented in an iterative process for continuous refinement to improve research efficiency and eventual application (Skivington et al. 2021).

As introduced in the previous BOL development (<u>Section 2.8.2</u>), a mixed methods cohort study was conducted to explore the feasibility, acceptability and potential benefits of BOL to support LBP self-management in the workplace. A recent cross-sectional study reported a higher prevalence of LBP among healthcare workers (n=569, 84.7%) compared to other occupations (Gilchrist and Pokorná 2021). Similarly, transport sector workers with the occupational nature of long sedentary hours, were also found to have a high LBP prevalence (n=513, 69%) (Ganasegeran et al. 2014). Employees in higher education institutions (HEI) also experience a high prevalence of LBP (n=479, 61.2%) due to prolonged sitting and lack of physical activity (Hanna et al. 2019). Therefore, the aim of this chapter was to assess the technological feasibility, acceptability, and potential benefits of utilising BOL for LBP self-management in those working sectors.

#### 6.2 Aims and Objectives

The aim was to evaluate the technological feasibility, acceptability, and potential benefits of utilising BOL for LBP self-management in working populations from healthcare, HEI and transport sectors.

**Objective 1**: To determine the feasibility of recruiting participants with LBP from the workplace by assessing the appropriateness of the screening process and completion rates both at baseline and following a 4-week BOL intervention.

**Objective 2**: To determine the technological feasibility of the BOL intervention by analysing the number of times the BOL intervention was accessed and usage of BOL intervention modules.

**Objective 3**: To determine the acceptability of the BOL intervention using a validated questionnaire based on the Technology Acceptance Model (TAM).

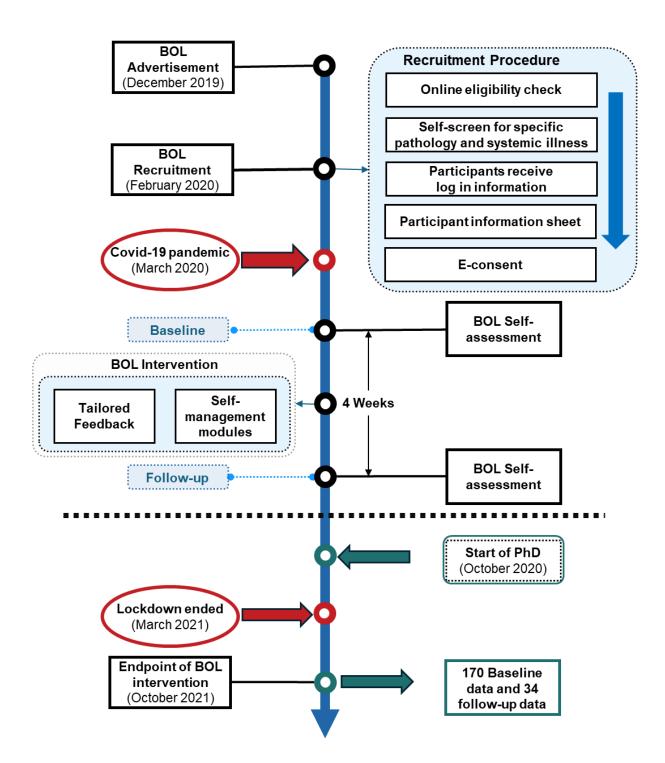
**Objective 4**: To explore the potential benefits of the BOL intervention on individual's health (pain intensity, LBP-specific disability, physical activity levels, exercise self-efficacy), work (SA) and healthcare resources usage for LBP (use of medication and healthcare service), including reported behavioural changes post-intervention.

**Objective 5**: To explore experiences of participants with the BOL intervention focussing on exploring changes in behavioural intention of participants towards using BOL to support their LBP self-management, value of individualisation, and general satisfaction with the platform.

For greater clarity, the five objectives were addressed using both quantitative and qualitative data sources. Quantitative analyses provided objective metrics on the engagement, usage, and technology acceptability, while qualitative data offered complementary insights into user experiences of the technological feasibility, acceptability, and potential benefits. This chapter presents only the quantitative results, with qualitative findings being reported separately in the next chapter.

## 6.3 Study design

This was a large cohort study using a prospective, single-arm, before and after study design. The study was conducted between December 2019 and October 2021 with the design and timeline detailed in **Figure 6-1**.



**Figure 6-1.** Study design and timeline of the BACK-on-LINE<sup>™</sup> mixed methods cohort study.

# 6.3.1 Participants

Participants were volunteer healthcare practitioners from NHS Wales, employees from Transport of London (TFL) and Cardiff University (CU) with self-reported LBP with fulfilling the following selection criteria:

# 6.3.1.1 Eligibility

Participants who meet the following criteria were included in the study:

- 1) Age over 18 years
- 2) Employment affected by self-reported LBP
- 3) Access to internet
- 4) Able to read and understand English

# Exclusion - Potential participants were not eligible if:

- 1) Under 18 years of age
- 2) Report clinical indicators of potentially serious spinal pathology or systemic illness at self-screening when answering questions recommended by NICE clinical guidelines (National Guideline 2016) during the recruitment process
- 3) Pregnancy/breast feeding
- 4) Involved in any other LBP research

# 6.3.1.2 Sampling

A non-probability convenience sampling was adopted to recruit working population with self-reported LBP in the UK. Participants accessed the online platform of BOL to self-select for study involvement, rather than being selected by the researcher for potential candidates. This recruitment strategy has been recognised as a more effective screening process in previous internet studies on chronic pain (Owen et al. 2014; Miller et al. 2017). Voluntary access to the BOL by participants was consistent with the study's requirement for internet availability and helped avoid the burden associated with the inability to participate in study recruitment due to the restrictions imposed by pain (Owen et al. 2014). These proactively engaged participants who believed they could benefit were considered to have higher motivation to engage in the intervention, which would provide a more accurate sample, thus improving external validity (Owen et al. 2014). Also, for a feasibility study, this recruitment strategy was considered cost-effective and beneficial in determining the sample size required for future trials of BOL (Stratton 2021).

#### 6.3.1.3 Study setting

The study was mainly conducted in the workplace of healthcare organisations (NHS) for its high prevalence of LBP (Landry et al. 2008; Şimşek et al. 2017). In addition to healthcare organisations, participants were recruited from other occupations with high prevalence of LBP where sedentary behaviours are common, including transport companies (Kresal et al. 2015) and education (Santos et al. 2018). To broaden the participant pool, this study adopted a multi-centre study with participant recruitment taking place in various organisations from Wales and England secure large enough sample and enhance the generalisability and application of the findings (Kumar et al. 2013).

## 6.3.1.4 Sample size

According to the Welsh Government, at the time of the BOL intervention disseminated by Sheeran et al. in December 2019, there were 81,541 registered staff in NHS Wales (StatsWales, 2020). Considering the 1-month period prevalence of LBP was reported as 28.5% among all the working population in the UK (Macfarlane et al. 2012), this study estimated that 23,000 NHS staff in Wales were likely to be experiencing LBP at any point during the intervention period. It was conservatively estimated more than 2,300 people (10% of total estimated LBP population in NHS Wales) could be reached during the dissemination of BOL.

Compared to controlled experimental designs where sample sizes can be calculated by setting standardised deviation, statistical power and effect size, calculating sample sizes for single-arm feasibility studies has additional complexities due to the lack of a parallel group design (Totton et al. 2023). An inadequate sample size may not demonstrate reasonable power, while a very large sample may increase the complexity of the study and escalate costs (Martínez-Mesa et al. 2014). Teresi et al. suggested that feasibility studies with a single group should have at least 70 participants to generate an acceptable confidence interval (width of 95% CI = 0.15 - 0.24), representing a margin of error between 0.075 - 0.12 (Teresi et al. 2022). In addition, the NIHR recommended that the sample size of feasibility studies should be based on practical considerations to reasonably evaluate feasibility process outcomes (Hooper 2019). Previous DHSMIs for chronic diseases has reported an average user retention rate of 57% (95% CI: 43% - 71%) across 17 studies (Meyerowitz-Katz et al.

2020). Therefore, following the NIHR recommendations on sample size for feasibility trials, the required sample size for this mixed-methods BOL study was calculated by estimating the proportion of participants remained in the study after the 4-week BOL intervention (Hooper 2019).

Considering the above factors, the sample size was calculated using the following formula (Daniel and Cross 2018).

$$n = \frac{N \cdot Z^2 \cdot p \cdot (1-p)}{E^2 \cdot (N-1) + Z^2 \cdot p \cdot (1-p)}$$

where *n* is the sample size for the mixed methods BOL study, *N* is the total population size (2300 LBP population from NHS Wales expected to be reached), *Z* is the critical value for 95% confidence level in a two-tailed test, *E* is the margin of error, *p* is the expected retention rate.

From this calculation, therefore, the expected sample size was calculated to be 93 participants to estimate a retention rate of 50% with a 95% confidence interval of  $\pm 10\%$  for a population size of 2300.

#### 6.3.2 Ethical approval and recruitment procedure

The mixed methods BOL study was approved by both the Research Ethics Committee of School of Healthcare Sciences, Cardiff University on 31 July 2019 (<u>Appendix 10</u>), the National Health Service Health Research Authority (HRA) and Health and Care Research Wales (HCRW) on 02 December 2019 (<u>Appendix 11</u>).

Through the research group links with the Occupational Health and Staff Well-being Departments, agreement was obtained from participated worksites to assist in promoting the study widely through weekly staff newsletters, well-being and health emails, and email signatures. Recruitment procedures and project management activities were standardised across all worksites. Potential participants were firstly self-identified by accessing information about the study as advertised using an e-leaflet containing a brief outline of the study and a weblink of accessing the study information. This leaflet was distributed by on-site research contact (occupational health manager

or physiotherapist) within each site via weekly staff newsletters, well-being and health email communications or e-mailshots. Paper leaflets were also distributed in areas frequented by staff. Staff workrooms and break rooms, which are frequently visited during shifts and breaks, were chosen as the main locations for leaflet distribution. Leaflets were also placed in informal locations, such as staff social areas and the gym to promote staff engagement. In addition, paper leaflets were strategically displayed in the meeting rooms with high volume of usage to attract the attention of a diverse range of staff where possible, such as managers, supervisors and other members of staff when attending meetings, seminars or training sessions.

Potential participants were recruited in the study through the following four steps.

# 1. Eligibility check:

Using the link on the e-leaflet, potential participants visited BOL online platform to access the eligibility check list which contained the following questions: "Do you have low back pain that affects your work?" "Are you over the age of 18?" "Do you have access to the internet?" "Are you pregnant or breast feeding? "Are you involved in any other low back pain research?"

Participants had to tick yes or no to answer the above questions based on their own conditions. Failure to meet any of the above would be notified as not eligible for the study and appreciated for their participation so far. Participants who fit the criteria would undergo further self-screening for LBP.

# 2. Self-Screen:

For the purpose of study safety and mitigating potential risks, participants were asked to complete the self-screening tool. This tool was designed based on the guidelines from NICE (National Guideline 2016) on the identification of clinical indicators associated with specific pathology or systemic illness. Detailed questions are listed below:

- 1) Is your low back pain constant and worsening for the past four weeks?
- 2) Did your low back pain start or get much worse following a fall?

- 3) Did your low back pain coincide with feeling unwell, e.g. Fever, chills, night sweats (with no other explanation)?
- 4) Do you have altered or loss of sensation around your back passage or genitals (noticeable, e.g. When wiping after going to the toilet)?
- 5) Are you experiencing any unexplained widespread weakness in one or both legs?
- 6) Do you have difficulty passing or controlling urine or faeces?
- 7) Did your low back pain coincide with any unexplained trouble walking (e.g. Limping, tripping, falling, feeling unsteady on your feet)?

Participants who answered "no" to all the above questions proceeded to receive the participant information sheet (PIS) on BOL intervention, which provided them with further details about the study. Those who answered "yes" to any of the questions were notified about their ineligibility and were sincerely thanked for their participation thus far. Furthermore, they were advised to seek medical advice for their well-being if the back problem persisted.

## 3. Participant information sheet (PIS):

After completing the self-screening check, participants were provided with the PIS on the mixed methods BOL study's nature, significance, implications and risks of the research, along with their right to withdraw from participation at any point (<u>Appendix 12</u>). PIS was formatted into online sections that the participants were required to scroll through, with an option at the end to participate, withdraw or need to talk to someone before deciding. Following this, a contact point for further information was supplied. The research team would be notified of the inquiry of assistance and respond to the number stated by participants within 24 hours on working days.

#### 4. Consent:

An e-consent was used to obtain, confirm and document informed consents from participants in the study (<u>Appendix 13</u>). Complying with regulations of the General Data Protection Regulation, HRA and the Medicines and Healthcare products Regulatory Agency, the e-consent used in this study included a declaration for participants to state their agreement to the recruitment procedure. Participants were required to review each statement in the e-consent form and select whether to

participate in the intervention, share anonymised data or participate in future BOL studies. After submitting their full name and contact details, participants were then given the option to print or download the PIS and their e-consents. All the completed e-consents were automatically collected into a separate data collection Excel spreadsheet and stored on a secure central web server at Cardiff University to ensure a clear audit trail. After the completion of the consent process, an automated email containing a unique 8-digit code and a hyperlink directing to the BOL login page was sent to the participant, which allowed participants to access BOL.

#### 6.3.3 Intervention

Participants who have provided informed consent were directed to access the BOL online platform through a link in their email and used a unique 8-digit number to log in. Consented participants were required to complete the BOL self-assessment at baseline to receive feedback on pain classifications, physical activity levels and sedentary behaviours. Guidance and links to the recommended BOL resources was also provided in the feedback. Participants were allowed to use BOL for LBP self-management in the workplace over a 4-week period and access BOL intervention contents based on their preferences. After the 4-week intervention, participants were reminded by email to complete the BOL self-assessment again to obtain further feedback. Details of the BOL intervention contents were described in <u>Chapter 4</u>.

## 6.3.4 Data collection

The BOL online platform commenced operation and participant recruitment in February 2020. BOL was integrated with an automated data collection system, which captured and stored the usage data from participants when using BOL for LBP self-management. Participants' responses in the BOL self-assessment (baseline and 4-week follow-up) were automatically collected and stored. Participants who failed to complete the follow-up self-assessment after 4 weeks of BOL intervention were contacted by the research team to collect information on outcomes related to healthcare resource use, disability, work and LBP, and reasons for withdrawal from the study. All data obtained through the BOL platform were rigorously encrypted using randomly generated 8-digit codes and securely stored in the database and registered equipment of Advanced Research Computing at Cardiff University.

#### 6.3.5 Outcome measures

The primary and secondary outcomes are fully detailed in **Table 6-1** and <u>Appendix 8</u>. Primary Feasibility Outcomes were focused on the feasibility of BACK-on-LINE<sup>TM</sup>, including recruitment and intervention use. Recruitment feasibility was measured by tracking the number participants accessing BACK-on-LINE<sup>TM</sup>, including those screened, eligible, consenting, and completing the self-assessment. Intervention feasibility was assessed through usage data (logins, modules accessed, time spent) and by monitoring withdrawals and retention rates at 4 weeks (at least one website visit).

Secondary Measures (Table 6-1) included:

- Baseline Demographics: Gender, age, occupation, and employment status.
- BACK-on-LINE<sup>™</sup> Acceptability: Assessed using a validated questionnaire based on the Technology Acceptance Model (TAM) with determinants including Behavioural Intention (BI), Perceived Ease of Use (PEU), Perceived Usefulness (PU), Prior Experience (PE), and Self-Efficacy (SE) (Lee and Lehto 2013).
- **Potential Healthcare Benefit**: Data on healthcare resource use for LBP (GP visits, medications, physiotherapy) 4 weeks before and after using BACK-on-LINE<sup>™</sup>.
- Potential Work Benefit: Total sickness absence days due to LBP 4 weeks before and after using BACK-on-LINE<sup>™</sup>.
- Potential Health Benefit: LBP-related outcomes, including pain intensity measured by the numeric pain rating scale (NPRS) (Kahl and Cleland 2005), disability assessed by the Roland and Morris Disability Questionnaire (RMDQ) (Roland and Fairbank 2000), physical activity levels assessed using the Short Form International Physical Activity Questionnaire (IPAQ-SF) (Craig et al. 2003), and exercise self-efficacy assessed using a modified Self-Efficacy for Exercise scale (Resnick and Jenkins 2000). These were assessed at baseline and post-BACK-on-LINE<sup>™</sup> intervention. Behaviour changes data on pain management, work, daily activities, and exercise were assessed after 4 weeks of BACK-on-LINE<sup>™</sup> intervention using a brief questionnaire developed for this study.

Category	Outcome	Measurement instruments	Measurement points	
	Acceptability	Modified Technology Acceptability Model questionnaire	4 week follow up	
	Pain intensity	Numerical pain rating scale	Baseline and 4- week follow-up	
	Back pain specific disability	Roland and Morris Disability Questionnaire	Baseline and 4- week follow-up	
	Physical activity	The International Physical Activity Questionnaire - short form	Baseline and 4- week follow-up	
Secondary outcomes	Exercise self- efficacy	Modified Self-Efficacy for Exercise scale	Baseline and 4- week follow-up	
	LBP related healthcare resource use	Brief questionnaire in the BOL self-assessment tool developed for this study	Baseline and 4- week follow-up	
	Time off work	Brief questionnaire in the BOL self-assessment tool developed for this study	Baseline and 4- week follow-up	
<b>BOL</b> · BACK-on-L	Behaviour changes	Brief questionnaire in the BOL self-assessment tool developed for this study	4-week follow-up	

 Table 6-1.
 Summary of the secondary outcome measures

BOL: BACK-on-LINE™

## 6.4 Data processing and analysis

Responses from participants' self-assessment, data collection at baseline and at 4week follow-up and data on BOL platform access and usage were exported in separate Excel spreadsheets from the BOL back-end data management portal called BOL dashboard. Descriptive statistics were used to describe the baseline characteristics of the study population grouped by occupations (Healthcare, Transport, HEI) using means (SD) or numbers (percentages).

LBP specific disability (RMDQ) scores were trichotomised into mild disability (score <7.0), moderate disability (score  $\geq$ 7.0 and <14.0), and severe disability (score  $\geq$  14), analysed as an ordinal variable (Roland and Morris 1983). The cut-off points of pain intensity were consistent with previous studies on pain, with mild pain corresponding

to NPRS  $\leq$  3, moderate pain to 4-6, and severe pain to  $\geq$  7 (Forchheimer et al. 2011; Boonstra et al. 2016). Potential differences between groups at baseline were assessed using analysis of variance (ANOVA) for numerical variables and the chi-square ( $x^2$ ) test for categorical variables. Stata software (17, Stata Corp LLC, College Station, Texas, U.S.) was used for all data processing and statistical analysis.

# Feasibility

Descriptive statistics were used to report the feasibility of recruitment and BOL intervention. Feasibility of recruitment was assessed through the number of successful and failed attempts of self-screening, eligibility checks, downloading PIS, selecting participant options and signing e-consents. Monthly recruitment rates of different occupations over the intervention period were also calculated. The feasibility of the intervention was assessed by the average number of logins per BOL user over the study period. The number of visits to the different modules and toolkits of the BOL intervention was counted and reported as the usage of BOL. Also, retention rates (completion of baseline and 4-week follow-up self-assessments) were reported to quantify the intervention feasibility.

# Acceptability

Descriptive analyses were performed based on the five determinants outlined in the TAM questionnaire (Chauhan and Jaiswal 2017). The proportion of participants who indicated agreement and somewhat agreement was computed to assess the acceptability of the BOL intervention.

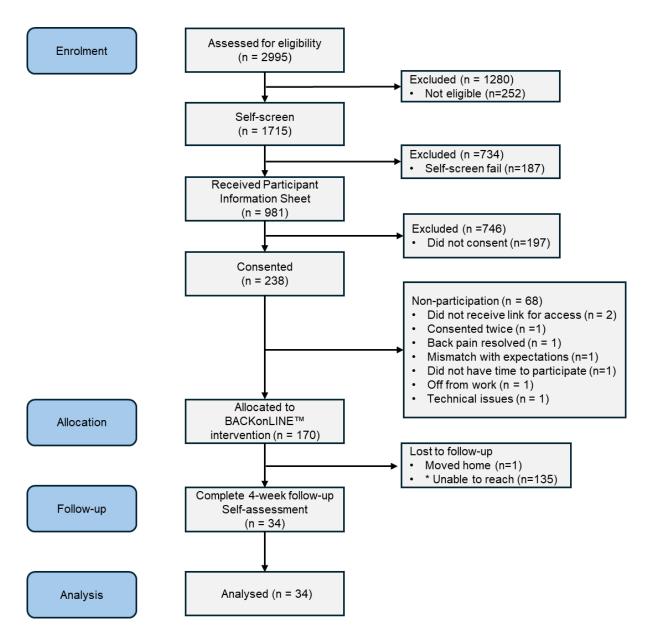
# **Potential benefits**

Exploratory analysis was conducted to explore the differences in the health, work and healthcare resources usage data (e.g., disability/pain/physical activity level, days of SA, visits to GP, number of prescriptions taken for LBP), and scores on additional measures (exercise efficacy) before and after the intervention. Due to the small sample size at follow-up, descriptive statistics were used to summarise outcomes and difference post-BOL intervention with means, standard deviations (SDs) and confidence intervals (CIs).

The behaviour changes were assessed by exploring the modified behaviours on pain management, work engagement, daily activities and exercise after the BOL intervention. Participants were asked if they continued to follow the recommended advice and activities from the BOL after the intervention or no longer felt pain. Those who answered 'yes' were asked to indicate areas of change and describe the changes. A deductive qualitative content analysis (Elo and Kyngäs 2008) was used to analyse the text responses describing the behaviour changes from participants in the BOL adherence questionnaire. Based on the predefined model in previous BOL research (Alothman et al. 2019), the individualised content of the BOL intervention addressed seven domains associated with LBP, including pain relief, sleep, mood, work, daily living, physical activity/exercise, and exercise routine for LBP. These key domains were selected to develop the categorisation matrix for the content analysis (Elo and Kyngäs 2008). Based on the structured matrix, participant responses were reviewed and coded to match the behaviour change categories. Trustworthiness of the content analysis was ensured by the investigator triangulation (Archibald 2016). Coding and categorisation of data was carried out by one investigator (MC) and the results were discussed with the supervisor (LS). Another supervisor (VS) reviewed the results of the discussion to ensure coding accuracy and resolve any discrepancies occurred in the discussion. Microsoft Excel was used to organise and analyse the qualitative data.

# 6.5 Results

From February 2020 to October 2021, 238 individuals from 14 different worksites in 3 different working sectors consented to participate in the BOL intervention. **Figure 6-2** presents the status of the participant enrolment. Of the 238 consented participants, 170 participants from healthcare (NHS Wales), HEI (CU) and transport (TFL) completed the BOL baseline self-assessment. A detailed summary of the participating worksites grouped by occupation is presented in **Table 6-4**.



# Figure 6-2. Flow diagram of the participants eligible, recruited, included, and followed

# up in analysis.

\***Unable to reach**: The follow-up coincided with the COVID-19 lockdown, and the occupational health team suspended all research activities to help with the covid effort. Therefore, the research team had to contact participants individually.

#### 6.5.1 Participant characteristics

The detailed characteristics grouped by occupations are summarised in **Table 6-2**. Overall, the sample in the study was of working age (mean = 42.7 years, SD = 9.9) and predominantly female (n=119, 70.0%). Most participants included in this study were in full-time employment (n=162, 95.3%) with an average of 36.0 working hours per week (SD=9.8) with the remainder reporting as self-employed. The self-reported daily sitting time at baseline was 8.0 hours (SD=2.9). Nearly half of the participants (47.6%) had a history of SA due to LBP, but most of them (82.9%) returned to work and remained in the same job. Over one third of the participants (37.7%) experience LBP for more than 6 months in the current episode. Most of the participants (65.2%) used self-bought medications to help manage LBP, while a smaller proportion (25.2%) were on prescription medication for their LBP. Most participants (77.6 - 91.8%) did not seek professional healthcare service (NHS, occupational health or private physiotherapy) for LBP in the recent 4 weeks. No significant differences were found between participants from the healthcare, HEI, and transport sectors in terms of demographics, work, and healthcare resources use for LBP at baseline.

	Healthcare (n=108)	HEI* (n=40)	Transport (n=22)	p-value
Demographic				
Age (years), mean (SD*)	42.3 (9.9)	43.1 (10.0)	44.0 (10.2)	0.747
Female, n (%)	79 (73.2)	24 (60.0)	16 (72.7)	0.288
Employment status, n (%)				0.502
Employed	103 (95.4)	39 (97.5)	20 (90.9)	
Self-employed	5 (4.6)	1 (2.5)	2 (9.1)	
Work-related outcomes				
Working hours per day, mean (SD)	36.0 (9.5)	36.9 (10.4)	34.1 (10.4)	0.570
Sitting hours per day, mean (SD)	8.3 (3.0)	7.8 (2.6)	7.2 (3.1)	0.233
Role change for LBP*, n (%)				0.313
Remained in the same role	97 (89.82)	35 (87.5)	18 (81.82)	
Moved to a new role	8 (7.41)	4 (10.0)	3 (13.6)	
Left job but able to return to work	/	1 (2.5)	1 (4.55)	
Other	3 (2.78)	1	/	
Duration of current LBP* episode, n (%)				0.580
Less than 1 week	16 (14.8)	6 (15.0)	6 (27.3)	
1 - 4 weeks	20 (18.5)	8 (20.0)	2 (9.1)	
1 - 3 months	17 (15.7)	6 (15.0)	2 (9.1)	
3 - 6 months	11 (10.2)	6 (15.0)	6 (27.3)	
Over 6 months	44 (40.8)	14 (35.0)	6 (27.3)	
Sickness absence due to LBP, n (%)				0.180
Did not have time off	54 (50.0)	20 (50.0)	15 (68.2)	
1 - 4 weeks	33 (30.5)	18 (45.0)	4 (18.2)	
1 - 2 months	10 (9.3)	1 (2.5)	1 (4.5)	
over 2 months	11 (10.2)	1 (2.5)	2 (9.1)	
Healthcare resource use for LBP				

 Table 6-2. Baseline characteristics of the 170 participants grouped by working sectors.

Number of medications taken for LBP*, n (%)				
Prescription				0.994
None	77 (71.3)	33 (82.5)	17 (77.3)	
1 - 2 types	26 (24.1)	6 (15.0)	4 (18.2)	
Over 2 types	5 (4.6)	1 (2.5)	1 (4.5)	
Self-bought medication				0.599
None	35 (32.4)	20 (50.0)	4 (18.2)	
1 - 2 types	58 (53.7)	17 (42.5)	15 (68.2)	
Over 2 types	15 (10.9)	3 (7.5)	3 (13.6)	
Number of visits for LBP in last 4 weeks, n (%)				
NHS*				0.483
None	85 (78.7)	30 (75.0)	17 (77.3)	
1 - 4 times	22 (20.4)	8 (20.0)	4 (18.2)	
Over 4 times	1 (0.9)	2 (5.0)	1 (4.5)	
Occupation health				0.169
None	99 (91.7)	37 (92.5)	20 (90.9)	
1 - 4 times	9 (8.3)	1 (7.5)	/	
Over 4 times	/	/	2 (9.1)	
Physiotherapist				0.073
None	96 (88.9)	33 (82.5)	19 (86.4)	
1 - 4 times	11 (10.2)	6 (15.0)	1 (4.5)	
Over 4 times	1 (0.9)	1 (2.5)	2 (9.1)	

SD: Standard deviation; HEI: Higher Education Institution; LBP: Low Back Pain; NHS: National Health Service

A detailed description of LBP-related patient reported outcome measures (PROMs) is summarised in **Table 6-3**. Largest proportion of participants self-reported a moderate LBP (46.5%, NPRS = 4 - 6) and mild disability (58.2%, RMDQ < 7). As measured by the IPAQ-SF, the largest group of participants were at high physical activity level (38.8%), slightly more than those at moderate (28.2%) and low physical activity level (33.0%). The mean of exercise self-efficacy score (total score = 70) of all participants at baseline was 43.8 point (SD = 13.9). No significant difference was found in baseline data of LBP-related PROMs between different occupations.

**Table 6-3.** Baseline low back pain related Patient Reported Outcome Measures grouped by occupations.

	Healthcare Transport		HEI*(n=22)	p-
	(n=108)	(n=40)	IILI (II-22)	value
Pain intensity (NPRS*), n (%)				0.181
Mild (0 - 3)	31 (28.7)	18 (45.0)	5 (22.7)	
Moderate (4 - 6)	49 (45.4)	17 (42.5)	13 (59.1)	
Severe (7 - 10)	28 (25.9)	5 (12.5)	4 (18.2)	
Low back pain specific disability				0.194
(RMDQ*), n (%)				0.194
Mild (0 - 6)	68 (63.0)	8 (36.4)	23 (57.5)	
Moderate (7 - 14)	25 (23.1)	10 (45.4)	12 (30.0)	
Severe (Over 14)	15 (13.9)	4 (18.2)	5 (12.5)	
Physical activity levels (IPAQ-SF*), n				0.764
(%)				0.764
Low	34 (31.5)	16 (40.0)	6 (27.3)	
Moderate	30 (27.8)	10 (25.0)	8 (36.4)	
High	44 (40.7)	14 (35.0)	8 (36.4)	
Exercise self-efficacy, mean (SD)	43.7 (13.8)	44.7 (12.6)	42.6 (17.3)	0.238

**SD**: Standard deviation; **HEI**: Higher Education Institution; **LBP**: Low Back Pain; **NPRS**: Numerical Pain Rating Scale; **IPAQ-SF**: International Physical Activity Questionnaire-Short form; **RMDQ**: Roland Morris Disability Questionnaire

#### 6.5.2 Recruitment feasibility and retention

The flowchart of **Figure 6-2** summarises recruitment and the identified reasons from participants for non-engagement and dropping out. Over the 20-month study period, a total of 6552 visits to the BOL welcome page were recorded. Of the recorded visits, 2995 completed the eligibility check, of which 8.4% of attempts were failed for not meeting eligibility criteria for participation in the study (e.g., LBP did not affect work, pregnant, being involved in other pain research). Among the 1715 visits continued to

the process of self-screen, 10.5% was recorded as fail for revealing red flags signs indicating serious pathology or systemic disease according to the NICE guidelines (National Guideline 2016). The e-consent page was accessed 887 times, where 22.2% did not provide informed consent and opted out. Finally, a total of 238 individuals fulfilled the study criteria and consented to participate. An average of 11.9 participants with LBP were recruited per month from three working sectors. The largest proportion of participants (n=128, 54.6%) were recruited from 10 NHS sites in the healthcare sector. While the highest recruitment rate was found in HEI sector, with an average of 4 participants recruited per month per site.

A total of 170 BOL baseline self-assessments were completed, with a conversion rate of 2.6% (6552 total visiting times) from clicking on the Welcome page to completing the self-assessment. Participants recruited from NHS sites reported the highest completion rate of the baseline self-assessment (108/128, 84.4%). A total of 25 participants completed the follow-up self-assessment on potential benefits and acceptability at 4 weeks with a retention rate of 14.7%. 19 participants further reported their adherence to the specific activities recommended by the BOL after intervention. The BOL follow-up self-assessment completion rate ranged from 3.4% to 50.0% between the work sectors. Participants recruited from NHS sites reported the highest completion rate in both BOL self-assessment and additional measures after the 4-week intervention (12.5-17.2%), higher than that in HEI (7.5%-12.2%) and transport (0-7.1%). Detailed data on consenting, recruitment, baseline completion and retention rate of BOL study grouped by working sectors is summarised in **Table 6-4.** 

**Table 6-4.** Number of participants consented, completed the baseline and 4-week follow-up BACK-on-LINE<sup>™</sup> self-assessment and other measurements grouped by working sectors.

		_	Baseline	Follow-	up completion, % of co	onsented
Site Name	Consented	Recruitment rate*	completion*, – % of consented	BACK-on- LINE™ self- assessment	Measures of potential benefits and acceptability	Measures of behavioural changes
Healthcare	128	6.4	108 (84.4%)	22 (17.2%)	16 (12.5%)	16 (14.8%)
Cardiff and Vale University Health Board	31	1.6	25 (80.6%)	4 (12.9%)	2 (6.4%)	2 (8.0%)
Cwm Taf Morgannwg University Health Board	29	1.5	27 (93.1%)	1 (3.4%)	1 (3.4%)	1 (3.7%)
Betsi Cadwaladr University Health Board	25	1.3	23 (92.0%)	7 (28.0%)	5 (20.0%)	5 (21.7%)
Royal United Hospitals Bath NHS Foundation Trust	12	0.6	11 (91.7%)	2 (16.7%)	2 (16.7%)	2 (18.2%)
Welsh Ambulance Services NHS Trust	12	0.6	11 (91.7%)	6 (50.0%)	4 (33.3%)	4 (36.4%)
Velindre NHS Trust	7	0.4	5 (71.4%)	/	/	/
Hywel Dda University Health Board	4	0.2	3 (75.0%)	1 (25.0%)	1 (25.0%)	1 (33.3%)
Health Education Improvement Wales	4	0.2	3 (75.0%)	1 (25.0%)	1 (25.0%)	1 (33.3%)
Aneurin Bevan University Health Board	2	0.1	2 (100%)	/	/	/
Swansea Bay University Health Board	2	0.1	/	/	/	/

Higher Education Institution Cardiff University	82	4.1	40 (48.8%)	10 (12.2%)	8 (9.8%)	3 (7.5%)
Transport Transport for London	28	1.4	22 (78.6%)	2 (7.1%)	1 (3.6%)	/

\*Recruitment rate: consented participants per month (20 months) \*Baseline Completion: All 170 participants completed the BACK-on-LINE<sup>™</sup> self-assessment and measures on potential benefit of healthcare resources, work and health \*Other measures: Measures on acceptability and potential benefit of healthcare resources, work and health \*Retention rate: the number of individuals who completed the follow-up self-assessments (BOL, acceptability, potential benefits, adherence) as a proportion of the total

number of participants completed all the baseline self-assessments

# 6.5.3 Technological feasibility of the intervention

Technological feasibility was assessed using counts of access to the feedback page and intervention modules in total and per participant. In the 20-month study period, 170 participants accessed the feedback page for a total of 1,742 times, with an average of 10.25 visits per participant.

The most frequently accessed was the feedback on participants' pain type (636 visits), with an average 3.74 visits per participant. Participants in the NP group had average number of visits 16.9 times higher than that of those in the NC group. Participants who were categorised as moderate and high PA level (114/170, 67.1%) based on the IPAQ-SF had more frequent visits to their PA scores (2.61 visits per participant) than those at low PA level (1.2 visits per participant). Participants without sedentary behaviour (18/170, 10.6%) had a higher average visit to their sedentary scores than those with sedentary behaviour (3.50 and 1.83 visits, respectively). All the individualised content provided by the BOL recorded visits by participants, ranging from 12 to 193 visits, indicating that all digital components of the BOL intervention were functioning properly. The detailed usage of the BOL feedback and individualised intervention contents is summarised in **Table 6-5**.

Feedback type and individualised	Total visits (average per	Subgroups visits* (average per participant)		
content	participant)	NC (n=124)	NP (n=46)	
Your pain type	636 (3.74)	83 (0.67)	553 (12.02)	
Get your spine fit for work module	/	29 (0.23)	193 (4.19)	
Get your mind fit for work module	/	/	88 (1.91)	
		Low PA (n=56)	Moderate/high PA (n=114)	
PA score	365 (2.15)	67 (1.20)	298 (2.61)	
Resilient spine toolkit	1	21 (0.37)	/	
Moving with pain	/	12 (0.21)	/	
Resilient spine toolkit	/	/	93 (0.82)	
Physical job toolkit	/	/	15 (0.13)	
		Non-sedentary (n=18)	Sedentary (n=152)	
Sedentary score*	342 (2.01)	63 (3.50)	279 (1.83)	
Static job toolkit	48 (0.28)	/	/	
Communication skills	47 (0.28)	/	/	

Table 6-5. Usage of the BOL feedback and individualised intervention contents

BOL: BACK-on-LINE<sup>™</sup>; NC: nociceptive pain; NP: Nociplastic pain; PA: physical activity;

\*Subgroup visits: The number of times that participants clicked on the individualised intervention content in their personal feedback, which does not include visits by participants in other subgroups.

\*Sedentary Score: Sedentary and non-sedentary participants received the same individualised content as these resources address common workplace issues related to LBP. Both non-sedentary and sedentary participants may benefit from the Static Job Toolkit's ergonomic guidance to prevent strains or injuries in static postures, while Communication Skills may help individuals effectively communicate their needs with employers to promote active breaks between jobs.

# 6.5.4 Technology acceptability

Responses from the TAM questionnaire showed that participants in this study had a very good familiarity with internet (25/25, 100%) and enjoyed using digital technology for self-management activities (24/25, 96%). Most participants agreed that their employers offered sufficient support and resources to help them adapt to the BOL in the workplace (21/25, 84%).

There is an agreement on the Perceived Ease of Use (PEU) and Perceived Usefulness (PU) of the BOL. Most participants found the BOL easy to use (24/25, 96%) and agreed that it was easy to integrate BOL advice and guidance into their work routines (22/25, 88%). A large proportion of participants agreed that BOL provided valuable information for LBP self-management (20/25, 80%) and improved their efficiency in managing LBP (16/25, 64%). In addition, after the 4-week intervention, more than half of the participants agreed to continue using BOL (15/25, 60%) and would strongly recommend BOL to others (18/25, 72%). **Table 6-6** provides detailed information on the technology acceptability of BOL.

		Number					Agreement
Determinant	Items	Strongly Disagree	Disagree	Somewhat agree	Agree	Strongly Agree	rate* (%)
	I intend to use BACK-on-LINE <sup>™</sup> to assist my low back pain self-management	3	7	7	7	1	60
Behavioural Intention (BI)	I intend to use BACK-on-LINE <sup>™</sup> in the next few months	1	10	10	3	1	56
	I will strongly recommend others to use BACK-on-LINE <sup>™</sup>	1	6	11	6	1	72
Perceived usefulness	I believe BACK-on-LINE <sup>™</sup> is informative for low back pain self-management Using BACK-on-LINE <sup>™</sup> enhances my	0	5	10	7	3	80
0	effectiveness in managing my low back	0	9	9	5	2	64
	I find the BACK-on-LINE <sup>™</sup> easy to use	0	1	4	12	8	96
Perceived ease of use	I find that interacting with BACK-on-LINE <sup>™</sup> does not demand much attention	0	9	11	5	0	64
(PEU) It is easy to integrate	It is easy to integrate BACK-on-LINE <sup>™</sup> advice and guidance into my work	0	3	9	11	2	88
Drior	I enjoy using smartphone apps and computers to help my physical activity	0	1	7	10	7	96
Prior experience	I am comfortable using internet.	0	0	7	14	4	100
(PE)	The administration has provided most of the necessary help and resources to get used to BACK-on-LINE <sup>™</sup>	0	4	12	6	3	84

# Table 6-6. Responses to the modified Technology Acceptance Model questionnaire for BACK-on-LINE<sup>™</sup> at follow up

Self-efficacy	I am confident in using the BACK-on- LINE <sup>™</sup> without any further manuals or instructions	0	0	10	11	4	100
(SE)	I am confident using BACK-on-LINE <sup>™</sup> and all its different aspects of advice and	0	0	10	10	5	100
	resources offered		_	_	_	_	

\*Agreement rate: Proportion of participants rating "Somewhat Agree", "Agree", and "Strongly Agree".

# 6.5.5 Potential health, work, and healthcare benefits

After the 4-week intervention, 25 patients from healthcare, HEI and transport sectors completed the follow-up BOL self-assessment, measurements on potential benefits and the TAM questionnaire. Given the small post-intervention sample and the lack of a control group, the pre- and post-intervention data is presented descriptively in **Table 6-7** below.

No substantial differences were observed in SA within the last 4 weeks before and after the intervention. There was an increasing trend in the proportion of participants reporting mild pain after the intervention. Compared to the baseline, the proportion of participants at moderate and high PA levels remained unchanged (n=14, 56%), but the mean total score of exercise self-efficacy increased by 1.04 points (95% CI: -5.96 - 8.04). In terms of healthcare resource use, it appears that more participants stopped visiting the NHS or taking self-bought medications for LBP after the intervention.

	Total (	(n=25)
	Baseline	Follow-up
Work related outcomes		
Sickness absence due to LBP, n (%)		
Did not take time off	11 (44.0)	12 (48.0)
Less than 1 week	4 (16.0)	3 (12.0)
Between 1 to 2 weeks	4 (16.0)	4 (16.0)
Between 3 to 4 weeks	6 (24.0)	6 (24.0)
Health related outcomes		
Pain Intensity (NPRS), n (%)		
Mild (0 - 3)	8 (32.0)	12 (48.0)
Moderate (4 - 6)	13 (52.0)	10 (40.0)
Severe (7 - 10)	4 (16.0)	3 (12.0)
Low back pain specific disability (RMDQ), n (%)		
Mild (0 - 3)	14 (56.0)	15 (60.0)
Moderate (4 - 6)	8 (32.0)	6 (24.0)
Severe (Over 7)	3 (12.0)	4 (16.0)
Physical activity levels (IPAQ-SF), n (%)		
Low	11 (44.0)	11 (44.0)
Moderate	7 (28.0)	6 (24.0)
High	7 (28.0)	8 (32.0)
Exercise self-efficacy, mean (SD)	40.8 (12.0)	41.8 (18.1)

**Table 6-7.** Data on LBP-related patient reported outcome measures, work-related outcomes and healthcare resource use before and after the 4-week intervention

Number of medications taken for LBP, n (%)		
Prescription		
None	17 (68.0)	16 (64.0)
1 - 2 types	7 (28.0)	7 (28.0)
Over 2 types	1 (4.0)	2 (8.0)
Self-bought medication		
None	12 (48.0)	18 (72.0)
1 - 2 types	12 (48.0)	7 (28.0)
Over 2 types	1 (4.0)	/
Number of visits for LBP in last 4 weeks, n (%)		
NHS		
None	18 (72.0)	22 (88.0)
1 - 4 times	6 (24.0)	1 (4.0)
Over 4 times	1 (4.0)	2 (8.0)
Occupation Health		
None	24 (96.0)	21 (84.0)
1 - 4 times	1 (4.0)	2 (8.0)
Over 4 times	/	2 (8.0)
Private Physiotherapist		
None	21 (84.0)	21 (84.0)
1 - 4 times	3 (12.0)	1 (4.0)
Over 4 times	1 (4.0)	3 (12.0)

Healthcare resource use

**SD**: Standard deviation; **LBP**: Low Back Pain; **NPRS**: Numerical Pain Rating Scale; **IPAQ**: International Physical Activity Questionnaire-Short form; **RMDQ**: Roland Morris Disability Questionnaire; **NHS**: National Health Service

Of the 19 participants who completed the additional measurement of adherence to BOL recommended activities, half of the participants (n=10, 52.6%) reported a modification of their behaviour after using BOL for 4 weeks, with 7 participants providing specific descriptions of the changes.

The results of the deductive content analysis of the free-text comments revealed positive behavioural changes post-intervention with participants stating adoption of the BOL recommended physical activity for LBP self-management, as well as optimising their existing exercise routines to alleviate LBP. One participant (1/7) reported adding new exercises from the BOL platform meeting their own needs for self-management: "I started doing activities including yoga, Pilates, and Nordic walking to assist pain and mobility" (ID 37089235). Pain-relieving strategies adapting to an individual's own circumstances was also reported: "I keep moving alongside use of medication to

manage pain which I can adjust if I have been doing more exercise " (ID 41202029). Behavioural changes to help improve sleep were also reported: "I now sleep with a back pillow between my knees which is helping" (ID 40942882). Also, participants mentioned efforts to maintain physical activity during their daily work: "I try to stay active through the working day" (ID 22828769). Full summary of behaviour changes together with quotes are presented in <u>Appendix 9</u>.

#### 6.6 Discussion

Following the NIHR/MRC framework for designing and evaluating complex health interventions, this study assessed the technological feasibility, acceptability and potential benefits of an individualised DHSMI (BOL intervention) to support LBP self-management in the workplace from healthcare, transport and HEI sectors. The discussion in this chapter is structured using the four main objectives: 1. To determine the feasibility of recruitment and retention of participants with LBP from workplace; 2. To determine the technological feasibility of the BOL intervention related to usage of the intervention; 3. To determine the acceptability of BOL to support LBP selfmanagement; 4. To explore the potential benefits of the BOL intervention on health, work, and healthcare resources including the reported behavioural changes made post intervention. The user experience of using BOL for LBP self-management in workplace, regarding the objective 5 of this study, is discussed in the next chapter.

# 6.6.1 Feasibility of recruitment and retention

The BOL online platform, while attracting a significant number of potential participants with 6,552 visits, achieved a relatively low conversion rate of 2.6%, with only 170 participants completing the baseline self-assessment. This conversion rate is consistent with similar studies such as the DHSMI study by Celedonio et al. (2024), which reported a conversion rate of 2.78% (Celedonio et al. 2024). However, both these studies fall below the median conversion rate of 3.6% for online recruitment in healthcare services reported by Unbounce (2021), and the average conversion rate of 4% found across 35 online studies using a single social platform (Whitaker et al. 2017).

The lower conversion rate observed in the BOL study, compared to the higher benchmarks reported by Unbounce (2021) and Whitaker et al. (2017), highlights the variability in conversion rates across studies. This variation is influenced by numerous

factors, including the heterogeneity of target populations, the design and attractiveness of the user interface (Hentati et al. 2021), the simplicity of the recruitment process (Denison-Day et al. 2023), the use of incentives (Watson et al. 2018), the accuracy in targeting the intended audience (Murray et al. 2016), and the visibility of the recruitment platform (McRobert et al. 2018). Additionally, recruitment strategies that incorporate behavioural economic theories have been shown to enhance conversion rates in recent clinical studies (Van Mierlo et al. 2016; Greene et al. 2023; Stoffel et al. 2024).

For BOL, which was at the feasibility testing phase, the high conversion rates reported in other digital studies imply that there is potential for further optimisation of current BOL recruitment strategies. For instance, Whitaker et al.'s (2017) systematic review highlighted the significant range in conversion rates, with the highest being 29.5% in a study that used a single recruitment strategy (Facebook) and recorded 1,121 visits to the study website out of 56,621 reached individuals, ultimately collecting baseline data from 330 smoking participants (Carter-Harris et al. 2016). In contrast, another study using the same recruitment strategy but targeting a broader population of smokers achieved a much lower conversion rate of 1.3% (Ramo et al. 2014). These results suggest that future BOL studies need to consider not only regional demographic characteristics and LBP prevalence but also potential saturation during the online recruitment process (Zlotorzynska et al. 2021). Simply increasing study publicity and extending the recruitment period may not yield more baseline data but could instead lead to higher costs and inefficient use of research funds.

In other aspects of BOL recruitment, a total of 238 participants from 3 different working sites consented to participate in this study over the 20-month study period. The recruitment rate across these sites was 3.97 participants per site per month, higher than the median recruitment rate of 0.95 participants per site per month for RCTs funded by the National Institute for Health Research (NIHR) in the UK over the last 20 years (Jacques et al. 2022). In this current study, however, the impact of COVID-19 significantly disrupted established channels of communication between the research team and study participants. The occupational health sites at collaborative workplaces , which previously served as important points of contact for maintaining participant engagement and collecting reasons for dropout, were closed during the study due to

a shifted focus towards Covid-19. This led to the research team contacting participants individually, potentially reducing recruitment efficiency. The shift to remote work and online communication also made it more challenging to reach participants and gather timely information about their reasons for dropout (Kaur et al. 2022).(Koo and Skinner 2005)

Among those who consented but did not complete the baseline self-assessment (n = 68), only 11.8% responded to contact from the research team, and the reasons for dropout were often personal (e.g., pain disappeared, left work, no time to participate). Additionally, technical issues played a role. Two participants reported not receiving the initial email invitation with login information, possibly due to spam filters triggered by the automated BOL system sending large volumes of emails in a short period, as reported similarly elsewhere (Bailey et al. 2015). Furthermore, the email security systems at participating sites may have filtered out follow-up emails containing web links due to cybersecurity concerns, which is a known issue in digital studies (Koo and Skinner 2005).

These challenges suggest that despite recruiting participants from multiple settings, the low conversion rate in the BOL study was likely influenced by the complexity of the online consent process, technological challenges and the unique difficulties of recruiting within workplace environments. To improve conversion rates in future research, it will be important to simplify the consent process, build trust through clearer communication and transparency, and address privacy concerns directly. Additionally, considering optimal recruitment strategies that align with the characteristics of the target population and the experimental design, rather than focusing solely on higher conversion rates, will be crucial. Future research should explore which combinations of online recruiting strategies could enhance participant engagement, improve baseline completion, and ultimately increase the final conversion rate for BOL.

With regards to retention, 34 participants completed the follow-up BOL selfassessment, with a retention rate of 20% at 4 weeks. Consistent with BOL, the unsatisfactory retention rates have been a concern in previous digital intervention studies, particularly of DHSMIs for chronic conditions (Sinha et al. 2022). An analysis of 93 mobile applications with more than 10,000 downloads within the Google Play Store developed for mental health self-management demonstrated a median retention rate of only 3.3% at 4 weeks with highest rate of 15% (Baumel et al. 2019). Across eight large digital intervention studies focusing on self-management of chronic disease, the longest time for 100,000 participants to engage in the intervention and maintain self-management using pre-developed DHSMIs was 26 days, with half of the participants discontinuing the self-management at 5.5 days of intervention (Pratap et al. 2020).

One of the barriers reported in previous DHSMIs for working population was lack of time (Carolan and de Visser 2018). Consistent with this finding, the only participant who clarified reasons for dropping out of the BOL intervention indicated that moving home during COVID-19 resulted in insufficient time to continue participating in the BOL intervention. Based on the results of a SR of studies on the use of DHSMI in LBP patients, it was concluded the retention rate in studies with an RCT design would be higher (n=6, 61.5 - 97.8%) than that in retrospective cohort studies (n=3, 17.8 - 28.0%) (Lewkowicz et al. 2021). One of the included RCTs in using the app-based DHSMI (Kaia) developed for LBP self-management reported a 4-week retention rate of 75.4% (Clement et al. 2018). Contrary to the views of Lewkowicz et al. (2021), in another retrospective study using Kaia in the LBP population, a favourable 4-week retention rate (60%) was also observed (Huber et al. 2017). It is worth noting that these data were derived from samples of existing Kaia subscribers who had already paid for the Professional version of Kaia thus were already highly motivated group and with vested interest to participate. When it comes to newly developed work-based interventions designed to help people remain active and working, the motivation thus may be significantly more challenging to maintain.

Based on this study results and its discussion, several strategies could be implemented in future BOL intervention studies simplifying the intervention and reducing time commitments to accommodate busy schedules. Besides offering individualised feedback, it is essential to incorporate other behavioural incentives, such as progress tracking to motivate continued participation (Nurmi et al. 2020) and improved communication through incorporating follow-ups (van Tilburg et al. 2024). In addition, recruitment efforts can be targeted towards individuals more likely to benefit from the intervention, such as participants with higher disability or longer SA duration

(Watson et al. 2018). Practices that integrate social or peer support elements can also be used to foster a sense of community and engagement (Smit et al. 2021). These approaches, individualised to the needs of the target population, could lead to higher retention rates and more effective outcomes.

#### 6.6.2 Technology feasibility of BOL intervention

Participants who completed the baseline BOL self-assessment accessed feedback on pain types, physical activity levels, and sedentary behaviour 1,742 times over 20 months, with each of the 170 participants averaging 10.25 visits to the feedback page. In a pilot study of another DHSMI (selfBACK) for LBP self-management, the number of visits to the application per person reached 65 in 51 participants with LBP during the 6-week intervention period (Sandal et al. 2020), which is 6.3 times the average access to BOL. In a mixed-methods study that also used selfBACK, 16 participants with LBP accessed the selfBACK application on average 6.2 times per day over a 4week period, representing an average of 173.6 visits per person over the study period (Nordstoga et al. 2020), which is nearly 17 times higher than that of BOL. Some underlying factors may have contributed to lower access to BOL. SelfBACK adopted an external device (wrist band) to monitor and track the daily steps of participants, which provided customised LBP management content based on the physical activity level of the user. At the same time, selfBACK delivered a daily reminder to the user via the mobile application to prompt access. These practices have become increasingly popular among DHSMIs for self-management purposes (Oakley-Girvan et al. 2022), especially those based on mobile applications, which have been found to increase user engagement and awareness (Peng et al. 2016). The use of real-time monitoring to provide more individualised visualisation of data was deemed to improve user engagement and satisfaction (Jeffrey et al. 2019), and eventually advanced user behaviour change (Oakley-Girvan et al. 2022). In other DHSMI studies that used external devices to monitor steps and provide interventions based on unidimensional physical activity levels, similar high user visits (175.3 visits per person) were observed, however, 22.5% of these visits were only to view step counts (Edney et al. 2019). Although selfBACK reported higher user visits, it did not report the number of visits to specific intervention modules, leaving it unclear on the actual number of visits made by participants to the individualised selfBACK intervention contents.

The recommended toolkits within the two main modules of the BOL intervention (Get your spine/mind fit for work, Table 3-1) all recorded usage by participants in this study. The recorded usage of the BOL intervention modules and toolkits demonstrates that participants engaged with BOL and accessed the provided resources in the BOL intervention. This indicates that the BOL intervention content is accessible and technologically feasible to support self-management of LBP in the workplace. But it was also noted that there was considerable variation in the average number of visits to different individualised components of BOL intervention, ranging from 0.13 to 12.02 visits per participant (Table 6-4). Varied visit frequency was also observed among participants in the 6-week pilot study of selfBACK (Sandal et al. 2020). E-health literacy and the capacity to effectively use digital tools was suggested as potential contributor to variation in access (Western et al. 2021). Previous research has shown that the ability to find, understand, and critique health-related guidance and to take action through digital approaches is insufficient among populations of low socioeconomic status (Neter and Brainin 2012), thereby resulting in a digital divide (Latulippe et al. 2017). As socioeconomic data on education, income, and other socioeconomic data were not collected in this BOL study, it is uncertain whether the low utilisation of the intervention was associated with the socio-demographic characteristics of the participants or other factors. In addition, it was noted that the average number of visits to some intervention content was less than one (Table 6-4). This average number of visits per participant was calculated assuming that all 170 participants accessed the individualised intervention content after completing the baseline BOL self-measurement, however, only 25 participants completed all of the self-assessments after 4 weeks. Without data confirming the number of participants who actually accessed the BOL intervention, it cannot definitively conclude that there was non-usage of BOL as the current results only represent the potential minimum average number of visits per participant. Further analysis would be needed to explore the reasons behind this variation and assess actual engagement levels among BOL participants.

In summary, to enhance the technological feasibility of the BOL intervention and improve user engagement, several strategies can be implemented. First, incorporating real-time monitoring through wearable devices could individualise the intervention and make it more interactive (Nordstoga et al. 2020). Introducing daily reminders via the

mobile application would help maintain user awareness and encourage regular access (Kayyali et al. 2017). As well as individualising content to the pain mechanisms, varying the BOL content delivery, could sustain user interest and motivation (Nurmi et al. 2020). Whilst the BOL content and user interface was deemed easy to use (Sheeran 2024b), offering additional support would ensure that all participants, regardless of digital literacy, can effectively engage with the intervention (Schouten et al. 2022). Lastly, fully tracking the usage of specific modules would provide valuable insights into which components are most engaging, allowing for targeted improvements. These strategies collectively aim to create a more accessible, engaging, and effective intervention for participants managing LBP.

#### 6.6.3 BOL intervention acceptability

The results of the TAM questionnaire for BOL showed that the majority of participants' responses agreed with the ease of use (62/75, 82.7%) and usefulness (36/50, 72.0%) of the BOL. According to the TAM (Silva 2015), PU and PEU are key factors influencing acceptability of technology and are affected by several factors such as the social influence (Beldad and Hegner 2018). Previous research indicated that the support from colleagues and employers can affect an individual's decision to embrace new technologies (Venkatesh and Davis 2000). In this study, the majority of participants responses agreed that the administration at their workplace provided adequate help and resources necessary to facilitate their adjustment to the BOL (21/25, 84.0%). This support from workplaces likely contributed to the positive perceptions of PEU, as communication, assistance and collaboration within a supportive environment has been found to enhance individual's confidence in navigating new technologies (Chao 2019), leading to a higher acceptability of health interventions (Svanholm et al. 2023).

In addition, previous research indicated that user characteristics such as prior experience with technology and self-efficacy can also affect perceptions of PU and PEU (Venkatesh and Davis 2000). In this study, participants demonstrated good technological acceptability, with most participants accepted the use of the internet and digital equipment to help improve their physical activity (49/50, 98.0%). Also, all the participants agreed that they were confident in using BOL and its provided resources without guidance (50/50, 100%). These findings suggest that participants' prior experience with technology likely contributed to their positive perceptions of both PU

and PEU. The high self-efficacy demonstrated by participants may facilitate engagement with the BOL intervention, as users who believe in their ability to effectively use technology are considered more likely to adopt and sustain usage (Bandura 1977). The acceptability results of BOL is consistent with another pilot study of a DHSMI (EPIO) for chronic pain self-management, in which most participants found the EPIO useful (39/45, 87%) and easy to use (42/45, 93%) (Bostrøm et al. 2020). But in another DHSMI (ACTonPain) for self-management of chronic pain, only 59.1% (68/115) of responses agreed with the acceptability (Lin et al. 2018). Similar to BOL, both ACTonPain and EPIO were self-directed and used by participants without guidance. However, the percentage of participants with college degrees and above in the ACTonPain study was only 15.6% (Lin et al. 2018), a much lower level of education than the sample in the EPIO study (56%) (Bostrøm et al. 2020). In some cases, for individuals without adequate knowledge and experience of active engagement behaviours, it would require a stronger sense of self-efficacy to achieve the targeted behavioural change (Bandura 1977).

As noted in studies exploring the role of technology in promoting health behaviours, the strong acceptance of digital tools to improve pain self-management highlights the growing trend to utilise technology in health interventions (Stoumpos et al. 2023). Therefore, the positive acceptance of using BOL for LBP self-management from participants in this study provided insight into the broader picture of integrating technology into workplace LBP management strategies. For future DHSMIs on LBP, it would be useful to assess how different user characteristics (e.g., previous experience using DHSMI, self-efficacy, and technology literacy) may influence the PU and PEU. Also, qualitative methods (e.g., interviews or focus groups) are needed to gain deeper insights into users' experiences and barriers encountered during the intervention to further enhance the acceptability of the DHSMI. Furthermore, for the management of LBP in the workplace, adequate support at the time of DHSMI implementation may help to optimise acceptability and increase overall participant engagement.

While the findings indicate a positive acceptance of the BOL intervention, it is important to acknowledge that these findings are based on the responses of participants (n = 25) who completed the intervention and remained in the follow-up. This sample may be potentially biased as those participants who dropped out may have had different

perceptions that were not captured in this study. A qualitative interview study on the selfBACK intervention revealed that participants who withdrawed from the intervention reported the technical difficulty as the primary reason for their discontinuation (Svendsen et al. 2022a). Participants who experienced technology issues when using the DHSMIs may not exhibit a high level of technology acceptance as the participants in this BOL intervention study. Thus, the high acceptance rate in this study should be interpreted with caution, considering that participants who dropped out may face barriers to praticipation or hold less favorable views.

However, it is important to point out that the sample used in the acceptability assessment, while may not being fully representive of the target population, reflected the study design and the iterative nature of DHSMI development. This selection ensures that feedback is gathered from engaged users who are most likely to benefit from and shape the refinement of the BOL intervention, as to help identify strengths and usability issues that need be addressed before the broader implementation. Reaching out to participants who have dropped out may introduce further bias if responses were from those who dropped out for reasons unrelated to technology or intervetion itself, such as recovery of LBP and changed life focus indentified in this study. In addition, the ethical considerations, such as participant's voluntary participation, anonymity and confidentiality, also prevent researchers from collecting detailed feedback from those who choose to withdraw. Future studies should aim to refine the sample in the acceptability assessment by including feedback from participants who discontinue the intervention, thus providing a more comprehensive understanding of the acceptability of BOL intervention.

#### 6.6.4 Potential benefits of the BOL intervention

In this study, only one participant stopped taking short-term SA (<1 week) within the 4-week BOL intervention compared to the baseline. It is important to note that this study recruited individuals with LBP who remained in the workplace, and those who were on sick leave at the time of recruitment may not have been reached or included in the BOL recruitment process. This exclusion may undermine the potential benefits of BOL intervention as a previous meta-analysis showed that DHSMIs could improve work-related outcomes among LBP population in the workplace (Russo et al. 2021). In the SR (**Chapter 5**), one study assessed the effects of DHSMIs on the work-related

outcomes and reported significant improvement in productivity and presenteeism after 4 months intervention (Irvine et al. 2015). A recent RCT also found that using DHSMI developed for workplace mental health significantly reduced employee stress and increased productivity and motivation after 7 days. Kulkarni et al. (2022) believed that this improvement in productivity stemmed from the positive impact of DHSMIs on work-related stress in the workplace (Kulkarni et al. 2022). Interestingly, a recent SR reported that DHSMIs containing components designed to address mental disorders in the workplace significantly improved the depression and anxiety but less effective on SA (Moe-Byrne et al. 2022). Combined with the exploratory findings from this study, current evidence suggested that productivity of the workplace LBP population may be mediated by the effects of stress levels. Future BOL studies may benefit from collecting psychological outcomes from participants before and after the intervention to help identify factors associated with improved work-related outcomes.

In terms of the pain intensity, 16% of the participants (4/25) reported a decrease from moderate and severe pain to mild pain after the 4-week BOL intervention. This finding is consistent with the previous research on DHSMIs for LBP. For instance, a recent meta-analysis by Hong et al. (2024) found that DHSMIs led to a small but significant reduction in pain intensity (MD = -0.18, 95% CI: -0.44 to 0.08) across two RCTs (Hong et al. 2024). Another meta-analysis by Scholz et al. (2024) further supported these findings, showing significant effects of DHSMIs on pain intensity (MD = -0.24; 95% CI: -0.40, -0.09) (Scholz et al. 2024). Despite these improvements, the effects of DHSMIs are generally small to moderate. For example, Du et al. (2020) demonstrated that DHSMIs were associated with modest reductions in pain intensity (MD = -0.27, 95%) CI: -0.43, -0.11) at short-term follow-up (4-8 weeks) (Du et al. 2020). These outcomes often fall short of the minimal clinically important difference (MCID) required for clinical interventions in LBP, which is typically defined as a one-point reduction in the NPRS for pain (Salaffi et al. 2004). In addition, the variability in the content, design, and implementation of DHSMIs across studies makes it challenging to pinpoint the most effective elements. Future RCTs of DHSMIs developed using standardised frameworks will be important in identifying the key components of DHSMIs that effectively reduce pain intensity in workers with LBP and enhancing intervention outcomes.

Regarding the PA, participants of vigorous physical activity levels increased by 4% (1/25) and the mean of total exercise efficacy score improved by 1.04 point (95% CI= -5.96 - 8.04) after the 4-week BOL intervention. Whilst the causal relationship cannot be established, of the participants with self-reported behavioural changes post- BOL intervention (n=10), 30% reported changes in exercise participation and 10% reported developing active exercise routines for LBP. In agreement with this pattern, a SR by Nicholl et al. (2017) observed an improved physical activity levels associated with using the DHSMI for LBP, although the effects were not significant (Nicholl et al. 2017). According to Oliveira et al. (2018), one potential explanation for the lack of significant effects of DHSMI on PA levels in LBP patients is lack of exercise specificity (Oliveira et al. 2018a). Rhodes et al. (2009) suggested that there is a need to enhance exercise self-efficacy in self-management of MSK pain to maintain motivation in exercise participation and thereby promote the sustainability of behaviour change (Rhodes and Fiala 2009). Also, Shawcross et al. (2021) believed that increasing the readiness to make behavioural changes related to exercise participation would further enhance the perceived work ability in working population with LBP (Shawcross et al. 2021).

As the first-line treatment option for LBP by NICE (National Guideline 2016) and other mainstream clinical guidelines (Bailly et al. 2021), exercise has been recognised as one of most effective non-pharmacological management of LBP in both clinical and occupational settings (Chou et al. 2017; Sundstrup et al. 2020). However, consistent with the findings of previous studies of DHSMIs, the short-term (4-12 weeks) DHSMIs incorporating exercise only reported a small effect on pain intensity (MD = -0.28, 95%) CI: -0.52, -0.05), and disability (MD = -0.30, 95% CI: -0.52, -0.08) in patients with LBP (Rathnayake et al. 2021). It is not difficult to observe that the primary outcome measures of existing studies of DHSMIs for LBP self-management centred on pain intensity and disability directly related to LBP, with limited evidence on exercise-related outcomes. Future research needs to integrate measures of the behaviour and motivation associated with readiness to exercise participation (e.g. exercise selfefficacy). Also, considering the small to moderate intervention effects of DHSMIs for LBP self-management on pain and disability (Nicholl et al. 2017; Du et al. 2020; Rathnayake et al. 2021; Valentijn et al. 2022; Scholz et al. 2024), future research should consider shifting emphasis towards the promotion of sustainable behavioural changes associated with physical activities, rather than focusing on pain and disability improvement.

Regarding the healthcare resources usage, it is worth highlighting that there was a reduced number of self-purchased medications used in the LBP self-management after the BOL intervention, with a similar trend towards lower visits to the NHS. This finding is positive as NICE guidelines now endorse careful use of non-steroidal antiinflammatory drugs for LBP and to avoid drugs such as opioids, gabapentin or benzodiazepines which may cause addiction or withdrawal symptoms (National Guideline 2016). This finding is also consistent with the results of Toelle et al.'s study, where the intervention group using an individualised DHSMI (Kaia) for LBP selfmanagement reduced pain medication intake at three-months follow-up (Toelle et al. 2019). Results from another RCT conducted in patients with persistent LBP also showed a significant decrease in medication use at the 6- and 12-month follow-ups in the control group using a DHSMI (eSano BackCare-DP), and a significantly lower number of visits to primary care than the control group receiving usual care (Sander et al. 2020). When interpreting the healthcare resources usage finding in this study, however, it is important to stress that the COVID-19 pandemic struck in the middle of the study with access to healthcare resources diverted to prioritise COVID-19 care. A recent SR reported that the COVID-19 resulted in a 37% decrease in overall healthcare utilisation, 42% decrease in visits for primary care and 32% decrease in the use of NSAIDs (Moynihan et al. 2021; Le-Dang et al. 2024). Therefore, appropriately powered and controlled RCT is needed to fully evaluate the effect of BOL on healthcare resource use.

Among the 19 participants who completed the additional measurement of adherence to the BOL recommended activities, over half (n=10, 52.6%) reported positive modifications in their behaviours after using BOL for four weeks. Apart from adopting recommended physical activities and optimising existing exercise routines, one participant commented on balancing medication use with increased physical activity, demonstrating a growing recognition of the importance of proactive pain management post- BOL intervention. Moreover, reports of behavioural changes aimed at improving sleep quality further emphasised that the BOL intervention content underscores the multifaceted nature of LBP. Importantly, one participant reported following the BOL feedback and maintaining active throughout the workdays, which aligns with recommendations for integrating movement into daily routines to mitigate the effects of prolonged sitting (Shrestha et al. 2016). This commitment to staying active during work indicates that self-management after the BOL intervention may extend beyond following recommended exercises to developing active lifestyles. Future studies need to explore in depth the mechanisms underlying the development of these behavioural changes and validate these findings in larger populations to enhance the adherence to the BOL and its effectiveness on LBP.

#### 6.6.5 Strengths and limitations

As a feasibility study, this BOL study demonstrated a successful recruitment. It recruited 11.9 participants per month across 3 work sites. BOL in-house designed, automated online data collection platform was able to collect anonymous data on intervention usage as well as all the recruitment steps from the welcome page to obtaining a consent, thus offering high level of granularity to inform future recruitment process. Another strength is good baseline completion rate (>70%) and intervention content usage (accessed 10.25 times per participant). It also has high levels of acceptability with 82.7% of participants perceiving that the BOL was easy to use, 72% perceiving useful in assisting self-management of LBP in the workplace and 72% would recommend BOL to others.

Limitations of this study include not collecting sociodemographic data (ethnicity, income, education, geographic location, etc.) at the baseline assessment. Therefore, the health literacy and technology literacy of the BOL participants associated with self-management was unspecified. However, online recruitment and intervention delivery would indicate a certain level of technology literacy and interest in self-management among the participants. Also, 70% of the participants (n=119) were female, potentially limiting the generalisability of the findings. However, this is a common finding with previous studies extensively demonstrating that the prevalence of LBP is generally higher in female than in male (Wáng et al. 2016; Bizzoca et al. 2023). In addition, although participants with LBP were recruited across a wide range of occupations (healthcare, HEI, and transport), most of the participants completing the 4-week follow-up were from the healthcare sector (64.7%), thus the findings of this feasibility study may be more applicable to this occupational population.

Another limitation of this study is that the changes in health, work and healthcare resource uasge observed in the exploratory analysis cannot be fully attributed to the 4-week BOL intervention, as this study was designed as a prospective single group pre- and post-intervention study. Without a control group, any improvements observed could have been due to natural symptom fluctuations, the passage of time, or other unmeasured factors rather than the intervention itself (Evans 2010). However, given that the primary objective was to evaluate feasibility and acceptability, a control group was not included, which is appropriate for this type of study as it helps limit costs (McKillip 1992). Also, the observed patterns of change are consistent with findings from other DHSMI research, which highlight the potential value of further investigation of the BOL intervention. Future RCTs with the control group design will help determine the effectiveness of the BOL intervention.

By far the most significant weakness of this study was the low retention rate with 85.3% not completing the follow-up data collection. Inadequate follow-up completion increased the difficulty of interpreting the feasibility and acceptability findings across occupations. Whilst low retention and engagement is a known issue in DHSMI interventions, particularly related to pain management, it is likely that low retention in this study was severely impacted by the COVID-19 pandemic with the recruitment and intervention coinciding to the day with COVID-19 first lockdown (Ciotti et al. 2020). This led to an immediate discontinuation of the occupational health services across all three work sectors with their workload diverted to assist with the COVID-19 efforts, effectively seizing all but COVID-19 related research support. This meant that an effective pathway of contact with participants was lost, making it challenging to identify the reasons for participants not completing the baseline and follow-up self-assessments. Future studies should consider implementing enhanced retention strategies to improve data completeness and minimise attrition.

#### 6.7 Conclusion

This study was designed as a prospective single-group pre- and post-intervention study to assess the feasibility, acceptability, and potential benefits of the BOL intervention for self-managing LBP in the workplace. The primary objectives were to determine the feasibility of recruitment and retention, assess the technological feasibility of the intervention, evaluate its acceptability, and explore potential health and work-related benefits. A key strength of this study was the successful recruitment of participants across multiple workplace settings, demonstrating the feasibility of implementing the BOL intervention in diverse occupational environments. Additionally, the study's design and automated data collection platform allowed for the collection of detailed usage data, providing insights into how participants engaged with the intervention. However, the study also faced significant limitations, including a low retention rate, which was likely exacerbated by the COVID-19 pandemic. The findings indicated some positive changes, such as a reduction in moderate to severe pain and a decrease in medications usage and NHS visits following the BOL intervention. These results align with other research on digital health self-management interventions (DHSMIs), which have shown similar improvements. While appropriate for this type of feasibility study, the lack of control group limited the ability to definitively attribute observed improvements to the BOL intervention, as these could have been influenced by external factors such as the passage of time or other biases. Furthermore, the lack of sociodemographic data limited the ability to explore how factors like health and technology literacy might have influenced participant engagement and outcomes.

Overall, this study successfully demonstrated the feasibility of recruiting participants from multiple workplace settings and provided preliminary evidence of the intervention's technological feasibility and acceptability. The next section presents the qualitative exploration of participants' experiences using the BOL intervention for LBP self-management in the workplace, offering valuable insights into the technological feasibility, acceptability, and perceived usefulness of the intervention.

# 7. Chapter 7: Phase 3 User experience of using the BACK-on-LINE<sup>™</sup> intervention for LBP self-management in the workplace

# 7.1 Introduction

Chapter 7 presented initial evidence of the technological feasibility, acceptability and potential benefits of the BOL intervention to support the self-management of LBP in the working population was obtained. However, human health behaviour is a complex interplay of factors such as motivations, expectations, attitudes and requirements toward the use of DHSMI for self-management (Clohessy et al. 2024). It is difficult to fully understand how these factors determine individual health behaviours based on quantitative results alone. The NIHR/MRC framework for the development and evaluation of complex interventions recommends involving participants during the feasibility phase to help refine factors of uncertainty in the recruitment, data collection, and retention of the intervention (Skivington et al. 2021). To further explain the uncertainties in Chapter 7 feasibility, acceptability results such as the low retention rates, gualitative evaluation of participants' experiences of using the BOL intervention was carried out to identify potential facilitators and barriers to inform for future development (Svendsen et al. 2020). This chapter describes aims, objectives, methods and results of this qualitative evaluation followed by a discussion of those results.

# 7.2 Aims and objectives

The qualitative part of the study aimed to explore participants' experiences and perceptions of the BOL intervention through the following objectives:

- 1. Assess participants' access to and ease of use of the BOL platform.
- 2. Evaluate the amount, clarity, usefulness, and participants' preferences regarding the intervention content.
- Explore participants' perceptions of how BOL supports keeping people in work and its impact on their confidence and ability to self-manage LBP in the workplace.
- 4. Determine the functions or components participants would like to see in future versions of BOL.

# 7.3 Methods

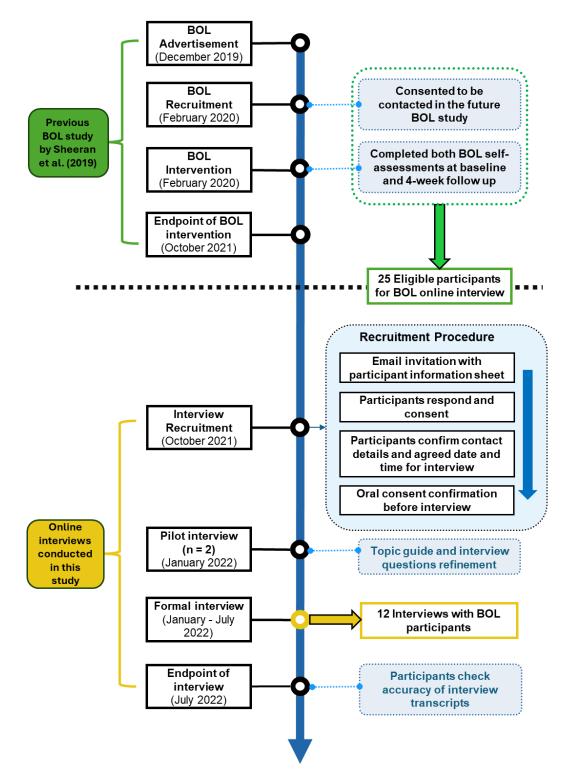
# 7.3.1 Study design

As detailed in <u>Chapter 3</u>, a semi-structured interview using open-ended questions was selected to collect qualitative data for the Phase 3 of this PhD project. Interviews were chosen for its flexibility and adaptability (Pathak and Intratat 2012; Ruslin et al. 2022), allowing for in-depth exploration of participants' thoughts, feelings, and beliefs (Ruslin et al. 2022), which yielded rich and contextually detailed qualitative data (Dilshad and Latif 2013). Due to travel restrictions caused by the COVID-19 pandemic, a telephone interview was selected for this study (Carr and Worth 2001). With advances in technology, data generated from telephone interviews are considered to have comparable quality to face-to-face interviews (Carr and Worth 2001).

# 7.3.2 Sampling and recruitment

For participants who have provided informed consent to be contacted in the future in the previous BOL study, a purposive sampling strategy was used to recruit those who had used the full BOL intervention for 4 weeks and completed the BOL self-assessment again after 4 weeks (Ames et al. 2019). This sampling strategy aimed to ensure that participants had a complete experience of the BOL intervention so that the participant's perceptions of the BOL self-assessment, feedback, and specific modules of the intervention content could be identified, thus providing detailed information for future iterations of BOL.

Three rounds of email invitations were sent to recruited eligible participants (n=25). Given the considerable time gap between BOL intervention completion and the interview for some participants, a link to re-access the demonstration of BOL intervention modules was also attached to the recruitment emails to motivate engagement and contribution. Once participants expressed interest in participating in the study, the researcher (MC) contacted them to schedule an interview. To mitigate recruitment challenges and increase participant response rates (Abdelazeem et al. 2022), a research incentive of £30 was offered to each participant after completing the interview. The flowchart for the timeline and recruitment process of telephone interviews with BOL participants is demonstrated in **Figure 7-1**.



**Figure 7-1.** Flowchart of telephone interviews with working populations with low back pain who participated in the BACK-on-LINE<sup>™</sup> mixed methods study **BOL**: BACK-on-LINE<sup>™</sup>

In the reflexive thematic analysis (RTA), data saturation is not deemed an appropriate concept for determining sample size, as the approach does not assume that meaning

is self-evident in data, or that themes are simply discovered within the data (Braun and Clarke 2021b). Instead, the final sample size was determined by the conceptual density and quality of the data collected to address the study aims (Braun and Clarke 2021b). The decision to stop recruitment was guided by the depth of insight gained from participant interviews rather than the absence of new properties or additional data (Braun and Clarke 2021b). Therefore, this study prioritised data sufficiency to ensure that the findings are shaped by a deep engagement with the data rather than predefined sample size expectations. Also, the participants in this interview presented a diverse profile of demographics and LBP characteristics, containing different occupations, pain intensities, levels of disability, and physical activity levels, which would help to enhance the generalisability and representativeness of the findings.

#### 7.3.3 Data collection and processing

#### 7.3.3.1 Development of the topic guide

A topic guide has been highlighted as an important tool to provide a flexible and structured framework of questions with flexibility, ensuring certain key themes or topics were focused and for conducting semi-structured interviews in qualitative research (DeJonckheere and Vaughn 2019). This approach allowed the researcher to maintain consistency in the wording and order of questions across all interviews. For the design of a topic guide, it was suggested that research interviews should be centred on a small number of open-ended questions to elicit the views and opinions of participants (Creswell and Creswell 2017). In the recent expert consensus, in addition to focusing on participants' perceptions of the information and advice provided in the DHSMI, further emphasis has been placed on a person-centred approach, highlighting the factors that enhance or obstruct users' participation in behaviour change and self-management (Michie et al. 2017).

Adhering to this tenet, a topic guide was developed by researchers (LS, MC) for this interview to provide a clear roadmap in exploring the experiences of people with LBP using BOL intervention in the workplace. Based on the TAM (ease of use, perceived usefulness) and the structure of the BOL (self-assessment, feedback, intervention content), the topic guide was developed with four sections of questions: 1. Access to the BOL; 2. Perceptions of the BOL components; 3. Perceptions of using BOL to

support the self-management of the LBP in the workplace; and 4. Recommendations for the future development of the BOL. These questions were formulated in line with the aim to explore participants' experience and perceptions on using BOL to support self-management of LBP in the workplace. Thus, researchers were able to effectively compare responses across participants, which contributed to the subsequent theme identification and data analysis. <u>Appendix 14</u> provides a copy of the pre-pilot interview topic guide.

As a pivotal role within the research process, the pilot interview afforded novice researchers an opportunity to develop their repertoires of interview skills (Berg and Lune 2014). To assess the feasibility of the topic guide for this study, two pilot interviews were conducted prior to conducting the data collection. The pilot interview aimed to facilitate the identification and resolution of latent challenges, including participant recruitment, time scheduling, and interview recording. Furthermore, it empowered researcher (MC) to make judicious adjustments based on insights gathered from the pilot phase. These adaptations, in turn, contributed to the enhancement of the topic guide and interview procedure.

With the consent of the participants, two pilot interviews were conducted following the pre-developed topic guide. The feedback from the two pilot participants, who were both CU employees, was very informative. Based on the researchers' (MC) observations, certain modifications were applied to the topic guide to shorten the length of the interview. From the feedback from the pilot participants, refinements were made to the wording of certain questions, ensuring simple terminology and short sentences. The final version of the topic guide was developed in discussion with supervisor (LS). A summary of the changes to the questions in the topic guides is presented in **Table 7-1**.

		(* L	
Table 7-1. Com	parison of interviev	v questions pre and	post pilot interviews.

Pre-pilot interview version	Status	Post-pilot interview version	
Q1. How did you come across the advert of BOL?	Unchanged	Q1. How did you come across the advert for BOL?	
Q2= Can you recall how easy was it for	Sub	Q2. How easy was it for you to access BOL?	
you to access BOL?	questions added	If any issues reported:	
	auueu	Q2a. Can you specify the problem?	

		Q2b. Were there any other problems accessing the tool from then on?	
<ul> <li>Q3= At the start of BOL, you were asked to fill in a self-assessment so we could give you feedback on the type of your pain. We also sent you a copy of this self-assessment before this interview. How did you find the self- assessment?</li> <li>Q3a. Can you recall any questions you had difficulty in answering?</li> <li>Q3b. What did you think about the length? Can you recall how long it took?</li> <li>Q3c. Is there any other feedback you would like to give about the self- assessment?</li> </ul>	Simplified	Q3. So, at the start of the back online, you were asked to fill in a self- assessment. And so, we could give you feedback on your low back pain. Can you remember anything about the self- assessment?	
Q4= What did you think of the amount of information in the feedback? Was it too much too little?	Unchanged	Q4b. What did you think of the amount of information in the feedback? Was it too much too little?	
Q5= Was this feedback useful? (If yes- why do you think it is useful? / If no- what information would you prefer to have) Simplified		Q4c. How useful was to receive the feedback?	
Q6= Do you think this feedback reflected your understanding of your own LBP problem? (If no- can you specify the difference?)	Unchanged	Q4a. Do you think this feedback reflected your understanding of your own LBP problem? (If no- can you specify the difference?)	
Q7= Would there be anything else you would like to receive feedback on?	Unchanged	Q4d. Would there be anything else you would like to receive feedback on?	
Q8= How did you find the resources overall?	Description added	Q5. With the feedback you were given links with resources specific to you. How did you find the resources overall?	
Q8a. Did you find the resources useful and relevant to your LBP problem?	Unchanged	Q5a. Did you find the resources relevant to your LBP problem?	
Q8b. Have you use any of the advice to help you manage your own LBP?	Unchanged	Q5b. Have you used any of the advice to help you manage your own LBP?	
Q9= Can you recall which aspects of the resources you found most useful?	Unchanged	Q5c. Can you recall which aspects of the resources you found most useful?	
Q10= Which aspects of the resources you found least useful?	Unchanged	Q5d. Which aspects of the resources you found least useful?	
Q11= Was there any additional information you would like to have had?	Unchanged	Q5e. Was there any additional information you would like to have had?	
	Newly Added	Q6. In terms of the feedback, did you realise the feedback was on the basis of your self-assessment?	
Q12= Did you think BOL helped you stay in work (If yes: how did BOL help; If not: why did you so/ What changes might have made a difference?)	Simplified	Q7. What do you think that BOL helped you stay in work?	
Q13= We know that in some cases it is helpful to the employers to know about the back problem of their workforce to help modify the environment if possible. What information would you be or not be willing to share with the employer?	Divided into two sub questions	Q9. We know that it is important about workforce MSK health so that employer could put in strategies to help employee's health and wellbeing. Q9a. What anonymous information about you low back pain would you willing to share with the employer?	

		Q9b. What anonymous information would you not willing to share?
Q14= At what point do you think it would be most useful to have access BOL?	Deleted	
Q15=Do you think the tool would have worked better if it was given to you by a clinician or someone in your workplace occupational health setting to help guide you through how to use the BOL tool?	Question order changed	Q8. Do you think the tool would have worked better if it was given to you by a clinician or someone in your workplace occupational health setting to help guide you through how to use the BOL tool?
Q16= Overall is there anything else you would like to give us feedback on to help us improve BOL?	Unchanged	Q10. Overall is there anything else you would like to give us feedback on to help us improve BOL?

BOL: BACK-on-LINE<sup>™</sup>

# 7.3.3.2 Telephone interview

This study conducted telephone interviews via Skype calls (Lo lacono et al. 2016) using high fidelity digital recording. The telephone interviews via Skype were audioonly and did not include video conferencing to ensure compliance with the confidentiality and anonymity provisions in the informed consent form. The length of the interview was approximately 20-30 minutes. Prior to the commencement of the interviews, participants confirmed that they had a safe and private space to talk during interview. Participants were informed that their participation was voluntary and that they retained the right to withdraw at any time during the interview. After receiving verbal informed consent from the participant, the interview formally began. Interviews with all participants were conducted in English. Open-ended questions were used in the interviews, with prompts focused on ease of use, perceived usefulness, content relevance, and suggestions for future development.

All interviews were audio-recorded and transcribed verbatim using a speech transcription application (Otter.AI) (Corrente and Bourgeault 2022). The researcher reviewed each interview transcript by listening to the recordings to correct transcription errors generated by the application. For data security protection, the audio recordings were removed from the Otter platform by the researcher (MC) after transcription. Transcripts were also returned to participants for accuracy check.

# 7.3.4 Data analysis

Interview transcripts were imported to NVIVO (Version 12) for reflexive thematic analysis (RTA), which has been widely used in qualitative research (Morton et al. 2021;

Lee et al. 2023; Babbage et al. 2024). Setion 3.3 summarised the rationale for selecting RTA as the method of qualitative analysis for this study.

RTA is not confined to a specific theoretical framework, which provides researchers the flexibility to draw from various paradigms depending on the nature of the research question (Trainor and Bundon 2021). This theoretical flexibility enabled us to approach the analysis within a pragmatic paradigm, allowing for the coding and interpretation of data in alignment with our research objectives and perspective. RTA prioritises understanding the richness of meaning that participants attribute to their experiences rather than simply counting the number occurrences of specific keywords (Byrne 2022), making it well-suited for exploring complex interventions like the BOL from various perspectives. Unlike more structured and prescriptive forms of TA, RTA values researcher subjectivity and emphasises an iterative and reflexive engagement with data (Byrne 2022). This is particularly relevant for DHSMIs like BOL, which are developed through an iterative process of co-production between researchers and participants (Gélinas-Bronsard et al. 2019). Therefore, this study followed the six-steps process (data familiarisation, data coding, generating themes, developing themes, refining themes, writing up) outlined by Braun and Clarke to conduct an RTA (Braun and Clarke 2019) to gain nuanced insights into participants' experiences of interacting with the BOL. The six-step process of conducting an RTA to analyse participants' experiences of interacting with the BOL is as follows:

### Step 1: Familiarisation with data

The first phase was a process of familiarisation, which required the researcher (MC) to immerse themselves in the dataset and engage in critical questioning (Braun and Clarke 2022). First, after each interview, the researcher (MC) transcribed each audio recording into an initial sample using Otter ai (Corrente and Bourgeault 2022). Following the completion of the transcription, the researcher (MC) assessed the accuracy of the transcribed text by listening to the interview recordings and making corrections where necessary. Also, the researcher (MC) ensured that the transcripts were encrypted with the participant's unique 8-digit code to ensure the anonymity of all identifiable personal data. This combination highlighted the influence of researcher throughout the data collection and analysis process, even within ostensibly straightforward transcriptions. As argued by Braun and Clarke, the transcript is "a

product of the interaction between the recording and the transcriber" (Clarke and Braun 2013, p. 162). The researcher (MC) deepened the familiarity with the data through the process of data collection, auditory review of interview recordings, and refinement of transcriptions to ensure precision. Throughout this stage, identified patterns and ideas for coding within the context of the familiarisation process were recorded.

## Step 2: Data coding

In the second phase, meticulous analysis and coding were conducted on each interview script to capture the researchers' own perceptions of the data. It started with initial coding at the semantic level, whereby participants' explicit statements were interpreted descriptively using short phrases. By combining contextual understanding, efforts were made to consider each line of content from various angles, mitigating the risk of semantic loss and thereby maximising the capture of potential dataset patterns. During the initial coding stage, the researcher (MC) made notes on responses that were directly related to the interview question, as well as those displaying innovative insights. These codes were interpreted empathetically and discussed by the researcher with the supervisors (LS and VS) on a regular basis, with a focus on seeking to understand the experiences of participants.

# **Step 3: Generating initial themes**

Patterns and the personal ideas developed in the first stage of the familiarisation process contributed to the initial theme development. During this phase, initial themes were developed using an iterative visual mapping (**Figure 7-2**) centred on the characteristics of DHSMIs, including accessibility of BOL platform, functionality of BOL intervention components, and user experience interacting with BOL. The whole dataset was utilised to develop potential themes with codes being cross-referenced with the original text to ensure their relevance to the themes. Candidate themes were refined through comparisons across codes and data to ensure coherence.

### Step 4: Developing and reviewing themes

At this stage, the structure of the provisional themes and sub-themes was further refined. The supervisory team conducted regular meetings to discuss the integration of codes and continuously reviewed the provisional themes developed in Step 3, thus

facilitating the formulation of sub-themes clusters. Codes exhibiting a high degree of conceptual overlap were merged into a single code. In addition to this, the boundaries of main themes were defined and adjusted to avoid repeated coverage. This process was iterative and recursive with codes and themes being questioned and discussed with supervisors (LS and VS) to connect with existing themes or help identify new themes.

### Step 5: Refining, defining and naming themes

The objective of this phase was to further refine and define the themes, thereby avoiding excessive diversity and complexity (Braun and Clarke 2006). Braun and Clarke suggested that researchers conducting RTA should be clear about the essence of each theme, thus defining what aspect of data should be captured by each theme (Braun and Clarke 2006). Accordingly, the themes, sub-themes, and code were explicitly summarised for its focus, with clear boundaries between each other. Each code and theme were reviewed and agreed upon by the supervisory team to ensure a coherent and consistent narrative of all themes.

#### Step 6: Writing up

After identifying the final themes, a report of the findings was produced. Illustrative interpretation and a selection of quotes across the dataset, which best reflect the theme or sub-theme, were integrated to provide reflexive, contextualised and original analysis (Clarke and Braun 2013). The results were reported with further analysis linked to existing literature to develop an argument relevant to the research question of this thesis (<u>Chapter 3</u>).

### 7.3.5 Ethics

Ethical approval for the telephone interview with BOL participants was granted on 30 July 2019 from the Research Ethics Committee of School of Healthcare Sciences, CU (<u>Appendix 10</u>), HRA and HCRW (<u>Appendix 11</u>). For participants in the mixed methods BOL study who provided electronic informed consent to be contacted in future BOL studies, emails were sent to recruit for participation in the telephone interviews. A PIS clarifying the aim, procedure and content of the interviews, as well as the measures taken to protect the security of personal data, was attached to the email invitations to provide complete information (<u>Appendix 12</u>). Participants were

provided with sufficient time to read the information, consider any implications and ask the researcher any questions before deciding to participate. After obtaining the participant's informed consent to participate in the BOL interview (Appendix 13), the researcher (MC) proceeded to communicate with the participant to schedule the telephone interview. Prior to the start of each interview, the researcher (MC) reconsent (verbal informed consent) with the participant to ensure that the participant was fully aware of the aims and procedures of the study. At the beginning of the interview, the researcher (MC) verbally explained the study to the participant, which covered main points described in the PIS provided to the participant. All participants were informed that the data might be used for future research purposes and interviews would be transcribed anonymously without disclosing personal information. Interviews were conducted on a voluntary basis, and participants could withdraw from the study at any time without any consequences.

Audio files of the interviews were stored on encrypted electronic devices registered with Cardiff University, which were only accessible to the research team. Transcribed audio files were anonymised by removing the names or other identifiable content. All the audio recordings and transcripts were encrypted in accordance with Cardiff University's data protection policy using 8-digit ID. Participant personal information and 8-digit ID matching information were stored on a secure server at Cardiff University, stored separately from the transcribed audio files, to ensure that the content of the recordings could not be linked to identifiable personal information. There was no face-to-face contact between participants and any member of the research team, indicating a highly unlikely risk of incidental disclosure.

### 7.3.6 Reflexivity

To draw meaningful data interpretations, it is essential to acknowledge the researcher's positionality and continuously engage in reflexive practice to ensure the rigor in qualitative analysis (Olmos-Vega et al. 2023). Positionality refers to the researcher's social background and personal experiences, including factors such as age, race, gender, and socioeconomic status, which can influence the research process (Wilson et al. 2022). Reflexivity involves a continuous process of self-examination and critical reflection on how these factors may affect the data collection, analysis, and interpretation (Olmos-Vega et al. 2023).

The researcher (MC) of this study has a physiotherapy background and expertise in musculoskletal disorders, which facilitated a deeper understanding of the participants' LBP experiences. However, as a member of the BOL research team, this familiarity also required a conscious effort to recognise and mitigate any preconceived notions that may influence the interpretation of participants' experiences of using the BOL. To enhance transparency, participants were informed that their own experiences, instead of the researcher's perspectives, were central to the study. A reflexivity journal was also maintained throughout the study to document personal reflections, decision-making processes, and potential biases (<u>Appendix 15</u>). This practice aligns with the RTA principles, which emphasise the importance of the researcher's active role in the construction of knowledge and the need for transparency in the research process (Braun and Clarke 2019).

## 7.4 Results

7.4.1 Descriptive statistics of interview participants

Qualitative interviews were conducted with 12 participants who had completed the baseline and follow-up BOL self-assessments and undergone a 4-week BOL intervention. Based on the dataset of the baseline measurements used in <u>chapter 6</u>, the mean age of the participants in this interview was 47.67 years (SD = 7.4), ranging from 32 to 57 years. Most of these participants were female (n=10, 83.3%). More than half of the participants (n=7, 58.3%) were from the NHS. All participants were full-time employees, with an average weekly working time of 36.75 hours (SD = 12.4). Most participants (n=8, 75%) in this interview self-reported current episodes of LBP for more than 6 months. More than half of the participants (n=7, 58.3%) had SA from work due to LBP. One-third of the participants were classified as having NP based on the BOL self-assessment.

Participants in this interview showed similar distribution across pain intensity and physical activity levels. The majority of the participants were at moderate risk of developing persistent disability and mild LBP specific disability level (**Table 7-2**).

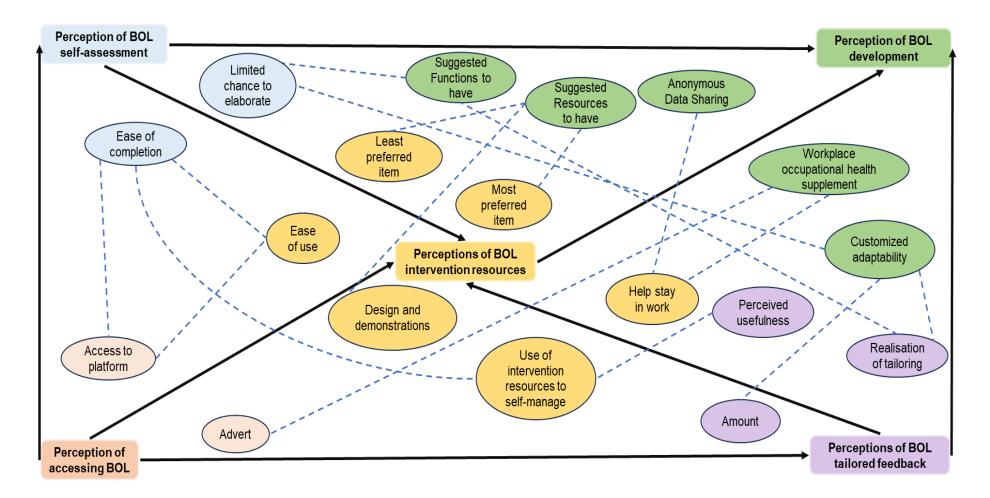
	n	Percentage (%)	
Pain intensity (NPRS)			
Mild (0 - 3)	4	33.3	
Moderate (4 - 6)	4	33.3	
Severe (7 - 10)	4	33.3	
Low back pain specific disability (RMDQ)			
Mild (0 - 6)	7	58.3	
Moderate (7 - 14)	4	33.3	
Severe (Over 14)	1	8.3	
Risk of persistent disability (SBST)			
Low	1	8.3	
Moderate	8	66.7	
High	3	25.0	
Physical activity levels (IPAQ-SF)			
Low	5	41.7	
Moderate	3	25.0	
High	4	33.3	

**Table 7-2.** Low back pain related patient reported outcome measures for participants in the Back-on-Line<sup>™</sup> telephone interview.

**NPRS**: Numerical Pain Rating Scale; **IPAQ-SF**: International Physical Activity Questionnaire-Short form; **SBST**: STarT Back Screening Tool; **RMDQ**: Roland Morris Disability Questionnaire

# 7.4.2 Overall themes

Following the six-steps of the RTA, an initial visual mapping was produced to explore the relationships and hierarchies among themes to help inform the main and sub-themes (**Figure 7-2**). After iterative discussion, 5 main themes and 15 sub-themes were finally identified (**Figure 7-3**).



**Figure 7-2.** Initial visual mapping of the themes and sub-themes of user experience using Back-on-Line<sup>™</sup> for low back pain self-management

LBP: Low back pain

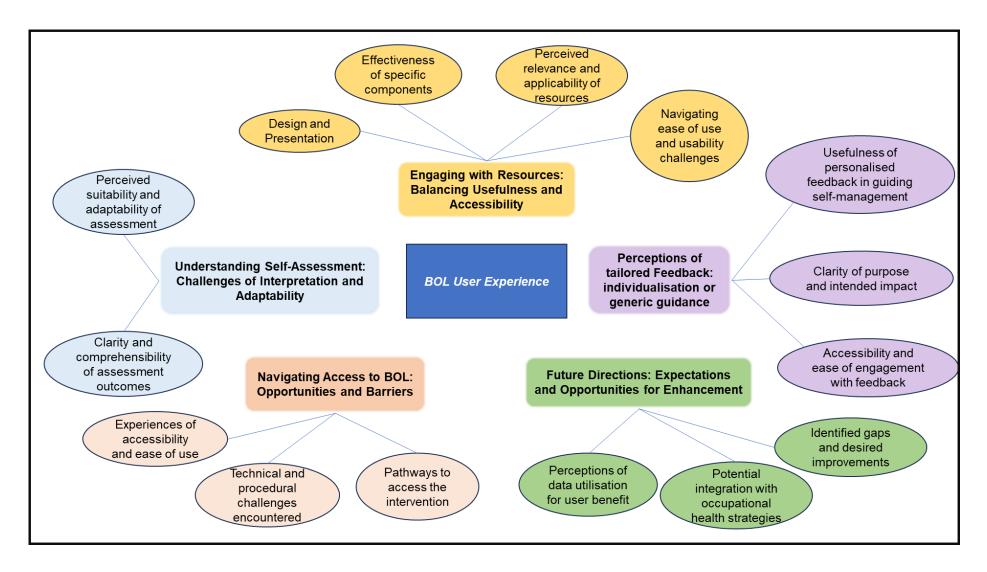


Figure 7-3. The final thematic map for the main themes and sub-themes of Back-on-Line<sup>™</sup> user experience.

# 7.4.3 Theme 1: Navigating Access to BOL: Opportunities and Barriers

The interviews provided useful insights for improving the recruitment process and optimising the platform's functionality in the future. This theme explored the recruitment process and participants' perceptions about the ease of accessing the BOL platform.

# Sub-theme 1: Pathways to access the intervention

Majority of participants found the platform easy to access following the online link accessed via occupational health department and social media. Most participants (10/12) were informed about the BOL intervention and possibility to use it through workplace communications with the remaining 2 accessing BOL through social media.

"I am a frontline NHS worker, and I am pretty certain it came up in one of our emails from work. I saw the email about it or the advertisement about it. And I thought, oh, yeah, that sounds good, so I volunteered." – **76090624** 

*"I believe it was promoted, boarded or advertised by our internal occupational health department where I work." – 18942865* 

From the participants' accounts, it is clear that workplace communication and discussion from colleagues helped to advertise the BOL platform, as illustrated by the following quotes.

"My senior manager contacted me and said: 'There is this program they are trialling at the moment called Back-on-Line. Why don't you sign up for it?' So that is why I ended up signing onto it." – **79904664** 

*"I think a colleague mentioned it to me at work because I was suffering from back pain." - 94798702* 

# Sub-theme 2: Experiences of accessibility and ease of use

Almost all interview participants (11/12) agreed that initial access to the BOL platform was very simple and straightforward, with no problems being encountered during the process.

# "Yeah, the access was fine. Yeah, there was no problem accessing it. No issues at all getting these things working." – **95321812**

*"It was quite easy to follow, very accessible. And I think it was fairly straightforward. I have not accessed it for a while, but I took it the other day because of the email. And it was still easy to access. So overall, it has been very good." – 52999224* 

# Sub-theme 3: Technical and procedural challenges encountered

In previous email communications with BOL participants, it was discovered that some participants did not receive the first email containing their login information (<u>Chapter</u> <u>6</u>). Majority of participants did not report issues with access though two participants still reported experiencing issues with remembering their login information.

"Oh, sorry. I cannot remember. It has been two years. I do not remember there was a link or something." - **79415993** 

7.4.4 Theme 2: Understanding Self-Assessment: Challenges of Interpretation and Adaptability

Overall, participants found the BOL self-assessment to be a comprehensive LBP measurement tool, but it needs to be improved in terms of completion time and adaptability.

# Sub-theme 1: Clarity and comprehensibility of assessment outcomes

Most participants (9/12) were satisfied with BOL self-assessment and reported that the self-assessment was very comprehensive in collecting LBP information and was not difficult to complete:

*"I remember. It was not too long to complete, but it was comprehensive, covering a range of questions about various aspects of that condition, lifestyle, and everything else. So, it was very comprehensive. It did not take me too long to rattle through and get my views." - 18942865* 

But there were inconsistent voices between participants on the ease of completion. Two participants found that the wording of questions between different domains was repetitive.

*"I can remember there were a number of different surveys that were based on different questionnaires or based on different papers. And they all sort of asked the same sorts of questions with subtly different wordings. It did feel like you were going around in circles a little bit because it felt a bit repetitive. You were getting the same questions time after time." – 95321812* 

Two participants commented that the questionnaire took too long to complete and suggested that the number of questions could be reduced to limit the completion time:

"I have not faced any problem answering these questions, but the problem is that the question is too lengthy. We do not have much time to spend in the office. So that is the problem." - **32360180** 

# Sub-theme 2: Perceived suitability and adaptability of assessment

Despite the multi-domain design of the BOL self-assessment to fully characterise LBP, one participant still encountered barriers preventing them from accurately detailing their pain due to the nature of their occupation or pain and wished to have options allowing explanation of personal situation:

"I remember finding it quite difficult to answer because I work very erratic shifts. So, when it said: 'on an average or other typical day, how long do you spend standing?'. Well, it varies hugely. At work, we are talking 12 hours. Not at work is different, and saying an average day is quite difficult because one day, I will literally be standing on my feet and holding patients around for 12 hours nonstop. But on a day when I am at home, I might well be doing sewing or something one day, which, as a result, I will be sitting longer. So, it was quite difficult to answer that question accurately because of my circumstances, which is why I am saying, in some ways, being able to put on a bit more explanation would have been helpful in my case." – **76090624**  One participant noted that there was a lack of appropriate options to elaborate on the recurring nature of LBP in specific questions:

"I cannot recall when I originally completed the assessment, whether there was an option for me to explain that I was not experiencing back pain at the time because it is kind of like a recurrent issue, potentially now and then. I keep my posture and look after my back the way I should, you know, and then the pain gradually goes away eventually. But I cannot remember if there was an option to kind of explain the nature of my own personal back pain in that way. That is not an ongoing thing all the time, and we are not experiencing it right now. But it is something that I am aware of. I am conscious, and I take steps to manage and look after my conditions to minimise or lessen any opportunity to reoccur again." - **18942865** 

One participant commented that the travelling restriction of COVID-19 prevented fully determining the recovery of LBP and being unable to accurately answer BOL self-assessment questions about the physical activity.

"The only comment is when I get the pain, it was light, just not too bad for me. There was not an option for slight pain at that time. I do not want to say I do not have any pain at all, but there is pain. Also, I used to play tennis before my injury two or three years ago and have not had a chance yet to go back to check on that. But I am 100% sure my back is good enough for me to play tennis. So now, because I had COVID in the last two months and did not go back to exercising. It is going to be a while before we find that out. That is my only comment about the self-assessment for someone who has light back pain. I mean, the back is improving, but it is light and not as bad as before." – **79415993** 

7.4.5 Theme 3: Perceptions of tailored Feedback: individualisation or generic guidance

After completing a self-assessment, patients were provided with individualised feedback based on their LBP types and detailed explanations about pain-contributing factors, performance of physical activity and sedentary behaviours. Receiving

individualised feedback on their type of pain and self-management content was generally well received by most participants.

## Sub-theme 1: Accessibility and ease of engagement with feedback

Regarding the accessibility of BOL feedback, no participants reported issues with access to the BOL feedback. However, due to the time interval between the intervention and the interview, one participant experienced issues in recalling how the feedback could be accessed repeatedly.

"I believe I went through everything that was in the email. I do not remember exactly what, but I remember that I did go through all the links and maybe the assessment and this. I believe I did. I am sorry, I cannot remember." - **79415993** 

# Sub-theme 2: Clarity of purpose and intended impact

The structed feedback in three individualised factors to LBP self-management (pain mechanism, physical activity level, sedentary hours) was generally well received, with one participant commenting that this division avoided the overflow of information while keeping the individualising of the content:

"Yes, I did figure out that they would have different components, and then depending on how you answered, they would tailor it. They would not give you all the information from all the components, and the program would just select the bits that were relevant to you. Because otherwise, it is overwhelming. Isn't it? And it is not personalised, either. So yeah, I mean, that aspect was really good." - **79904664** 

Regarding the understanding of individualised intervention, participants have expressed differing opinions. Some (4/12) believed that supplementary material was required to enhance the individualised experience, particularly in highlighting the characteristics of an individual's LBP. One participant indicated that there was a similarity between the individualised feedback from BOL and those common recommendations of LBP.

*"I like to say no. It sounds quite generic. It did not feel very personalised to me. But maybe my back pain is just very typical. And that is why I felt generic because I am just typical." - 95321812* 

Although there were inconsistent opinions regarding the individualising of BOL intervention, more participants (8/12) fully understood the feedback and linked the provided advice to develop their own strategies for LBP self-management. Two participants expressed their adherence to the feedback and described changes in their work style to better manage LBP:

"Yes, and I have followed some of the guidance as well. I have been very mindful that I do not spend too much time sitting because it does have an impact on my mental well-being as well. I have used, you know, taking time out from working and sitting, stretching my back as much as I can. But as I say now, I have added times into my daily calendar to make sure I take those breaks, even if it is not a meeting, even if it is just a walk around the garden or to do some stretching or something like that." - 94798702

"Yeah, I did follow them like the warm-up before starting work. I did follow them, and they were useful. Warm up and do some exercises during the work, like every 2 hours and move to your left and right. Yes, I find them all useful when I do them, which makes my back a lot better." – **79415993** 

**Sub-theme 3: Usefulness of personalised feedback in guiding self-management** All participants agreed that the content of the feedback was appropriately designed and not overwhelming:

# *"It is about right. I mean, it is quite readable before the screen in five minutes. It is just enough to be getting on with, and I like to read it." – 95321812*

As some participants noted, the right amount of feedback content was not simply about just enough. They considered the amount of feedback content to be in a good balance.

"I do not think it is too much. I tend to like loads of information, unlike a lot of people who do not like that much information. But I actually like it a lot. So you know, it could have been more as far as I am concerned. But it seems like a good compromise between too little and too much. Saying everything that needs to be said, I guess. Yeah. And I thought it was not too much information. It was not overwhelming. And it was not overloaded like the website was not overloaded with information, which I think is a really good thing." – **79904664** 

Though they had already been equipped with knowledge of LBP self-management, one participant still expressed the interest in having more information in the BOL feedback:

"Personally, I could have done perhaps with a little bit more, but that is largely because I have worked in a health care situation anyway. And I have a pretty good understanding of what caused my back pain and how to best deal with it. Anyway. So, in a sense, personally, I could have done with more, but actually, because I already had a good understanding. I think if I had not, it would have been perfect because more would have been confusing." - **41274057** 

Apart from the overall satisfaction with the amount of feedback, all the participants demonstrated a high degree of agreement about the accuracy and usefulness of individualised feedback. One participant praised the usefulness of the new information in the feedback for self-awareness of LBP, especially in promoting working and living with pain.

"Yeah. So it is saying that pain is not a good indicator of back injury when to stop because the saying that it is going to hurt, but you got to kind of push through that by being obviously sensible and pushing through it, but do not stop just because you think like, oh, actually, this is beginning to wait now, or that is not a good indicator of what is happening to you. Before, I had not quite realised. I had always thought, well, actually, now I am actually beginning to hurt, and I will stop. But it is saying actually, no, you should not, you should carry on." - **76090624** 

As described by one participant, the coverage of BOL feedback was not a simple listing of information but resonated with their own personal understanding:

"If I can add my own personal perspective, I think I have got an ongoing back issue that has been on and off over the years, and I have had MRI scans and things in the past. So, I have quite a reasonably good understanding of what the cause or potential cause of this might be and how to manage it. I have done lots of physio work in the past. So, it kind of resonated very well because it kind of encapsulated advice and medical opinions I have received over the years. Certainly, from that point of view, it was about right. " - **18942865** 

Even for participants who expressed having good understanding of their LBP, BOL feedback could still provide some useful new insights. The extra support from BOL was deemed a valuable expansion of self-management knowledge as commented by one participant:

"I mean, I have got a pretty good grasp of what my back pain is and what caused it and the best way of dealing with it. I already had a reasonably good understanding of that. So, in some respects, it did not tell me very much that I did not know, but a couple of the bits of advice were new to me, which was useful, like the exercises that you have in a word, the ones I read pretty much any way, but read a couple of again is 'Oh, yeah, that sounds interesting, and I have not run across that one'." -

### 76090624

In addition to being identical to the self-understanding, one participant expressed that the feedback was consistent with what they have been told by medical professionals:

# "Yeah, it matches what the doctors say regarding the basic reason for the pain. It is more informative than anything else because, as I said, this matches what the professionals I have seen for my back pain." - **37804173**

7.4.6 Theme 4: Engaging with Resources: Balancing Usefulness and Accessibility Exploration of participants experiences and perceptions of the LBP self-management resources generated several sub-themes as follows:

# Sub-theme 1: Design and Presentation

Some participants (2/12) commented that the clarity and smoothness of the BOL intervention content through multimedia formats created a pleasant and attractive browsing environment:

"I thought the site was really good. Yeah, the graphics was really good. You know, I thought that the exercises were like the graphics for the exercises, if I can remember. My husband works in sort of web development like e-learning, and he was saying: 'oh, these are really good'. So whoever made graphics like these are good graphics. And the way it was described was really good. It was quite attractive. It was quite sort of interactive to use." – **79904664** 

*"It is nice that the font was nice and big, was not all teeny tiny print, and I seem to say very smoothly from one bit to the next." – 76090624* 

One participant praised the aesthetic quality BOL for its logical layout of the embedded modules and toolkits to present the overarching intervention content:

*"I did like the way it was divided up, so I like the static job toolkit, the physical job toolkit and the resilient spine toolkit. I liked them. And I quite like the breakdown in terms of the recommendations for different modules on how to manage and deal with that in terms of not just the physical side, getting your spine and everything else." –* **18942865** 

Some participants (2/12) commented that they were happy to further contribute to the design of the BOL platform to enhance the user visual and interactive experience:

"Okay, probably the website is not very appealing and a bit clunky. I think it should be more interactive. So probably make it more, I would not say flashy but something more appealing to people." - **37804173** 

"Possibly make the whole thing look a bit slicker, perhaps? Yes, it put me very much in mind of the training modules or my hospital uses of computer learning. I mean, personally, I do not mind that too much because I am a bit older. I am not going to compete against anything like that. But I could see perhaps some younger people might want a little snazzier and sleeker." – **76090624** 

### Sub-theme 2: Navigating ease of use and usability challenges

Most participants (11/12) rated the intervention content as easy to understand and very helpful with one participant sharing the experience of easily navigating the BOL modules and toolkits without the need for extra instruction during use:

"I think it was quite intuitive to use. I do not think it was difficult. Like I could tell that when these diamond-shaped boxes come up, or circles or squares or whatever, I just needed to click on them and did not need to have somebody tell me that I needed to sort of click on different areas. I just went around the whole thing myself. Yeah, I do not think I would have needed any advice on the actual process of navigating the site." – **79904664** 

BOL strived for individualising while ensuring that the intervention content remained as easy to use as possible. However, the diversity of occupations and work environments brought some challenges. Such was the difficulty experienced by one participant in following the BOL guidance:

"Keeping it to a routine and getting your sleep all in a regular habit and all that kind of thing. Because of the job I do (night shift work), it is just impossible. It is frustrating when they say, oh, yes, you know, go to bed at the same time and get plenty of sleep. It is like, no, well, tried to be fine". – **76090624** 

### Sub-theme 3: Effectiveness of specific components

Participants reported feeling equipped with self-management information they were able to use to support and reinforce their existing knowledge in managing their LBP. One participant reported that BOL helped them manage their pain with greater confidence, whilst reinforcing their confidence in effectiveness of the approach they had adopted previously.

"That is useful and reassuring, something I have been doing for a long time. Like exercises recommended by different practitioners that I have seen for my back pain. So, it is reassuring that I am doing the correct exercise." **-37804173**  One participant reported pain relief following BOL intervention which led to a reduction in the need for medication.

"Yeah, I think it has done, and I think it is even reducing medication. I know that I used to take a lot of oral morphine and things like that for my pain. I have been working with the pain clinics to reduce the medication I am using. You know, exercises and things like that could help more." - **94798702** 

In addition, participants conveyed new insights they gained through the BOL intervention, which in some cases prompted them to refine and modify their LBP management strategies. Through their interactions with the BOL, they were able to access advice and guidance from a variety of perspectives, thus expanding their LBP management approach.

"So, I get to try those exercises and find they were easy to do whatever, but I kind of find my own regime. I have already known this is adequate for my needs. I know I have got that additional set of recommended exercises that I can try and fall back on if I want to try something different." – **18942865** 

While most of the participants (8/12) used BOL as LBP intervention guidance, some participants (4/12) further reflected on their previous management practices and reshaped into new strategies for LBP management using BOL:

"In fact, I never really had the same problem again. Although I have got a slight residual back pain, that is what I was interested in going back to the exercise modules. I think it was useful at that time, but I did stop using it when my back pain got better. And I think that is a mistake. That people make that they do not continue doing the exercises as a maintenance program to sort of as a preventative thing." – **79904664** 

Most participants (10/12) actively followed BOL recommended exercises and incorporated these into their daily lives and work routine, reporting positive impacts of the BOL intervention on helping to stay in work:

"I am always surprised how little one has to do to make quite a significant difference. It is like some of the stretches. I started doing it in the morning while I was working. There was a moment that I could do a couple of them, particularly the one where you are leaning forward and then leaning back. It is surprising just doing that a couple of times makes quite a surprising difference." - 41274057
"Well, I tend to do a few quick exercises while I am at work, you know, in the corner of the theatre or the office or whatever, if the opportunity allows. Back-on-Line just sort of makes me feel yes, okay, carry on doing that." – 76090624

One participant further complimented the BOL guidance for its usefulness in reinforcing job stability:

"I think the guidance from the back online for my back pain is very good. Now, I am practising and able to manage because I am a pro. I realised that I have a problem with long sitting, maybe because of my chair and the way of sitting is not that friendly (for the spine). So, all these exercises are really good for us while working." – 32360180

Apart from the exercises, two participants reported following the intervention guidance on workplace safety and ergonomics by modifying office equipment:

"I have actually purchased those high desks that you can stand up. Because I did not want to be sitting down all the time, and standing does help." - 94798702
"Useful, there were a couple of us that did the survey, and we did ask for better chairs. And BOL did sort of encourage us to, you know, be safe while we are at work." – 52999224

In addition, two participants mentioned that BOL facilitated workplace communication on LBP issues through the involvement of employers:

"They are really, really useful because now my boss will understand. You know, she makes me put in my diary specific times 15 minutes to take a walk during a break so that I am not sitting at the computer all day long." - **94798702** 

# "Yeah, we tend to ask our line manager, and she was very encouraging. I think she took part in the survey as well." – **52999224**

One participant believed that BOL promoted actively engagement in teamwork, sharing personal experiences and emotions due to the increased communication between staff, thus reducing stress and feelings of loneliness.

"I even introduced these BOL exercises to my office. Because there are some ladies out there, they cannot keep their foot on the floor while they are sitting because they are very short. So some are using desktops where the gap between the desktop and their chair is too far, then they have to lean. That brings us so many issues. Many staff members told me that these exercises are very useful for them to manage their back pain." – **32360180** 

# Sub-theme 4: Perceived relevance and applicability of resources

Most participants (10/12) expressed that all components were useful.

# "I actually think it was all useful...I mean, I cannot see anything else. I thought it was a really good course." - **79904664**

Some participants (2/12) felt that components overlapped with the knowledge they already possessed seemed to lack substantial usefulness. However, they shared the common view that none of the BOL components were redundant or needed to be removed:

"So the least useful will be all that just tell me stuff I have heard before. But I think for me, and it is supposed to be things like how to sit properly because I have been told how to sit properly since I went to work 30 years ago. These assessments, you know, are something you have to do every year. Those are things I know already. But I think, you know, for someone who is starting to suffer, it is nice to emphasise the importance of that. So I think it is very difficult to say that there is one thing that is least important, really." – 95321812

Most participants interviewed (8/12) expressed a preference for exercise-related content in the BOL intervention. Of note, two participants especially preferred chair-

based exercises that could be easily done in an office environment.

"Exercises, I used all of them. There are all the exercises I do anyway, but there are a couple that you could do when you are seated in a chair, which I have not run across before, so they were quite nice." - 76090624
"Definitely the exercises. I did do some of the exercises whilst you know I am sitting. You know, I can feel my back niggling, and I will do kind of, you know, the one where you slumped forward and sit back up. I do still use some of the exercises from within there. That is the part that I used the most." – 13992711

Apart from exercise, two participants reflected the information about mental toughness in the resilient spine module was another preferred part of BOL intervention.

"It is about the mental, the mental aspect as well, because that is a very important part of any ongoing, whatever back pain or other pain in the body. So, I think it is a really important aspect, but perhaps it does not get covered as much. So, if I am honest with you, this whole experience is probably the first time that I have noticed or seen that coming to the fore." – **18942865** 

7.4.7 Theme 5: Future Directions: Expectations and Opportunities for Enhancement Suggestions for the future development of the BOL intervention were obtained to contribute to the further refinement and development of BOL, leading to a more individualised intervention for the LBP self-management.

# Sub-theme 1: Perceptions of data utilisation for user benefit

One target of BOL was to promote health related communication at the workplace and thereby improve the work environment. This social support enabled though communication may increase the engagement and motivation of employees and encourage more effective adherence to the intervention programme. However, any pain-related health data shall always require the consent of the patient and ensure confidentiality. BOL participants shared their opinions regarding sharing anonymous LBP data with their employers. Most participants (11/12) indicated their willingness to share information about LBP with their employers in the form of an anonymous message. One participant felt that this would disclose the severity of the LBP problem

in the workplace and help to raise awareness of occupational health and change working patterns.

"Yeah, I am all for that. I am very open and very happy to share whatever is necessary because I am understandable. It will help to build the bigger picture of understanding the extent of issues and the extent of how people are responding to treatments or something else as well. So, it is all important." - 18942865

Consistent with this idea, another participant supported that data on LBP in the workplace would help organisations to inform workplace health management policies, while employers could adopt a more proactive organisational approach to LBP management than conservative workplace health promotion.

"I am quite open. I know it can help. You know musculoskeletal is one of the most common sickness reasons for people to be off work. I know that from my own organisation. I see it in the data. Do we educate people enough about sitting at desks? No. Definitely not. And I do not think employees should have to ask for kind of desks or those sorts of things. I think it would be really useful when you join an organisation, you indicate that you do suffer. You do not even have to ask that question. You know, I had been very willing to share with my employer that we might have low back pain issues." – 13992711

### Sub-theme 2: Potential integration with occupational health strategies

Two participants hoped that BOL could be incorporated into primary care services to some extent to dispel concerns about the accuracy and validity of the content of the intervention.

"Yeah, if the GP could recommend it or something like that. You know, if you go somewhere with back pain, it would be good for them to acknowledge this tool." – 94798702

As for the BOL, which focused on the health of the working population, the integration with workplace well-being appeared to be more popular than the compatibility with traditional healthcare. Through the occupational health departments at the workplace,

BOL had the potential to function more seamlessly and naturally as a significant force for workplace improvement:

"I think in terms of coming through it, it probably resonates more for the workplace and workforce perspective if it is directly through the occupational therapist if you let me recommend. If someone is off for long-term back-related problems, then occupational health may be involved. And this can be the way of saying, 'Okay, this is how we are going to help you manage to do this'. It might be an easy way. Yeah, I think overall it would probably be better coming from occupational health, in a sense, because then you have got that kind of official workplace stamp on it." - **18942865** 

## Sub-theme 3: Identified gaps and desired improvements

One participant echoed the idea that the BOL would benefit from developing the ability to provide more adapted intervention content based on changes in the individual status:

"But things change, right? So it will be good to have a follow-up, and then if things change, probably get different exercises, you know, different recommendations for your pain because obviously this is based on the pain type when I fill the assessment." – **37804173** 

As well as the availability of individualised intervention content, the individualised demands from participants were also worth being addressed in the future. One participant pointed out that the demands could be stratified between LBP patients with different levels of self-management capabilities thus providing content individualised to the user's self-management ability and helping different users acquire self-management skills progressively.

"On the whole, I think it is very good. Possibly an extra button to say you want to know more details. So for people like me or others who have got a good grasp of it, to get more information without overwhelming people for whom this is all new because then they could read the basic stuff, which you have got here. And then once they have got familiar with that, possibly the opportunity of saying: 'Once you understand this, this is working for you. This is sort of like extra information if you want it'." – **41274057**  The demand for different levels of individualising was also reflected in participants with a well-developed background of self-management knowledge. One participant preferred to have the autonomy to receive more professional feedback after completing the intervention.

"Maybe that would be a way of feeding back for the patients to be able to say these are the things I have changed because of the information I was given. Maybe I am now standing up or walking or doing more exercise, or I have lost weight or sleeping better. I have changed my mattress or whatever it might be. It does need that sort of you are giving me advice, and these are the exercises that I have done. And then a way of saying that now I feel better because of that. That will be sort of proof that BOL works. It sort of needs that bit of data gathering." – **95321812** 

Furthermore, given the changing circumstances of the individual's lifestyle and work pattern, alternative individualised intervention was suggested. Some participants (4/12) were hoping to employ the BOL intervention more flexibly to better accommodate their own situations.

"You could kind of have a section saying this is what you ideally would do. However, if it is because of your job or your home circumstances or whatever, you cannot find a way around it. Maybe you cannot get necessarily eight hours of sleep at night or at a regular time. If, occasionally, you cannot do that, here are some ideas. It might take somebody to come up with an idea that you have thought of. Okay, so if you cannot get proper hours or sleep at the right time, take a nap or whatever, and you could do that to help ease your back pain." - **76090624** 

While most participants (10/12) demonstrated a strong preference for the BOL exercise guidance, they also provided suggestions for improvements to this component. Considering the safety of the intervention, one participant suggested more assistance for individuals with low physical activity levels and the middle-aged population.

"The only thing I can think of is just some advice for exercise if you are over a certain age and you have not exercised for a while. I am actually 56 now, and I kind of do not exercise very much. I am thinking because obviously, they talked about exercise in this, but I kind of think like: If you are older, should you be more careful about starting on an exercise machine? Maybe more information on exercises for older people." – **79904664** 

As well as making suggestions in terms of resource content, participants also provided valuable feedback on functions they would like to have. Regarding recommendations for future functional development of BOL, more than half of the participants (8/12) indicated their interest in mobile and offline versions of BOL.

"I would imagine an App version, or something might be handy for people because then in their lunch break or in their coffee break or something like that. They could just do a couple of exercises or even show it to someone else who is saying: 'Oh God, you know, I have got low back pain here too.' 'Oh, yeah. So, this is really good. Why don't you register with this?' And also, sometimes when you are trying to learn the exercises, if you have got it on your computer, it can be awkward sometimes sort of making sure you have got enough room to be able to do the exercise and see the screen at the same time." – **76090624** 

7.5 Discussion

7.5.1 Summary of findings

The aim of this qualitative evaluation was to explore participants' experiences and perceptions of using the BOL intervention, focussing on its access and ease of use, clarity, relevance of the intervention content and its perceived usefulness in self-management of LBP. In addition, the study gathered feedback to guide potential future development of BOL.

Participants generally found the BOL intervention accessible and easy to use, with most reporting no significant issues in accessing the platform and navigating its features. The content was well-received, particularly the exercise modules, which were highlighted as clear, relevant, and beneficial for managing LBP. However, some participants noted that certain aspects of the self-assessment were repetitive and time-consuming, and the individualised feedback, while useful, sometimes felt generic

rather than fully individualised. Suggestions for future development included enhancing the individualisation of content, providing options for more detailed information, and creating a mobile or offline version of BOL for greater flexibility and convenience. Overall, while the BOL intervention showed promise, participants identified several areas for improvement, particularly in enhancing the specificity and interactivity of the resources.

Discussion of the results in light of previous research on DHSMIs is provided below in sections coinciding with this study objectives on access and ease of use, BOL content, adaptability and individualisation and future development. The study strengths and weakness are then discussed to contextualise the interpretation of the findings.

### 7.5.2 BOL access, ease of use

Overall, the interviewed participants found the intervention easy to access and use, while some highlighted the self-assessment was long and repetitive. As described in Chapter 5 (Section 5.2.2), the BOL self-assessment consisted of 42 questions. At the same time, the self-assessment included a series of other PROMs including NPRS, RMDQ and TAM. This may have led to the notion of the self-assessment being repetitive as the participants unlikely realised what was the BOL self-assessment and what were the additional measures. Previous research showed that questionnaire of a relatively long length (more than 20 items) may lead to respondent fatigue, loss of motivation, and result in providing low-quality responses for quick completion of the questionnaire (Cape 2010; O'Reilly-Shah 2017; Jeong et al. 2023). For time-pressured working populations, utilising short breaks to engage in individualised selfmanagement activities from BOL may be more advantageous for well-being and productivity than repeatedly disrupting work to complete lengthy self-assessments. Previous research has provided some potential optimisation strategies, such as allowing participants to save and return later (Belisario et al. 2015), and using skip logic to reduce the number of questions that participants answer with no change in situation (Edwards 2010). These practices may help to further address individual unique needs thereby enhancing the individualising of BOL. Future research could also streamline the BOL self-assessment to include the most accurately discerning questions.

Most participants found the access to BOL to be easy and reported having no issues accessing the platform, with two individuals reporting forgetting login details after a period of time since their initial self-assessment. The emergence of access issues suggested that BOL participants may be unable to receive feedback as expected, preventing the shaping of the potential benefits of the intervention, even causing participants withdrawal (Hanney et al. 2022). For the ease of access to BOL, participants used an encrypted 8-digit ID to log in. However, recent research indicated that among users who are accustomed to using self-created account and passwords in digital applications, this practice can still lead to user forgetfulness (Chaudhary et al. 2019). In addition, for participants without regular BOL usage, the memory decay may occur more rapidly when the login information is not regularly reinforced or utilised (Schoenfeld, 2020). Recent SR suggested that consistent interaction with DHSMIs is the key factor of sustained user engagement and retention (Saleem et al. 2021). To address this issue of forgetting login details, several strategies can be implemented, including features such as single sign-on (SSO) options, which allow users to log in using existing accounts from the BOL platform, thereby reducing the need to remember their IDs. Also, the BOL could provide users with the option to acquire ID through a straightforward process (e.g. using the e-mail address registered at participation). In addition, incorporating automated email reminders or mobile notifications could also be an approach to prompting BOL users to log in and engage with the platform regularly (Boucher and Raiker 2024).

### 7.5.3 BOL content

The key focus of the BOL intervention was to empower the working population to regain autonomy over the management of their LBP through the provision of individualised self-management guidance and advice. Exercise to alleviate LBP and strengthen the spine was a significant part of the intervention. This is in accordance with Office for Health Improvement and Disparities to integrate physical activity into daily life through e-Learning towards the goal of "Everybody Active, Every Day" (England 2014). Encouragingly, during interviews, BOL participants highlighted that the most useful aspect of the intervention was the recommended exercises, which they proactively incorporate ed into their daily routines and work lives. These exercises were described as significantly improving their ability to manage pain while continuing to work. The integration of exercise into daily life has been well documented in

previous studies, such as increasing daily walking time through walking meetings (Ahtinen et al. 2016), climbing stairs instead of taking the lift (Thomas et al. 2015), and home-based exercise (Jakobsen et al. 2015). These interventions tended to be feasible and effective for MSK pain because the exercises were related to specific functions associated with daily living and could be performed at any time without the need to set aside a specific time.

For the BOL intervention, the focus on providing individualised feedback and suggestions may be an underlying reason for the voluntary behavioural changes reported by participants. This was supported by Mikolaizak et al. (2022), whose qualitative study of the eLiFE programme found that, even in the absence of ongoing self-monitoring, an individualised intervention integrated into an existing routine of daily living was able to result in some positive behavioural change in a short period of 4 weeks (Mikolaizak et al. 2022). Previous research has also shown that integrating individualised activities into daily routines can contribute to long-term adherence over non-individualised, structured exercise programmes (Clemson et al. 2012). This integration would be important for long-term adherence and effectiveness as it minimises disruption to daily activities and promotes sustainable behavioural modifications (Lachman 2006).

Furthermore, participants' responses in this study indicated that BOL provided the opportunity to drill down on topics they found difficult to discuss in general, such as requests for ergonomic adjustments in the workplace, flexible working arrangements, and improvements in the work environment. This is in agreement with previous research that showed that DHSMIs can promote greater self-disclosure of undesirable behaviours and sensitive issues (Marcu et al. 2022b). As an important technique in DHSMIs, facilitating self-disclosure in participants has also been found to increase user engagement in cognitive-behavioural interventions (Goh et al. 2023). However, some concerns remained about the accuracy and validity of the BOL assessments and associated self-management knowledge received before visiting primary care. For future BOLs, gaining formal recognition from the government or health authorities (e.g., NHS, HSE) may help to increase the credibility and perceived validity of the BOL for users, as well as increase the engagement of healthcare professionals to improve the promotion of BOL. However, before this can be achieved, robust validation of self-

assessment and evaluation of the effectiveness of BOL intervention are needed to ensure that the BOL accurately reflect participants' LBP conditions and promote effective self-management strategies.

### 7.5.4 Relevance and individualisation of BOL

The rationale behind BOL's provision of individualised LBP self-management was not to overwhelm users with a large amount of vastly generic text but instead to provide evidence-based resources individualised to the needs of the individual by considering pain mechanisms underlying the LBP of each individual. There is a limited number of DHSMIs designed for LBP offering individualised content, but for individualised DHSMI like SelfBACK, which anticipated to increase the perceived personal relevance and applicability of the advice, good engagement and eventual effectiveness has been reported (Sandal et al. 2021). In this study, 75% (8/12) participants recognised that the BOL intervention was based on their BOL self-assessment and agreed that the BOL provided individualised advice. The remaining participants did not realise the content was individualised. This could be explained by allowing the users to access all the resources once they accessed and completed the individualised resources.

A notable strength of BOL was its classification of users into distinct pain subgroups, which informed the individualised intervention content. Participants recognised that this approach provided structure to their self-management strategies and allowed for differentiation between pain mechanisms. However, some expressed a need for refinement, particularly in incorporating personal factors such as work schedules, preferred exercise routines, and psychological well-being. This is consistent with the previous SR that DHSMIs for MSD should account for individual work environments and behavioural preferences to improve adherence and outcomes (Tersa-Miralles et al. 2022). In addition, participants acknowledged that BOL provided a degree of individualisation based on their self-assessment responses, but their experiences varied regarding its perceived usefulness. While some users found the individualised recommendations relevant to their needs, others expected a more dynamic and adaptive system that could respond to changes in their condition over time. This aligns with the broader research indicating that DHSMIs need to evolve with user needs to maintain engagement and efficacy (Michie et al. 2017).

All the information participant received was based on their self-assessment, whereas changes in LBP presentation may create different needs. The fluctuating nature of LBP posed new challenges to the adaptability of the BOL self-assessment with scores reflecting state of the condition in that point in time. Participants commented that the perceived pain intensity, symptoms, and level of life and work disruption experienced varies and so conducting a single BOL self-assessment may not truly reflect the condition. Therefore, the participants expressed that they hoped to have the opportunity to reflect their changing nature of LBP on the BOL self-assessment. Previous studies provided potential strategies for future BOL self-assessment by incorporating more branching logic (Kaiser et al. 2019). For example, by asking "Are you currently experiencing an episode or exacerbation of low back pain?". If answered "yes," then the full BOL self-assessment would be performed directly. If the answer is "no," an appropriate question asking about typical or average levels would be used, thereby inferring natural fluctuations and better reflecting recurring nature of LBP (Macedo et al. 2014). However, although more branching logic could improve the user's individualising experience, it would also lead to more questionnaire items. Considering the existing need to optimise the BOL self-assessment items, it needs to be carefully considered how to balance the use of branching logic.

### 7.5.5 Suggestions for future BOL development

Several areas for improvement were discussed including enhancing the access, interactivity of the resource and specificity. Regarding accessibility, improvements were deemed to be important. Recent DHSMIs for LBP management in the workplace have been developed in the format of smartphone mobile applications (Apps) (Irvine et al. 2015; Jorvand et al. 2020; Svanholm et al. 2023). This is because nowadays 65% of the global population were reported to own a smartphone (Candussi et al. 2023), which makes it easy to access the intervention at any time and from anywhere. Also, participants in this study were not office based and so whilst they are not easily able to use computers in work, they can access BOL using smart phones (Portoghese et al. 2014). Offline data packages in the app version of BOL were also recommended by the participants. They believed it could be helpful for them to have quick access to the required intervention content, such as exercises to alleviate LBP in the workplace, thus facilitating the self-management of the LBP. In addition, mobile apps have the capacity to utilise in-built smartphone features such as sensors (GPS, accelerometers,

cameras), notifications and connectivity to provide more interactive and contextsensitive interventions based on the user's real-time status and environment (Klasnja and Pratt 2012).

Participants emphasised the importance of maintaining their anonymity when using BOL and supported sharing anonymised data with employers to ensure appropriate occupational health support. Anonymity in DHSMIs has been shown to encourage participants to disclose sensitive information and engage more fully with the intervention (Howarth et al. 2018). This approach is particularly valuable in addressing issues like hostile work environments, job insecurity, stigma, and discrimination faced by people with LBP (Penn et al. 2020; Yang et al. 2023). However, concerns about data security and privacy remain significant barriers to DHSMI use (Svendsen et al. 2020), exacerbated by cybersecurity issues like identity theft and malicious apps (Pool et al. 2020). Therefore, future development of the BOL app must prioritise user data security and privacy protection. Additionally, the design should consider the technology literacy of different populations, ensuring that the app is easy to use and does not inadvertently widen the digital divide, especially for those with lower socio-economic status (Neter and Brainin 2012; Kumar et al. 2019).

# 7.5.6 Strengths and limitations

This study gained an in-depth understanding of participants' experiences of using BOL for LBP self-management, providing valuable qualitative insights into the technological feasibility, acceptability, and potential benefits of BOL. The strength of this study was the detailed depiction of how LBP population incorporated the recommendations from the BOL intervention into their daily lives and work, which is difficult to capture through quantitative BOL self-assessment. Most participants reported that they understood the feedback provided in the BOL intervention and were able to integrate it into their own LBP management routine, suggesting that the content of the BOL intervention was intuitive and easy to understand. In addition, this study revealed that participants incorporated BOL-recommended exercises in their work routines, highlighting the potential of BOL intervention to have a positive impact on behaviour change in the workplace. Participants also reported a positive influence of the BOL intervention on their ability to effectively manage LBP whilst continuing to work, which highlighted the potential for benefits of the BOL intervention in maintaining productivity.

The study had some limitations, particularly related to the time gap between the completion of the BOL intervention and the interviews. The COVID-19 pandemic resulting in difficulty to contact the participants through the occupational health service. Some participants were interviewed as long as 12 months after their participation, which could have affected the clarity of their memories and limited their contributions. To mitigate this, participants were provided with a demonstration of the BOL intervention in the recruitment email and were given the opportunity to revisit their individualised feedback and advice from BOL.

Another weakness of the study is the inherent bias of interviewing only those participants who completed the BOL intervention, potentially missing the perspectives of those who did not engage or dropped out. This is a common issue in intervention development research, as it limits the understanding of barriers to engagement and the reasons for non-completion (Skea et al. 2019). To address this, future studies could incorporate follow-up with non-completers through brief surveys or targeted interviews, which could provide valuable insights into the challenges faced by this group. Additionally, implementing real-time feedback mechanisms during the intervention could help identify and address issues as they arise, potentially reducing dropout rates and capturing a more comprehensive range of participant experiences (Bentley et al. 2019; Marcu et al. 2022a).

### 7.6 Conclusion

This chapter presents the results of telephone interviews with BOL participants regarding the use of BOL for LBP self-management. Participants shared their perceptions about BOL's accessibility, self-assessment, feedback, and LBP self-management resources, along with suggestions for future development. Overall, participants indicated that they could conveniently access BOL from their workplace and complete the online self-assessment with ease and without guidance. The BOL feedback was generally viewed as comprehensive and aligned well with participants' understanding of their condition. The exercise-related suggestions were particularly appreciated and were often incorporated into daily routines to improve LBP self-management.

The study had several limitations, including the time gap between the completion of the BOL intervention and the interviews, with some participants interviewed up to 12 months later, potentially affecting the clarity of their memories. Additionally, the focus on participants who completed the intervention may have missed the perspectives of those who did not engage or dropped out, limiting the understanding of barriers to engagement. Future studies should include follow-up with non-completers and implement real-time feedback mechanisms to better capture and address challenges as they arise.

Participants acknowledged the ease of access, intuitiveness of content, and overall usefulness of BOL, but perceptions of the individualisation of the intervention were mixed. Some participants felt that the BOL self-assessment did not fully accommodate their fluctuating LBP and unique work schedules. To improve individualisation, participants suggested adding adaptive content to cope with changes in LBP and work circumstances, as well as designing a less burdensome self-assessment. Additionally, developing a mobile application version of BOL with enhanced accessibility and smartphone functionality was recommended to better meet the needs of participants for LBP self-management in the workplace.

# 8. Chapter 8. Summary and discussion

## 8.1 Introduction

This final chapter of the thesis begins by outlining the overarching aims and objectives of this PhD project. It will then provide a summary of the main findings and discuss how these contribute to the existing body of evidence on DHSMIs for LBP in the workplace. Key strengths and limitations of this PhD project studies is then offered to contextualise the contributions together with recommendations for future research.

## 8.2 Aims and objectives

The aim of this PhD research was to enhance the understanding and application of DHSMIs for workplace LBP, focusing on individualised approaches. This involved developing and validating a pain classification self-assessment tool and evaluating the feasibility, acceptability, potential benefits and user experiences of the BOL intervention for LBP self-management in the workplace.

Reflecting on the results of the literature review in <u>chapter 2</u>, this PhD project had three key objectives: 1) carry out a systematic review of literature appraising the evidence around the effects and overall quality of DHSMIs for LBP self-management in workplace settings with specific focus on individualisation; 2) establish psychometric properties of the revised online version of BOL self-assessment and 3) assess feasibility, acceptability and potential benefit of BOL for LBP self-management together with qualitative evaluation of user experiences.

8.3 Summary of findings and contribution to knowledge

8.3.1 Phase 1: Systematic review of DHSMIs for LBP in the workplace

The DHSMIs for the self-management of LBP in the workplace were found to be developed as online platforms (del Pozo-Cruz et al. 2012a; Irvine et al. 2015) and mobile applications (Almhdawi et al. 2020; Cimarras-Otal et al. 2020; Anan et al. 2021). The five eligible studies reviewed in this SR involved work-based DHSMIs that included exercise in workplace (Almhdawi et al. 2020; Anan et al. 2021), modification of work activities (Irvine et al. 2015; Cimarras-Otal et al. 2020), workplace ergonomics

education (del Pozo-Cruz et al. 2012a). Only one study referred to theoretical underpinning of the designed intervention, namely Social Cognitive Theory and Theory of Planned Behaviour, and form of individualisation by classifying the dominant work activities (Irvine et al. 2015). The SR found moderate level evidence for short to middle term (6 weeks - 9 months) positive effects of the DHSMIs on pain intensity, disability, and physical performance of people with LBP. The evidence for the effects of DHSMIs on quality of life, psychosocial factors, and work performance was mixed across included studies. The DHSMI individualised by work activities did not demonstrate any significant additional effect on LBP than the general DHSMI.

In accordance with contemporary clinical guidelines for LBP self-management (National Guideline 2016), DHSMIs in the reviewed studies mainly included content of education material and exercise, which is consistent with findings in previous SRs by Nicholl et al. (2017) and Lewkowicz et al. (2021). The lack of high-quality RCTs together with low level of reporting of theoretical frameworks underpinning the interventions found in this study expanded the observations made in other systematic reviews of DHSMIs for LBP (Nicholl et al. 2017; Lewkowicz et al. 2021). Most notably, this study corroborates the scarcity of individualised DHSMIs at the workplace highlighted in previously by Moe-Byrne et al. (2022). Previous SRs have generally considered customised functional components as individualisation (Nicholl et al. 2017; Lewkowicz et al. 2021), ambiguating the concept of individualisation and resulting in the included DHSMIs not considering individual need, preference or the mechanisms of LBP. These results highlight the importance of utilising appropriate intervention development framework when designing complex work-based interventions such as MRC guidance utilised in this PhD project.

There is moderate effect of work-based DHSMIs on pain intensity (Mean difference= -3.34 to -0.26) and disability (Mean difference= -7.36 to -6.10) of workers with LBP observed in this study. The reported changes in disability of the included RCTs in this study are higher than the clinical standard of minimum level of detectable change (Stratford and Riddle 2016), highlighting the potential clinical significance of the DHSMIs on LBP-related disability. This finding is consistent with the previous SR which also observed an improvement in pain intensity and disability associated with using the DHSMI for LBP but of small effect size (Nicholl et al. 2017). In addition, distinct

absence of measuring work-related outcomes such as the effect on sickness absence and presenteeism also corroborates with findings from other systematic reviews on LBP management (Nicholl et al. 2017; Lewkowicz et al. 2021; Blake et al. 2024). Focusing on these outcomes is essential for determining the overall value of DHSMIs and their potential for widespread adoption in workplace settings. Therefore, the Phase three feasibility study of this PhD project included work related outcomes in the battery of measured outcomes in preparation for a future controlled trial.

8.3.2 Phase 2: BACK-on-LINE<sup>™</sup> self-assessment - Determination of the cut-off point and evaluation of the psychometrics properties of the BACK-on-LINE<sup>™</sup> selfassessment in the workplace LBP population

This phase established a cut-off point for the BOL self-assessment to classify subgroups of the LBP population in the workplace based on pain mechanism into nociceptive and nociplastic pain. The new cut-off point showed good diagnostic accuracy with high sensitivity (0.889) and moderate specificity (0.724) against the SBST with a similar construct as a reference standard. The results of the test-retest reliability analyses showed that the BOL self-assessment had good agreement over a 4-week period (ICC = 0.88; 95% CI: 0.78-0.94). Also, Cronbach's alpha for internal consistency was over 0.80, further confirming the reliability of the tool. Moderate correlations were found between the BOL self-assessment and other validated LBP measurement instruments with similar constructs, including SBST (r=0.67, p<0.001). This suggests that the BOL self-assessment has good construct validity related to LBP-related pain, disability, and risk of chronicity. In addition, the significant differences in the mean of NPRS, RMDQ, and SBST scores were observed in the BOL selfassessment subgroups. This demonstrates the excellent known-groups validity of the BOL self-assessment to discriminate between NC and NP subgroups in the workplace LBP population. Furthermore, the BOL self-assessment demonstrated good criterion validity in discriminating high-risk disabling LBP populations based on other standards of pain intensity (AUC=0.67, 95% CI: 0.57-0.77), duration (AUC=0.68, 95% CI: 0.59-0.76), disability (AUC=0.77, 95% CI: 0.66-0.88) and SA from work (AUC = 0.71, 95% CI: 0.60-0.82).

Our study's findings demonstrate that the BOL self-assessment performs well in classifying subgroups of the LBP population in the workplace based on nociceptive and nociplastic pain mechanisms. This is supported by the good diagnostic accuracy of the BOL self-assessment when compared to the SBST, a widely used clinical tool known for its focus on assessing key psychosocial factors influencing chronic LBP outcomes. The BOL self-assessment also showed good test-retest reliability (ICC = 0.88) and high internal consistency (Cronbach's alpha > 0.80), similar to the established reliability of the SBST as reported in previous studies (Hill et al. 2008; Pilz et al. 2017; Giusti et al. 2021)

In terms of construct validity, our study found moderate correlations between the BOL self-assessment and other validated LBP measurement instruments, including the SBST (r=0.67, p<0.001), suggesting that both tools are effective in capturing pain, disability, and risk of chronicity in LBP populations. However, the BOL self-assessment differs from the SBST in its focus. While the SBST emphasises psychosocial factors relevant to primary care, the BOL self-assessment is individualised to the workplace setting, capturing a broader construct of pain and disability related to working environments.

The BOL self-assessment outperformed the SBST in discriminating high-risk disabling populations with high pain intensity (NPRS  $\geq$ 7; AUCs=0.67 and 0.54, p=0.017), long LBP duration ( $\geq$ 6 months; AUCs=0.68 and 0.53, p<0.001), sever disability (RMDQ  $\geq$ 14; AUCs=0.77 and 0.54, p<0.001) and long SA from work ( $\geq$ 4 weeks; AUCs=0.71 and 0.52, p=0.016). This finding aligns with the understanding that the SBST, originally developed for predicting future disabling LBP in primary care settings, may be less suited for identifying long-term LBP risks in workplace environments (Kendell et al. 2018). This distinction highlights the relevance of the BOL self-assessment in occupational health, particularly for LBP management over extended periods, and highlights the need for such tools that can effectively capture the complex interplay of factors influencing the transition from acute to chronic LBP (Stevans et al. 2021).

A limitation of the BOL self-assessment tool is its focus on only two pain mechanisms, nociceptive (NP) and nociplastic (NC) pain, without addressing neuropathic pain, which may be less relevant in workplace settings where individuals with high-intensity

neuropathic pain are likely to seek medical help and be unable to self-manage (Doneddu et al. 2023). Given the LBP complexity and its fluctuating nature, however, future BOL research should refine pain classification to include neuropathic pain, as distinguishing between these mechanisms could provide more nuanced insights into LBP management.

8.3.3 Phase 3: Technological feasibility, acceptability, potential benefit of BACK-on-LINE<sup>™</sup> and qualitative evaluation of user experience

Third phase of this PhD project assessed recruitment and technological feasibility, acceptability and potential benefits of the individualised BOL intervention, followed by a qualitative evaluation of the user experience. The study successfully demonstrated the feasibility of recruiting participants from multiple workplace settings and provided preliminary evidence of the BOL intervention's technological feasibility and acceptability. While the lack of a control group was appropriate for this form of feasibility study (McKillip 1992), it limited the ability to definitively attribute observed improvements to the intervention, as these could have been influenced by external factors such as time or other biases (Evans 2010). Despite this limitation, the study observed positive outcomes, including reductions in moderate to severe pain, visits to NHS and usage of medication, aligning with similar research on DHSMIs for LBP (Toelle et al. 2019; Sander et al. 2020; Hong et al. 2024; Scholz et al. 2024).

A key strength of the study was the successful recruitment of participants across diverse occupational environments, demonstrating the intervention's broader applicability. The design and automated data collection platform provided detailed insights into participant engagement, with the BOL platform recording 6,552 visits over 20 months and 238 participants recruited. However, challenges exists such as low retention rates, likely exacerbated by the COVID-19 pandemic, and the reliance on self-reported data introduced potential biases (Sterne et al. 2019). Whilst COVID-19 saw an explosion of digital health interventions and platforms both in market and utilisation (Getachew et al. 2023), this study highlights that for workers with LBP to properly engage with DHSMIs, human support and occupational system within which the intervention operates may still be necessary to ensure engagement. This is of

particular importance in DHSMIs for LBP given the number of studies reporting very low engagement, irrespective of the pandemic era (Beukenhorst et al. 2022; Marcuzzi et al. 2023). Future research needs to give attention both to the intervention design promoting interaction and system within which the interventions function to address those low engagement levels. Moreover, known factors related to sociodemographic data like health and technology literacy would be helpful in future research to explore effect on participant engagement and outcomes (Neter and Brainin 2012; Kumar et al. 2019; Western et al. 2021).

Interviews with 12 participants revealed that the BOL intervention was generally wellreceived. Participants found the online platform easy to access, with the selfassessment being comprehensive and the individualised feedback well-designed, balanced, and helpful, especially for those already familiar with LBP self-management. Many participants reported independently using the BOL resources to enhance their self-management strategies, often incorporating exercise-related suggestions into their daily routines. Despite these positive aspects, some participants noted that the BOL self-assessment did not fully accommodate their fluctuating LBP and unique work schedules, suggesting a need for more adaptive content. Lack of perceived responsiveness of DHSMIs has been reported by individuals with LBP in research previously including insufficient individualisation to meet the needs of the individual (Svendsen et al. 2022a) and inadequate just-in-time feedback based on user responses (Nahum-Shani et al. 2018). Whilst caution is necessary regarding the potential high level of complexity in DHSMIs as stressed by Murray et al. (2016), these findings highlight the importance of incorporating sufficient complexity and responsiveness in DHSMI design to ensure ongoing relevance, known to further improve engagement (Saleem et al. 2021).

Finally, the study also highlighted some limitations, such as focusing on participants who completed the intervention, which may have overlooked the perspectives of those who did not engage or dropped out, limiting the understanding of barriers to engagement. This is a recognised issue in literature concerned with methodological design of intervention development and evaluation. Previous research on the development of complex health interventions has recommended to incorporate the views of non-completers through follow-up surveys or interviews to ensure that

responses of those not completing the intervention are considered to inform further development where appropriate (Levati et al. 2016). Future research should involve a fully powered randomised controlled trial within workplace settings to better assess the efficacy of the BOL intervention, explore strategies to enhance retention and participant engagement, and consider developing a mobile application version with improved accessibility and functionality (Heijsters et al. 2022; Marcu et al. 2022b; De Angelis et al. 2024).

#### 8.4 Strengths and limitations

To the best of knowledge, this 3-phase study provided the first synthesis of the effects and intervention content of DHSMIs used for LBP in the workplace, with a particular focus on individualisation. The main strength of this study was following the standardised NIHR/MRC framework for the development and evaluation of complex interventions and adopted of a mixed-methods research design, which provided comprehensive evidence of the feasibility and acceptability of BOL in supporting LBP self-management in the workplace. A large dataset (n=136) obtained across diverse occupational settings was used in the psychometrics properties evaluation of the BOL self-assessment, which enhanced external and internal validity of the results. Also, the interviews with BOL participants were analysed using the reflexive thematic analysis, incorporating reflexivity into the thematic analysis thereby increasing the credibility of the findings.

There are limitations in each of the three phases in this study. Considering that DHSMI is in a fast-evolving field, the conclusions of the SR in the first phase of this study may not be applicable as more research is conducted. The second phase of the study did not fully demonstrate the construct validity of the work-related domain (PW) because the data were derived from another BOL study which did not include work-related measurement instruments. However, it can be argued that good construct validity of other sub-domains and the overall BOL measurement tool reflect that the construct of LBP-related work factors as measured by PW is unique comparing to other constructs. In the third phase, the collaborating occupational health department had to change its work activity due to COVID-19, leading to incomplete collection of reasons for participant dropout from the study. Also, there was a long gap between the completion of BOL intervention with the interview for some participants and the quantitative data

used was collected in the form of self-reported data, thus may introduce potential self-reporting bias and recall bias (Althubaiti 2016). However, the triangulation of mixed data from multiple sources collected by different BOL researchers over multiple time periods may contribute to the credibility and validity of the data (Moon 2019).

The NIHR/MRC framework provided a structured and systematic approach to the development and evaluation of the BOL intervention, ensuring that the BOL intervention is theoretically grounded, feasibility-tested, and iteratively refined before advancing to the future large-scale evaluation. In the absence of a structured development and evaluation model, the development of the BOL intervention might have focused more on direct practical implementation rather than ensuring the reliability and validity of the BOL self-assessment classification for individualisation. However, while beneficial for complex interventions, the NIHR/MRC framework does not explicitly address factors critical to digital interventions, such as user engagement, technological feasibility, adaptive functions and individualisation. Other existing frameworks, such as the IDEAS and the Design Thinking framework, may provide complementary strengths. The IDEAS framework, designed specifically for digital interventions to change health behavior, emphasises user-centered design, behavioral theory, and iterative refinement based on real-world feedback, which allows interventions to evolve dynamically instead of following a structured phased approach (Mummah et al. 2016). The Design Thinking framework facilitates problem-solving through empathy, prototyping, and iteration to ensure the stakeholder involvement at every step of the design process and responsiveness to user needs (Krolikowski et al. 2022). Integrating the NIHR/MRC framework with other digital health-based frameworks may enhance future iterations of BOL development and evaluation while maintaining methodological rigor. This approach could have allowed for more flexibility in adapting BOL based on emerging evidence of technology advancement and user feedback without being bound by predefined phases.

## 8.5 Recommendations for future research

This thesis contributes to the learning and development of DHSMIs by validating the BOL self-assessment and evaluating the technological feasibility, acceptability, and potential benefits of the BOL intervention. Based on the findings from the Phase 2 and Phase 3, several recommendations can be made for the development of the BOL self-

assessment tool. First, there is a need to optimise the adaptability of the online BOL self-assessment tool. Integrating the function to save and resume the self-assessment would offer greater flexibility, enabling participants to complete the tool at their own pace without the concern of losing their progress in the event of interruptions and repeating previously answered questions. A notification system indicating the time remaining and the number of questions left to complete could also enhance the user experience (Conrad et al. 2010). This would help individuals manage their time more effectively, preparing them for the completion of the tool without the need to rush or skip questions due to time constraints. Furthermore, the BOL self-assessment may benefit from extra branching options to tailor the questions to the user's specific circumstances, such as whether they work during the day or night shifts. Providing questions that reflect the user's work patterns can help to enhance the user's feelings of relevance when completing the BOL self-assessment (Petty et al. 1986), thus contributing to the user engagement with the BOL intervention. This approach may also help to provide a more nuanced understanding of an individual's experience of pain in the workplace, which could enhance the individualisation of the BOL intervention content.

In addition, the development of the BOL self-assessment should consider the optimisation or inclusion of more work-related items in the PW domain to better capture the challenges faced by individuals in the workplace due to LBP. Including questions that focus on the specific difficulties experienced in workplace settings would provide a more nuanced understanding of how LBP impacts the work capability, thereby enhancing the relevance and applicability of the tool in real-world contexts. Last but not least, the version of the BOL self-assessment tool used in this study focused on only two pain mechanisms: nociceptive (NC) and nociplastic (NP) pain, which needs to consider the inclusion of the neuropathic pain category in the future iterations. This distinction would allow for a more comprehensive classification of pain mechanisms and provide more nuanced insights into LBP management. By providing a more precisely discrimination between these pain subgroups, it is beneficial for the BOL to provide users of different pain mechanisms with more individualised intervention, aiming to increase the effectiveness of self-management strategies.

Based on the findings in Phase 3 and the feedback from BOL users, future development of the BOL intervention should prioritise several key enhancements to increase its individualisation and user engagement. First, there is a clear need to improve the technological adaptability and functionality of the intervention. This could be achieved by incorporating just-in-time adaptation mechanisms (Nahum-Shani et al. 2018) or the artificial intelligence (AI) (Bohr and Memarzadeh 2020; Tagliaferri et al. 2020; Anan et al. 2021; Marcuzzi et al. 2023) to better match the users' characteristics and patterns of engagement, and increase the responsiveness to the evolving user needs throughout the course of their self-management journey. As suggested by the BOL users, the development of a mobile application version of the BOL integrated with offline modules should be considered. This would provide users with greater flexibility to engage with the tool, even in low-connectivity environments (e.g. railway workers in the rural areas or underground, healthcare workers in areas shielded from signals due to medical devices), thereby broadening its accessibility and usability. The integration of offline functionality would also support users to continue their self-management practices, regardless of disruption to their access to the internet. Furthermore, the introduction of interactive features, such as a diary to monitor pain progress and track self-management activities, could greatly enhance user engagement (Irvine et al. 2015). By allowing users to record their experiences and reflect on their progress, these features would foster a sense of ownership and accountability. The incorporation of reward mechanisms for achieving milestones could serve as an additional motivator, encouraging sustained participation and adherence to the intervention (Michaelsen and Esch 2023). These enhancements would not only improve the usability of the BOL but also promote more sustained and meaningful engagement, ultimately leading to better self-management outcomes for users with LBP.

Following the NIHR/MRC framework, the next stage for the development of BOL is a comprehensive evaluation of its effectiveness. Based on the findings from 3 phases, this research offers insights into the methodological and pragmatic considerations necessary for the future advancement of the BOL self-assessment and intervention, particularly in the context of a full randomised controlled trial (RCT). To further refine the theoretical frameworks and examine the outcome pathways of the BOL intervention, future research should conduct a full RCT comparing BOL against best available evidence-based occupational care. The systematic review in Phase 1

highlighted the limitations of previous RCTs of DHSMIs for LBP in the workplace, such as the lack of work-related outcome measures, inconsistency in the measurement selection, and heterogeneity of control group settings. To address these limitations, a future RCT of the BOL intervention should incorporate standardised and validated work-related outcome measures to facilitate a more precise evaluation of how the intervention influences work capacity, absenteeism, and presenteeism among individuals with LBP. Future trials of DHSMIs should also adopt a more consistent and theoretically grounded approach to outcome measurement selection, aligning with established frameworks for evaluating complex interventions. This would enhance comparability across studies and contribute to a more robust evidence base for the effectiveness of DHSMIs in workplace settings. Standardisation in measurement tools and assessment time points would also improve the reliability and interpretability of findings. Furthermore, careful consideration should be given to the selection and structuring of control groups to minimise heterogeneity and ensure meaningful comparisons. The inclusion of a control group that receives unindividualised evidencebased intervention, rather than usual care, would provide a greater insight into the impact of individualisation on DHSMIs for LBP.

As discussed in Chapter 6, several challenges were identified in the participant engagement and follow-up, providing valuable lessons for optimising study design. Future BOL trials need to consider external challenges that could influence the participant engagement and data collection. The COVID-19 pandemic demonstrated how unprecedented events, including the temporary closure of occupational health departments and shifted life foucs, can impact recruitment and follow-up procedures. To mitigate these risks, future BOL trials should incorporate a multi-channel recruitment strategy that are not dependent on the workplace access. Social media platforms could help maintain participant enrolment even when direct workplace engagement is not feasible (McRobert et al. 2018; Torous et al. 2021; Goldman et al. 2023). Building collaborations with remote occupational health services or telehealth providers could also ensure the continued study dissemination despite physical site closures (Giansanti 2023).

Another critical challenge identified in this study is the blocking of invitation emails due to institutional filters and web security settings. Many workplace email systems employ

strict filtering mechanisms that may classify emails containing direct web links to the BOL as spam and entirely prevent their delivery. To address this issue, researchers should work closely with IT departments in targeted organisations to pre-authorise study emails and ensure they reach employees' inboxes. Alternative communication channels, such as digital noticeboards and professional network announcements, should be explored to complement email-based recruitment. Previous study has also highlighted the benefits of providing quick-response (QR) codes to streamline the process and facilitate easier access for both online recruitment and onsite study enrolment (Gu et al. 2016).

Moving forward, the next phase of research should focus on implementing these methodological improvements in an RCT to evaluate the effectiveness of BOL. This includes clearly defining the intervention components, ensuring adequate power through appropriate sample size estimation, and employing strategies to mitigate dropout rates. Future studies should aim to establish the effect of BOL intervention on health, work and healthcare related outcomes while incorporating a process evaluation to assess equality of engagement across different job hierarchies and socio-economic statuses. Following the latest NIHR/MRC framework, future research also need to include an assessment of the expenditure of effort and funding to achieve target effectiveness using BOL (Skivington et al. 2021).

## 8.6 Conclusion

The NICE updated the guidelines for LBP management and promoted selfmanagement, keeping active and staying in work (National Guideline 2016), but existing support is mainly provided within primary care settings. DHSMIs provides an opportunity for addressing the complex demands of LBP on individuals, especially the working-age population. BACK-on-LINE<sup>™</sup> has been developed as an individualised DHSMI based on PMC model accessible to people with LBP in the workplace, aiming to address the issue of existing DHSMIs of focusing on unidimensional factors and providing generic LBP advice with minimal individualisation as recommended within clinical guidelines. However, a comprehensive investigation into its development and effectiveness has not yet been fully realised. Following the UK NIHR/MRC framework for the development and evaluation of complex interventions, this thesis applied a mixed-methods research design to assess the technological feasibility, acceptability, and potential benefits of using BOL to support LBP self-management in the workplace.

Findings of this PhD project indicate that work-based DHSMIs for LBP have short to middle term positive effects on pain intensity, disability, and physical performance of people with LBP in the workplace. Psychometric evaluation results suggest that the BOL self-assessment is a reliable and valid tool for accessing LBP with the established new cut-off point. This study successfully demonstrates the feasibility of recruiting participants from multiple workplace settings and provided preliminary evidence of good technological feasibility and acceptability BOL intervention. Interviews with BOL participants revealed that BOL is generally well-received.

Individualisation, adaptability and functionality are recommended as key elements of future development of BOL intervention, with a need to streamline the BOL self-assessment. Future research needs to comprehensively assess the effectiveness of BOL, refine the theoretical frameworks and outcome pathways of the BOL intervention.

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### Appendices

## Appendix 1. Current version of the BACK-on-LINE<sup>™</sup> self-assessment





#### 2. About my back pain

2.1 Do you know what caused your current back pain?

Yes (0) No (2) Not sure (1)

2.2 How long have you had this current episode of back pain?

0-7 days (0) 8-14 days (0) 15 days to 1 month (0) More than 1 month (0) More than 3 months (1) More than 6 months (2)

2.3 On the scale below where 0 means no pain, and 10 means worst possible pain

How intense is your pain right now?

Sliding scale 0-10

2.4 How intense was your pain on average last week?

Sliding scale 0-10

Scoring rule (0-3) (0), 4-6 (1), 7-10 (2)

2.5 What do you think is wrong with your back? (free text)

2.6 If you have been treated for back pain, were you satisfied with your treatment?

Yes, I was satisfied with the treatment (0) I was neither satisfied nor dissatisfied with the treatment (1) No, I was not satisfied with the treatment (2) I was never treated for back pain (0)

2.7 Do you currently take medication to manage your back pain? Yes No

2.8 What medication do you currently take to manage your back pain? Please tick all that apply.

Paracetamol (0) Ibuprofen (also known as Nuromol) (1) Naproxen (2) Diclofenac (2) Celecoxib (2) Codeine/Co-codamol (2) Tramadol (3) Amitriptyline (3)

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	Gabapentin (3) Pregabalin (also known as Lyrica) (3) Duloxetine/Cymbalta (3) Buprenorphine (known as BuTrans, Transtec) (3) Morphine (also known as Oramorph, MST, Zomorph) (3) Oxycodone (also known as Longtec, Shorttec) (3) Fentanyl (patches) (also known as Durogesic or Matrifen) (3) Other (1)
2.9 Ho	ow effective is the medication in reducing your back pain? Effective (0) Not sure (1) Ineffective (2)
2.10	Where is your pain? Please tick <b>all</b> that apply Neck (1) Right shoulder (1) Left shoulder (1) Right arm (1) Upper back (1) Lower back (1) Right buttock (1) Left buttock (1) Right hip (1) Left hip (1) Right leg (1) Left leg (1)
2.11	Is your pain there all the time?
M	y pain is there all the time (2) y pain comes and goes (0) ot sure (1)
2.12	What type of pain is it? Please tick <b>all</b> options that apply Deep (1) Nagging (1) Dull (1) Sharp (1) Shooting (1) Dull ache (1) Like an electric shock (1) Burning (1) Pressure (1) Stinging (1) Aching (1) Throbbing (1) Spread over a wide area (1)
2.13	When is your pain at its worst? It depends on what I do (0) In the morning (0) During the day (0)
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At the end of the day (0) My pain is there all day long (2)

2.14 Is your back pain getting better, staying the same or getting worse?

My pain is getting better (0) My pain is the same (1) My pain is getting worse (2)

2.15 Can you ease your back pain?

Yes (0) Sometimes (1) No (2)

2.16 What eases your back pain? Please tick all that apply

l avoid activities that cause me pain (2) Taking medication (1) Changing positions (0) Lying down (0) Sleep (0) Walking (0) Standing (0) Sitting down (0) Exercise/stretching (0) Massage (1) Hot/cold pack (0) Other (0)

2.17 What aggravates your back pain? Please tick all that apply

Sitting down (0) Standing (0) Walking (0) Lying down (0) Exercise (2) Lifting/ carrying load (0) Forward bending (stooping) (0) Working on a computer (0) Housework/Gardening (0) Any activity that I do for a long period of time increases my back pain (1) Everything I do causes me pain (2)

2.18 Is this the first time you have experienced this type of pain? Yes (0) No (1)

2.19 Other than your back pain, do you experience any other sensations? Please tick all that apply

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Pins and needles (1) Numbness (1) Tingling (1) Burning (1) Stinging (1) Pressure (1) None of the above (0)

2.20 Does your back pain wake you up at night?

Yes (2) Sometimes (1) No (0)

2.21 If you wake up with back pain, can you get back to sleep? Yes (0) Sometimes (1) No (2)







- 3 How my back pain impacts on my work
- 3.1 How many hours per a week on average do you work?
- 3.2 'I believe that my job caused /contributed to my back pain.

Agree (2) Neither agree nor disagree (1) Disagree (0) Not applicable (0)

3.3 I feel supported by my line manager and/or co-workers,

Agree (0) Neither agree nor disagree (1) Disagree (2) Not applicable (0)

3.4 How much is your back pain affecting your work?

Not at all (0) Sometimes (0) Frequently (1) I am unable to work because of my back pain (2) Not applicable (0)

3.5 Are you currently off work right now because of your back pain?

Yes (2) No (0)

3.6 How long have you been off work?

Less than 3 months (1) Between 3 to 6 months (2) More than 6 months (3)

 3.7 How likely is it that you would return to work within six months? Very Likely (0) Likely (1) Not sure (2) Unlikely (3)

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#### 4 How my back pain impacts on my lifestyle, social and family life

4.1 I can't do my normal daily activities because of my back pain

agree (2) neither agree nor disagree (1) disagree (0)

4.2 My back pain is affecting my social life

agree (2) neither agree nor disagree (1) disagree (0)

4.3 My back pain is affecting my relationships with my significant others

agree (2) neither agree nor disagree (1) disagree (0)

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#### 5. How my back pain impacts on me personally

5.1 My back pain makes me feel stressed/anxious.

agree (2) neither agree nor disagree (1) disagree (0)

5.2 Stress increases my back pain.

agree (2) neither agree nor disagree (1) disagree (0)

5.3 Being active and exercise increases my back pain.

agree (2) neither agree nor disagree (1) disagree (0)

5.4 Since my back pain started, I feel more tired.

agree (2) neither agree nor disagree (1) disagree (0)

5.5 Irrespective of my back pain I continue to take interest and/or pleasure in doing things.

agree (0) neither agree nor disagree (1) disagree (2)

5.6 My family and friends understand what I'm going through with my back pain.

agree (0) neither agree nor disagree (1) disagree (2)

5.7 I am very confident that my back pain will eventually go away.

agree (0) neither agree nor disagree (1) disagree (2)

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**Appendix 2**. Previous version of the BACK-on-LINE<sup>™</sup> self-assessment developed by Alothman et al. (2017)

## **BACKonLINE**<sup>™</sup>

## A: Pain behaviour

P.B.01. Do you know what caused your current back pain? 0-Yes 2-No 1-Not sure

P.B.02. If yes, choose an option from the list below:
1-Car accident
0-Sport injury
0-Lifting/bending accident
0-Falling down
0-Other trauma
1-Work related
0-Other
1-Nothing specific
1- I don't know

P.B.03. What do you think is wrong with your back? Please tick **all** options that apply 1-Wear and tear

- 1 -Arthritis
- 1 -Osteoporosis
- 1 -Bad posture
- 1 -Weak core muscles
- 1 -Muscle/ligament problem
- 1 -Disc problem
- 0 -Not sure

P.B.04. If you have been treated for back pain, were you satisfied with your treatment?

0-Yes, I was satisfied with the treatment
1-I was neither satisfied nor dissatisfied with the treatment
2-No, I was not satisfied with the treatment
0 -I was never treated for back pain

P.B.05. What medication do you c<mark>urrently</mark> take to manage your back pain? Please tick **all** options that apply 1-Paracetamol/ Panadol 1-Ibuprofen 1-Codeine 1-Diazepam 2-Morphine 2-Amitriptyline 2-Duloxetine/Cymbalta 2-Gabapentin 1-Tramadol 1-Hydrocodone
1-Cortisone
1-Acetaminophen
1-Glucosamine
1-Valium
1-Naproxen
1-Other
0-I don't take any medication for my back pain

P.B.06. How effective is the medication in reducing your back pain?
0-Effective
1-Not sure
2-Ineffective
0- I don't take any medication for my back pain

P.B.07. Where is your pain? Please tick **all** body areas that apply 1-Neck 1-Right shoulder 1-Left shoulder 1-Right arm 1-Left arm 1-Upper back 1-Lower back 1-Right buttock 1-Right buttock 1-Right hip 1-Left hip 1-Left hip 1-Right leg 1-Left leg P.B.08. Is your pain there all the time?

2-My pain is there all the time 0-My pain comes and goes 1-Not sure

P.B.09. What type of pain is it? Please tick **all** options that apply 1-Deep 1-Nagging 1-Dull 1-Sharp 1-Shooting 1-Dull ache 1-Like electric shock 1-Burning 1-Pressure 1-Stinging 1-Aching 1-Throbbing 2-Spread over a wide area P.B.10. When is your pain at its worst?

In the morning

 During the day
 at the end of the day

 2-My pain is there all day long

P.B.11. Can you ease your back pain? 0-Yes 1-Sometimes 2-No

P.B.12. How do you ease your back pain? Please tick **all** options that apply 0-Medication/pain killers 0-Rest 0-Walking 0-Standing 0-Standing 0-Sitting 0-Exercise 0-Massage 0-Hot pack 0-Cold pack 0-Cold pack 0-Other 2-I am unable to ease my back pain

P.B.13. In general, is your back pain getting better, staying the same or getting worse?
O-My pain is getting better
1-My pain is the same
2-My pain is getting worse

P.B.14. From the list below, please tick **all** the activities that make your pain worse. **0**-Sitting relaxed **0**-Sustained sitting 0-Sitting up straight 0-Standing 0-Sustained standing 0-Walking 0-Fast walking 0-Lying on your side curled up 0-Running 0-Lifting **0**-Forward bending (stooping) 0-Cycling 0-Overhead reaching 0-Working on a computer 0-Hoovering 0-Shopping **0**-Gardening 1-Any activity that I do for a long period of time increases my back pain

### 2-Everything I do causes me pain

P.B.15. From the list below, please tick **all** the activities that stop or decrease your pain.

0-Walking
0-Standing
0-Lying on your side curled up
0-Running
0-Cycling
0-Changing positions
0-Sitting down
0-Stretching exercises (for example: bending forward, bending backwards, reaching upwards)
0 Moving about
1-Pain medication
2- Lavoid activities that cause me pain
3-Nothing Ldo stops my pain

P.B.16. Is this the first time you have experienced this type of pain? 0-Yes 2-No

1-Not sure

P.B.17. If you had a previous episode of back pain, what helped in making your pain better? Please tick **all** options that apply

1-pain Medication
1-injection
1-avoiding activities that caused me pain
0-Walking
0-Standing
0-Standing
0-Sitting
0-Exercise
0-Heat pack
0-Cold pack
1-massage/physiotherapy/chiropractor/osteopathy
0-Other
2-Nothing helped
0-I can't remember

P.B.18. Other than your back pain, do you experience any of the following? Please tick all options that apply
1-Pins and needles
1-Numbness
1-Tingling
1-Burning
1-Stinging
1-Pressure
0-None of the above

P.B.19. Please tick **all** the areas where you experience this feeling:

1-Neck
1-Right shoulder
1-Left shoulder
1-Right arm
1-Left arm
1-Upper back
1-Lower back
1-Right buttock
1-Right buttock
1-Right hip
1-Left hip
1-Right leg
1-Left leg
0- Not applicable

P.B.20. On average, how many hours do you sleep?

hours	minutes

P.B.21.Does your back pain wake you up at night? 2-Yes 1-Sometimes 0-No

Number	score
of hours	
*Score <sup>5</sup> for P	B.20 <sup>2</sup>
5-7	1
8+	0

P.B.22. If you wake up with back pain, can you get back to sleep? 0-Yes 1-Sometimes 2-No

# B: Back pain and work:

W.01. how strongly do you agree with this statement : 'I believe that my job caused /contributed to my back pain'

2-Agree1-Neither agree nor disagree0-Disagree0 -Not applicable

W.02. Do you feel supported by your boss and/or co-workers? 0-Yes 2-No 1-I don't know 0 -Not applicable

W.03. How is your back pain affecting your work?
O-Not at all
O-Sometimes
1-Frequently
2-I am unable to work because of my back pain
O -Not applicable

W.04. Are you off work right now because of your back pain? 2-Yes 0-No 0 -Not applicable

W.05. How long have you been off work?
1-Less than 3 months
2-Between 1 to 6 months
3-More than 6 months
0 -Not applicable

W.06. How likely it is that you would return to work within six months?
1-Likely
2-Not sure
3-Unlikely
0 -Not applicable

## C: Back pain and lifestyle:

## Do you agree with the following statements?

L.01. 'I can't do my normal daily activities because of my back pain'
2- agree
1- neither agree nor disagree
0- disagree
L.02. 'My back pain is negatively affecting my social life'
2- agree

1- neither agree nor disagree

0- disagree

L.03. 'My back pain is affecting my relationship with my significant other'
2- agree
1- neither agree nor disagree
0- disagree

L.04. 'I don't know what makes my back pain worse or what eases it '
2- agree
1- neither agree nor disagree
0- disagree

## D: Perception of back pain:

### Do you agree with the following statements? P.01. 'My back pain makes me feel stressed/anxious' 2- agree 1- neither agree nor disagree 0- disagree

P.02. 'Stress increases my back pain'

2- agree

1- neither agree nor disagree

0- disagree

P.03. 'Physical activity increases my back pain'

2- agree

1- neither agree nor disagree

0- disagree

P.04. 'Since my back pain started, I feel more tired'

2- agree

1- neither agree nor disagree

0- disagree

P.05. 'I have lost interest and/or pleasure in doing things because of my back pain'

- 2- agree
- 1- neither agree nor disagree
- 0- disagree

P.06. 'I don't think my family and friends understand what I'm going through with my back pain.'

- 2- agree
- 1- neither agree nor disagree
- 0- disagree

P.07. 'I don't think my back pain will ever go away.'

- 2- agree
- 1- neither agree nor disagree
- 0- disagree

Phase	Development	Detailed Contribution
Alothman's	BACKonLINE™	Generated the initial pool of self-assessment items for
PhD Study	Self-assessment	BACKonLINE™ from the available literature
	(Version 1.0) - 55	
	items	
	BACKonLINE™	Conducted two rounds of Delphi study which
	Self-assessment	1) Decided the self-assessment items and scoring rules
	(Version 1.1&1.2)	for each question
	- 39 items	2) Created the logic construction for individualising
		interventions to LBP subgroups
	Readability of	1) The Flesch Reading Ease (FRE) and Plain English
	BACKonLINE™	Campaign (PEC)
	Self-assessment	<ol><li>Collect the feedback for typographic factors and</li></ol>
	(Version 1.3&1.4)	comprehension of BACKonLINE™ through focus
	- 39 items	groups (n=7) and telephone interviews (n=5)
	Psychometric	Provided the preliminary reliability and validity of
	Properties of	BACKonLINE <sup>™</sup> self-assessment questionnaire in LBP
	BACKonLINE™	patients (n=35).
	Self-assessment	
	(Version 1.5)- 39	
	items	
	Concept structure	Developed based on the face-to-face interviews (n=35)
		regarding patient's expectations in:
	BACKonLINE™	1) The delivery methods of BACKonLINE™
	Self-management	<ol> <li>The contents of BACKonLINE<sup>™</sup> self-management</li> </ol>
Chagrants		intervention
Sheeran's	BACKonLINE™ Solf management	Developed interactive web-based multimedia contents
work with	Self-management intervention	with a technology company (Eggu) providing innovative
Department of Work	(Frontend	digital learning solutions for self-directed online education
and	development)	
Pensions	BACKonLINE™	1) 4 questions removed and 2 added questions
(DWP)	Self-assessment	2) Scoring rules minor changes (Following updated
	(Version 2) - 34	NICE guidelines on pain medication)
	items	
	BACKonLINE™	Corporate with a software engineer (Jeff Morgan) and
	online platform	developed database and dashboard for accessing BOL
	Version 1 -	database based on the Cardiff University Advanced
	(Backend and	Research Computing.
	Database	
	development)	
	Battery of	1) Modified Technology Acceptability Questionnaire
	BACKonĹINE™	2) Healthcare Resource Use
	evaluation	3) Exercise Self Efficacy
	questionnaires	4) Adherence to Specific Activities
	(Version 1)	
	Launch of	A prospective longitudinal study was conducted to
	BACKonLINE™	provide BACKonLINE™ to NHS Wales staff with self-
	online platform	reported Low Back Pain from 20th November 2019. By
	(Version 1)	the end of October 2020, the automated data
		management system collected 150 baseline
1		BACKonLINE <sup>™</sup> self-assessment

**Appendix 3.** Detailed contribution of BACKonLINE<sup>™</sup> development

Chen's PhD Study	Reliability and Validity of BACKonLINE™ Self-assessment (Version 2) - 34 items	<ol> <li>Re-calculated the cut-off points for the updated BACKonLINE<sup>™</sup> self-assessment questionnaire based on the collected 150 LBP patients baseline data</li> <li>Validated the test-retest reliability and internal consistency of BACKonLINE<sup>™</sup> self-assessment</li> <li>Validate BACKonLINE<sup>™</sup> self-assessment in discriminating LBP subgroups among working population using STarTBack Screening Tool as reference</li> </ol>
	Feasibility Evaluation of BACKonLINE™ intervention	<ol> <li>Reported the feasibility of recruiting working population self-reported LBP from healthcare, transport and academia.</li> <li>Reported the feasibility of providing BACKonLINE ™ interventions to support LBP self-management by assessing the usage of individualised intervention contents</li> </ol>
	Acceptability Evaluation of BACKonLINE™ intervention	<ol> <li>Reported the perceived usefulness of BACKonLINE<sup>™</sup> intervention in support self-managing LBP</li> <li>Reported the ease of use regarding experience of using BACKonLINE<sup>™</sup> and intention for future use</li> </ol>
	Potential benefits evaluation of BACKonLINE™ intervention	<ul> <li>By analysing the data of 34 patients who completed baseline and follow-up BACKonLINE <sup>™</sup> self-assessment:</li> <li>1) Reported the changes in pain conditions</li> <li>2) Reported the changes in lifestyle and workability</li> <li>3) Reported the changes in healthcare resources use</li> </ul>
	Suggestions for future BACKonLINE™ development iteration	<ul> <li>Developed based on the telephone interviews (n=12) exploring patient's experiences of using BACKonLINE<sup>™</sup> and feedback regarding:</li> <li>1) The functionality of BACKonLINE<sup>™</sup> (ease of access, technical issues)</li> <li>2) The clarity of BACKonLINE<sup>™</sup> feedback contents (pain contributors, sedentary behaviour and physical activity level)</li> <li>3) The usefulness of BACKonLINE<sup>™</sup> intervention contents (help stay in work and support LBP selfmanagement)</li> <li>4) The expectations of future BACKonLINE<sup>™</sup> (Mobile application, adaptivity, preferred elements and functions)</li> </ul>

**Appendix 4.** A demonstration of the content within different toolkits of the BACK-on-LINE<sup>™</sup> intervention.



**Appendix 5.** Example of search terms used in searching the Cochrane Library for the systematic review

Database: Cochrane Library

exp Back pain/ (back pain\* OR backache\*):ti,ab,kw (spin\* near/2 pain\*) OR (lumbar near/2 pain\*) OR (pelvi\* near/2 pain\*) OR (thoracic near/2 pain\*):ti,ab,kw (Web-based intervention\* OR Internet-based intervention\* OR Online intervention\*):ti,ab,kw (Digital near/2 intervention\*):ti,ab,kw (Digital health\* OR mHealth\* OR eHealth\* OR e-health\* OR Mobile health\*):ti,ab,kw Exp Internet/ (Web\* OR Website\* OR Web site\* OR Webpage\* OR Web page\* OR Online\*):ti,ab,kw Exp Computers/ Exp Software/ Exp Mobile applications/ (App\* OR Online application\* OR App\* OR Internet-based application\* OR Computer-based application\*):ti,ab,kw Exp smartphone/ (Smart phone\* OR iPhone\* OR android\* OR Mobile device\*):ti,ab,kw Exp Wearable Electronic Devices/ #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 Exp Occupational Health/ (Occupational Wellness\* OR Occupational Wellbeing\* OR Occupational well-being\* OR Occupational Safety\* OR Occupational setting\* OR Working Conditions\* OR Work Environment\*):ti,ab,kw Exp Workplace/ (Factory\* OR Company\* OR Office\* OR Warehouse\* OR Industr\* OR Worksite\* OR Organisation\* OR Organization\* OR business\* OR workspace\* OR workstation\* OR Work Activities\*):ti,ab,kw Exp Work/ Exp Occupations/ (Employe\* OR employment\* OR Worker\* OR Staff\* OR career\* OR job\* OR labor\* OR labour\*):ti,ab,kw #18 or #19 or #20 or #21 or #22 or #23 or #24 Randomi\*ed Controlled Trials **Clinical trials** Randomi\* next trial\* Randomly near2/ (allocated OR assigned) (Single OR double OR triple OR treble AND (blind\* OR mask\*))

**Appendix 6**. Demonstration of the screening process for the systematic review of the effects of Digital Health Self-management Interventions on low back pain in the workplace using the Rayyan tool

🛱   🍙   🎽 Systematic Review   Need	ed Training? 🖲   😑 🧿 🔞 🌔
Overview Review Data Screening Full Text Screening Q Search	Upgrade 😅
Showing 4,103 Articles	les 🕞 Add PDF \cdots 🔗 Criteria 🗦 Filters
	Sort Filters Q
□ Trtle ↓ Date ↓	
Return to work with chronic low back pain: using an evidence-based approach along with the occupational therapy framework.       2008-08-01         X Minghao       Non-HCT       Effect of Motor Control Exercises Versus Graded Activity in Patients With Chronic Nonspecific Low Back Pain: A Randomized Controlled       2012-03-01         Trial_corrected][published erratum appears in PHYS THER 2012; 92(4):631]       2012-03-01       2012-03-01	Select All CinshLris 439 Cochrane.ris 1769
K Minghao Non-digital     The Predictive Validity of OMPQ on the Rehabilitation Outcomes for Patients with Acute and Subacute Non-Specific LBP in a Chinese 2013-09-01     Population.     X Minghao Non-RCT	Embase.ris 641 Medline.ris 239 WOSI.ris 1000
Hands-on versus hands-off techniques for the prevention of perineal trauma during vaginal delivery: a systematic review and meta-	WOS2.ris 1000     WOS3.ris 336     pubmed-3AND11AND1-se_ 33     ▶

**Appendix 7.** Normality Results of the variables used in assessing known-groups validity of BACKonLINE<sup>™</sup> self-assessment

Variable	Shapiro- Wilk test, p-value	Normal Distribution	Test method Selected
RMDQ Score	<0.001	Non-normal	Nonparametric test (Wilcoxon Signed Rank Test)
PB	<0.001	Non-normal	Nonparametric test (Wilcoxon Signed Rank Test)
PW	<0.001	Non-normal	Nonparametric test (Wilcoxon Signed Rank Test)
BOL Total	<0.001	Non-normal	Nonparametric test (Wilcoxon Signed Rank Test)
PL	0.96	Normal	t-test
PP	0.18	Normal	t-test

**BOL**: BACKonLINE<sup>™</sup>; **RMDQ**: Roland Morris Disability Questionnaire; **PB**: Pain Behaviour; **PL**: Impact of LBP On Lifestyle; **PW**: Impact of LBP On Work; **PP**: Pain Perception

Appendix 8. Summary of the outcome measures used in the mixed methods BACK-on-LINE™ study					
Category	Measure and reference	ltem	Assessing	Reliability and Validity	Evaluation time-points
Primary outcomes					
Recruitment feasibility	Monitoring anonymous usage data (automated data collection)	N/A	Number of individuals self- screened, consented, completing BOL self- assessment (Baseline and 4 week follow up)	N/A	4 week follow up
Intervention feasibility	Monitoring anonymous usage data (automated data collection)	N/A	Number of user logins and accesses to BOL and intervention modules	N/A	4 week follow up
Secondary outcomes					
Acceptability	Technology Acceptability Model questionnaire (King and He 2006)	13	Questions related to behavioural Intention (BI) regarding the use of BOL intervention, perceived ease of use (PEU) and perceived usefulness (PU), prior experience (PE) and self- efficacy (SE) regarding the use of internet and mobile applications are scored on a 5-point scale from strongly agree (5) to strongly disagree (1).	Internal consistency: 0.895 for PU; 0.873 for PEU (King and He 2006)	4 week follow up
Pain intensity	Numerical pain rating scale (Kahl 2005)	2	Patients rate their average pain intensity in a particular time frame (current and over the past 2 weeks) on 11-point rating scales ranging from no pain (0) to extreme pain (10). Patients indicate whether	Test-retest reliability: 0.67- 0.96 (Kahl 2005)	Baseline and 4-week follow- up
Low back pain specific disability	Roland and Morris Disability Questionnaire (RMDQ) (Roland and Fairbank 2000)	24	each item on the list applies to them on the day of scale completion by selecting "yes" or "no." The RMDQ score is calculated by summing the number of items selected by the patient, with scores ranging from 0 to 24, where a higher score indicates a higher level of disability. Patents indicate whether they	Internal consistency: 0.89; Test-retest reliability: 0.85 (Jenks 2022)	Baseline and 4-week follow- up
Risk of persistent disability	STarT Back Screening Tool (SBST) (Hill et al. 2008)	9	disagree or agree with items covering modifiable prognostic indicators including bothersomeness, disability and mood during based on their experiences and symptoms over the past 2 weeks. Total score (0-9)	Test-retest reliability: 0.73 (Hill et al. 2008)	Baseline and 4-week follow- up

			determines their risk group classification.		
Physical activity	The International Physical Activity Questionnaire - short form (IPAQ- SF) (Craig et al. 2003)	7	Patients provide time spent walking, undertaking vigorous and moderate activity, as well as time spent sedentary over the past 7 days	Test-retest reliability: 0.707; Internal consistency: 0.895 (Flora, 2023)	Baseline and 4-week follow- up
Exercise self- efficacy	Modified Self- Efficacy for Exercise scale (Resnick and Jenkins 2000)	7	Patients rate on a scale of 0 to 10 to reflect their confidence in completing activities suggested by the BOL intervention in the face of obstacles Patients are asked how many	Internal consistency: 0.92 (Resnick and Jenkins 2000)	Baseline and 4-week follow- up
LBP related healthcare resource use	Brief questionnaire in the BOL self- assessment developed for this study	5	times they visit NHS services, occupation health practitioners and private LBP related therapy in the last 4 weeks. Patients are also asked to list the prescription and self-bought medication in the last 4 weeks.	N/A	Baseline and 4-week follow- up
Time off work	Brief questionnaire in the BOL self- assessment developed for this study	1	Patients are asked how much time they have had off work in the past 4 weeks	N/A	Baseline and 4-week follow- up
Adherence to BOL specific activities	Brief questionnaire in the BOL self- assessment developed for this study	3	Patients are asked whether they modified behaviours on pain management, work engagement, daily activities and exercise. If yes, patients are asked to indicate the modified area and specify the changes. Patients are also asked if they have stopped activities because they no longer are experiencing pain	N/A	4-week follow- up

BOL: BACK-on-LINE™

**Appendix 9.** Deductive content analysis of text responses from participants (n=7) on their behaviour changes after 4-week BackonLine intervention

Theme and categories	Responses, n	Illustrative quotes (code)
Pain relief	1	"Keep moving alongside use of medication to manage pain which I can adjust if I have been doing more exercise and feel it has had a negative impact/will have a negative impact in terms of the pain." -ID 41202029 (Pain relief by staying active and adjust medications)
Sleep	2	<ul> <li>"I now sleep with a back pillow between my knees which is helping." - ID 40942882 (Sleep with pillows between legs)</li> <li>"I no longer sleep lying on my left side due to the severe pain in my hip which is deferred pain from my lower back." - ID 76090624 (Sleep position changed due to hip pain from lower back)</li> </ul>
Work	1	"I try to stay active through the working day." - ID 22828769 (Work with active movement)
Daily living	1	"I stopped cleaning." - ID 94798702 (Daily living with reduced housework)
Physical activity/exercise	3	<ul> <li>"I now advise any partners not to throw me when doing martial arts." - ID 76090624 (Reduce back strain during exercise)</li> <li>"My back often hurts when I ride and now, I curtail my rides to accommodate it." - ID 76090624 (Modify gesture during exercise)</li> <li>"I don't do some exercises like playing tennis for my back pain." - ID 79415993 (Avoid exercise that trigger back pain)</li> </ul>
Exercise routine for low back pain	1	"I started doing activities including yoga, Pilates, and Nordic walking to assist pain and mobility." - ID 37089235 (Adding mobility exercises into exercise routines for back pain)

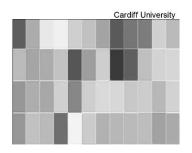
**Appendix 10.** Ethical approval for the mixed methods BACK-on-LINE<sup>™</sup> study from the Research Ethics Committee of School of Healthcare Sciences, Cardiff University

School of Healthcare Sciences Head of School and Dean Professor David Whittaker

Ysgol Gwyddorau Gofal lechyd Pennaeth yr Ysgol a Deon Yr Athrawes David Whittaker

31 July 2019





Liba Sheeran Cardiff University School of Healthcare Sciences

Dear Liba

# **BACK-on-LINE<sup>TM</sup>: Internet based personalised self-management support system for people with back pain**

At its meeting of *30 July 2019* the School's Research Ethics Committee considered your research proposal. The decision of the Committee is that your work should:

Proceed subject to the resubmission and approval of minor amendments made by the Committee Chair.

The Committee has asked that the lead reviewers' comments be passed onto you and your supervisor, please see attachment and further comments from a member of the Committee.

The proposal, amended in the light of the above points and in discussion with your supervisor, should be emailed to me for consideration by the committee Chair. You should email your response to

When resubmitting your revised proposal you should provide a covering letter highlighting how and where you have amended the revised proposal, in the light of the above comments. You should clearly indicate the page number and line number/s, and you might find the following table a means of reporting the amendments you have made to the proposal. In addition, the changes should be highlighted in the revised documentation using the track changes facility.

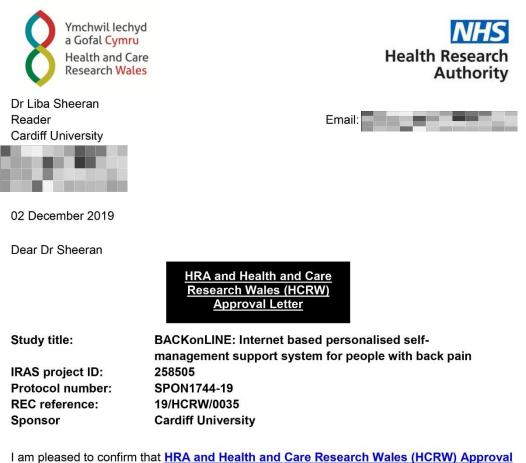
Comment/Amendment required.	My Response is;	Location in text i.e. page and line number.

Cardiff University is a registered charity, no. 1136855 Mae Prifysgol Caerdydd yn elusen gofrestredig, rhif 1136855 Please do not hesitate to contact me if you have any questions.

Yours sincerely



Mrs Liz Harmer – Griebel Research Administration Manager **Appendix 11**. Ethical approval for the mixed methods BACK-on-LINE<sup>™</sup> study from the National Health Service Health Research Authority and Health and Care



has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, <u>in</u> line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

# How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see <u>IRAS Help</u> for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations? HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to <u>obtain local agreement</u> in accordance with their procedures.

What are my notification responsibilities during the study?

The "<u>After HRA Approval – guidance for sponsors and investigators</u>" document on the HRA website gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, including:

- Registration of Research
- Notifying amendments
- Notifying the end of the study

The <u>HRA website</u> also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

### Nho should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is 258505. Please quote this on all correspondence.

Yours sincerely, Carl Phillips Approvals Specialist

Email:

Copy to: Ms Helen Falconer

2

## List of Documents

## The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	Version	Date
Copies of advertisement materials for research participants [leaflet digital]	1.1	02 December 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)	N/A	01 August 2019
IRAS Application Form [IRAS_Form_27112019]	N/A	27 November 2019
IRAS Checklist XML [Checklist_27112019]	N/A	27 November 2019
IRAS Checklist XML [Checklist_02122019]	N/A	02 December 2019
IRAS Checklist XML [Checklist_23102019]	N/A	23 October 2019
Letter from funder [Letter from funder]	N/A	25 September 2018
Letter from sponsor [sponsor letter]	N/A	21 October 2019
Non-validated questionnaire [Time off work baseline - 4 week follow up]	1.0	20 November 2019
Non-validated questionnaire [Adherence to BOL specific activities (4 week follow-up)]	1.0	20 November 2019
Non-validated questionnaire [LBP related healthcare resource use (baseline, 4 week follow up)]	1.0	20 November 2019
Non-validated questionnaire [Back-on-Line Survey_Self Assessment]	1.1	02 December 2019
Organisation Information Document [OID]	1.0	01 October 2019
Other [recruitment protocol ]	1.1	20 November 2019
Other [recruitment procedure]	1.0	01 October 2019
Other [Ethical approval from School of HC, Cardiff University]	1.0	15 August 2019
Participant consent form [Focus Groups]	1.1	20 November 2019
Participant consent form [Interviews]	1.1	20 November 2019
Participant consent form [BOL]	1.1	20 November 2019
Participant information sheet (PIS) [BOL]	1.1	20 November 2019
Participant information sheet (PIS) [Focus Groups]	1.1	20 November 2019
Participant information sheet (PIS) [Interviews]	1.1	20 November 2019
Referee's report or other scientific critique report [Referee's report]		01 October 2019
Research protocol or project proposal [Protocol]	1.1	20 November 2019
Schedule of Events or SoECAT [soecat]	1.0	01 October 2019
Summary CV for Chief Investigator (CI) [CV for CI]		01 October 2019
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study Flow Chart]	1.1	20 November 2019
Validated questionnaire [The Roland-Morris Disability Questionnaire (baseline, 4-week follow up)]		N/A
Validated questionnaire [The Keele STarT Back Screening Tool]	N/A	N/A
Validated questionnaire [Technology Acceptability Questionnaire (4 week follow-up)]	N/A	N/A
Validated questionnaire [Modified Self-Efficacy for Exercise scale ]	N/A	N/A
Validated questionnaire [Pain Intensity (baseline, 4 week follow up)]	N/A	N/A
Validated questionnaire [International Physical Activity Questionnaire (IPAQ) short form ]	N/A	N/A

3

### Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Multi NHS organisation study, all research activities.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	There is no funding, resources or equipment provided to the participating NHS organisations	Local Collaborators are expected to be in place where central study staff will be present at the participating organisation to undertake research procedures	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research activities listed in the research application would be expected to hold Letters of Access if focus groups were held in clinical areas. Letters of focus groups were held in non- clinical/administrative buildings.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.

## Appendix 12. Participant information sheet for the qualitative telephone interview





- Opinions about the online recruitment (including what you thought about the low back pain self-screen)
- Opinions about the BACK-on-LINE<sup>TM</sup> resources and how informative and relevant they were
- Opinions on whether you were able to understand and follow the information
- · Opinions on whether what it helped you to modify behaviours
- · Opinions on what impact did that have on your confidence levels and ability to manage your back pain.
- Expectations regarding recovery

The interview will be audio-recorded.

You will receive a link to the BACK-on-LINE<sup>TM</sup> website to encourage feedback and discussions around the specific aspect of the intervention content.

If you take part in the interview you will be remunerated £75 for your participation. Refreshments will be available during the focus groups.

### What will I have to do?

We will ask you to sign an electronic consent form and you should be aware of the following before you participate:

- After signing informed electronic constent you will receive an invite to attend the focus group with date, time
  and instructions how to get there.
- The interview will take 30 minutes and will be conducted over the telephone and at mutually conventient time.
- It will be conducted by the principal investigator (Dr Liba Sheeran) or the co-investigator (Dr Valerie Sparkes) together with a research assistant taking notes.
- You may be asked questions that include the following:
  - o An update of your condition
  - An update on the impact of your condition in every day life
  - $\circ$  ~ What care and treatment have you received before BACK-on-LINE  $^{TM}$
  - Opinions about the online recruitment (including what you thought about the low back pain selfscreen)
  - o Opinions about the BACK-on-LINE<sup>TM</sup> resources and how informative and relevant they were
  - o Opinions on whether you were able to understand and follow the information
  - o Opinions on whether what it helped you to modify behaviours
  - Opinions on what impact did that have on your confidence levels and ability to manage your back pain.
  - Expectations regarding recovery
- The interview will be audio-recorded.
- At the end of the interview you will be asked to send us form to remunerate you for your participation with £75 into your bank account. This will be handled by the School finance office.

### What is being tested?

We will explore your experiences using BACK-on-LINE<sup>TM</sup> self-management support system potential to benefit people by helping them better amange their back problems.

### What are the possible disadvantages and risks of taking part?

There is no disadvantage or a risk in taking part other than time burden for which you will be renumerated. There maybe a discussion around sikness absence due to back pain, but you do not have to provide this information if you don't wish to. Information will be stored confidentially and will only be shared anonymously with NHS Wales with your employer not be able to trace the information back to individuals.

Version Date: 27/6/2019 IRAS Project ID: 258508 2

version 1



### What are the possible benefits of taking part?

We cannot promise that this study will help you to improve your back pain but the information we obtain from the study will help to improve development and designing treatment for back pain conditions. Nevertheless, all resources provided within BACKonLINE<sup>TM</sup> are evidence based and follow current clinical guidelines with hope of upskilling' people to manage their back problem better.

### What if there is a problem?

If you have any concerns about any part of the study, you should ask the researcher and she will do their best to answer your questions and deal with your concerns. If you are still unhappy and wish to make a formal complaint, you should contact:

Dr Kate Button Director of Research Governance School of Healthcare Sciences

#### Will my taking part in this study be kept confidential?

All information which is collected about you will be kept strictly confidential. The researcher will maintain your privacy and confidentiality using a unique 8-digit code not accessible to anyone except the researcher. 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. The data will be stored in an encrypted and password protected computer known only by the researcher. This data will only be used for this study and future studies will not have access to it unless further agreement from you is requested and consent obtained. Data identifiable to you will be stored securely at Cardiff University and accessed only by the principal researcher. In addition, the data will be kept for a minimum of fifteen years and disposed of securely according to the recommendations of the Data Protection Act 2018.

Anonymised data arising from the study will be shared with NHS Health Boards in Wales to help develop their support services for staff. Your NHS employer will not be able to trace any of the information we provide back to individuals.

#### How will my data be managed?

Cardiff University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Cardiff University will keep identifiable information about you for 15 years after the study has finished.

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



### What will happen to the results of the research study?

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The researcher may publish the study in academic journals and present the results at conferences. In addition, the main findings will be disseminated to all participants via an online link which will be sent to your email. The findings will also be made available to the funder (the UK Government Departments of Work and Pensions and Health and Social Care). Only anonymised results will be published, you will not be identified in any report or publication.

### Who is organising and funding the research?

This research is jointly funded by the Department of Work and Pensions and the Department of Health and Social Care Work and Health Challenge' Fund.

### Who has reviewed the study?

The study has been reviewed by the Cardiff University School of Healthcare Sciences Research Ethics Committee and Health and Care Research Wales Cardiff University is the Sponsor for the study, in accordance with the UK Policy Framework for Health and Social Care Research.

### Further information and contact details

Principal Researcher: Dr Liba Sheeran

Telephone:

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## Appendix 13. E-consent form

CAERDYD	
	Electronic Consent Form
	Title of the study:
	Qualitative evaluation using interviews
8	BACK-on-LINE <sup>TM</sup> : Internet based self-management support system for people with back pain
Na	ame of Researcher: Dr Liba Sheeran
	o participate in this project you need to confirm your agreement with each of the atements below. Please tick each box.
1.	I confirm that I have read and understand the information sheet (date $20/11/19$ , version 1.1 Interview) for the above study and have had opportunity to ask questions. (*required).
2.	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected but any data collected up to the point of my withdrawal will be kept. (*required)
3.	I understand that my details will be linked to a unique identifier to ensure confidentiality. (*required)
4.	I confirm that data from the study can be used in the final report and other academic publications and may be presented at conference, I understand that these will be used anonymously. (*required)
5.	I agree to be audio-recorded during the interview (*required)
б.	I give consent for the use of verbatim anonymised quotes in publications and conference presentations. (*required)
7.	I agree for you to share my anonymised data with external collaborators in the UK and abroad, including commercial companies. (optional)
8.	I agree to take part in the above study. (*required)
Da En	rticipant's name ate of Birth nail address ate of Consent
	By pressing the submit button I agree to take part in this study
	'Submit'
Da	te: 20/11/19 1

Date: 20/11/19 IRAS Project ID: 258508

version 1.1

Appendix 14. Topic guide for the pilot interviews.

## 1. Intro, ground rules and consent

*Introduction*: "Good morning/afternoon and thanks for taking the time for this interview to tell me about your experience using Back-on-Line. First let me introduce myself, my name is Minghao Chen I am 2<sup>nd</sup> year PhD student from School of Healthcare Sciences at Cardiff University, and I will be conducting the interview. You were invited because you have and used BOL tool to help manage your back problem.

**Confirm Consent:** You gave us your consent to this interview at the start of the study but to remind you let me go through what this interview will involve.

Interview details: The interview will last around 15 minutes, and you will be asked about whether you found information in the BOL modules relevant, informative and how useful was it to you personally. We will also ask you what you thought about the self-assessment whether you agreed with the feedback given to you after the selfassessment and what you thought about the advice and guidance provided. Finally, we will ask you whether BACK-on-LINE<sup>TM</sup> helped you to stay in work and whether you are feeling more confident managing your condition having used BACK-on-LINE<sup>TM</sup>. There are no wrong answers, please feel free to share your point of view. We are just as interested in negative comments as positive comments.

**Confidentiality:** The interview will be audio-recorded and then the audio file will be transcribed by myself. All the information will be kept confidential, your identity will not be revealed at any point. We may use some of the quote from the interview, but your identity will be kept confidential.

**Take any questions:** Do you have any questions at this stage? THANK YOU! I will now begin the recording

**Re-confirm informed consent:** Firstly, I would like you to re-confirm your consent to this interview: Would you now please verbally confirm that you were informed about the purpose of this interview, you were given an opportunity to ask questions and give consent to this interview to take place please?

Consent must be obtained and recorded before moving to next step

## (2) Questions

## Part 1: Accessing BOL

Q1. How did you find BOL? (If they can't recall say: We asked your employer to advertise BOL in your workplace so you may have seen an advert or been recommended it by Occupational health practitioner in your work. Can you recall how you came across the advert?)

Q2= Can you recall how easy was it for you to access BOL?

- Prompts: After you consented to the study, you would have been sent an email with a link and your unique 8-number identifier for you to access BOL, how easy was the process to follow?
- If any issues reported:

- Can you specify the problem?
- Were there any other problems accessing the tool from then on?

## Part 2: Using BOL for LBP self-management

Q3= At the start of BOL, you were asked to fill in a self-assessment so we could give you feedback on the type of your pain. We also sent you a copy of this self-assessment before this interview. How did you find the self-assessment?

- Can you recall any questions you had difficulty in answering?
- What did you think about the length? Can you recall how long it took?
- Is there any other feedback you would like to give about the self-assessment?

"After completing the self-assessment, we gave you feedback on likely type of your LBP and also you were given your physical activity (PA) score (low, moderate/high) and sedentary score (sitting hours)."

Q4= What did you think of the amount of information in the feedback? Was it too much too little?

Q5= Was this feedback useful? (If yes-why do you think it is useful? / If no-what information would you prefer to have)

Q6= Do you think this feedback reflected your understanding of your own LBP problem? (If no- can you specify the difference?)

Q7= Would there be anything else you would like to receive feedback on? (If no response, give prompts: Would you like some advice on whether it is safe to exercise/go to work?)

*"After BOL self-assessment, you were able to access self-management information relevant to you.* 

Q8= How did you find the resources overall?

- Did you find the resources useful and relevant to your LBP problem?
- Have you use any of the advice to help you manage your own LBP?

Q9= Can you recall which aspects of the resources you found most useful? Q10= Which aspects of the resources you found least useful?

 Examples for prompts: video exercises, advice about posture, amount of sitting, medications, how to speak to your boss about you LBP, how PA can impact on your LBP

Q11= Was there any additional information you would like to have had?

- e.g., Would you have liked more guidance on whether to work or seek help like going to a doctor or physiotherapist?

## Part 3: Role of BOL in supporting LBP in the workplace

Q12= Did you think BOL helped you stay in work (If yes: how did BOL help; If not: why did you so/ What changes might have made a difference?)

Q13= We know that in some cases it is helpful to the employers to know about the back problem of their workforce to help modify the environment if possible. What information would you be or not be willing to share with the employer?

Q14=at what point do you think it would be most useful to have access BOL? E.g., when you start employment? when you start having back problems? annually as a reminder?

Q15=Do you think the tool would have worked better if it was given to you by a clinician or someone in your workplace occupational health setting to help guide you through how to use the BOL tool?

## Part 4: Recommendations

'Thank you very much and to our last question:'

Q16= Overall is there anything else you would like to give us feedback on to help us improve BOL?

- Putting it on app
- Making it work offline
- Adding wearable techniques like watch to give more specific feedback
- Prompts to change posture or PA habits

## 3. Ending

"Thank you again for making the time to join this interview. I will now stop the recording

Next step will be to transcribe the audio file and wonder whether you would mind if I sent you a copy of this to check whether it accurately reflects your responses?

## Many thanks again

**Appendix 15.** Reflexive commentary of the reflexive thematic analysis for the interviews with BACK-on-LINE<sup>™</sup> users.

## Step 1: Familiarisation with data

During the process of familiarisation, I reflected upon whether my own role might influence the interpretation of the data and the identification of themes. Exploring how I perceived participants' understanding of these experiences and how my position interacted with these experiences, and I found this process to be thought-provoking. As an individual without the experience of having LBP, I was continually reminded of the influence my role could bring to the analysis process as I kept reading about patients' experiences of pain affecting their work. Furthermore, as a researcher with hypotheses about the study, the question arose whether it might influence the identification and interpretation of themes. Instead of raising concern or anxiety, this reflexive process aroused me to intensify a deeper engagement with the interview transcripts.

## Step 2: Data coding

I found myself overly fixated on a specific narrative sentence during the coding process, neglecting the broader contextual discourse and the patterns across the dataset. This improper undivided focus resulted in some complex and repetitive preliminary coding. Therefore, in the first round of discussions, my supervisor and I revised part of the codes while ensuring that the coding remained sufficiently specific and retained meaningful content. Further coding was conducted to address the interview content I had either overly generalized or ignored. These additional supplements enriched the coding and provided preliminary categorisation, enabling the capture of common patterns among participants.

## Step 3: Generating initial themes

Linguistic disparities created considerable challenges in comprehending the subtle meanings of vocabulary for a non-native English user, especially when capturing common patterns in recognising initial themes. I had to constantly review whether I accurately synthesised what the participants were expressing rather than overinterpreting it myself. For instance, I initially categorised 'accessibility of BOL' under the 'functionality' theme and the 'research dissemination' under 'advocacy', as no pattern seemed common to both themes. However, through discussion with the supervisory team in the reflexive TA process, I came to realise that both themes encompassed participants' perceptions of accessing BOL.

### Step 4: Developing and reviewing themes

As I moved into developing and reviewing themes, I became increasingly aware of the complexity in balancing coherence and specificity. It is challenging to determine whether certain codes should remain separate or be merged under a broader theme. At times, I found myself inclined to preserve codes that seemed meaningful on an individual level, even when they overlapped conceptually with others. Through discussions with my supervisory team, I was encouraged to critically evaluate whether my initial reluctance to merge codes was driven by a desire to retain every nuance or whether it truly added value to the overall thematic structure. This process of refining and restructuring the themes challenged me to step back and reconsider the boundaries of each theme, ensuring they were distinct yet comprehensive. Moreover, I had to actively reflect on whether my own preconceptions about DHSMIs and BOL were subtly shaping the way I grouped participants' experiences. I recognised that some themes initially reflected my own assumptions rather than the experiences participants described.

### Step 5: Refining, defining and naming themes

At this stage, I found myself questioning whether the themes I had identified truly captured the core essence of participants' experiences. It took multiple rounds of refinement to clarify the distinctions between overlapping ideas and trim redundant sub-themes. Initially, I was hesitant to remove certain sub-themes, fearing that doing so might oversimplify participants' narratives. Engaging in reflexive discussions with my supervisory team provided a valuable external lens on the themes I was shaping. At times, their questions exposed underlying biases in my interpretations—particularly when I unconsciously prioritised perspectives that aligned with my prior knowledge of digital interventions. This prompted me to return to the transcripts and interrogate whether my thematic structure was fully representative of participants' voices rather than inadvertently reinforcing my existing perspectives. Through this reflexive process, I reached a stage where I felt confident that each theme was meaningfully distinct and capable of providing a clear, coherent narrative of participants' experiences.

## Step 6: Writing up

The process of writing up the findings brought its own set of challenges. At times, I caught myself focusing on quotes that resonated with my own views. I had to remind myself about selecting quotes that reflected the full range of perspectives rather than those that simply reinforced my expectations. Regular discussions with my supervisory team continued to be a critical part of this stage, as they encouraged me to reflect on my own position within the research. These conversations not only helped refine the analysis but also acted as a form of methodological triangulation, ensuring that my interpretations were critically examined. I also reflected on my role as a researcher without experience of living with LBP, recognising that my engagement with the data was inevitably shaped by this positionality. Rather than viewing this as a limitation, I sought to use this awareness to remain open to perspectives that challenged my assumptions. By embracing these reflexive practices throughout the analysis, I aimed to present findings that represent both participants' experiences and my own positional influences.