COmbining brief interventions for Modifiable health Behaviours withIN a routine physiotherapy consultation for pEople with a rotator cuff Disorder: development and testing in a single-arm feasibility study

(COMBINED)

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Abstract

Background: Musculoskeletal conditions pose a significant burden and healthcare challenge, and current physiotherapy treatments often have uncertain clinical effects. Modifiable lifestyle factors such as smoking, overweight/obesity and physical inactivity are associated with the onset and persistence of musculoskeletal conditions. However, physiotherapists do not routinely integrate health behaviour change approaches into their management plans. A rigorously developed intervention that integrates a brief behaviour change intervention (brief intervention) to target these modifiable health behaviours within a routine physiotherapy consultation could improve patient outcomes and help address this current healthcare problem. Shoulder rotator cuff disorders, a common musculoskeletal condition, served as a test case to achieve the project's aims.
Aims: (1) To develop and test a physiotherapist-supported treatment approach, 'The COMBINED approach', that combines a brief intervention to target modifiable health behaviours, with current management strategies, within a routine physiotherapy consultation for people with a rotator cuff disorder; (2) to understand how best to support physiotherapists to integrate such an approach into clinical practice.
Methods: The COMBINED approach was developed using a theory-, evidence-, and pragmatic-based approach, consisting of five interconnected workstreams (WS) within a multistage mixed methods design: (WS1) Narrative review to identify a range of brief interventions; (WS2) Stakeholder engagement co-design; (WS3) Prototype design, informed by behaviour change theory; (WS4) Prototype testing and refinement in a mixed-methods usability study; (WS5) Non-randomised mixed-methods feasibility study.
Findings: (WS1) A narrative review identified 14 potential brief interventions to form a component of The COMBINED approach; (WS2) 25 stakeholders attended a series of 4 co-design workshops. Stakeholders selected a suitable brief intervention from WS1 to form a component of The COMBINED approach and informed the intervention design. Potential implementation barriers and facilitators were identified; (WS3) Barriers and facilitators were mapped to behaviour change theory to identify important targets for behaviour change. Behaviour change techniques were selected to address these barriers and design intervention components. A prototype included (i) a patient-level intervention (brief intervention; supporting resources); (ii) a clinician-level intervention (implementation toolkit); (WS4) The prototype was feasible and acceptable; however, refinements were required to improve fidelity; (WS5) The feasibility of a future definitive trial was demonstrated in terms of intervention fidelity, patient recruitment, and acceptability. Identification of factors influencing implementation will inform further refinements in readiness for a future, large, randomised controlled trial.
Conclusion: The COMBINED approach has been developed through a rigorous intervention development process, making an original contribution to new knowledge. This novel intervention to address the modifiable health behaviours associated with a rotator cuff disorder, and a comprehensive implementation strategy to support physiotherapists to implement this approach, is now ready for evaluation in a future randomised controlled trial.

Research Outputs

Conference Presentations

- **Bury J.,** Yeowell G., Jinks C., Callaghan, M., and Littlewood C. 'Combining brief interventions with usual care to target lifestyle factors associated with shoulder rotator cuff disorders: Non-randomised feasibility study (COMBINED)', *Chartered Society of Physiotherapy Conference*. Manchester, October 2024. **Platform presentation accepted**
- **Bury J.,** Yeowell G., Jinks C., Selfe, J., and Littlewood C. 'The COMBINED approach: Development of a physiotherapist-supported treatment approach that integrates health behaviour change for the management of rotator cuff disorders', *Sports Kongres.* Copenhagen, February 2024. **Poster presentation**
- **Bury J.,** Jinks C., Selfe J., and Yeowell G. 'Development of a theoretically-informed patient- and clinician-level intervention to support health behaviour change for people with a rotator cuff disorder', *World Physiotherapy Congress.* Dubai, May 2023. **Platform presentation**
- **Bury J.,** Yeowell G., Jinks C., Selfe J., and Littlewood C. 'Development and testing of The COMBINED approach to integrate health behaviour change for people with rotator cuff disorders', *Physiotherapy Research Society conference.* Manchester, April 2023. **Platform presentation**
- **Bury J.,** Yeowell G., Jinks C., Selfe J., and Littlewood C. 'What do stakeholders want from a physiotherapy-supported treatment approach that supports health behaviour change within a consultation for shoulder pain?', *National Institute for Health & Care Research (NIHR) Academy Conference*. Leeds, November 2022. **Poster presentation**
- **INVITED SPEAKER: Bury J**. 'Health behaviours and shoulder outcomes: Is it time for a new approach?', *British Elbow & Shoulder Society Annual Scientific meeting.* Liverpool, June 2022. **Platform presentation**
- **Bury J.,** Yeowell G., Jinks C., Selfe J., and Littlewood C. 'Development of an intervention 'The COMBINED approach' to optimise current treatments for people with a rotator cuff disorder', *Physiotherapy UK Conference.* Online, November 2021. **Poster presentation**
- **Bury J.,** Yeowell G., Jinks C., Selfe J., and Littlewood C. 'The COMBINED approach: Combining brief interventions for modifiable health behaviours with a best practice advice intervention for people with a rotator cuff disorder', *British Elbow & Shoulder Society Annual Scientific meeting.* Online, June 2021. **Platform presentation**

Publications

- **Bury J.**, Yeowell G., Jinks C., Selfe J., and Littlewood C. (2022) 'Development of an intervention 'The COMBINED approach' to optimise current treatments for people with a rotator cuff disorder', *Physiotherapy*. 114, p. e174. doi: 10.1016/j.physio.2021.12.146

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Abbreviations

AMED	Allied and Complementary Medicine Database
APEASE	Affordability, Practicability, Effectiveness, Acceptability, Side-effects/Safety, Equity
BCT	Behaviour Change Technique
BCTTv1	Behaviour Change Technique Taxonomy (v1)
BI	Brief Intervention
BMI	Body Mass Index
BPA	Best Practice Advice
CI	Confidence Interval
CiNAHL	Cumulative Index to Nursing & Allied Health
CMO	Chief Medical Officer
COM-B	Capability, Opportunity, Motivation and Behaviour
CRF	Case Report Form
DIBQ	Determinants of Implementation Behaviour Questionnaire
DoH	Department of Health
GP	General Practitioner
GUIDED	GUIDance for the rEporting of intervention Development
GRAMMS	Good Reporting of A Mixed Methods Study
HR	Hazard Ratio
HCP	Healthcare professional
HCPC	Health and Care Professions Council

IRQ	Interquartile range
MECC	Make Every Contact Count
MEDLINE	Medical Literature Analysis and Retrieval System Online
MeSH	Medical Subject Headings
MI	Motivational Interviewing
NCSCT	National Centre for Smoking Cessation & Training
MRC	Medical Research Council
NHS	National Health Service (in the United Kingdom)
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
OR	Odds Ratio
PHE	Public Health England
PI	Principal Investigator
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
REC	Research Ethics Committee
RCT	Randomised Controlled Trial
RC	Rotator Cuff
RDS	Research Design Service
SMD	Standardised Mean Difference
TDF	Theoretical Domains Framework
TIDieR	Template for Intervention Description and Replication

UK	United Kingdom
VBA	Very Brief Advice
VBI	Very Brief Intervention
WHO	World Health Organisation
WS	Workstream
YLD	Years Lived with Disability

Chapter 1 Thesis Introduction

1.1 Chapter Introduction

This thesis presents a doctoral research project that developed a new physiotherapist-supported intervention, 'The COMBINED approach', that integrates a brief intervention (BI) to identify and address modifiable lifestyle factors within a routine physiotherapy consultation for people with rotator cuff (RC) disorders. This chapter introduces the background to the problem this research aims to address. It sets the scene within the wider context of the challenges in managing people with musculoskeletal conditions, introduces key information about the association between lifestyle factors and musculoskeletal disorders, before outlining the focus of this thesis on shoulder RC disorders. A rationale for the need for change and the purpose of this programme of research is provided. The thesis aims and objectives, and the thesis structure, are outlined before describing what The COMBINED approach is. Finally, the anticipated contribution to new knowledge is presented.

1.2 Background

1.2.1 Burden of musculoskeletal disorders

Musculoskeletal disorders comprise of several conditions affecting the bones, joints, muscles, and spine including arthritis conditions, fibromyalgia, osteoporosis and back, knee, neck and shoulder pain (Versus Arthritis, 2023; Office for Health Improvement and Disparities, 2022). They are a significant burden globally and, in the UK, with implications for individuals, society, and healthcare (Cieza *et al.*, 2020; Liu *et al.*, 2022; Versus Arthritis,

2023). More than 20 million adults in the UK, which is approximately 30% of the UK adult population, are living with a musculoskeletal condition (Versus Arthritis, 2023; Global Burden of Disease Collaborative Network, 2019). Musculoskeletal conditions are reported as one of the main determinants of years lived with disability (YLDs), which is a metric of a disease's prevalence combined with the disease's degree of disability (Cieza *et al.*, 2020; Office for health Improvement & Disparities, 2022). Pain and disability, as a consequence of living with a musculoskeletal condition, can affect a person's activities of daily living, their mood and quality of life (Ingram and Symmons, 2018; Versus Arthritis, 2023). Often underplayed in comparison to other chronic conditions, musculoskeletal pain was reported in a New Zealand survey to be comparable in terms of reduced quality of life to diabetes, chronic liver disease and cancer (Taylor, 2005). Several qualitative studies have reported individuals living with a musculoskeletal condition can describe this as a highly distressing experience, with one study reporting the impact of shoulder pain led some to suicidal thoughts (Maxwell, Robinson and Mccreesh, 2021). Another study involving people with osteoarthritis awaiting joint replacement surgery reported 35% and 22% of patients awaiting total hip and knee replacements respectively, rated their quality of life as worse than death (Clement *et al.*, 2021).

Living with a musculoskeletal condition can affect an individual's ability to work, contributing significantly to societal burden (Public Health England (PHE), 2019; Versus Arthritis, 2023). With 23.3 million workdays lost in 2021 due to musculoskeletal conditions, they were the third most common cause of sick leave and not being in

employment, costing approximately £100 billion annually (PHE, 2019; Office for National Statistics, 2022).

Furthermore, musculoskeletal conditions pose a significant economic impact on healthcare and burden on NHS services, including GP consultations, prescriptions, physiotherapy services, investigations, hospital admissions and surgery (Ingram and Symmons, 2018; Versus Arthritis, 2023). They account for 1 in 7 GP consultations, with 20% of adults in the UK consulting their GP each year with a musculoskeletal condition (Jordan *et al.*, 2014; Office for Health Improvement and Disparities, 2022) and represent the highest need for rehabilitation globally (Cieza *et al.*, 2020). Over £5 billion annually is spent by the NHS alone on the management of people with musculoskeletal conditions (PHE, 2019). People who live with a musculoskeletal condition are also more likely to report living with other chronic conditions, for example cardiovascular disease and diabetes (Williams *et al.*, 2018), adding further to the economic and healthcare burden.

The prevalence of musculoskeletal conditions significantly increases with age, accounting for only 11% in under 35-year-olds, to 61% in over 65-year-olds (Global Burden of Disease Collaborative Network, 2019; Versus Arthritis, 2023). It is predicted that the proportion of the UK population aged 65 years and over will rise from 18% in 2016, to 24% in 2041 (Ingram and Symmons, 2018; Office for National Statistics, 2022). Therefore, with an ageing population, the number of individuals living with a musculoskeletal condition is expected to increase, become more burdensome, and constitute a significant healthcare challenge for an already overstretched NHS, unless action is taken (Ingram and Symmons, 2018; PHE, 2019).

Shoulder pain is one example of a common burdensome musculoskeletal condition, with prevalence in the general population reported at 7-26%, increasing with age (Luime *et al.*, 2004; Murphy and Carr, 2009; Lucas *et al.*, 2022). Approximately 1% of adults consult their GP annually in the UK with a new presentation of shoulder pain (Mitchell *et al.*, 2005), which accounts for 2-4% of all GP consultations (Linsell *et al.*, 2006). Shoulder pain can cause physical and emotional distress, severely impacting on quality of life, and can affect an individual's ability to work (Maxwell, Robinson and Mccreesh, 2021). Hence, they will account for a proportion of the 23.3 million workdays lost in 2021 due to musculoskeletal conditions. The RC muscles and tendons are widely regarded as a common contributor of shoulder pain, implicated in approximately 70% of patients (Mitchell *et al.*, 2005). RC disorders (described further in Chapter 2, section 2.2.1) are the focus of the research in this thesis, the rationale for which will be provided in section 1.3.

1.2.2 Challenges of musculoskeletal management

Clinical guidelines for managing musculoskeletal conditions, including low back pain, shoulder pain, and osteoarthritis, recommend providing advice and education for self-management, reassurance, and exercise (including specific exercise, such as strengthening exercises and/or general exercise), along with adjunct treatments such as manual therapy (National Institute for Health and Care Excellence (NICE), 2016; Lin *et al.*, 2019; Rees *et al.*, 2021; NICE, 2022). These interventions are commonly part of the management strategies offered by physiotherapists (Smith *et al.*, 2017; Bury and Littlewood, 2018; Holden *et al.*, 2018; Moffatt *et al.*, 2024). Additionally, pain medication,

corticosteroid injections, and surgical interventions may be recommended where appropriate (NICE, 2016; Rees *et al.*, 2021; NICE, 2022).

Although physiotherapists have a role in the management of people with musculoskeletal conditions, clinical practice can be variable and not always in-line with current best evidence (Lin *et al.*, 2019; Zadro, O'Keeffe and Maher, 2019). For example, the use of acupuncture is still evident as a management strategy (Bury and Littlewood, 2018; Holden *et al.*, 2018; French *et al.*, 2020; Moffatt *et al.*, 2024), despite guidelines not recommending it as a treatment due to a lack of evidence for its effectiveness (NICE, 2016; NICE, 2022). Physiotherapists' beliefs in the effectiveness of certain treatments may be based on their clinical experience and observed patient outcomes, rather than evidence, leading to the continued use of non-evidence-based interventions (Foster *et al.*, 2009). Variability in clinical practice may reflect the lack of consistent, high-quality evidence from trials testing the effectiveness of common interventions for some musculoskeletal disorders, such as exercise, manual therapy and corticosteroid injections, with often small to moderate, short-term benefits reported (Foster *et al.*, 2009; Babatunde *et al.*, 2017). This lack of robust evidence can make decision-making challenging for clinicians (Babatunde *et al.*, 2021).

A systematic overview of treatment options for five common musculoskeletal pain disorders in primary care (back, neck, shoulder, knee and multi-site pain) reported moderate to strong evidence of medium to large effect sizes for exercise (e.g., Standardised Mean Difference, SMD 0.65 [95% CI -0.09 to 1.39] for multi-site pain, & Relative Risk, RR 7.74 [95% CI 1.97 to 30.32] for shoulder pain) and psychosocial

interventions (e.g., pooled Mean Difference, MD -5.18 [95% CI -9.79 to -0.57] for pain on a scale of 1 to10). In the short-term, strong evidence supported medium to large effect sizes for corticosteroid injections for the relief of moderate to severe knee and shoulder pain (e.g., RR: 3.11 [95% CI 1.61 to 6.01] for knee pain) pain. There was limited evidence of small effect sizes on pain and function for self-management advice and education (e.g., MD -3.2 points [95% Confidence Interval, CI -5.1, -1.3] on a 0-100 scale for back pain). There was limited evidence for the benefits of surgery for specific shoulder, neck, back and knee conditions, with evidence suggesting surgery is not superior to less invasive treatments, such as exercise, in the long term. Due to low-quality evidence, there was uncertainty regarding the effectiveness of manual therapy (Babatunde *et al.*, 2017).

In contrast to these findings suggesting the effectiveness of exercise in the management of musculoskeletal pain, a systematic review and meta-analysis of 79 randomised controlled trials (RCTS) evaluated the effects of exercise training compared to placebo, true control (wait- list control or no treatment control) or usual care (standard medical care not including physical therapies, education, psychotherapies or surgery) for people with chronic musculoskeletal pain. Their analysis found there was no difference between exercise training and non-exercise placebo treatments for managing people with chronic musculoskeletal pain (Hedges' g 0.94 [95% CI −0.17-2.06], P=0.098, I^2=92.46%, studies: n=4), but it was more effective than true, no intervention controls (g 0.99 [95% CI 0.66-1.32], P < 0.001, I^2=92.43%, studies: n=42), and usual care controls (g 0.64 [95% CI 0.44-0.83], P < 0.001, I^2=76.52%, studies: n=33). However, these findings were based on very low-quality evidence (Miller *et al.*, 2022).

A similar picture exists for the management of RC disorders, with all current treatments for RC disorders only offering, on average, small to moderate benefits at best and a lack of evidence demonstrating the effectiveness of one treatment over another (Roddy *et al.*, 2020; Babatunde *et al*., 2021; Hopewell *et al.*, 2021). As a result, the optimal way to manage this common and burdensome problem is not known and over 50% of patients experience persistent shoulder pain or reduced function up to 2 years later (Linsell *et al.*, 2006). A large 2x2 factorial RCT (n=708), the GRASP trial, compared the clinical and cost-effectiveness of two exercise interventions for the treatment of RC disorders, with or without a corticosteroid injection. Regarding the exercise interventions, no evidence of a difference was found between a physiotherapist-supported, progressive exercise programme (≤6 sessions), and best practice advice (BPA) (one session) in improving shoulder pain and function over 12 months. The BPA intervention was recommended for the management of people with RC disorders, considering that a more intensive, supervised exercise intervention was not superior. However, some participants continued to experience pain and reduced shoulder function after 12 months (Hopewell, Keene, Marian, *et al.*, 2021). The GRASP trial is described in detail (Chapter 2, section 2.2.2), but is introduced here as it forms part of the rationale for the focus on RC disorders (section 1.3).

1.2.3 Risk factors and musculoskeletal disorders

There are a number of complex interacting factors known to contribute to the onset and persistence of musculoskeletal conditions including biological, psychological, social and environmental factors (Clark and Ellis, 2014; Office for health Improvement & Disparities,

2022; Versus Arthritis, 2023; Nijs *et al.*, 2024). Some of these risk factors are considered 'non-modifiable' such as increasing age, ethnicity, gender, genetics, and largely non-modifiable, social deprivation and work environment (Landmark *et al.*, 2013; Office for health Improvement & Disparities, 2022; Witkam *et al.*, 2022).

However, several risk factors can be regarded as 'modifiable' and therefore might be useful treatment targets in the prevention and management of musculoskeletal disorders. These modifiable factors might include patient self-efficacy, fear-avoidance, patients' beliefs (Miles *et al.*, 2011), and lifestyle factors, such as unmanageable stress, smoking, overweight/obesity and physical inactivity (Dean and Söderlund, 2015; Nijs and Reis, 2022; Office for Health Improvement and Disparities, 2022).

Lifestyle factors are increasingly recognised as being associated with musculoskeletal conditions, including smoking (Landmark *et al.*, 2013; Al-Bashaireh *et al.*, 2018; Micheletti *et al.*, 2019), overweight/obesity (Shiri *et al.*, 2010; Ackerman and Osborne, 2012; Landmark *et al.*, 2013; Paulis *et al.*, 2014; Hussain *et al.*, 2017; Walsh *et al.*, 2018) and physical inactivity (Smuck *et al.*, 2014; Micheletti *et al.*, 2019). Physical inactivity is defined as not engaging in sufficient moderate to vigorous physical activity (MVPA) to meet the recommendations outlined in relevant guidelines (Bull *et al.,* 2020), with the UK Chief Medical Officers' (CMO) Physical Activity Guidelines used in this thesis (DHSC, 2019).

A state-of-the-art review synthesised the evidence on lifestyle factors and musculoskeletal health, concluding "sufficient evidence exists to support physical therapists considering incorporating lifestyle behaviour assessment in patients with

chronic musculoskeletal signs and symptoms including chronic pain, and consider lifestyle factors as potential confounders to the patient's presentation." (Dean and Söderlund, 2015, p. 5).

Systematic review evidence from 243 articles reported a negative effect of smoking on health outcomes in musculoskeletal pain (Al-Bashaireh *et al.*, 2018). A cross-sectional study surveyed 10,427 working adults in Denmark and found smoking was positively associated with a higher risk of musculoskeletal pain (e.g., smoking ≥20 cigarettes/day Relative Risk RR 1.38 [95% CI 1.24-1.54] for low back pain and RR 1.33 [1.19-1.48] for neck-shoulder pain). Being physically active (≥5 hrs/week) was also found to be positively associated with a lower risk of musculoskeletal pain (RR 0.95 [95% CI 0.90–1.00] for low back pain and RR 0.90 [95% CI 0.82–0.99] for neck-shoulder pain) (Micheletti *et al.*, 2019).

In a longitudinal study, data was included from 9281 individuals from the English Longitudinal Study of Ageing. Over a mean follow-up time of 7.8 years, obesity was positively associated with increased rates of osteoarthritis (Hazard Ratio HR 1.37 [95% CI 1.23-1.52]). Furthermore, the risk of developing osteoarthritis increased by 1% for each 1kg/m^2 increase in BMI, and by 3% for every 5 cm increase in waist circumference (Witkam *et al.*, 2022). A systematic review and meta-analysis of 28 articles reported a significant association between total body fat mass and musculoskeletal pain (SMD 0.49 [95% CI 0. 37–0.61] $p < 0.001$) based on evidence from the included cross-sectional studies included in the meta-analysis (n=14). Longitudinal studies suggested that higher body fat may increase the risk of developing or worsening joint pain, however they concluded additional high-quality studies are needed (Walsh *et al.*, 2018).

The reasons why these lifestyle factors might contribute to the onset and persistence of musculoskeletal conditions are not fully understood, but biomechanical and systemic inflammatory mechanisms have been proposed (Malfliet *et al.*, 2021).

It is also predicted, along with an ageing population, there will be a rise in the prevalence of some of these risk factors including obesity and physical inactivity levels (Ingram and PHE 2019). Given the likely multi-factorial nature of musculoskeletal disorders it seems sensible to suggest that there is a need for comprehensive, multidimensional treatment approaches to effectively manage people with musculoskeletal conditions in the long-term, given the unremarkable treatment effects reported to date (Cunningham and Kashikar-Zuck, 2013).

However, despite the increasing evidence of the associations between lifestyle factors and musculoskeletal pain, treatments provided by a physiotherapist largely remains focused on a biomechanical and structural-based approach (Hutting *et al.*, 2020; Moffatt *et al.*, 2024). This approach fails to address the complex multidimensional factors in managing people with musculoskeletal disorders.

1.2.4 A call for change

In response to the burden of musculoskeletal conditions and uncertain clinical outcomes, there have been calls for a public health approach to transform musculoskeletal health including in the UK from Versus Arthritis (formerly Arthritis Research UK), the largest UK musculoskeletal charity, Public Health England (PHE) and in the NHS Long Term plan (NHS, 2019; Arthritis Research UK, 2014; PHE, 2019).

PHE (2019) set out a vision in their 5-year musculoskeletal strategic framework to "Improve the musculoskeletal health of the population in England across the life-course, supporting people to live with good lifelong MSK [musculoskeletal] health and freedom from pain and disability" (p. 9). PHE recognises in the framework that physiotherapists are key to lead on supporting musculoskeletal health and wellbeing to address the challenges of the increasing burden on healthcare (PHE, 2019).

A public health approach includes greater recognition of lifestyle factors and the influence they have on musculoskeletal health, as well as the potential to improve patient outcomes through targeted lifestyle interventions (PHE, 2019). To support this vision, the implementation of current evidence-based behaviour change interventions by healthcare professionals (HCPs) into routine practice to address the risk factors contributing to musculoskeletal health is recommended by PHE and NICE (NICE, 2007, NICE, 2014; PHE, 2019). BIs are one example of a type of behaviour change intervention that "involves oral discussion, negotiation or encouragement, with or without written or other support or follow-up" (NICE 2014, p. 27) to motivate patients to change behaviours, for example to stop smoking. Because BIs typically only take a few minutes to deliver and have been shown to be cost-effective, they are endorsed as an approach to health behaviour change (NICE, 2013; PHE, 2017; NICE, 2018; WHO, 2022).

Make Every Contact Count (MECC), The Department of Health's initiative, is one example of a BI aimed at having good quality conversations around lifestyle behaviours to improve individual and population-level health and wellbeing (PHE, 2016). MECC has been designed to be delivered opportunistically in routine consultations by HCPs during the

millions of interactions with patients daily. HCPs are advised to encourage individuals to change their behaviour by raising awareness of the risks, for example of smoking, and signposting individuals for further support (PHE, 2016). However, despite MECC's large-scale rollout and MECC policy now being part of NHS standard contract (NHS England, 2017), there is evidence that it has not been effectively implemented widely in healthcare practice, and that HCPs find delivering behaviour change interventions challenging (Keyworth *et al.*, 2020a; Hartley, Ryad and Yeowell, 2023). Barriers to delivery include time, conflicting priorities in a consultation, and a lack of HCP confidence, knowledge and skills in delivering behaviour change interventions (Keyworth *et al.*, 2020a; Hartley, Ryad and Yeowell, 2023).

1.3 Project Rationale

In summary, musculoskeletal conditions are a significant burden and healthcare challenge, which are expected to increase with the ageing population and a rise in risk factors linked to lifestyle behaviours (Clark and Ellis, 2014; Ingram and Symmons, 2018; PHE, 2019). Current treatments by a physiotherapist for people with musculoskeletal conditions are variable, with uncertain clinical effects. There is a need to think differently to develop and test new approaches within physiotherapy that if effective, safe, and affordable can be scaled into the NHS. There is an opportunity to improve patient outcomes by considering the modifiable lifestyle factors associated with the onset and persistence of musculoskeletal disorders as important treatment targets. Addressing these factors with evidence-based behaviour change interventions, such as BIs, is one approach to optimising current treatments provided by a physiotherapist. However,

currently this opportunity is often missed by physiotherapists and there is an implementation gap of evidence-based BIs into practice that warrants further investigation (Keyworth *et al.*, 2020a).

Given this, it is now important to investigate whether physiotherapists can integrate a systematic assessment of modifiable lifestyle factors within their usual assessment processes and intervene with evidence-based BIs combined with current evidence-based treatments. The proposed research intends to develop a structured approach to integrating BIs targeting key modifiable health behaviours into physiotherapy practice, which could address the problems outlined above. There is a need to better understand the potential barriers to, and facilitators of, integrating a BI into current physiotherapy practice for the management of people with musculoskeletal conditions, what a new treatment approach might look like, and how physiotherapists can be supported to implement such an approach in practice.

The rationale for focusing on one musculoskeletal condition within this thesis is to use this as a test case and aligns with the fellowship funding that supported completion of this PhD. It is recognised that focusing on a broader range of musculoskeletal conditions was also justifiable. This PhD builds on the GRASP trial (section 1.2.2), which recommended a BPA intervention (Hopewell, Keene, Marian, *et al.*, 2021). However, patients continued to report shoulder pain and disability at 12 months, indicating a need for further development of this current evidence-based intervention. This provides the rationale for focusing on RC disorders, a common and burdensome musculoskeletal condition. Additionally, my personal experience as a musculoskeletal physiotherapist,

with a special interest in shoulder conditions has influenced this thesis. I see the challenges faced by this patient population and the frustration with poor long-term outcomes for patients.

1.4 Thesis Aims and Objectives

The overall aims of this thesis were to:

1. Develop and test a physiotherapist-supported treatment approach, 'The COMBINED approach,' that combines a BI to target modifiable health behaviours with current management strategies within a routine physiotherapy consultation for people with a RC disorder;
2. Understand how best to support physiotherapists to integrate such an approach into clinical practice.

The overall thesis objectives were to:

1. Explore the evidence-base to i) identify underpinning theory to inform the development of The COMBINED approach; ii) review the evidence-base to identify BIs for smoking cessation, weight loss and increasing physical activity, that have potential to be adapted to this population and setting;
2. Understand the barriers to, and facilitators of, implementation of a proposed COMBINED approach in clinical practice;
3. Identify the needs of those delivering and receiving the intervention, including the training needs of the physiotherapists to deliver a new intervention;

4. Co-design The COMBINED approach with key stakeholders and design an early draft (prototype) of the intervention;

5. Conduct iterative usability testing and refinement of The COMBINED approach prototype (V1.0) with a small sample of the population to investigate usability, acceptability, and feasibility of the intervention;

6. Conduct a single-arm feasibility study to evaluate the implementation of The COMBINED approach (V2.0) to facilitate ongoing refinements, including the strategies for implementation, in readiness for a definitive trial.

1.5 The COMBINED approach

In this thesis I have developed The COMBINED approach, which I introduce here for clarity, although the specific components are yet to be defined. The COMBINED approach is a multilevel intervention to target both patient-level behaviour change with respect to the modifiable health behaviours, and clinician-level behaviour change with respect to implementation into practice. It intends to (1) help patients improve their shoulder pain by identifying and assessing the lifestyle factors associated with the onset and persistence of a RC disorder and, where appropriate, the delivery of a BI to address these as part of a management plan, supported by a physiotherapist; (2) enable and support physiotherapists to effectively combine a health behaviour change approach within a routine consultation for people with a RC disorder.

How The COMBINED approach was developed is detailed in Chapters five to nine of this thesis (Figure 1.1). The research involved two stages: 1) development; and 2) testing of The COMBINED approach across five workstreams (WS).

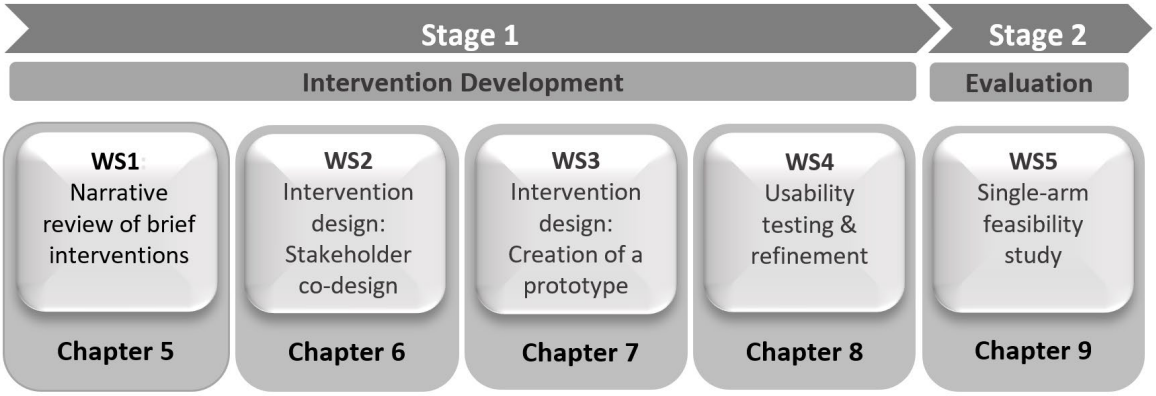

Figure 1.1 Intervention development and testing process of The COMBINED approach
WS, Workstream

In this intervention development context, 'testing' refers to the early testing of a prototype intervention, to assess outcomes of feasibility, acceptability and fidelity, with the purpose of refining the intervention prior to a definitive trial. 'Testing' in this thesis does not refer to the clinical or cost effectiveness of the intervention, and intermediate outcomes were not evaluated at this stage. The research in this thesis focused efforts on the actions of development and early testing, with the purpose of producing an optimised intervention that is feasible, acceptable and able to be delivered by physiotherapists as intended, in advance of a definitive trial. Thereby, these actions may increase the chances of successful future implementation in a definitive trial where clinical and cost-effectiveness will be evaluated (Proctor *et al.*, 2011; O'Cathain, Croot, Duncan, *et al.*, 2019).

Throughout this thesis, I refer to The COMBINED approach interchangeably as a '(complex) intervention', often in the context of the intervention development process, and a 'treatment approach'. 'Treatment approach' was felt to best describe the resulting intervention and a more engaging way to communicate with clinicians and patients.

1.6 Thesis Structure

An overview of the thesis structure is presented in Figure 1.2. To address the aims and objectives, this thesis is structured as follows:

Chapter Two: Literature Review

Chapter two presents a narrative literature review focused on two areas: (1) current management of RC disorders, including the association between certain lifestyle factors and RC disorders and the current physiotherapy role in health behaviour change approaches, and possible reasons why this is not routine practice; (2) behaviour change theory to underpin intervention development.

Chapter Three: Research methodology

Chapter three describes and justifies the theoretical position of pragmatism underpinning this thesis and the multiphase mixed methods design as the methodological approach taken to address the thesis aims and objectives.

Chapter Four: Approaches to complex intervention development

Chapter four presents an overview of the different intervention development approaches and justifies the use of a theory-, evidence- and pragmatic-based approach that draws on

recommended principles and actions from current intervention development guidance, as a rigorous, comprehensive and transparent approach. This chapter also highlights the central role of stakeholders, including patient and public involvement, in this thesis.

Chapter Five: Narrative review of brief interventions

Chapter five presents a narrative review which aimed to identify potential BIs for use in The COMBINED approach. This narrative review, which forms WS1 in the intervention development process (Figure 1.1), addresses objective 1ii. Fourteen BIs were identified and summarised narratively, which informed WS2 in the next chapter.

Chapter Six: Intervention design (part one) - Stakeholder engagement co-design

Chapter six describes a series of online stakeholder engagement workshops, using principles of co-design, as the first part of designing the intervention. This co-design study, which forms WS2 in the intervention development process (Figure 1.1), addresses objectives 2, 3 and 4. The decision-making processes to select a BI called 'Moving Medicine' to form a component of The COMBINED approach is outlined, and potential implementation barriers and facilitators are identified. Finally, it presents the ideas that were generated regarding the content, format and delivery of The COMBINED approach. The findings in this chapter identified a need to focus on supporting physiotherapists' behaviour change for future successful implementation, and consequently the need for a multi-level intervention to target both patient and clinician behaviour change.

Chapter Seven: Intervention design (part two) - Creating a prototype

Chapter seven describes the translation of findings from WS2 to inform the components of a prototype of The COMBINED approach, as the second part of designing the intervention. The creation of a prototype forms WS3 in the intervention development process (Figure 1.1), and addresses objective 4. It describes the systematic process using the COM-B model of behaviour change theory (Michie, van Stalen and West, 2011; Michie, Atkins and West, 2014) and the Theoretical Domains Framework (Cane *et al*., 2012; Michie, *et al*., 2005) to map the barriers and facilitators from WS2 to relevant behaviour change techniques to design specific intervention components. The first version of The COMBINED approach prototype is presented with a logic model.

Chapter Eight: Usability testing and refining of The COMBINED approach prototype

Chapter eight describes a mixed methods usability study to test and refine The COMBINED approach prototype, which forms WS4 in the intervention development process (Figure 1.1) and addresses objective 5. The prototype was refined based on observations, interviews and fidelity assessments. The findings from this study identified a need to refine the implementation strategies to support the physiotherapists deliver the approach in practice. Version two of The COMBINED approach prototype is presented.

Chapter Nine: Feasibility testing of The COMBINED approach prototype

Chapter nine describes a multicentre, mixed methods single-arm feasibility study to evaluate the implementation of The COMBINED approach prototype, which forms WS5 in the intervention development process (Figure 1.1) and addresses objective 6. Self-report surveys, observations and audio-recordings of the consultation, and semi-structured

patient interviews informed further refinements to The COMBINED approach prototype. A final optimised version of The COMBINED approach is presented, which will be evaluated in a future definitive trial.

Chapter Ten: Discussion and conclusion

Chapter ten discusses the key findings across all five WSs in this thesis and how the research aim has been achieved to develop and test a physiotherapist-supported treatment approach, 'The COMBINED approach,' that combines a BI to target modifiable health behaviours with current management strategies within a routine physiotherapy consultation for people with a RC disorder. Recommendations for next steps, informed by a final stakeholder event that discussed future scalability and implementation, are provided. Overall strengths and limitations of the project will be summarised before the main conclusions of this thesis are outlined, with recommendations for future research.

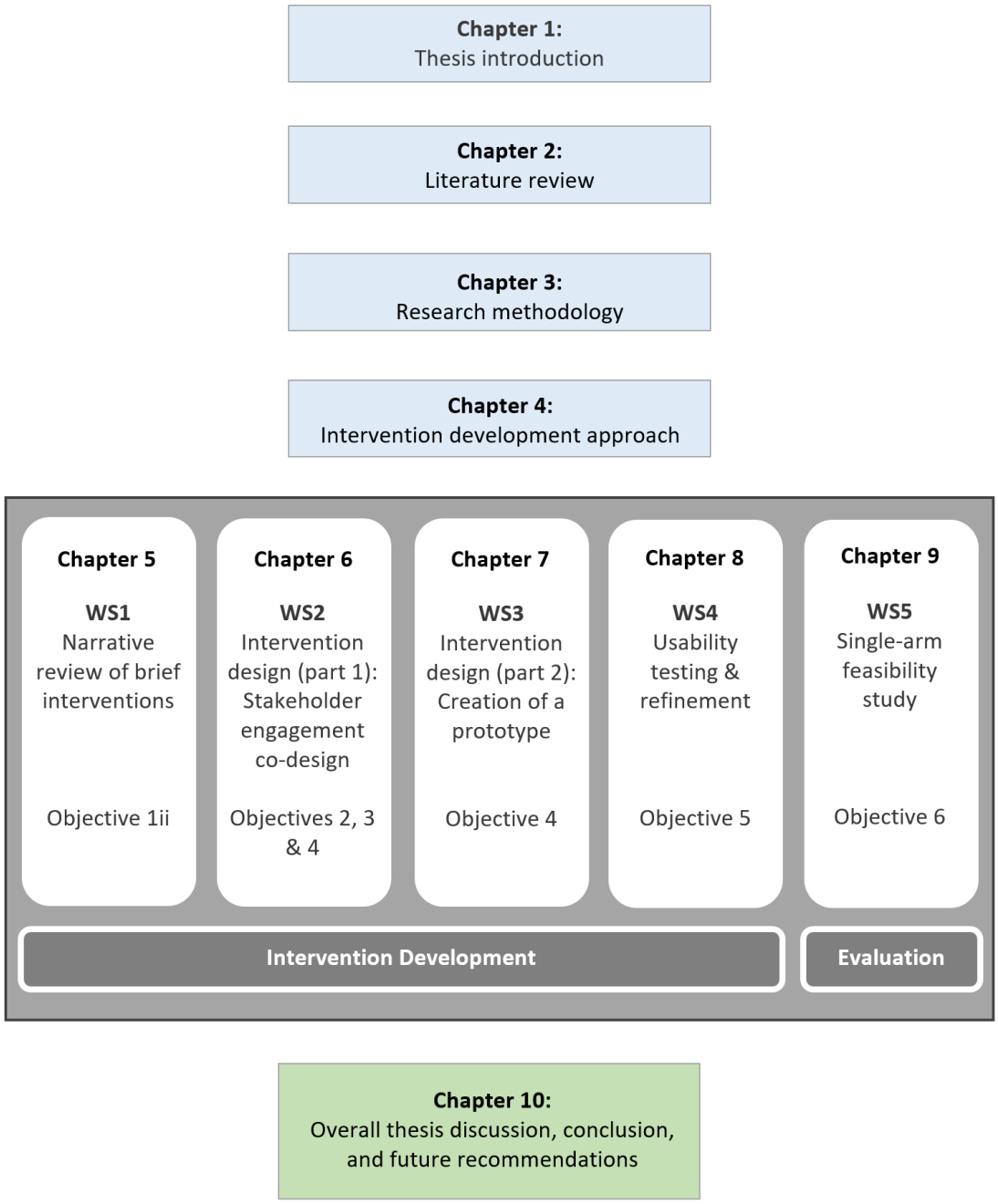

Figure 1.2 Overall thesis chapter structure
WS, Workstream

1.7 Impact of COVID-19 on the PhD project

The earlier stages of my PhD were undertaken at the start of the global COVID-19 pandemic, which presented several challenges and a requirement to adapt the research plan in response. Firstly, due to lockdown and social distancing restrictions, adaptations to the data collection and recruitment processes in the stakeholder co-design workshops (WS2) and the usability study (WS4), necessitated a move to remote methods. Secondly, at the time of the usability study (WS4) the NHS was still experiencing disruptions to services resulting from the pandemic, including longer waiting lists and restrictions on face-to-face contact, with many physiotherapy consultations still taking place remotely. As a result, this study was conducted in a private physiotherapy clinic that was not experiencing the same disruptions. However, the plan to recruit participants via adverts in a university setting was significantly impacted as many university staff and students were still not coming on site. As a result, the study recruitment process experienced delays, and amendments to the recruitment strategies and timelines had to be made to overcome these challenges.

Despite these challenges, methodological rigor was maintained throughout and changes to the data collection processes were evaluated as part of the study. Reflections on these adaptations identified advantages in some cases, and lessons learnt from this experience will inform future research. These will be discussed in the corresponding chapters.

1.8 Anticipated Contribution to New Knowledge

New knowledge has been generated through the development and early testing of a novel intervention to address the modifiable health behaviours associated with a RC disorder, including a greater understanding of how best to support physiotherapists to implement this approach into practice.

1.9 Chapter Summary

This chapter has set the scene and background to this study. It has introduced the broader context of musculoskeletal conditions including the challenges faced by physiotherapists, patients, and healthcare in their management as the underpinning rationale for this research. The rationale for the specific focus on RC disorders as an exemplar condition has also been outlined.

In the next chapter, I critically reviewed the literature to further explore the key issues that have been introduced in this chapter. The thesis will now focus on the development of The COMBINED approach in relation to the target focus of RC disorders.

Chapter 2 Literature Review

2.1 Chapter Introduction

This chapter provides a critical review of relevant literature. Firstly, it reviews the literature on rotator cuff (RC) disorders, the lifestyle factors associated with this condition and brief interventions (BIs) as a behaviour change intervention to address these factors within consultations. Secondly, it reviews behaviour change theory that underpins the intervention development within this thesis.

2.2 Rotator Cuff Disorders

2.2.1 Definition, terminology and pathoaetiology

RC disorder refers to shoulder pain involving the RC muscles and tendons of the shoulder, although what causes the pain in this condition is still poorly understood and will be discussed in this section. Patients commonly present with pain over the top and lateral side of the shoulder, which is usually exacerbated by overhead activity, and night pain is often reported. On physical examination of the patient, following the exclusion of cervical spine involvement, they usually have full passive range of movement of the shoulder, with pain reproduced on active movements of the shoulder and against resistance (Rees *et al.*, 2021).

There have been numerous terms used for disorders involving the RC muscles and tendons over the years, largely changeable due to the evolving understanding of, or lack of, the pathoaetiology (Littlewood *et al.*, 2019; Witten *et al.*, 2023). In 1972 the term subacromial impingement dominated due to the attribution of symptoms to mechanical

impingement of the shoulder RC tendons by orthopaedic surgeon Charles Neer, II (Neer, 1972). This resulted in the development of a common operation called a subacromial decompression, thought to be a solution to the impinged soft tissues, which has now been challenged (Beard *et al.*, 2017; Paavola *et al.*, 2018), this will be discussed further in section 2.2.2. Over the last 30 years, there has been a circular debate regarding the underlying pathoaetiology and subsequent terminology (Littlewood *et al.*, 2019; Witten *et al.*, 2023). In the 1990s the condition was often labelled as supraspinatus tendinitis, suggesting a primary inflammatory cause. In the 2000s a degenerative cause of the muscles and tendons was implied, with a label of supraspinatus tendinosis, followed by a return to the inflammatory model as the underlying pathoaetiology (Dean *et al*., 2013). Evolving terminology has also included RC tendinopathy, subacromial pain syndrome and RC related shoulder pain. These latter terms, while moving away from the mechanistic labels, lack any specificity, which is reflective of current understanding that the pathoaetiology of shoulder tendon disorders is still not well known (Littlewood *et al.*, 2019; Witten *et al.*, 2023).

This lack of consistency and direction towards a preferred term highlights that we still do not know what to call conditions involving the RC muscles and tendons (Littlewood *et al.*, 2019; Witten *et al.*, 2023). As there is no preferred term, for the purpose of this thesis the term ‘rotator cuff disorder’ was adopted to align with the terminology used in a recent trial, the GRASP trial (Hopewell, Keene, Marian, *et al.*, 2021), which this research draws on within the development of The COMBINED approach (section 2.2.2). Furthermore, The COMBINED approach will be relevant to both acute and chronic RC disorders.

Although the pathoaetiology of RC disorders is poorly understood, key risk and prognostic factors have been identified including: i) biomechanical factors/work-related factors, for example, repeated overhead movements, overload (Roquelaure *et al.*, 2011), ii) non-biomechanical factors, for example, increasing age, sex, genetics factors (Roquelaure *et al.*, 2011; Grusky *et al.*, 2022), iii) biochemical factors, for example, inflammation (Dean *et al.*, 2013), iv) central nervous system sensitivity (Borstad and Woeste, 2015; Sanchis *et al.*, 2015), v) psychosocial factors, for example, pain self-efficacy, patient expectation (Roquelaure *et al.*, 2011; Chester *et al.*, 2016) and vi) lifestyle factors, for example, smoking (Grusky *et al.*, 2022). This highlights the likely multidimensional nature of RC disorders suggesting a range of factors might contribute to treatment outcomes and the need for multidimensional thinking when considering treatment.

Biomechanical and psychosocial factors are routinely considered as part of physiotherapy assessment and treatment. However, lifestyle factors are less commonly considered as part of physiotherapy care for patients with RC disorders (Moffatt *et al.*, 2024), as discussed in Chapter 1, section 1.2.3. Critically, these lifestyle factors could be modified through clinical intervention, unlike other factors outlined above, for example, age, and to some extent occupation.

2.2.2 Current treatments for rotator cuff disorders

Current guidance suggests referral for physiotherapist-led treatments in the first instance (Rees *et al.*, 2021), which commonly includes exercise for the muscles and tendons, advice and education for self-management strategies, reassurance, manual therapy,

electrical modalities such as extracorporeal shockwave therapy, acupuncture or multi-modal treatments (Bury and Littlewood, 2018; Moffatt *et al.*, 2024). More invasive treatments include corticosteroid injections and surgery, which historically have been provided as hierarchical treatments when treatments provided by a physiotherapist, as described above, have failed to offer sufficient benefit to the patient (Rees *et al.*, 2021). However, currently it is not known what the best way is to treat RC disorders, with only modest effect sizes shown when these treatments are tested in trials and no significant differences between different treatment groups commonly observed (see below).

A comprehensive systematic review and network meta-analysis compared the effectiveness of different treatments for RC disorders on the primary outcomes of shoulder pain and function in the short term (⩽3 months) and long term (⩾6 months) (Babatunde, *et al*., 2021). The review included 99 trials, 6764 patients and evaluated 20 treatment options. Overall, most treatment options demonstrated small to moderate effect sizes, with no significant differences when comparing different treatments on pain and function. The primary analysis suggested that both exercise and laser therapy may offer similar benefits for pain and function across various follow-up periods. Laser therapy showed greater short-term effects at 2–6 weeks, although this finding was supported by only one trial. Exercise demonstrated greater benefits in the longer term (standardised mean difference 0.39 [95% confidence interval CI 0.18, 0.59]) at 3–6 months compared to control. Sensitivity analyses, which excluded studies with a higher risk of bias, indicated the effects of exercise remained robust for pain and function only up to the 3-month follow-up. After ranking the treatments based on their probability of being most effective

for pain and function outcomes, acupuncture, manual therapy, exercise, exercise plus manual therapy, laser therapy and Microcurrent (TENS) had the highest probability in the short term (2-6 weeks). In the longer term (3-6 months), exercise, laser therapy and extracorporeal shock wave therapy (ESWT) showed the highest probability of effectiveness for pain and function outcomes. However, there was low certainty for most treatment options based on methodological concerns and small study sizes, therefore strong recommendations towards one treatment over another could not be made (Babatunde, *et al*., 2021).

Several National Institute for Health and Care Research (NIHR) funded randomised controlled trials (RCTs) have investigated the effectiveness of physiotherapist-led exercise interventions (Roddy *et al.*, 2020; Hopewell, Keene, Marian, *et al.*, 2021). Firstly, the SUPPORT trial evaluated an individualised, progressive exercise programme supervised by a physiotherapist, versus an exercise leaflet. It also compared an ultrasound-guided versus an unguided corticosteroid injection in a 2x2 factorial RCT involving 256 participants (Roddy *et al.*, 2020). The primary outcome measure was the Shoulder Pain and Disability Index (SPADI) total score (pain and function dimensions) (MacDermid, Solomon and Prkachin, 2006) at 6 weeks, 6 months and 12 months. A greater improvement in the total SPADI score was observed with the physiotherapist-led exercise programme compared to the leaflet at 6 months (adjusted mean difference −8.23 [95% Confidence Interval CI −14.14 to –2.32]). However, the difference was of borderline clinical significance (Minimal Clinically Important Difference = 8 points) and only at the 6-month timepoint shown above (6 weeks: −1.60 [−6.99 to 3.80]; 12 months: −4.25 [−11.48

to 2.99]). There was no significant clinical difference maintained at 12 months. The study showed no significant between-group differences between the guided and unguided injection groups at any timepoint (6 weeks: −2.04 [−7.29 to 3.22]; 6 months: −2.36 [−8.16 to 3.44]; 12 months: 1.59 [−5.54 to 8.72]). Given that the exercise programme was only marginally better than a leaflet but was more time and cost intensive requiring 6-8 treatment sessions over a 12–16-week period, its clinical value could be questioned.

Secondly, the GRASP trial (introduced in Chapter 1, section 1.2.2), a large 2x2 factorial RCT involving 708 participants, evaluated the clinical and cost-effectiveness of two exercise interventions for treating RC disorders, with or without a corticosteroid injection (Hopewell, Keene, Marian, *et al.*, 2021). The trial compared a progressive exercise programme involving up to six sessions with a physiotherapist to a single session of best practice advice (BPA). This single session included exercises, but focused on self-management, delivered in a 60-minute consultation with a physiotherapist. The primary outcome measure was the SPADI score over 12 months. Results showed no significant difference in SPADI scores between the two exercise interventions over 12 months (adjusted mean difference –0·66 [99% CI –4·52 to 3·20]) and uncertainty in cost-effective recommendations. Additionally, there was no significant difference observed between corticosteroid injection versus no injection over 12 months (–1·11 [–4·47 to 2·26]). (Hopewell, Keene, Marian, *et al.*, 2021). The GRASP trial is the largest multicentre RCT to date evaluating the effectiveness of exercise interventions and corticosteroid injections in people with RC disorders. Conducted across 20 NHS Trusts with a large, adequately powered sample and rigorous strategies to minimise bias (including randomisation,

allocation concealment, and intention-to-treat analysis), the GRASP trial represents the most robust and current evidence to date on the effectiveness of exercise interventions and corticosteroid injections for RC disorders.

The GRASP trial, like the SUPPORT trial, highlights that more comprehensive interventions may not provide additional benefit over less intensive interventions. Additionally, in both trials at 12 months, most participants still reported pain and reduced function, indicating that symptoms often persist long-term despite receiving an exercise programme and corticosteroid injection.

As part of the GRASP trial (Hopewell, Keene, Marian, *et al.*, 2021), a systematic review was conducted. Firstly, they evaluated the outcomes of supervised exercise compared to unsupervised exercise, or no intervention, in individuals with a RC disorder, excluding those requiring surgery. Out of seven identified trials, most reported minimal or no difference in outcomes between supervised and unsupervised exercise at 6 and 12 months, except for the SUPPORT trial as described previously. The trials varied in quality, were small, except two which were of moderate size (271 and 256 participants each), and only two out of the seven trials included longer-term follow-up at 12 months. Heterogeneity across the studies also prevented synthesis of the data. Secondly, they compared the effects of corticosteroid injection versus no injection in individuals with a RC disorder. One small trial (n=50) found no significant difference in shoulder pain and function at 3 or 6 months. In comparing corticosteroid injection versus placebo injections, ten trials were identified, with only four considered suitable to include in the meta-analysis. Short-term benefits (≤8 weeks) were observed for shoulder pain and function

with corticosteroid injection compared to placebo injection, but the benefits were not maintained in the medium-term (3-6 months) (Hopewell, Keene, Marian, *et al.*, 2021).

This systematic review is consistent, firstly, with other studies demonstrating uncertainty over supervised or unsupervised exercise (Liaghat *et al.*, 2021). Further uncertainty is highlighted in other studies regarding the superiority of one specific exercise compared to another, whether a specific exercise strategy is superior to a general one, and the optimal dose (Shire *et al.*, 2017; Naunton *et al.*, 2020; Lafrance *et al.*, 2021). Secondly, the systematic review is consistent with other studies evaluating the effects of corticosteroid injection. In a previous systematic review and meta-analysis involving 726 patients with RC tendinosis, corticosteroid injections were found to provide temporary pain relief in a small percentage of patients but did not show any beneficial effect on the course of shoulder tendinosis. This review concluded that due to the associated costs, potential risks of discomfort and harm, and the risk of further tendon degeneration, the use of corticosteroid injections should be carefully considered (Mohamadi *et al.*, 2017).

When exercise therapy is compared to other treatments, including surgery, exercise has been reported to provide similar patient outcomes and lower risk and costs (Paavola *et al.*, 2018; Challoumas *et al.*, 2019). A systematic review of 12 RCTs compared surgery to no treatment, sham surgery and exercise-based physiotherapy on all tendinopathies. Six of these studies evaluated surgery compared with treatments provided by a physiotherapist in shoulder tendinopathy (RC disorders). Assessing pain, function, range of movement and tendon force, there was no difference between physiotherapy and surgery in the medium term, and in the long term for pain, treatment success and quality

of life (Challoumas *et al.*, 2019). However, three of the studies were rated as poor quality and three as moderate quality.

An updated Cochrane review synthesised the evidence regarding the benefits and risks of surgery compared to placebo, no intervention, or non-surgical treatments (including exercise) in individuals with RC disease (Karjalainen *et al.*, 2019). This review included eight trials with 1,062 participants. There was high certainty evidence of no clinically important difference between surgery and placebo on pain, function and health-related quality of life. Seven trials compared surgery with exercise therapy, with moderate certainty evidence of no clinically important difference between surgery and exercise at three months, six months and two years for pain (Karjalainen *et al.*, 2019).

In summary, all current treatments for RC disorders only offer, on average, small to moderate benefits at best (Babatunde *et al.*, 2021; Hopewell *et al*., 2021; Roddy *et al*., 2020). Despite uncertain clinical effectiveness of physiotherapist-supported interventions, including exercise, they continue to be recommended within treatment guidelines (Rees *et al.*, 2021). Considering more recent evidence regarding the effectiveness of injections and surgery (Karjalainen *et al.*, 2019; Hopewell, Keene, Marian, *et al.*, 2021), providing effective non-surgical treatments options are even more important. Based on the literature reviewed, it can be concluded that there is insufficient evidence on the optimum way to effectively reduce the long-term burden of shoulder pain associated with RC disorders. This presents a challenge for treating physiotherapists, and limited evidence-based treatment options for patients. We therefore need to optimise our

current approaches and think differently about how we manage this common and burdensome condition.

Finally, given that the GRASP trial is current best evidence, as reasoned above, with the single session of the BPA intervention showing no difference to a structured, supervised exercise programme (Hopewell, Keene, Marian, *et al.*, 2021), the BPA intervention warrants further consideration in the development of The COMBINED approach. The BPA intervention included a single, face-to-face, 60-minute consultation with a physiotherapist and included:

- A shoulder examination;
- A set of simple self-guided exercises, supported by a video resource, with instruction of how to progress or regress the exercises;
- A detailed advice booklet;
- Exercise action planner diary.

The BPA intervention will be discussed further in Chapter 6 & 7.

2.3 Lifestyle Factors and Underpinning Mechanisms

There is evidence of an association between three key lifestyle factors and the onset and persistence of RC disorders. These key lifestyle factors are i) smoking (Viikari-juntura *et al.*, 2008; Bishop *et al.*, 2015; Grusky *et al.*, 2022); ii) overweight/obesity (Viikari-juntura *et al.*, 2008; Rechardt *et al.*, 2010; Titchener *et al.*, 2014); and iii) physical inactivity (Viikari-juntura *et al.*, 2008).

While there may be an association with other lifestyle factors such as alcohol, nutrition, sleep quality and unmanageable stress, there is a scarcity of evidence in the literature describing these links to RC disorders. In contrast, there is an increasing body of evidence from large epidemiological and case-control studies demonstrating a positive association between smoking, overweight/obesity, and physical inactivity and the onset and persistence of RC disorders. The focus of this research on these three target behaviours within the development of The COMBINED approach is based on the current evidence of their association with RC disorders, and therefore the potential to influence patient outcomes with a rigorously developed intervention targeting these lifestyle factors. The association of these three lifestyle factors and RC disorders will now be described and discussed, highlighting the evidence and rationale for their inclusion in The COMBINED approach.

In a large UK case-control study, 5000 patients were randomly selected from a national GP database (THIN) with RC disease (Titchener *et al.*, 2014). RC disease was defined as an umbrella term, that included terms synonymous with RC disorder, for example subacromial impingement and RC tendinitis. Each patient was matched individually with a control based on age (+/- 3 years), sex, and primary care practice. Demographic data included 5266 women and 4734 men, with a median age at diagnosis of RC disease of 55 years (interquartile range, 44-65 years). The study found that cases of RC disease had increased BMI compared to controls (median cases, 26.5 vs 25.9; $P < .0001$, Mann Whitney U test). Overweight (BMI 25.1-30) and obesity (BMI 30.1-40) were significantly associated with RC disease (Odds Ratio OR:1.23, 95% CI: 1.10-1.38; OR: 1.25, CI: 1.09-1.44

respectively). However, no significant association was found in the morbidly obese group (BMI >40). Furthermore, after adjustment for consultation rate (mean number of GP consultations/year during the total registration period), which was considered a strong predictor of receiving a diagnosis of RC disease, a significant association only remained in the overweight group (OR: 1.15, CI 1.02-1.31) (Titchener *et al.*, 2014).

A population-based study in Finland recruited 6237 individuals, over 30 years of age, with shoulder pain and RC tendinitis (synonymous term with RC disorder) from university hospital regions in a stratified cluster design (Rechardt *et al.*, 2010). Participants took part in a structured clinical interview by a trained nurse, and examination by a trained physician. RC tendinitis was diagnosed on clinical examination and was defined as pain for at least 3 months in the RC region, a painful arc through shoulder abduction and/or pain on resisted movements. Demographic data showed 2850 men, with a mean age of 50.8 years, and 3387 women, with a mean age of 52.9 years, were recruited. For a sample of 2819 participants with RC tendinitis, waist circumference was significantly associated with an increased risk of RC tendinitis in both men (shown as a range for the categories of waist circumference measuring 94.0-101.9 cm and ≥ 102.0 cm: OR 1.4-2.0, 95% CI 0.8-3.5) and women (shown as a range for the categories of waist circumference measuring 80.0-87.9 cm and ≥ 88.0 cm: OR 1.5-1.6, CI 0.7-3.5), and waist-to-hip ratio (a measure of fat distribution around the waist) in men (OR 2.4, CI 0.7-8.4), suggesting abdominal obesity as a risk factor for RC tendinitis (Rechardt *et al.*, 2010).

In a cross-sectional study, 163 participants were recruited from an occupational health service in primary care, with upper extremity symptoms, including shoulder, elbow and

wrist disorders (Rechardt *et al.*, 2013). Mean age was 45 years old and the majority (86%) of participants were female. Obesity was found to be significantly associated with higher levels of pain intensity in upper extremity soft tissue disorders. Among all weight-related factors (BMI, waist circumference, waist-to-hip ratio), abdominal obesity measured by waist circumference showed the strongest association (OR 3.2, 95% CI 1.3 to 7.9). However, this was a small sample size, and while it did include RC tendinitis, it also included other conditions broader than the RC disorder population and therefore the results should be interpreted with caution (Rechardt *et al.*, 2013).

Grusky *et al*. (2022) conducted a systematic review and meta-analysis examining the relationship between aging and smoking with RC disease. The meta-analysis consistently demonstrated an association between increased age and RC disease. From 10 studies comparing current smokers (6493 cases) to non-smokers (12,985 controls), the findings indicated current smokers, independent of age, were approximately twice as likely to have RC disease compared to non-smokers (OR = 1.94, 95% CI = 1.52–2.48).

In terms of physical activity, a systematic review of risk factors and shoulder pain from 14 included studies found a preventive effect from exercise (Viikari-juntura *et al.*, 2008). They also identified associations between weight-related factors and the incidence of shoulder pain, as well as smoking, although these were less consistent. Their findings suggested a metabolic pathophysiological process may contribute to shoulder disorders (Viikari-juntura *et al.*, 2008).

Increasing evidence suggests that lifestyle factors contribute to the onset and persistence of musculoskeletal conditions primarily through systemic mechanisms (Rechardt *et al.*, 2010; Robinson *et al.*, 2016; Hansson and Skiöldebrand, 2019; Klyne *et al.*, 2021; Malfliet *et al.*, 2021; Docherty *et al.*, 2022). In particular, obesity, smoking and physical inactivity increase the production of pro-inflammatory mediators, called cytokines, which prolong inflammation and sensitivity to pain (Viikari-juntura *et al.*, 2008; Rechardt *et al.*, 2010; Bishop *et al.*, 2015; Docherty *et al.*, 2022). Pro-inflammatory cytokines have been specifically linked with shoulder disorders (Rechardt *et al*., 2010). Cytokines are molecules that regulate the immune system in health and disease, of which we need a balance of anti-inflammatory and pro-inflammatory cytokines to maintain tissue homeostasis. Elevated pro-inflammatory cytokines impact local tissue health through interactions between systemic and local inflammatory systems. Increased systemic inflammation triggers a pro-inflammatory response in tissues, thereby altering the inflammatory environment in musculoskeletal tissues (Klyne *et al.*, 2021). Furthermore, physical activity has been found to reduce the pro-inflammatory cytokines, and elevate the anti-inflammatory cytokines, highlighting the modifiable nature of these factors (Klyne *et al.*, 2021).

Considering the characteristics of people with RC disorders in the trials SUPPORT and GRASP (Roddy *et al.*, 2020; Hopewell, Keene, Marian, *et al.*, 2021), (discussed in section 2.2.2), it is interesting to see that 54% and 45% of participants respectively were previous or current smokers; and 71% and 69% respectively were overweight or obese. There was no data on physical activity levels. Given these factors are linked to modifiable health

behaviours that can be changed, it is plausible to consider their role in managing RC disorders. Considering the modest treatment effects with exercise, treatments for a RC disorder may need to go beyond an exercise programme targeting biomechanical mechanisms. Instead, treatments should also address the systemic inflammatory mechanisms through lifestyle behaviour change, reigniting the inflammatory debate discussed in section 2.2.1.

However, physiotherapists do not routinely integrate a systematic assessment of the three key modifiable health behaviours within consultations and do not routinely address these as part of a management programme for people with a RC disorder (Lowe *et al.*, 2017; Bury *et al.*, 2022). The reasons for these warrants further exploration and will be covered in section 2.4.5.

2.4 Brief Interventions

2.4.1 What is a Brief Intervention?

A BI is a structured, person-centred, evidence-based approach to target lifestyle factors and initiate patient behaviour change, for example to stop smoking, be more physically active or eat more healthily. While there is no single definition, the National Institute for Health and Care Excellence (NICE) (2014) define a BI as a type of behaviour change intervention that "involves oral discussion, negotiation or encouragement, with or without written or other support or follow-up. It may also involve a referral for further interventions, directing people to other options, or more intensive support... typically taking no more than a few minutes for basic advice" (p. 27). Due to this broad definition,

BIs are described more as a set of techniques employed together to change health behaviours (NICE, 2014; Lamming *et al.*, 2017). Subsequently, a range of BIs exist, varying in length, structure, lifestyle target, who delivers it, the setting, the underpinning theory and the skills and training required to deliver it. Further exploration is needed to understand which of these aspects within a BI is important to patients and clinicians.

BIs range from basic advice to extended approaches. Longer approaches often include an assessment of readiness to change, exploration of personal motivations for change, strategies to build motivation and self-efficacy, and support for planning such as setting goals or an action plan. As the definition suggests, a BI may or may not include written or other support, for example patient resources or signposting to other services, and may or may not include a follow-up to review the health behaviours. Basic advice can take as little as 30 seconds, often referred to as brief advice or a very brief intervention, through to extended BIs taking up to 30 minutes to deliver. BIs can also be delivered over several consultations to build on previous conversations. See Table 2.1 for definitions of BIs.

Table 2.1 Definitions of Brief Interventions

Term	Definition*
Very brief intervention or very brief advice	"Can take from 30 seconds to a couple of minutes. It is mainly about giving people information or directing them where to go for further help. It may also include other activities such as raising awareness of risks or providing encouragement and support for change" (pp. 31-2).
Brief intervention	"Involves oral discussion, negotiation or encouragement, with or without written or other support or follow-up. It may also involve a referral for further interventions, directing people to other options, or more intensive support... typically taking no more than a few minutes for basic advice" (p. 27)

Extended brief intervention	"is similar in content to a brief intervention but usually lasts more than 30 minutes and consists of an individually-focused discussion. It can involve a single session or multiple brief sessions." (p. 28)

*Definitions from: National Institute for Health and Care Excellence, 2014.

Despite the broad definitions (Table 2.1), BIs are structured conversations based on a framework to deliver specific components that are common to most BIs. The framework will depend on the intended length of the BI. For example, very brief interventions or brief advice are commonly based on the 3 A's approach (ask, advise, act) framework (Department of Health, 2009) and includes:

- **Ask** about and record the health behaviour, e.g., smoking status;
- **Advise** patient about personal health benefits e.g., raising awareness of the risks associated with their condition or general health and the benefits of changing the behaviour;
- **Act** on patient's response, e.g., refer to a local smoking cessation service if the patient is motivated to change.

A similar framework is the 5 A's approach (ask, advice, assess, assist, arrange) framework (Fiore *et al.*, 2008) that builds on the 3 A's framework and typically underpins a longer BI. The additional components to the 3A's include:

- **Assess** motivation to change (typically using the stages of change model);
- **Assist** patients in their behaviour change attempts, e.g. build motivations and self-efficacy to change and assist in making plans to make changes.

FRAMES (Feedback, Responsibility, Advice, Menu, Empathy, Self-efficacy) is another commonly used framework to deliver a BI and includes the following elements:

- **Feedback** - on the patient's health risk related to their health behaviour;
- **Responsibility** - emphasise change is the patient's responsibility;
- **Advice** - provision of clear advice when requested;
- **Menu** - provide options for change;
- **Empathy** - an approach that is warm, reflective and understanding;
- **Self-efficacy** - optimism about their behaviour change.

FRAMES originated from the field of motivational interviewing (MI), a common approach used in delivering BIs to achieve person-centred communication, which is fundamental to any BI (World Health Organisation (WHO), 2022) (see section 2.4.2). MI is defined as a "directive, client-centred counselling style for eliciting behaviour change by helping clients to explore and resolve ambivalence. It is most centrally defined not by technique but by its spirit as a facilitative style for interpersonal relationship" (Rollnick and Miller, 1995, p. 325). This 'spirit' of MI includes eliciting motivation to change from the client and building a collaborative therapeutic relationship through partnership. Principles of MI include the use of open-ended questions, affirmations, reflective listening, and expressing empathy to support self-efficacy and build motivations to change. Collaborative goal setting and action planning are also key principles (Rollnick and Miller, 1995). MI is discussed further in Chapter 7.

2.4.2 Person-centred approach

BIs are grounded in a person-centred approach, characterised by viewing the patient holistically, sharing power and responsibility, and fostering a therapeutic alliance (Paul-Savoie *et al.*, 2018). Therapeutic alliance is a relationship between patients and clinicians built on trust and mutual respect, facilitating collaboration towards shared treatment goals. Building a therapeutic alliance requires good communication skills, including the ability to explore patient's concerns and preferences (Sidani and Fox, 2014).

Underpinning person-centred care is shared-decision making, support for self-management and person-centred communication (Hutting *et al.*, 2022), which are also essential principles for delivering a BI in any new approach. Shared decision-making is "a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care" (NICE, 2021, p. 5). Self-management support "aims to equip patients with skills to actively participate and take responsibility of their chronic condition in order to function optimally" (Jonkman et al., 2016, p. 35).

One of the challenges to integrating the principles of a person-centred holistic approach into practice is that clinicians traditionally focus on a biomechanical approach (Hutting *et al.*, 2020). Furthermore, person-centred communication involves a non-judgemental approach that explores patient's preferences through active listening, which is atypical of the often didactic consultations between patients and clinicians (Newman *et al.*, 2016; Lin *et al.*, 2020).

Person-centred communication requires a more health coaching style, which facilitates a shift from a clinician-centric 'fixer' approach ("what's the matter with you?"), to an empowering 'enabler' approach ("what matters to you?") (Newman *et al.*, 2016). Health coaching, underpinned by behaviour change theory, is defined as "helping patients gain the knowledge, skills, tools and confidence to become active participants in their care so that they can reach their self-identified health goals" (Bennett *et al*., 2010, p. 24).

Health coaching is a collaborative approach, with patients as active partners rather than passive recipients of care, recognising them as the expert in managing their condition (Bennett *et al.*, 2010). Encouraging patients to generate their own solutions and building on their knowledge is more effective in facilitating behaviour change than providing generic information (Lawrence *et al*., 2016; WHO, 2022). This approach aligns with person-centred principles by fostering a partnership between patients and clinicians, emphasising patient-centred goal-setting, and empowering patients to actively manage their own decisions and care (Newman *et al.*, 2016).

In summary, the effective delivery of a BI requires a person-centred approach and health coaching style of communication to facilitate health behaviour change. Given that physiotherapists typically adopt a directive style of communication and a role as 'fixer' in clinical practice (Newman *et al.*, 2016; Lin *et al.*, 2020), addressing the training needs of physiotherapists to employ a person-centred approach, including health coaching skills, is an important consideration in the development of The COMBINED approach.

2.4.3 Effectiveness of brief interventions

BIs are endorsed by WHO and NICE as effective strategies for facilitating health behaviour change (NICE, 2014; WHO, 2022). Cost-effectiveness analysis suggests that investing in the implementation and scaling-up of BIs to mitigate disease burden associated with lifestyle risk factors is justified (WHO, 2022).

A wealth of evidence suggests that BIs delivered by HCPs can effectively produce small but important changes in behaviour. Systematic review evidence has shown BIs to have a positive impact on health behaviours such as smoking (Stead *et al.*, 2013), physical activity levels (Orrow *et al.*, 2012; Lamming *et al.*, 2017), and weight loss or dietary behaviours (Whatnall *et al.*, 2018). With regards to smoking cessation, a Cochrane review compared the effectiveness of a brief advice intervention with more intensive interventions delivered by physicians to smokers during routine consultations (Stead *et al.*, 2013). From 42 RCTS, 17 RCTs showed a brief advice intervention compared to no advice or usual care significantly increased quit rates (relative risk (RR) 1.66, 95% confidence interval (CI) 1.42 to 1.94). There was no difference found between the brief advice and intensive subgroups. The authors concluded that assuming an unassisted quit rate of 2-3%, a brief advice intervention can increase the quit rate by a further 1-3% (Stead *et al.*, 2013).

Similarly, with respect to physical activity, a systematic review of reviews with 16 included reviews, showed BIs are effective in the short-term (4-12 weeks) in increasing self-reported physical activity levels. However, they found a lack of evidence to support their impact long-term (Lamming *et al.*, 2017). They also concluded a lack of consistency in the

definition of BIs meant the duration of delivery was anything up to 30 minutes, highlighting that many BIs are not feasible for delivery in a healthcare consultation (Lamming *et al.*, 2017). This requires careful consideration during the intervention development stage of this PhD to ensure practical relevance to the NHS context.

In relation to BIs to change dietary behaviours, a systematic review of 45 RCTs/pseudo RCTs concluded BIs demonstrate short-term effectiveness on nutrition outcomes, and are a cost-effective, simple approach to target dietary behaviour change (Whatnall *et al.*, 2018). The limitations of all these systematic reviews discussed is the lack of evidence for long-term behaviour change. However, an RCT of 1882 eligible patients investigated the long-term effectiveness of a BI on weight loss outcomes in patients with obesity in primary care. This study found that a physician-delivered BI resulted in a mean weight change of 2·43 kg at 12 months, compared 1·04 kg with a basic advice intervention that indicated health benefits from weight loss. This yielded an adjusted difference of 1·43 kg (95% CI 0·89–1·97). Furthermore, the BI targeting weight loss was found to be acceptable to patients (Aveyard *et al.*, 2016).

Regarding cost-effectiveness, a systematic review and meta-analysis of RCTs, and another systematic review of economic evaluations, assessed the effectiveness of physical activity promotion in primary care. They found that BIs achieved comparable effects to more costly and time-intensive interventions (Orrow *et al.*, 2012; Vijay *et al.*, 2016). According to NICE, delivering BIs falls below their cost per quality-adjusted life-year (QALY) threshold, making it one of the most cost-effective clinical interventions (NICE, 2014; NICE, 2006). As a result, several national guidelines recommend delivering BIs in

healthcare. NICE has produced UK guidance for BIs related to physical activity (NICE, 2013) and smoking cessation (NICE, 2018). Additionally, Public Health England (PHE) has provided guidance for HCPs to deliver BIs for weight loss (PHE, 2017).

Interestingly, there seems to be no difference in effectiveness between a BI and more intensive interventions, including interventions targeting smoking (Stead *et al.*, 2013), and physical inactivity (NICE, 2013). However, interventions lasting more than five minutes have been reported as more effective for improving physical activity levels than those lasting less than five minutes (NICE, 2013). This is an important consideration for the BI component of The COMBINED approach. The elements that appear to be key to effectiveness are person-centred communication and shared decision-making to facilitate health behaviour change (WHO, 2022).

2.4.4 Make Every Contact Count (MECC)

One of the most prominent BIs in UK healthcare is the Department of Health's Make Every Contact Count (MECC) initiative (PHE, 2016), covered briefly in Chapter 1, section 1.2.4. The core MECC definition is "MECC is an approach to behaviour change that uses the millions of day-to-day interactions that organisations and individuals have with other people to support them in making positive changes to their physical and mental health and wellbeing" (PHE, 2016, p. 7).

MECC uses brief and very brief interventions, as described in section 2.4.1. Figure 2.1 shows different behaviour change interventions and where MECC (brief interventions and very brief interventions) fits, represented in the blue and pink steps of the pyramid.

Figure 2.1 Behaviour change interventions mapped to Make Every Contact Count
(Source: Public Health England, 2016, p. 15 (Behaviour change interventions diagram by Health Education England – Wessex Team))

MECC has been designed to be integrated into routine care without adding to already busy workloads. MECC demonstrates how a relatively low-cost BI can be delivered opportunistically by any HCP during routine consultations to support health behaviour change at an individual and population-level (Lamming *et al.*, 2017; PHE, 2016).

Given the prominence and exposure of MECC it would be reasonable to think MECC has been effectively implemented widely in healthcare practice. However, a national survey in 2017 found a lack of awareness of MECC policy and missed opportunities by HCPs to address health behaviours opportunistically within routine consultations (Keyworth *et al.*, 2018). Only 31% of HCPs surveyed were aware of MECC policy, and although 56% of HCPs

felt their patients would benefit from MECC, they did not deliver it in 50% of the cases where they saw a need. The authors highlighted that a greater awareness of MECC policy does not mean higher use. The same authors repeated the survey in 2024 to understand the impact of COVID-19 on the delivery of MECC. Although awareness of MECC policy increased from 31% to 52%, HCPs perceived fewer patients would benefit (56% in 2017 versus 50% in 2024) and they were delivered to a lower proportion of patients (50% in 2017 versus 38% in 2024) (Keyworth *et al.*, 2024). This reduction in engagement with the delivery of opportunistic BIs over time warrants further investigation to ensure maximum engagement with The COMBINED approach.

While MECC is an exemplary and creditable BI, there are some key differences to highlight in reference to the intended purpose of The COMBINED approach. Firstly, MECC is opportunistic and often unrelated to the presenting condition, raising awareness of risks in relation to general health and wellbeing, considering these as separate entities. The purpose of The COMBINED approach is to raise awareness of the links specifically related to the onset and persistence of their RC disorder and therefore make interconnected links between lifestyle factors and the management of their musculoskeletal condition.

Secondly, MECC is often perceived as an 'add-on' within consultations secondary to addressing the primary complaint. Along with the disconnected approach to the presenting condition, this may not highlight the equal importance of addressing lifestyle factors within a management plan. The COMBINED approach intends to be an 'integrated approach', meaning the lifestyle factors are considered throughout the consultation for a RC disorder, including during history-taking, examination and treatment discussions. This

approach prioritises health behaviour change and shoulder-specific rehabilitation as equally important aspects in managing a RC disorder, emphasising to patients they both deserve equal focus within their overall management plan.

Thirdly, MECC implementation has faced challenges, with clinicians sometimes unaware or not fully engaged with its policies, indicating a need for a more systematic and supported integration into physiotherapy practice. This suggests a need for innovative approaches and further investigation to effectively implement interventions like The COMBINED approach.

2.4.5 Barriers and facilitators to delivery of brief behaviour change interventions

Despite the potential of BIs in facilitating health behaviour change, barriers to their delivery are widely cited in the literature. Keyworth *et al.* (2020a) conducted a systematic review of systematic reviews, synthesising common barriers and enablers to delivering brief behaviour change interventions across patient-facing HCP groups. The primary outcome was barriers and facilitators to HCPs providing either health behaviour change advice and/or interventions to patients, with 36 included reviews. The findings were reported as groups of themes depending on if they were identified as a barrier, a barrier and enabler, or an enabler to delivering behaviour change interventions. A conceptual map of these key findings, with relevant evidence, is shown in Appendix A. The themes from this review of reviews will be discussed and compared to wider literature.

Common barriers to delivery of brief behaviour change interventions included:

1) Perceived lack of time to deliver behaviour change interventions

Seventeen systematic reviews consistently identified time as a barrier to delivering behaviour change interventions, which was applicable to all HCP groups and health behaviours. Time is the most cited barrier in the wider literature (Chisholm *et al.*, 2012; Keyworth *et al.*, 2018, 2019; Albert *et al.*, 2020), including specific to physiotherapy studies (Walkeden and Walker, 2015; Parchment *et al.*, 2023). Extending consultation times is impractical, therefore it may be more effective to reframe clinicians' perceptions of health behaviour change as an integral part of consultations, rather than an additional thing to do. Providing clinicians with a structured, time-efficient approach could also be advantageous.

2) Perceived lack of prioritisation of health behaviour change as a clinical priority

Fifteen systematic reviews reported a lack of prioritisation for delivering behaviour change interventions, both personally and within the ethos of the organisation. Five of the 15 reviews reported that HCPs tend to focus on the patients' presenting symptoms and disease management. In the wider literature, a survey of 216 Australian physiotherapists found similar results, with most respondents highlighting the patient's presenting musculoskeletal problem was a higher priority than addressing physical activity levels (Kunstler *et al.*, 2019). Highlighting explicit links between the lifestyle factors within the management of musculoskeletal condition may help reframe clinicians' perceptions of health behaviour change as an important priority of the consultation.

3) HCPs' perceptions of patient motivation

Nine systematic reviews reported on how the HCPs' perceptions about the patient's motivations and ability to change health behaviours, which was generally pessimistic, determined how likely HCPs would address behaviour change within a consultation. Compared to other studies, a qualitative study with 28 UK HCPs reported a perceived lack of patient engagement by HCPs, and the belief that patients would not be receptive or have the ability to change their behaviours. Another qualitative study involving a questionnaire (n = 1646) and semi-structured interviews (n = 21) found that the perceived patient receptiveness influenced whether the HCP broached the topic of weight loss (Holden *et al.*, 2019). In both studies, HCPs made a conscious decision about which patients to engage with based on their perception of how patients would respond to conversations about lifestyle (Holden *et al.*, 2019; Keyworth *et al.*, 2019).

Despite the pessimistic perception by HCPs in relation to patients not wanting to receive behaviour change interventions, or be motivated to change (Keyworth *et al.*, 2020a), this is in contrast to the literature showing patients do expect HCPs to initiate lifestyle discussions even when it is not initiated by the patient, and find it acceptable (Aveyard *et al.*, 2016; Black, Ingman and Janes, 2016; Kunstler *et al.*, 2019; Keyworth *et al.*, 2020b). A survey of 230 physiotherapists in the United States (US) explored patient's perspective of physiotherapists discussing several lifestyle-related topics. They found most respondents felt physiotherapists should discuss physical activity levels (91%), maintaining a healthy weight (73%), smoking cessation (51%), with less agreeing it should include advice on fruit and vegetable consumption (32%) (Black, Ingman and Janes, 2016). In terms of motivation, a qualitative interview study with 24 patients in GP practice found patients

were particularly motivated to change if there was a positive impact on their existing health condition and would help with self-management (Keyworth *et al.*, 2020b). These findings are important to highlight patient expectations in relation to behaviour change conversations, and strategies to increase patient motivation by linking the health behaviours to their existing condition, where appropriate. These findings may be reassuring to HCPs and an important strategy to support HCP engagement.

Common barriers and enablers identified in the systematic review (Keyworth *et al.*, 2020a) included:

1) Perceptions of the knowledge or skills to support patient behaviour change

Twenty systematic reviews reported a lack of HCP knowledge of the available resources, such as signposting information, to facilitate behaviour change. A lack of skills and training in behaviour change was reported in six of the twenty systematic reviews, with having the right skillset identified as a key enabler. A perceived lack of confidence in the HCPs capability to effectively facilitate behaviour change with patients was reported in seven of the twenty reviews. Knowledge, skills and confidence to deliver behaviour change interventions are common across the wider literature (Chisholm *et al.*, 2012; Dewhurst *et al.*, 2017; Allison *et al.*, 2019; Holden *et al.*, 2019; Keyworth *et al.*, 2019). Training, as well as other strategies to address these will be an important consideration in the development of The COMBINED approach.

2) HCPs' own health behaviour

The HCPs' own health behaviours were identified as a perceived barrier in ten systematic reviews, with positive health behaviours more likely to influence the delivery of a behaviour change intervention. Similar to the wider literature, physiotherapists who were physically active were more likely to promote physical activity (Kunstler *et al.*, 2019; Bright *et al.*, 2021), and similarly for physiotherapists with a healthy diet (Bright *et al.*, 2021). Several studies have also highlighted HCPs' perception of the importance of being a role model with regards to the health behaviours and the belief that unhealthy behaviours would undermine the credibility when discussing health behaviour change with patients (Keyworth *et al.*, 2019). Studies involving patients have reported a general preference by the patient for the HCP to be a role model (Black, Ingman and Janes, 2016; Keyworth *et al.*, 2019), with one interview study confirming that a role model with respect to their health behaviour was perceived by patients as increasing the credibility of the information (Keyworth *et al.*, 2020b). The US survey by Black *et al* (2016) found most respondents expected physiotherapists to be role models when discussing physical activity (83%), maintaining a healthy weight (72%), and not smoking (64%). The expectation that HCPs should be role models for these behaviours warrants further investigation.

Key enablers identified in this systematic review of reviews (Keyworth *et al.*, 2020a) included training, time, having a conducive environment, organisational system support, having a positive attitude and having a structured approach to delivering behaviour change interventions. Interestingly, what they found was if the HCP could link the lifestyle

conversation to the presenting condition, a behaviour change intervention was more likely to be delivered (Keyworth *et al.*, 2020a).

In addition to the barriers reported in the systematic review of systematic reviews (Keyworth *et al.*, 2020a) other studies reported a fear of offending patients and affecting the therapeutic alliance by having conversations about lifestyle (Chisholm *et al.*, 2012; Keyworth *et al.*, 2018; Bright *et al.*, 2021). Given that patients expect behaviour change conversations and find them acceptable, as highlighted above, this may be a perception by the HCPs that needs addressing.

While a number of barriers and facilitators are cited in the literature, further investigation of these in the context of implementing The COMBINED approach will ensure context-specific barriers are understood, along with relevant facilitators. In summary, BIs are evidence-based and cost-effective. A major strength of BIs is their brevity, meaning they can be implemented by HCPs in routine consultations with patients, without impacting too much on their clinical time. BIs can also be delivered by any HCP with appropriate training, without requiring specialist skills. However, previous studies have reported implementation barriers to their delivery by HCPs, which warrants further exploration within the development of any new approach for RC disorders.

2.5 Behaviour Change and Behaviour Change Theory

2.5.1 Role of the physiotherapist in health behaviour change

Physiotherapists can play a key role in supporting health behaviour change. They are well-placed given their frequent one-to-one contact with patients and are considered a

trusted, credible source of behaviour change advice (Dean *et al*., 2016; McPhail *et al*., 2014). Physiotherapy consultations, although still time-pressured, are typically longer in duration compared to other professions such as GPs and surgeons, providing a greater opportunity to raise awareness of the impact of lifestyle risk factors with RC disorders. Furthermore, physiotherapists typically have contact with patients over multiple consultations, which is important for building therapeutic alliance and integral to facilitating a behaviour change approach. However, delivering behaviour change interventions is relatively new for physiotherapists, and a frequently cited barrier to their delivery is the lack of undergraduate training to prepare them for this role. This highlights the need for a shift from the traditional 'taught' physiotherapy role (Dean *et al*., 2016; Hartley *et al*., 2023; Walkeden & Walker, 2015).

A recent qualitative study explored physiotherapists' perception of their evolving role, particularly as health promoters supporting patient wellbeing. This emerging role was seen as crucial to align practice with future population needs and to 'future-proof' the profession. However, barriers to this evolving role, included lack of time, skills and confidence (Hartley, Ryad and Yeowell, 2023). Therefore despite efforts to evolve the physiotherapy role, this has not been fully embraced in practice (Hartley, Ryad and Yeowell, 2023).

Barriers to delivering behaviour change interventions, along with the evolving physiotherapy role more generally, highlights that any potential impact of The COMBINED approach on patient outcomes is dependent on the behaviour change of the HCPs (physiotherapists) to successfully implement The COMBINED approach into practice.

Therefore, an assessment and understanding of HCP behaviours that are likely to influence implementation is crucial and must be considered, along with strategies to overcome them, in the development of The COMBINED approach.

2.5.2 Behaviour change theory

It is recognised that changing behaviours is challenging, but can be more effective if an intervention is based on behaviour change theory (Michie *et al.*, 2008). Behaviour change theories can be used to understand factors underpinning HCP behaviour in relation to implementation, and to inform intervention design (Michie *et al.*, 2008). The Medical Research Council (MRC) framework for developing and evaluating complex interventions advocates a theoretical underpinning in intervention development, based on the suggestion that an intervention based on theory is more effective, and gives a greater understanding of what works in what context (Michie *et al.*, 2008; Skivington *et al.*, 2021).

The purpose of The COMBINED approach is to bring about a change in behaviour of those receiving it, which includes the patients with respect to their identified health behaviours, but also of the physiotherapists to implement The COMBINED approach into clinical practice. It was therefore important to underpin the development of this intervention with appropriate behaviour change theory. However, multiple behaviour change theories exist, including the Theory of Reasoned Action (Fishbein, 1979), Social Cognitive Theory (Bandura, 1998), the Theory of Planned Behaviour (Ajzen, 1991), and Normalisation Process Theory (May *et al.*, 2007), making it difficult for researchers to select the most

appropriate theory (Nilsen, 2015). Furthermore, across these theories, many constructs overlap, such as self-efficacy, beliefs, intention, and social norms (Michie, *et al*., 2005).

The Theoretical Domains Framework (TDF) was developed to simplify the number of theories and overlapping constructs, meaning researchers do not have to select one particular theory (Michie, *et al*., 2005). The TDF is a validated framework, developed using a rigorous consensus approach, that integrates 33 behaviour change theories into 14 domains of behavioural determinants (Cane *et al*., 2012; Michie, *et al*., 2005). The focus of the TDF is to assess implementation behaviours and inform intervention design *(*Atkins *et al., 2017;* Cane *et al*., 2012; Michie *et al*., 2005). These domains are (1) knowledge; (2) skills; (3) social/professional role and identity; (4) beliefs about capabilities; (5) optimism (6) beliefs about consequences; (7) reinforcement; (8) intentions; (9) goals; (10) memory, attention, and decision processes; (11) environmental context and resources; (12) social influences; and (13) emotion; (14) behavioural regulation (Cane, Connor and Michie, 2012). In intervention design, the implementation barriers and facilitators are mapped to the behavioural domains to understand and explain the current implementation behaviours, and subsequently mapped to appropriate behaviour change techniques (BCTs) to identify components within an intervention that are tailored to target the HCPs behaviours (Michie, 2008; Cane, Connor and Michie, 2012).

In addition to the TDF, the COM-B model of behaviour change intends to represent the primary drivers of behaviour and is a foundation for designing behaviour change interventions (Michie, van Stalen and West, 2011; Michie, Atkins and West, 2014). COM-B stands for Capability, Opportunity, and Motivation – Behaviour, and it is considered that

all three are necessary for behaviour change to occur (Michie, van Stalen and West, 2011; Michie, Atkins and West, 2014) (Figure 2.2).

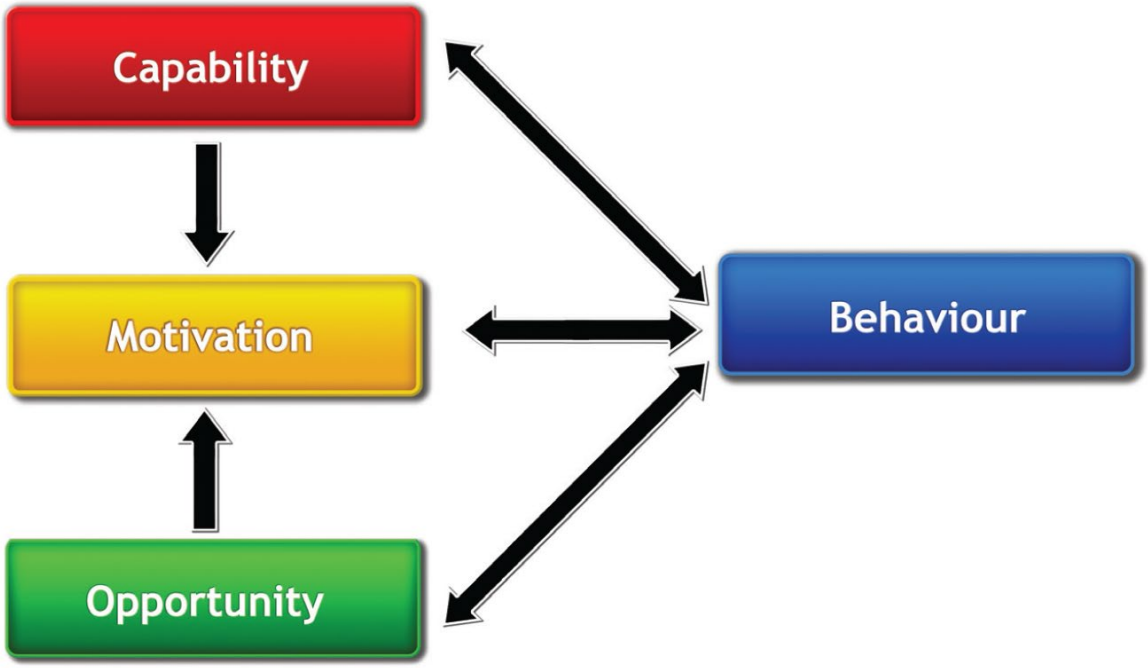

Figure 2.2 The COM-B model
(Source: Michie et al., 2014, p. 62, Figure 1.4)

For example, to implement an evidence-based intervention into practice, an individual needs the necessary skills (Capability), the time and resources (Opportunity), and the desire (Motivation) for the behaviour to occur. Like the TDF, the COM-B model can be used to understand the influences on HCP behaviour and identify behavioural targets in intervention design, often referred to as a behavioural diagnosis (Michie, Atkins and West, 2014).

COM-B and the TDF are commonly used together, and complement each other, with COM-B recommended as an initial behavioural diagnosis to then help identify the most

important TDF domains to focus on for behaviour change (Michie, van Stalen and West, 2011; Cane, Connor and Michie, 2012). The COM-B and TDF domains can be mapped onto each other, with the TDF providing a more comprehensive understanding of behaviours in relation to COM-B. For example, the COM-B may identify capability as a barrier to behaviour change in implementing a BI. Mapped to the TDF, a greater understanding of what it is about capability can be gained, such as a lack of HCP knowledge or skills. In this way, the intervention components can be more targeted to address these barriers (Cane, Connor and Michie, 2012). Figure 2.3 shows how the domains of COM-B and the TDF are related. This process will be discussed further in Chapter 7.

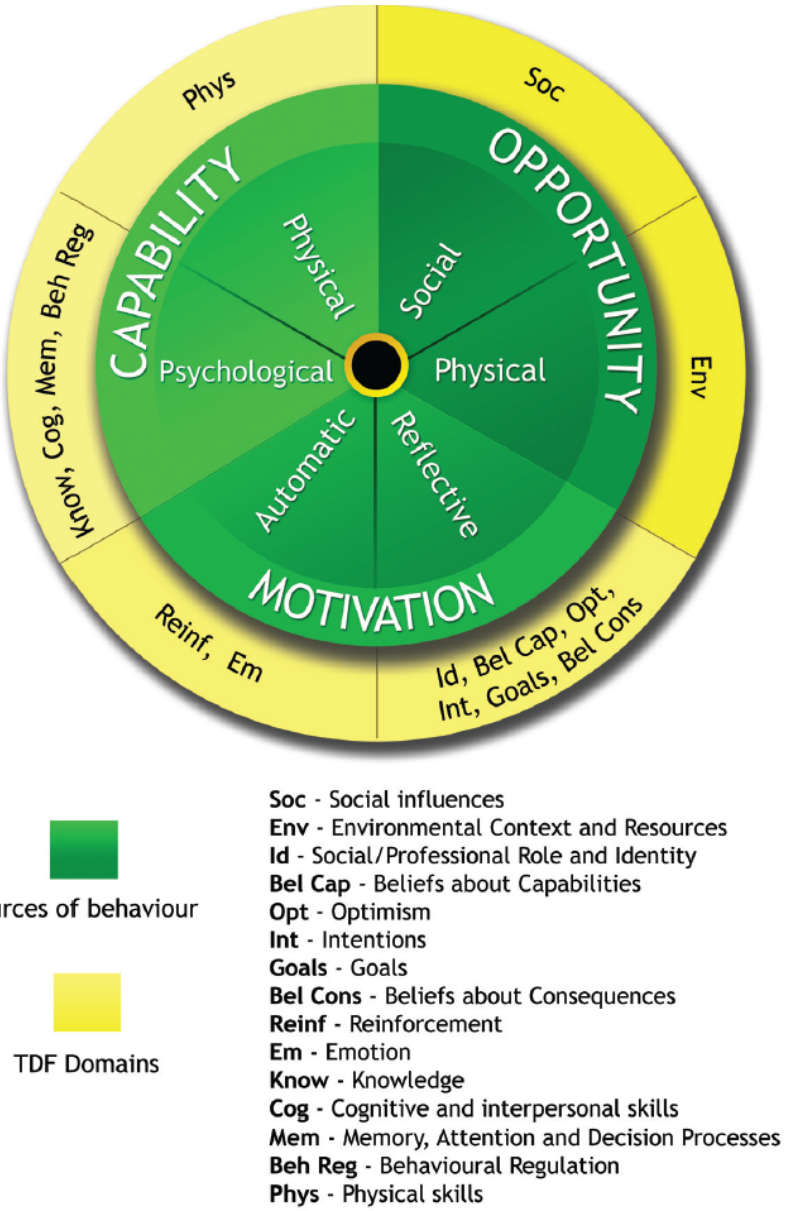

Figure 2.3 TDF domains linked to COM-B components
(Source: Michie et al., 2014, p. 92, Figure 1.7).

After conducting a behavioural diagnosis using the COM-B model and the TDF, relevant Behaviour Change Techniques (BCTs) can be selected to target specific domains to support HCPs in changing their behaviour. A BCT is defined as "an active component of an intervention designed to change behaviour" (Michie *et al*., 2014, p. 145). The characteristics of a BCT are that they are observable, replicable, irreducible components

designed to change behaviour within an intervention, and are essential active ingredients of the intervention (Michie, Atkins and West, 2014). Examples of BCTs include goal-setting, prompts/cues, habit formation, and self-monitoring of behaviours. To synthesise the number of different BCTs with varying terminology, the BCT taxonomy project developed a BCT taxonomy v1 (BCTTv1). The taxonomy includes 93 BCTs organised into 16 groups, which can be used in interventions to support behaviour change (Michie, Richardson, Johnston, Hardeman, *et al.*, 2013). This process will be described further in Chapter 7. The selection and rationale for the underpinning theory used in the development of The COMBINED approach will be discussed in Chapter 4, section 4.3.4.

2.6 Chapter Summary

This chapter has reviewed the literature underpinning the rationale for the research in this thesis. It has highlighted the current challenges with the management of RC disorders and the evidence of association with modifiable lifestyle factors as an important consideration to optimise current treatments for people with RC disorders and address this challenge. It has discussed BIs as a behaviour change strategy to address the associated lifestyle factors and the potential barriers to implementation. Finally, it has outlined potential behaviour change theory that could be drawn on as the underpinning theoretical basis for the development of The COMBINED approach. The next chapter will outline the methodological approach taken within this thesis.

Chapter 3 Research Methodology

3.1 Chapter Introduction

This chapter outlines the theoretical position and rationale for a pragmatic approach in this PhD thesis and describes the mixed methods research involving the iterative collection, analysis and integration of both qualitative and quantitative data, framed within a multistage design.

3.2 Background

The overall aim of this thesis was to develop and test a physiotherapist-supported treatment approach, 'The COMBINED approach,' that combines a brief intervention (BI) to target modifiable health behaviours with current management strategies within a routine physiotherapy consultation for people with a rotator cuff (RC) disorder; and to understand how best to support physiotherapists to integrate such an approach into clinical practice. To address the uncertainty about what a new approach should entail, a multistage mixed methods design, underpinned by a pragmatic perspective, was employed. This is discussed further in the sections that follow.

3.3 Theoretical Perspective - Pragmatism

The theoretical perspective that has underpinned this PhD thesis is pragmatism. Emanating from the critique of opposing paradigms, positivism and constructivism, pragmatism emerged in the late 19th and early 20th centuries as a philosophical movement focused on the practical nature of reality and finding solutions to problems in

the real-world, informed by human experience (Johnson and Onwuegbuzie, 2004; Morgan, 2007; Cornish and Gillespie, 2009; Greene and Hall, 2010).

Methodologically, pragmatists believe in using the best research methods, or tools, to address the problem that are appropriate to the current situation, rather than favouring one research or philosophical approach over another (Cornish and Gillespie, 2009; Greene and Hall, 2010; Shaw, Connelly and Zecevic, 2010). The research question, or problem, is therefore the guiding focus of the research design, with the purpose of finding workable solutions (Johnson and Onwuegbuzie, 2004; Cornish and Gillespie, 2009; Greene and Hall, 2010).

Pragmatists reject the possibility of a single reality, total objectivity and an absolute truth associated with positivism, as well as complete subjectivity aligned with constructivism (Giddings and Grant, 2007; Cornish and Gillespie, 2009; Tashakkori and Teddlie, 2010). Pragmatism is based on the ontological belief in the practical, rather than idealistic, nature of reality and that reality may be interpreted in different ways, in different situations, which is continually changing (Johnson and Onwuegbuzie, 2004; Cornish and Gillespie, 2009; Biesta, 2010).

As such, pragmatism explores the use of multiple approaches and different methods, which may include integrating methods from what can be considered as competing paradigms (Johnson and Onwuegbuzie, 2004; Shaw, Connelly and Zecevic, 2010; Tashakkori and Teddlie, 2010; Creswell and Plano Clark, 2018). This is a common criticism of pragmatism, that anything is permissible, if it is of practical benefit (Denscombe, 2008;

Morgan, 2014). The positivism versus constructivism debate, previously referred to as a 'paradigm war', are considered by purists as dichotomous, arguing that the methodological approaches, based on different philosophical beliefs, are not compatible (Johnson and Onwuegbuzie, 2004; Tashakkori and Teddlie, 2010; Creswell and Plano Clark, 2018).

However, rather than viewing these as opposing, pragmatists argue that each approach serves a different, but complementary purpose that is meaningful to understand a problem more thoroughly and investigate different aspects of the research question (Johnson and Onwuegbuzie, 2004; Cornish and Gillespie, 2009; Feilzer, 2010; Tashakkori and Teddlie, 2010). The choice of approach is dependent on the situation and how well they serve to achieve the desired outcomes (Biesta, 2010; Creswell and Plano Clark, 2018).

In terms of epistemology, pragmatists believe knowledge is constructed through people's everyday experiences and their interaction with the environment. Knowledge is then evaluated based on its consequences in action, for example, does the knowledge solve the problem of everyday action and does it work in practice (Morgan, 2007; Cornish and Gillespie, 2009; Greene and Hall, 2010). This inquiry and reflection linked to context and everyday experience is underpinned by the belief in collaboration, discussion, consultation, and participation in social connections to solve problems, with democracy at the core (Johnson and Onwuegbuzie, 2004; Cornish and Gillespie, 2009; Greene and Hall, 2010; Allemang, Sitter and Dimitropoulos, 2022).

3.3.1 Justification of theoretical perspective

The principles of pragmatism, as outlined above, offers an explanation to why I, as a clinician, would align with such a philosophy that focuses on real-world problems and application to practice. Furthermore, pragmatism values the experiential knowledge of individuals to understand and solve problems collaboratively (Johnson and Onwuegbuzie, 2004; Cornish and Gillespie, 2009; Greene and Hall, 2010; Allemang, Sitter and Dimitropoulos, 2022), particularly when there are challenges that need to be addressed for successful implementation (Glasgow, 2013).

To develop and test a prototype intervention to tackle real-world healthcare problems, taking into account the contextual factors and complexity of physiotherapy practice, and where the experiences of individuals and their environments are fundamental to its successful implementation, pragmatism aligns with the specific aims of this PhD thesis (Chapter 1, section 1.4)(Shaw, Connelly and Zecevic, 2010).

Interventions developed for healthcare often encounter barriers to implementation due to problems with their use within complex, real-world settings (Glasgow, 2013). The underpinning focus of this thesis, aligned with pragmatism, has been to make The COMBINED approach as relevant and practical for physiotherapy practice, to support future implementation. Aligned with Dewey's underpinning principles of collaboration, discussion, consultation, and participation in social connections to solve problems (Allemang, Sitter and Dimitropoulos, 2022), there has been a focus on meaningful involvement and collaboration with stakeholders throughout this programme of research.

Addressing a problem through experimentation in context to create and evaluate a workable and useful intervention is an important principle in pragmatic research (Cornish and Gillespie, 2009).

3.4 Reflexivity

In addition to acknowledging how my theoretical perspective has shaped decisions throughout this PhD research, including methodological and intervention design choices, I recognise the importance of personal reflexivity in conducting research. This includes acknowledging how my own assumptions, beliefs and experiences may have shaped my research, the interpretations made, and the knowledge produced.

Reflexivity refers to a critical self-awareness by the researcher of the influence they have had on the research process, including the research question, research setting, interpretation of findings and knowledge production (Pillow, 2003; Probst and Berenson, 2014). Personal influencing factors could include my gender, class, ethnicity, life experiences and clinical experiences. The critical self-reflection on the influence of my position on the research process, and strategies to mitigate this, will be embedded throughout this thesis for the purpose of transparency, credibility and rigor (DeSouza, 2015).

3.5 Mixed Methods Research

3.5.1 Definition

Mixed methods research typically integrates both qualitative and quantitative approaches in a single study, or over multiple phases of a research study, usually with the aim of increasing breadth and depth of understanding and/or to corroborate findings (Johnson and Onwuegbuzie, 2007). It is recognised, however, that some authors do not limit this definition to the requirement for a qualitative and quantitative approach, but rather the combination of any methods, including multiple quantitative approaches (no qualitative methods) or multiple qualitative approaches (no quantitative methods) (Bazeley, 2017). The key element of mixed methods research, which separates it from the term multi-methods, is the need for a strategy for integrative analysis (Johnson and Onwuegbuzie, 2007; Tashakkori and Teddlie, 2010; Fetters, Curry and Creswell, 2013; Creswell and Plano Clark, 2018). Integration of the data and their results as a core component of mixed methods research will be discussed later in section 3.5.4.

Johnson (2007) reported 19 different definitions of mixed methods research by experts in this field. In recognition of the varying definitions of mixed methods research, Creswell and Plano Clark (2018) propose a definition of mixed methods research based on underpinning core characteristics. These include the:

1. Systematic collection and analysis of both quantitative and qualitative data in relation to the research questions and hypotheses;
2. Integration of the quantitative and qualitative data and their results;

3. Application of a specific research design to organise and conduct study procedures coherently;
4. Use of theory and philosophy to frame study procedures.

In this thesis, these core characteristics have been embedded to guide the planning and conducting of specific procedures to ensure a robust approach. In relation to characteristic 4, my philosophical approach framing the study procedures has been outlined in section 3.3 of this chapter. The underpinning theory informing this research is detailed in Chapter 4, section 4.3.4. Characteristics 1-3 and how they have guided the mixed methods research in this thesis will be discussed further in sections 3.5.3 and 3.5.4. First, I will provide a rationale for the use of a mixed methods research methodology in this thesis.

3.5.2 Justification for a mixed methods approach

The philosophical assumptions of pragmatism to integrate different approaches and methods guided by the research problem, align with, and underpin my choice of, a mixed methods research methodology (Johnson and Onwuegbuzie, 2007; Morgan, 2007; Shaw, Connelly and Zecevic, 2010; Tashakkori and Teddlie, 2010; Creswell and Plano Clark, 2018).

The research in this thesis has utilised the most appropriate methods, depending on the context and the intended outcome (Biesta, 2010). This has included valuing both quantitative and qualitative approaches, typically associated with opposing positivist and constructivist paradigms respectively (Johnson and Onwuegbuzie, 2004; Morgan, 2007;

Tashakkori and Teddlie, 2010; Creswell and Plano Clark, 2018). In this way, mixed methods research is considered to compensate for the strengths and weaknesses of each approach, for example, the ability to both generalise findings and understand multiple perspectives from human experience (Giddings and Grant, 2006; Johnson and Onwuegbuzie, 2007; Creswell and Plano Clark, 2018).

Mixed methods research is increasingly utilised in healthcare research, and within physiotherapy practice, to more effectively address the complex health issues identified in clinical practice (Giddings and Grant, 2006; Shaw, Connelly and Zecevic, 2010; Fetters, Curry and Creswell, 2013). Healthcare clinicians value both qualitative and quantitative techniques to inform and improve treatments and the healthcare we provide, which is reflective of clinical practice (Giddings and Grant, 2006). Physiotherapists commonly base clinical decisions on both objective evidence, including measurements, tests and outcomes, and the patients' subjective experience of their problem.

Mixed methods research is therefore practical and intuitive to physiotherapy practice and can allow for a more comprehensive approach to address the multiple study objectives, and inform the complexity of physiotherapy practice, that could not be achieved with a single approach (Shaw, Connelly and Zecevic, 2010). There is a wealth of evidence demonstrating the effective use of mixed methods research in physiotherapy studies (Dennett *et al.*, 2022; Gleadhill *et al.*, 2022; Pires *et al.*, 2022; van Tilburg *et al.*, 2022).

3.5.3 Multistage mixed methods design

An advanced multistage mixed methods framework was used in this thesis, which is commonly used in intervention development research whereby initial qualitative findings are used to inform the development of an intervention, which is then tested quantitatively (Creswell and Plano Clark, 2018).

3.5.4 Integration in mixed methods research

Creswell and Plano Clark (2018) define integration as "the point in the research procedures where qualitative research interfaces with quantitative research" (p. 220). Integration is a key defining component of mixed methods research and forms core characteristic 2, described in section 3.5.1 (Creswell and Plano Clark, 2018). The intent of integration in the mixed methods research in this thesis is outlined below at the design, methods, and interpretation and reporting levels (Fetters, Curry and Creswell, 2013; Creswell and Plano Clark, 2018).

Integration through design:

The research in this thesis involved multiple points of qualitative and quantitative data collection, analysis, and integration. An advanced multistage framework was therefore selected to guide the mixed methods research in this thesis, incorporating a combination of the core basic designs outlined by Creswell and Plano Clark (2018) (Appendix B).

In the first stage, or workstream (WS) as referred to in this thesis, a narrative review study was conducted, with the qualitative synthesis informing the second WS, a co-design study. Data collected and analysed from WS2 informed the intervention design, where in

the third WS, a prototype was built by incorporating key findings from WS2 to operationalise components for inclusion in the intervention. In the fourth and fifth WS the intervention prototype was tested and refined in a mixed methods study. Figure 3.1 shows how the stages of mixed methods research in this thesis are linked.

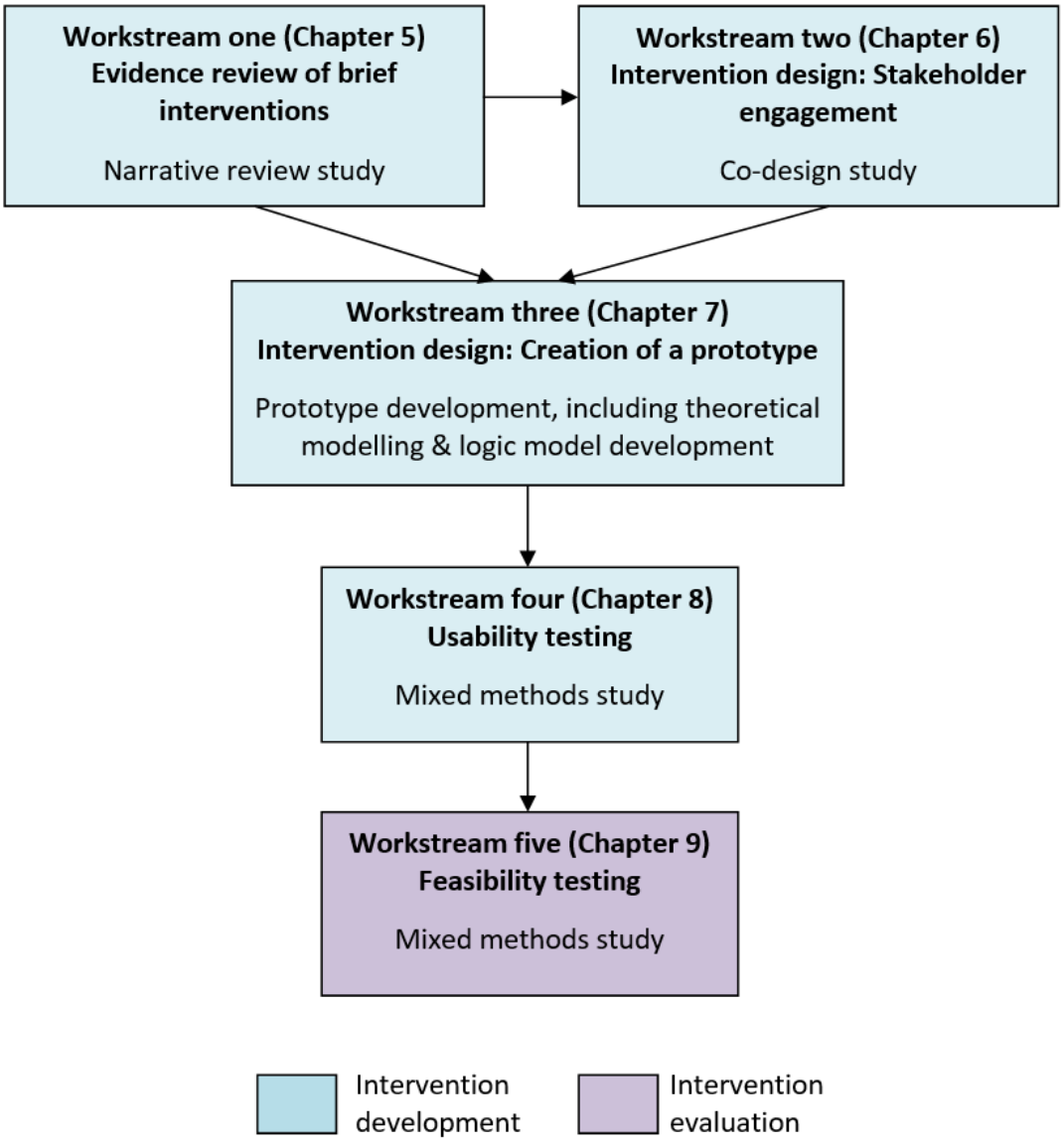

Figure 3.1 Stages of mixed methods research to develop and test The COMBINED approach

Largely, an exploratory sequential design was employed, with initial qualitative data collection and analysis informing the development of a quantitative feature (the intervention), followed by testing of the new intervention quantitatively. Each study informed the next stage. However, study four and five also included qualitative data collection and analysis in a convergent design. The data were collected and analysed separately, before integrating to give a more complete understanding of the problem. Equal weighting was placed on the quantitative and qualitative methods.

Integration through methods:

Integration at the methods level in this mixed methods research occurred through embedding, which refers to the integration of qualitative and quantitative data collection and analysis at multiple points (Fetters, Curry and Creswell, 2013).

Integration at interpretation and reporting level:

Integration at the interpretation and reporting level occurred predominantly through narrative in this thesis (Fetters, Curry and Creswell, 2013). However, a joint display, described as a visual display of the qualitative and quantitative data together, (Fetters, Curry and Creswell, 2013) was used in stage three. Here a matrix was used to show how the qualitative findings in stage two were explicitly linked to the quantitative features of the intervention in stage 3 (Chapter 7).

Fit of data integration:

In this thesis, the fit of integration was expansion, whereby the quantitative and qualitative features addressed different aspects to expand insights and increase the breadth and depth of understanding to the problem (Fetters, Curry and Creswell, 2013).

3.5.5 Validity of mixed methods research

One of the key considerations and debates in mixed methods research is concerned with its validity of mixed methods, leading to the development of several validity frameworks (Dellinger and Leech, 2007; O'Cathain, Murphy and Nicholl, 2010; Tashakkori and Teddlie, 2010; Creswell and Plano Clark, 2018). Creswell & Plano Clark (2018) offer some guiding principles of validity to mitigate against any potential pitfalls when drawing inferences from integrated data. Specific to the mixed methods research in this thesis, this included:

- Transparent reporting of how each key qualitative finding is related to the development of specific quantitative elements (or intervention components) – this is shown in Chapter 7;
- Systematic processes when designing the quantitative elements, such as testing the developed intervention materials and resources – this occurred in WS4 (Chapter 8);
- Not selecting the same participants to test the intervention quantitatively, that were involved in the initial qualitative study to inform the intervention components – in WS4 and WS5 the participants selected were not involved in WS2.

The guidelines for Good Reporting of A Mixed Methods Study (GRAMMS) were also used to improve the quality of this mixed methods research (O'Cathain, Murphy and Nicholl, 2008) (Appendix C).

Mixed methods research is not without additional challenges. Reported to be time and resource intensive, it also requires research skills and an in-depth understanding of both quantitative and qualitative methods (Giddings and Grant, 2006; Johnson and Onwuegbuzie, 2007; Skamagki *et al.*, 2022). I have undertaken research training in quantitative and qualitative methods and was guided by my supervisory team's expertise in designing and conducting mixed methods research.

3.6 Chapter Summary

This chapter has outlined and justified the use of a mixed methods approach from a pragmatic perspective, with the overall purpose to conduct research that can guide the next steps in a programme of research that would inform physiotherapy practice. It has illustrated the iterative collection, analysis and integration of both qualitative and quantitative data, framed within a multistage design, to meet the core characteristics of mixed methods research ensuring a comprehensive and rigorous approach to this research. The next chapter will outline key concepts related to complex intervention development in healthcare. The intervention development approach that has guided this programme of research in this thesis will be discussed.

Chapter 4 Approaches to Complex Intervention Development

4.1 Chapter Introduction

This chapter presents an overview of key concepts related to complex intervention development. The approach taken to intervention development in this thesis will be outlined as a theory-, evidence- and pragmatic-based approach (O'Cathain, Croot, Duncan, *et al.*, 2019; Skivington *et al.*, 2021) underpinned by collaboration with stakeholders, including patient and public involvement (PPI).

4.2 Complex Interventions in Healthcare

In healthcare, patients often present with complex problems, including co-morbidities and lifestyle behaviours that necessitates a complex intervention to manage them in an effective manner (O'Cathain, Croot, Duncan, *et al.*, 2019). Complex interventions include a number of interacting components, and target multiple behaviours, groups, settings or levels within an organisation. Furthermore, the complexity will depend on the degree of flexibility of the intervention components, the level of skills required for delivery, or if it requires those delivering or receiving the intervention to adopt new behaviours (Craig *et al.*, 2008; Skivington *et al.*, 2021).

In healthcare, many complex interventions are either ineffective when tested in trials, or not implemented into practice, considered as research waste (Contopoulos-ioannidis *et al.*, 2008; Bleijenberg *et al.*, 2018; Goodwin *et al.*, 2019; O'Cathain, Croot, Duncan, *et al.*, 2019). A lack of a rigorous approach to intervention development, or inadequate time

spent on development and optimisation prior to a definitive trial, might subsequently lower the chance of an intervention showing a positive treatment effect (Bleijenberg *et al.*, 2018; Goodwin *et al.*, 2019; O'Cathain, Croot, Duncan, *et al.*, 2019).

Furthermore, if implementation is not considered throughout intervention development, the intervention may never be adopted into clinical practice (O'Cathain, Croot, Duncan, *et al.*, 2019). Reasons may include the intervention being too costly, or not practical to use in a healthcare setting, for example, requiring too specialist skills to deliver, impractical delivery time or not fitting with the values and preferences of those who will use the intervention (O'Cathain, Croot, Duncan, *et al.*, 2019). These reasons for implementation failure are important considerations, that highlight the need for a rigorous intervention development process.

4.3 Complex Intervention Development

4.3.1 Intervention development approaches

Intervention development refers to the entire process from the idea through to the intervention being ready for formal feasibility, pilot or evaluation of effectiveness (Skivington *et al.*, 2021) and should continue until the intervention is anticipated to have a worthwhile effect (Craig *et al.*, 2008). There are multiple published approaches and frameworks to guide intervention development work.

Different approaches and common actions have been synthesised into a taxonomy of intervention development approaches, with eight categories identified (O'Cathain, Croot, Sworn, *et al.*, 2019). Categories included partnership, target-population centred, theory

and evidence-based, implementation-based, efficiency-based, stepped or phased based, intervention-specific and combination. Eighteen possible actions to use when developing an intervention are also recommended (O'Cathain, Croot, Sworn, *et al.*, 2019).

Intervention development guidance has been produced, consisting of key principles and actions as a series of 'considerations' during the development process (O'Cathain, Croot, Duncan, *et al.*, 2019), discussed in further detail in section 4.3.4. This guidance recognises the evidence gap that including all or any of these actions results in a more effective or successful health intervention. Instead, each action should be considered based on its contextual relevance and feasibility. The guidance can be used alongside a published approach or drawn on as part of a 'pragmatic approach'. The pragmatic approach is defined as using a set of self-selected actions, often within a mixed methods design (O'Cathain, Croot, Duncan, *et al.*, 2019). A pragmatic intervention development approach aligns with my pragmatic perspective underpinning this thesis.

4.3.2 Selection of a theory, evidence and pragmatic approach

One of the categories highlighted in the taxonomy is a theory and evidence-based approach (O'Cathain, Croot, Sworn, *et al.*, 2019). It has been reported that systematically integrating relevant theory and best evidence might be more likely to contribute to a clinically effective intervention that is implementable (Craig *et al.*, 2008; O'Cathain, Croot, Duncan, *et al.*, 2019). In contrast, however, other studies, including a systematic review of systematic reviews (Dalgetty, Miller and Dombrowski, 2019), have reported that theory-based interventions were no more effective than interventions that were non-theory

based. The authors however do highlight that due to methodological quality and poor reporting of the included studies, the potential for theory to contribute to a more successful intervention cannot be dismissed (Prestwich *et al.*, 2014; Dalgetty, Miller and Dombrowski, 2019). Theory-based interventions though, do help to understand behaviours, which was important in the development of The COMBINED approach. The intervention can then be designed to target and bring about a change in behaviour (Michie *et al.*, 2005; Michie, 2008; French *et al.*, 2012).

As a theory- and evidence-based approach, I selected the Medical Research Council (MRC) Framework (2008) as the overarching published approach for its credibility and wide use in intervention development (Craig *et al.*, 2008; Bleijenberg *et al.*, 2018; O'Cathain, Croot, Duncan, *et al.*, 2019). The systematic process to integrate relevant theory and best available evidence also aligns with a mixed methods design (O'Cathain *et al.*, 2019). The MRC framework describes an iterative process from development to implementation across four interconnected stages (Figure 4.1), of which this thesis will cover the development and feasibility stage (described further in section 4.3.4).

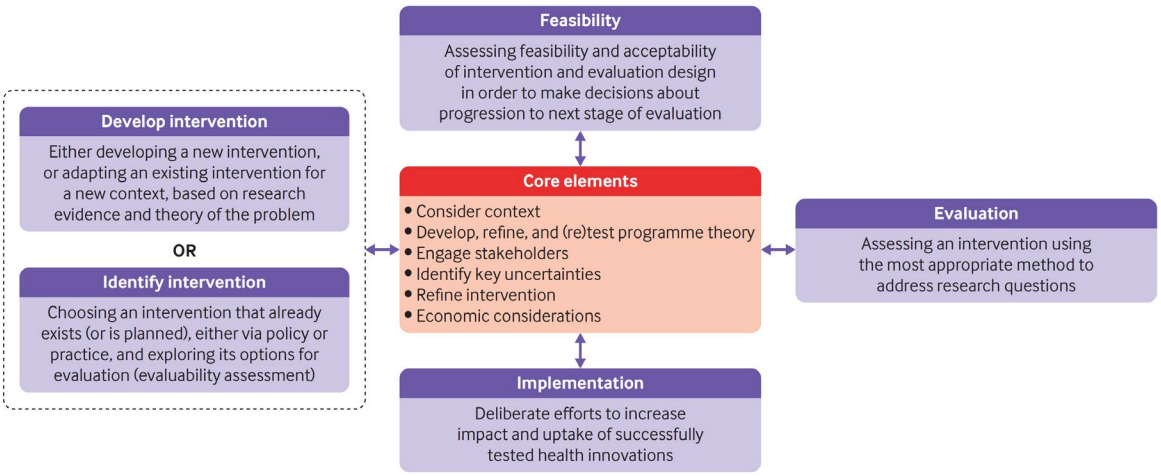

Figure 4.1 Key elements of the MRC development and evaluation process
(Source: Skivington *et al.*, 2021, p. 4, Figure 1).

The MRC framework is commonly criticised for the lack of detailed guidance regarding specific actions or steps to take, particularly in the development phase (French *et al.*, 2012; Wight *et al.*, 2015). For this reason, the MRC framework is often combined with other approaches to improve the quality of the intervention development process (Bleijenberg *et al.*, 2018b). The updated framework (2021) builds on the 2008 framework considering recent advances in theory and methods, in particular the recognition that intervention development is more than just identifying if it is effective. Acceptability, scalability, cost-effectiveness and transferability across contexts are just as pertinent, and ultimately will influence if an intervention is implementable in real-world practice. The framework outlines six core elements to be considered across all four stages supporting this shift in focus. These include: considering context; developing and refining programme

theory; engaging stakeholders; identifying key uncertainties; refining the intervention; and economic considerations (Skivington *et al.*, 2021).

I chose a pragmatic approach to intervention development (as described in section 4.3.1) to complement the MRC Framework (2021) using a framework of principles and actions, self-selected for their relevance to my context. These overarching principles and actions for good intervention development, and the intended outcomes are shown in Figure 4.2.

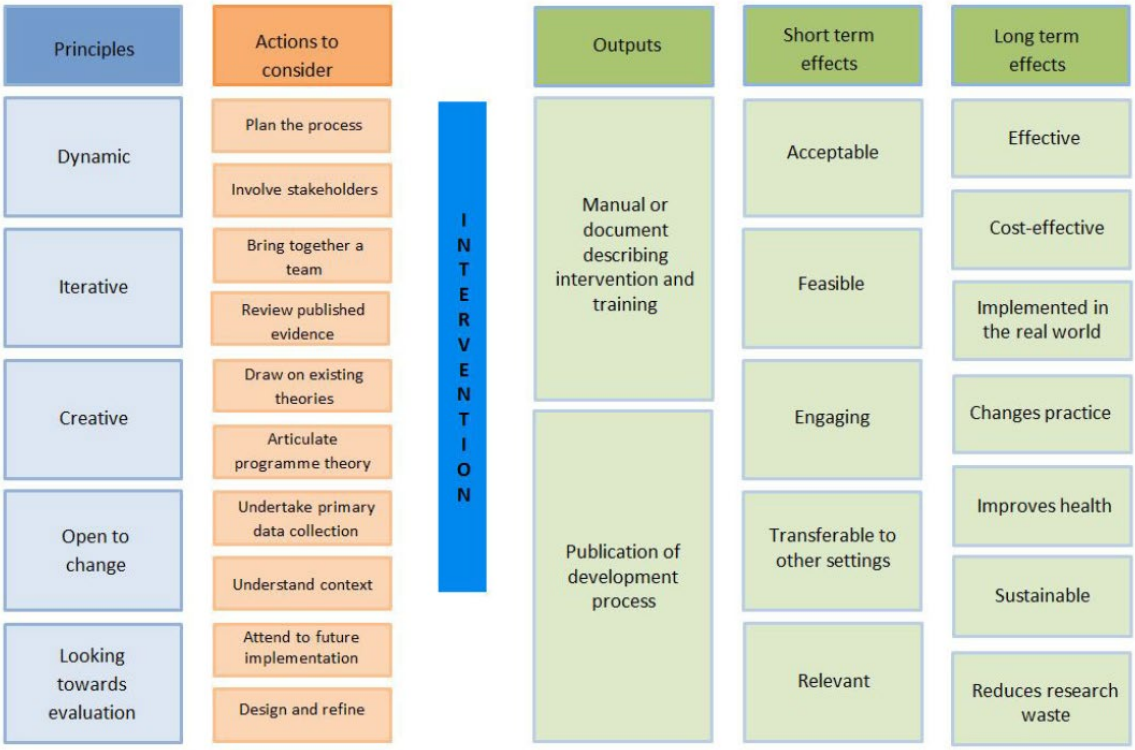

Figure 4.2 Logic model for intervention development
(Source: O'Cathain, Croot, Duncan, *et al.*, 2019, p. 4, Figure 1).

4.3.3 Intervention development and testing of The COMBINED approach

In this thesis, the research involved two stages: 1) development; and 2) testing of The COMBINED approach (Figure 4.3). This research will focus efforts on the early actions of

development, with the purpose of achieving the short-term effects shown in Figure 4.2, with a view to increasing the chances of achieving the long-term effects.

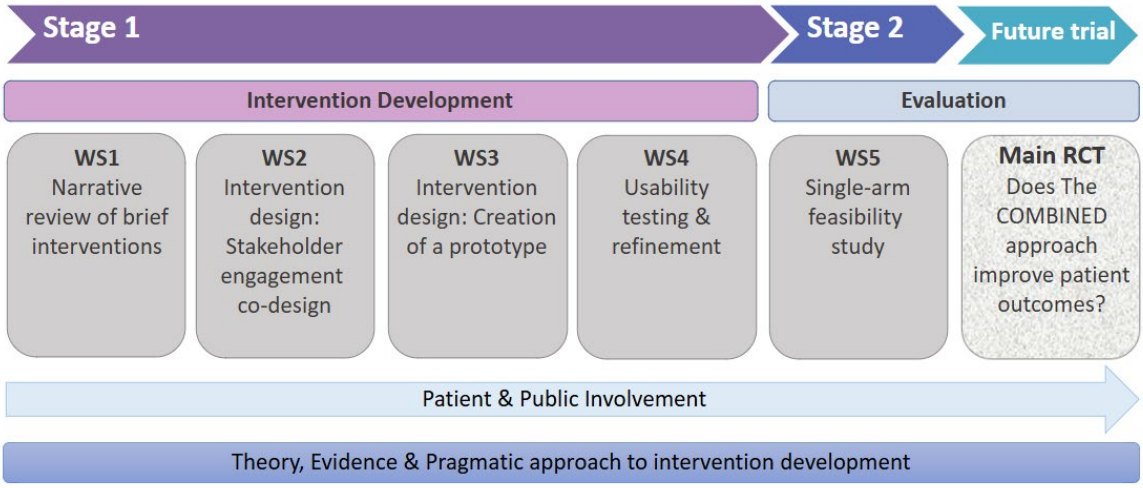

Figure 4.3 Development and testing of The COMBINED approach
WS, Workstream; RCT, Randomised controlled trial

4.3.4 Operationalising an evidence-, theory- and pragmatic-based approach

The key principles of intervention development (Figure 4.2) and how they aligned with my pragmatic-based approach are presented in Table 4.1.

Table 4.1 Key principles of intervention development and their application in this thesis

Principle	Application
Dynamic/ iterative	Development of The COMBINED approach involved moving between overlapping stages e.g., reviewing evidence, drawing on existing theory and involvement of stakeholders. Cycles of iterative prototype testing were planned to gain early feedback to inform intervention refinements.
Creative	Working creatively with stakeholders through co-design, and patient and public involvement, informed the design of intervention components, e.g., an infographic.
Open to change	Thinking evolved throughout the process of intervention development as findings emerged e.g., the need for a multi-level intervention to additionally support

	clinician behaviour change and the addition of a new component - audit and feedback. The decision was also taken to spend longer in the development phase than originally planned due to the emerging complexity of the problem and a history of previously failed similar interventions, largely Making Every Contact Count (MECC).
Forward looking to future evaluation and implement-ation	Embedded throughout. The focus was on the practical use of the intervention and stakeholder involvement to enhance future implementation. The use of theory helped to understand potential barriers to, and facilitators of, implementation. Early testing identified key uncertainties and ensured the intervention was optimised for future evaluation, as well as thinking about future trial processes.

I will now take each action from the logic model for intervention development (Figure 4.2) and outline the considerations and relevance to the development of The COMBINED approach. The actions were not necessarily completed in this order, or in a linear way, but have been presented as such for clarity.

1. Plan the development process

The first action in the guidance involves identifying what intervention development approach, or actions, will be used to guide the process. This has been described in section 4.3.2 as a theory- and evidence-based approach, using the MRC Framework, and a pragmatic approach, self-selecting the following actions.

2. Involve stakeholders, including those who will deliver, use and benefit from the intervention

This action was fundamental to The COMBINED approach, and a key underpinning value aligned with pragmatism (Glasgow, 2013; Allemang, Sitter and Dimitropoulos, 2022), to ensure the resulting intervention met stakeholders needs, was acceptable, and that any

barriers to implementation could be addressed with practical solutions (Skivington *et al.*, 2021).

Stakeholders are considered to be individuals that the intervention targets, deliver the intervention, will be impacted professionally or personally, or are engaged in the development of the intervention (Skivington *et al.*, 2021). The stakeholders in this research were predominantly end users, which I define as those who will deliver, or receive the intervention, and in this context were physiotherapists and patients. I also considered wider stakeholders that would have a shared interest or expertise in the development of the intervention. This included NHS clinical service managers, shoulder surgeons, GPs and experts in behaviour change or public health.

Patient & public involvement (PPI) were also integral to this process and considered key stakeholders. PPI involvement was planned from the start and ran throughout the PhD at different stages. I worked with stakeholders in several ways throughout the intervention development process, which is outlined in Figure 4.4.

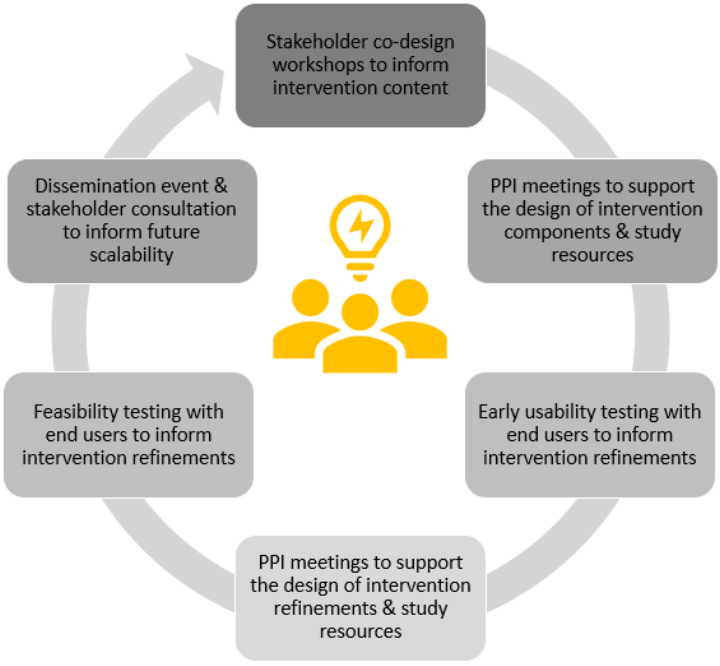

Figure 4.4 Stakeholder involvement throughout this thesis
PPI, Patient and Public Involvement

3. Bring together a team and establish decision-making processes

The team primarily consisted of the PhD supervisory team, which had expertise in the relevant problem, complex intervention development and mixed methods approaches. Advisors were also included where specific expertise was required. This included a health psychologist and behavioural scientist who advised on behaviour change aspects and supported the mapping of theory to intervention components, and a public health expert who advised on health behaviour change interventions and resources. I also consulted with an intervention development expert, and lead author of this guidance, which was funded through this fellowship. She advised at key points in the process with the purpose of adding rigour, with suggestions informing a more comprehensive approach.

In terms of the decision-making process, I established within the principles of co-design that final decisions were made by myself and the supervisory team (discussed further in Chapter 6, section 6.2). Decisions regarding intervention content were also guided by the APEASE (Affordability, Practicability, Effectiveness, Acceptability, Side-effects/Safety, Equity) criteria (Michie, Atkins and West, 2014), described in Chapter 7, section 7.5.

4. Review published research evidence

Identifying the evidence-base, prior to commencing the intervention development process, is the first step in the development stage of the MRC Framework (Craig *et al.*, 2008). In this thesis, the reasons for reviewing research evidence included to:

- Understand the context, including potential barriers of and facilitators to implementing such an approach e.g., a BI/health behaviour change;
- Identify if there are any existing interventions similar to the proposed approach;
- Identify existing BIs targeted at smoking cessation, weight loss/healthy diet and increasing physical activity levels that could be adapted to form a component of the intervention;
- Review further evidence as uncertainties emerge and new intervention components are added e.g., uncertainties around implementation and changing healthcare professional behaviour change, which identified audit and feedback as an important strategy to include as a new component.

5. Draw on existing theories

Identifying and developing theory is the second step in the development stage of the MRC Framework (Craig *et al.*, 2008). The COMBINED approach is a behaviour change intervention, guided by psychological theories, including the COM-B model and the Theoretical Domains Framework (TDF), both explained in Chapter 2, section 2.5.2. The TDF, with its integrative framework for understanding implementation behaviours, was particularly relevant given the focus on implementation within The COMBINED approach. The COM-B model was used to conduct an initial behavioural diagnosis, with the TDF providing deeper insights into the barriers of and facilitators to implementation. The Behaviour Change Technique Taxonomy v1 (BCTTv1) informed the design of the intervention components by guiding the selection of appropriate BCTs, linked to the TDF, to address the identified barriers and facilitate behaviour change (see Chapter 7).

6. Articulate programme theory

A logic model, or programme theory, to describe how the intervention is intended to achieve its outcomes is recommended to be developed and refined as the intervention is tested (Craig *et al.*, 2008; O'Cathain, Croot, Duncan, *et al.*, 2019). A preliminary logic model is presented in Chapter 7, which was refined after intervention testing.

7. Undertake primary data collection

The use of both qualitative and quantitative research methods throughout the different stages of intervention development are recommended, and common in a pragmatic approach (Craig *et al.*, 2008; O'Cathain, Croot, Duncan, *et al.*, 2019). As described in

Chapter 3, I employed a multi-phase mixed methods design. The stages are shown in Figure 4.3.

8. Understand context

The importance of understanding context is to develop an intervention that has considered the potential factors that could affect implementation in that context (O'Cathain, Croot, Duncan, *et al.*, 2019). Contextual factors include those related to the individual who will use the intervention, culture, setting, organisation, as well as wider factors such as economic, social or political influences (Craig *et al.*, 2018).

The strategies employed for understanding contextual factors, including reviews of the evidence-base, stakeholder co-design, and the testing in practice with non-participant observation, have been outlined in the corresponding chapter (Chapters 5-6, and 8-9).

9. Pay attention to future implementation of the intervention in the real world

Effective implementation is described when "complex interventions are made workable and integrated in everyday health care practice" (May *et al.*, 2007, p. 2). As described throughout this thesis, implementation was a key action and focus of this research. Aligned with the theoretical perspective of pragmatism, the goal was to develop an intervention that was practical to, and implemented into, physiotherapy practice. Implementation was considered by:

- Involving stakeholders in the design process that would adopt this intervention in the future;

- The use of the TDF to understand and address implementation issues;
- The development of a multi-faceted implementation strategy to support physiotherapists to deliver the intervention in practice;
- Involving stakeholders in the early testing stage to assess acceptability, feasibility and engagement;
- Evaluation of implementation outcomes, including assessments of fidelity, acceptability and factors influencing implementation.

10. Design and refine the Intervention

Design, although used interchangeably with 'development', refers to a part of the intervention development process where ideas are generated about the concept, content, format, and delivery of the intervention (O'Cathain, Croot, Duncan, *et al.*, 2019; Rousseau *et al.*, 2019). This may include a modelling process, which is the third step in the development stage of the MRC Framework, to create an early draft or prototype of the intervention or some of its components. This modelling process involves prioritising components and making refinements until a full prototype of the intervention is available (Bleijenberg *et al.*, 2018b).

The design phase in this thesis includes the stakeholder co-design (Chapter 6) that generated practical ideas and recommendations to inform the content of intervention, and the subsequent mapping of barriers and facilitators to behaviour change techniques to operationalise intervention components (Chapter 7). As described earlier (action 3),

the APEASE criteria was used to prioritise components. A prototype of the intervention components was then created.

Refining, or optimisation, relates to making changes to improve the prototype version of the intervention (O'Cathain, Croot, Sworn, *et al.*, 2019). This approach is recommended through rapid cycles of testing, with a small sample of the target population, to evaluate acceptability, feasibility, and engagement (Craig *et al.*, 2008; O'Cathain, Croot, Duncan, *et al.*, 2019; Skivington *et al.*, 2021).

Iterative testing and refinement were conducted in the usability study (Chapter 7) and continued in the context of a feasibility study (Chapter 8). This was to ensure any issues could be addressed in advance of a future definitive trial.

11. End the development phase

Defining the end of the development phase is a grey area in the literature as development and refinement may continue into the evaluation phase, and even after implementation. There are no established criteria for ending the intervention development phase and transitioning to the feasibility, pilot or evaluation phase (Hoddinott, 2015; Croot *et al.*, 2019; O'Cathain, Croot, Duncan, *et al.*, 2019).

In this thesis, the end of the development phase was defined as the point up to feasibility testing. Although The COMBINED approach continued to be refined in the feasibility stage, I considered that the intensive development stage had ended, whereby any major issues emerging had been addressed. O'Cathain, Croot, Duncan, *et al.*, (2019) liken this to

the idea of data saturation and information power, synonymous with qualitative research methods, when fewer issues requiring refinement emerge.

Finally, it is Important to transparently describe both the intervention and the intervention development process to enable replication, support implementation and allow transferability of the intervention in other contexts (Craig *et al.*, 2008; Glasziou *et al.*, 2008; Hoffmann *et al.*, 2014). The intervention will be described using the Template for Intervention Description and Replication (TiDIER) guidelines (Hoffmann *et al.*, 2014).

The intervention development process will be reported using the GUIDance for the rEporting of intervention Development (GUIDED) (Duncan *et al.*, 2020). Detailed reporting will permit others to learn from this process and form opinions about the quality of the intervention development process. Furthermore, it will add to the evidence base on the relationship between certain intervention development approaches and the resulting effectiveness or success of the intervention in the future (O'Cathain, Croot, Duncan, *et al.*, 2019).

4.4 Chapter Summary:

I have outlined the selection of a theory-, evidence- and pragmatic approach to intervention development using the MRC Framework, complemented with key principles and core actions suggested by experts as good practice for intervention development. This approach is comprehensive, rigorous and practical, with the aim of developing a potentially effective intervention that is also feasible, acceptable and implemented into practice. The next chapter presents the first stage in the intervention development

process, a narrative review to identify and summarise a range of brief (behaviour change) interventions, that could potentially form a component of The COMBINED approach.

Chapter 5 A Narrative Review of Brief Interventions to Inform the Development of The COMBINED Approach

5.1 Chapter Introduction

This chapter reports on the first workstream (WS) in the intervention development stage of this thesis (see Figure 5.1). This WS involved a narrative review to identify a range of brief interventions (BIs) that could potentially form a component of The COMBINED approach. The results of this chapter feed into Chapter six where stakeholders' views informed the decision-making process of selecting one of these identified BIs to adapt and develop as a component of The COMBINED approach.

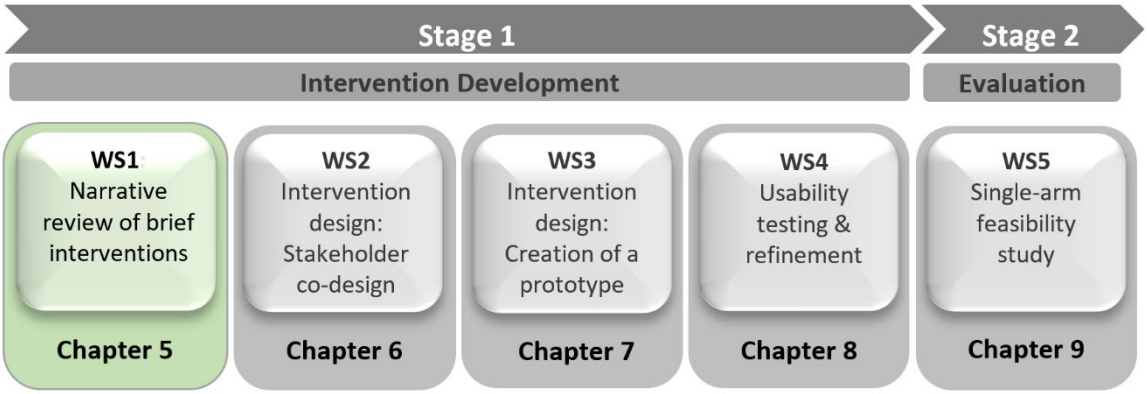

Figure 5.1 to show where this chapter fits within the intervention development process
WS, Workstream

5.2 Background

BIs were described in Chapter 2, section 2.4, and justified as a suitable evidence-based behaviour change strategy to identify and address the lifestyle factors associated with rotator cuff (RC) disorders within a routine physiotherapy consultation. There are an

abundance of initiatives, tools, resources, policies, guidance and published papers reporting on BIs to support health behaviour change. Although these are not specifically aimed at musculoskeletal health, they offer an opportunity to select an existing BI to adapt and develop for use in this context. Chapter 2, section 2.4.1 highlighted BIs are not homogenous, but there is a lack of evidence about which aspects of a BI are superior to another in terms of the likelihood of bringing about behaviour change, as well as which aspects are feasible and acceptable to intervention providers (Lamming *et al.*, 2017). It is important for future implementation to understand which of these varying aspects of BIs are important to stakeholders, including patients who will receive, and clinicians who will deliver the intervention in practice, given the different challenges, priorities and time constraints they face. These preferences will likely influence stakeholders' decision in the next WS as to which BI they feel would be the 'best fit' to form a component of The COMBINED approach. This decision of 'best-fit' will focus on a BI that is practical, feasible and acceptable to deliver within routine clinical practice by a physiotherapist alongside a best practice advice (BPA) intervention. It was therefore important that stakeholders were involved in the decision-making regarding the selection of any BI.

5.3 Workstream One Aims

The aim of this narrative review study was to identify and summarise a range of BIs that have been developed to target the following risk factors (i) smoking, and/or (ii) overweight/obesity, and/or (iii) physical inactivity, with the potential to be used as a basis

for further development and adaptation to deliver within a different context and to form a component of The COMBINED approach (Thesis objective 1ii, Chapter 1, section 1.4).

5.4 Definitions and Terminology of Brief Interventions

The lack of consistent terminology and definitions for BIs is recognised (Lamming *et al.*, 2017). The term 'brief intervention' is also used interchangeably with other terms, such as 'brief advice' (NICE, 2013). In the absence of a standard definition as to what constitutes a 'very brief' or 'brief' intervention, and 'very brief' or 'brief' advice, all of these terms were considered in this review, but collectively referred to throughout this chapter as a 'brief intervention'. The definitions used in this review are shown in Table 5.1

Table 5.1 Definitions used in this narrative review

Term	Definition*
Very brief intervention or very brief advice	"Can take from 30 seconds to a couple of minutes. It is mainly about giving people information or directing them where to go for further help. It may also include other activities such as raising awareness of risks or providing encouragement and support for change" (pp. 31-2).
Brief intervention or brief advice	"Involves oral discussion, negotiation or encouragement, with or without written or other support or follow-up. It may also involve a referral for further interventions, directing people to other options, or more intensive support... typically taking no more than a few minutes for basic advice" (p. 27)

*Definitions from: National Institute for Health and Care Excellence, 2014.

The BI definition does not explicitly state the typical maximum duration of the BI. Given that 'extended' BIs are defined as lasting more than 30 minutes, for the purpose of this review a BI was considered as one that lasted between a few minutes and up to a maximum duration of 30 minutes. Extended BIs were not included in this review as they were considered impractical to implement into a routine physiotherapy consultation.

5.5 Methods

5.5.1 Narrative review

Narrative reviews offer researchers a flexible approach to synthesise diverse knowledge sources, including from published studies and non-research evidence sources, unlike systematic reviews (Mays, Pope and Popay, 2005; Greenhalgh, Thorne and Malterud, 2018; Sukhera, 2022). During the preliminary scoping of the literature during the development of this PhD fellowship proposal, it was evident that BIs were reported across a broad range of knowledge sources. This included published primary research studies as well as non-research evidence sources, such as government policies, the National Institute for Health and Care Excellence (NICE) guidance, and websites. It was therefore considered appropriate to conduct a narrative review to meet the aims of this WS.

Furthermore, the purpose was not to comprehensively search for all possible BIs but to identify a manageable number to present to the stakeholder group. Additionally, synthesising the data was not intended since not all sources reporting BIs would include this information. Therefore, a more formal systematic review search was not considered to be indicated.

Methods for conducting narrative reviews (Grant & Booth, 2009; Pope, Mays and Popay, 2007) and guidance (Mays, Pope and Popay, 2005) have been published to help researchers take a rigorous approach when undertaking narrative reviews, which were used to guide this review process.

5.5.2 Inclusion and exclusion criteria

The focus of this review was on sources that either reported/described a BI, reported the development or evaluation of a BI, or reported the use of a BI in clinical practice (Table 5.2).

Table 5.2 Knowledge sources used in this narrative review

Research evidence & non-research evidence sources used for this narrative review
• Electronic database searches • Hand searches of the references of retrieved literature • Citation searching • Web searching • Personal knowledge through clinical experience • Discussions with experts in the field of public health

The primary studies or other knowledge sources (Table 5.2) reporting BIs were considered for inclusion if they:

- Met the definition of a (very) brief intervention or (very) brief advice (Table 5.1);
- Were developed for delivery in a healthcare/clinical context;
- Addressed the target risk factor(s): smoking and/or physical activity and/or overweight/obesity;

Studies/sources not published in English were excluded. If a BI targeted multiple lifestyle factors, these were excluded if it was beyond the three specified target behaviours.

Specific inclusion and exclusion criteria were established based on the PICOS framework: Population (P), Intervention (I), Comparator (C), Outcome (O), and Study type (S) (Higgins *et al.,* 2019). See Table 5.3.

Table 5.3 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Population BIs targeting smoking cessation, diet/weight loss, and/or physical activity in adults (≥18 years old) within healthcare or clinical settings **Intervention** Interventions that met the BI definition (Table 5.1) and targeted one or more of the specified risk factors: smoking, physical inactivity and/or overweight/obesity **Comparator** Primary studies with any form of control, including usual care or alternative advice/intervention group, as well as non-research evidence sources without direct comparators **Outcomes** Primary studies reporting on behaviour change outcomes (e.g., smoking reduction, weight loss, changes in physical activity levels or dietary behaviours) or implementation factors (e.g., feasibility, acceptability, practicality), as well as non-research evidence sources without specified outcomes **Study type** All relevant evidence sources that described, developed, evaluated, or reported the use of a BI in clinical practice. This included primary studies (e.g., RCTs, quasi-RCTs, exploratory studies) as well as non-research sources (e.g., policy papers, NICE guidance and websites)	**Population** Non-clinical populations or settings (e.g., university-based interventions) and individuals under 18 years old **Intervention** Extended BIs (exceeding 30 minutes) and those targeting multiple lifestyle factors beyond the three specified behaviours: smoking, physical inactivity, and overweight/obesity **Outcomes** Primary studies not focused on behaviour- or implementation-related outcomes **Study type** Study protocols, purely qualitative studies, editorials, commentary and opinion papers, abstracts (sources lacking sufficient detail about the BI), as well as studies not published in English

BI, Brief Intervention; RCT, Randomised Controlled Trial, NICE, National Institute for Health and Care Excellence

5.5.3. Data sources & search strategy

The process started with a literature search, conducted between the 11th June and 22nd June 2020 on the following databases: AMED, CiNAHL, MEDLINE, Cochrane library, NICE evidence search. The following keywords were used: (1) brief intervention, very brief intervention, brief behaviour/behavior change intervention, brief lifestyle intervention,

brief advice AND (2) (i) physical in/activity, sedentary behaviour/behavior, exercise; (ii) smoking, smoking cessation; (iii) weight, overweight, obesity, diet, nutrition, weight loss, weight management. Where applicable Medical Subject Headings (MeSH) terms were used. A date limit was applied to enable identification of contemporary BIs and associated resources in the last 5 years (2015-June 2020) given the volume of BIs available. An example of a database search strategy is shown in Table 5.4.

Table 5.4 Example search strategy

	Search Term
1	brief intervention* OR very brief intervention* OR brief behavio* change intervention OR brief lifestyle intervention OR brief advice
2	physical *activity OR sedentary behavio* OR exercise
3	smoking OR smoking cessation
4	weight OR overweight OR obesity OR diet OR nutrition OR weight loss OR weight management
5	1 AND 2
6	1 AND 3
7	1 AND 4

The formal electronic searches were then complemented by a search on Google Scholar, plus web searches (Google) to identify any web resources including web pages, resources, guidance and policy papers. These were undertaken in the same time period using the same keywords. Forward citation searching on Google Scholar and hand searches of the reference lists of the retrieved literature were undertaken to identify additional relevant studies meeting the inclusion criteria. The Google Scholar citation searching involved screening articles in the 'cited by' list for the included primary research studies. Public

Health experts were also consulted via email and/or Microsoft Teams to signpost to any additional sources or BIs currently endorsed by Government bodies such as Public Health England (PHE), NICE, or the NHS. These included PHE Yorkshire and Humber leads for healthy weight, physical activity and tobacco, and Public Health associates from the Local Authority and Health Education England. Finally, my own personal knowledge and clinical experience of BIs was drawn on.

For primary studies that were identified, once duplicates were removed, the titles and abstracts were screened for initial eligibility. If a study was considered to meet the inclusion criteria, the full text articles were assessed for eligibility. For other sources, including policies, guidance papers and web pages, again after removing any duplicates, the content was assessed for eligibility. I conducted all searches and screening assessments; however, decisions were regularly discussed with the wider supervisory team.

5.5.4 Data extraction

For each source reporting on a BI, the following data was extracted into a pre-developed table: first author/year of publication (if applicable), type of evidence of the included BI; lifestyle target, context the BI was developed for or delivered in, participants (if applicable), and intervention details, including how it is defined/described, length of the BI, content and any detail on training or resources used.

5.5.5 Quality appraisal

Quality assessment is not always relevant or present in a narrative review (Grant and Booth, 2009). A formal quality assessment was not conducted because of the inclusion of diverse knowledge sources, beyond published primary research, for which assessment criteria would not be applicable.

5.6 Results

5.6.1 Study selection

Figure 5.2 shows the flowchart of the study selection process.

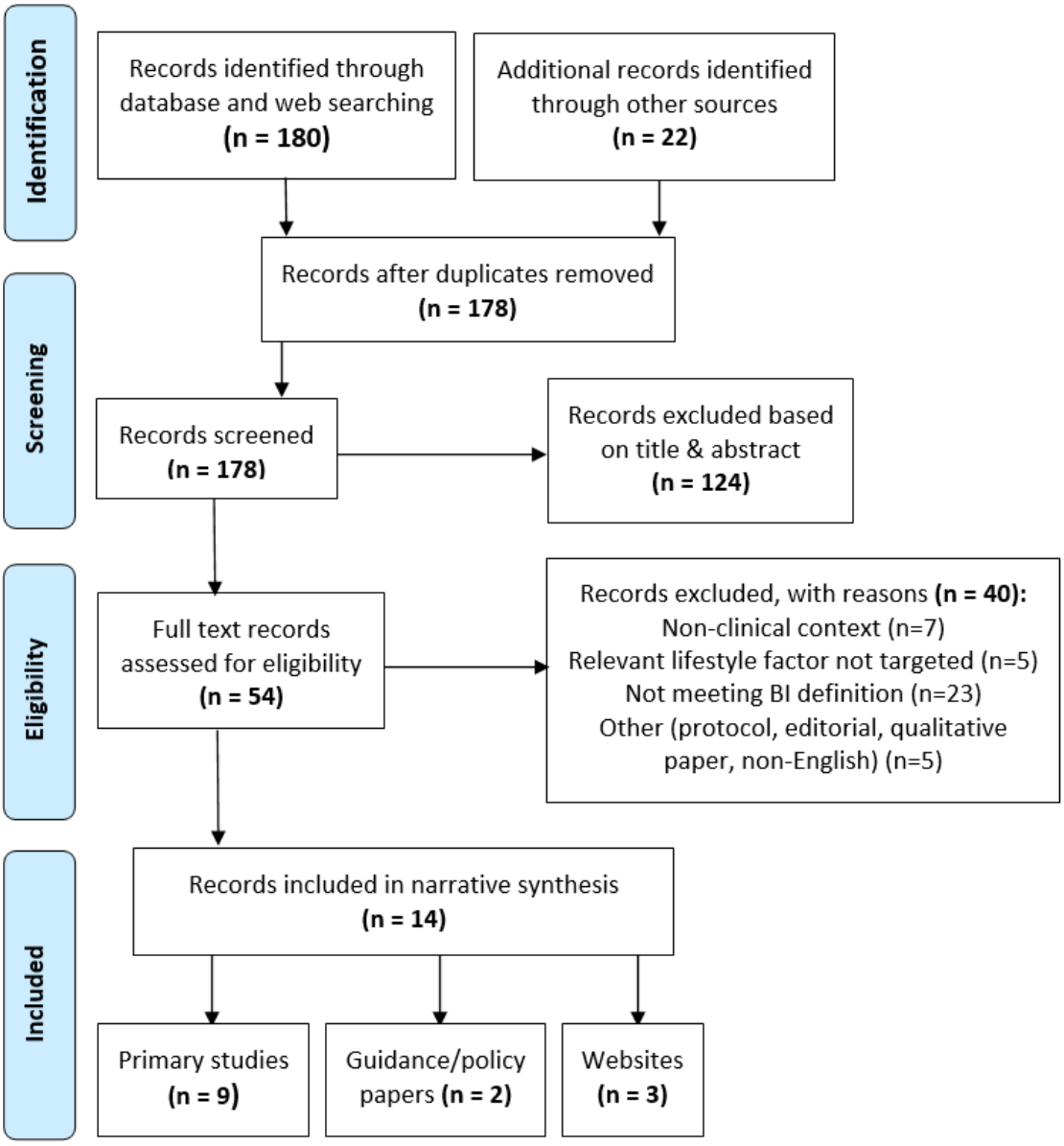

Figure 5.2 Study selection process

5.6.2 Key characteristics

Table 5.5 shows the key characteristics of the BIs included in this review.

Target health behaviour or risk factor

Four of the 14 BIs targeted smoking cessation (Li *et al*., 2017; Hooten *et al*., 2019; *National Centre for Smoking Cessation and Training (NCSCT)*, no date (n.d.); NICE, 2018), five BIs targeted increasing physical activity levels (*Moving Medicine*, n.d.; Williams *et al.*, 2015; Babwah *et al.*, 2018; Hardeman *et al.*, 2020; Waite *et al.*, 2020), four targeted weight loss (Aveyard *et al*., 2016; Beeken *et al*., 2017; Lerdrattanasakulchai & Palawisuth, 2018; PHE, 2017) and one targeted all lifestyle factors (*MECC Link*, n.d.). The latter resource was still designed to select a BI to target a single health behaviour rather than a BI to target multiple health behaviours.

Contextual factors

The majority (10/14) of the BIs included were conducted/developed in the UK (Aveyard *et al.*, 2016; Beeken *et al.*, 2017; Hardeman *et al.*, 2020; *MECC link*, n.d.; *Moving Medicine, n.d.*; *NCSCT*, n.d.; NICE, 2018; PHE, 2017; Waite *et al.*, 2020; Williams *et al.*, 2015). One was conducted/developed in Trinidad (Babwah *et al.*, 2018), one in the USA (Hooten *et al.*, 2019), one in Thailand (Lerdrattanasakulchai and Palawisuth, 2018) and one in Hong Kong (Li *et al.*, 2017).

Table 5.5 Key characteristics of the included BIs

First author & date	Type of evidence	Lifestyle target	Context	Participants (if applicable)	Intervention Detail
Aveyard 2016	Research (Parallel, 2-arm RCT)	Weight / obesity	Delivered by GPs in primary care (UK)	n=1882 Inclusion: ≥18 years, BMI ≥30 kg/m² (≥25 kg/m² Asian ethnicity), raised body fat % (defined in accordance with age & sex)	Intervention: A brief (30 secs) intervention for obesity. GPs provided 30 secs of brief advice and referral to weight management support (free prescription to a commercial weight management service), with a 4-week follow-up. Control: Advice that their health would benefit from weight loss. Training: 90 min online course.
Babwah 2020	Research (Non-randomised cluster pilot study)	Physical Activity	Delivered by GPs in a chronic disease clinic (Trinidad)	n=5 health centres (n=216 participants) Inclusion: Sedentary patients (no form of exercise in the last 3 months)	Intervention: Very brief (1-2 mins) intervention to change exercise behaviour. Included outlining the health benefits of exercise tailored to their condition, plus a written exercise prescription for home-based activities. Control: Usual care. Training: 60-minute training programme in prescribing exercise.

Beeken 2016	Research (Parallel, 2-arm RCT)	Weight	Delivered by nurses or healthcare assistants in primary care (UK)	n=537 Inclusion: Patients with obesity (BMI ≥30 kg m^2); ≥18 years	Intervention: A brief (30 min) leaflet-based intervention for weight control based on habit-formation theory (10TT); included a 10TT (Ten Top Tips) leaflet, logbook for self-monitoring of weight, card with guidance on food labels all described in a single 30-min session (via a flip chart). The leaflet was mailed out again at 3 months. Control: Usual care. Training: Training session and scripts provided.
Hardeman 2020	Research (Parallel, 2-arm RCT)	Physical Activity	Delivered by nurses or healthcare assistants during NHS Health checks (UK)	n=1007 Inclusion: Healthy adults aged 40 to 74 years eligible for an NHS Health Check.	Intervention: A very brief (5 min) PA intervention ('Step it Up') - pedometer-based. Included 1 session of Step it Up: 5-min discussion (face-to-face), pedometer, written materials, goal-setting/action-planning and step chart. Control: NHS Health Check only. Training: 3-hour training session.
Hooten 2018	Research (Parallel, 2-arm RCT)	Smoking	Delivered by respiratory therapist or nurse research coordinators in a pain speciality outpatient clinic (USA)	n=100 Inclusion: ≥18 years old, chronic pain of >3 months duration, smokes at least 10 cigarettes/day	Intervention: A brief (<20 min) smoking cessation intervention in the context of chronic pain. Based on 5 A's model: ask, advise, assess, assist, arrange follow-up. Included 1 session of MI and psychoeducation on harmful effects of smoking on health and encouragement to enhance motivation and self-efficacy, plus a psychoeducational component on associations between cigarette smoking and chronic pain.

					Control: Brief non-tailored control smoking intervention (same as above without the tailored links to chronic pain). Training: Research coordinators had previous training in MI.
Lerdrattan-asakulchai 2018	Research (Parallel, 2-arm RCT)	Weight	Delivered by researchers in an outpatient clinic (Thailand)	n=64 Inclusion: Patients with obesity (BMI ≥30 kg m^2); ≥18 years	Intervention: A brief (15 min) lifestyle modification programme based on the included 10TT programme as described above (Beeken at al 2019), plus a wristband adjunct to act as a cue/reminder in the habit loop. Included all components above, other than a 15 min initial session (instead of 30 mins) and the addition of a follow-up at 2, 4, 6 & 12 months. Control: Brief lifestyle modification program alone. Training: Not discussed.
Li 2017	Research (Parallel, 2-arm RCT)	Smoking	Delivered by trained nurses in a diabetes clinic (Hong Kong)	n=557 Inclusion: diagnosis of type 2 diabetes >6/12, ≥18 years old, smoking at least two cigarettes per day over the past 30 days, able to communicate in Cantonese	Intervention: Brief (20 min) stage-matched smoking cessation intervention. Included counselling using the 5 A's model: ask, advise, assess, assist, arrange follow-up, a diabetes-specific leaflet (highlighted links between smoking and diabetes), a self-help leaflet on quitting smoking and tailoring based on the transtheoretical model of behaviour change. Patients received a 'booster' session (30 mins) of the BI at 1 & 4 weeks to enhance self-efficacy and overcome any barriers.

					Control: Usual care plus simple brief advice and self-help leaflet on quitting smoking. Training: Nurses were trained for the smoking cessation counselling.
MECC link	Website or Web App	Smoking, physical activity & healthy diet/weight (as single BIs)	For any HCP (setting non-specific) (UK)	N/A	A flexible VBI and signposting tool that has been designed to support positive behaviour change as part of the PHE initiative 'Making Every Contact Count' (MECC). It helps health professionals to raise awareness, motivate and signpost individuals to support health and wellbeing improvements. It covers a range of key healthy lifestyle topics, including smoking, physical activity and healthy diet/weight. It is based on open questions using the 3 As model: ask, assist, act and includes easily accessible tools, resources and signposting to recommended local and national support services. Online training available
Moving Medicine	Website	Physical Activity	For any HCP (setting non-specific) (UK)	N/A	Developed by the Faculty of Sports and Exercise Medicine UK (which is part of the Royal College of Physicians) in partnership with PHE & Sport England. It provides evidence-based, condition-specific information for HCPs to integrate PA conversations into routine clinical care and resources to support patient behaviour change. It is embedded in a time-based framework (1-min, 5-min or more minute conversations tailored to the patient's needs and time available) based on

					established behavioural change techniques and MI theory. Offers online training for a fee.
National Centre for Smoking Cessation & Training (NCSCT)	Website	Smoking	For any HCP (setting non-specific) (UK)	N/A	The NCSCT, created by the Department of Health, is a social enterprise developed to support the delivery of effective evidence-based smoking cessation interventions and very brief advice (VBA) on smoking. It includes training (online, virtual and face-to-face services) and supporting resources for specialist stop smoking practitioners and HCPs who have contact with smokers. It is based on the 3 As model: ask, advise, act and is built upon evidence-based BCTs.
Stop smoking interven-tions & services: NICE guideline 2018	NICE Guidance paper	Smoking	For any HCP in primary care and community settings (UK)	N/A	Includes information on stop smoking interventions and services providing recommendations for HCPs who engage with people who smoke and links to stop smoking services. Recommendations include 1) At every opportunity, ask people if they smoke and advise them to stop smoking based on their preferences and needs; 2) Ensure VBA (30 secs) is delivered in-line with the NCSCT training module on VBA; 3) Refer those who want to stop smoking to local smoking cessation support. It also recommends all frontline HCPs should have training to deliver VBA and signpost to local smoking cessation services, including as part of their undergraduate and postgraduate core curriculum.

Thompson 2017: Let's Talk About Weight	PHE Guidance paper	Weight	For any HCP (setting non-specific) (UK)	N/A	A step-by-step evidence-based guide to BIs (30 secs) for weight management with adults for healthcare professionals. It provides practical advice and tools on how to discuss weight loss with overweight and obese patients. It is based on the 3 A's model: ask, advise, assist from the BWeL trial (Aveyard *et al* 2016). The guide recommends follow-up consultations to review a patient's situation. It includes resources for further learning and information.
Waite 2020	Research (Exploratory/ feasibility study)	Physical Activity	Delivered by physio-therapists in hospital inpatients (UK)	n=264 Inclusion: Current inpatients identified as moderately inactive or inactive (General PA questionnaire)	Intervention: A brief (<30 mins) MI behavioural change intervention with referral to a community PA programme or independent plan; delivered in a single face-to-face session. Included MI BCTs, joint goal-setting and resources - PHE infographic start active, stay active (withdrawn). Control: No control. Training: 4-day intensive MI course.

Williams 2015	Research (Cluster RCT)	Physical Activity	Delivered by nurses or healthcare assistants in GP practice (UK)	n=21 GP practices (315 participants) Inclusion: Aged 16-65 yrs, 1 or more chronic condition that would benefit from increased PA; sedentary (not meeting CMO PA guidelines)	Intervention: A BI to promote walking within general practice based on theory of planned behaviour delivered in x2 30 min sessions and a 20 min follow-up. Includes MI techniques to enhance planned behavioural control & self-efficacy; goal-setting, action-planning, progress review, positive feedback; and resources: 2 leaflets promoting the benefits of walking (available). Control: Information provision on the benefits of walking. Training: x 2 training session (7 hours).

RCT, Randomised Controlled trial; BMI, Body Mass Index; PA, Physical Activity; BI, Brief Intervention; VBI, Very Brief Intervention; VBA, Very brief advice; MI, Motivational interviewing; BCT, Behaviour Change Technique; PHE, Public Health England; CMO, Chief Medical Officer

The settings ranged from primary care (4/14) (Aveyard *et al.*, 2016; Beeken *et al.*, 2017; NICE, 2018; Williams *et al.*, 2015), speciality clinics, such as a diabetes clinic (5/14) (Babwah *et al.*, 2018; Hardeman *et al.*, 2020; Hooten *et al.*, 2019; Lerdrattanasakulchai and Palawisuth, 2018; Li *et al.*, 2017), and inpatients (1/14) (Waite *et al.*, 2020). Three (3/14) were non-specific to a particular setting (*MECC link, n.d.; Moving Medicine, n.d.; NCSCT, n.d.*). In terms of who delivered the BIs, or who it is aimed at for delivery, four BIs were for delivery by nurses or healthcare assistants (Beeken *et al.*, 2017; Hardeman *et al.*, 2020; Li *et al.*, 2017; Williams *et al.*, 2015), two by GPs (Aveyard *et al.*, 2016; Babwah, *et al*., 2018), one by a respiratory therapist or nurse (Hooten *et al.*, 2019), one by a physiotherapist (Waite *et al.*, 2020) and one by the researcher (Lerdrattanasakulchai and Palawisuth, 2018). The remaining five BIs were aimed at any HCP to deliver (*MECC link, n.d.; Moving Medicine, n.d.; NCSCT, n.d.*; NICE, 2018; PHE, 2017).

The time for delivery of the BI ranged from 30 seconds to 30 minutes, with 5 of the shorter BIs referred to as either a very brief intervention (Babwah, *et al*., 2018; Hardeman *et al.*, 2020; *MECC link*, n.d.) or very brief advice (*NCSCT, n.d.*; NICE, 2018). One website (*Moving Medicine, n.d.*) offered a range of time-based frameworks depending on the patient's needs and the available time of the HCP.

Content

All the included BIs were delivered face-to-face, with five (5/14) delivering this in a single session (Babwah, *et al*., 2018; Beeken *et al.*, 2017; Hardeman *et al.*, 2020; Hooten *et al.*, 2019; Waite *et al.*, 2020). One BI consisted of two initial 30-minute sessions (Williams *et al.*, 2015). Of the BIs that included follow-up (8/14), four encouraged follow-up, but with

flexibility around this (*Moving Medicine, n.d.; NCSCT, n.d.*; NICE, 2018; PHE, 2017). Three BIs reported specific time points for follow-up ranging from one 4-week follow-up (Aveyard *et al.*, 2016), two follow-ups at 1-week and 4-weeks (Li *et al.*, 2017), to four follow-ups over a 12-month period (Lerdrattanasakulchai and Palawisuth, 2018). One BI included a 30-minute follow-up, but with no time-point specified (Williams *et al.*, 2015). The MECC link website was not explicit in arranging a follow-up or not, beyond signposting.

Only three (3/14) BIs were described as have an underpinning theory. One BI was based on habit formation theory (Beeken *et al.*, 2017), one was based on the transtheoretical model of change (Li *et al.*, 2017) and one was based on the theory of planned behaviour (Williams *et al.*, 2015). Four (4/14) BIs were based on motivational interviewing approaches (Hardeman *et al.*, 2020; *Moving Medicine*, n.d.; Waite *et al.*, 2020; Williams *et al.*, 2015).

Three (3/14) BIs were designed to be tailored to a specific condition or context. One BI was tailored to chronic pain by including a psychoeducational component to address the associations between smoking and chronic pain (Hooten *et al.*, 2019). One BI was tailored to a specific condition by highlighting the links between smoking and diabetes, as well as using the transtheoretical model of behaviour change (Li *et al.*, 2017). The Moving Medicine website offers a range of condition-specific consultation guides and resources, such as for musculoskeletal pain, cancer and stroke. It also provides time-specific options depending on the situation, including a 1-min, 5-min or a more-minute conversation.

Seven (7/14) BIs included signposting or referral to another service, such as a commercial weight management service (Aveyard *et al.*, 2016; *MECC link, n.d.; Moving Medicine, n.d.; NCSCT, n.d.*; NICE, 2018; PHE, 2017; Waite *et al.*, 2020). In terms of resources used several BIs included the use of goal-setting, written materials, action-planning and self-monitoring. This ranged from poor detail regarding the content of these to freely available resources. Overall, the reporting of the intervention content varied, with many lacking the detail needed to allow for reproducibility of the intervention, or its components.

Training to deliver the BI

All but one study (Lerdrattanasakulchai and Palawisuth, 2018) mentioned training to deliver the BI. Three BIs (3/14) mentioned that training was provided, but with no detail regarding this (Beeken *et al.*, 2017; Hooten *et al.*, 2019; Li *et al.*, 2017). Out of the others, training varied from 60 minutes (Babwah, *et al*., 2018), 90 minutes (Aveyard *et al.*, 2016), 3 hours (Hardeman *et al.*, 2020), 7 hours (Williams *et al.*, 2015), to a 4-day intensive course (Waite *et al.*, 2020).

Some sources provided access to or directed users to free online training (*MECC, n.d.; NCSCT, n.d.*; PHE, 2017). The Moving Medicine website offers a course available for a fee, although it is not essential for using the BIs and resources. Similarly, the reporting of the training content varied with regards to the level of detail to allow for reproducibility.

5.7 Discussion

5.7.1 Summary of findings

This narrative review has identified and summarised 14 BIs deemed potentially suitable to present to the stakeholder group in WS2 for assistance with selection and adaptation to form a component of The COMBINED approach. The review has also provided insights into the breadth of BIs available and associated resources for HCPs to deliver as part of routine care.

Considerable variations in BI definitions were identified along with vast differences in the time taken to deliver them. Some defined as a BI varied between 20-30 minutes to deliver (Beeken *et al.*, 2017; Hooten *et al.*, 2019; Li *et al.*, 2017; Waite *et al.*, 2020; Williams *et al.*, 2015). One BI took 1-2 minutes to deliver and was defined as a 'very brief intervention' (Babwah, *et al*., 2018), yet another took only 30 seconds to deliver but was defined as a 'brief intervention' (Aveyard *et al.*, 2016) and a similar BI was defined as 'very brief advice' (*NCSCT*, n.d.). A review of systematic reviews of physical activity BIs similarly found a broad and inconsistent range of definitions of BIs, suggesting many BIs are considered too long to be practical and implemented in clinical practice (Lamming *et al.*, 2017).

Only one BI included in this narrative review offered time-variable options to tailor to the clinical situation (*Moving Medicine, n.d.*). These options include a 1-minute conversation when time is limited to sow the seed of change and invite the patient for further discussion at another visit; a 5-minute conversation integrated into a clinical consultation

to build readiness to change and support change planning; and a more-minute conversation when physical activity is the primary focus of the consultation. Lack of time is a widely cited barrier for implementing BIs into clinical practice (Keyworth *et al.*, 2020a). Therefore, the time intensity of delivering the BI will be an important consideration for the stakeholders in WS2 when selecting the most suitable BI to integrate into routine consultations.

However, there is also a balance regarding what clinicians can effectively address with a BI that takes 30 seconds to deliver. Such brief exposure may limit the impact on patient behaviour change and, consequently, long-term effectiveness, particularly when addressing multiple behaviours or barriers to change. While very brief advice has been shown to be effective, interventions lasting more than 5 minutes have been suggested to produce more effective results (NICE, 2013).

There were similar variations between the BIs in terms of how resource-intensive they were to deliver. For example, one BI did not include the use of any supporting materials (Aveyard *et al.*, 2016), whereas another included written materials, a pedometer, goal-setting, action-planning and a step chart for self-monitoring, in addition to the 5-minute discussion (Hardeman *et al.*, 2020). One BI was designed to offer a range of supporting materials tailored to the patient's preferences and needs. These included a self-monitoring diary, a workbook to build motivation to change, resilience strategies and action planning, patient information leaflets and signposting information (*Moving Medicine*, n.d.).

Follow-up consultations varied from no follow-up (Babwah, *et al*., 2018; Beeken *et al.*, 2017; Hardeman *et al.*, 2020; Hooten *et al.*, 2019; Waite *et al.*, 2020), to four follow-ups over a 12-month period (Lerdrattanasakulchai and Palawisuth, 2018). Including follow-up appointments as part of the BI can be important for patients, providing external accountability, support for behaviour change, motivation and building self-efficacy (Ahern *et al.*, 2013). The training required to deliver the BI also varied from 60 minutes (Babwah, *et al*., 2018) to a 4-day intensive course (Waite *et al.*, 2020). Being too resource-intensive in terms of the time for follow-up and training may add additional barriers to delivery in practice and are important considerations in the development of The COMBINED approach for future successful implementation.

Intervention reporting lacked sufficient detail for transparency and replication. Only one study reported a TIDieR (template for intervention description and replication) checklist (Williams *et al.*, 2015). Several studies did not mention the training required for intervention delivery, while others reported training was provided, but without specifying the content. Availability and replication of additional resources also varied across the BIs. For example, a BI using a Department of Health resource has since been withdrawn (Waite *et al.*, 2020). The three websites provided the most reliable sources of current resources adaptable for use in different contexts.

This review has identified variability among BIs in terms of resource-intensity and comprehensiveness of content, as well as variability in the level of detail provided for reproducibility. These factors will influence the selection and application of a BI in the next stage of intervention development (WS2).

5.7.2 Study limitations

One of the criticisms of narrative reviews is the potential for biases and subjectivity in selecting studies to support a particular world view (Grant and Booth, 2009; Greenhalgh, Thorne and Malterud, 2018). However, these concerns can be mitigated to some degree through systematic methods, as applied in this review, including pre-determined search strategies, clear inclusion/exclusion criteria, data extraction tables, and consultation with the supervisory team on decisions for inclusion, aligned with the study aims (Greenhalgh, Thorne and Malterud, 2018). Utilising specific methods and guidance, drawing on systematic review methods, also enhanced the quality, transparency and reproducibility of this narrative review.

Furthermore, subjectivity played a lesser role in this review given the purpose was to select a number of BIs to inform decision-making as part of the intervention development process, and not to answer a specific research question. My worldview of pragmatism, and clinical experience, was important during the selection process to meet the requirements of developing an intervention that was ultimately fit for purpose and deliverable in a physiotherapy clinical context.

There is the possibility that relevant BIs were missed due to the defined inclusion criteria, particularly the inclusion of more recent BIs, and inconsistencies in defining 'brief intervention'. However, this review did not intend to identify an exhaustive list of all possible BIs, which would be impractical to present to the stakeholder group in the next stage of development.

5.8 Conclusion

This narrative review has identified and summarised 14 BIs for potential use in The COMBINED approach. The review highlights variations in time, resources and training required to deliver each BI, which are important factors for discussing stakeholders' preferences. These considerations will guide the appropriate selection and application of a BI within The COMBINED approach and inform future real-world implementation.

5.9 Chapter Summary

This chapter has reported on WS1 in the intervention development process, of which the findings will inform WS2 in Chapter 6. The next chapter describes a series of co-design workshops with stakeholders to select which BI would be the best-fit for The COMBINED approach, and to inform the design of the intervention.

Chapter 6 Designing The COMBINED Approach – Part one: Stakeholder Engagement Co-design

6.1 Chapter Introduction

This chapter describes a series of stakeholder co-design workshops as the second workstream (WS) in the intervention development stage of this thesis (Figure 6.1). Stakeholders' views generated ideas to inform the content of The COMBINED approach, including the selection of one of the identified brief interventions (BIs) to adapt and develop as a component of The COMBINED approach and identifying factors influencing implementation.

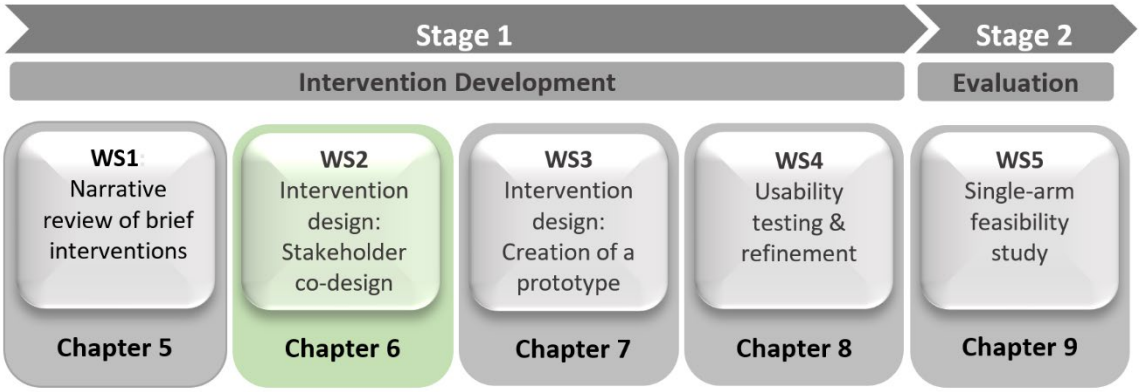

Figure 6.1 to show where this chapter fits within the intervention development process
WS, Workstream

6.2 Background

As previously described (Chapter 4, section 4.3.3), action 10 of the intervention development process is to design and refine the intervention. Intervention design is a distinct part of the intervention development pathway described as 'the part of development concerned with generating ideas for and making decisions about an

intervention's content, format and delivery' (Rousseau *et al.*, 2019, p. 1). The design phase in this thesis was outlined as occurring across two parts: Part 1 - stakeholder engagement co-design that generated practical ideas and recommendations to inform the content of intervention and identified barriers of, and facilitators to, implementation; Part 2 – mapping the barriers and facilitators to the COM-B model and Theoretical Domains Framework (TDF), and selection of behaviour change techniques to operationalise intervention components to create a prototype. This chapter describes Part One; the first step in this design process, and Chapter 7 reports the second step in the design process; Part Two. This work was carried out iteratively, rather than in a linear way as the steps suggest. For example, the mapping of barriers and facilitators to COM-B and the TDF were conducted iteratively between each workshop and finalised after all four workshops. It will be reported, for ease of the reader, in a linear way with the findings of the stakeholder engagement co-design (Chapter 6), followed by the mapping process and creation of a prototype (Chapter 7).

The design process within this thesis has been informed by Rousseau *et al* (2019) who identified different modes of design. These include informed design, which typically involves a series of stakeholder engagement workshops and draws on various sources of knowledge, with decision-making often occurring within the research team rather than with stakeholders. Structured design includes identifying intervention components based on a pre-existing framework or theory.

In this thesis, the first part of the design process (stakeholder engagement co-design) was predominantly in the informed design mode as it involved a series of stakeholder

engagement workshops as a source of information, but these were considered in conjunction with other sources of knowledge and evidence. Final decision-making, although informed by the stakeholders, occurred beyond the workshops by the research team. The second step, described in Chapter 7, followed a structured design as intervention components were identified based on a mapping process using COM-B and the TDF.

The optimal way of working with stakeholders in intervention development is recommended through collaborative approaches such as consultation, co-design or co-production, using creative ways to generate ideas to inform the development process (O'Cathain, Croot, Duncan, *et al.*, 2019). Formal research methods, such as interviews and focus groups, while important for understanding experiences, do not facilitate the involvement of stakeholders in developing interventions (Knowles *et al.*, 2018).

Stakeholder engagement, described as collaboration with end users in the research process (Camden *et al.*, 2015), can range in the level of collaboration from consultation, to co-design, to co-production. These approaches are on a scale of increasing effort, risk and level of partnership in the decision-making process. For example, consultation may involve simply asking stakeholders views on a discrete part of the development process, whereas co-production tends to consider stakeholders as equal partners within a research team, and equal power in the decision-making process (Harrison *et al.*, 2019; Slattery, Saeri and Bragge, 2020).

Co-design is a broad term described as “the meaningful end-user engagement in research design and includes instances of engagement that occur across all stages of the research process and range in intensity from relatively passive to highly active and involved” (Slattery, Saeri and Bragge, 2020, pp. 2-3)**.** For meaningful collaboration where the views of all stakeholders are included and embedded within the process, co-design was chosen over consultation. Co-production was considered not relevant as stakeholder engagement was for a discrete part of the process rather than the entire research process. Decisions were to be made by the research team, drawing on ideas generated from stakeholders along with other sources of knowledge, rather than aiming for an equal partnership.

6.3 Workstream Two Aims and Objectives

The aim of this stakeholder engagement co-design study was to create knowledge using co-design to inform the content of The COMBINED approach prototype and training package for the physiotherapists (Thesis objective 2-4, Chapter 1, section 1.4).

Specific objectives were to:

1. Understand current practice and management of rotator cuff (RC) disorders in relation to identifying and addressing the three key lifestyle factors;
2. Review 14 candidate BIs and generate recommendations to select a BI to adapt and form a component of The COMBINED approach;
3. Understand barriers to, and facilitators of, implementation of The COMBINED approach to managing RC disorders in clinical practice;

4. Generate a wide range of ideas and recommendations towards design elements of the intervention, to inform the development of The COMBINED approach prototype;
5. Identify the training needs of the physiotherapists to deliver The COMBINED approach;
6. Evaluate the online platform for conducting co-design with stakeholders.

6.4 Methods

6.4.1 Study design

A series of virtual stakeholder engagement workshops were conducted using principles of co-design including (Harrison *et al.*, 2019):

- Establishing ground rules;
- Building and maintaining relationships;
- Respecting and valuing all perspectives and contributions;
- An approach to encourage all participants to actively contribute to hear all voices;
- Working together to achieve shared values and collective decision-making;
- Open, transparent and honest communication.

Prior to COVID-19 the stakeholder engagement workshops were to be planned as a face-to-face full day event (discussed in Chapter 1, section 1.7). However, due to lockdown and social distancing alternative online methods, including the use of interactive tools, had to be considered. As a relatively new platform for conducting co-design, this was evaluated as part of the research process.

6.4.2 Ethical approval process/data protection and ethical issues

On advice from the head of the faculty Research Ethics Committee (REC), ethical review and approval was sought in relation to (1) collection and storage of personal data for the purpose of describing the characteristics of the group, and (2) video recording and storage of the workshop discussions. Informed consent was obtained from all stakeholders prior to their participation in the workshops for the purpose described above. Favourable ethical review was confirmed on the 16th of December 2020 by the Health, Psychology and Social Care REC at Manchester Metropolitan University (EthOS reference: 25512) (Appendix D).

6.4.3 Identification of key stakeholders

Stakeholders described in this guidance include individuals targeted by the intervention, those involved in its development or delivery, or where their professional or personal interests are impacted (Skivington *et al.*, 2021). The following key stakeholders were identified (1) Physiotherapists and patients as the primary target population who will be directly affected by the intervention; (2) wider medical professionals such as GPs and orthopaedic surgeons who directly work with the target population; (3) stakeholders with specialist expertise such as in behaviour change or public health to advise on key design aspects in relation to these areas.

The intention was to recruit up to six patients with experience of shoulder pain and/or experience of attending a physiotherapy service with a musculoskeletal condition, 10-15

clinicians, predominantly physiotherapists, but also medical professionals (GPs/orthopaedic surgeons), and 1-2 behaviour change or public health experts.

Professionals were identified through the research team's professional networks. Patient stakeholders were identified through existing patient & public involvement groups that the research team had previously been involved with. Potential stakeholders were approached via an introductory email (using non-NHS email addresses) inviting them to take part. This email included an information sheet (Appendix E) outlining their expected contribution, time requirements and the offer of a £25 voucher per workshop as a thank you for their time. For individuals where a non-NHS email address was unknown, they were contacted by direct messaging through social media (Twitter/X) and, if they were interested in taking part, requested to provide a non-NHS email contact.

6.4.4 Consent

Following expression of interest in taking part, all stakeholders had an individual online meeting before the workshop to ask questions and ensure they were comfortable with use of the technology. Audio consent was taken for the purpose outlined in section 6.4.2, by reading the statements from the consent form (Appendix F) and the stakeholder audibly confirming their consent, recorded through Microsoft Teams.

6.4.5 Data collection and analysis

The workshops were held and recorded through Microsoft Teams. The demographic data, the workshop discussions captured in the recordings and chat function in Microsoft Teams, as well as ideas generated through creative activities, such as a virtual whiteboard

were considered as data. The data was stored securely on my personal university OneDrive, with access only by the immediate research team.

Data collection and analysis were iterative, with preliminary findings analysed and interpreted following each workshop, which informed the content of the next workshop. Following completion of all four workshops, the ideas generated across the workshops were brought together. A rapid approach to analysis was employed to manage the large volume of data generated through the structured discussions and to conduct analysis between each workshop. This approach included synthesising the discussions from the workshops by writing summary notes directly from the recordings, text chat and other activities of collective insights and perspectives shared by the participants, rather than full transcription and individual quotes.

Analysis occurred in the following ways:

1) Debriefing immediately after each workshop with the supervisory team to share my preliminary reflections and interpretations. The purpose was to check I had captured all perspectives, confirm my reflections and interpretations by asking me critical questions of these, and facilitate reflexivity;

2) Making summary notes after each workshop integrating the recorded discussions, the chat text and any ideas generated through other activities, such as the virtual whiteboard.

3) Synthesising and organising the summary notes based on interrelated concepts and shared meanings to capture collective insights and perspectives;

4) Summarising the preliminary interpretations to the stakeholders and reviewing these at the beginning of the next workshop. The purpose was to clarify any points and check with the stakeholders that I had captured all discussions and represented their points as they were intended. This process supported transparency in the interpretations that guided the decision-making in this co-design process and promoted reflexivity by avoiding my own assumptions.

Point 1 and 4 together, helped to maintain rigour and relevance of the findings in co-design. Further analysis involved mapping the collected data to the COM-B model and TDF. Although this process was iterative during the co-design workshops, it will be reported in the next step of the design process (Chapter 7).

6.4.6 Co-design workshop process

A series of four linked virtual stakeholder engagement workshops were conducted through Microsoft Teams, held two weeks apart between February and March 2021. Each workshop was held for two hours, between 6.00 pm. 8.00 pm, to allow those working to participate. The workshops included both professional and patient stakeholders in the same workshop. It was encouraged that the stakeholders attended all four workshops so that ongoing ideas could be developed and expanded during each workshop, however it was not essential.

The content of the workshops covered four elements: (1) provision of evidence and information to the stakeholders to understand the purpose of the research and; (2) provision of evidence and information to the stakeholders on the identified BIs from WS1;

(3) drawing on the experiences of the stakeholders about (i) current practice and integrating the assessment and management of lifestyle factors into a routine consultation for RC disorders; (ii) suitability of the BIs to form a component of The COMBINED approach; (iii) ideas for integration of the BI with the Best Practice Advice (BPA) intervention, highlighted from the GRASP trial as current best practice (Chapter 2, section 2.2.2) (Hopewell, Keene, Marian, *et al.*, 2021); (iv) potential barriers to, and facilitators of, implementing The COMBINED approach; (v) training needs of the physiotherapists; (4) Evaluation of the process. Figure 6.2 shows the structure of the co-design workshops, but discussions were iterative, for example, training needs were identified across all four workshops and not just in the structured discussion in workshop four.

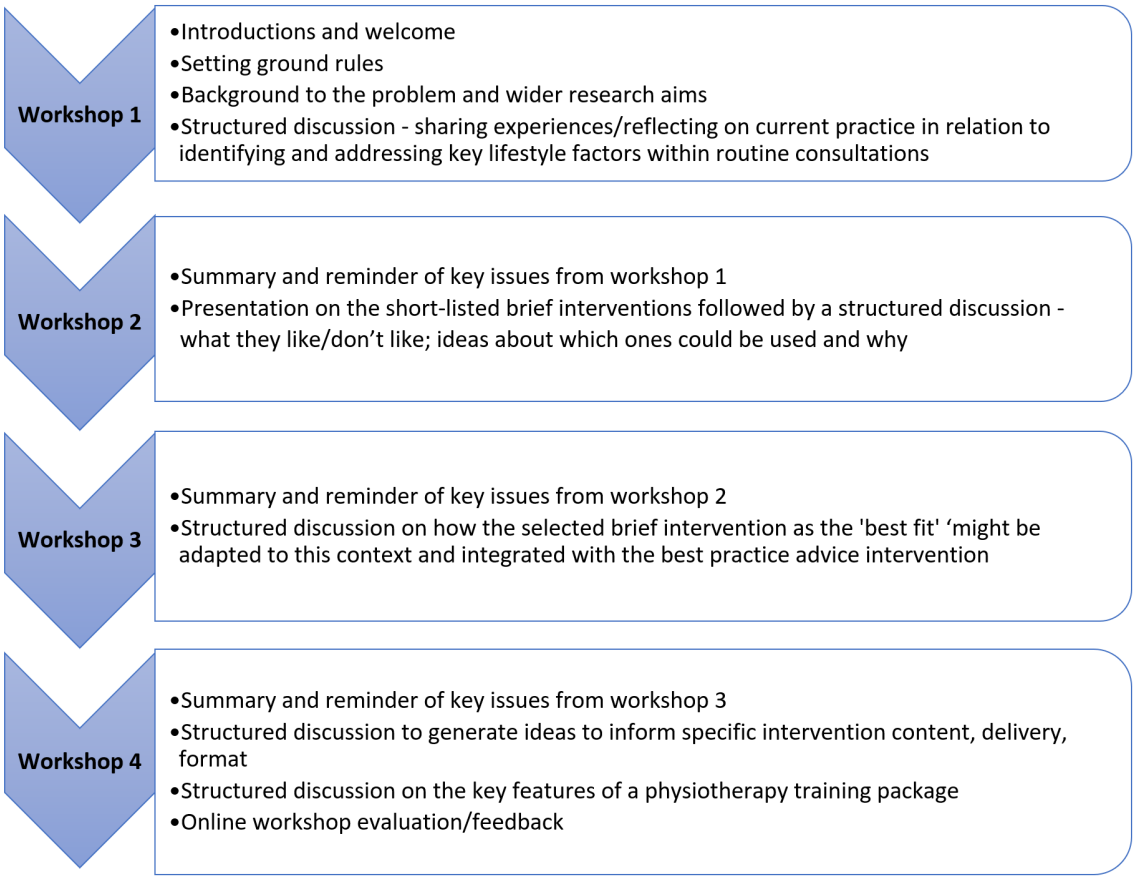

Figure 6.2 Workshop structure & content

I led each workshop, facilitated by three supervisors (CL, GY, CJ) who attended each workshop. Their role was to monitor conversations in the chat and facilitate discussion, encouraging the involvement of all stakeholders, and aligning with the principle of co-design, ensuring all voices were heard. Debriefing immediately after each workshop with the supervisory team, and before each workshop with the stakeholders, enabled me to share my reflections and interpretations, as discussed in section 6.4.5. Sharing a summary of my reflections with the stakeholders at the beginning of the workshop also helped to stimulate further discussion, building on ideas formed from earlier workshops.

Strategies for communication/participation

Various workshop activities and interactive methods were used to encourage stakeholder participation. Standard methods included speaking on the video and using the chat facility on Microsoft Teams. Other online interactive tools included 'Mentimeter', such as generating word clouds, and Jamboard, a collaborative digital interactive whiteboard, used to share ideas in real time. Jamboard involved stakeholders posting their thoughts on post-it notes on a virtual whiteboard, which I could then organise into shared ideas/themes after the workshop. These tools were used for specific activities during the workshop to supplement the discussions, for example, to post on the Jamboard what they liked/didn't like about a BI or what would help them deliver The COMBINED approach in practice. The multiple strategies for communication enabled the stakeholders to contribute in various ways, including anonymously.

6.4.7 Evaluating the process

Feedback was sought about participating in the co-design workshops, particularly the online setting of these workshops in the context of COVID-19. Evaluation of the workshops included my reflections, which were shared with the group, a discussion with the stakeholders in the final workshop, and anonymous evaluation via the Jamboard.

6.5 Findings

6.5.1 Stakeholder characteristics

A total of 26 stakeholders consented to take part in the workshops. Twenty-four stakeholders attended workshop one and two, 20 attended workshop three, and 19

attended workshop four. The stakeholder characteristics from the workshops are shown in Table 6.1.

Table 6.1 Stakeholder characteristics (n=26)

	n	%		n	%
Sex			**Years of professional experience**		
Female	20	77	5-10 years	3	12
Male	6	23	11-15 years	7	27
			16-20 years	6	23
Role			21-25 years	4	15
Physiotherapist (by background)	19	73	> 25 years	2	8
Mainly clinical	13	50	N/A (patients)	4	15
Service delivery manager	1	4			
Clinical academic	3	12	**Location (of work)**		
Academic	1	4	Derby	5	19
Public health	1	4	Gloucester	1	4
Orthopaedic surgeon	1	4	Manchester	3	12
GP	1	4	Liverpool	1	4
Health psychologist	1	4	Sheffield	1	4
Patient	4	15	Chesterfield	1	4
			Huddersfield	2	8
			Birmingham	4	15
Clinical speciality			London	1	4
Upper limb	14	54	Doncaster	1	4
Musculoskeletal	5	19	Middlesbrough	1	4
Public Health	1	4	Leicester	1	4
N/A	6	23	N/A (patients)	4	15

6.5.2 Summary of workshop discussions

Initial discussions indicated that clinicians generally find initiating conversations about lifestyle challenging, and while it is something they 'should' be doing, overall, it isn't happening in practice. They were asked to record their initial thoughts via Mentimeter on integrating an approach to identify and address lifestyle factors within a routine consultation for RC disorders. A word cloud representing these thoughts was produced,

with the larger words reflecting more responses (Figure 6.3). Words included ‘awkward,’ ‘uncomfortable,’ ‘taboo’, ‘change of practice’ and ‘patient motivation’. The word cloud was stimulus to discuss and understand these challenges further.

Figure 6.3 Initial stakeholder thoughts on The COMBINED approach (Mentimeter)

Fear and anxiety were apparent amongst the clinicians in initiating lifestyle conversations. Some of these concerns were from personal bad experiences, such as defensive patients, uncomfortable conversations, and complaints, which had led to a fear of litigation. The clinicians were also fearful of upsetting or offending the patient and undermining the therapeutic relationship. This fear and anxiety were underpinned by the clinicians’ perception that firstly, patients do not want to have lifestyle conversations, secondly, do not expect it in a physiotherapy consultation, particularly for their shoulder pain, and thirdly, do not want to change or will be motivated to change. However, there was a mismatch of this perception with the patient stakeholders in the group, who all reported

they were important conversations to be had. The patients voiced that even if the conversations are awkward and uncomfortable, they appreciate an honest dialogue, which might make them do something about it. One patient said she would be upset if she hadn't heard about something she could do to help her shoulder condition and to give people the best chance of getting better they need to be told about the lifestyle factors. By not having these conversations, patients are not getting the whole picture about their shoulder condition, removing the opportunity for them to change something that might help. One patient stakeholder shared an honest and powerful account of her experience when she was excessively drinking following a divorce. Her GP broached the subject of her drinking while she attended for something unrelated, and even though she found it uncomfortable, she took it on board and did something about it. She now thanks her GP for having that conversation and felt it saved her life, stressing that "no matter how uncomfortable it may feel, they are really important conversations that clinicians should be having with their patients".

Clinicians held the belief that patients expect GPs and other medical professionals to initiate lifestyle conversations, but not physiotherapists. In contrast to this, some patients expressed a preference for having these conversations with a physiotherapist over a surgeon for example, reflecting they would open up more as you tend to have more appointments, and therefore a trusting relationship, with a physiotherapist. One patient asked the question: 'If physios aren't having these conversations, who is?'.

Many clinicians lacked self-belief or confidence in approaching patients and then supporting behaviour change. Confidence was particularly low for targeting weight

management and smoking cessation, as opposed to physical activity, as they are not 'experts' in this area. Conversations about weight were repeatedly brought up in the workshops as challenging, perceived as a more sensitive topic than the other two lifestyle factors, with the potential to affect therapeutic alliance more. One of the patients felt therapeutic relationship shouldn't be affected as the relationship should be a 'joint partnership' that requires commitment from both the clinician and what patients can do for themselves. For supporting behaviour change, the clinicians were concerned that they would not 'have the answers' related to these topics, for example, strategies for weight management.

Clinicians felt they needed a 'way-in' to feel comfortable initiating lifestyle conversations, ideally where this had been pre-empted with the patient. Suggestions for a way-in included an infographic displayed in waiting rooms or a simple patient resource to explain the links between the lifestyle factors and shoulder pain. Both the clinician and patient stakeholders agreed this approach should be perceived by patients as 'something that we do with everyone', so it doesn't feel targeted, for example, to someone who is visibly overweight.

Clinicians in the group reported a lack of knowledge of the systemic inflammatory links between the lifestyle factors and RC disorders, and the ability to summarise this in simple terms to patients. Some could understand these links better to a lower limb or back problem via biomechanical mechanisms, and therefore didn't seem applicable to the shoulder. There was a perception from the clinicians that patients wouldn't understand these links readily in relation to their shoulder pain either.

The clinicians reported a lack of coaching skills required to deliver aspects of the BI and support health behaviour change, including communication skills to have empathetic, non-judgemental conversations and to explore and strengthen patient motivations to change. Physiotherapists discussed that traditionally they have been 'problem-solvers' giving what 'we' think patients need and then wanting to 'fix' the problem. They reported coaching skills were not a core component of undergraduate training and therefore not what they were taught to do. The medical professionals in the group, in contrast, reported their training does include developing skills to have difficult or sensitive conversations generally, which are transferable skills to having lifestyle conversations. One of the patients shared her experience of a smoking cessation service, where she felt she was being 'told what to do', which had felt patronising to her, and reinforced the importance of an empathetic, supportive approach.

This move away from the 'traditional' physiotherapy approach was referred to by one stakeholder as a 'monumental shift' from what we currently do and a 'real leap' for physiotherapists by another, highlighted as a potential threat to their identity. It was discussed that this 'new approach' required a change in mindset, both by the physiotherapist, but also the patient to reframe what physiotherapy treatment is to manage patient expectations. Clinicians believed integrating the assessment and management of lifestyle factors would not meet patient's expectation of physiotherapy for their shoulder pain. If treatments were not focused on 'shoulder-specific rehab' and the consultation was spent discussing smoking cessation, there was concern about a potential mismatch of expectations resulting in a negative experience for both the

physiotherapists and patients. One patient stakeholder confirmed this perception and described it as a 'balancing act' as she was happy to receive information about smoking cessation, for example, but would expect most of the consultation to be 'targeting the direct physical aspects of my shoulder rehabilitation'.

Practical issues were also discussed, with time a particular point of discussion. Physiotherapists felt the first patient consultation is time pressured with the priority to complete an assessment, make a diagnosis and build a therapeutic alliance. One physiotherapist described it as 'just trying to get through the consultation'. Subsequently, an assessment of lifestyle factors had not previously been considered a priority. It was perceived that integrating an assessment and management of lifestyle factors within a routine consultation had the potential to 'open up a can of worms'. Other practical issues included a lack of knowledge of available support services and evidence-based information to signpost the patient to, as well as organisational barriers such as local availability, access and referral pathways to support services. There was also a discussion about the practicalities of combining the BPA intervention with the BI. Stakeholders expressed that follow-up support was a crucial aspect for both patients and clinicians for supporting behaviour change and had doubts about the one-off session within the BPA not enabling a follow-up consultation.

A discussion occurred about the expectation of clinicians being a role model for patients and that not knowing patient's preference regarding this was a concern to the physiotherapists as this may affect how patients respond to these conversations. Patients' opinions were divided regarding this. Some felt a role model in relation to the health

behaviour they are discussing was important to have confidence in what the physiotherapist was saying. In contrast, others reflected they would find a role model more intimidating and harder to relate to. They would want someone who was ‘a bit like me’ who could truly empathise and understand their challenges. This approach was described as a ‘friendly neighbour’, rather than ‘advice on high’.

Despite the initial concerns raised by the group, highlighted by the word cloud (Figure 6.3), there was also a general positivity and excitement about The COMBINED approach. One physiotherapist liked the concept of The COMBINED approach and could ‘see this as part of what we do’. One physiotherapist returned to the second workshop reporting she had started to initiate lifestyle conversations with patients, although she had struggled with this. There was a general feeling of wanting to do better and that this is important, but there was a conflict between what is a ‘nice idea’ versus the reality of implementing it, which was perceived as complex. However, one physiotherapist stated, ‘we need to challenge ourselves and step up; the conversation is moving on’.

6.5.3 Selection of a BI

The stakeholders were presented with information on each BI, to understand the range of BIs available and aspects within them, for example, the time and training to deliver the BI, and the content. This included showing online videos where available, for example, the National Centre for Smoking Cessation training had videos online explaining their BI and how to deliver it in practice. It also included looking at website content, for example,

Moving Medicine webpages. A summary of the BIs identified from Chapter 5 is shown in Table 6.2 as a reminder.

Table 6.2 Summary of candidate brief interventions from the narrative review

	Source	Summary of Brief Intervention
1	Research study (Aveyard 2016)	BI to target obesity; 30 secs to deliver; includes brief advice and offer of referral to a commercial weight management service; 4-week follow-up; 90-minute online training course
2	Research study (Babwah 2020)	BI to target physical activity; 1-2 mins to deliver; includes brief advice and a prescription for home-based exercises; 60-minute training course
3	Research study (Beeken 2016)	BI to target weight; 30 minutes to deliver; includes leaflet with advice and self-monitoring logbook
4	Research study (Hardeman 2020)	BI to target physical activity; 5 minutes to deliver; includes discussion, written materials, pedometer, goal-setting, action-planning and step chart; 3-hour training session
5	Research study (Hooten 2018)	BI to target smoking; 20 mins to deliver; includes MI and psychoeducation
6	Research study (Lerdrattanasakulchai 2018)	BI to target weight; 15 mins to deliver; includes leaflet with advice and self-monitoring logbook and a wristband for habit formation; follow-up at 2, 4, 6 & 12 months
7	Research study (Li et al 2017)	BI to target smoking; 20 mins to deliver; includes advice, exploration of readiness to change and a leaflet; follow-up at 1 & 4 weeks
8	Website (MECC link)	BI to target all key lifestyle factors; flexible time to deliver; includes advice and signposting; online training available; follow-up flexible
9	Website (Moving Medicine)	BI to target physical activity; flexible time to deliver including 1-min, 5-min and more-minute conversations; includes MI including exploring personal motivations to change, signposting and optional resources for action-planning and self-monitoring diary; follow-up flexible; online training available (at a cost)
10	Website (NCSCT)	BI to target smoking; 30 secs to deliver; includes brief advice and signposting; online and face-to-face training available
11	NICE guidance (2018) Stop smoking interventions & services	BI to target smoking; 30 secs to deliver; includes brief advice and signposting; online and face-to-face training available through the NCSCT
12	PHE guidance (2017) Let's talk about weight	BI to target weight; 30 secs to deliver; includes advice and signposting; recommends follow-up; resources available for further learning

13	Research study (Waite 2020)	BI to target physical activity; 30 mins to deliver; includes MI, goal-setting, leaflet with resources and referral to community exercise programme or home-based plan; 4-day intensive course
14	Research (Williams 2015)	BI to target physical activity; 2 sessions of 30 mins each to deliver; includes MI, goal-setting, action-planning, leaflets; 20-min follow-up; 7-hour training over 2 sessions

BI, Brief intervention; MI, Motivational interviewing; MECC, Make Every Contact Count; NCSCT, National Centre for Smoking Cessation & Training; NICE, National Institute for Health & Care Excellence; PHE, Public Health England

After the presentation of each BI the stakeholders were asked their opinions about what they liked and did not like, thinking about how this might work/feel in practice for the clinicians and patients. The feedback from stakeholders included verbal discussion, text chat, and posting their thoughts on a Jamboard. Based on collective discussions across the range of BIs presented, key aspects were identified as important 'must haves' of a BI to form a component of The COMBINED approach. These are summarised in Figure 6.4.

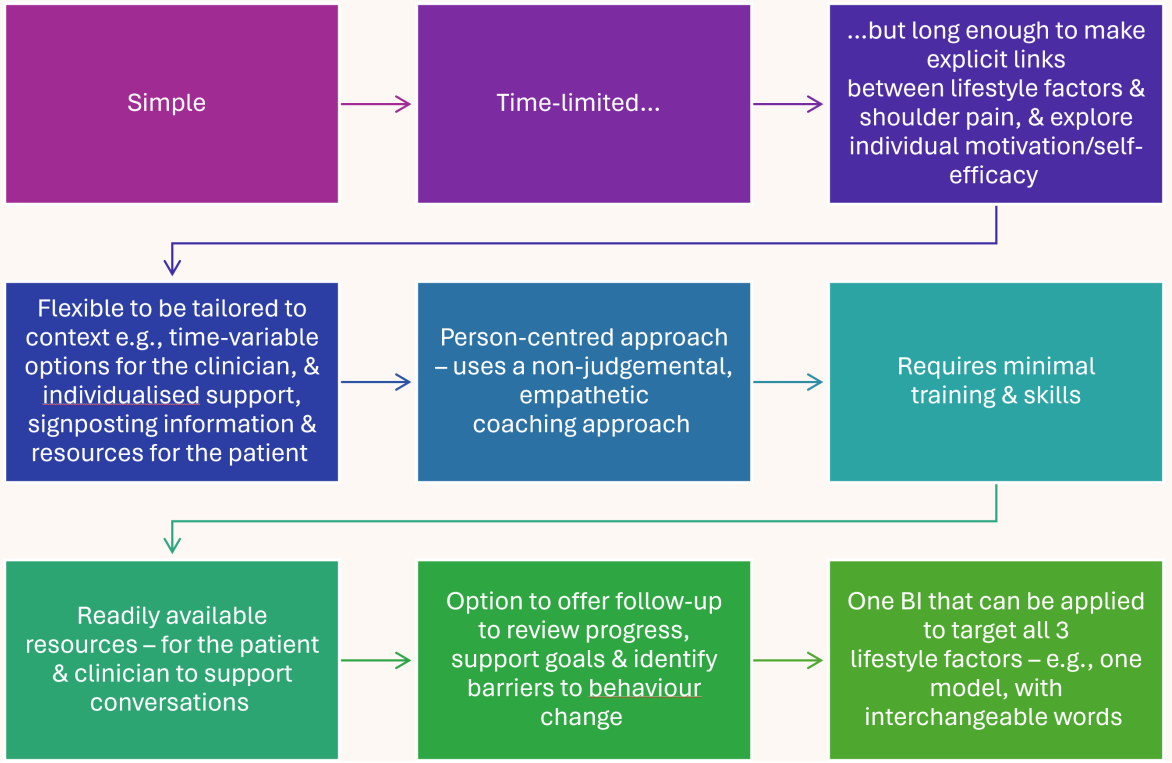

Figure 6.4 Important components of a brief intervention
BI, Brief Intervention

Through a structured discussion these key principles for a BI were applied to the candidate BIs and either excluded or included/short-listed. Six BIs were excluded based on the time for delivery, considered not feasible in practice. From Table 6.2, these included BIs 3, 5, 6, 7, 13 and 14. Six BIs were excluded based on the lack of opportunity to make explicit links between the lifestyle factors and shoulder pain, and for a person-centred approach to explore patient values, motivations to change, and self-efficacy. These included BIs 1, 2, 8, 10, 11, 12 (Table 6.2). One BI was excluded as it was pedometer-based, and not able to be applied to target all 3 lifestyle factors. This was BI 4 (Table 6.2).

The resulting BI was the Moving Medicine online resource. Moving Medicine had all the key components of a BI that were important to the stakeholders. Although it targets physical activity it was felt it was easily adaptable to target the other health behaviours (smoking, healthy diet). A concern was raised about fitting the content of the BI within the stated timeframe, which needs considering during further development of The COMBINED approach. An example Jamboard of stakeholders' thoughts about Moving Medicine that supplemented the discussion is shown in Figure 6.5. The Moving Medicine components and resources will be discussed in detail in Chapter 7.

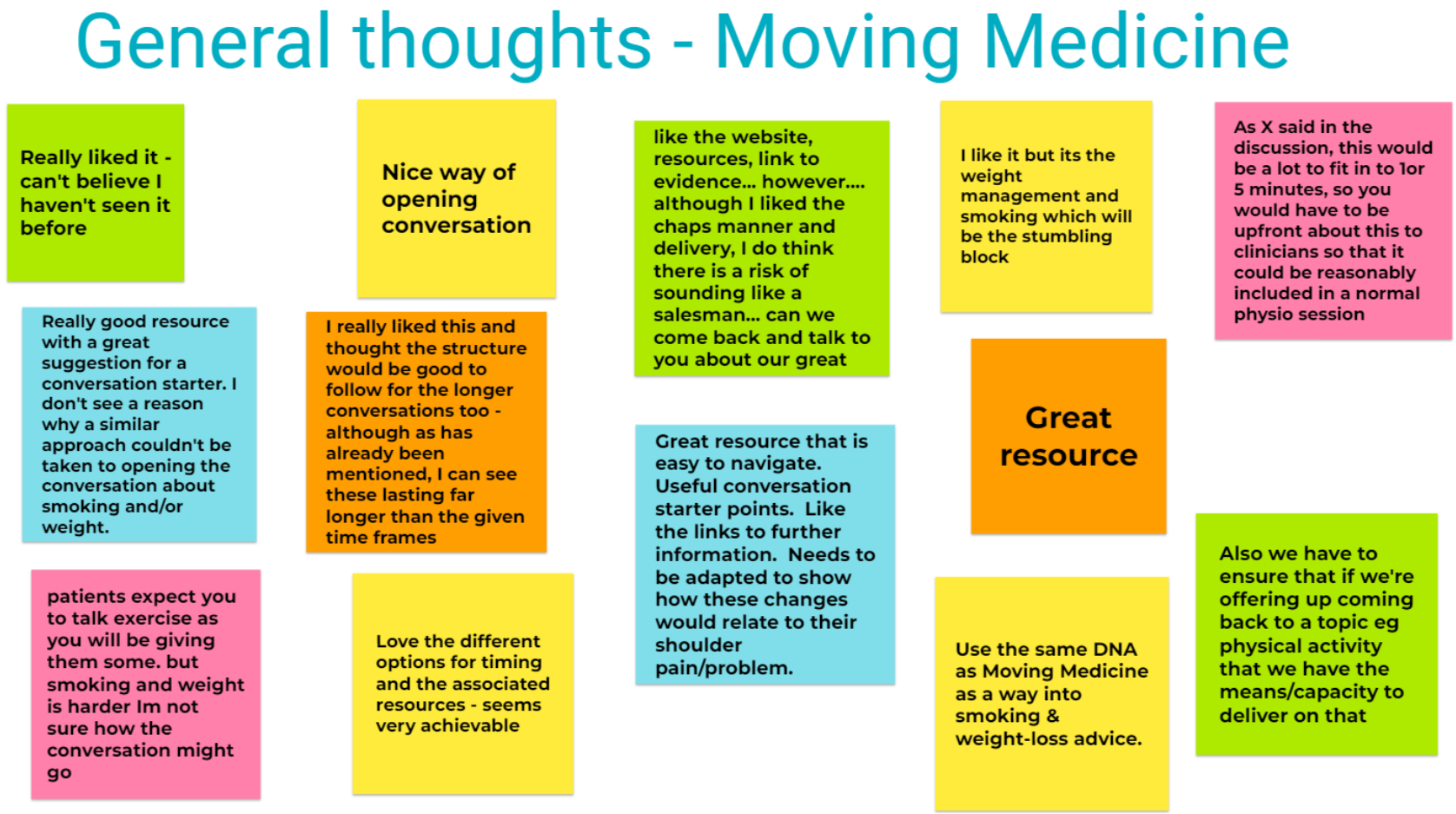

Figure 6.5 Summary of stakeholders' perspectives of Moving Medicine

6.5.4 Recommendations for implementation support

Throughout all four workshops, stakeholders provided recommendations to inform the content of The COMBINED approach. These recommendations were based on what stakeholders considered important for the approach to be usable and acceptable in practice. Key considerations included not adding burden to already time-pressured, busy workloads and addressing stakeholders' lack of knowledge, skills and confidence to implement this approach. The training needs of the physiotherapists, as well as additional strategies for implementation support were also generated across all four workshops. The recommendations based on my analysis included:

- Having a simple, time-limited approach;
- Having a standardised, structured approach that can be normalised and embedded into every consultation;
- Providing clinicians with scripts to support the conversation, particularly conversation starters;
- Developing an infographic with easy to explain information for the patient about the links between lifestyle factors and shoulder pain;
- Having a 'way-in' – e.g., the infographic displayed in waiting rooms;
- Providing patient resources to support behaviour change;
- Providing information on support services to signpost the patient to;
- Providing physiotherapists with training, with a particular focus on

    - Systemic inflammatory mechanisms underpinning the links between the lifestyle factors and shoulder pain
    - Coaching and communication skills
    - How to deliver a BI – including initiating the conversation, raising awareness of the links, supporting health behaviour change;
- Providing ongoing support.

An example of recommendations from the Jamboard to supplement the discussions is shown in Figure 6.6.

Figure 6.6 Recommendations for supporting physiotherapists implement The COMBINED approach – organised into themes

6.5.5 Workshop evaluation

The online co-design workshops generally received positive feedback from the stakeholders (Figure 6.7). This included greater accessibility, and convenience in relation to the time of the workshops and not having to travel. It was reported that the variety of ways offered to contribute, such as the chat function or the anonymous JamBoard, was less intimidating than directly speaking for some stakeholders. This approach enabled those less likely to speak up in a group setting to contribute effectively. It was felt there had been rich and honest dialogue despite being in an online format, which could have been considered a barrier by some to engagement. There was also feedback that from being part of this process, the stakeholders had either started to use or were planning to use elements of this approach in their own clinical practice (highlighted in the green post-it notes in Figure 6.7). Having a series of workshops gave time and space for reflection in between, both by the stakeholders to build on their thoughts and ideas in subsequent workshops, but also by the research team to share and develop ideas further.

Disadvantages (also shown in Figure 6.7) of the online platform were mainly around the technology. These included connection issues and the use of new technology as a new way of working, such as Microsoft Teams and the interactive online whiteboard. Many reported difficulties in having normal free-flowing conversations due to the inability to pick-up on non-verbal cues, as well as potentially developing more of a relationship if it had been face-to-face. Some felt the dual discussions and chat text were at times distracting.

Figure 6.7 Stakeholder workshop evaluation

6.6 Discussion

6.6.1 Summary of findings

This chapter has outlined how stakeholder engagement through co-design methods generated ideas to inform the content of The COMBINED approach prototype. The stakeholders selected a BI, Moving Medicine, based on key aspects that were important to them and considered as fit-for-purpose. They offered insights into potential barriers to, and facilitators of, intervention implementation, which was an important first step for understanding what needs to be targeted to influence behaviour. Stakeholders also identified key recommendations for the intervention to be practical, relevant and acceptable to the target population, for example a simple, time-limited approach. These findings also helped to identify recommendations for supporting physiotherapists to deliver The COMBINED approach in practice, including training needs of the physiotherapists and content for components of The COMBINED approach to support implementation, for example, an infographic, scripts and resources.

A key finding from this study has been the identification of a complex range of factors with respect to the behaviour change of the physiotherapists to implement this approach in practice. The intention was to understand the physiotherapists' training needs to inform a training package prior to delivery of The COMBINED approach. Insights revealed the need for a greater focus on supporting the behaviour change of the physiotherapists to deliver the intervention beyond a training package. The need for a multi-level intervention was therefore required to target both patient-level behaviour change with respect to the modifiable health behaviours, and clinician-level

behaviour change with respect to implementation behaviours, through a comprehensive implementation strategy.

Key barriers to delivering The COMBINED approach in practice included the physiotherapists' lack of skills, such as health coaching, and lack of knowledge of the links between the lifestyle factors and shoulder pain and of resources or services to signpost the patient. This is consistent with other studies that found HCPs lacked the skills to deliver a behaviour change intervention or knowledge of the available resources, such as signposting information, to help facilitate behaviour change (Keyworth *et al.*, 2020a). Based on this, specific skills training and provision of signposting resources is a key area to support implementation of this approach.

A perceived lack of time was felt to be a barrier in the context of an already time-pressured consultation, meaning that delivering a health behaviour change intervention was not considered a priority. Time is the most cited barrier in the literature, consistent across all HCP groups and health behaviours (O'Donoghue *et al.*, 2014; Walkeden and Walker, 2015; Keyworth *et al.*, 2020a; Hartley, Ryad and Yeowell, 2023). Similarly, a perceived lack of prioritisation, with a tendency for HCPs to concentrate solely on disease management and presenting symptoms, has been previously reported (Keyworth *et al.*, 2020a). These findings are supported by several qualitative studies in which HCPs reported having tight schedules to see their allocated patients, making it challenging to address behaviour change while focusing on the primary problem (O'Donoghue *et al.*, 2014; Walkeden and Walker, 2015; Keyworth *et al.*, 2019).

As a potential facilitator, suggesting more time in consultations to deliver The COMBINED approach would be unrealistic. What is important is how this approach is framed to the physiotherapists: as integral to the management of a RC disorder, considering what we know about the lifestyle links with shoulder pain, rather than an add-on or additional task; and to replace passive, non-evidence-informed treatments, such as manual therapy, with current best practice. It is also important that the physiotherapist frames this approach accordingly to the patient as an important aspect of their 'physiotherapy' treatment, to manage expectations of what constitutes physiotherapy treatment.

The stakeholders in this study reported a lack of confidence as a barrier regarding their ability to have effective behaviour change conversations, particularly in relation to weight. Consistent with other literature that specifically involved physiotherapists, weight was also perceived to be more difficult to address and often approached from an exercise perspective (O'Donoghue *et al.*, 2014; Walkeden and Walker, 2015; Hartley, Ryad and Yeowell, 2023) or avoided altogether in some cases (Allison *et al.*, 2019). In one qualitative study 90% of the physiotherapists surveyed focused on exercise prescription in the management of overweight and obesity, rather than diet (O'Donoghue *et al.*, 2014). Other qualitative interview studies support the findings that raising the issue of weight was considered a sensitive topic, made easier by addressing it routinely with everyone (Holden *et al.*, 2019). How to effectively build the confidence of the physiotherapists to have lifestyle conversations, including weight, will need to be considered. The message needs to be clear that they are not expected to be experts in these health behaviours. Rather they are acting in a facilitating and empowering role to raise awareness of the links between the health

behaviours and their condition, strengthen motivations to change, build self-efficacy and signpost to expert services.

There was a negative perception from the physiotherapy stakeholders regarding how receptive patients would be to engage in lifestyle conversations and subsequently their interest and motivation to make positive behaviour changes. Other studies report similar findings that HCPs' perception of patient receptiveness influenced the likelihood of delivering interventions, reporting a general pessimistic view about the abilities, motivations and desire of the patients towards changing their health behaviour (Holden *et al.*, 2019; Keyworth *et al.*, 2020a). In several qualitative studies, HCPs believed most patients would find these conversations unacceptable and respond negatively (O'Donoghue *et al.*, 2014; Keyworth *et al.*, 2019). Highlighted by these findings, and in the literature, there appears to be a commonly held belief that patients do not want this information, would find it inappropriate and would lack the motivation to make positive changes. As a result, HCPs consciously decide whether to provide behaviour change advice based on these perceptions, rather than on patient need (Holden *et al.*, 2019; Keyworth *et al.*, 2019).

However, there was dissonance between the views of the physiotherapist and patient stakeholders. Patients did want these conversations, felt they were important, and acceptable. The patients' views in this stakeholder work are supported by research that suggests patients are receptive and find health behaviour change conversations positive, acceptable, appropriate, and helpful (Aveyard *et al.*, 2016; Keyworth *et al.*, 2020b). Based on the contrasting views between the physiotherapists and patients,

there is a need to address the physiotherapists' perceptions regarding this. This may be a useful motivational strategy, and facilitator, for the physiotherapists.

The physiotherapists perceived their own health behaviours as a potential barrier to delivering this approach and not knowing if healthy behaviours were perceived by the patient as positive or negative. Research has shown there is a greater likelihood of delivering behaviour change interventions if HCPs exhibit positive health behaviours themselves. For example, HCPs who are physically active are more likely to provide physical activity advice (Kunstler *et al.*, 2019; Bright *et al.*, 2021). Conversely, if the HCP perceived themselves as unhealthy, it was seen as damaging to the credibility of the information they provided to patients (Walkeden and Walker, 2015; Keyworth *et al.*, 2019). What is possibly more important is the skills, knowledge, and confidence to have effective health behaviour change conversations in a non-judgmental and empathetic manner, regardless of their own health behaviours.

The physiotherapists in this study described their own fear and anxiety as a barrier to having health behaviour change conversations, particularly in relation to offending or upsetting the patient, or negatively effecting the therapeutic relationship. This was a genuine fear through reported experiences of this happening in practice. Similarly, Keyworth *et al* (2019) found HCPs reported instances where behaviour change interventions affected therapeutic alliance, and therefore were cautious in discussing health behaviour change. They highlighted that this perhaps reflects a didactic understanding of health promotion, perceived as 'preaching'. Emphasising the role of the physiotherapist in a coaching capacity through training may give them the knowledge, skills, and confidence to effectively have these conversations in a non-

judgemental and empathetic way. Ensuring that physiotherapists are equipped with the knowledge regarding the specific links between the health behaviours and shoulder pain and subsequently the importance of this to managing their condition (as opposed to general health and wellbeing) may also be a key factor to initiating these conversations effectively (Keyworth *et al.*, 2019).

6.6.2 Study strengths

A strength of this study was the meaningful engagement with multiple stakeholders through co-design, generating a wide range of perspectives and rich insights that have informed the content of The COMBINED approach prototype. It is recognised that interventions tested in trials do not always change practice or impact on patient-relevant outcomes. Reasons for this can be the intervention is not acceptable, affordable or operationally feasible (Goodyear-Smith, Jackson and Greenhalgh, 2015). Co-design, placing those who will receive or deliver the intervention in practice at the core, has been key to addressing potential implementation barriers from the outset, with clear direction from the stakeholders for components to support implementation (Goodyear-Smith, Jackson and Greenhalgh, 2015; O'Cathain, Croot, Duncan, *et al.*, 2019).

The online platform for stakeholder engagement co-design was a new way of working for both the stakeholders and the research team. I had initial concerns regarding the ability to build relationships, maintain engagement and stimulate interaction in this environment, as well as the commonly reported issue of online 'screen fatigue' (Anh, Whelan and Umair, 2023). Furthermore, potential technology issues around access, connection and the skills required could lead to potential digital exclusion of some

stakeholders. However, evaluation of the platform was positive, with barriers of geographical distance, time burden, and access to venues overcome. As a result, the workshops were well attended by a range of stakeholders from different geographical areas, that perhaps wouldn't have been as wide-ranging if the workshops had been face-to-face. The strength of this was gaining a range of perspectives to inform the design of The COMBINED approach prototype.

Furthermore, interactive methods for communication such as the virtual whiteboard, enabled everyone to contribute ideas and all voices to be heard, aligned with the principles of co-design. The anonymous contribution of ideas helped overcome barriers for those who were less comfortable speaking in the group. Social desirability bias may also have been reduced where stakeholders offer perspectives based on what is perceived as favourable by the group or the research team, for example, overreporting the extent they integrate an assessment and management of lifestyle factors in practice.

6.6.3 Study limitations

There are limitations to this study that need to be acknowledged. Firstly, the intention to involve a range of key stakeholders was achieved, however there was a lack of attention paid to group diversity, for example, most stakeholders were female, and although data was not collected on ethnicity, a lack of ethnic diversity was noted by the group. The stakeholders reflected this may affect the relevance of this approach to other ethnic groups, for example, it was reported that some cultures view weight as a sign of health. To ensure The COMBINED approach is relevant and sensitive to a diverse range of cultures, efforts to increase diversity in the patient and public

involvement group to support the design of the patient-facing resources was a priority moving forwards.

Secondly, this was a mixed group of stakeholders including clinicians and patients. Potentially a hierarchical situation could have prevented the patient voice been heard. However, there did not seem to be any evidence of the clinicians dominating the conversations, with the patients appearing comfortable to voice their opinion throughout the workshops.

Thirdly, stakeholders volunteered to take part in the co-design workshops in their own time. It is likely this group were motivated and engaged individuals, and potentially more on board with this approach than others. Therefore, their views and recommendations may not be representative of other stakeholders.

6.7 Conclusion

Stakeholder engagement, through co-design methods have informed the design of The COMBINED approach prototype. These insights serve as a starting point for understanding what needs to be targeted to influence behaviour. A greater focus on HCP behaviour change is required to implement the approach in practice, necessitating a multi-level intervention targeting both patient- and clinician-level behaviour change. These insights will inform the design of a comprehensive implementation strategy. Including stakeholders' needs in the design process, particularly of those who will deliver and receive The COMBINED approach in practice, ensures for a more likely practical, and usable intervention in practice.

6.8 Chapter Summary

This chapter has described the process of stakeholder engagement with co-design methods as the first step in the design process of The COMBINED prototype. The next chapter describes the second step in the design process involving the mapping of the barriers and facilitators identified in this chapter using the COM-B model and TDF to systematically design and develop The COMBINED approach prototype.

Chapter 7 Designing The COMBINED approach – Part two: creating a prototype

7.1 Chapter Introduction

This chapter describes the translation of different sources of information and ideas to design and create the components of The COMBINED approach prototype, including findings from the stakeholder engagement co-design in workstream (WS) 2, Chapter 6, and input from patient and public involvement (PPI). It describes the systematic process of using behaviour change theory to map relevant behaviour change techniques (BCTs) to target the implementation barriers and facilitators from WS2. It also describes the decision-making process about intervention content, format and delivery to design specific intervention components. The first version of The COMBINED approach prototype is presented. A logic model of The COMBINED approach is also presented. Figure 7.1 shows where this chapter fits within the intervention development process.

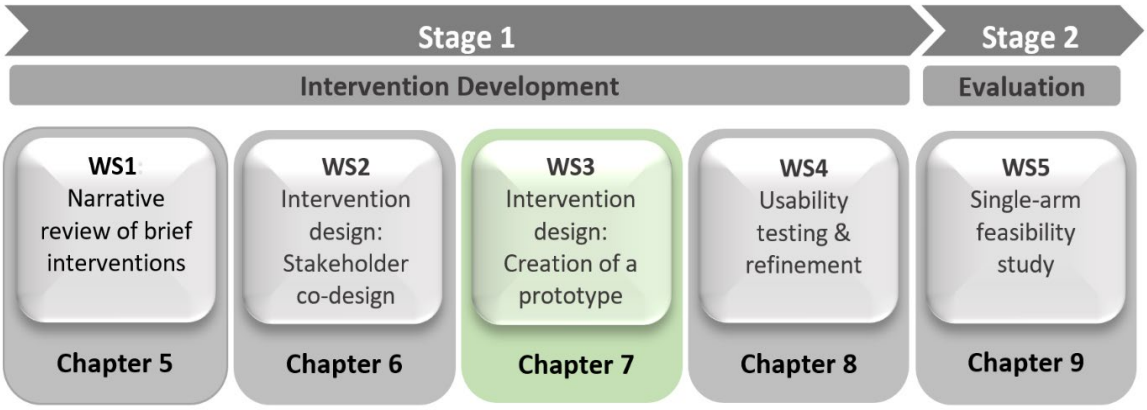

Figure 7.1 to show where this chapter fits within the intervention development process
WS, Workstream

7.2 Background

Part 2 of the design process involved the mapping of barriers and facilitators to the COM-B model and the Theoretical Domains Framework (TDF). BCTs were then selected to operationalise intervention components and create a prototype of The COMBINED approach (V1.0). The resulting prototype design was a multi-level intervention including: (1) A patient-level intervention – delivered by physiotherapists to target patient behaviour change with respect to the modifiable health behaviours; (2) A clinician-level intervention (a multi-faceted implementation toolkit) – delivered by the research team to target clinician behaviour change with respect to implementation.

The multi-faceted 'implementation toolkit' was designed alongside the patient-level intervention and refers to a collection of comprehensive strategies, resources and materials to support the physiotherapists effectively deliver The COMBINED approach in practice. The implementation toolkit intends to improve the knowledge, skills and confidence of the physiotherapists to deliver The COMBINED approach, and to ensure the intervention is delivered as intended.

Each component within the prototype was designed or developed in a different way, some of which were already developed, for example, the BI as part of Moving Medicine. Other components were adapted, for example, the patient resources as part of Moving Medicine, or designed from their inception, such as the infographic in the implementation toolkit. For ease of explanation, this chapter will present the design process by component, rather than reporting by methods and findings.

7.3 Workstream Three Aim & Objectives

The aim of this workstream was to design and create a prototype version of The COMBINED approach (Thesis objective 4, Chapter 1, section 1.4).

Objectives included to:

1) Translate findings from different sources and information to design intervention components for a patient-level and clinician-level intervention;

2) Use behaviour change theory to (i) systematically map implementation barriers and facilitators to domains of behaviour and (ii) identify and select appropriate BCTs to inform intervention components within an implementation toolkit;

3) Develop intervention components, including adapting resources and developing new components;

4) Develop a logic model of The COMBINED approach, including proposed mechanisms of action and outcomes.

7.4 Patient-level intervention

The patient-level intervention includes the following integrated components:

- A BI based on the Moving Medicine resource to identify, assess and target the key lifestyle factors smoking, overweight/obesity and physical inactivity
- A shoulder assessment and treatments based on the principles of the Best Practice Advice (BPA) intervention from the GRASP trial (Chapter 2, section 2.2.2)

- Patient resources to support behaviour change, including an activity workbook for action-planning, and self-monitoring diaries for each of the health behaviours.

7.4.1 The Brief Intervention - Moving Medicine

Moving Medicine is an online resource aimed at supporting healthcare professionals (HCPs) to have person-centred conversations with patients about physical activity (*Moving Medicine*, n.d). Using a time-based framework, the conversations include a 1-minute, 5-minute and more-minute conversation. The conversations and resources are also condition-specific, including for musculoskeletal pain. Details of how Moving Medicine was developed was published after the narrative review (Chapter 5) and stakeholder workshops (Chapter 6). Moving Medicine was developed using a rigorous mixed methods user centric approach, using co-design, literature review and a Delphi study. Moving Medicine was also informed by the Behaviour Change Wheel, a theory- and evidence-based intervention development approach (Reid, Caterson, *et al.*, 2022a, 2022b; Reid, Smith, *et al.*, 2022). The theory- and evidence-based resources include resources for the HCP, including scripts to support the conversation, and patient resources, including an activity workbook to support action-planning and self-monitoring diaries. The resources are freely available.

The 5-minute conversation was selected as the basis of the BI in The COMBINED approach. The 1-minute conversation was designed to initiate a conversation about physical activity when the clinician had little time but would include inviting the patient to discuss physical activity at their next appointment. The more-minute conversation would not be feasible to deliver within a routine physiotherapy

consultation, based on the key recommendations from the stakeholders in Chapter 6. Evidence also suggests that BIs of five minutes or longer, are more effective at initiating behaviour change than shorter BIs (NICE, 2013).

The 5-minute conversation is based on a three-step framework engage, explore, decide, to build readiness to change and support planning for change, shown in Figure 7.2.

ENGAGE	Open the conversation	*"Would you be happy to spend 4-5 minutes talking about something that can make a big difference to your future health and wellbeing?"*
	Assess impact of the condition	*How has your condition affected your physical activity levels and the things you enjoy?*
EXPLORE	Find out what they already know	*"What do you know about the benefits of physical activity in people with your condition?"*
	Share benefits	*Can I share some other things people find beneficial to see what you make of them*
	Encourage reflection	*"What do you make of what I have just said?"*
	Make it personal	*"What would be the top 2-3 reasons for you personally becoming more active, if you decided to?"*
DECIDE	Summarise without adding anything new	*"Can I summarise what I think you have said?"*
	Ask the key question	*'So, what do you think you will do?'*
	Agree a plan	*"Can I share with you some things people find helpful when making a plan?"*
	Arrange follow up	*"How would you feel about coming back another time to build on the thoughts and ideas you've shared with me today?"*
	Signpost support organisations	*"There are some great, free resources available here and on other websites by people who understand what it's like living with your condition if you'd be interested to have a look"*

Figure 7.2 Structured framework of the 5-minute conversation
Source: *Moving Medicine*, n.d.

The 5-minute framework was used as the basis for the BI with some tailoring of the conversation to fit with the context of RC disorders and the other two lifestyle factors,

smoking and overweight/obesity. The key elements of the person-centred conversation, which were embedded as part of The COMBINED approach were to:

- Ask-Share-Ask - ask permission, find out what the patient already knows, ask what they make of what you have just said;
- Make it personal – explore personal motivations to change;
- Summarise the conversation;
- Agree a plan;
- Arrange follow-up;
- Signpost

These elements are based on motivational interviewing (MI) principles (previously described in Chapter 2, section 2.4.1), and are key to having a non-judgemental, person-centred conversation. The framework also links to a script on the website to support HCPs to have physical activity conversations. The script is part of the implementation toolkit and will be discussed in that section.

The two patient resources described above needed to be adapted to supporting smoking cessation and a healthy diet, which I did using credible sources such as NHS websites. These were also reviewed by the supervisory team (examples are provided in Appendices G-H). The resources were adapted with permission from, and subsequently reviewed by, the Moving Medicine team.

7.4.2 The Best Practice Advice (BPA) intervention

The BPA intervention evaluated in the GRASP trial (Hopewell et al., 2021), is considered current best evidence (discussed in Chapter 2, section 2.2.3). The BPA included a single face-to-face 60-minute session with a physiotherapist and included:

- A shoulder examination;
- A set of simple self-guided exercises, supported by a video resource, with instruction of how to progress or regress the exercises;
- A detailed advice booklet for self-management;
- Exercise action planner diary.

At the time of development of The COMBINED approach, the GRASP trial had only just been published and the resources were not freely available. I had been involved in the GRASP trial as a site Principal Investigator and knew the content of the BPA intervention. As the resources were not available, I drew on principles of the BPA intervention to inform the patient-level intervention. The shoulder-focused treatments included:

- Reassurance – relating to the diagnosis and prognosis of their condition;
- Education – on their condition, including what a RC disorder is and the management strategies;
- A progressive loaded exercise programme – up to three exercises, with instructions for progression and regression;
- Self-management advice – including on pain management, sleep and activity modification.

These principles were included in the training package for the physiotherapists (section 7.5.2).

How the BI and BPA were integrated in a routine physiotherapy consultation will be covered in the step-by-step-guide as part of the clinician-level intervention.

7.5 Clinician-level intervention – Implementation toolkit

As described, the clinician-level intervention was a multifaceted implementation toolkit to support physiotherapists deliver The COMBINED approach in practice. The components of the implementation toolkit were designed in a systematic process, underpinned by behaviour change theory. The first step involved a mapping process to build the intervention content including: (1) mapping the barriers and facilitators identified in the stakeholder engagement workshops (Chapter 6) to the COM-B model for an initial behavioural analysis. This was followed by using the TDF to gain a detailed understanding of the behavioural domains influencing implementation of The COMBINED approach and identifying the theoretical constructs to target for change; (2) mapping the behavioural domains to evidence-based BCTs using the Behaviour Change Technique Taxonomy V1 (BCTTv1) to target the behavioural domains and specify intervention content (Michie *et al.*, 2008; Michie, Richardson, Johnston, Abraham, *et al.*, 2013) (discussed in Chapter 2, section 2.5). The BCTs were the 'active ingredient' of the intervention (Michie, Atkins and West, 2014). The BCT taxonomy and definitions can be found at https://www.bct-taxonomy.com/.

To facilitate the mapping process, I developed a matrix in Microsoft excel (Table 7.2, section 7.5.1). The completed matrix was reviewed by two experts in behaviour

change, a health psychologist and behavioural scientist, to verify the decisions made in the mapping process.

Following the mapping process, once the BCTs had been selected to construct the intervention content, the next step was to identify how the content (each BCT) would be operationalised and how it would be delivered to the intended target population. This was informed predominantly by the views and preferences expressed by the stakeholders in the workshops, for example, a preference for a face-to-face workshop, and specific requirement for an infographic and scripts. The content was also informed by pragmatic decisions made by the research team such as the time and practicality to design components. Decisions were made on the final intervention components during meetings with the supervisory team. The decision-making process in selecting intervention components was informed by the APEASE criteria (Acceptability, Practicability, Effectiveness, Affordability, Safety, and Equity) for designing and evaluating interventions.

APEASE is a framework to guide an assessment of, and therefore decisions about, proposed intervention components (Michie, Atkins and West, 2014; Public Health England, 2019). The APEASE criteria are shown in Table 7.1. The different criterion reflects that intervention design is not just about evidence of effectiveness when selecting intervention components, but other criterion, such as acceptability and practicability are important considerations for future implementation. It is recognised there is an element of subjectivity when making decisions using the APEASE criteria, but the framework offers a tool for transparent decision-making. While other decision-making criteria exist to help prioritise intervention components, such as

MoSCoW (Must have, Should have, Could have, Won't have) (Kuhn 2009) the APEASE criteria was selected for both its comprehensive evaluation and focus on implementation in intervention design. The APEASE criteria was used pragmatically, as not all criteria were relevant to assessing each intervention component.

Table 7.1 APEASE criteria for assessing interventions, intervention components & ideas

Criterion	Description
Affordability	How far can it be afforded when delivered at the scale intended? Can the necessary budget be found for it? Will it provide a good return on investment?
Practicability	Can it be implemented at scale within the intended context, material and human resources? What would need to be done to ensure that the resources and personnel were in place, and is the intervention sustainable?
Effectiveness & cost-effectiveness	How effective is the intervention in achieving the policy objective(s)? How far will it reach the intended target group and how large an effect will it have on those who are reached?
Acceptability	How far is it acceptable to key stakeholders? This includes the target group, potential funders, practitioners delivering the interventions and relevant community and commercial groups.
Side-effects/ safety	What are the chances that it will lead to unintended adverse or beneficial outcomes?
Equity	How far will it increase or decrease differences between advantaged and disadvantaged sectors of society?

Reproduced from Public Health England, 2019, pp. 15-16, Table 1

In addition to using APEASE, BCTs were added or removed following the refinement phase of the intervention development, reported in Chapter 8.

7.5.1 Mapping process and selection of intervention components

Table 7.2 shows the matrix table of the mapping process described above, including the barriers and facilitators mapped to the TDF domains, the BCTs to target the domains and the selected intervention components based on the APEASE criteria.

Twelve domains from the TDF were identified as necessary for HCP behaviour change. The mapping process identified 20 out of a possible 93 BCTs to target the 12

behavioural domains. The most frequently selected BCTs included: instruction on how to perform the behaviour, demonstration of the behaviour, behavioural practice/rehearsal, feedback on the behaviour, prompts/cues, framing/reframing, persuasive communication, information about others' approval and verbal persuasion about capability.

The mode of delivery was predominantly through an interactive training workshop (and training pack), to include specific skills training and a practical session to put these skills into practice. The remaining BCTs were delivered through the provision of supporting resources and educational materials.

Table 7.2 Mapping process and selection of intervention components

Barriers / Facilitators	**TDF Domain (Michie *et al*, 2005)**	**BCTs (labels from BCTTv1 Michie *et al*., 2013)**	**Operationalised BCT**	**Mode of delivery/format**	**Meets APEASE criteria**
Physiotherapists lack skills to deliver this approach including coaching, person-centred communication and behaviour change skills Provision of study-specific skills training, patient simulations and scripts	Cognitive and interpersonal skills	4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour 8.1 Behavioural practice/rehearsal 8.7 Graded tasks 2.2 Feedback on behaviour 1.2 Problem solving 7.1 Prompts/cues 3.1 Social support	Provide training to upskill physiotherapists in study-specific skills Provide observable examples of these skills in practice Provide opportunity to practice skills, starting with easy to perform tasks and increasing difficulty Provide feedback to the physiotherapists on their performance Provide opportunity for problem-solving Provide scripts to support the conversations in practice	Training workshop (face-to-face) Training pack Example role play videos of different scenarios Role-play simulations in the training Scripts	Yes (acceptable, practical, affordable)

Physiotherapists lack knowledge regarding the links/mechanisms between the lifestyle behaviours and shoulder pain Education to raise awareness of the links/mechanisms	Knowledge	4.1 Instruction on how to perform a behaviour 5.1 Information about health consequences 3.1 Social support	Provide evidence-based education about the links	Training workshop (face-to-face) Training pack	Yes (acceptable, practical, affordable)
Physiotherapists lack understanding and knowledge of patient resources to support these conversations and where to signpost the patient to Provision of patient resources Education and raised awareness of services available to signpost to	Knowledge Memory, attention and decision processes	4.1 Instruction on how to perform a behaviour 7.1 Prompts/cues 3.1 Social support	Provide physiotherapists with resources to support the conversations Provide a menu of support services to signpost the patient to, relevant to each health behaviour	Training pack and patient pack to include supporting patient resources & signposting information	Yes (acceptable, practical, affordable)
Physiotherapists lack knowledge and skills to summarise the health behaviour links in lay terms to patients Easy to explain information for the patient	Knowledge Cognitive and interpersonal skills Memory, attention and	4.1 Instruction on how to perform a behaviour 7.1 Prompts/cues 12.5 Adding objects to the environment	Provide education to highlight the health behaviour links and to support the conversation with the patient Provide a resource to support the conversation	Training workshop/pack Infographic to visually highlight the health behaviour links and aid the	Yes (acceptable, practical, affordable)

	decision processes	3.1 Social support		conversation with the patient	
Doesn't happen in routine practice Make it a standardised/structured approach; normalise into every assessment	Behavioural regulation	4.1 Instruction on how to perform a behaviour 7.1 Prompts/cues 8.3 Habit Formation	Provide a standardised assessment and structured approach Provide opportunity to practice skills	Step-by-step guide to highlight the structure of the consultations Role play scenarios in training	Yes (acceptable, practical, affordable)
Lack of availability/access to local support services Better links to gyms, commercial weight management groups, smoking cessation services	Environmental context and resources	4.1 Instruction on how to perform a behaviour 12.2 Restructuring the social environment	Provide information regarding availability of local services and access times Engage with local services to create better links	Information pack Communication with local services	No – not practical to understand all local contexts
Organisational barriers may hinder integration of BIs into physiotherapy consultation	Environmental context and resources	1.2 Problem solving 3.1 Social support	Identify individual organisational barriers to integration	N/A	No - not practical during intervention design, but will be

Identify these organisational barriers and how to overcome them					explored during evaluation
Time-limited consultations Having a simple, time-limited, structured approach; scripts to support the conversation; utilise pre-appointment time e.g. self-assessment forms, letters, patient information in waiting rooms	Environmental context and resources	4.1 Instruction on how to perform a behaviour 12.1 Restructuring the physical environment 7.1 Prompts/cues 13.2 Framing/reframing 3.1 Social support	Design a simple, time-limited, structured approach Provide supporting physiotherapy resources and educational materials for brief, but good-quality conversations Key messages as part of the training regarding current best practice for the management of RC disorders	Training workshop/pack Step-by-step guide Scripts	Yes (acceptable, practical, affordable) – except sending out pre-appointment information which is dependent on local context and impractical)

Perception of a change to current role; threat to identity of the 'traditional' physiotherapist Skills training; driving a change in thinking and practice Reframing what is 'traditional' physiotherapy	Beliefs about capabilities Professional role and identity	13.2 Framing/reframing 6.3 Information about others' approval 9.1 Credible source 15.1 Verbal persuasion about capability 13.5 Identity associated with changed behaviour	Deliver key messages as part of training to reframe the focus of 'traditional physiotherapy' and RC management Use a credible source to reinforce the key messages Challenge physiotherapists to consider their identity associated with changed behaviour	Training workshop Pre-recorded video from a credible source, to include in the training	Yes (acceptable, practical, affordable)
Beliefs that initiating these conversations will be hard/ they will be delving into something complex Conversation starters and having a 'way-in', e.g., the links with the shoulder pain and pre-appointment information to patients to pre-empt these conversations including having an environment that promotes information regarding healthy lifestyles	Beliefs about capabilities Beliefs about consequences Professional role and identity	4.1 Instruction on how to perform a behaviour 1.2 Problem-solving 7.1 Prompts/cues 12.1 Restructuring physical environment 12.5 Adding objects to the environment 15.1 Verbal persuasion about capability	Provide training to upskill physiotherapists in study-specific skills Provide observable examples of these skills in practice Provide opportunity to practice skills, starting with easy to perform tasks and increasing difficulty Provide feedback to the physiotherapists on their performance	Training workshop (face-to-face) Training pack Example role play videos of different scenarios Role-play simulations in the training Scripts Step-by-step guide	Yes (acceptable, practical, affordable)

Clear structured assessment/questions; scripts Self-belief/confidence in approaching patients (particularly in relation to weight); lack of ability to have these conversations Mentoring/support; study specific skills training, problem-solving around different clinical scenarios Communication to address misbeliefs	6.1 Demonstration of the behaviour 8.1 Behavioural practice/rehearsal 2.2 Feedback on behaviour 6.3 Information about others' approval 13.2 Framing/reframing 3.1 Social support 4.4 Behavioural experiments	Provide opportunity for problem-solving Provide scripts to support the conversations in practice Deliver key messages as part of training that you don't need to be an expert in smoking cessation, weight loss or physical activity to provide effective brief advice Provide positive affirming patient feedback from the stakeholder workshops as part of training to address misbeliefs Provide supporting physiotherapy resources and educational materials including scripts/ conversation starters, pre-appointment patient information offering a 'way-in' and a step-by-step guide	Infographic as above Post training 1:1 online support

			Ask physiotherapists to bring up the subject of health behaviour change (after training) and to note/monitor the patient's reaction to this (annoyed, defensive, happy) – particularly in relation to weight Offer ongoing support to the physiotherapists post-training		
Belief that it may undermine the therapeutic alliance/ negatively effect rapport Communication skills training on how to have these conversations in a non-judgemental way An approach of 'we do this with everyone', rather than targeted at individuals	Beliefs about consequences Professional role and identity	4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour 8.1 Behavioural practice/rehearsal 2.2 Feedback on behaviour 15.1 Verbal persuasion about capability 6.3 Information about others' approval	Provide study-specific skills training (as above) Provide positive affirming patient feedback from the stakeholder workshops as part of training Provide a standardised approach and language to ensure this is approached in a non-judgemental/ targeted way Ask physiotherapists to bring up the subject of health behaviour change	Training workshop/ pack – with patient feedback included Step-by-step guide Scripts	Yes (acceptable, practical, affordable)

		4.4 Behavioural experiment 3.1 Social support	(after training) and to note/monitor the patient's reaction to this (annoyed, defensive, happy)		
Perceptions of the physiotherapists regarding patient's beliefs including they: (i) don't want to change behaviour/won't adhere to it; (ii) wouldn't expect it or want to discuss health behaviour change with a physiotherapist in this context (referral to physiotherapy for a shoulder problem); (iii) won't understand the links between their health behaviours and their shoulder problem; (iv) would not meet expectations of what they have come to physiotherapy for e.g., shoulder-specific rehabilitation; (v) will become defensive	Beliefs about consequences Professional role and identity	4.1 Instruction on how to perform a behaviour 6.3 Information about others' approval 15.1 Verbal persuasion about capability 13.2 Framing/reframing	Provide positive affirming patient feedback from the stakeholder workshops as part of training to address misbeliefs Deliver key messages as part of training to reframe the focus of 'traditional physiotherapy' and RC rehabilitation and the potential benefits to patients in this new approach	Training workshop/pack	Yes (acceptable, practical, affordable)

Positive reaffirming quotes from patients/case studies that patients are receptive and find this acceptable to create more positive beliefs Reframing what is viewed as 'physiotherapy treatment'					
Physiotherapist's perceptions and concerns about being role models to enable the conversation Skills training on how to have non-judgemental conversations regardless of own health behaviours	Beliefs about consequences Professional role and identity	13.1 Identification of self as a role model 15.1 Verbal persuasion about capability 4.1 Instruction on how to perform a behaviour 6.1 Demonstration of the behaviour 8.1 Behavioural practice/rehearsal 2.2 Feedback on behaviour 3.1 Social support	Training to include skills in non-judgemental conversations Verbal messages that own behaviour may be an example to others Provide patient feedback from the stakeholder workshops as part of training	Training workshop/pack	Yes (acceptable, practical, affordable)

Health behaviour change is not a priority Educate on the links and potential importance/benefits of including health behaviour change as part of the management plan for RC disorders; get individual buy-in; capitalise on the 'excitement' around this	Goals Intentions Optimism	4.1 Instruction on how to perform a behaviour 13.2 Framing/reframing 15.1 Verbal persuasion about capability 8.3 Habit formation	Education on the links specifically with RC disorders, and not just non-communicable disease/general health Framing/reframing what constitutes 'treatment' and this approach is part of that, not an add-on if time – how to 'sell' this approach to patients and manage their expectations	Training workshop/pack	
Fear/anxious about litigation, complaints from the patient, undermining the therapeutic alliance or upsetting the patient Positive reaffirming quotes from patients/case studies that patients are receptive and find this acceptable to create more positive beliefs; Be extremely clear with patients about why these issues are important and of direct relevance to their shoulder condition;	Emotion	15.1 Verbal persuasion about capability 13.2 Framing/reframing 4.1 Instruction on how to perform a behaviour 4.4 Behavioural experiment 3.1 Social support	Provide positive affirming patient feedback from the stakeholder workshops as part of training Reinforce the health behaviour links/evidence in the training and to clearly communicate to patients why the physiotherapist is asking these questions Ask physiotherapists to bring up the subject of health behaviour change (after training) and to note/monitor the patient's	Training workshop/pack Step-by-step guide – particularly setting the scene	Yes (acceptable, practical, affordable)

		reaction to this (annoyed, defensive, happy) Reinforce key messages to the patient regarding the things they can do to help their shoulder pain Build case studies (post intervention delivery) of how this is received by patients/examples of good practice

TDF, Theoretical Domains Framework; BCT, Behaviour Change Technique; APEASE, Affordability, Practicability, Effectiveness, Acceptability, Side-effects/Safety, Equity; RC, Rotator Cuff

7.5.2 Development of the implementation toolkit prototype

The next step was to develop a prototype of the intervention components. Each component will now be described in turn.

Training package

A theoretically informed training package based on the BCTTv1 (Michie, Richardson, Johnston, Abraham, *et al.*, 2013) was developed and included a 3-4 hour face-to-face practical, skill-based training workshop, a training pack and the offer of 1:1 support post training. I developed the content of the training package, reviewed by the supervisory team. The content of the training package linked to the BCTs is shown in Table 7.3.

Table 7.3 Theoretically informed components of the training package

Training component	Application of BCT in training package
A power point presentation: • Background to the study – RC disorders; evidence for lifestyle factors and links with RC disorders; principles of BPA; BIs; study aims • Development of the intervention • Health coaching/MI approaches • What The COMBINED approach is – the intervention components • How to deliver The COMBINED approach • Study procedures	**4.1 Instruction on how to perform a behaviour** E.g., verbal and written instructions were given on how to deliver The COMBINED approach, including the BI using MI techniques **5.1 Information about health consequences** E.g., verbal and written instruction was given about the potential health consequences of delivering The COMBINED approach to patients **13.2 Framing/reframing** E.g., reframing what the focus of 'traditional physiotherapy' is and what is perceived as 'treatment' **15.1 Verbal persuasion about capability** E.g., encouraging the physiotherapists they can successfully deliver The COMBINED approach **13.5 Identity associated with changed behaviour** E.g., challenging the participants to consider their identity associated with new behaviours (integrating a BI into practice)

	13.1 Identification of self as a role model E.g., encouraging the participants to be a role model for patients and other clinicians
Freely available videos on MI	**4.1 Instruction on how to perform a behaviour** Videos on the principles of MI and delivery of MI skills in practice
Practical session on MI components	**4.1 Instruction on how to perform a behaviour** Verbal and written instructions were given on principles of MI and how to put into practice **8.1 Behavioural practice/rehearsal** Participants practiced MI skills in groups of three (one person wanting to change a behaviour; one person practicing MI skills; one person providing feedback) **8.7 Graded tasks** Role play interactions became increasingly more complex e.g. the first exercise included asking open-ended questions, exploring personal motivations to change and offering affirmations. The second exercise added further components of MI, such as reflections and summarising **2.2 Feedback on behaviour** Participants received and gave feedback on their MI skills in role play by peers and the trainers **1.2 Problem solving** E.g., participants discussed any challenges they faced in the practical exercise
Role play videos (developed with a PPI member)	**6.1 Demonstration of the behaviour** Video examples of delivery of The COMBINED approach **1.2 Problem-solving** Different clinical scenarios in the video examples, e.g., a defensive patient
A video from an internationally renowned shoulder expert endorsing The COMBINED approach principles	**6.3 Information about others' approval** Visual communication about what others' think about The COMBINED approach **9.1 Credible source** Visual communication from a credible source

Training pack, including: • Power point slides • Patient resources (activity workbook and self-monitoring diaries) • Supporting clinician resources (e.g., infographic, step-by-step guide, scripts, signposting information) • Study procedures • Role play videos • Signposting to the Moving Medicine website for further information	**7.1 Prompts/cues** E.g., information provided to prompt the behaviour (delivery of The COMBINED approach)
Online top-up training session (optional)	**3.1 Social support** Ongoing support provided online to recap on any information or discuss any concerns

BCT, Behaviour Change Technique; RC, Rotator Cuff; BPA, Best Practice Advice; MI, Motivational Interviewing; BI, Brief Intervention

Step-by-step guide

A step-by-step guide was developed to support the physiotherapists deliver The COMBINED approach. This outlined the processes to follow including the identification, assessment and management of the lifestyle factors integrated with their usual assessment procedures for a RC disorder. It also incorporated the key elements of the BI and person-centred communication. The guide directed the physiotherapist to other resources, such as the infographic to discuss the lifestyle links with shoulder pain and the signposting information (discussed below). I initially developed the guide, with input from the supervisory team and PPI. Specifically, the patient-directed language under setting the agenda and discussing treatment options were discussed with the PPI group for appropriateness. The PPI group requested a change from setting the scene with "I'd like to ask you some questions about your shoulder pain, as well as your **lifestyle factors**" to **'other things in your life'**. The step-by-step guide is shown in Figure 7.3.

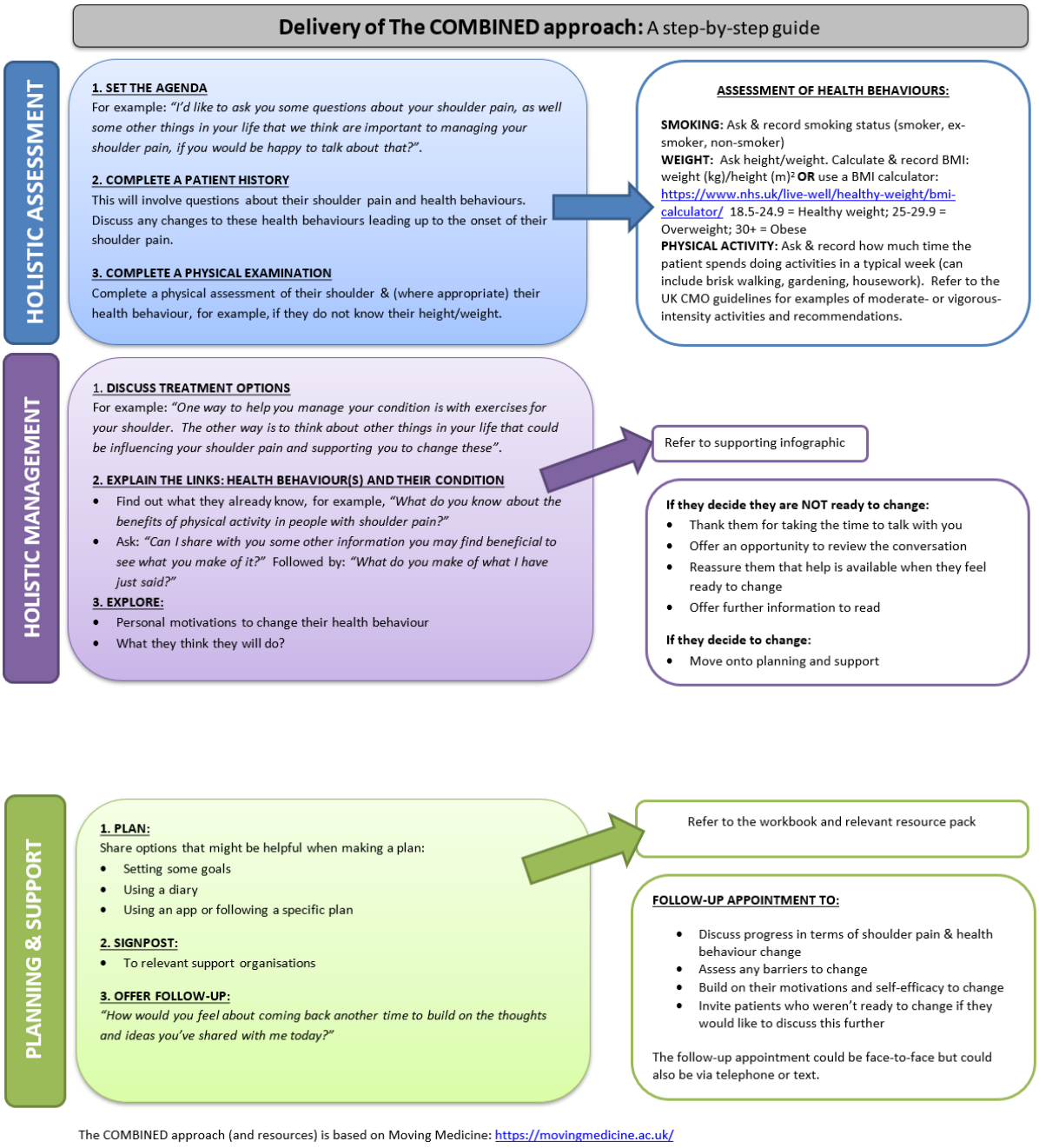

Figure 7.3 Step-by-step guide to delivering The COMBINED approach

Scripts

The scripts were based on the BI framework shown in Figure 7.2 to further support the conversations by the physiotherapists and were available as a resource from Moving Medicine. It included key conversation starters, identified in the stakeholder workshops (Chapter 6) and key elements of person-centred communication. The scripts were adapted for relevance to shoulder pain and the specific health behaviours. For example, the original wording stated, *"Would you be happy to spend 4-5 minutes talking about something that can make a big difference to your **future health and wellbeing**?"*. This was changed to *"Would you be happy to spend 4-5 minutes talking about something that can make a big difference to your **shoulder condition**?"*. Where it referred to the health behaviour change as increasing physical activity, this was adapted to insert any of the relevant health behaviours where applicable, for example, stopping smoking. The script is included in Appendix I.

Infographic

An infographic to highlight the links between shoulder pain and the health behaviours in a simple way was highlighted as a key component in the stakeholder workshops (Chapter 6; WS2) to support physiotherapists deliver The COMBINED approach by: 1) displaying the infographic in waiting areas for patients to pre-contemplate the link and avoid this being a surprise during the consultation; 2) offering 'a way-in' with the conversation between the physiotherapist and patient, using the infographic as a prompt for further detail about the patient-specific health behaviours and the links with shoulder pain. It would also be provided to patients as a resource to summarise the key links. The infographic is both patient- and clinician-facing, however it was considered as part of the physiotherapist's implementation

toolkit as this was a key implementation facilitator highlighted by the physiotherapist stakeholders in the workshops.

The infographic was designed with input from PPI. PPI was involved throughout all stages of the research in this thesis, in line with the NIHR standards for PPI in research (NIHR, 2019), but they were particularly integral to this stage. The iterative process of development with the PPI group is now reported using the GRIPP2 short form (Staniszewska *et al.*, 2017).

The PPI group

1. Aim

To support the design of an infographic, as well as review other patient-facing study documents for the refinement stage (Chapter 8). To create a diverse PPI group to ensure the infographic and patient-facing information are culturally sensitive and relevant - feedback from the stakeholder workshops (Chapter 6) reported a lack of patient diversity, particularly in relation to ethnicity. The stakeholders felt a diverse patient perspective was important as certain lifestyle factors are perceived differently by different cultures, for example, weight is seen as a sign of health in some cultures and therefore The COMBINED approach may not be relevant or sensitive.

2. Methods

Efforts to achieve a diverse PPI group included seeking advice and support from the Yorkshire and Humber Research Design Service (RDS). The RDS shared information with existing PPI groups in the Yorkshire & Humber Clinical Research Network and ethnic minority

groups via email. Posters were also emailed to the following groups to be displayed in local community areas:

- Deep End Group – Yorkshire & Humber ethnic minorities in research group;
- Manchester City Council;
- Black Asian and Minority Ethnic Research Advisory Group (BRAG);
- Black and Minority Ethnic – Manchester BME Network;
- Queer Black, BAME and POC Charities, Organisations and Community Groups.

Nine public contributors volunteered to be part of the PPI group. To focus on the infographic design ideas, two online meetings were held, lasting two hours each. Demographic details of the group were taken to evaluate the diversity of the group (Table 7.4). The details were not linked to any identifiable data such as their name, and were stored on my university OneDrive, which only I had access to. In addition, three members volunteered information that they had autism and could offer a neurodiverse perspective.

Table 7.4 Patient & Public Demographic Data

Age	Gender	Ethnicity	Employment
62	Female	White British	Retired
65	Male	White English	Carer
76	Female	White British	Retired
51	Female	White British	Volunteer
65	Female	White British	Retired
44	Female	White other	Full-time employed
64	Male	White British	Part-time employed

61	Female	White British	Retired
46	Female	Asian British Pakistani	Unemployed

The infographic was designed in an iterative process. In the first meeting, the group were presented with information on the links between the health behaviours and shoulder pain, including the inflammatory systemic mechanisms underpinning this. They were also briefed on what an infographic is, with examples, and what the specific purpose of the infographic was in this study.

They were then presented with examples of general infographics to discuss what they liked/didn't like regarding the design, colour schemes, fonts, images/pictures and balance of images and text. We then discussed the actual content and wording of the information to go on the infographic. This information informed a first draft of an infographic, along with general guiding principles of infographic design, for example, to use a maximum of 3-5 colours, use colours with consistency and purpose, limited fonts and to create a visual analogy (ARC West Seminar, 2022; Social Research Association Training Course, 2021).

3. Results

The key feedback from the PPI members included:

- To start with a question to draw attention or a call to action;
- To use colours in a traffic light system - red to highlight behaviours you don't want, through to green for the behaviours you do want;

- Use an image as a focal point to reinforce the message that there are links between the health behaviours and shoulder pain;
- To not include text detail on systemic inflammation, but to leave this for the physiotherapist to go through in the consultation, tailored to the individual patient needs and preferences for further information;
- To be simple and eye-catching with minimal writing on it;
- Use of cartoon style figures or icons, rather than images;
- To share a positive message – what can be done rather than what shouldn't be done;
- Important to get across this is a treatment partnership between the physiotherapist and the patient and you are going to tackle these factors together;
- Narrative needs to be about the patient taking responsibility for their own health in a non-judgemental way.

Several designs were put together incorporating the ideas and thoughts generated. These were presented at the second meeting and the features were discussed including what they liked/didn't like from each design until they were merged into one final design. The final infographic design is shown in Figure 7.4.

4. Discussion and conclusions

PPI was effective in designing an infographic and influenced all aspects of the infographic.

5. Reflections/critical perspective

The group worked well together and offered insightful feedback. Several of the members were experienced PPI members, which helped. Despite efforts to create a diverse PPI group, the majority were female and White British. Additional strategies are required in the future to enhance diversity further.

Figure 7.4 Infographic design

Signposting to support services

A lack of knowledge of support services to signpost the patient to was identified as a barrier to implementation of The COMBINED approach in the stakeholder workshops (Chapter 6). This resource is patient-facing, however as it was a key facilitator to implementation it was considered as part of the implementation toolkit. Support services, relevant to each health behaviour, was collated and developed into a signposting resource using information available as part of Moving Medicine (*Moving Medicine*, n.d.), Make Every Contact Count (MECC) link (*MECC Link*, n.d.) and NHS websites, such as eat well (NHS, n.d.).

The intention to include national signposting was for applicability to different geographical locations in the refinement stage (Chapter 8) and feasibility study (Chapter 9), and for practicality rather than identifying local support services. In addition to the resource, the physiotherapist could signpost the patient, where applicable, to local services. The signposting resource is shown in Figure 7.5.

Patient Support Services

Stop Smoking Support

- Call the free '**Smoke-free'** National Helpline to speak to a trained, expert adviser on 0300 123 1044. Smoke-free has lots of free support including a smartphone app, email programme or text messages that will keep you focused wherever you are.
- You can also speak to your doctor, pharmacy team or local Stop Smoking Service for expert advice on stop smoking medicines.
- Get further information from the National Health Service https://www.nhs.uk/better-health/quit-smoking/ including help to find a local Stop Smoking Service.

Healthy Diet Support

- The Public Health England **'One You'** Website contains a wealth of information on different food choices and healthy recipes https://www.nhs.uk/live-well/eat-well/
- Download the '**NHS weight loss guide'**, a free 12-week diet and exercise plan https://www.nhs.uk/live-well/healthy-weight/start-the-nhs-weight-loss-plan/
- Visit the healthy eating page on the **'Change for life'** website which has loads of great information about food and drink swaps for a healthier diet https://www.nhs.uk/change4life/food-facts and an extensive list of recipes https://www.nhs.uk/change4life/recipes
- Try the **'Be Food Smart app'!** See how much sugar, sat fat and salt is really inside your food and drink - just by scanning the barcode from your mobile phone.
- Get further information from the National health Service https://www.nhs.uk/better-health/lose-weight/ on commercial and local authority healthy lifestyle services. Your GP surgery may refer you to other services, such as **local weight loss groups**. These could be provided by the NHS, or may be commercial services that you pay for.

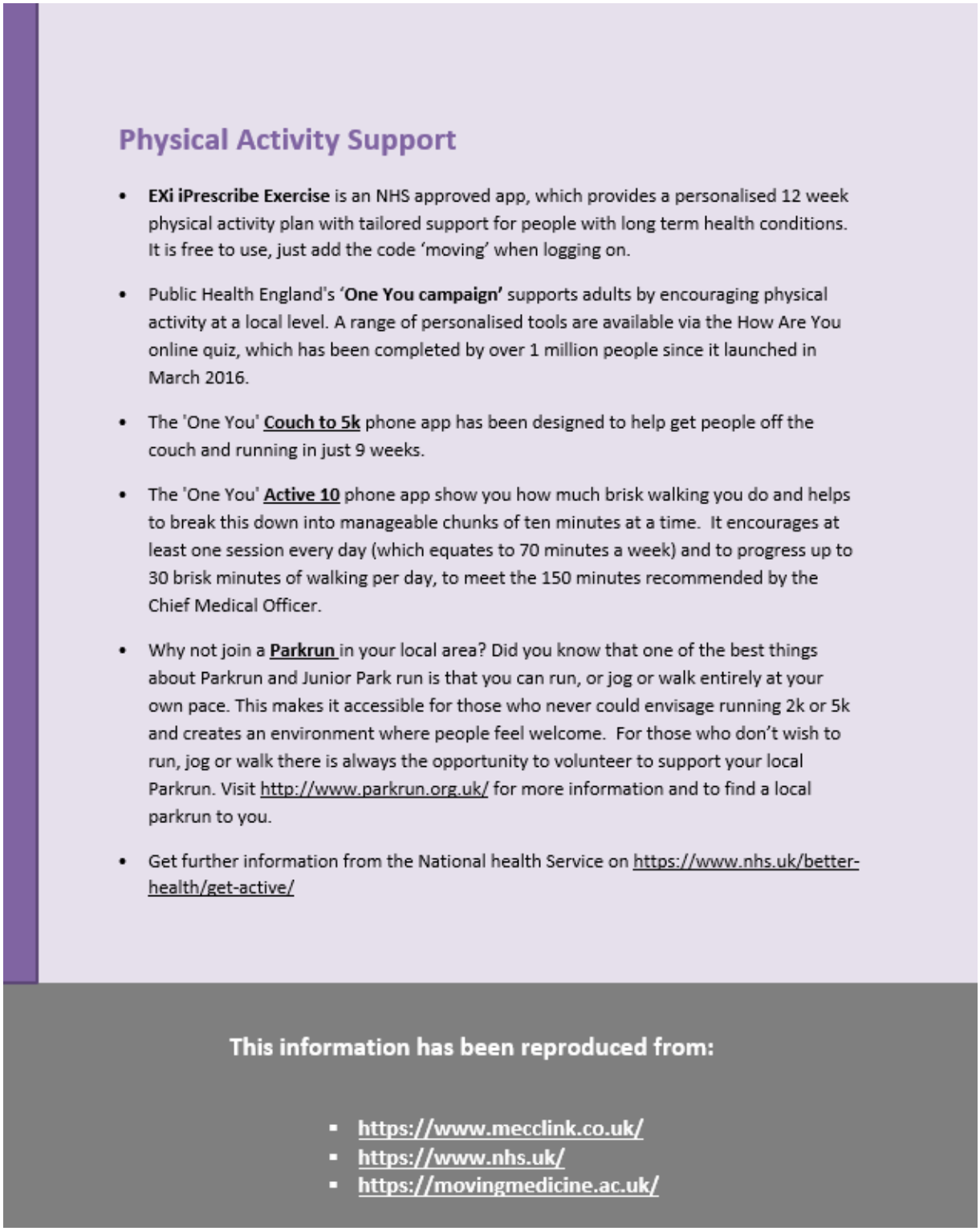

Figure 7.5 Signposting resource

7.6 TIDieR checklist to describe The COMBINED approach

Table 7.5 shows the TIDieR checklist for The COMBINED approach (Hoffmann *et al.*, 2014).

Table 7.5 Description of The COMBINED approach intervention using the TIDieR checklist

Name	The COMBINED approach
Why	The COMBINED approach seeks to (1) help patients improve their shoulder pain by assessing and addressing the lifestyle factors associated with the onset and persistence of a rotator cuff disorder through the delivery of a brief intervention within a routine physiotherapy consultation; (2) enable and support physiotherapists through an implementation toolkit to effectively integrate a brief intervention within a routine consultation for people with a rotator cuff disorder.
What	*Materials:* The COMBINED approach involves two levels 1) a brief intervention integrated within a routine consultation targeting patient behaviour change with respect to the relevant lifestyle risk factors and 2) an implementation toolkit as a strategy to support delivery by physiotherapists. Materials used for each level will be: 1. Patient-level intervention a. Workbook for each relevant lifestyle factor (smoking cessation, healthy diet, physical activity) which includes assessing confidence and personal importance of behaviour change, setting goals and action planning –adapted from movingmedicine.ac.uk b. Self-monitoring diaries for each relevant lifestyle factor (smoking cessation, healthy diet, physical activity) - adapted from movingmedicine.ac.uk 2. Clinician-level implementation strategy (toolkit) a. PowerPoint training slides b. Role play videos c. Videos on motivational interviewing d. Video from an internationally renowned shoulder expert endorsing The COMBINED approach

	e. Signposting to the Moving Medicine website (https://movingmedicine.ac.uk) f. Step-by-step guide to delivering The COMBINED approach g. Scripts h. Infographic highlighting links between the lifestyle factors and shoulder pain to display as posters in patient waiting areas and as an aid for discussion in the consultation i. Signposting information to national support services/websites *Procedures:* 1. Patient-level intervention Patients will attend one initial physiotherapy consultation, and offered one follow-up consultation, where they will receive The COMBINED approach intervention. The intervention consists of: a. A brief intervention based on the Moving Medicine resource to identify, assess and target the key lifestyle factors smoking, overweight/obesity and physical inactivity (https://moving medicine.ac.uk) b. A shoulder assessment and treatments based on the principles of the Best Practice Advice intervention from the GRASP trial (Hopewell *et al* 2021) c. Patient resources to support behaviour change (Workbook and self-monitoring diaries) 2. Clinician-level implementation strategy (toolkit) Clinicians will receive the clinician-level implementation toolkit, before delivering The COMBINED approach to patients as described above. The toolkit is a multi-faceted implementation strategy that intends to support clinicians to effectively deliver the patient-level intervention as intended. The multi-faceted strategy will consist of: a. A theoretically informed training package including a practical, skill-based workshop and an optional online top-up training session b. Resources as described under materials c. Regular communication and support from the Chief Investigator

Who provided	1. Patient-level intervention: The patient-level intervention will be delivered by HCPC registered physiotherapists who treat this patient population. Physiotherapists will be invited to participate in the study, consented and participate in the training before delivering The COMBINED approach in practice. 2. Clinician-level implementation strategy: The training will be delivered, and the supporting resources distributed, by the research team. The research team delivering the training are physiotherapists by background and have expertise in the management of rotator cuff disorders and in the development of The COMBINED approach intervention.
How	1. Patient-level intervention: The patient-level intervention will be delivered individually at a face-to-face physiotherapy consultation 2. Clinician-level implementation strategy (toolkit): The training workshop and supporting resources will be delivered to physiotherapists in a face-to-face group session. The online top-up training session will be delivered in a group session, although this may include smaller groups to deliver the training in-line with individual site set-up and recruitment as the purpose of this training is to bridge the gap between the training workshop and delivery of the intervention to the first recruited patient participant.
Where	1. Patient-level intervention: The patient-level intervention will be delivered within a musculoskeletal physiotherapy department at the participating sites. 2. Clinician-level implementation strategy (toolkit): The training workshop will be delivered at a university building or at the participating NHS site. The online top-up training will be delivered via Microsoft Teams.
When and how much?	1. Patient-level intervention: The patient-level intervention will be delivered within an initial physiotherapy consultation lasting up to 60 minutes, and at a follow-up consultation lasting up to 30 minutes. 2. Clinician-level implementation strategy (toolkit):

	The training workshop will be delivered once over a 3-4 hour session. The online top-up training will last up to 60 minutes.
Tailoring	1. Patient-level intervention: The patient-level intervention will be standardised with a step-by-step guide and materials provided to the clinicians, however delivery of the brief intervention by clinicians may need to be tailored according to individual patient needs. For example, some patients may not want to discuss lifestyle factors within the consultation and not all aspects of The COMBINED approach will be delivered, others may want to spend longer discussing the role of lifestyle factors in the management of their rotator cuff disorder. Integration of The COMBINED approach within the consultation can be tailored as this will depend on how the conversation naturally occurs and certain cues received from the patient about their lifestyle. It is also acknowledged that within the consultation unforeseen issues may arise which clinicians may have to deal with as a priority, preventing the delivery of The COMBINED approach. 2. Clinician-level implementation strategy (toolkit): Standardised training will be delivered using pre-developed PowerPoint slides, videos, and resources to ensure consistency of the clinician training and of the patient-intervention delivery. The practical role-play sessions, discussions and top-up training will be tailored to clinician's needs.
Modifications	N/A as intervention not delivered yet
How well	Planned: Intervention fidelity will be assessed.

7.7 Logic Model

Figure 7.6 shows The COMBINED approach logic model

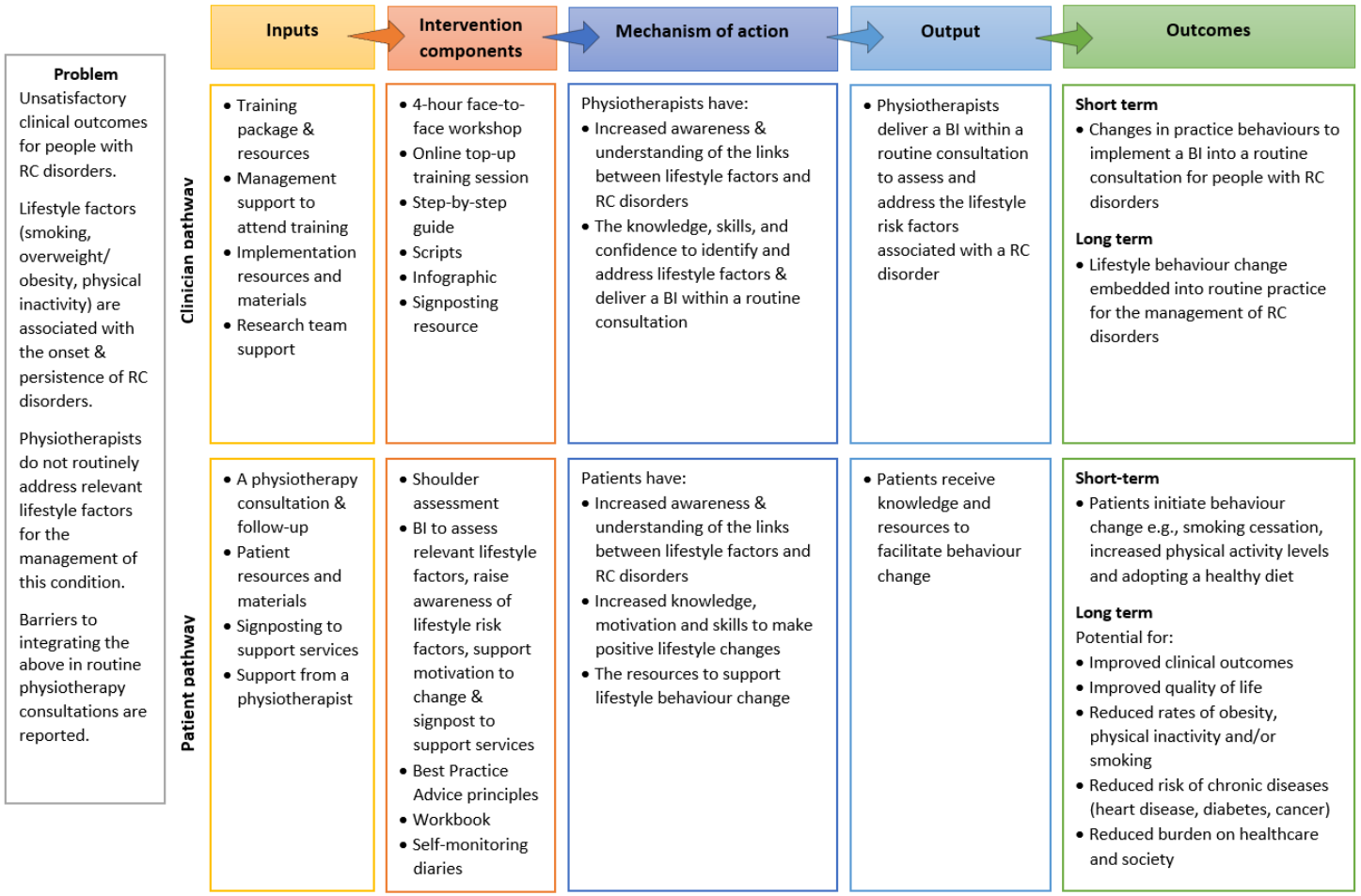

Figure 7.6 The COMBINED approach logic model

7.8 Discussion

This chapter has described the systematic design process of a first version of The COMBINED approach prototype. The patient-level intervention components were based on Moving Medicine as the BI component, and a BPA intervention for managing RC disorders. Components developed in the clinician-level implementation toolkit included multi-faceted strategies such as a theoretically informed training package and additional resources to support physiotherapists deliver The COMBINED approach in practice. PPI input informed the design process.

As highlighted in Chapter 2 (section 2.5) the Medical Research Council framework for developing and evaluating complex interventions advocates a theoretical underpinning in intervention development, based on the suggestion that an intervention based on theory is more effective, and gives a greater understanding of what works in what context (Craig *et al.*, 2008; Michie *et al.*, 2008). Drawing on existing theories to develop an intervention is also a key action in the pragmatic approach I have taken to intervention development (Chapter 4, section 4.3). The use of the COM-B model of behaviour change was useful as an initial behavioural diagnosis and simple to use. The TDF was particularly relevant due to the focus on implementation. The mapping process was more challenging because some barriers and facilitators could be included across several domains. Reviewing the mapping process with behaviour change experts helped justify the subjective decisions made, but it also highlighted the overlap between some of the domains and the inherent subjectivity involved.

The BCTTv1 was used to connect the theory about which behaviours need to change with the choice of BCTs to achieve the desired behaviour change. Building and reporting the active ingredients of The COMBINED approach in a comprehensive and transparent way, using a decision-making framework, aligns with the guidance on providing a transparent rationale for selecting intervention content and thorough reporting (Hoffmann *et al.*, 2014). This level of detail supports replication and future implementation. Numerous healthcare studies have reported the use of the TDF together with the BCTTv1 in the design phase of intervention development to understand influences on clinical behaviour and select appropriate strategies to target these within the intervention (Riordan *et al.*, 2020; Arden *et al.*, 2021; Turner *et al.*, 2021).

Often the design elements of intervention development are neglected, under-reported and rarely done in detail in intervention development studies (Rousseau *et al.*, 2019). I have explicitly defined my mode of design, including an informed design mode in the first step of the design process (Chapter 6) and a structured design mode in the second step (Chapter 7). I have also highlighted how decisions were made by the research team using the APEASE criteria, increasing the transparency of the design process to support future replication and implementation.

A toolkit containing multifaceted implementation strategies was identified as important by the stakeholders and the content informed by stakeholder co-design and theory. A toolkit is recognised as supporting the implementation process including adoption, implementation and sustainment, with the potential to improve patient outcomes

(Thoele *et al.*, 2020). This is important given the challenges of integrating evidence-based interventions into clinical practice (Thoele *et al.*, 2020).

Finally, it was recognised from the stakeholder workshops (Chapter 6) that efforts were needed to increase the diversity of patient perspectives. Although the PPI group was more diverse than the stakeholder workshops, identifying members from underserved groups remained challenging, despite efforts. More work will be needed in the refining and evaluation stages, for example, in the selection of sites and the recruitment processes, to address this issue.

7.9 Conclusion

A systematic and comprehensive approach has been used to design The COMBINED prototype, underpinned by behaviour change theory and transparent decision-making, with PPI input. The design process has described the translation of ideas and information to the design and creation of components into a working prototype. The COMBINED approach prototype (V1.0) is a multi-level, multi-faceted intervention comprising a patient- and clinician-level intervention. The COMBINED approach prototype, including the implementation toolkit, needs to be tested and refined with key stakeholders (end-users).

7.10 Chapter Summary

This chapter described the design of the first version of The COMBINED approach prototype. The next chapter describes a mixed methods study to refine and optimise the prototype.

Chapter 8 Usability testing & refining of The COMBINED approach prototype (V1.0)

8.1 Chapter Introduction

This chapter reports the fourth workstream (WS) in the intervention development stage of this thesis, a mixed methods usability study, to investigate the usability, acceptability, and feasibility of The COMBINED approach prototype intervention (Figure 8.1). The findings from this study identified key intervention refinements. Version two of The COMBINED approach is presented.

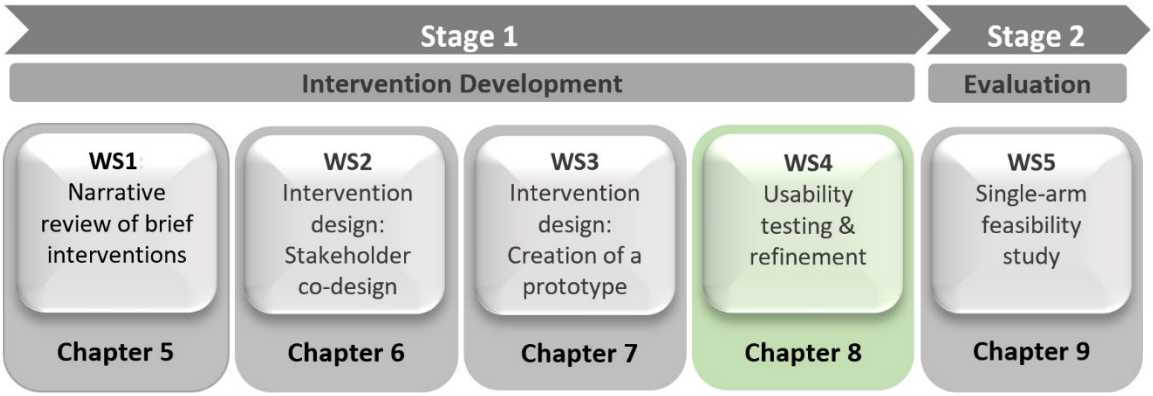

Figure 8.1 to show where this chapter fits within the intervention development process
WS, Workstream

8.2 Background

As described in Chapter 4 (section 4.2.3; action 10) refining, or optimising interventions, relates to making changes to improve the prototype version of the intervention (O'Cathain, Croot, Sworn, *et al.*, 2019), based on feedback from stakeholders. This is recommended through rapid cycles of testing, with a small number of the target

population, to evaluate acceptability, feasibility, and engagement, which would continue until the resolution of any identified issues (Craig *et al.*, 2008; O'Cathain, Croot, Duncan, *et al.*, 2019; Skivington *et al.*, 2021).

Usability testing is a commonly used method to optimise an intervention (prototype) by observing those both receiving and delivering it and making changes to the intervention as new insights emerge (O'Cathain, Croot, Sworn, *et al.*, 2019; Barnum, 2020). Also referred to as formative testing, this indicates that it is still part of the intervention development process, with the purpose of problem identification and resolution, as well as knowledge generation regarding the user's experience to inform further development (O'Cathain, Croot, Sworn, *et al.*, 2019; Barnum, 2020). Testing and refinement are important to identify any potential problems and solutions in advance of a costly, future feasibility study (O'Cathain, Croot, Duncan, *et al.*, 2019).

8.3 Workstream Four Aims and Objectives

The aim of this usability study was to investigate the usability, acceptability, and feasibility of The COMBINED approach prototype (V1.0) with the purpose of informing iterative design refinements (Thesis objective 5, Chapter 1, section 1.4).

The study objectives included:

1) Exploration of clinician's user experience of The COMBINED approach prototype;
2) Exploration of the patient's user experience of The COMBINED approach prototype;
3) Identification of key recommendations for refinements to The COMBINED approach prototype;

4) Evaluation of intervention fidelity.

8.3.1 Definitions

Definitions are provided below in relation to the study aim to investigate the usability, acceptability and feasibility of The COMBINED approach.

A widely used definition of usability by the International Organization for Standardization is, “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use” (International Organization for Standardization, 2018). This is a central standard in usability testing that considers user’s needs and satisfaction to develop products or interventions, which was a key consideration in this study.

Acceptability, feasibility and fidelity are indicators of implementation success and preconditions to achieving potential changes in patient outcomes or practice (Proctor *et al.*, 2011). I have drawn on the following definitions by Proctor *et al* (2011) for their relevance to considerations of implementation in the intervention development process:

Acceptability is defined as “the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory. Acceptability should be assessed based on the stakeholder’s knowledge of or direct experience with various dimensions of the treatment to be implemented, such as its content, complexity, or comfort” (Proctor *et al.*, 2011; p. 67).

Feasibility, in the context of intervention feasibility, as opposed to the definition of a feasibility study, is defined as “the extent to which a new treatment, or an innovation, can

be successfully used or carried out within a given agency or setting" (Proctor *et al.*, 2011; p. 69).

Fidelity refers to "the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers" (Proctor *et al.*, 2011; p. 69).

8.4 Study Design

8.4.1 Methods

This mixed methods study included the following qualitative and quantitative methods:

Observations

Non-participant observation of the physiotherapy consultations was used to assess the intervention being used in practice and observe behaviours and interactions. This included, for example, how patients responded to being asked about lifestyle factors, how patients and clinicians engaged with the intervention, and any challenges or examples of good practice. My understandings and interpretation of this data were used to inform the interviews and key refinements (WS4 objectives 1-3)

Interviews

Semi-structured interviews with patients and clinicians were used to assess the user experience, for example, what they liked/did not like about this approach, to evaluate acceptability of The COMBINED approach and to make sense of their behaviours from the non-participant observations (WS4 objectives 1-3).

Intervention fidelity assessment

Intervention fidelity was assessed to determine how well The COMBINED approach was implemented into practice (WS4 objectives 3-4).

Figure 8.2 shows how each of the methods of investigation address the aims and objectives in this workstream.

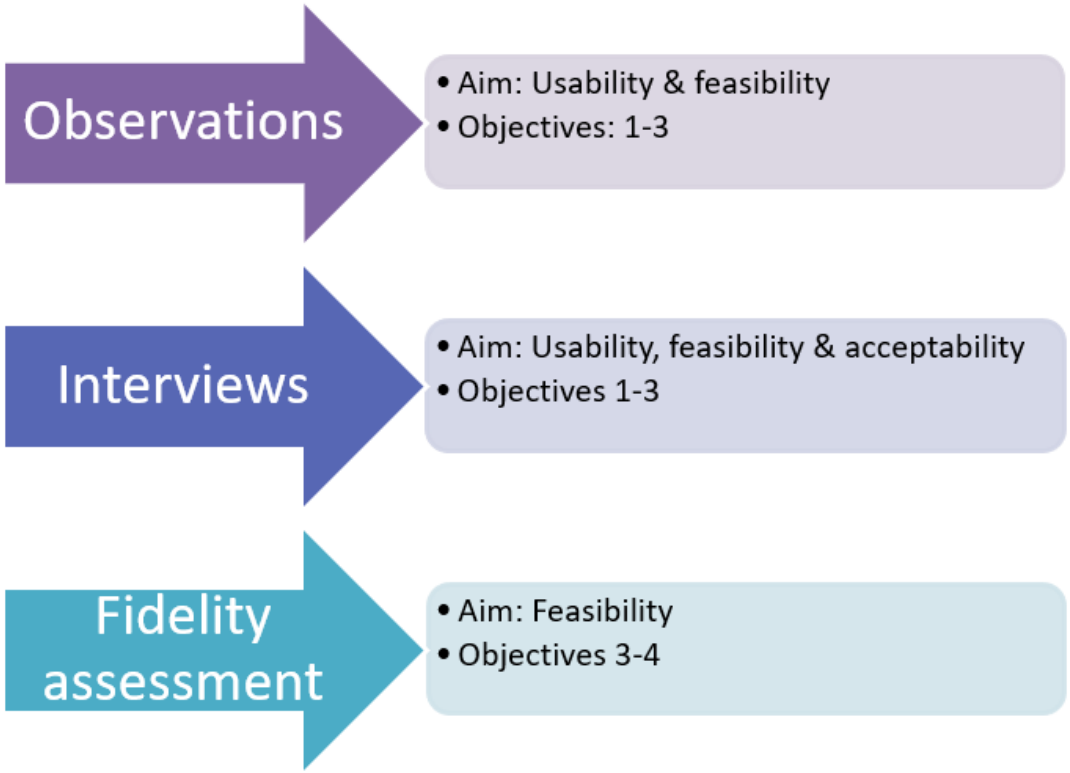

Figure 8.2 Methods linked to WS4 aims and objectives

Together, these methods provided a more comprehensive understanding of how The COMBINED approach was implemented and received in practice to inform refinements. The non-participant observations complemented the interviews by observing actual, rather than reported events, and they were used to interrogate the interview data.

Observation in addition to participant accounts is suggested to be particularly important when trying to understand more about processes or behaviours (Ritchie *et al.*, 2014).

The mixed methods approach was both sequential, with the observation and fidelity assessments conducted together prior to the interviews, and convergent. Although equal priority was given to both methods in terms of their importance for achieving the research aim and informing intervention refinements, the qualitative component (observations and interviews) was more substantial in terms of data collection and analysis. In comparison, the quantitative component (fidelity assessment) played a smaller role in the overall study.

8.4.2 Study Setting

The usability testing study was undertaken at a single site within a private musculoskeletal physiotherapy service within a university.

8.4.3 Participants

8.4.3.1 Eligibility Criteria

Participants included: 1) Physiotherapists; 2) Patients with a rotator cuff (RC) disorder.

1) Physiotherapists were eligible if they were:

- a qualified (Health and Care Professions Council (HCPC) registered) musculoskeletal physiotherapist working within the selected private physiotherapy clinic;
- willing to consent to the study procedures, including attending a training session, video-recording the consultations and interview participation;

- able to undertake a remote interview via Microsoft Teams.

2) Patients were eligible if they were:

- aged 18 or over;
- (i) diagnosed with a RC disorder as per the diagnostic criteria in the British Elbow and Shoulder Society/British Orthopaedic Association guidelines. This involves a systematic approach to rule out other sources of pain first including the cervical spine, shoulder instability, acromioclavicular joint and the shoulder joint, before conducting tests to suggest a RC disorder, including pain through the movement of abduction and on resisted tests (Rees *et al.*, 2021). As a specialist HCPC registered shoulder physiotherapist, I confirmed the diagnosis prior to eligibility via clinical assessment on Microsoft Teams), and (ii) either:
    - Smokes (tobacco) and/or
    - Has a BMI greater than 25kg/m^2 and/or
    - Does less than 150 mins of moderate-intensity or less than 75 minutes vigorous-intensity activities/week;
- able to attend at least one face-to-face physiotherapy consultation;
- able to give full informed consent;
- willing to consent to the study procedures, including videorecording the consultation and interview participation;
- able to undertake a remote interview via Microsoft Teams.

8.4.3.2 Sample Size

The sample size was determined by the purpose of the study to test The COMBINED approach prototype in a small sample of the target population. Within usability (formative) testing, it is suggested that samples of 5 to 7 participants per cycle can identify the majority of usability issues (Kushniruk and Patel, 2004). In addition, prototype refinement is typically achieved within 2 to 3 cycles of testing (Stinson *et al.*, 2013). Based on this, the intention was to recruit six patient participants. Three physiotherapist participants were intended to be recruited to ensure they could gain experience in delivering The COMBINED approach to two patients each, enabling them to provide feedback to inform design refinements.

Two rapid iterative cycles of testing and refinement were planned, however due to recruitment issues and delays from the clinic in study set-up, pressures within a time-limited fellowship meant only one cycle was completed. This will be discussed further within the study limitations (section 8.7.3).

8.4.3.3 Recruitment

Physiotherapists

Physiotherapists working in the private physiotherapy clinic were invited to take part in the study through an email invitation with a participant information sheet (PIS) attached (Appendix J), cascaded by the clinic's clinical lead. Following expression of interest in participation via return email, I arranged a mutually convenient time via Microsoft Teams to discuss participation, check eligibility, and take informed consent. Audio-consent was

taken via Microsoft Teams by reading the template consent form (Appendix K) and asking the participant after each statement to audibly confirm their consent for the recording.

Patients

Patients were invited to take part through an advert placed across the university premises (targeting university staff and students) and in community areas, such as local shops. The advert was also disseminated via the physiotherapy clinic's social media platforms, through the research team's professional networks via (non-NHS) email, and various university channels including Microsoft Teams chat, online groups, Moodle site and staff intranet. A free initial consultation and one follow-up consultation was offered to patients, funded through the National Institute for Health and Care Research (NIHR) fellowship funding for this PhD.

Patients were requested to email me to express interest and enable a PIS to be emailed (Appendix L). If they wished to participate, a remote screening assessment via Microsoft Teams was arranged to check eligibility, including an online shoulder assessment, and to take informed consent (as described above) (Appendix K). Once eligibility was confirmed, the patient's details were emailed to the physiotherapy clinic administrator to arrange an initial physiotherapy consultation.

8.4.4 Study Procedures

Once all the physiotherapists had provided consent, a mutually convenient date for the training workshop was agreed. The physiotherapists attended a 3-hour face-to-face workshop, delivered on university premises. I delivered the training content (presented in

Chapter 7), supported by a member of the supervisory team (CL). The physiotherapists were provided with a training manual, which included the slides from the workshop and the other components of the implementation toolkit, including the scripts, step-by-step guide, infographic, signposting information, and patient resources. Physiotherapists were asked to record, on a provided postcard, any reflections from the training workshop to aid memory recall in the interview later. I also recorded my own reflections on the training workshop.

Following recruitment of a patient participant, the trained physiotherapists delivered The COMBINED approach intervention during their arranged physiotherapy consultation. The physiotherapists were again asked to record any reflections on a postcard, for later recall, of their experiences of intervention delivery, including any issues as they arose or to reflect on what went well, what did not work, and any suggested changes to The COMBINED approach.

The physiotherapy consultation lasted up to 60 minutes. A follow-up consultation, lasting up to 45 minutes, was offered to the patient based on a shared clinical decision between the physiotherapist and patient. Where a follow-up consultation was required, this was requested around 2 weeks after the first consultation, to ensure this was delivered in the study's timeframe.

8.4.5 Data Collection

Demographic data

Demographic details were collected from each physiotherapist and patient participant using Microsoft Excel for Microsoft 365 (Version 2310). Clinical data to confirm a diagnosis of a RC disorder and the presence of any lifestyle factors were also collected from the patient participants.

I observed all consultations and recorded them via Microsoft teams. Microsoft Teams is approved by Manchester Metropolitan University as a secure platform appropriate for online data collection. Field notes were made to record any initial thoughts and reflections from the researcher perspective. The consultations were recorded to allow for further viewing by the supervisory team (CL, GY, CJ, JS) to discuss my interpretations, as well as collecting data with regards to the fidelity assessment.

Intervention fidelity was assessed using a pre-determined fidelity checklist (Appendix M), by identifying and coding what components of The COMBINED intervention were delivered in relation to the training, how they were delivered, and specific practices carried out during the consultation.

Further information was also recorded, such as the length of the consultation, how the resources were discussed and viewed, where any obstacles occurred, interactions and emotions and examples of good practice. The fidelity assessments and interpretations were discussed regularly with the supervisory team to verify my judgements made and the reasoning behind my decisions.

Interviews

All interviews were conducted and recorded online via Microsoft Teams. The patient participants were interviewed straight after their initial consultation, with the purpose of exploring their immediate reaction to receiving The COMBINED approach. They were directed to a quiet location in the physiotherapy clinic, where they had access to Microsoft Teams. The physiotherapist participants were interviewed at an agreed time after completion of the training and experience of delivery of The COMBINED approach.

The semi-structured interviews were guided by a topic guide (Appendix N-O). Prior to commencement it was verbally confirmed that the participant was happy to proceed with the interview, as previously consented. Field notes were made to record any initial thoughts and reflections from the researcher's perspective. Each interview recording was viewed by the supervisory team (CL, GY, CJ, JS) to discuss my reflections, as well as offer advice to improve interview techniques or inform refinements to the topic guide. All data was stored on the university OneDrive.

8.4.6 Data Analysis

Video-recordings from the observed consultations were analysed and coded using the fidelity checklist. Descriptive statistics (percentages) were used to analyse the quantitative data from the fidelity checklists and demographic data.

The observation data was documented and analysed at two levels. Firstly, it was analysed descriptively to add detail on specific practices during the consultation, for example, the length of the consultation and other shoulder treatments offered. Secondly, my

subjective reflections and interpretations as a complete observer were linked to the data, for example, my insights on why challenges may have occurred.

Interview recordings were transcribed using a transcription service to facilitate a more rapid analysis between the originally planned iterations of testing. NVivo for Windows software (2020 release) was used to support the data analysis process. Reflexive thematic analysis, using an inductive approach, was used to analyse the qualitative data. Drawing on Braun and Clarke's reflexive approach to thematic analysis, this included a flexible, systematic and rigorous approach to identifying patterns within data to provide a rich and detailed understanding (Braun and Clarke, 2019, 2022). I engaged with the data and actively generated themes, while transparently acknowledging and valuing my subjective assumption. Reflexive thematic analysis involves six phases (Braun and Clarke, 2022):

Phase 1: Familiarising yourself with the dataset.

This step was considered particularly important as transcription was undertaken by a third party, which is often the first step to immersion in the data and familiarisation. To counteract this, I listened to each interview recording at least once afterwards and subsequently checked the transcripts against the recordings for accuracy. Each transcript was then read several times, making familiarisation notes, including anything of interest and reflections on my own assumptions and initial thoughts.

Phase 2: Coding.

Transcripts were coded by systematically and comprehensively going through each data item several times, with codes often changing during this process. At the end of this

process, a list of all the codes was collated. Further notes were made regarding my own reactions to the data coding and assumptions.

Phase 3: Generating initial themes.

Away from the data, the process started of actively organising the codes with shared patterns and ideas to build potential themes. This was done initially using mind maps to cluster similar codes into a theme, which was later organised into a table with a list of themes and all the relevant codes. This was an iterative process going backwards and forwards between the themes, codes and the data items.

Phase 4: Developing and reviewing themes.

The initial themes were presented and discussed at a supervisory meeting to ensure they were rich enough, had a central organising concept and seemed reflective of both the coding labels and the entire dataset. The themes were revised, including collapsing themes together where there was overlap, and reviewing initial theme names.

Phase 5: Redefining, defining and naming themes.

The final theme names were refined and decided, with a summary of each theme produced.

Phase 6: Writing up.

The order of the themes to be presented and appropriate example quotes to illustrate each theme were decided and written up in the results section of this chapter. The analysis was discussed in relation to the study objectives and wider literature.

8.4.7 Intervention Refinements

The observation, interview and fidelity data were brought together to identify the intervention refinements required. The refinements were considered and prioritised with the supervisory team (CL, GY, CJ, JS) in relation to the APEASE criteria (described in Chapter 7, section 7.5).

8.4.8 Ethical Approvals

Favourable ethical review was confirmed on the 20th of December 2021 by the Faculty of Health and Education REC at Manchester Metropolitan University (EthOS reference: 37460) (Appendix P).

8.4.9 Patient and Public Involvement (PPI)

PPI members reviewed the patient-facing materials for this study. Feedback from the members informed changes to the content of the PIS, including removal of text where it was felt to be repetitive, the addition of a paragraph to say that routine NHS care would not be affected if they chose to withdraw from the study and to make the sentence bold that says the consultations will be videorecorded. They also highlighted the importance of the treating physiotherapist to emphasise to the patient that there is no obligation or pressure to continue with treatment at the private physiotherapy clinic beyond the two funded treatments. They advised being clear with the patient about this from the start and to highlight this with the treating physiotherapists, which was built into discussions in the physiotherapy training workshop.

8.5 Results

8.5.1 Participant Characteristics

Figure 8.3 shows the flow of patient participants through the study. Table 8.1 and 8.2 outline the patient and clinician participant characteristics respectively.

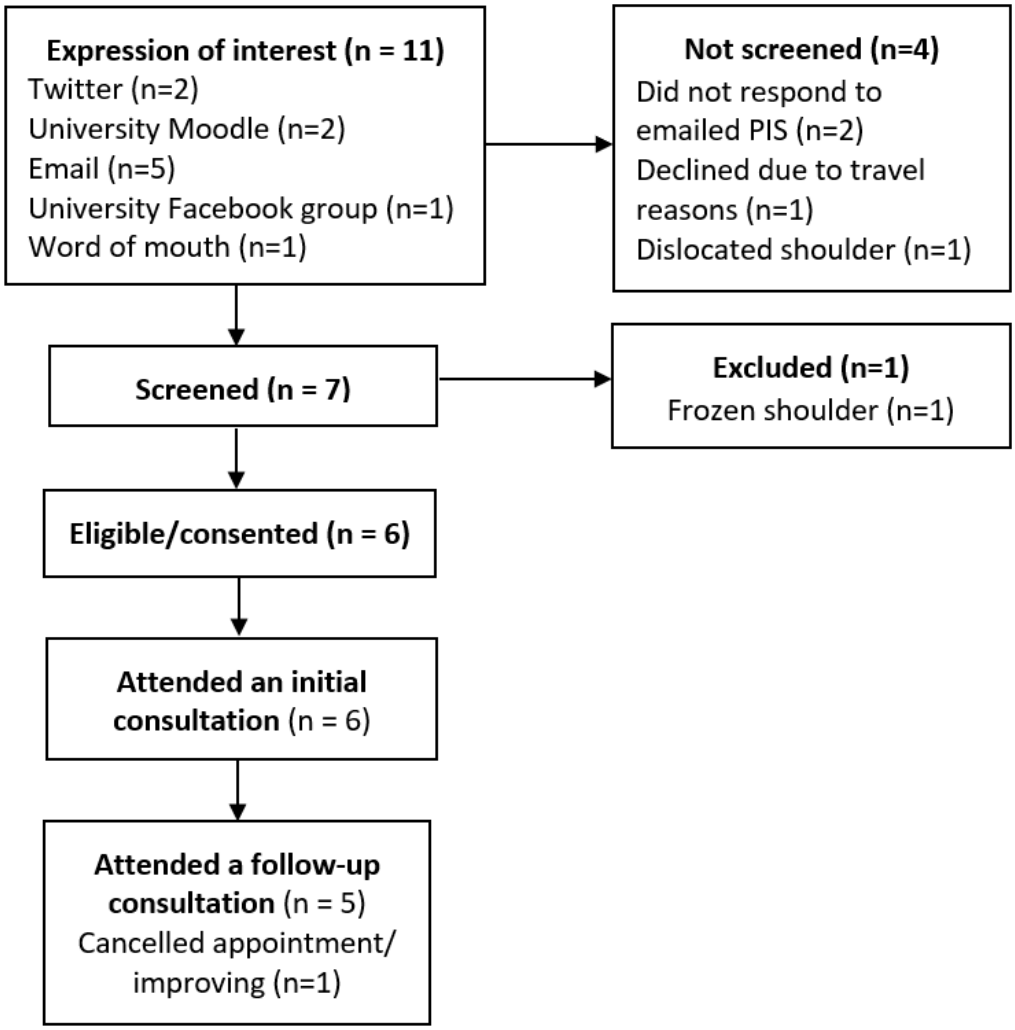

Figure 8.3 Study flow of patient participants
PIS, Participant Information Sheet

Table 8.1 Patient characteristics (n=6)

	n (%)		n (%)
Sex		**Employment Status**	
Female	2 (33)	Employed Full-time	4 (67)
Male	4 (67)	Student	1 (17)
Ethnicity		Retired	1 (17)
White British	4 (67)	**Lifestyle Factor**	
White other (European)	2 (33)	Smoker	0 (0)
Age (years)	**Mean (range)**	Overweight/obese	6 (100)
	55 (39-65)	Physically inactive	6 (100)

Table 8.2 Clinician characteristics (n=3)

Participant ID No.	Sex	Ethnicity	Professional role	Setting	Years qualified
PHY-1	Male	White British	Lecturer/musculoskeletal physiotherapist	University/private clinic	13
PHY-2	Male	British Pakistani	Senior musculoskeletal physiotherapist	Full-time NHS; 1 evening/wk private clinic	12
PHY-3	Male	White British	Lecturer/clinical lead	University/private clinic	33

8.5.2 Fidelity Assessment Findings

For the initial consultations, the fidelity assessment (using video recordings) showed that overall, only 40% of the aspects of the intervention were delivered as intended in line with the training. This ranged between 19%-69% fidelity for individual physiotherapists. Out of the 16 aspects of the intervention to be delivered there were common areas with low fidelity:

- Setting the scene - only two out of six consultations included setting the scene as part of the intervention;
- Screening for lifestyle factors - most physiotherapists screened for the lifestyle factors, such as identifying if they smoked and general activity levels. However, only two out of six consultations included an objective assessment of the lifestyle factors, such as measuring height and weight to calculate their BMI, or establish a baseline physical activity level for monitoring;
- Explanation of links between lifestyle factors and shoulder pain: only two out of six consultations involved a comprehensive explanation from the physiotherapist of the links between identified lifestyle factors and their shoulder condition;
- Motivational interviewing (MI) techniques – underpinning MI principles were generally poorly executed, particularly in exploring personal motivations to change and developing an action plan using reflective listening skills;
- Utilisation of resources – Overall, resources were poorly utilised, particularly the infographic and signposting information. The patient resources (activity workbook and/or diary) were more frequently used, however there was some confusion in the explanation to patients between the action planner in the workbook versus the patient diary;
- Best Practice Advice (BPA) principles – while some physiotherapists offered reassurance to patients and prescribed a progressive loaded exercise programme, there was minimal provision of self-management advice.

For the follow-up consultations, overall, 60% of the aspects of the intervention were delivered as intended in line with the training. This ranged between 0%-100% for individual physiotherapists. Out of the 4 aspects to be delivered, patients' progress in relation to their health behaviour change was frequently discussed in the consultations. However, there was limited exploration into potential barriers. In four out of five follow-up consultations, conversations were tailored to strengthen motivations to change and self-efficacy, where appropriate.

As part of the fidelity assessment, I also made notes on other observations of practice. These are summarised in Table 8.3 for all the fidelity assessments.

Table 8.3 Summary of observation practices from the fidelity assessments

Observation Practices	Researcher notes
Length of consultation	• Initial consultation: Range = 40-60 mins; Mean = 50 mins • Follow-up: Range = 16-45 mins; Mean = 33 mins
Other treatments provided	• Shoulder mobilisations • Progressive loaded shoulder exercises • Shoulder stretches • Cervical spine mobilisations • Extracorporeal shockwave therapy
Resources used	• Three forgot to give the information pack to the patient with the infographic and signposting information in or they didn't have access to the resources on the day. • Some only very briefly referred to the resources/information pack at the end of the consultation. Very rarely were patients offered a choice in relation to the different resources available to them. The infographic was not used as intended to explain the links. • There was some confusion over the diary and the action planner in the activity workbook. • When the action planner was completed in the consultation, it took ~20 mins.
Interactions/ emotions	• Both patients and clinicians seemed comfortable discussing lifestyle factors; patients appeared open to lifestyle discussions • One patient appeared dismissive – physiotherapist managed the situation well using motivational interviewing skills

Challenges identified	• Defensive/dismissive patient • Time taken to complete action-planner • Often it didn't feel combined throughout • No assessment of the lifestyle factors • Missed opportunities to link the health behaviours specifically with their shoulder pain
Areas of good practice identified	• Dealing with a more challenging patient • One patient expressed a reluctance to do more shoulder exercises that haven't helped in the past – Physiotherapist focused solely on health behaviour change in this consultation

8.5.3 Interview Findings

Clinician Interviews

All three physiotherapists participated in an interview. The length of interviews ranged between 51 and 65 minutes (mean length = 58 minutes). Four themes were identified: 'A paradigm shift in clinical practice'; 'preparedness to deliver The COMBINED approach'; 'perceived lack of patient engagement'; 'planning for future implementation'.

Theme 1: A paradigm shift in clinical practice

This theme has three sub-themes, which are used to present the findings: Subtheme 1 - Challenging attitudes and beliefs; Subtheme 2 - Ingrained practice behaviours are a barrier to an integrated approach; Subtheme 3: Evolution of thinking and a mindset shift. The themes relate to the conflict between how physiotherapists routinely do things in clinical practice and the perceived paradigm shift needed to integrate this new approach. It highlights how structured processes, habits and beliefs are a challenge to integration of The COMBINED approach and that acknowledging and challenging beliefs could enable healthcare professional (HCP) behaviour change.

Subtheme 1: Challenging attitudes and beliefs

All participants acknowledged that integrating The COMBINED approach into practice was a fundamental change in their understanding, beliefs and usual way of thinking when managing RC disorders. For some, this was related to their lack of knowledge of the systemic mechanisms between the lifestyle factors and the onset and persistence of a RC disorder. As a result, they questioned this evidence-base supporting the effect of changing these health behaviours on the clinical outcomes of people with RC disorders, which affected initial engagement with the delivery of The COMBINED approach.

> "You're almost dropping a bombshell, we're doing this combined approach because this is the information that we think might have an influence on shoulder pain…This is probably the trickiest concept for a lot of the physios to get their head round, which is about this idea of systemic inflammation and how these lifestyle factors could be influencing a shoulder pain" (PHY-1)

> "I'm a bit agnostic in that I'm sure there is some association between these lifestyle factors and rotator cuff conditions. And I think the intervention you have come up with is probably the best we can do to change those lifestyle factors. So, I guess we'll see, won't we, in terms of what it does for the shoulder." (PHY-3)

This lack of knowledge of systemic inflammatory mechanisms was highlighted further by their current understanding of the links between lifestyle factors (overweight/obesity) and musculoskeletal pain from a biomechanical loading perspective, making this even more questionable in relation to a shoulder condition.

> "That's what was interesting about the shoulder one because obviously other areas of the body, hips, knees, there are going to be weight management aspects and all those types of things there, but with the shoulder to change lifestyle factors, you wouldn't necessarily appreciate it having a large effect on the person's symptoms. That is quite a big shift." (PHY-1)

Personal biases and beliefs were recognised to have influenced their engagement with, and behaviours in, the delivery of The COMBINED approach. To mitigate against this, one physiotherapist felt they needed to understand this underpinning evidence more and recommended providing further optional reading as part of the training package. It was also suggested that an important facilitator would be to explore personal biases and beliefs in the training workshop, prior to the delivery of the approach.

> "We want to fast track that a little bit [our engagement with The COMBINED approach] and identify our biases, if we wanted to follow this approach, how are we going to work around that? One for me was, I need to go and read the evidence base, if I understand it and believe it, that's what I need." (PHY-1)

Subtheme 2: Ingrained practice behaviours are a barrier to an integrated approach

Another challenge to delivering The COMBINED approach was ingrained processes, behaviours and habits. It was apparent that their usual approach to assessment involved a systematic and repetitive process, which didn't include an assessment of lifestyle factors. There was a clear conflict between how the physiotherapists usually do things in practice and integrating The COMBINED approach that disrupted that flow.

> “It was quite a daunting prospect actually...I’m used to not having to think too deeply about what I’m doing, it just becomes quite automatic.” (PHY-2)

> “It was just a change, you know, when you’ve seen a lot of folk, as you know, you get into a sort of rhythm of how this goes…and so, coming off that pathway to incorporate something new then, was a bit of a challenge to begin with” (PHY-3)

Part of challenging usual practice behaviours was related to the routine assessment that the physiotherapists conducted, based on what they considered to be the most important components.

> “The biggest barrier for me was my own perception of how I should spend the time in that session. And that, leading up to being involved in this study, I hadn’t prioritised the issues that you're interested in as being some of the top issues I needed to deal with.” (PHY3)

This challenge of needing to shift from usual practice behaviours ultimately affected the accomplishment of delivering an integrated approach. Finding a balance between the usual way of working and what was required to be delivered as part of The COMBINED approach was reported to be difficult, which often meant they were considered as two separate components. Offering more direction on this in the training was considered beneficial.

> “Although I’m aware that we’re trying to make them seamless so it shouldn’t be, Okay, now we’re doing the physio side and now we’re doing the motivational interviewing side.” (PHY-2)

Participants recognised The COMBINED approach required a fundamental shift from their traditional paternalistic approach towards a more person-centred approach. The challenges in adopting a non-directive coaching style that recognises the patient as an expert in the management of their condition, highlighted the need for more training in this area.

> "I think what it highlighted really strongly for me is that we take this really paternal approach of really dictating almost or heavily directing what the patient should do and the decisions that are made…That was quite different and quite difficult for me." (PHY-2)

Participants reported that this traditional approach was a reflection on undergraduate training that doesn't appear to incorporate aspects of health behaviour change and continues to have a biomechanical focus.

> "…What will probably come out is, we've always been taught this way, it's quite a shift from how I've always approached seeing a patient. We do it in class, we've got a set standard that comes from the CSP [Chartered Society of Physiotherapy] that we must meet and teach particular things and it's very much about structure because we teach anatomy, it's about biomechanics so we teach that…so those are my biases because that's where my teaching has come from, that's hard to then shift out of that..." (PHY-1)

Subtheme 3: Evolution of thinking and a mindset shift

After the physiotherapists had experienced delivering the COMBINED approach it became clear there was a mindset shift in their prior attitudes and beliefs.

> "When I saw the first patient, I wasn't quite sure I really understood the evidence behind what I was giving them, I didn't believe in what I was giving them fully, and then I was like, oh right, now I can see where this fits...Now, I'm happy to go with that combined approach and maybe this is the more important factor" (PHY-1)

Theme 2: Preparedness to deliver The COMBINED approach

This theme has two sub-themes, which are used to present the findings: Subtheme 1 - Acquiring new knowledge and skills; Subtheme 2: Practice and feedback facilitate behaviour change. This theme relates to the knowledge, skills and strategies required to prepare physiotherapists to effectively deliver The COMBINED approach in clinical practice. It highlights the implementation strategies that were considered beneficial and any required refinements. The importance of practice and feedback were particularly considered as key strategies to supporting HCP behaviour change.

Subtheme 1: Acquiring new knowledge and skills

The training workshop was generally reported as a positive experience for the participants with an open forum for discussion and clear aims of what the study was aiming to achieve. It was however acknowledged that learning MI skills, that were an essential part of the BI, and putting this into practice was challenging.

> "The motivational interviewing is so odd, I was wrestling with it, it's so hard to teach, I was thinking how would I teach it? …It's a real skill. In order to teach it and practice it, that's the real challenge. (PHY-1)

The practical aspect of role play within the training workshop was highlighted as particularly useful for practicing MI skills but had not featured heavily enough. The participants reported one of the barriers to this had been running out of time on the day, due to a tightly packed programme. It was recommended to reduce some of the background to the study within the training workshop to make more time for practical aspects. More practice was highlighted as important to improve their skills in this area to effectively execute this as part of The COMBINED approach.

> "I think I would probably have liked to have practiced a little bit more…I think maybe I only did it once which was maybe not enough for me because I wasn't definitely perfect when I did it the first time and then the next time I did it was the real thing so that was maybe not enough practice for me." (PHY-2)

A challenge for the participants after acquiring new knowledge and skills, was the length of time between the training workshop and seeing their first patient as part of the study. Subsequently, some of this learning had been forgotten. Top-up training nearer to recruitment, or a video with a short synopsis of the training, was recommended.

> "When it came to the first patient, I think some of the themes that we'd gone over from the training, because of time frame that we had between them for various logistical type stuff… unfortunately, some of the messages that you'd mentioned,

I've then got to go and revisit because they just weren't as fresh in my memory." (PHY-1)

Participants did feel they had been provided with sufficient resources to refer back to, as well as offers of support from the research team to refresh any training, but clinical pressures made it difficult to prioritise this in preparation for their first patient. It was recommended that providing the training materials electronically would facilitate this, rather than having to locate their paper copies.

Participants generally reported feeling confident following the training to deliver The COMBINED approach. However, in practice the reality was they were not sufficiently equipped with the knowledge and skills. Having more tangible clinical examples of how and when to deliver this in practice, as well as a more prescriptive approach was recommended.

"Although I felt confident at the time, when it came to actually executing it with patients, I felt a little bit unprepared from a practical aspect. So, I felt I had a good theoretical knowledge, but the execution wasn't as smooth as I probably would have liked really." (PHY-2)

The participants found the step-by-step guide and the scripts as part of the implementation toolkit helpful towards the delivery of The COMBINED approach in practice, particularly as a summary resource that was easy to glance at.

"In terms of, you've had a busy day and then this is in the diary. The big colourful crib sheets are always useful. I guess I'm a bit like most clinicians, we don't want

to read a great big load of text, I just want the edited highlights. So, things that just brought the edited highlights out and made it easier to actually physically take into the consultation was useful" (PHY-3)

Explaining the concept of systemic inflammation at a patient-friendly level was highlighted by participants as a challenge. The infographic, while useful to raise awareness of the links between the lifestyle factors and RC disorders, it did not support the conversation as to why the lifestyle factors are linked to their shoulder pain. Further detail outlining the underpinning mechanisms of systemic inflammation at both a patient- and clinician-level was recommended.

"I think the link to the systemic inflammation bit is the key bit, how well the things that affect us in our life, nutrition, sleep, the bits that we mentioned in the study, how do they have an effect on some of these systemic inflammation and then developing other pathologies…whether or not that jumps out enough, and what that exactly means and what it's also linked to." (PHY-1)

Finally, the patient resources were acknowledged by the participants as important to support them in facilitating health behaviour change with patients. This included knowing about various support services to promote signposting, and the workbooks and diaries to promote adherence and accountability.

"Anything that encourages adherence, I think is a really good idea. So no, I really like those…I think having it as a key part of the session where you know that it's

going to be reviewed, it's probably going to influence behaviour more…that's where they're strong, when they're a focus of the review session." (PHY-3)

Subtheme 2: Practice and feedback facilitate behaviour change

It was clear from all participants that practice and repetition within the clinical setting, supported by feedback, was highly valued as facilitating the delivery of The COMBINED approach. In terms of practice, all participants reflected on the improved execution and confidence in their delivery of The COMBINED approach with the second patient.

> "With the first patient I certainly felt more uncomfortable. I felt when they said certain things that I wasn't sure what to respond with next. It was more difficult. Whereas when it came to the second patient, I'd adapted and learnt a little bit more about how I could keep the conversation moving, how I could facilitate it essentially." (PHY-2)

The critical element of practice and gaining experience in delivering The COMBINED approach was feedback on their execution, particularly to improve the fidelity of what was delivered. General feedback to the physiotherapists on their delivery had been found to be useful, but individual feedback was considered by the participants as more effective. It was also recommended as part of a future trial to have a period of practice with a patient, and feedback, before seeing patients as part of the study.

> "Some of that feedback that I'd got back from yourself was then really useful, I was like, I'm on the right track here, this is what she's looking for…There needs to

be practice with a patient, a real patient, and then it needs feedback, those are my two take homes." (PHY-1)

Participants also felt there was a requirement for ongoing support, mentorship and/or training as an addition to the strategies in the implementation toolkit, particularly to maintain good intervention delivery, as well as supporting HCP behaviour change in the long-term.

Theme 3: Perceived lack of patient engagement

This theme relates to the physiotherapists' perception that patients would not be receptive to conversations about the identified lifestyle factors as part of a physiotherapy consultation for their shoulder condition.

The physiotherapist's expectation was that patients would not consider lifestyle behaviour change as an important part of managing their shoulder pain, in comparison to what would be considered as more traditional physiotherapy treatments.

> "I guess there's a discrepancy between what I think the expectations of patients are, and what a patient's expectations really are... "Yeah, yeah, do we need to talk about my diet and physical activity here? I've come with my shoulder pain, can't we be talking about that?" (PHY-3)

In reality, they found the patients were open and receptive to this approach.

> They [patients] seemed very happy to be talking about that. They didn't seem to be having any, "Why are we talking about this?" kind of resistance that I thought

there might be…After the first one, I realised, actually, this is definitely acceptable to people, let's just get on with it (PHY-3)

However, it was recognised these particular patients had prior awareness of the aim of the study and that lifestyle conversations would be part of the consultation. Knowing this had reduced some of their anxiety to initiating the conversations. The patients were felt to be already highly motivated to change, with some patients actively bringing lifestyle discussions up themselves.

Theme 4: Planning for future implementation

This theme has two sub-themes, which are used to present the findings: Subtheme 1 - Uncertainties for future implementation; Subtheme 2: The COMBINED approach is relevant to physiotherapy practice. This theme relates to considerations for the next steps and for future implementation. It highlights key uncertainties of The COMBINED approach and endorsements that validate the relevance and value of The COMBINED approach to physiotherapy practice.

Subtheme 1: Uncertainties for future implementation

It was agreed amongst the participants that the study participants, and the patients they generally see in private practice, potentially differed in their demographics to the patient population in the NHS.

…My patients were very learned and able to research things themselves and access the resources but some places I do work at, that's not the case. Different

> socioeconomic demographic, not as much English speaking or people as well educated maybe and implementing the combined approach would certainly be more challenging in those areas." (PHY-2)

The patient demographics, along with additional pressures in the NHS in comparison to private practice, left an uncertainty as to if The COMBINED approach could work in the context of the NHS.

> "It's been piloted here because we had the value of time and a motivated cohort, so it was easy to see whether or not it even worked at all, which it did. It's a high-pressured environment, patient after patient, we don't have that here; we can give ourselves a bit of space…That is going to be quite challenging for the NHS" (PHY-1)

Subtheme 2: The COMBINED approach is relevant to physiotherapy practice

Despite some of the challenges experienced and initial apprehension in delivering this approach, there were some clear endorsements and benefits seen to integrating such an approach that was encouraging for future implementation.

Following experience of delivering The COMBINED approach it was expressed by the participants that it was both relevant to clinical practice and practical to implement. Time was not reported as a significant barrier to integrating this approach as first thought.

> "It's thorough, you know, you've done it as thoroughly as you can. But at the same time, it's still practical in terms of being able to get that intervention done within

the time that most physios will have to do it. So pragmatically, it looks like it's the best balance. You've given people an intervention that's practical and pragmatic." (PHY-3)

Patient interviews

All six patients took part in an interview immediately after their first physiotherapy consultation. The length of interviews ranged from 17 to 44 minutes (mean length = 29 minutes). Three themes were generated: Lifestyle conversations are expected and acceptable; the importance of person-centred care; empowerment to take control. The themes and subthemes are described below with illustrative anonymised quotes to support key findings.

Theme 1: Lifestyle conversations are expected and acceptable

This theme has two sub-themes, which are used to present the findings: Subtheme 1 - Receptiveness to health behaviour change; Subtheme 2: The missing link. This theme outlines patients' expectations and receptiveness to physiotherapists identifying and addressing lifestyle factors associated with a RC disorder, within a routine physiotherapy consultation. Patients commonly expected lifestyle discussions to form part of medical assessments and was no different in a physiotherapy consultation. The COMBINED approach, which includes the delivery of a BI as a strategy for health behaviour change, was considered acceptable to patients and of importance for the management of their shoulder condition. Raising awareness of the lifestyle links specifically to their shoulder

condition was important for behaviour change, but potentially a difficult concept to understand.

Subtheme 1: Receptiveness to health behaviour change

Participants reported it was expected within any medical consultation to be asked standard questions about their lifestyle, regardless of the clinician's background. This prior expectation highlighted that lifestyle conversations specifically as part of a physiotherapy consultation was both appropriate and acceptable, with many participants describing this as encouraging.

> "One would hope that all health professionals talk about lifestyle and so I think it is really good… it's actually quite encouraging to see because it has an impact, it has. I mean you see the impact on weight, for example, for a lot of things. So not even talking about that, would be wrong." (PT-6)

Most participants were open and receptive to discussing their lifestyle and health behaviour change. There was a recognition that generally people already know themselves what they need to do with regards to health behaviour change, but reinforcement by an HCP can be influential.

> "I didn't find it difficult at all because I do understand. It's not something I'm deliberately fighting against. It's something that I'm finding hard to do and to find the time to fit in, but I do know it's there. I've not got a problem having a conversation with anybody about this. It's not an issue." (PT-5)

However, participants highlighted that part of that receptiveness may have been due to prior awareness of the study objectives and that it would entail questions about their lifestyle in the consultation and had been screened for these as part of the study eligibility. Although many felt, had they not known in advance, their reaction wouldn't have changed.

> "Part of that is that I was expecting it anyway, but if those questions had come out the blue, I wouldn't have reacted in any other way that I have. It's information that's required." (PT-7)

In contrast, there were a few participants that expressed finding health behaviour change conversations uncomfortable due to a feeling of 'shame' surrounding this. However, their experience of this in this study hadn't been a negative one.

> "I hate those conversations because I feel embarrassed, I feel ashamed of myself because I know very well that I should have a better diet and that I should do more exercise, actually doing those things is a different case." (PT-8)

> "Always a bit of a difficulty, I think, because I know somewhere that I've let myself down. So, when somebody asks you about that, obviously to be truthful, but it's not necessarily very easy to talk about…there was a bit of resistance to it. I didn't feel entirely comfortable, but it wasn't a big deal." (PT-9)

The participants' experience of receiving The COMBINED approach was generally described as positive. Some were pleasantly surprised with the depth of information gathered and the focus on lifestyle factors as part of the physiotherapy assessment.

> "I wasn't expecting it to be as lengthy which was good. I didn't expect to have that much in the way of a conversation with regard to background, neither did I expect the advice in respect of lifestyle to be as straightforward. Normally you go away, and these are the exercises that you need to do and there is no question and no advice in regard to perhaps you could think about something else, so, that was unexpected." (PT-7).

There were only two recommendations made to improve the consultation. Firstly, one person felt the physiotherapist could have set the scene more to explain what would be happening during the consultation, particularly regarding The COMBINED approach. Secondly, not many patients had their BMI assessed during the consultation, but this was picked up by one patient as important to him to reinforce behaviour change. Both actions were components of The COMBINED approach and should have been completed by the physiotherapist. These comments by the participants reinforce the importance of these components and the requirement to emphasise these as part of the training.

Subtheme 2: The missing link

Participants were asked in the interview about their understanding of the information regarding the links between the lifestyle factors and their shoulder condition that was provided in the consultation. Some found it surprising that these factors could impact their shoulder and hadn't made the links previously.

> “I wouldn't link my lifestyle with my shoulder necessarily. I would link it with my heart, I would link it with my, other things in my body, high cholesterol, things like that, but not the shoulder. That was a surprise.” (PT-9)

The participants felt the explanation by the physiotherapist about these links made sense to them, and they understood this. However, when asked about their understanding of this, only one participant could recall information specifically about systemic inflammation. For others, it was still unclear or reported in relation to more biomechanical factors such as general exercise causing movement at the shoulder or less mechanical load.

> “I think it was explained really well and rather than saying, we need to get the inflammation down so it feels better, actually saying well no, the lack of exercise and being overweight, these are contributory factors to inflammation…it all makes sense really.” (PT-4)

This lack of patient understanding of the lifestyle links to their shoulder pain following the consultation highlighted that it is a difficult concept to understand, particularly when the depth of information provided by individual physiotherapists varied. Refinements to the information provided to the physiotherapists in the training workshop and the resources to explain these links to patients was identified as something that needs to be developed.

> “I think it would have been useful to go into a bit more detail about the impact of diet and activity, yes…just make the links really, I mean what is it about my diet that is going to help my shoulder.” (PT-8)

However, the importance of including health behaviour change as part of the management plan for their RC disorder was still met with a few reservations, with some questioning this link and the potential impact of this to resolve their symptoms related to their shoulder condition.

> "I don't want to sound negative on this point but it's almost like I need to do something I guess and see a result because it's all well and good saying, "This will improve things" … I can't say that I believe that all these changes will resolve it, I don't believe that. I don't think it can resolve it fully that way, but I think I can probably understand why it would improve" (PT-5)

Theme 2: The importance of person-centred care

This theme has three sub-themes, which are used to present the findings: Subtheme 1 - Relational skills for effective communication; Subtheme 2 – Facilitating a holistic approach; Subtheme 3: Therapeutic alliance is not undermined. This theme encompasses the essence of person-centred care and the principles of which were central in ensuring participants felt listened to, seen as a whole, not judged, and ultimately comfortable in discussing potentially sensitive topics. These key factors contributed to developing a strong therapeutic alliance.

Subtheme 1 – Relational skills for effective communication

All participants commented on specific relational skills that had led to effective communication and a non-judgemental approach, which made them feel comfortable when discussing their lifestyle factors during their consultation.

> "I think it was all really good, he came and explained and introduced himself, he asked the questions in a polite, professional manner and never at one time did I feel like I was being judged or anything like that..." (PT-4)

The way information was communicated by the physiotherapist was described as an empathetic approach and they felt listened to during the consultation, which was important to them.

> "He explained what he was going to do, as I said, a couple of times, lovely approach, listened, felt as if there was some empathy there with what was going on and, overall, I had quite a pleasant experience if you could put it that way." (PT-7)

The approach taken by the physiotherapist was described as non-paternalistic, which made them feel like an equal. Both factors, synonymous with a person-centred approach, were pivotal to ensuring the participants were open and receptive to discussing health behaviour change.

> "I really like the way that [name] was with me. He was very gentle, he was very compassionate, but I felt he also treated me like an equal and in that sort of relationship, I can take what you're going to give me in terms of information…so, to me, that created the sort of relationship that would make me receptive to those things" (PT-8)

The non-paternalistic approach was recognised as facilitating the participants to come up with their own solutions, and the potential impact that addressing these lifestyle factors may have on their shoulder pain.

> "…People often come to their own conclusion when you actually help them rather than you telling them that there is a link or like it was done today, does it surprise you that we find this? So, the people go through their own thinking process and realise that yes it could actually have something to do [with it]." (PT-6)

Subtheme 2 – Facilitating a holistic approach

The participants were asked what The COMBINED approach had meant to them after their experience of the consultation. It was referred to as a more holistic approach than what they either expected or have previously experienced.

> "I think the combined thing of, it's like a whole lifestyle…it was explained to me, it's not just a one-step approach, it's a multi-faceted approach to treatment really. It's not just exercise, it's sorting your weight out, which means sorting your diet out as well. It's almost like there's no aspect that it doesn't cover, if that makes sense. (PT-4)

Furthermore, they reported feeling this approach was integrated throughout the consultation. The participants' description of this integrated, holistic and multi-faceted approach illustrated the essence of The COMBINED approach.

> "It wasn't just your usual physio assessment, the functions and do that, do that, can you lift that. It was from the beginning, so it [lifestyle discussions] was included in the first part, in the first chatter we went to. I think it felt combined because we kept going back and fore and it was part of every discussion." (PT-6)

The outcome of this more holistic approach was a positive experience for participants and one where the benefits were clear.

> "He seemed to take me a bit more seriously and have a bit more of a broader view of what was going on in my life." (PT-9)

Subtheme 3: Therapeutic alliance is not undermined

It was clear from the participants that The COMBINED approach did not undermine this therapeutic relationship and appeared to only strengthen it. This was particularly apparent in the descriptions from those participants that compared this approach to previous experiences of physiotherapy.

> "I probably got more out of today than I have ever got from previous physiotherapy appointments because there has been that personal approach, that asking, that detail and questions and a way forward, so yes, thank you for that." (PT-7)

Theme 3: Empowerment to take control

This theme has two sub-themes, which are used to present the findings: Subtheme 1 - The trigger for change; Subtheme 2: The tools to enable change. This theme outlines the

impact of The COMBINED approach on the participants' motivation and confidence to enable change and being empowered to take control of their own health for the management of their shoulder condition.

Subtheme 1: The trigger for change

All participants described the consultation as providing some kind of trigger or switch that offered reinforcement and a motivation to initiate behaviour change, particularly knowing now that it might have an impact on their shoulder pain. For some, it was about sowing a seed, that might bring them closer to readiness to change.

> "I think I'm hopeful that I will use this as a trigger to do a little bit more because I don't want to be in pain all the time…So I'm hopeful of sticking to it. I've got to just find that switch to go, "Okay, well let's do something now." (PT-5)

For some participants, an important factor was the timing of this consultation and the resources to support change with their current motivation and readiness to change.

> "It's almost like perfect timing really with doing this study and my mentality to lose weight and do some more exercise, and then this coming along as well with the stuff to fill out, they both complement each other. It's almost like perfect timing really, almost like fate." (PT-4)

Participants described feeling they had been offered a way forward with new possibilities. This was particularly apparent for those who had received previous physiotherapy for this

condition and felt powerless, with nothing left to try. They described feeling encouraged, hopeful, positive, determined and motivated to make changes.

> "There seems to be a clear connection with it. Then there must be a clear way out as it were...I can have more of an effect on my condition now than I thought before." (PT-9)

By offering a way forwards, participants felt empowered that they now had some control of their own health and the management of their shoulder condition.

> "So, what my experience in the past has been, it's been a focus upon the mechanics of it, so there's your shoulder pain, this is what's going on, this is what you need to do. But there has been no finding out, well why is it like that, why has it got like that, what have you done, what are you doing to yourself to approach it, is there anything else you can be doing." (PT-7)

However, participants recognised that despite being motivated to change, behaviour change can be hard.

> "I think I'm always very, very conscious and very aware that I should be doing more, and I think I said to [name], I frequently think, right we're starting this week and I'll do more stuff but I find it difficult to maintain. So yes, I mean something like this, it always makes me go, right I'm going to do this now, but I know from experience that I find it really hard to sustain that." (PT-8)

Subtheme 2: The tools to enable change

Participants generally reported the resources provided would be useful tools to support their ability to take control of their health and make a change. It was appreciated that this was provided from what they believed to be a credible source.

> "Something like this is really helpful because it's basically telling you what to do and you're getting the advice from a reputable, reliable source, not just from some nobody off YouTube or something like that." (PT-4)

The activity workbooks provided to the participants to encourage setting goals, and an action plan, were perceived as important in their behaviour change efforts. Having some accountability, either in the form of the self-monitoring diaries or a follow-up with the physiotherapist was also considered to be fundamental to supporting them with their goals and any potential barriers to change.

> "I need to be knowing that I've got a goal there and this is what I need to do to get to that. That's the thing that would keep me going, keep me engaged, not just, go away and do more exercise." (PT-8)

8.5.4 My Reflections

Reflections on the training workshop

One of the challenges was the mismanagement of time during the workshop, resulting in insufficient time to comprehensively deliver all aspects of the training, such as the practical training on MI skills and going through the supporting resources, such as the patient workbooks. This was partly due to the large amount of group discussion on aspects of the training. This likely left the physiotherapists underprepared to deliver

certain aspects of The COMBINED approach in practice, contributing to the low fidelity. In recognition of this, a top-up training session was offered to the physiotherapists, but this was not taken up. The next iteration of training will incorporate this learning by reducing the training content in some areas and allocating more time for practical activities, which the physiotherapists identified as important.

Reflections on observation findings

Figure 8.4 includes a summary of my observations and interpretations linked to these.

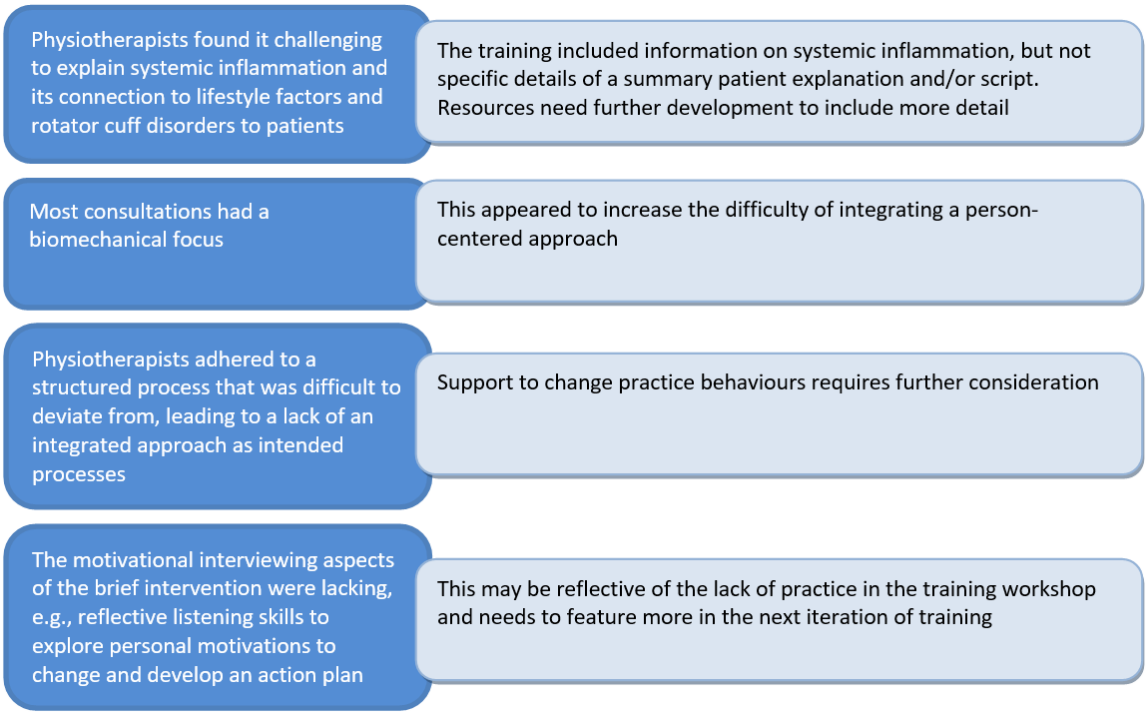

Figure 8.4 Summary of observations and my interpretations

From the initial observations, it was clear that there were missing aspects of The COMBINED approach and fidelity was low. It was felt appropriate to offer interim feedback to the physiotherapists to enable them to approach the next patient differently, rather than to wait until the end of the study. An improvement in fidelity post feedback was observed, with greater integration within the consultation, more elements of the MI approach within the delivery of the BI and more engagement with the resources.

8.6 Intervention refinements

8.6.1 Table of changes

The analysis of the quantitative and qualitative findings has informed intervention refinements. The potential changes to consider and the adaptations made to The

COMBINED approach are summarised in Table 8.4. The APEASE criteria was used to guide the decision-making on which changes to make.

8.6.2 Version 2.0 The COMBINED approach

In summary, version 2.0 of The COMBINED approach included:

- An enhanced training package – Stronger focus on challenges identified in the usability study, facilitated discussion to explore personal beliefs and biases that would limit engagement with The COMBINED approach, more practical sessions, mandatory top-up training session, electronic training pack and resources, optional references related to underpinning mechanisms;
- A more simple, prescriptive approach – including the removal of the BPA intervention as a component of The COMBINED approach, more guidance on the integration of The COMBINED approach within usual processes, a more detailed infographic to explain the underpinning systemic inflammatory mechanisms;
- Audit & feedback;
- Study inclusion criteria - no longer a requirement for the participant to have an identified lifestyle factor. Identification and screening for lifestyle factors will be part of the intervention.

An updated TIDieR checklist and revised logic model to reflect these changes are shown in Appendix Q and R respectively.

Table 8.4 Intervention changes to consider

Feedback/Issue identified (Source)	Suggested change to the intervention to address the issue	Agreed change (meets APEASE criteria)
Ran out of time in the training workshop: 1. Unable to cover all the content 2. Not enough time spent practicing motivational interviewing skills as part of the brief intervention or how to deliver The COMBINED approach (researcher's reflections; physiotherapy interviews)	Reduce the theoretical content of the training workshop, particularly the detail on the intervention development process to ringfence more time for the practical session Increase the time of the training (1 day training and a ½ day practical session was suggested)	Yes (acceptable, practical, affordable) No (not likely to be acceptable to and practical for physiotherapists and NHS managers) – could increase the training workshop by 1 hour
Gap between training workshop and delivering The COMBINED approach to the first patient. Subsequently some of the information was forgotten. (researcher's reflections; physiotherapy interviews)	Optional top-up training had been offered, but this should be a mandatory component of the implementation toolkit and offered to individual sites nearer to patient recruitment Summary videos of the training workshop for physiotherapists to revisit before the first consultation Provision of the training package as a digital copy and an expectation that the physiotherapists allocate some preparation time with the training pack and resources before the consultation	Yes (acceptable, practical, affordable) No (not practical to do for the next iteration, but a future consideration) Yes (acceptable, practical, affordable)

Low intervention fidelity/missing components of The COMBINED approach: 1. Inconsistent setting of the scene (observation; fidelity assessment; patient interviews) 2. Patients not assessed with regards to the lifestyle factors, particularly BMI and baseline physical activity levels (observation; fidelity assessment; patient interviews) 3. Lack of prioritisation when patients present with multiple health behaviours (observation) 4. Motivational interviewing aspects of the brief intervention poorly executed (observation; fidelity assessment; physiotherapist interviews) 5. Best practice advice components not consistently executed (observation; fidelity assessment)	Greater focus on the low fidelity components in the training workshop Remove from the study inclusion criteria that the patient participants need to have one of the contributing lifestyle factors and have been assessed for this in advance – the physiotherapists will then need to screen for, and assess the lifestyle factors as a component of The COMBINED approach Offer a more simple prescriptive approach, including removal of best practice advice as one of the components of The COMBINED approach. Reflect this in the step-by-step guide. Opportunity for role play/practice in delivering The COMBINED approach in the training workshop Practice period with patients in clinical practice to develop a level of competency prior to delivering The COMBINED approach to a study participant Audit and feedback – observe the physiotherapist delivering The COMBINED approach in practice followed by individual feedback. Use this process to offer general feedback to other physiotherapists to share challenges and examples of good practice Long-term support, training and mentorship	Yes (acceptable, practical, affordable) Yes (acceptable, practical, affordable) Yes (acceptable, practical, affordable) Yes (acceptable, practical, affordable) No (not practical for the feasibility study due to time-pressures, but a future consideration) Yes (acceptable, practical, effective, affordable) No (N/A for the feasibility study, but a future consideration)

Practice behaviours, processes and beliefs were a barrier to engagement with and integration of The COMBINED approach leading to missed opportunities in the consultation for teachable moments (observation; fidelity assessment; physiotherapist interviews)	Facilitate a discussion in the training that explores the physiotherapist's attitudes and beliefs in relation to integrating The COMBINED approach into clinical practice and address these Offer a more prescriptive approach and guidance on when/how to integrate The COMBINED approach Develop clinical scenarios of how this has been integrated in practice Practice, audit and feedback as above	Yes (acceptable, practical, affordable) Yes (acceptable, practical, affordable) No (not practical to develop until observed examples of good practice, but should be a future consideration) Yes (acceptable, practical, affordable)
Inconsistent quality of patient explanation re: links between the lifestyle factors and shoulder condition; limited understanding and recall of these links by the patient (observation; fidelity assessment; physiotherapist interviews; patient interviews)	Greater focus in the training workshop on underpinning mechanisms of systemic inflammation More detailed infographic to support physiotherapists to explain the underpinning mechanisms to patients and as a resource for the patient to take away (patient-level explanation) Provide more detailed information and evidence/references regarding the underpinning mechanisms as an optional clinician resource (clinician-level explanation)	Yes (acceptable, practical, affordable) Yes (acceptable, practical, affordable) Yes (acceptable, practical, affordable)

Patient resources not always used by the physiotherapists as intended: 1. Patients not offered a choice/ preference for the resources (observation) 2. Some patients not offered the resources at all (observation; fidelity assessment; physiotherapist interviews; patient interviews) 3. Physiotherapists not familiar with the patient resources resulting in some confusion over the resources and a lack of tailored advice and signposting (observation; physiotherapist interviews) 4. Time was a barrier to working through the workbooks in the first consultation (observation; physiotherapist interviews)	More focus and guidance on the patient resources in the training workshop Expectation that the physiotherapists allocate some preparation time with the resources before the consultation Guidance to hand out the resources to the patient in the first consultation, but to utilise the time in the follow-up consultation to review these with the patient	Yes (acceptable, practical, affordable) Yes (acceptable, practical, affordable) Yes (acceptable, practical, affordable)
Study participants may not be representative of the patient population in the NHS and therefore still a key uncertainty if The COMBINED approach will be acceptable and feasible in the context of the NHS	To progress from a single-centre to a multi-centre feasibility study in the NHS with the aim of increasing diversity.	Yes (acceptable, practical, affordable)

8.6.3 Refined resources

One aspect of the intervention refinements identified from both the observations and interviews was the need for a more detailed infographic to support physiotherapists to explain the underpinning systemic inflammatory mechanisms to patients and as a resource for the patient to take away. The original infographic was refined, with input from my PPI group, by including a second page with the additional detail on. This is shown in Figure 8.5. The clinician's step-by-step guide was also updated to reflect the feedback (Appendix S).

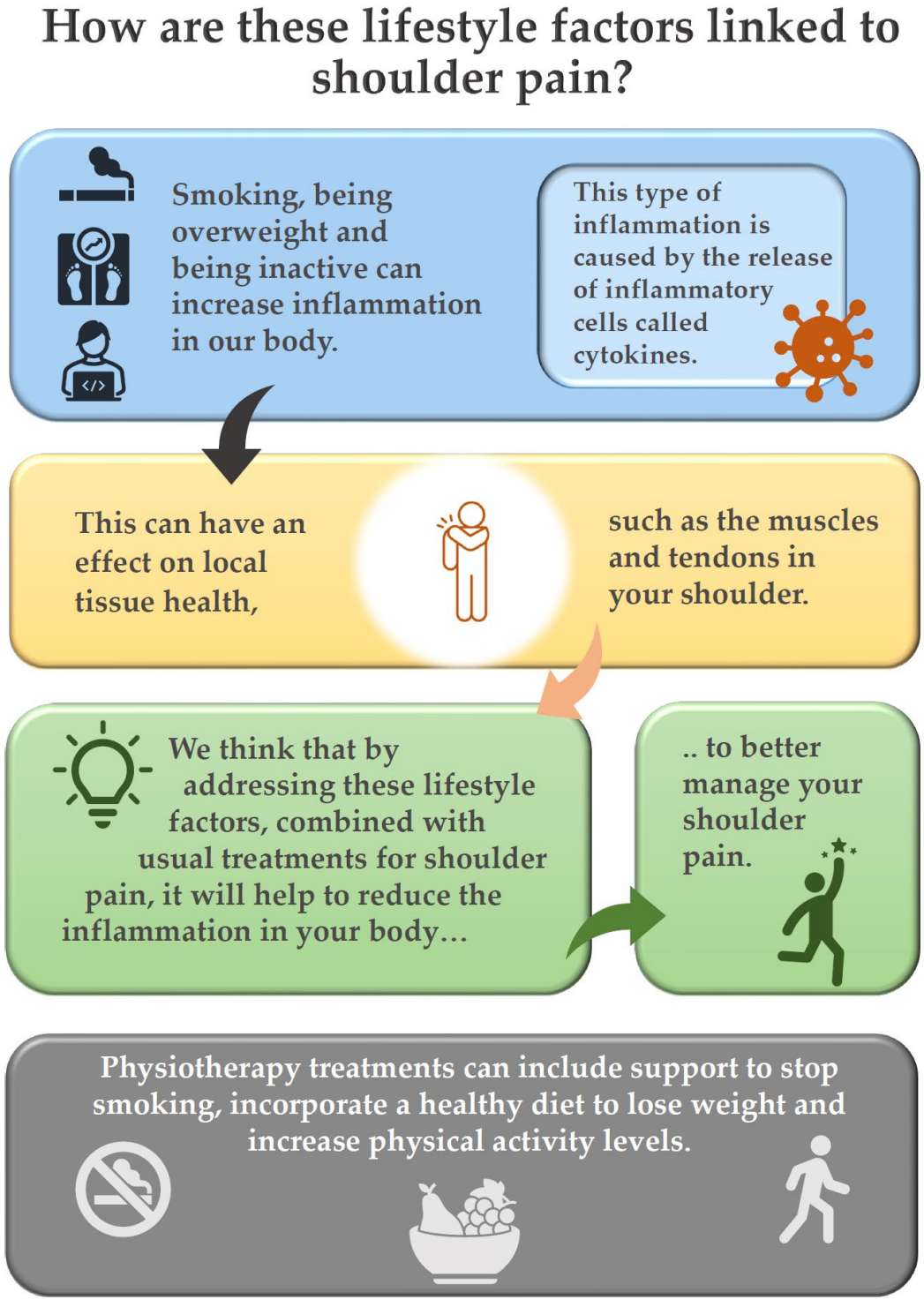

Figure 8.5 Revised patient infographic

8.7 Discussion

8.7.1 Summary of Findings

This usability study examined the usability, acceptability, and feasibility of The COMBINED approach prototype (V1.0) and has identified key design refinements. The findings in particular identified low levels of fidelity in the delivery of the approach impacted predominantly by physiotherapists' attitudes, beliefs and practice behaviours. Integrating The COMBINED approach was a fundamental shift in behaviours of the physiotherapists. Patients, however, found The COMBINED approach to be acceptable.

Analysis of the observations, fidelity assessments and interviews identified several barriers and facilitators, linked to the COM-B model of behaviour change and the Theoretical Domains Framework (TDF), which impacted on the implementation of The COMBINED approach in practice. Firstly, in relation to capability, barriers to implementation in the TDF domain 'Knowledge' included the physiotherapists lack of knowledge regarding the links between the lifestyle factors and RC disorders. This impacted on their ability to explain this link to patients and develop their understanding of this to support behaviour change. Suggested facilitators included education, training, and more detailed information in the form of references and a revised infographic to explain the links. Barriers linked to the TDF domain 'Cognitive and interpersonal skills' included a lack of skills in MI for effective communication and a person-centred approach in health behaviour change conversations. It was felt more rehearsal and practice in the training workshop would be a key strategy to facilitate this. Barriers linked to 'Behavioural

regulation' included the ingrained processes and habits of the physiotherapists which meant integration of The COMBINED approach was impacted. A more-prescriptive approach was suggested to facilitate this integration.

Secondly, in relation to Motivation, there were several barriers identified in the TDF domains 'Beliefs about capabilities', 'Beliefs about consequences' and 'Professional role and identity'. These were largely regarding the physiotherapists' underpinning attitudes and beliefs about integrating The COMBINED approach into clinical practice, demonstrated to be a fundamental shift from their usual approach. Furthermore, it included the perception that patients would not be receptive to lifestyle conversations as part of a physiotherapy assessment. An important facilitator was highlighted as repetition and practice with patients that demonstrated both the usefulness of the approach, as well as a positive reception from patients. Identifying and addressing physiotherapists' attitudes and beliefs may also help to facilitate these barriers. On reflection, I hadn't fully appreciated the impact of their beliefs on the physiotherapists' engagement with and their delivery of The COMBINED approach. It was clear that any held beliefs needed to be addressed at the beginning of the study.

Thirdly, barriers to the TDF domain 'Goals, intentions and optimism' identified that The COMBINED approach was not a priority for some of the physiotherapists in the face of other clinical pressures. This included prioritising any pre-consultation preparation and prioritising the delivery of components of The COMBINED approach over usual practices, for example, manual therapy. Top-up training and ongoing support was suggested to facilitate this barrier.

Many of the barriers and facilitators had previously been identified in the stakeholder workshops (Chapter 6). This highlights that despite training the physiotherapists in a standard way and offering supporting resources as part of the implementation toolkit, more comprehensive strategies are required to support HCP behaviour change. Interestingly, time was not identified as a barrier to implementation in this study, despite being widely cited as a barrier in the stakeholder workshops, which is promising for integrating The COMBINED approach within usual practices.

Similar to the stakeholder workshop findings, there were no significant barriers identified from the patient perspective and The COMBINED approach was found to be acceptable. In this study, three issues were identified by the patients including not having a detailed introduction to the consultation, not having their BMI assessed, and a lack of information about how changing the health behaviours would impact on their shoulder condition. However, these should have been delivered as part of The COMBINED approach, emphasising the need to address these further in the training with the physiotherapists. This information offers positive reinforcement of the value of these components to The COMBINED approach, as well as reassurance that having health behaviour change conversations did not affect the therapeutic alliance between patients and physiotherapists. A widely cited facilitator by the patients in this study to having health behaviour change conversations included the person-centred approach, and the resources for accountability and adherence to behaviour change.

The theoretically based implementation toolkit had included 20 behaviour change techniques (BCT's). Refinement of The COMBINED approach included looking back at

these BCTs and having critical discussions with experts to identify which ones appeared to have been important to addressing the TDF domains and which, if any, were missing. It was agreed that all the included BCTs had been cited as important but had perhaps not been sufficiently delivered. For example, repetition, practice and feedback were cited as important. Practice and feedback were performed in the training workshop as simulations, but not enough time was felt to be dedicated to this. Furthermore, it became apparent that practice and feedback with an actual patient was valued by the physiotherapists and appeared to be an effective strategy to improve fidelity. Feedback had not been planned, but due to initial observations revealing low intervention fidelity, this was provided to the physiotherapists. Whilst any improvements cannot be directly attributed to feedback, there appeared to be an increase in engagement with The COMBINED approach, and an increase in fidelity. This was also recognised by the physiotherapists and led to audit and feedback being added as an additional component within the implementation strategy to support HCP behaviour change.

Audit and feedback in healthcare is defined as a 'summary of the clinical performance of healthcare provider(s) over a specified period of time' (Ivers et al, 2012, p. 6). Audit and feedback are an effective strategy to support HCP behaviour change, with the aim of improving professional practice (Ivers *et al*, 2012; Johnson and May, 2015).

Analysis of the observation data (video recordings) identified further key issues. Firstly, there was a lack of objective assessment of the health behaviours, for example measuring height and weight to calculate BMI. I reflected this may be due to the pre-screening where objective assessments had already taken place prior to the consultation. The

physiotherapists may therefore have felt this was unnecessary. However, this finding is consistent with other studies where physiotherapists infrequently assessed weight objectively (Holden *et al.*, 2019). Emphasising the importance of objective assessments of the health behaviours in future training, and not pre-screening for the lifestyle factors as part of the inclusion criteria, are suggestions to address this issue.

Secondly, there had been regular missed opportunities by the physiotherapists to discuss and address relevant lifestyle factors within the consultation, even when patients offered cues. Particularly, opportunities to link the role of relevant lifestyle factors to systemic inflammation, and the onset and progression of their shoulder condition was lacking, which was an integral part of The COMBINED approach. This resulted in misinterpretation and poor recall by the patients as to these links, which may result in patients overlooking the relevance and importance of the lifestyle factors in the management of their RC disorder. The patient cues that were not responded to could be partly explained by the ingrained practice behaviours, whereby physiotherapists were focused on a set process of assessment that did not allow deviation from to discuss health behaviour change when the opportunity presented itself. This signifies the lack of a patient-directed conversation, and therefore a person-centred approach in these consultations.

Missed opportunities are described as patient consultations where a relevant health behaviour was discussed, but the HCP failed to link the health behaviour to their presenting condition or attempted to promote behaviour change (Cohen *et al.*, 2011). Missed opportunities have been previously reported in other studies examining HCPs integrating health behaviour change interventions in routine consultations (Nelson *et al.*,

2016; Keyworth *et al.*, 2018). Supporting the findings in this study, Nelson *et al.* (2016) found that patients expected, and wanted to have, lifestyle conversations, but practitioners failed to respond to opportunities where a conversation could have been initiated around health behaviour change. Similarly, they found a focus on usual processes and information gathering resulted in these missed opportunities.

The opportunity to make explicit links between a relevant health behaviour and a presenting condition is described as a 'teachable moment', which is a strategy to motivate health behaviour change (Cohen *et al.*, 2011). Previously, the evidence to support teachable moments were in relation to more serious health-related concerns, such as a diagnosis of cancer, however it has been shown that less significant health events can also present as a teachable moment (Cohen *et al.*, 2011). Furthermore, it has been shown that teachable moments that link health behaviour change advice to the diagnosis of the presenting condition resulted in a 2-4 fold increase in patient recall of the discussion, which is important for motivating health behaviour change (Flocke and Stange, 2004). Patient recall in this study could have potentially been improved, had more teachable moments occurred. For teachable moments to be effective, HCPs firstly need to have the necessary skills to explore what is important to the patient and their personal motivations to change, to then make any links in relation to this (Cohen *et al.*, 2011). In The COMBINED approach these skills were intended to be put into practice using MI principles, however this was poorly executed in this study. Secondly, teachable moments need to occur throughout the consultation, including while taking a patient history, making a diagnosis, and discussing treatment options (Cohen *et al.*, 2008). Again, this was

a fundamental aspect of The COMBINED approach with the intention to emphasise to patients that addressing the lifestyle factors and shoulder-specific rehabilitation were both equally important, but this integration did not happen in practice.

To enable effective communication skills within health behaviour change conversations, and to empower and enable patients to take control of their own health, MI is a key activity within person-centred care (NHS Health Education England, 2017; Hutting, *et al.*, 2022). It was observed within this study that there was a strong biomechanical focus within the consultation, and subsequently these aspects were poorly executed within the delivery of The COMBINED approach. The challenge of adopting a person-centred approach, due to HCPs commonly focusing on biomechanical approach, is highlighted in the wider literature (Hutting *et al.*, 2020). Furthermore, it was evident these skills require more repetition, practice and feedback within the clinical setting.

These key issues have highlighted a need to refine the training workshop with a focus on supporting physiotherapists to recognise and take advantage of cues and opportunities for a teachable moment, and strategies to improve their MI skills as part of this.

8.7.2 Study Strengths

A strength of this study is the comprehensive use of mixed methods and involvement of end users to test and refine the prototype intervention, recognised as an important step for successful intervention development (O'Cathain, Croot, Duncan, *et al.*, 2019). For example, observations were important to observe actual, rather than just reported practice. The interviews were important to draw on experiential knowledge and address

issues of importance and relevance to end users, therefore each method provided complementary and additional insights. The flexible and responsive approach, which is a key principle to good intervention development (O'Cathain, Croot, Duncan, *et al.*, 2019), allowed for the early identification of key issues in the delivery of The COMBINED approach and to intervene with feedback to prevent poor practices persisting throughout the study. Key additional strategies to support HCPs deliver The COMBINED approach in practice, with fidelity, were identified. Improving fidelity during the intervention development process is important for increasing the chance of future effectiveness (Bleijenberg *et al.*, 2018a; Goodwin *et al.*, 2019; O'Cathain, Croot, Duncan, *et al.*, 2019).

8.7.3 Study Limitations

The are limitations to this study. One limitation is the context in which the study took place, limiting the representativeness of this study. A private physiotherapy practice was selected for practical and efficiency reasons due to the current COVID-19 pressures on the NHS. Many services were still experiencing disruptions to services, including longer waiting lists and restrictions on face-to-face contact, with many physiotherapy consultations still taking place remotely. This context may present with different pressures to the NHS, however, early testing was to identify more generally if physiotherapists could be trained to deliver The COMBINED approach and to understand the experience of physiotherapists and patients in relation to this. One of the physiotherapists also worked full-time in the NHS, with an expectation that we could draw on that experience.

Another limitation is that only one cycle of testing and refinement was able to be completed. Initially I experienced challenges with recruitment, but also a lack of engagement from the clinical team, meaning patients were not booked in for appointments in a timely manner. A pragmatic decision was made to not conduct a second cycle within the time-pressures of this PhD fellowship. Substantial learning had been received from one cycle, with clear identification of changes that could be easily made to refine The COMBINED approach. It was agreed with the supervisory team that a second cycle was unlikely to add anything further to this. Furthermore, in this context, it was identified that the patient participants were highly motivated and engaged, and lacked diversity, therefore they were unlikely to be representative of patients in the NHS. This strengthened the justification for not conducting a second cycle in the private practice as it was considered more important to move to a multi-centre feasibility study to address key uncertainties in an NHS context, where future implementation is planned. Intervention refinements would be ongoing and therefore the second cycle would be conducted in the context of a feasibility study. My development, as part of a training fellowship, gained through the experience of conducting a multi-centre feasibility study, was also a priority.

8.7.4 Reflexivity

My role as the interviewer, as well as the intervention developer, may have influenced the collection and interpretation of the data. For example, the physiotherapists and patients may have felt the need to report more positive accounts of the intervention. To mitigate this, I had emphasised to participants prior to the interviews that this study was

not to assess their performance, but to gain their feedback (both positive and negative) to improve the intervention as part of the development process. The data analysis was supported through discussions with the supervisory team to prevent any researcher bias in interpreting the data. Reflexive notes were also made to be transparent in my interpretations. As a result, I felt there was a mix of both positive and negative feedback, that felt open and honest.

My own beliefs about the value and importance of The COMBINED approach meant I failed to recognise early on that others might not hold the same beliefs. It only became apparent following delivery of The COMBINED approach in practice, and fully understood in the interviews with the physiotherapists, that The COMBINED approach did not initially align with their attitudes and beliefs. This impacted on the physiotherapists' engagement with The COMBINED approach. This has been important learning for me to understand the importance of establishing individual attitudes and beliefs from the outset to identify how these might be addressed to fully engage with The COMBINED intervention.

Lastly, my belief that the BPA intervention would be a suitable component to integrate with The COMBINED approach as current best practice was not supported in this study. Introducing a new approach that included additional components not currently used by physiotherapists added to the complexity. Consequently, moving forward the BPA intervention was removed as a component of The COMBINED approach and integrated with usual care.

8.8 Conclusion

Key insights from this early intervention testing have informed refinements to The COMBINED approach prototype, based on experiential knowledge of what is important to clinicians and patients who will use this intervention. This study has supported previous finding in this thesis that the successful implementation of The COMBINED approach is dependent on changing HCP behaviour change, particularly in relation to practice behaviours. Findings from this study have advanced the understanding of the comprehensive strategies required to support physiotherapists to deliver The COMBINED approach in practice and to enhance fidelity. Strategies include audit and feedback, as well as education on teachable moments and developing a more person-centred approach. Furthermore, the BPA intervention was deemed as unsuitable at this stage to integrate with The COMBINED approach. Changes will need to be made to the training package and resources in the implementation toolkit to develop an optimised version of The COMBINED approach (V2.0) to be tested and refined further in a feasibility study.

8.9 Chapter Summary

This chapter has described the early testing and refinement of The COMBINED approach prototype in the context of a usability study, with the purpose of making refinements. Chapter nine will present the findings of a mixed methods single-arm multi-centre feasibility study to evaluate the implementation of the second version of The COMBINED approach prototype. The intervention will be refined further in readiness for evaluation in a future definitive trial.

Chapter 9 Evaluation of The COMBINED Approach Prototype (V2.0) in a Single-arm Feasibility Study

9.1 Chapter Introduction

This chapter describes a mixed methods single-arm feasibility study to evaluate the implementation of the second version of The COMBINED approach prototype, as part of the evaluation stage (stage 2; workstream (WS) 5) of the intervention development process (Figure 9.1). Behavioural determinants, fidelity and patient acceptability were assessed to inform further refinements in readiness to be evaluated in a future definitive trial. A final optimised version of The COMBINED approach will be presented.

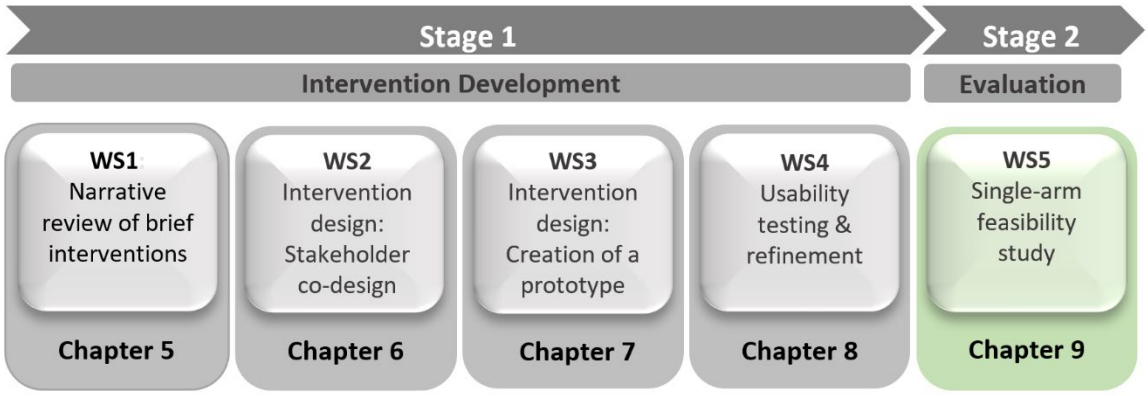

Figure 9.1 to show where this chapter fits within the intervention development process
WS, Workstream

9.2 Background

Version one of The COMBINED approach prototype was tested and refined in a first iteration of testing in a private physiotherapy clinic in the context of a small usability study (Chapter 8). The COMBINED approach prototype (V1.0) was found to be feasible and acceptable to both patients and clinicians. However, key issues were identified with

the delivery of The COMBINED approach by the physiotherapists in terms of the quality of implementation and fidelity. Learning from this early intervention testing study pointed to the need to refine the strategies in the physiotherapists' implementation toolkit to enhance implementation and fidelity of the COMBINED approach.

Only one cycle of iterative usability testing was completed in Chapter 8, which was reflected on in section 8.7.3. The decision was made to move onto the feasibility study as initial testing of The COMBINED approach prototype (V1.0) identified key uncertainties about delivery and implementation in practice in an NHS setting. As the feasibility study may facilitate further refinements to The COMBINED approach prototype (V2.0), it was considered the second cycle of iterative testing could be in the context of a feasibility study.

A feasibility study is recommended by existing guidance on the development of complex interventions as the next stage in this programme of work (O'Cathain, Croot, Duncan, *et al.*, 2019; Skivington *et al.*, 2021), and ahead of undertaking a definitive randomised controlled trial (RCT) to test clinical and cost effectiveness. Based on the key uncertainties identified from the usability chapter, The COMBINED approach was not deemed ready for testing in terms of evaluating clinical effectiveness. The focus of this study was therefore to address the main uncertainty of delivery and implementation of The COMBINED approach in the NHS. Furthermore, while several objectives could have been considered in this feasibility study, due to the delays experienced, the objectives were prioritised in the context of a time-limited fellowship.

9.3 Workstream 5 Aims and Objectives

The aim of the feasibility study was to evaluate the implementation of The COMBINED approach prototype (V2.0) to facilitate ongoing intervention refinements, including the strategies for implementation, in readiness for a definitive trial (Thesis objective 6, Chapter 1, section 1.4).

Primary objectives included to:

1. Assess the key domains of behaviour change influencing the implementation of The COMBINED approach among physiotherapists;
2. Assess the fidelity of The COMBINED approach;
3. Identify and make any required refinements to the intervention components of The COMBINED approach;
4. Explore the patient experience of receiving The COMBINED approach in an NHS setting.

A secondary objective was to:

5. Evaluate feasibility of recruitment in terms of numbers of patients who consent to the study who had an identified lifestyle factor: Smoke (tobacco); and/or had a BMI greater than 25kg/m^2; and/or do less than 150 mins of moderate-intensity or <75 minutes vigorous-intensity activities/week, to inform a future sample size calculation.

9.4 Study Design

9.4.1 Methods

This was a mixed methods, pragmatic, single-arm multicentre non-randomised feasibility study. The following quantitative and qualitative methods were used: To address WS5 objectives 1-3, and 5, both quantitative and qualitative methods were employed. Quantitative methods included a survey and fidelity assessment, and qualitative methods, involved non-participant observations. For WS5 objectives 3-4, qualitative methods were used, specifically semi-structured interviews. Together, these methods provided a comprehensive understanding of the feasibility of The COMBINED approach, including how well it was implemented and received within an NHS context, to inform refinements ahead of a future definitive trial. The approach was both sequential, with the surveys, non-participant observations and fidelity assessments conducted prior to the interviews, and convergent, with equal priority placed on each method.

The methods chosen for this feasibility study differed from those used in the usability testing study (Chapter 8) due to several practical and methodological considerations. Firstly, implementation issues identified in the usability study led to a focus on implementation-related barriers and facilitators, aligning with the use of a Theoretical Domains Framework (TDF)-based survey. Similar studies have effectively used TDF surveys to assess factors affecting the implementation of behaviour change interventions, supporting its application here (Keyworth *et al.*, 2019; Hollis *et al.*, 2021; Meade *et al.*, 2023). Secondly, in-depth thematic analysis of clinician and patient interviews was not

feasible within the project's timeframe. Therefore, clinician surveys were used alongside patient interviews to efficiently gather data on implementation factors and patient experiences. Thirdly, as this PhD formed part of a training fellowship, employing different methods was valuable for my professional development and allowed for adaptation to meet specific study objectives and constraints.

A dynamic approach to testing was adopted in this study, recognised as an approach in intervention development (O'Cathain *et al.*, 2015). The purpose of a dynamic approach is to be responsive to what is working or not working to optimise the intervention, implementation strategies and trial conduct, and make any necessary changes during the study.

9.4.2 Study setting

Musculoskeletal physiotherapy services across four NHS Trusts – selected for heterogeneity including geographical location, patient diversity, and a mix of general musculoskeletal and shoulder specialist units.

9.4.3 Participants

9.4.3.1 Eligibility criteria

Participants included: (1) physiotherapists; (2) patients with a rotator cuff (RC) disorder.

1) Physiotherapists were eligible if they were:

- A qualified (HCPC registered) physiotherapist involved in the management of patients with a RC disorder at one of the trial sites;

- Willing to consent to the study procedures, including attending a training workshop, audio-recording of the consultations and audit/feedback on intervention delivery.

2) Patients were eligible if they were:

- Aged 18 or over;
- Diagnosed with a RC disorder as per the diagnostic criteria in the British Elbow and Shoulder Society guidelines (Rees *et al.*, 2021) as outlined in Chapter 8 (section 8.4.3);
- Able to attend at least one face-to-face physiotherapy consultation. Eligibility was confirmed via physical examination at this session as per the criteria above;
- Able to give full informed consent;
- Willing to consent to the study procedures, including audio-recording of the consultations.

The exclusion criteria for the patient participants were:

- Significant trauma;
- Neurological or inflammatory causes of their shoulder pain;
- Any clinical indications of serious pathology.

Participants were not excluded based upon protected characteristics for example, age and ethnicity. Anyone referred into the physiotherapy department with a RC disorder

were eligible to take part in the study. Measures in place included support for the consent process, consultation or patient interviews where required, for example, if verbal translation was needed via a hospital interpreter, personal interpreter or telephone translation service.

9.4.3.2 Sample size

The sample size for this study was set to provide sufficient data to achieve the study objectives and was based on a time-based recruitment period. I planned to recruit as many patient participants as possible over a period of 4-6 months, reflecting staged opening to recruitment across the four NHS sites for the purpose of informing the feasibility of recruitment of a future main trial. We planned to recruit at least two physiotherapists per site from four NHS sites (eight physiotherapists in total), based on the number of clinicians required to deliver The COMBINED approach to the expected patient recruitment target.

Data from a previous physiotherapy-led RCT in this same patient population, the GRASP trial (Hopewell, Keene, Heine, *et al.*, 2021), recruited on average 1.4 patients/month. Over a 4–6-month period it was expected a total of 22 to 34 patients from all four sites could be recruited. However, recruitment of 12-15 participants over the specified recruitment period would provide sufficient data to meet the study objectives.

For the patient interviews I planned to recruit an initial sample size of 10-12 patients, using information power as a stopping criterion, for example, when sufficient rich

information from the data had been gathered to adequately address the study aims and objectives (Braun and Clarke, 2022).

9.4.3.3 Recruitment

Physiotherapists

A principal investigator (PI) was designated at each NHS site, who facilitated and supported the recruitment of the physiotherapists. The PI engaged with physiotherapy colleagues through team meetings, informal discussions and/or email, for expressions of interest. Interested participants were sent a participant information sheet (PIS) (Appendix T) and, if willing and eligible, were consented to take part in the study by the local PI (consent form shown in Appendix U).

At some sites the PIs were also a treating physiotherapist, who I screened for eligibility and consented to the study remotely through Microsoft Teams (procedure as outlined in Chapter 8, section 8.4.3.3). The audio-recording was saved on the secure Manchester Metropolitan University OneDrive and deleted from the recording device. A paper copy of the consent form was signed and dated by proxy, uploaded to the university OneDrive for storage in the master site file, and then destroyed.

Patients

Potential participants were identified at sites by the local PI and/or clinicians as members of the patient's existing clinical care team. The recruitment process was dependent on individual site procedures but included identifying potentially eligible participants from referrals on a physiotherapy waiting list during routine departmental screening or in

triage clinics. The patient was provided with a PIS (Appendix V) via post, email or face-to-face and contacted (after a minimum period of 24 hours later) by the PI via telephone to discuss participation in the study. Interested and eligible participants were pre-screened for inclusion (stage 1 eligibility) during this call by the PI regarding the clinical diagnosis and eligibility criteria. If eligible at this stage, an appointment was made to attend the physiotherapy department for final screening (stage 2 eligibility) to confirm eligibility and the diagnosis of a RC disorder. Written informed consent was taken from willing and eligible participants by the PI (or a delegated member) (consent form shown in Appendix W). The patient then continued with a physiotherapy consultation with the treating physiotherapist to deliver the intervention.

Where a patient did not meet the eligibility criteria at this final screening appointment, they continued with a physiotherapy assessment and treatment as part of usual care, but not as part of the study. If a patient declined participation or was ineligible, their physiotherapy treatment was processed as usual and the information recorded on a screening log, including reasons for this, to identify any barriers to recruitment to inform plans for the main trial.

For the patient interviews, during the initial consent process patients had the option to consent to further contact to participate in an interview. If they consented, they were provided with an additional PIS (Appendix X) detailing the procedures for the interview and contacted by me following their consultation and invited to participate in a short telephone interview at their convenience. Purposive sampling was used to gain a range of perspectives including patients from different sites, those with a range of lifestyle factors

(including no lifestyle factors), and with respect to gender and ethnicity. Audio-consent (Appendix Y) was taken prior to the interview. The audio-recording and paper copy were stored as outlined in the physiotherapist section above.

Figure 9.2 shows the study overview and recruitment process.

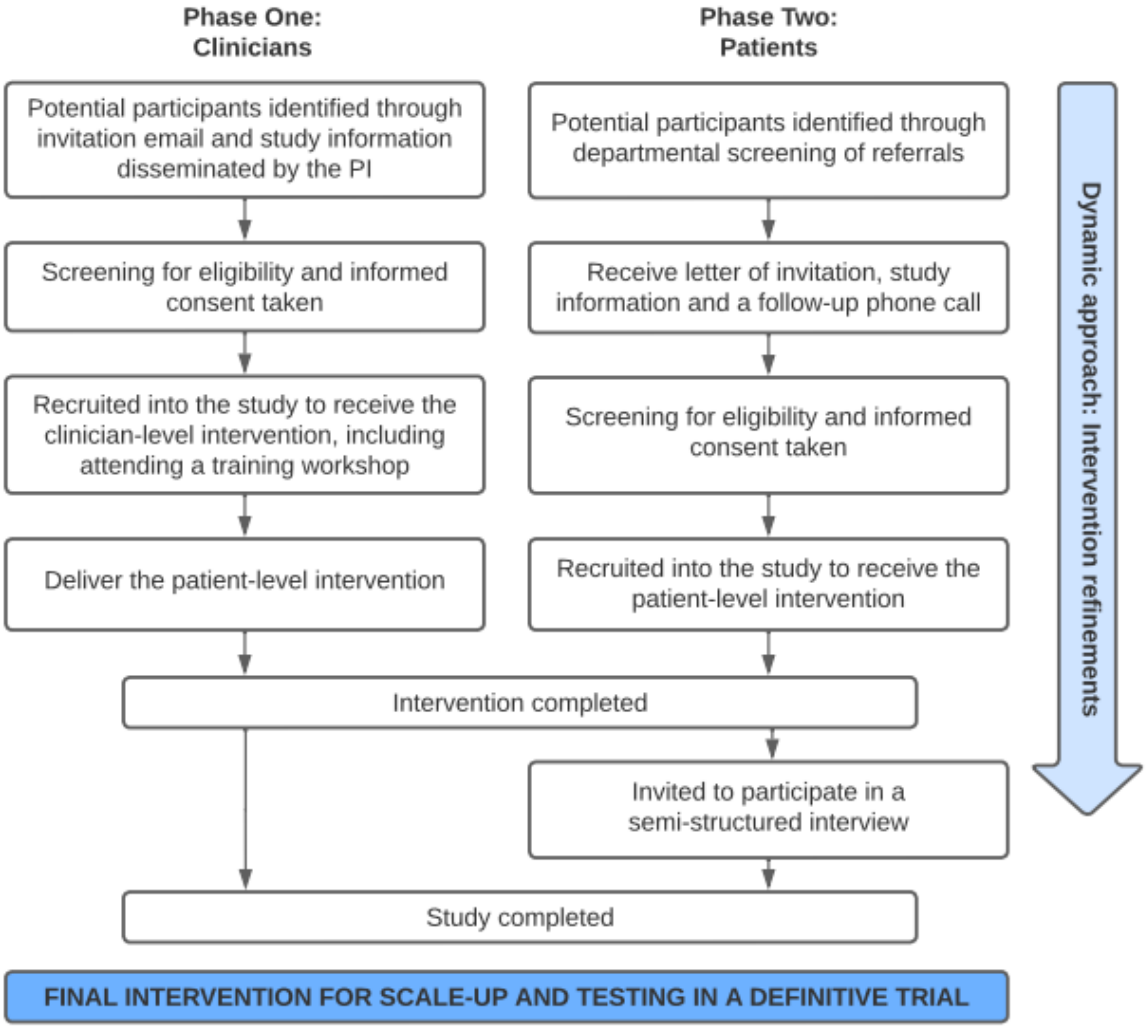

Figure 9.2 Study overview and recruitment processes

9.4.4 Study procedures

Physiotherapists

The participating clinicians attended a 4-hour face-to-face workshop at a central location on university premises. The training content (previously described in detail in Chapter 7, and 8) was delivered by me, supported by a member of the supervisory team (CL). The physiotherapists were provided with a training pack, which included the slides from the workshop and the other components of the implementation toolkit (discussed in detail in Chapter 7 and 8), including the scripts, step-by-step guide, infographic, signposting information and patient resources. Following the training workshop, each site was offered an online top-up training session via Microsoft Teams prior to seeing their first patient.

A selection of physiotherapists across the participating sites were observed (subject to patient and clinician consent) delivering The COMBINED approach by me, conducted in real-time either face-to-face or online (Microsoft Teams). If these methods were not convenient, the audio-recordings were used post-consultation. The purpose of the observations was three-fold, firstly for audit and feedback, as an implementation strategy in the toolkit; secondly, to facilitate the dynamic approach (described in section 9.4.1) to identify early issues and make changes; thirdly, to enable my reflections and interpretations on the delivery of The COMBINED approach. Challenges to intervention delivery were identified and discussed, and feedback provided where necessary, to improve fidelity. Individual timely feedback was initially offered to the physiotherapist regarding intervention delivery including challenges and examples of good practice,

followed by general feedback to the other participating physiotherapists via email. The physiotherapists were also requested to complete a self-report fidelity checklist using a case report form (CRF) (Appendix Z).

Patients

Patients attended an initial 60-minute consultation with a physiotherapist where they received The COMBINED approach intervention (described in detail in Chapter 7 and 8).

One of the changes made from the usability study (Chapter 8) was to identify as part of The COMBINED approach if the patient had any relevant lifestyle factors as part of the assessment. If no relevant lifestyle factors were identified, this was recorded on the CRF (described above) by the treating physiotherapist and the consultation continued as per usual care. If the patient had an identified relevant lifestyle factor, the physiotherapist continued to deliver The COMBINED approach and recorded the relevant lifestyle factors on the CRF. Patients with an identified relevant lifestyle factor were offered a 30-minute follow-up appointment, approximately two weeks later, to discuss progress with regards to their shoulder pain and any agreed behaviour change goals with respect to the lifestyle factors.

9.4.5 Data collection

Table 9.1 provides a summary of the data collected and how it links to each objective of the feasibility study.

Table 9.1 Workstream 5 objectives linked to data source

Table 9.1 Objectives linked to data source	
Objective	**Data source**
1. Assess the factors influencing implementation	Self-report survey (physiotherapist)
2. Assess fidelity of delivery of the patient-level intervention	Audio-recordings of consultation/fidelity checklist Self-report fidelity checklist/participant contact form (physiotherapist)
3. Identify and make any refinements	Audit & feedback sessions Audio-recordings of consultation Self-report surveys (physiotherapist) Interviews (patient)
4. Explore the patient experience of receiving The COMBINED approach	Interviews (patient)
5. Evaluate patient recruitment in terms of identified lifestyle factors	Screening data/participant contact form

Demographic data

Demographic details were collected from each physiotherapist and patient participant using Microsoft Excel for Microsoft 365 (Version 2310) at study entry. Clinical data to confirm the presence of any relevant lifestyle factors (smoking status, BMI and/or physical activity levels) were also collected from the patient participants. This data was used to determine of how many patients recruited had one or more of the identified lifestyle factors.

The following data were collected from physiotherapist participants:

Self-report survey

Self-report surveys examined factors influencing implementation of the intervention using items from the Determinants of Implementation Behaviour Questionnaire (DIBQ) (Huijg, Gebhardt, Dusseldorp, *et al.*, 2014). This is an existing validated survey designed to measure factors based on the Theoretical Domains Framework (TDF), a comprehensive framework of determinants of healthcare professional (HCP) implementation behaviours. The DIBQ consists of 93 items covering 18 domains for evaluating implementation behaviour (Huijg, Gebhardt, Dusseldorp, *et al.*, 2014). Previous research studies assessing the psychometric properties of surveys using the TDF have shown good content and face validity, as well as internal consistency (Huijg, Gebhardt, Crone, *et al.*, 2014; Huijg, Gebhardt, Dusseldorp, *et al.*, 2014). The DIBQ has been designed to be applied flexibly to different contexts, with evidence highlighting the reliability and validity of adapting the DIBQ to different contexts (Taylor *et al.*, 2013).

Survey development

The existing extensive TDF survey items in the DIBQ were adapted for use in this study based firstly on considerations of feasibility and practicality (to limit survey length and participant burden), and secondly, relevance to assess the implementation behaviours in this context on the delivery of The COMBINED approach. A previous survey has been adapted from the DIBQ to evaluate implementation behaviours for Make Every Contact Count (MECC) (Meade *et al.*, 2023) and informed the development of the survey in this study.

The final survey (Appendix AA) contained 34 items based on 10 domains of the TDF, refined through consultation with the supervisory team, and included two open-ended questions on the barriers and enablers to delivery of The COMBINED approach. Participants rated their level of agreement with a statement on a 7-point Likert scale (1 = strongly disagree; 7 = strongly agree). A lower score on a domain indicates a stronger barrier to behaviour change. Previous studies vary in the domain score considered to indicate a potential barrier or facilitator, with some using the middle value of four as a cut-off (Doherty *et al.*, 2020), whereas other studies using a score less than six to limit reporting of potential social desirability in responses (Grady *et al.*, 2018; Hollis *et al.*, 2021). A score of less than six was considered in this study to indicate a potential barrier, in line with the justification of accounting for social desirability.

Physiotherapists completed the surveys post-training and post-intervention delivery.

Fidelity assessment

Fidelity was assessed by (i) a self-report checklist completed by the physiotherapist to record components of The COMBINED approach delivered in the consultation; (ii) audio-recordings of all sessions to allow actual observation of implementation to complement the self-reported data. A digital recorder was switched on by the physiotherapist at the start of each consultation (after checking that the patient had consented to their consultation being audio-recorded).

After receiving the recordings, I listened to the recording using a pre-defined fidelity checklist (Appendix BB) to determine which aspects of The COMBINED approach was

delivered to protocol and in accordance with the training, for example, whether the content of the training was evident in the physiotherapist's behaviour. Other observation practices were recorded such as, the length of the consultation, other shoulder treatments provided, how The COMBINED approach was integrated, and any adaptations made during delivery. The recordings, where necessary, were used to feedback to the physiotherapists to improve fidelity. A second reviewer (GY) reviewed a sample of the audio-recordings to verify my judgements and the rationale behind my decisions.

Audit and feedback sessions

Audit and feedback was a strategy in the implementation toolkit to target HCP behaviour change with regards to delivery of The COMBINED approach and to improve fidelity. It was also a source of data of my reflections and feedback from participants about the delivery of The COMBINED approach in practice. A log of the discussion points, observations of practice, feedback and any modifications to the intervention as a result were recorded on a proforma with pre-determined categories based on the RREAL (Rapid Research Evaluation and Appraisal Lab) sheet (Vindrola-Padros *et al.*, 2020) (Appendix CC). This data was iteratively fed back to the participating physiotherapists.

Data collection and analysis was conducted in parallel to rapidly share emerging findings with the clinician participants to make necessary changes to the intervention, implementation, or study design. Information per site was synthesised using the RREAL sheet to produce actionable feedback to the clinicians involved in the study.

The following data was collected from patient participants:

Patient interviews

Semi-structured interviews explored the patient experience of receiving The COMBINED approach. I conducted the interviews following a topic guide (Appendix DD), which were audio-recorded using a digital voice recorder. The audio-recording was saved on the university's secure OneDrive and deleted from the recording device.

All data were anonymised following initial consent, with participants assigned a study ID number. The data were stored on the university's OneDrive in a master site file, accessible only to me and one member of the supervisory team (GY). Data was transferred from NHS sites via NHS mail and the NHS-provided Egress, which is a secure method of transferring patient data in the NHS. This method was acceptable to both the NHS and the university sponsor.

9.4.6 Data analysis

Descriptive statistics (percentages/proportions) were used to analyse the quantitative data from the fidelity checklists, and demographic data, including the proportion of patients recruited to the study with an identified lifestyle factor. Descriptive statistics (median/inter-quartile range (IQR)) were used to analyse the survey data, recommended for ordinal data and a sample that is not normally distributed, with a potential skewed distribution (Marateb *et al.*, 2014). Median scores and IQR were calculated for each question, and overall, for each TDF domain. Changes to the median scores and IQR pre and post intervention delivery were reported. Items on the survey were both positively and negatively phrased, with negative items reverse scored during the analysis.

The qualitative data included observations, open ended responses on the survey and the patient interviews. The observation data was analysed and summarised narratively, linking my subjective reflections and interpretations to the data in relation to intervention fidelity and the audit and feedback sessions. Interview data was analysed using a deductive table-based approach based on a priori-defined themes using a RREAL sheet (Figure 9.8, section 9.6.6), for the purpose of efficiency, without compromising rigour (Vindrola-Padros *et al.*, 2020). An additional category of 'other' on the RREAL sheet allowed for emerging themes. Minimal transcription involved coding direct from the audio-recordings instead of transcripts, and synthesising the relevant data into one RREAL sheet under the applicable themes. Anonymised quotes were included in the RREAL sheet to illustrate the themes. The synthesis of data from all patient interviews onto a single RREAL sheet identified any gaps requiring further exploration with subsequent participants. This process also informed the stopping criterion, based on information power, as described in section 9.4.3.2.

9. 5 Ethical Principles

Favourable ethical review was confirmed by the West of Scotland REC 4 on the 7th of June 2023, the Health Research Authority on the 14th of June 2023 (reference: 23/WS/0073) and the Faculty of Health and Education REC at Manchester Metropolitan University on the 3rd of July 2023 (EthOS reference: 51451) (Appendices EE-GG).

9.6 Results

9.6.1 Study flow of participants

The study ran for four months between the 3rd of July to the 25th of October 2023. Overall, 17 patients and eight physiotherapists were recruited from four NHS sites. Two physiotherapists were lost to follow-up (survey data) as they did not end up delivering the intervention in their role as PI. Figure 9.3 shows the study flow of patient participants.

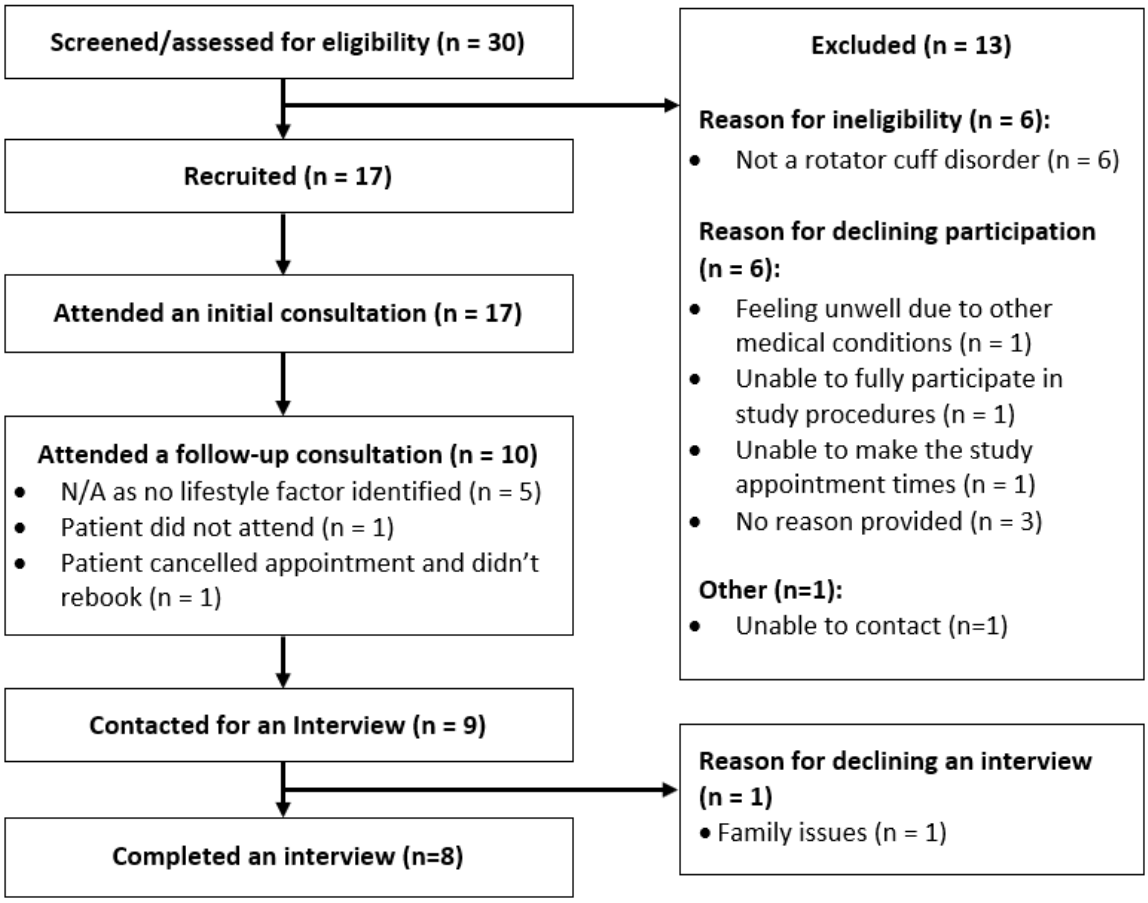

Figure 9.3 Study flow of patient participants

9.6.2 Participant characteristics

Patient and physiotherapist characteristics are presented in Tables 9.2 and 9.3 respectively.

Table 9.2 Patient characteristics

	n (%)		n (%)
Sex		**Employment Status**	
Female	9 (53)	Employed Full-time	8 (47)
Male	8 (47)	Unemployed	2 (12)
Ethnicity		Retired	7 (41)
White British	14 (82)	**Lifestyle Factor**	**n (%)**
Asian British Indian	2 (12)	Participants with no lifestyle factor(s)	5 (29)
White Irish	1 (6)	Participants with a lifestyle factor(s)*:	12 (71)
Age (years)	**Mean (range)**	Smoker	2
	59 (39-74)	Overweight/obese	10
		Physically inactive	7

* Participants may have one or more lifestyle factor

Out of the 12 participants with a lifestyle factor, seven (58%) had multiple lifestyle factors including: overweight/obese & physically inactive (n=6); physically inactive & smoker (n=1).

Table 9.3 Clinician characteristics

	n (%)		n (%)
Sex		**Professional Role**	
Female	4 (50)	Advanced Practitioner (Band 8a)	1 (13)
Male	4 (50)	Clinical Specialist (Band 7)	4 (50)
Ethnicity		Specialist Physiotherapist (Band 6)	3 (38)

White British	4 (50)	**Clinical speciality/setting**	**n (%)**
Asian British Pakistani	1 (13)	General MSK outpatients	6 (75)
White other	1 (13)	Upper limb specialist	2 (25)
White and Asian	1 (13)	**Number of years qualified**	**Mean (range)**
Mixed/multiple ethnicity	1 (13)		17 (6-34)

Table 9.4 shows the patient characteristics of the eight interview participants. The interviews were stopped at eight participants based on information power, as previously described (section 9.4.3.2).

Table 9.4 Interview participant characteristics

	n (%)		**n (%)**
Participant per site		**Employment Status**	
Site 1	3 (38)	Employed Full-time	4 (50)
Site 2	0 (0)	Retired	4 (50)
Site 3	3 (38)	**Lifestyle Factor**	**n (%)**
Site 4	2 (25)	Overweight/obese & physically inactive	3 (38)
Sex		Overweight/obese	1 (13)
Female	4 (50)	Smoker	1 (13)
Male	4 (50)	No lifestyle factor	2 (25)
Ethnicity			
White British	5 (63)		
Asian British Indian	2 (25)		
White Irish	1 (13)		

9.6.3 Fidelity assessment

All consultations were recorded. Three recordings were lost due to user error, but these consultations were observed enabling the fidelity checklist to be completed directly from the observation. For the initial consultation, the fidelity assessment showed that, overall, 82% of the aspects of the intervention were delivered as intended in line with the training. This ranged between 58-100% fidelity for individual consultations (67%-100% for individual physiotherapists). For part A of the fidelity assessment, involving the identification and assessment of the lifestyle factors for all the patients, this was performed with 96% fidelity. Only two out of the six physiotherapists did not set the scene as intended (asking permission) and only one physiotherapist did not assess BMI. However, this was related to the patient declining this to be performed.

Part B of the fidelity assessment, relevant to the patients with an identified lifestyle factor, involved the delivery of the brief intervention (BI) including the explanation of the links, the use of motivational interviewing (MI) skills to explore motivations to change, agreeing a plan and providing the resources to support behaviour change. This was performed with 67% fidelity. Common areas with low fidelity included: exploring personal motivations to change, with only five out of 12 consultations including this as per the training; agreeing a plan, included in only four out of 12 consultations; and signposting the patient to relevant support services, with six out of the 12 consultations not including this as intended, for example either not signposting at all, or providing the resources in the patient pack but not referring to this or offering any tailored information. The resources were generally well utilised, with only three out of 12 consultations where the

physiotherapist forgot to use the infographic, but all consultations provided and explained the activity workbooks and/or self-monitoring diaries.

For the follow-up consultations, overall, 80% of the aspects of the intervention were delivered as intended in line with the training. For individual consultations this ranged between 25-100%. Common areas with low fidelity included: three out of 10 follow-up consultations not discussing the patient's progress or exploring barriers in terms of health behaviour change efforts, and three out of 10 consultations not tailoring further conversations with respect to health behaviour change, for example building motivations to change and self-efficacy where appropriate.

A purposive sample of 12 audio-recordings (one initial consultation and one follow-up from each physiotherapist across all four sites) were reviewed by a 2nd reviewer (GY). One disagreement was resolved with discussion.

As part of the fidelity assessment, notes were made regarding other observations of practice. The observations are summarised across all the fidelity assessments and presented in Table 9.5.

Table 9.5 Summary of researcher observations linked to the fidelity assessment

Observation Practices	Researcher notes
Length of consultation	• Initial consultation: Range = 30-60 mins; Mean = 54 mins • Follow-up: Range = 15-45 mins; Mean = 30 mins
Other treatments provided	• Self-management advice • Shoulder exercises – range of movement and progressive loading • Shoulder mobilisations/soft-tissue massage
Resources used	• Some forgot to refer to the infographic and/or signposting information – all other resources used well • CMO guidelines consistently used during physical activity conversations • NHS BMI calculator consistently used in the consultation

Interactions/ emotions	• Both patients and clinicians generally seemed comfortable discussing lifestyle factors; patients generally appeared open to lifestyle discussions • Two patients were initially defensive – the physiotherapists managed the situation well using motivational interviewing skills
Challenges identified	• Defensive patient –declined having BMI assessed • One clinic didn't have access to scales, which relied on patient-reported weight • One physiotherapist treated the lifestyle factors and shoulder assessment as two separate entities, and therefore wasn't integrated throughout the consultation
Areas of good practice identified	• Consistent assessment of lifestyle factors e.g., BMI and physical activity levels as a baseline • Consistent explanation of the links between lifestyle factors and shoulder pain, with systemic inflammation as the underpinning mechanism • Some good examples of prioritising lifestyle factors to focus on and individualised tailoring when signposting to support services

CMO, Chief Medical Officer

9.6.4 Audit and feedback

Audit and feedback was conducted across initial and follow-up consultations in real time via face-to-face (n=7 consultation) and, online methods (n=4 consultations), and audio recordings post consultation (n=3 consultations). The physiotherapist participants were provided with verbal and written feedback to improve delivery of The COMBINED approach by sharing challenges and areas of good practice.

Common areas for individual feedback to improve delivery of The COMBINED approach included reinforcing the key MI aspects as part of the BI including asking permission, asking the patient what they already know/what they make of what they have just heard, emphasising personal choice/responsibility, exploring personal motivations, getting to an action plan; as well as utilising the resources in the implementation toolkit, such as the infographic and signposting information.

Table 9.6 shows an example of individual and collective feedback provided to physiotherapy participants based on a summary of several audit and feedback sessions.

Table 9.6 Summary of audit and feedback

Audit and Feedback	
Individual feedback	• Reminded physiotherapist of the components not used – infographic and signposting • Advised to get patient pack out in advance to remind them of the resources • To ask the patients 'what do you make of what I just said?' • As part of ask-share-ask – find out what the patient already knew about the links • Spend longer using motivational interviewing principles to explore personal motivations to change, then summarise. Don't move too quickly onto asking the patient 'what do you think you will do?'. • Make sure that the patient goes away with a clear plan in mind • When offering the patient resources – give more detail regarding what the diary and workbook might be helpful for
Collective feedback	• Have the patient folder out at the beginning of the consultation – which will be a reminder to refer to the infographic and signposting information, and to add the workbook and/or diary • There was a marked difference with the patients that were asked 'What do you make of what I have just said?' when discussing health behaviour change as a treatment option/after explaining why we think it will help with the management - it led into exploring their motivations and picked up any resistance early • Having scales has been really useful - where possible • Having the NHS BMI calculator open on a laptop/computer was really helpful - you can then show this to the patient to see where they are/how much weight it is recommending they lose - and then say....we can come back to this later, if you like? • The physio found taking their BMI worked better when going through the screening questions in the subjective history, instead of coming back to it in the physical assessment bit - e.g., do you smoke, how many days of the week are you active for 30 minutes or more, is it ok if I check your BMI? • Do BMI with everyone - one patient didn't look overweight, and was only slightly over, but then we discovered this isn't his normal weight for him and he has been steadily putting weight on, which he wanted to do something about • CMO physical activity guidelines - these were really useful to have out to help with the discussions around physical activity levels • Borderline patients - some patients have only been slightly overweight or might be very physically active, but not at a moderate intensity - discuss the links still with the patient, find out what they think about their PA

	levels/weight, and if it is something they would like to discuss as part of the management of their shoulder pain (for the reasons you have explained) • Don't move too quickly to asking, 'what do you think you will do?' - spend a few minutes using OARS to explore their motivations to change, before moving to an action plan. • If applicable, try to make a clear action plan with the patient, no matter how small, e.g., going to find out about local classes in the area - then you have something clear to come back to at their follow-up • Remember to explain the 2 patient resources before giving them out - the workbook is useful when thinking about change and making a plan/setting some goals. The diary is useful for monitoring your plan e.g., physical activity levels • With any resistance from the patient - emphasising personal choice, and also asking them what they think about their e.g. PA levels/is it something they want to talk about, has been helpful. • Overall, patients have appreciated the information and received this positively

9.6.5 Survey data

Table 9.7 presents the median score and IQR for each TDF domain. Five of the 10 TDF domains were identified as potential barriers (median domain score <6) influencing implementation behaviours at baseline (post training), including: beliefs about capabilities (median score 4); goals (median score 4.5); behavioural regulation (median score 4.5); environmental context and resources (median score 5); and emotion (median score 4.6).

Five of the 10 TDF domains were identified as potential facilitators (median domain score ≥6) at baseline, including: knowledge (median score 7), skills (median score 6), professional role and identity (median score 6), optimism (median score 6), and beliefs about consequences (median score 6).

Four of the ten TDF domains increased in median score post intervention delivery (beliefs about capabilities; behavioural regulation; environmental context and resources; and

emotion). The domains environmental context and resources, and emotions increased to a score of 6, therefore no longer considered a potential barrier. Changes in scores for the TDF domains post intervention delivery were not reflected in the higher scoring domains (≥6).

Table 9.7 Survey data

TDF domain subscale and relevant survey items (number of items)	Median Score (IQR) – Post training	Median Score (IQR) – Post intervention delivery
KNOWLEDGE (3) I am aware of the objectives of The COMBINED approach I am familiar with the content of The COMBINED approach I know how to deliver The COMBINED approach	7.00 (6-7)	7.00 (6-7)
SKILLS (3) I have received enough training to know how to deliver The COMBINED approach I have the skills to deliver The COMBINED approach During the training, I have had enough opportunity to practice delivering The COMBINED approach	6.00 (5.5-7)	6.00 (6-7)
PROFESSIONAL ROLE & IDENTITY (3) Delivering The COMBINED approach in routine consultations with patients is part of my work as a healthcare professional As a healthcare professional, it is my job to implement The COMBINED approach Delivering The COMBINED approach with my patients is consistent with my healthcare profession	6.00 (5-7)	6.00 (5-7)

BELIEFS ABOUT CAPABILITY (3) I am confident that I can deliver The COMBINED approach even when my patients are not motivated I am confident that I can deliver The COMBINED approach when there is little time For me, delivering The COMBINED approach with my patients seems/is easy	4.00 (4-5)	5.00 (4-6)
OPTIMISM (3) I am optimistic about the benefits of delivering The COMBINED approach With regard to delivering The COMBINED approach I'm always optimistic about the outcomes With regard to delivering The COMBINED approach I hardly ever expect things to go well[a]	6.00 (4.5-6)	6.00 (5-6)
BELIEFS ABOUT CONSEQUENCES (5) I believe that delivering The COMBINED approach is a good idea If I deliver The COMBINED approach, it will benefit my patients' health If I deliver The COMBINED approach it might damage my relationship with my patients[a] If I deliver The COMBINED approach, I would feel like I am making a difference to patients If I deliver The COMBINED approach, I feel my patients would appreciate it	6.00 (6-7)	6.00 (6-7)
GOALS (3) I have a clear plan of how I will deliver The COMBINED approach Generally, other aspects of care take precedence over delivering The COMBINED approach[a] Generally, there are more urgent priorities than delivering The COMBINED approach[a]	4.50 (4-5.5)	4.50 (3-6)
BEHAVIOURAL REGULATION (3) Delivering The COMBINED approach is something I can do automatically	4.50 (3-6)	5.00 (5-6)

I (will) keep track of how well I'm doing with regard to the delivery of The COMBINED approach It is possible for me to prioritise delivering The COMBINED approach		
ENVIRONMENTAL CONTEXT AND RESOURCES (5) Delivering The COMBINED approach is a good fit with routine clinical practice It is possible for me to adapt the delivery of The COMBINED approach in routine clinical practice to my patients' needs In the organisation I work in, supporting health behaviour change with patients is routine In the organisation I work in, there is sufficient time to deliver The COMBINED approach There is sufficient implementation support provided for delivering The COMBINED approach	5.00 (5-6)	6.00 (5-7)
EMOTION (3) I generally feel positive about delivering The COMBINED approach I generally feel nervous about delivering The COMBINED approach[a] Having to deliver The COMBINED approach adds to my feelings of stress at work[a]	4.50 (2.5-6)	6.00 (3-6)

Range 0-7. [a]Reverse scored item

From the open-ended questions, commonly reported enablers included: the training provided and support from the research team, including audit and feedback; the resources provided, particularly the step-by-step guide, infographic, scripts, signposting information and the patient activity workbooks and diaries; additional resources (not provided as part of the implementation toolkit) including Chief Medical Officer's (CMO) infographic on physical activity and NHS BMI calculator; practice/repetition with patients; increased time allocated as part of the study; and patient receptiveness and satisfaction. Commonly reported barriers included: Remembering all the different components and

resources; ingrained practice behaviours making it difficult to integrate The COMBINED approach; patient engagement; lack of knowledge of support services for signposting; equipment access, for example, scales to assess BMI; lack of time for personal preparation prior to delivery due to service pressures and priorities; and the knowledge that the consultations were being audio-recorded.

9.6.6 Patient interviews

Themes from the patient interviews are summarised in Table 9.8, including anonymised quotes to illustrate the themes.

Table 9.8 Summary of themes from patient interviews

Theme	Summary of interview findings	Illustrative Quotes
1. Experience of the consultation	Most participants expected, and were happy to be asked about, lifestyle factors in the consultation for their shoulder pain. Some thought this a positive thing, which they considered to be important and relevant to managing their condition.	There's nothing bad about somebody asking you do you smoke and things like that. If you go to the hospital or your GP they ask you certain things…so what's wrong with a physio asking for the same information? For me, it was completely normal that was discussed [PT-401]
	A few were surprised when asked about lifestyle factors, particularly weight, but still found this to be acceptable because it was explained to them why these questions were relevant to their condition.	It surprised me a little bit, probably because of my shoulder. I didn't expect it to be, any of them questions that would be, how do I put it, you know connected to my shoulder [PT-305]
	In terms of an assessment of the lifestyle factors, for example assessing BMI, most participants found this acceptable, relevant and understood why it was being done.	This is how you should start, you want to take their weight. I think that is important [PT-403]
	The participants acknowledged the physiotherapists communicated in a non-judgmental way, which contributed to a positive experience in discussing lifestyle factors.	It wasn't done in a derogatory way, you know, it was done in a supportive, matter of fact way, which is how it should be done, you know [PT-302]
	Participants reported they were happy to consider lifestyle behaviour change as part of the management plan for their shoulder condition as they were willing to give anything a try that might help their shoulder pain.	Definitely happy to do anything to do something with my shoulder…I'll try anything, you know, to sort of, well not to cure it, but anything that's going to make it better, I will try it [PT-105]

2. Understanding of the role of lifestyle factors in managing shoulder pain	Most participants understood from the physiotherapist's explanation why they were being asked about lifestyle factors during a consultation for their shoulder pain, and how it was important in managing their shoulder pain.	It's not just one element that can improve the problem, it can be more than just the physical/physiotherapy – it is about your lifestyle/diet and how much you are already contributing to the problem, or the resolution [PT-101]
	For some, however it was still difficult to understand the links with lifestyle factors in relation to their shoulder pain, and then why losing weight, for example, would help.	If it was a knee problem I had, fair enough, I would definitely want to lose weight, I would say ok, that makes sense sort of thing, or anything that I've got weight on, but you know it just didn't seem that it would make that much difference on my shoulder, because there's not much weight on my shoulders, except my head [laughs] [PT-105].
	Despite a lack of understanding for some, they were still happy to consider making changes to their lifestyle as they considered the physiotherapist the expert in this area.	It's still hard to understand why if I'm overweight, it would affect something at the top of my arm. I'm happy though that she's the specialist and knows what she's doing and saying, therefore it's something that I need to take on board and do something about it [PT-103]
	Despite participants feeling they had understood why lifestyle factors were an important influence to target within the management of their shoulder condition, when probed further in the interview, no participants were able to recall any specific information related to this, for example systemic inflammation. The majority discussed their understanding of weight on biomechanical mechanisms.	I understand about weight due to unnecessary stress on, heavier arm to carry around and things are stretched…and also if you're not moving the shoulder, you lose muscle [PT-302]

3. Impact of the consultation on health behaviour change	Most participants reported a positive impact of the consultation and subsequent efforts to make changes to their lifestyle with a clear plan to continue with the changes. For some, they had noticed improvements in their shoulder pain, but for others it was frustrating, because they hadn't yet noticed any change to their shoulder pain.	I thought enough is enough. The physiotherapist made me realise these things can have an effect, not just on the arm, but your body itself [PT-103] I had no idea it [smoking] could do that, so it obviously has made me a bit more motivated to try and stop smoking and you know, manage, be able to manage [PT-305] I have lost a bit of weight, so as far as I'm concerned, it's working…but my shoulder is still sore, which is a bit annoying sort of thing. I've lost all that lovely chocolate and biscuits and I'm still not getting any better, but I'm willing to keep going [PT-105].
4. Patient resources	There were mixed responses to the resources. Many felt that they looked useful and relevant but had only browsed through them since their consultation. Only a few participants had filled in either the activity workbook or diary or used the signposting information.	It is a prompt to say well can I have some stop smoking support, or can you recommend a diet for me and I know then that there are other referrals to be done that can support that. The more information you give people, the more educated they are about what they can eat, it should improve their health [PT-302] The food diary made me more conscious of what I am eating, especially at work [PT-401]
5. Meeting patient expectations	The consultation generally met the participants' expectations of physiotherapy treatment, and felt there was nothing missing from consultation.	It [the consultation] more than met expectations as I wasn't expecting that to be honest. It's nice to know they are thinking about more than just my shoulder and acting on it. I think it was beyond what I expected [PT-401]

	One participant reported how he came to physiotherapy with certain expectations of treatments, but his expectations changed during the consultation.	I went with "it's going to be an injection to get rid of the pain or surgery", even when the physio said she can get rid of the pain, I was still sceptical it would work. I was going in with the wrong mindset and I thought physio's not going to help this, but I'll go along anyway and see what happens. As it went along, I was more confident she was going to fix it in the long term [PT-103]
6. Recommendation for improvements	In terms of refinements to the consultation, or the provided resources, all participants were happy with these, and no suggestions were made for improvements.	Everything was clear and explained, everything was fine. I can't complain, put it this way. I don't think you could do anything more [PT-401]
7. Other emerging topics	None	

9.6.7 Intervention refinements

Suggestions for intervention refinements, informed by all data sources, included:

- CMO physical activity guidelines infographic and NHS BMI calculator to be a component of The COMBINED approach implementation toolkit for the physiotherapists;
- To adapt the step-by-step guide to assess BMI during screening questions within history taking, not during physical assessment, to improve the flow of the consultation;
- Further emphasis and practical skills training on MI aspects of the BI in the training workshop;
- Practice and repetition with patients in practice (prior to delivery of The COMBINED approach with a study participant) to help with memory/automaticity, practice behaviours and integrating The COMBINED approach, and confidence;
- Reinforce in the training workshop the patient receptiveness and engagement to increase physiotherapist's confidence;
- Clinical scenarios, particularly how to integrate The COMBINED approach with usual practice behaviours;
- Consider resources in different languages.

9.7 Discussion

9.7.1 Summary of findings

This feasibility study has evaluated the implementation of The COMBINED approach prototype (V2.0) to facilitate ongoing intervention refinements. An assessment of the key domains of behaviour change influencing the implementation of The COMBINED approach among physiotherapists identified several domains as key barriers. The domains included beliefs about capabilities, goals, behavioural regulation, environmental context and resources, and emotion. These domains indicated firstly that physiotherapists' confidence in delivering The COMBINED approach (beliefs about capabilities), particularly if there was not enough time, was low. Secondly, other priorities took precedence over The COMBINED approach (goals). Thirdly, delivering The COMBINED approach was not automatic (behavioural regulation). Fourthly, organisational context and implementation support (environmental context and resources) were a potential barrier. Lastly, delivering The COMBINED approach added to feeling nervous and stressed (emotions).

Positively, the domain score for emotions increased post-delivery of The COMBINED approach, suggesting that with practice and experience of delivering The COMBINED approach with patients, emotions are no longer a barrier. This may also have improved following the positive reception from patients to having lifestyle conversation, which in previous workstreams, physiotherapists' perceptions were that patients would respond negatively. Equally, the domain score for environmental context and resources improved post-delivery. One explanation for this could be that with experience using the resources

and the audit and feedback as part of the implementation toolkit, implementation support was no longer a barrier. Further refinements to The COMBINED approach will need to consider how to influence the domains of goals (i.e., priorities), beliefs about consequences (i.e., confidence) and behavioural regulation (i.e., automaticity) that were still considered barriers to implementation behaviours even post-delivery of The COMBINED approach. Although, it could be expected that with further practice, confidence and automaticity may improve further.

The domains identified as potential facilitators included knowledge, skills, professional role and identity, optimism, and beliefs about consequences. These domains are a positive finding indicating that firstly, sufficient knowledge and skills had been gained from the training to deliver The COMBINED approach. Secondly, physiotherapists felt The COMBINED approach was part of their role. Thirdly, physiotherapists were optimistic about their beliefs, and the delivery, of The COMBINED approach, and fourthly, physiotherapists believed The COMBINED approach was a good idea for patients and not detrimental to therapeutic alliance.

The potential facilitators identified in the survey are a positive finding and indicate a change from the potential barriers identified in the stakeholder workshops (Chapter 6) and the barriers identified in the usability study (Chapter 8). Knowledge and skills were previously identified as a barrier to delivery of The COMBINED approach, with issues identified with the delivery of the training package, but also refinements were required to the content. The enhanced training package and improved delivery by the research team may be one explanation why knowledge and skills were not identified as a barrier in this

study. Beliefs and attitudes had significantly impacted engagement with The COMBINED approach in the usability study, but perhaps addressing these this time in the enhanced training package facilitated their engagement. Another positive finding was that the physiotherapists in this study did not feel The COMBINED approach was detrimental to the therapeutic alliance with patients, both before or after delivery of The COMBINED approach, which was a concern and potential barrier identified in the stakeholder workshops.

Some of the barriers and facilitators identified in this study are consistent with other studies using the TDF to assess implementation barriers to delivering brief behaviour change interventions (Keyworth *et al.*, 2019; Hollis *et al.*, 2021; Meade *et al.*, 2023). One study similarly found beliefs about capabilities, goals and behavioural regulation as implementation barriers (Hollis *et al.*, 2021). The authors suggested that some domains may need extended evaluation periods as they are associated with longer-term behaviour determinants, for example, habits and memory, which may need further support strategies in addition to training. They also suggested some domains may be influenced more by organisational culture than other domains. Therefore, to address the barriers of behavioural regulation (i.e., automaticity) and goals (i.e., priorities), future changes may be needed in organisational systems and processes, or a positive organisational culture may need to be cultivated towards integrating behaviour change interventions. Additionally, strategies to support habit formation regarding implementation of The COMBINED approach may be required.

The facilitators identified in this study, social professional role and beliefs about consequences, are consistent with previous findings that HCPs believe delivering behaviour change interventions is part of their professional role (Keyworth *et al.*, 2018; Chisholm *et al.*, 2020; Hollis *et al.*, 2021; Hartley, Ryad and Yeowell, 2023). This is a positive finding as one study found HCPs who consider the delivery of brief behaviour change interventions as part of their role, are more likely to implement them in practice (Meade *et al.*, 2023).

The fidelity assessment showed that overall, 82% of the aspects of the intervention were delivered as intended in line with the training. This was a considerable improvement from the fidelity assessment in the usability study (Chapter 8) where only 40% of the aspects of the intervention were delivered as intended. Noticeably, there was an improvement in the assessment of the lifestyle factors, with all but one consultation including an assessment of BMI (which was due to the patient declining) and better baseline measures of physical activity levels. The BMI calculator was consistently used in the consultation and used as a tool for supporting health behaviour change conversations. In this study the patients were not pre-screened for a lifestyle factor as part of the eligibility screening like in the usability study, which may explain the increase in fidelity related to this aspect.

The other noticeable improvement from the usability study was the consistent linking of the lifestyle factors specifically to the shoulder condition, with good explanations of systemic inflammation as the underpinning mechanism. This meant that the opportunities for a teachable moment were increased compared to the usability study and no missed opportunities observed. This may be explained by the additional

information provided to the physiotherapists in the training workshop and the revised infographic to explain this to patients.

Although this study was conducted in a different context and with a different group of physiotherapists, the improvement in fidelity could be due to the refined implementation toolkit, in particular the addition of audit and feedback to improve fidelity. The areas of lower fidelity also had suggested there needed to be a greater focus on the MI aspects in the training.

Evaluation of the feasibility of recruitment (the number of patients who consented to the study and had an identified lifestyle factor), showed that 71% of participants recruited had a lifestyle factor. Overall, recruitment was positive with patients willing to be recruited, and 17 participants were recruited in a 4-month period, which was above average compared to the GRASP figures (section 9.4.3.2). Study recruitment was stopped after four months based on the pre-determined criteria that recruiting 12-15 participants over a 4-6 recruitment period would provide sufficient data to achieve the study objectives.

Exploring the patient experience of receiving The COMBINED approach found that lifestyle discussions and an assessment of lifestyle factors were expected and acceptable to patients, and in some cases improved their experience and expectations of the physiotherapy consultation. Furthermore, patients had initiated lifestyle behaviour change after the consultation. Despite patients reporting they understood the role of lifestyle factors in the management of their shoulder condition, there was poor

information recall about the underpinning systemic inflammatory mechanisms. Further work is needed to understand how to aid patient recall, which might be an important strategy to patients initiating and maintaining health behaviour change. Most patients also reported not using the resource pack post consultation, which included resources for supporting long term behaviour change such as action planning and self-monitoring. Future considerations need to include how we encourage increased engagement with the resources, such as electronic versions, and encouraging patients to complete these for review with the physiotherapist.

The findings identified refinements to The COMBINED approach (V2.0). Minor refinements to the components in the implementation strategy were identified, such as the step-by-step guide on when to assess BMI in the consultation, and the addition of the CMO physical activity guidelines and NHS BMI calculator into the toolkit. The physiotherapists were signposted to use these in the step-by-step-guide, but they were not a component of The COMBINED approach. All physiotherapists used these and found them helpful, suggesting they should be an additional component in the implementation toolkit. Findings indicated the MI aspects were a difficult skill to learn and a greater focus on this in the training, including practical skills, is required. This was similar feedback from the usability study (Chapter 8), and although there had been greater opportunities to practice these skills in the training, even further opportunities for practice are required.

Practice and repetition with actual patients in clinical practice was highlighted as important by the physiotherapists in the usability study (Chapter 8) and highlighted again in this study to increase physiotherapists confidence, improve the integration of The

COMBINED approach in the consultation and increase automaticity with regards to remembering all the different components and resources in The COMBINED approach. Having a period of practice with patients prior to delivering The COMBINED approach to study patients needs factoring into a main trial and may help with the barriers of behavioural regulation (i.e., automaticity) and beliefs about capabilities (I.e., confidence). Ingrained practice behaviours were also identified as a barrier to delivery in the usability study and again here. How physiotherapists can be supported to change ingrained practice behaviours and ensure The COMBINED approach is an integrated approach needs considering before a main trial.

The observations and the audit and feedback sessions have identified examples of good practice, particularly in relation to integration of The COMBINED approach within usual structured assessment processes, which can inform clinical scenarios and case studies as part of the next iteration of training. Seeing examples of The COMBINED approach delivered in practice has been a common suggestion by the physiotherapists across both studies (Chapter 8 and 9), but clear examples had not been available until now. Clinical scenarios and case studies can also include examples of common implementation issues experienced by the physiotherapists.

9.7.2 Study strengths

A strength of this study was the dynamic approach that allowed early identification of problems with intervention delivery and subsequent feedback to all participating physiotherapists. Another strength was the focus on implementation of The COMBINED

approach. While effectiveness is important to evaluate, unless implementation issues are addressed, it may never be implemented into practice. This focus on implementation adds confidence in the intervention that changes in future study outcomes are attributable to the intervention rather than variability in implementation (O'Cathain, Croot, Duncan, *et al.*, 2019; Skivington *et al.*, 2021).

9.7.3 Study limitations

A limitation of this study was the potential for social desirability bias in the survey responses from the physiotherapists, in that their responses may be based on what they believed would be viewed positively by the research team. However, a higher median score in the survey to identify a domain as a barrier, and anonymous completion, helped to mitigate this.

Audit and feedback were not possible at one of the NHS sites and the audio-recordings were not received until post-intervention delivery. Challenges to intervention delivery and fidelity were identified from the audio-recordings, but these had not been picked up early enough to intervene with support. This example highlighted the benefit of real-time, early feedback to address and improve any challenges with delivery of The COMBINED approach. The transfer of the audio-recordings was a challenge generally within the study, as most NHS sites did not allow the transfer of data using external devices that were not trust encrypted. This is a practical consideration for the main trial.

9.8 Conclusion

This study has demonstrated the feasibility of a future definitive trial including successful patient recruitment and intervention fidelity of The COMBINED approach prototype (V2.0), along with patient acceptability. Patients found The COMBINED approach acceptable and reported initiating health behaviour changes in their RC management. Factors influencing implementation, such as beliefs about capabilities (i.e., confidence), goals (i.e., relative importance), and behavioural regulation (i.e., automaticity) were identified and will guide refinements to the implementation toolkit in readiness for a future, large, RCT.

9.9 Chapter Summary

This chapter has reported on a feasibility study to evaluate the implementation of The COMBINED approach prototype (V2.0) across four NHS Trusts to facilitate further refinements in readiness for a definitive trial. The last chapter in this thesis is an overall discussion of the findings from each WS in this thesis, conclusion and next steps.

Chapter 10 Overall Discussion, Conclusion & Next Steps

10.1 Chapter Introduction

This final chapter brings together the workstreams (WSs) in this thesis to make overall inferences on this programme of research and how the thesis aims and objectives have been achieved. I will reflect on my own personal experiences and development throughout this PhD, and on the overall strengths and limitations of this research. I will outline how the research in this thesis has contributed to new knowledge before outlining the recommendations and next steps.

10.2 Overview

The overall aim of this thesis was to (1) develop and test a physiotherapist-supported treatment approach, 'The COMBINED approach,' that combines a brief intervention (BI) to target modifiable health behaviours with current management strategies within a routine physiotherapy consultation for people with a rotator cuff (RC) disorder; (2) to understand how best to support physiotherapists to integrate such an approach into clinical practice.

The overall thesis aims and objectives were achieved through five linked WSs using a theory-, evidence- and pragmatic-based approach within a multi-stage mixed methods programme of research.

10.3 Summary of Study Findings

The findings from my thesis revealed key insights for developing and implementing The COMBINED approach. Stakeholders in WS2 (Chapter 6) highlighted the need to change healthcare professional (HCP) behaviours and develop comprehensive implementation strategies to support physiotherapists deliver The COMBINED approach in practice. These insights informed the creation of a multi-level intervention and multi-faceted implementation toolkit. The design of The COMBINED approach prototype in WS3 (Chapter 7) involved mapping barriers and facilitators to behavioural domains and selecting evidence-based behaviour change techniques (BCTs), guided by the APEASE criteria. Early testing and refinement in WS4 (Chapter 9) showed The COMBINED approach was acceptable to patients but identified issues with intervention fidelity and physiotherapists' implementation behaviours. This led to prototype refinements including an enhanced training package, more comprehensive implementation strategies such as audit and feedback, and a decision to not integrate The COMBINED approach with the GRASP Best Practice Advice (BPA) intervention. The findings also informed the decision to focus on implementation behaviours in a non-randomised feasibility study, rather than proceeding to the planned randomised pilot and feasibility study.

Ultimately, while The COMBINED approach was feasible in terms of fidelity and patient recruitment and acceptability, barriers influencing implementation were identified including beliefs about capabilities (i.e., confidence), goals (i.e., priorities), and behavioural regulation (i.e., automaticity). Additionally, patient recall of the role of

lifestyle factors in managing shoulder pain was poor despite explanations from physiotherapists.

There were some consistent findings across the different WSs in this thesis, including: the need to focus on changing HCP implementation behaviours, particularly ingrained practice behaviours of the physiotherapists; physiotherapists consistently lacked confidence in delivering The COMBINED approach and supporting lifestyle behaviour changes; physiotherapists had misconceptions regarding patient receptiveness to a behaviour change intervention as part of their physiotherapy consultation for a RC disorder; the need for a familiarisation period for physiotherapists to practice delivering The COMBINED approach, involving patient interactions with feedback; the need for clinical scenarios and case studies to demonstrate integration of The COMBINED approach in practice.

These findings highlight the challenges of implementing any new approach and that strategies beyond training are required, such as the familiarisation period, case studies, and audit and feedback, for successful implementation. These findings are supported by another study that found additional strategies beyond training were required to facilitate factors influencing implementation of behaviour change conversations (Hollis *et al*., 2021). There is also a need to address the misconceptions of physiotherapists regarding patient receptiveness and motivation. This is a similar finding in the wider literature (Holden *et al.*, 2019; Keyworth *et al.*, 2019; Keyworth *et al.*, 2020a; O'Donoghue *et al.*, 2014), yet patient acceptability and positive motivation to change was consistent across the research studies in this thesis. A survey on people with obesity and HCPs in obesity

management revealed 47% of the people with obesity reported it took an average of nine years from the onset of weight struggles to having a discussion with an HCP. A perceived lack of patient interest and motivation were the main reasons HCPs did not initiate these conversations. However, 65% of people with obesity appreciated the HCP raising the issue of weight during their consultation (Hughes *et al*., 2021). These findings align with the findings in this thesis, highlighting the negative impact of HCP perceptions on delivering behaviour change interventions. This reinforces the need for a paradigm shift to address issues related to delivering behaviour change interventions in practice and to change HCP perceptions about patient motivation and interest.

The final aspect of this PhD involved sharing overall findings with the original stakeholder group during an online dissemination event to consult on the final intervention and scalability plans. Stakeholders expressed ongoing fear and emotional challenges regarding integrating lifestyle behaviour change interventions into routine practice. However, in the feasibility study, physiotherapists' negative emotions improved post-delivery. While this is a positive finding suggesting that with experience of delivering The COMBINED approach emotions are less of a barrier to implementation, it has highlighted there are still challenges to navigate within the wider physiotherapy community. Stakeholders also noted past negative experiences with patients, which might stem from a lack of person-centred communication, which is central to The COMBINED approach.

Stakeholders highlighted the need for organisational and structural support, such as departmental culture change, key opinion leaders, electronic template adjustments, and fitting interventions within current appointment times. While time was not seen as a

barrier in the studies within this thesis, it is recognised that the initial consultation for delivering The COMBINED approach in both studies was 60 minutes. NHS consultation times vary across organisations according to stakeholders (30-60 minutes). A recent survey of current (2023) UK physiotherapy practice indicated that the BPA intervention from the GRASP trial (Hopewell, Keene, Marian, *et al.*, 2021), considered as current best practice, had not been widely adopted into clinical practice (Moffatt *et al.*, 2024). It was reported that while 78% of respondents adopted the BPA intervention with some of their patients, only 9% of respondents adopted it with all of their patients. The main limiting factor for this was the requirement of a 60-minute consultation, which did not fit with clinical time constraints. Limited adoption of best practices like the BPA intervention due to time constraints suggest the need for flexible delivery models, such as spreading The COMBINED approach over multiple sessions. This model would work given that physiotherapists report treating RC disorders over several sessions. In the same survey, 68% of the survey respondents reported seeing patients 3-4 times, and only 6% of respondents would see them once (Moffatt *et al.*, 2024). Additionally, delivering training to more physiotherapists with current service pressures was raised by the stakeholders and requires further consideration before a main trial.

Organisational barriers were not addressed in this thesis but are recognised in the literature as crucial for influencing HCPs' prioritisation of behaviour change interventions and integrating them within organisational systems (Keyworth *et al.,* 2019; Keyworth *et al.,* 2020a). Addressing these barriers will be essential for future implementation. Strategies such as utilising key opinion leaders or champions can promote a positive

culture towards integrating brief behaviour change interventions into practice (Keyworth *et al.,* 2019; Parchment *et al.,* 2023).

10.4 Personal Reflection and Learning

As part of my NIHR Clinical Doctoral Research Fellowship application, the initial plan was to use intervention mapping to develop the intervention, followed by a randomised pilot and feasibility trial to evaluate the feasibility of The COMBINED approach and assess early signals of effectiveness using intermediate outcomes. This plan changed due to two main factors: the cancellation of the intervention mapping course because of COVID-19, and early findings from my research that indicated a need to extend the intervention development stage and focus on implementation to address the identified issues. The following is my reflection on this experience during my PhD fellowship.

Having to change the planned research in this PhD fellowship was challenging to navigate and, at times, overwhelming. I found the uncertainty related to this unsettling, creating a tension between following the original plan and responding to the findings from the research; often viewing the changes as a negative of things not going to plan. On reflection, however, this has ended up being a positive experience both for the intervention development process and for my own personal learning. Firstly, being flexible and open to change allowed my ideas to evolve and facilitated a much more comprehensive intervention development approach. Secondly, this process has facilitated significant personal development and learning of the intervention development process and new methods. Had I in fact proceeded to a randomised pilot and feasibility trial as

planned in this PhD fellowship, I would not have addressed the implementation issues ahead of a future trial and testing would have possibly shown no signal of effect, and therefore no further direction to go with this intervention. I now have a rigorously developed intervention, that has been developed with the best chance of being effective in a future trial.

In the future, I will draw on this experience and learning to inform my future research and recommend to others when I am part of a research team planning a trial, the steps required to rigorously develop an intervention; and an approach that evolves in response to the findings. Being reflective, constantly learning and evolving has been a positive to this PhD fellowship, my personal development and the intervention development process. I will be more open in the future to evolving my research ideas, recognising this is required to do research well. Given that this PhD is a training vehicle, I can now reflect on how this challenging experience has resulted in significant learning that will inform my future research practice.

10.5 Methodological Strengths

The COMBINED approach was developed systematically and rigorously based on a theory- and evidence-based approach, using the MRC Framework (Skivington *et al.*, 2021) and a pragmatic approach based on principles and actions common to intervention development approaches (O'Cathain, Croot, Duncan, *et al.*, 2019). A further strength is the involvement of key stakeholders throughout the development of The COMBINED approach, with co-design not often a feature within physiotherapy research. While a

rigorous approach and the involvement of stakeholders cannot guarantee producing an intervention that will be effective, this approach has increased the likelihood of effectiveness when tested in a future trial, and increased the confidence that it can be implemented as intended (O'Cathain, Croot, Duncan, *et al.*, 2019; Skivington *et al.*, 2021). Given the history of null results in rehabilitation trials, a focus on rigorous intervention development may reduce the likelihood of a null result and reduce research waste (Contopoulos-Ioannidis *et. al*., 2008; Goodwin *et al.*, 2019).

The focus on HCP implementation behaviours was a strength, with a congruent theoretical underpinning on behaviour change theory throughout this thesis. The COM-B model and the Theoretical Domains Framework (TDF) have been key to understanding the influences on implementation of The COMBINED approach to inform a comprehensive implementation strategy beyond standardised training. Increasing the chances an intervention will be adopted into clinical practice will also reduce research waste (Contopoulos-Ioannidis, *et al*., 2008; O'Cathain, Croot, Duncan, *et al.*, 2019). Further to this, my theoretical perspective of pragmatism guided the choice of methodology of a mixed methods design, with the ambition to produce an intervention that is practical and useful in real-world physiotherapy practice, also increasing the chances of future adoption.

The use of a transparent decision-making framework, the APEASE criteria (Michie, Atkins and West, 2014), along with the TIDieR checklist (Hoffmann *et al.*, 2014) and GUIDED framework (Duncan *et al.*, 2020) for reporting the intervention and intervention

development process respectively, has increased the transparency and credibility of the findings.

Aligned with principles and action for good intervention development I have evidenced how I have been flexible and open to change by responding to challenges within the research process, which evolved my thinking and strengthened this research.

10.6 Methodological Limitations

The focus on implementation of The COMBINED approach means any early signals of effectiveness have not yet been evaluated. However, early testing in the usability study identified uncertainties about the fidelity of the intervention and if The COMBINED approach can even be delivered in practice. These uncertainties needed to be addressed, rather than needing to address uncertainty around recruitment and randomisation, for example, in a randomised pilot and feasibility study. Therefore, the intervention was not considered ready for testing effectiveness at this stage.

A lack of diversity of both patient stakeholders and study participants was a limitation, potentially limiting the relevance and representativeness of the findings. Efforts to address this in the feasibility study included choosing NHS sites based on geographical locations serving diverse populations. While the diversity of participants did increase, I am cognizant of the need to increase inclusivity and diversity for the future definitive trial.

I have been involved in all aspects of this research process, including the development and early testing of the intervention, engaging sites and recruiting participants, delivering training and conducting interviews. Whilst this involvement has supported my

development, I'm aware of the possibility of bias. To mitigate this, I have been reflexive throughout this thesis and how my beliefs and experiences may have influenced the research process and interpretation of the results, including through critical discussions with the supervisory team.

10.7 Contribution to New Knowledge

This thesis has made an original contribution to knowledge through the development of a theory-, -evidence and pragmatic-based intervention to assess and address the modifiable health behaviours associated with the onset and persistence of a RC disorder and strategies, including a training package, to support physiotherapists to implement the intervention in practice. This thesis also adds to the existing literature exploring HCP implementation behaviours. The process of intervention development that was employed to develop The COMBINED approach is an example within physiotherapy that others can model on to develop physiotherapy interventions and implementation strategies, beyond a standardised approach to intervention training.

10.8 Next Steps

There are remaining key uncertainties and refinements to The COMBINED approach that still need to be addressed ahead of a large randomised controlled trial (RCT), which will inform the next steps. These include the need to:

- Address the identified behaviours influencing implementation, including goals, beliefs about capabilities, and behavioural regulation;

- Address widespread misconceptions in physiotherapists that patients are not receptive to lifestyle behaviour change;
- Address ingrained practice behaviours of physiotherapists, which includes an awareness of the organisational and system support required to facilitate the integration of The COMBINED approach into practice. Considerations include key opinion leaders to support positive culture change within organisations and departments, and changes to electronic physiotherapy templates;
- Consider the scalability of the training for the physiotherapists in the main RCT;
- Consider the scalability of ongoing monitoring of fidelity in the delivery of The COMBINED approach;
- Consider how to engage patients with the behaviour change tools in the resource packs and improve recall of information to understand the role of lifestyle factors in the management of their shoulder pain;
- Consider how to increase inclusivity and diversity in the main trial.

The next steps will now be to plan an application for funding to evaluate the effectiveness of The COMBINED approach in a large RCT. In the introduction of this thesis, I explained why RC disorders were a test case in this thesis. This was initially pinned on the BPA intervention, but evidence has shown this is no longer deliverable (Moffatt *et al*., 2024). As the rationale of this thesis was to address the burden of musculoskeletal conditions and the challenges with current treatments, there is a consideration of the pros and cons to evaluating The COMBINED approach in the next stage with a focus still on RC disorders,

or musculoskeletal conditions more broadly. This decision has not yet been made and requires further consideration.

10.9 Conclusion

Using a rigorous theory-, evidence- and pragmatic-based approach and multi-stage mixed methods programme of research, the aim to develop a novel intervention, The COMBINED approach, which includes an implementation toolkit to support physiotherapists deliver this approach in practice, has been achieved. The COMBINED approach has been shown to be deliverable, feasible and acceptable, and can be integrated alongside usual care in a routine physiotherapy consultation but needs to be supported by comprehensive implementation strategies.

The central role of stakeholders, including co-design, has informed the design of The COMBINED approach, helping to ensure its relevance and practicability for real-world physiotherapy practice. Key outputs are an optimised version of The COMBINED approach that is now ready for an application for funding and testing in a main randomised trial.

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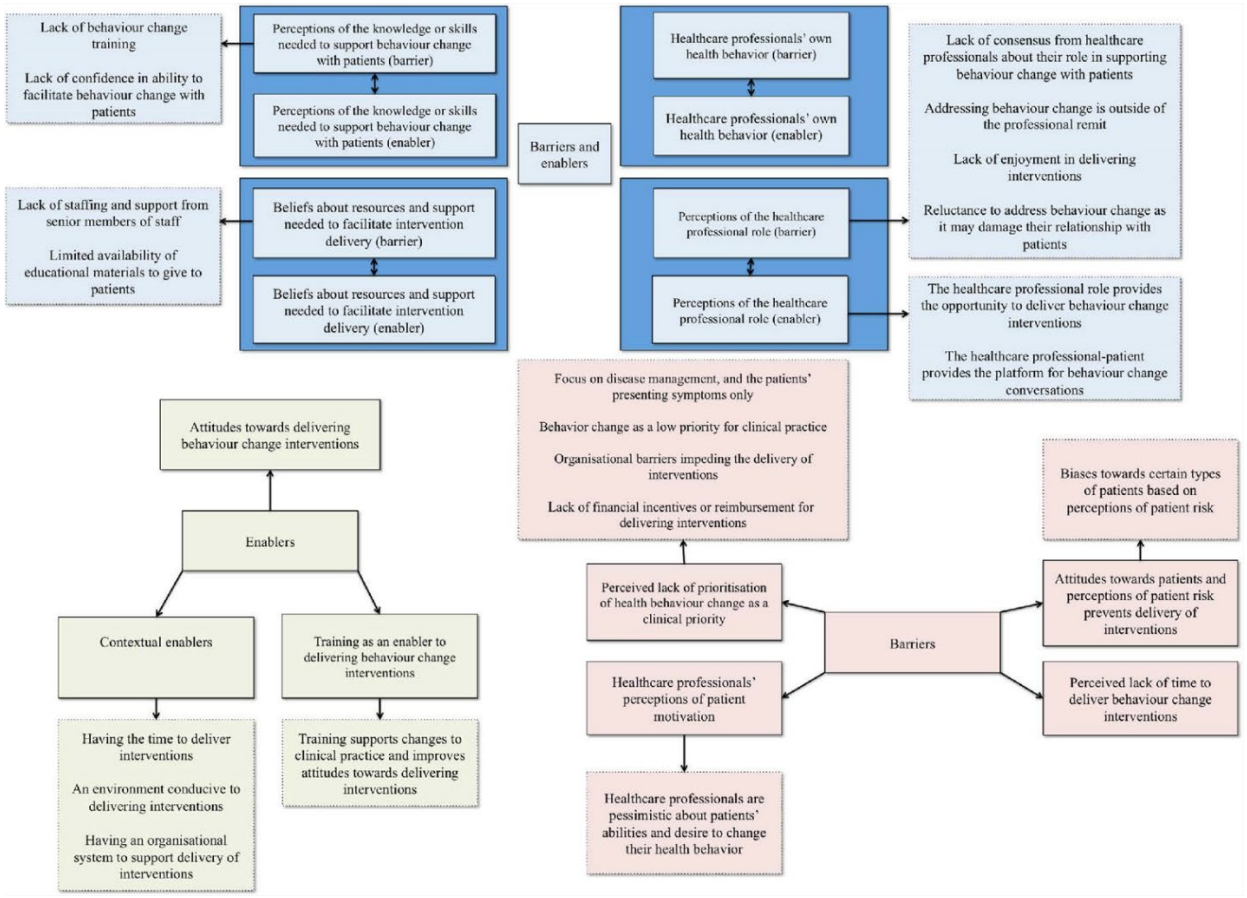
Appendices

Appendix A: Conceptual map of barriers and facilitators to delivering opportunistic behaviour change interventions



Source: Keyworth *et al.*, 2020a, p. 323, Figure 2

Appendix B: Typology of core mixed methods designs

Design	Intent	Procedures	Integration
Explanatory sequential	To use qualitative data to illustrate and understand quantitative findings	Two sequential phases: 1. Quantitative data collection and analysis, followed by 2. Qualitative data collection and analysis	1. Key quantitative results are selected that require further illustration qualitatively 2. Integrated inferences made between the quantitative findings and how the qualitative results explain these further
Exploratory sequential	To develop a quantitative feature, e.g., survey, intervention, measure, that is based on qualitative findings	Three sequential phases: 1. Qualitative data collection and analysis, followed by 2. Development of a quantitative feature, e.g., an intervention, followed by 3. Test the new feature quantitatively	1. Qualitative findings are integrated to build the quantitative feature 2. Quantitative and qualitative findings are integrated after testing to confer inferences
Convergent	To corroborate quantitative and qualitative findings to increase the depth of understanding of a problem	Four concurrent phases: 1. Collection of separate strands of qualitative and quantitative data 2. Analysis of separate strands of qualitative and quantitative data 3. Merging of the results 4. Interpretation of the level of convergence or divergence of the results and any relationships	Results of the quantitative and qualitative strands are merged to identify how they contrast or confirm against each other or increase the understanding.

Reproduced from Creswell and Plano Clark, 2018

Appendix C: Good Reporting of A Mixed Methods Study (GRAMMS)

Box 1 Good Reporting of A Mixed Methods Study (GRAMMS)

(1) Describe the justification for using a mixed methods approach to the research question

(2) Describe the design in terms of the purpose, priority and sequence of methods

(3) Describe each method in terms of sampling, data collection and analysis

(4) Describe where integration has occurred, how it has occurred and who has participated in it

Source: O'Cathain, Murphy and Nicholl, 2010

Appendix D: Ethics approval - stakeholder co-design workshops

16/12/2020
Project Title: Development of an intervention to optimise current treatments for people with a rotator cuff disorder

EthOS Reference Number: 25512

Ethical Opinion

Dear Julie Bury,

The above application was reviewed by the Health, Psychology and Social Care Research Ethics and Governance Committee and, on the 16/12/2020, was given a favourable ethical opinion. The approval is in place until 30/04/2021.

Conditions of favourable ethical opinion

Application Documents

Document Type	File Name	Date	Version
Project Protocol	JBury_COMBINED_V1.0_14thDec2020_Protocol-Template-for-Non-Medical-Research	14/12/2020	1.0
Additional Documentation	COMBINED_Consent-form_v1.0_14thDec2020	14/12/2020	1.0
Additional Documentation	COMBINED_Invitation-template_V1.0_14 Dec 20	14/12/2020	1.0
Additional Documentation	COMBINED_Participant-Information-Sheet_V1.0_14thDec2020	14/12/2020	1.0
Additional Documentation	2020.12.14_Reviewers_response_25512	15/12/2020	0.2

The Health, Psychology and Social Care Research Ethics and Governance Committee favourable ethical opinion is granted with the following conditions

Adherence to Manchester Metropolitan University's Policies and procedures

This ethical approval is conditional on adherence to Manchester Metropolitan University's Policies, Procedures, guidance and Standard Operating procedures. These can be found on the Manchester Metropolitan University Research Ethics and Governance webpages.

Amendments

If you wish to make a change to this approved application, you will be required to submit an amendment. Please visit the Manchester Metropolitan University Research Ethics and Governance webpages or contact your Faculty research officer for advice around how to do this.

We wish you every success with your project.

HPSC Research Ethics and Governance Committee

HPSC Research Ethics and Governance Committee

For help with this application, please first contact your Faculty Research Officer. Their details can be found here

Appendix E: Information sheet - stakeholder workshops

NHS Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Manchester Metropolitan University

Stakeholder Workshops

Information Sheet

COmbining brief interventions for Modifiable health Behaviours with a best practice advice INtervEntion for people with a rotator cuff Disorder (COMBINED)

1. Invitation to stakeholder workshops

My name is Julie Bury, and I am a Physiotherapist and Research Fellow at Doncaster and Bassetlaw Teaching Hospitals and a PhD student at Manchester Metropolitan University. This work is funded by the National Institute for Health Research as part of a Clinical Doctoral Research Fellowship.

You are being invited to take part in a series of virtual stakeholder workshops. Before you decide if you would like to take part, please take some time to read the following information so you understand why the workshops are being done and what it will involve. If anything is not clear, or you would like more information, please contact me.

2. Background

These stakeholder workshops are part of a programme of work that is looking at how we can improve current treatments for people with shoulder pain, that have been diagnosed with a rotator cuff disorder. The rotator cuff is a group of muscles and tendons which move and stabilise the shoulder joint, and problems with these muscles and tendons can result in pain and difficulty with everyday tasks.

Routine treatments for this condition include advice, exercise, steroid injections and surgery. However, data from studies testing these treatments suggest they offer, on average, only small to moderate benefits at best. Also, some patients don't always get better with these treatments and still report shoulder pain 12 months later.

From recent evidence, a best practice advice intervention has been shown to be effective. This was a single face-to-face session with a physiotherapist that offered a detailed assessment and prescription of individualised shoulder exercises, with a focus on self-management of their condition, supported by high-quality resources.

The evidence also suggests a link between certain lifestyle factors (or health behaviours) and the onset and persistence of rotator cuff problems. These factors are smoking, being overweight, and low physical activity levels. These are called 'modifiable health behaviours' because these health behaviours can be changed. A brief intervention that includes advice, encouragement and support can be used to help patients change the

health behaviour, for example to stop smoking, and typically takes 5-10 minutes to deliver.

We want to develop an intervention, The COMBINED approach, that physiotherapists can use in clinical practice that combines a brief intervention targeted at the three key health behaviours (smoking, weight, physical activity levels) that are thought to be linked to this condition, with a best practice advice intervention (shoulder exercises and self-management advice) for people with a rotator cuff disorder.

3. What is the purpose of the stakeholder workshops?

To ensure The COMBINED approach is acceptable and can be implemented in a future trial we want to gain the advice of a wide range of stakeholders and research partners (including patient representatives, physiotherapists, GPs, shoulder surgeons, academics and experts, for example, in public health. This is to gain a range of perspectives from people who are like those who will be in the future study, as well as drawing on specific expertise.

We are holding four linked workshops to work out together what The COMBINED approach should look like and what it should include. It is expected that between 15-25 stakeholders will be involved at each stage.

This is the first stage, before we can test if The COMBINED approach works in a future study.

4. Why have I been invited?

You have been invited to take part as a stakeholder with valuable knowledge and experience that will contribute to shaping the development of The COMBINED approach that can be tested in a future trial.

5. Do I have to take part?

It is up to you to decide. We will ask you to consider the information sheet and express formal interest, if you would like to attend the workshops, by return email. You will be invited to a pre-meeting prior to the workshops via Microsoft Teams to gain audio consent for video recording the workshops and storing some personal details (further details below). You are free to leave the workshops at any time, but any contributions up to that point will continue to be used.

6. What will I be asked to do?

You will be asked to provide some personal details, such as your professional role/expertise, location, years of experience, sex. This information is required only so that we can describe who has helped us in the workshops.

We will be running approximately four linked virtual workshops via Microsoft Teams, lasting approximately 2 hours each. You will be invited to attend all the workshops, but we realise it may not be practical to attend them all. The workshops will take place over a 3-month period.

You will be presented with various information to set the scene, introduce you to this problem under scrutiny and to understand the broader aims of the project. You will be

shown some different brief interventions, and we would like to discuss your thoughts and ideas about these, such as what you like/don't like and if you think they could be used in clinical practice by physiotherapists. We also want your thoughts on the best way to design The COMBINED approach, including what it should look like and how it should be delivered. Two-three facilitators from the research team will also be at the workshops and will help to bring all the ideas and information together.

The final workshop will involve physiotherapists only, who will be asked to share their thoughts and ideas about what should be included in a training package in order to effectively deliver The COMBINED approach.

The workshops will be video recorded, with your consent. These recordings will be used to form a collective summary of the discussions and will not be linked to a specific individual. Individual names or words will not be referred to and in this way, the summaries of the discussions will be anonymous.

Information from the recordings may be used in publications, but this will be anonymous and so you will not be identifiable. Recordings will be stored in a secure place and only kept until acceptance of the published report and/or completion of the PhD, whichever is later.

7. Are there any risks if I take part?

There are no anticipated risks associated with taking part in the workshops.

8. Are there any advantages if I take part?

There will be no direct benefit in taking part in these stakeholder workshops, but it will give us a better understanding of the views of patients and professionals in order to help us develop an intervention that will be acceptable to patients and clinicians and practical to deliver in clinical practice. If this is shown to be effective in a future study, then this initial work together will hopefully make The COMBINED approach more likely to be implemented into routine clinical practice to provide better care for patients in the future.

As a thank you for your time and contribution you will receive a £25 amazon gift voucher for each workshop attended, up to a maximum of £100 per person.

9. What will happen with the personal data I provide?

When you agree to be involved in the workshops, we will collect personally-identifiable information from you, such as your professional role/expertise, location, years of experience, sex.

Julie Bury, as the Chief Investigator (CI), will act as data custodian and handle any personal data as confidential and shall be handled and stored securely at all times. The CI will protect the security of Personal Data by maintaining, and monitoring compliance with the University's Information Security Policy and adhere to the University's Data Protection Policy and comply with the Data Protection Act (DPA) and the General Data Protection Regulation (GDPR).

We will not share your personal data collected with any third parties.

We will only retain your personal data for as long as is necessary to achieve the purpose of these workshops. This is considered to be until acceptance of the published report and/or completion of the PhD, whichever is later. This will be stored on a secure cloud-based application, OneDrive, which will only be accessed by the direct research team.

Manchester Metropolitan University is the Data Controller in respect of any personal data that you provide as a stakeholder. The University is registered with the Information Commissioner's Office (ICO) and manages personal data in accordance with GDPR and the University's Data Protection Policy.

For further information about use of your personal data and your data protection rights please see the University's Data Protection Pages.

10. What will happen to the information from the workshops?

The information generated from the workshops will be used to guide the development of The COMBINED approach that will be formally tested and developed further in a second stage of research.

The information may also be published in scientific journals and presented at scientific conferences describing this intervention development process.

11. Who has reviewed this stakeholder engagement process?

This stakeholder engagement process has been reviewed by academic supervisors and patient representatives (as part of patient and public involvement activity).

It has been reviewed by Manchester Metropolitan Health Psychology and Social Care University research ethics committee (Ethical approval number 2020-25512-21923).

12. Who do I contact if I have concerns about the stakeholder workshops or I wish to complain?

Should you have any general questions about the workshops or information contained within this information sheet, please contact the lead researcher in the first instance:

Julie Bury
Chief Investigator
Email: Julie.bury@stu.mmu.ac.uk

If you wish to complain or have any concerns about any aspect or the way you have been approached or treated during the course of this study, please contact:

Professor Chris Littlewood
Principal Supervisor
Faculty of Health, Psychology and Social Care, Manchester Metropolitan University, Brooks Building, 53 Bonsall Street, M15 6GX
Email: c.littlewood@mmu.ac.uk

Or you can contact the Faculty Head of Ethics:

Professor Khatidja Chantler
Head of Faculty of Health Psychology and Social Care Research Ethics and Governance
Faculty of Health, Psychology and Social Care
Manchester Metropolitan University
Brooks Building
53 Bonsall Street
M15 6GX
Telephone: +441612471316
Email: K.Chantler@mmu.ac.uk

If you have any concerns regarding the personal data collected from you, our Data Protection Officer can be contacted using the legal@mmu.ac.uk e-mail address, by calling 0161 247 3331 or in writing to: Data Protection Officer, Legal Services, All Saints Building, Manchester Metropolitan University, Manchester, M15 6BH. You also have a right to lodge a complaint in respect of the processing of your personal data with the Information Commissioner's Office as the supervisory authority. Please see: https://ico.org.uk/global/contact-us/

THANK YOU FOR CONSIDERING INVOLVEMENT IN THE STAKEHOLDER WORKSHOPS

Appendix F: Consent form - stakeholder workshops

NHS
Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Manchester Metropolitan University

CONSENT FORM

COmbining brief interventions for Modifiable health Behaviours with a best practice advice INtervEntion for people with a rotator cuff Disorder (COMBINED): Intervention development

The workshops will be held online and audio consent will be taken in the following way:

a) Thank the stakeholder for joining and state for the record the name of the person taking consent and the date.
b) Remind the stakeholder that the conversation is being recorded and wait for confirmation that this is acceptable to them.
c) State for the record the name of the stakeholder and their stakeholder identification number.
d) Record audio consent for the stakeholder workshops by reading the template consent form out loud, stating for the record the version number and version date of the consent form. Pause after each consent item to allow the stakeholder to audibly confirm for the recording.
e) Continue until all items on the consent form have been confirmed.

The following statements will be read out:

1	I confirm that I have read the information sheet version 1.0, date 14th Dec 2020, for the described stakeholder workshops.
2	I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
3	I understand that my involvement in the workshops is voluntary and that I am free to leave the workshops at any time, but any contributions up to that point will continue to be used.
4	I understand that all personal information will remain confidential and handled and stored securely at all times in line with the General Data Protection Regulation (GDPR).
5	I agree to the workshops being video recorded through Microsoft Teams for the purpose of the stakeholder workshops.
6	I understand and agree that the recordings collected during the workshops will be stored and will be shared with the immediate research team for the purpose of the stakeholder workshops.
7	I understand that the information discussed in the workshops is to be treated as confidential.
8	I agree to adhere to the ground rules that will be outlined for the workshops.
9	I am aware I can contact the research team if I wish to be informed about the outcomes of the stakeholder workshops.
10	I give permission for the researchers named in the information sheet to contact me in the future about the stakeholder workshops or other research opportunities.
11	I give permission for a fully anonymised version of the report of the stakeholder workshops to be deposited in an Open Access repository so that it can be used for future research and learning.

Audio consent recordings will be stored on Man Met's OneDrive using the stakeholder identification number.

FUNDED BY
NIHR | National Institute for Health Research

Appendix G: Example adapted patient workbook

Workbook for stopping smoking

This workbook has been adapted with permission from the Moving Medicine workbook for an active lifestyle

Moving Medicine

Personalised Plan for Stopping Smoking

This worksheet will help you generate your own, tailored plan for stopping smoking and staying stopped.

What role smoking currently plays in my life:

.....

.....

.....

How important is stopping smoking to me:

(Circle a number on the scale below)

Not important 0 1 2 3 4 5 6 7 8 9 10 Very important

Why did you choose this number and not a lower one?

.....

.....

.....

How confident I am that I will be able to stop smoking:

(Circle a number on the scale below)

Not important 0 1 2 3 4 5 6 7 8 9 10 Very important

Why did you choose this number and not a lower one?

.....

.....

.....

My 3 best reasons for stopping smoking are:

.....

.....

.....

This workbook has been adapted with permission from the Moving Medicine workbook for an active lifestyle

Differences I might notice in 6 months if I stop smoking include:

.....

.....

.....

Times in the past when I smoked less or was smoke-free include:

.....

.....

.....

Setting my goals

Setting goals can help you keep focussed and motivated. It is useful to consider both short and long term goals to break your progress up into achievable chunks. When setting goals it is useful to keep them:

- **Specific** – The goal should make it clear what you want to accomplish eg. to set a quit date to stop smoking.
- **Measurable** – Identify a way to measure and track progress toward the goal eg. to cut back by at least two cigarettes a day until my quit date.
- **Attainable** – Choosing very hard goals sets you up for failure so make them easy and realistic eg. If you have tried stopping smoking before without support, a better goal should be to stop smoking with the help of a local stop smoking service and/or stop smoking aids, rather than with willpower alone.
- **Relevant** – Make goals relevant to important things in your life. For instance, stopping smoking may help you to save money for a family holiday.
- **Time-framed** – Think about a clear time frame to achieve your goal. For instance starting on Wednesday, I will aim to cut back by at least two cigarettes a day until my quit date on the 1st July.

Short term goals	Medium term goals	Long term goals
What would you like to achieve in the next 2-4 weeks?	What would you like to achieve in the next 2-4 months?	What would you like to achieve in the next 6-12 months?

This workbook has been adapted with permission from the Moving Medicine workbook for an active lifestyle

How do I get there?

What will you need to do to accomplish your goals:

In the short term?	In the medium term?	In the long term?

What problems might you encounter and how will you overcome them?

It is important to prepare for setbacks and remember that there is more than one path to each destination

Problem 1:	Problem 2:	Problem 3:
How will I overcome this?	How will I overcome this?	How will I overcome this?

This workbook has been adapted with permission from the Moving Medicine workbook for an active lifestyle

Help I may need from others

It is important to get support along your journey.

Person 1:

.....

Help I may need from them:

.....

.....

.....

Person 2:

.....

Help I may need from them:

.....

.....

.....

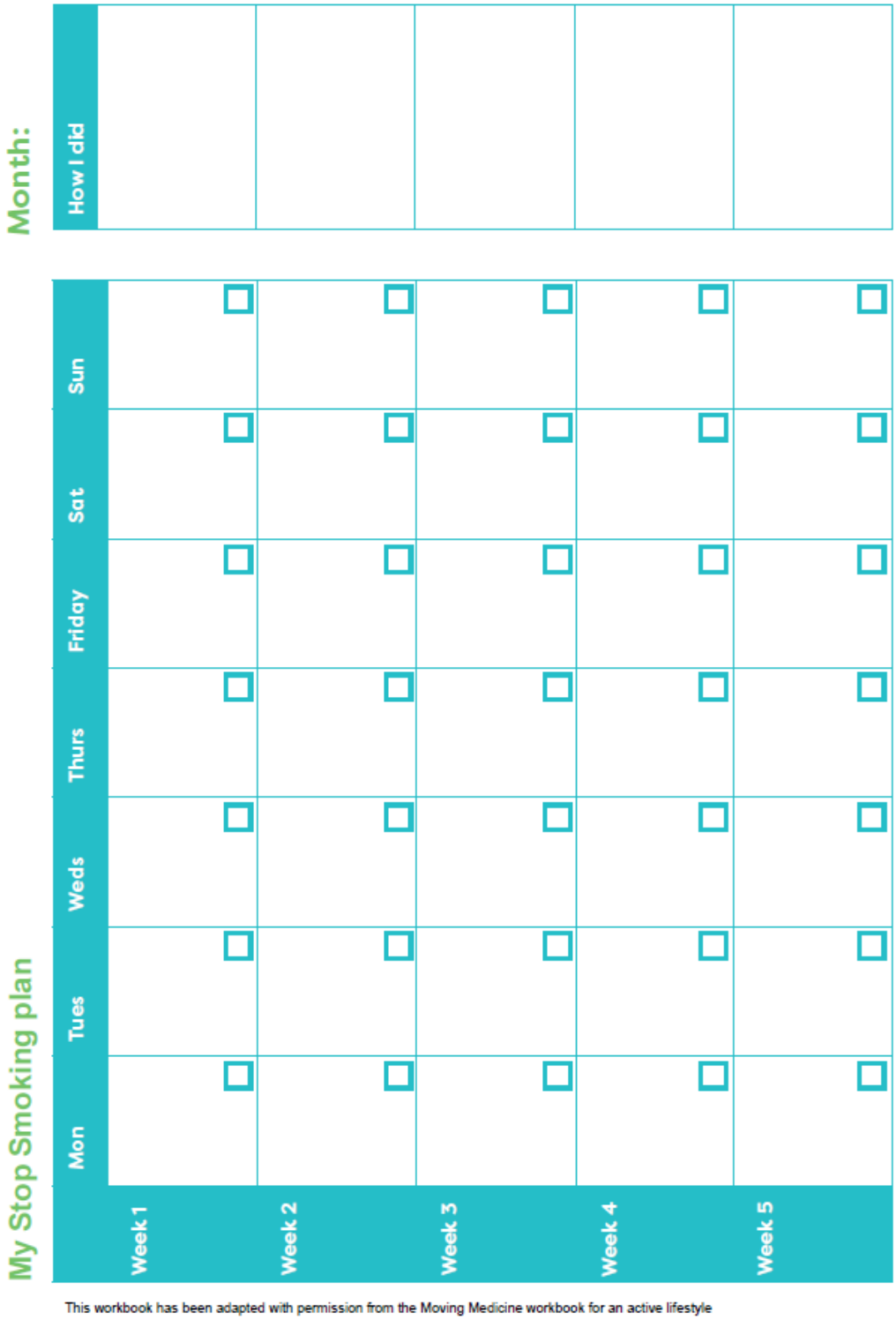
Taking Action

Now it's time to make your own action plan. Stopping smoking involves making small changes to your lifestyle that may help you resist the urge to smoke. Remember, getting support from experts will help.

Consider the following advice when filling in your plan

- Plan when you will quit - set a date.
- Many people try to stop smoking with willpower alone, but getting the right help through your local stop smoking service can increase your chances of stopping smoking for good by 3 times.
- Consider using stop smoking aids - research has shown a combination of these methods can be effective.
- Identify your smoking triggers (eg. after a meal) and have a plan if you are tempted to smoke.
- Keeping busy and being physically active can resist the urge to smoke.

This workbook has been adapted with permission from the Moving Medicine workbook for an active lifestyle



Reproduced from: *Moving Medicine*, n.d.

Appendix H: Example patient diary

Moving Medicine

Stop smoking diary

There are some useful FAQs to consider prior to completing your stop smoking diary.

What are smoking triggers?

Certain times of the day, places, activities or even certain foods can make you want to smoke. These are called triggers. Everyones triggers are different, but common ones might be when you drink your morning tea or coffee, having a drink with friends, when you drive or when you feel bored, worried or stressed. Even feeling happy can be a trigger.

How can I identify and avoid smoking triggers?

Keeping a diary can help you to spot your own smoking triggers. You can then develop strategies to avoid or manage them when they happen. This may involve changing some routines. Other things that might help are to drink some water, go for a walk or distract yourself until the craving has passed. Delaying the urge for just a few minutes usually means it passes.

What do I need to think about when planning to stop smoking?

Think about the following things when planning to stop smoking:

- Plan when you will quit - set a date.
- Many people try to stop smoking with willpower alone, but getting the right help through your local stop smoking service can increase your chances of stopping smoking for good by 3 times.
- Consider using stop smoking aids - research has shown a combination of these methods can be effective.
- Identify your smoking triggers (eg. after a meal) and have a plan if you are tempted to smoke.
- Stopping smoking involves making small changes to your lifestyle that may help you resist the urge to smoke.
- Keeping busy and being physically active can resist the urge to smoke.

This diary has been adapted with permission from the Moving Medicine physical activity diary

Your weekly stop smoking diary

Keep track of your smoking levels throughout each week and keep old diaries to track progress and share with your healthcare professional

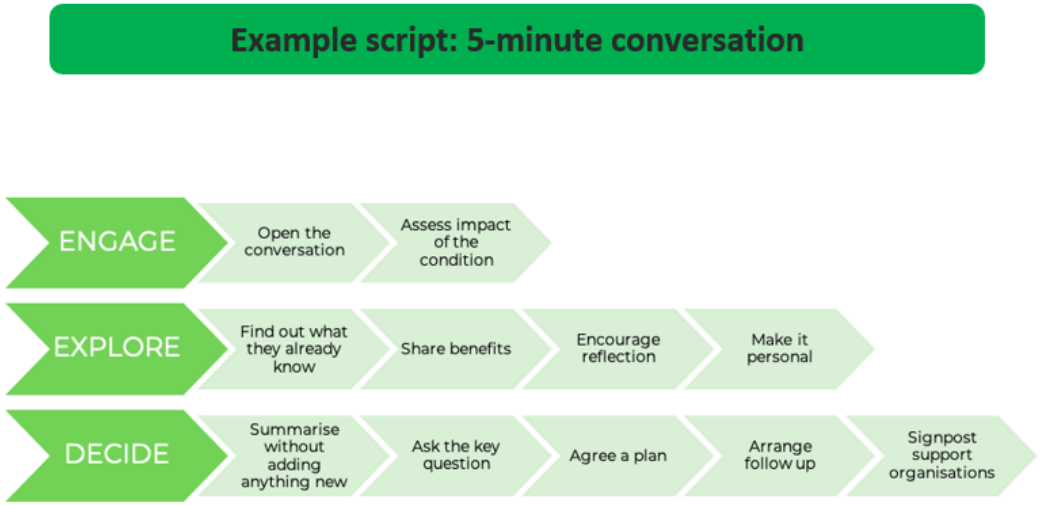
WEEK STARTING

Day	Cigarettes smoked (include time)	When/where, for example, after lunch; driving home, drinking with friends)	Total number of cigarettes smoked
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			

This diary has been adapted with permission from the Moving Medicine physical activity diary

Reproduced from: *Moving Medicine*, n.d.

Appendix I: Example Script



- The 5-minute conversation is designed to fit into a consultation addressing a range of aspects of patient management. These simple steps can help build readiness to change and help start a plan based on the individual's preferences.
- Find below some words that we find helpful to achieve a brief, person-centred 5-minute health behaviour conversation.
- This template is to help guide you – there are no rights or wrongs. Try using these words in your own consultations and see how they work for you.

This script has been adapted from the Moving Medicine resources: https://movingmedicine.ac.uk/

Moving Medicine

ENGAGE	Open the conversation	*"Would you be happy to spend 4-5 minutes talking about something that can make a big difference to your shoulder condition?"*
	Assess impact of the condition	*"How has your shoulder condition affected the things you enjoy?"*
EXPLORE	Find out what they already know	*"What do you know about the benefits of [insert as applicable] been more active/stopping smoking/having a healthy diet in people with shoulder pain?"*
	Share benefits	*"Can I share some other things people find beneficial to see what you make of them?"*
	Encourage reflection	*"What do you make of what I have just said?"*
	Make it personal	*"What would be the top 2-3 reasons for you personally [insert as applicable] becoming more active/stopping smoking/having a healthy diet, if you decided to?"*
DECIDE	Summarise without adding anything new	*"Can I summarise what I think you have said?"*

This script has been adapted from the Moving Medicine resources: https://movingmedicine.ac.uk/

Moving Medicine

Ask the key question	*'So, what do you think you will do?'*
Agree a plan	*"Can I share with you some things people find helpful when making a plan?"*
Arrange follow up	*"How would you feel about coming back another time to build on the thoughts and ideas you've shared with me today?"*
Signpost support organisations	*"There are some great, free resources available here and on other websites to support you if you'd be interested to have a look"*

This script has been adapted from the Moving Medicine resources: https://movingmedicine.ac.uk/

Moving Medicine

Reproduced from *Moving Medicine*, n.d.

Appendix J: Participant Information Sheet (Clinician) – Usability study

NHS Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Manchester Metropolitan University

ComBined

Participant Information Sheet (Clinician)

Combining treatments for shoulder pain (COMBINED).

1. Invitation to take part in a research study

My name is Julie Bury and I am a Physiotherapist at Doncaster and Bassetlaw Teaching Hospitals and a PhD student at Manchester Metropolitan University. I am the lead researcher on this project. This work is funded by the National Institute for Health Research as part of a Clinical Doctoral Research Fellowship.

We would like to invite you to take part in a research study, called 'COMBINED'. Our research project is part of a programme of work that is looking at how we can improve current treatments for people with shoulder pain, who have been diagnosed with a rotator cuff disorder. The rotator cuff is a group of muscles and tendons which move and stabilise the shoulder joint, and problems with these muscles and tendons can result in pain and difficulty doing everyday tasks.

Before you decide if you would like to take part, please take some time to read the following information to understand why the research study is being done and what it will involve. If anything is not clear, or you would like more information, please contact me (you will find my details at the end of this leaflet).

2. Background to the study

Routine treatments for a rotator cuff disorder include advice, exercise, steroid injections and surgery. However, information from studies testing these treatments suggest they offer only small to moderate benefits at best. Also, some patients don't always get better with these treatments and still report shoulder pain 12 months later.

Research also suggests a link between certain lifestyle factors and the onset and persistence of rotator cuff problems. These factors are smoking, being overweight, and low physical activity levels. A 'brief intervention' that includes advice, encouragement and support can be used as an effective way to help patients change the health behaviour linked to this factor, for example to stop smoking, to achieve a healthy diet or to increase physical activity levels.

We have designed an intervention with the help of patients and clinicians called 'The COMBINED approach'. Physiotherapists can use this new approach within a treatment session for people with a rotator cuff disorder that combines a brief intervention to target the health behaviours as described, together with their current treatments, such as exercises for strengthening the muscles and tendons of the shoulder. It also includes training and support for the physiotherapists to deliver this.

We would like to test this intervention with a few patients and physiotherapists to find out what they think of it. This will help us improve it further before testing it in a larger study.

3. Why have I been invited?

You have been invited to take part as you are a qualified physiotherapist working in the Manchester Movement Unit and may treat people who have a rotator cuff disorder.

We are looking for up to 3 physiotherapists and up to 12 patient participants to take part in the study.

4. Do I have to take part?

It is your decision if to take part or not. We will ask you to consider the information given in this sheet and if you would like to take part, express interest by return email (see details at the end of this leaflet). You will have the opportunity to speak to the lead researcher to discuss this information and ask any further questions.

You will be invited to an online meeting with the lead researcher to check that you meet the criteria for taking part in the study. We will then go through a consent form with you to show you agreed to take part, which will be recorded.

You are free to withdraw at any time, without giving a reason.

5. What will I be asked to do?

If you agree to take part, you will be asked to attend a half day (3-4 hours) training workshop, which will either be held on Manchester Metropolitan University premises or online via Microsoft Teams. This will introduce you to the study and provide you with the knowledge and skills to deliver The COMBINED approach intervention to patients.

After the training we will ask you to deliver the new COMBINED approach to a few patients. **We will ask you to video record these treatment sessions with patients.** We will then conduct an online interview with you about your experience of the training workshop and delivering the intervention to these patients. This will be recorded via Microsoft Teams and should last up to 30 minutes.

The recordings of the treatment sessions and the feedback from interviews will be used to make any necessary changes to improve The COMBINED approach intervention, including the training workshop. We will then repeat the cycle above which will include attending the training workshop and delivering The COMBINED approach to a few more patients. However, instead of an interview we would like you to take part in an online focus group with up to two other physiotherapists to find out what you think to the changes we have made and any further recommendations. This should last 1-2 hours and will be recorded via Microsoft Teams.

The video recordings will only be viewed by researchers directly involved in this study or for the purpose of supporting other research in the future.

6. Are there any risks if I take part?

There are no anticipated risks associated with taking part in this research study.

7. Are there any advantages if I take part?

If you agree to take part in this study, you will receive a training workshop which will include current evidence regarding the management of rotator cuff disorders.

By taking part you will be helping us to further develop The COMBINED approach with the aim of providing better care for patients with a rotator cuff disorder in the future.

8. What will happen with the data I provide?

When you agree to participate in this research, we will collect personally-identifiable information from you (such as name, sex, professional role), as well as special category data (such as ethnicity). We will also video record the treatment sessions and the online interview. When this is written up in a report, anything you say will be anonymised and you won't be able to be identified. If you withdraw from the study, we will keep the information about you that we have already obtained.

Julie Bury, as the lead researcher, will act as data custodian and handle any personal data as confidential and shall be stored securely at all times. The lead researcher will protect the security of Personal Data by maintaining, and monitoring compliance with the University's Information Security Policy and adhere to the University's Data Protection Policy and comply with the Data Protection Act (DPA) and the General Data Protection Regulation (GDPR).

We will only retain your personal data for as long as is necessary to achieve the research purpose, after which it will be destroyed safely by the lead researcher in line with standard procedures at Manchester Metropolitan University. Data collected may be used to support other research in the future, and may be shared with other researchers, where appropriate

through a data sharing agreement. We will not share your personal data collected with any third parties.

Manchester Metropolitan University is the Data Controller in respect of any personal data that you provide. The University is registered with the Information Commissioner's Office (ICO) and manages personal data in accordance with GDPR and the University's Data Protection Policy.

For further information about use of your personal data and your data protection rights please see the University's Data Protection Pages.

9. What will happen to the results of the research study?

The results of the research study will be used to inform further development of The COMBINED approach that will then be tested in a clinical trial. The results of this trial may inform future grant applications.

The information may also be published in scientific journals and presented at scientific conferences describing this intervention development process. Any quotes used from the interviews or recordings will be anonymised and so you or any third parties will not be identifiable. No videos or images will be used.

10. Who has reviewed this research project?

This research project has been reviewed by academic supervisors and patient representatives (as part of patient and public involvement activity).

It has been reviewed by Manchester Metropolitan University Faculty of Health and Education Research Ethics and Governance Committee (Ethical approval number 37460).

11. Who do I contact if I have concerns about this study or I wish to complain?

Should you have any general questions about the research study or information contained within this information sheet, please contact the lead researcher in the first instance:

Julie Bury
Lead researcher
Email: Julie.bury@stu.mmu.ac.uk

If you wish to complain or have any concerns about any aspect of the study or the way you have been approached or treated during the course of this study, please contact the Principal Supervisor:

Professor Chris Littlewood
Professor of Musculoskeletal Research

Faculty of Health and Education
Manchester Metropolitan University
Brooks Building
53 Bonsall Street
M15 6GX
Email: c.littlewood@mmu.ac.uk

Or, you can contact the Faculty Head of Ethics:

Professor Khatidja Chantler
Head of Faculty of Health and Education Research Ethics and Governance
Faculty of Health and Education
Manchester Metropolitan University
Brooks Building
53 Bonsall Street
M15 6GX
Telephone: +441612471316
Email: K.Chantler@mmu.ac.uk

If you have any concerns regarding the personal data collected from you, our Data Protection Officer can be contacted using the legal@mmu.ac.uk e-mail address, by calling 0161 247 3331 or in writing to: Data Protection Officer, Legal Services, All Saints Building, Manchester Metropolitan University, Manchester, M15 6BH. You also have a right to lodge a complaint in respect of the processing of your personal data with the Information Commissioner's Office as the supervisory authority. Please see: https://ico.org.uk/global/contact-us/

THANK YOU FOR CONSIDERING PARTICIPATING IN THIS PROJECT

Appendix K: Consent Form (Clinician & Patients) – Usability study

NHS
Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Manchester Metropolitan University

CONSENT FORM – For Patients & Clinicians

COmbining brief interventions for Modifiable health Behaviours withIN a physiotherapy consultation for pEople with a rotator cuff Disorder (COMBINED): Intervention development

Audio consent will be taken in the following way:

a) Thank the participant for joining and state for the record the name of the person taking consent and the date.
b) Remind the participant that the conversation is being recorded and wait for confirmation that this is acceptable to them.
c) State for the record the name of the participant.
d) Record audio consent by reading the template consent form out loud, stating for the record the version number and version date of the consent form. Pause after each consent item to allow the participant to audibly confirm for the recording.
e) Continue until all items on the consent form have been confirmed.

The following statements will be read out:

1.	I confirm that I have read the participant information sheet version 1.0, date 11th Nov 2021 for the above study.
2	I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
3	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.
4	I agree to participate in the project to the extent of the activities described to me in the above participant information sheet.
5	I agree to my participation being video recorded for analysis. No video clips will be published without my express consent (additional media release form).
6	I understand that data collected about me may be used to support other research in the future, and may be shared with other researchers, where appropriate through a data sharing agreement.
7	I understand and agree that my words may be quoted anonymously in research outputs.
8	I am aware I can contact the research team if I wish to be informed about this research.
9	I give permission for the researchers named in the participant information sheet to contact me in the future about this research or other research opportunities.

Audio consent recordings will be stored on Man Met's OneDrive

FUNDED BY NIHR | National Institute for Health Research

Appendix L: Participant Information Sheet (Patient) – Usability study

NHS Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Manchester Metropolitan University

Participant Information Sheet (Patient)

Combining treatments for shoulder pain (COMBINED).

ComBined

1. Invitation to take part in a research study

My name is Julie Bury and I am a Physiotherapist at Doncaster and Bassetlaw Teaching Hospitals and a PhD student at Manchester Metropolitan University. I am the lead researcher on this project. This work is funded by the National Institute for Health Research as part of a Clinical Doctoral Research Fellowship.

We would like to invite you to take part in a research study, called 'COMBINED'. Our research project is part of a programme of work that is looking at how we can improve current treatments for people with shoulder pain, who have been diagnosed with a rotator cuff disorder. The rotator cuff is a group of muscles and tendons which move and stabilise the shoulder joint, and problems with these muscles and tendons can result in pain and difficulty doing everyday tasks.

Before you decide if you would like to take part, please take some time to read the following information to understand why the research study is being done and what it will involve. If anything is not clear, or you would like more information, please contact me (you will find my details at the end of this leaflet).

2. Background to the study

Routine treatments for a rotator cuff disorder include advice, exercise, steroid injections and surgery. However, information from studies testing these treatments suggest people don't always improve much in terms of their pain and function and can still report shoulder pain 12 months later.

Research also suggests a link between certain lifestyle factors and the onset and persistence of rotator cuff problems. These factors are smoking, being overweight, and low physical activity levels. A 'brief intervention' that includes advice, encouragement and support can be used as an effective way to help patients change the health behaviour linked to this factor, for example to stop smoking, to achieve a healthy diet or to increase physical activity levels.

We have designed an intervention with the help of patients and clinicians called 'The COMBINED approach'. Physiotherapists can use this new approach within a treatment

session for people with a rotator cuff disorder that combines a brief intervention to target the health behaviours as described, together with their current treatments, such as exercises for strengthening the muscles and tendons of the shoulder. It also includes training and support for the physiotherapists to deliver this.

We would like to test this intervention with a few patients and physiotherapists to find out what they think of it. This will help us to improve it further before testing it in a larger study.

3. Why have I been invited?

You have been invited to take part as you may have a rotator cuff disorder. You need to be over 18 years of age and either:

- Smoke **and/or**
- Have a Body Mass Index (BMI) over 25kg/m2 - you can calculate this at https://www.nhs.uk/live-well/healthy-weight/bmi-calculator/) **and/or**
- Do less than 150 minutes/week of physical activity

We are looking for 12 participants to take part in the study.

4. Do I have to take part?

It is your decision if to take part or not. We will ask you to consider the information given in this sheet and if you would like to take part, express interest by return email (see details at the end of this leaflet). You will have the opportunity to speak to the lead researcher to discuss this information and ask any further questions.

You will be invited to an online appointment with the lead researcher to check that you meet the criteria for taking part in the study. This will include taking some details about your shoulder problem and an examination of your shoulder, for example looking at your shoulder movements. We will then go through a consent form with you to show you agreed to take part, which will be recorded.

You are free to withdraw at any time, without giving a reason. This will not affect any routine NHS care.

5. What will I be asked to do?

If you agree to take part, you will be asked to attend up to 2 free treatment sessions (up to one hour each) with a qualified physiotherapist in the Manchester Movement Unit. This is a private physiotherapy clinic within Manchester Metropolitan University.

During this treatment session you will be asked some questions about your shoulder pain and the other factors that could be influencing your shoulder pain, such as how active you are, as well as an examination of your shoulder. Different treatment options will then be discussed

with you. This will be very similar to what you would expect in a normal physiotherapy appointment. **The treatment sessions will be video recorded.**

Following the first appointment, we will ask you to take part in a short online interview with the lead researcher about your experience of your physiotherapy treatment session. This will be done in a quiet area straight after your appointment and will be recorded via Microsoft Teams. It is expected to take up to 30 mins.

A follow-up appointment will be discussed between yourself and the treating physiotherapist. If you attend this session, **this will also be video recorded**.

The video recordings of the treatment sessions and the interviews will be used to make any necessary changes to improve The COMBINED approach intervention before further testing. The video recordings will only be viewed by researchers directly involved in this study or for the purpose of supporting other research in the future.

6. Are there any risks if I take part?

There are no anticipated risks associated with taking part in this research study.

7. Are there any advantages if I take part?

If you agree to take part in this study, you will receive up to two free treatment sessions with a qualified physiotherapist in the private physiotherapy clinic, The Manchester Movement Unit (please see section below regarding payment of treatment fees). You will gain greater understanding of your shoulder condition and what you can do to help, which will inform an agreed treatment plan with your physiotherapist for managing your shoulder pain.

By taking part you will be helping us to further develop The COMBINED approach with the aim of providing better care for patients with a rotator cuff disorder in the future.

8. What do the treatment fees cover?

The research study will cover up to two free treatment sessions with a physiotherapist in the Manchester Movement Unit for the purpose of this research. There is no obligation to continue with treatment beyond this research study.

9. What will happen with the data I provide?

When you agree to participate in this research, we will collect personally-identifiable information from you (such as name, telephone number, age, and sex), as well as special category data (such as medical information and ethnicity). We will also video record the treatment sessions and the online interview. When this is written up in a report, anything

you say will be anonymised and you won't be able to be identified. If you withdraw from the study, we will keep the information about you that we have already obtained.

Julie Bury, as the lead researcher, will act as data custodian and handle any personal data as confidential and shall be stored securely at all times. The lead researcher will protect the security of Personal Data by maintaining, and monitoring compliance with the University's Information Security Policy and adhere to the University's Data Protection Policy and comply with the Data Protection Act (DPA) and the General Data Protection Regulation (GDPR).

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10. What will happen to the results of the research study?

The results of the research study will be used to inform further development of The COMBINED approach that will then be tested in a clinical trial. The results of this trial may inform future grant applications.

The information may also be published in scientific journals and presented at scientific conferences describing this intervention development process. Any quotes used from the interviews or recordings will be anonymised and so you or any third parties will not be identifiable. No videos or images will be used.

If you would like to be informed about the results of this study, you can contact the lead researcher via the details provided below.

11. Who has reviewed this research project?

This research project has been reviewed by academic supervisors and patient representatives (as part of patient and public involvement activity).

It has been reviewed by Manchester Metropolitan University, Faculty of Health and Education Research Ethics and Governance Committee (Ethical approval number 37460).

12. Who do I contact if I have concerns about this study or I wish to complain?

Should you have any general questions about the research study or information contained within this information sheet, please contact the lead researcher in the first instance:

Julie Bury
Lead researcher
Email: Julie.bury@stu.mmu.ac.uk

If you wish to complain or have any concerns about any aspect of the study or the way you have been approached or treated during the course of this study, please contact the Principal Supervisor:

Professor Chris Littlewood
Professor of Musculoskeletal Research
Faculty of Health and Education, Manchester Metropolitan University, Brooks Building, 53 Bonsall Street, M15 6GX
Email: c.littlewood@mmu.ac.uk

Or, you can contact the Faculty Head of Ethics:

Professor Khatidja Chantler
Head of Faculty of Health and Education Research Ethics and Governance
Faculty of Health and Education, Manchester Metropolitan University, Brooks Building, 53 Bonsall Street, M15 6GX
Telephone: +441612471316
Email: K.Chantler@mmu.ac.uk

If you have any concerns regarding the personal data collected from you, our Data Protection Officer can be contacted using the legal@mmu.ac.uk e-mail address, by calling 0161 247 3331 or in writing to: Data Protection Officer, Legal Services, All Saints Building, Manchester Metropolitan University, Manchester, M15 6BH. You also have a right to lodge a complaint in respect of the processing of your personal data with the Information Commissioner's Office as the supervisory authority. Please see:
https://ico.org.uk/global/contact-us/

THANK YOU FOR CONSIDERING PARTICIPATING IN THIS PROJECT

Appendix M: Fidelity checklist & observation proforma – Usability study

The COMBINED approach usability testing – Observation Proforma

Participant ID number:_____

FIRST APPOINTMENT WITH THE PHYSIOTHERAPIST

SECTION A: INTERVENTION FIDELITY

A1. Date of appointment: ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y) e.g. 01 / JAN / 2018

Is there evidence from the video observations that the physiotherapist:

A2. sets the agenda for the consultation (introduces the lifestyle factors/asks permission)

☐ Yes ☐ Partially ☐ No ☐ Unclear

A3. takes a patient history including:

(i) questions about their shoulder pain

☐ Yes ☐ Partially ☐ No ☐ Unclear

(ii) questions relating to the lifestyle factors (smoking, weight, and physical activity)

☐ Yes ☐ Partially ☐ No ☐ Unclear

A4. completes a physical examination including:

(i) a shoulder examination

☐ Yes ☐ Partially ☐ No ☐ Unclear

(ii) assessment of any relevant lifestyle factors (e.g., BMI)

☐ Yes ☐ No ☐ Unclear ☐ N/A

A5. discusses treatment options in relation to specific shoulder rehabilitation combined with supporting health behaviour change

☐ Yes ☐ Partially ☐ No ☐ Unclear

A6. (i) discusses the links between patient's shoulder condition and any lifestyle factors

☐ Yes ☐ Partially ☐ No ☐ Unclear

(ii) the infographic was used

☐ Yes ☐ Partially ☐ No

A7. explores patient's motivations relevant to health behaviour change

☐ Yes ☐ Partially ☐ No ☐ Unclear

A8. agrees a plan using:

(i) the action planner

☐ Yes ☐ Partially ☐ No ☐ Unclear

(ii) the self-monitoring diary

☐ Yes ☐ Partially ☐ No ☐ Unclear

A9. signposts the patient to further support services

☐ Yes ☐ Partially ☐ No ☐ Unclear

A10. offers shoulder-specific tailored treatments, including:

(i) reassurance/education

☐ Yes ☐ Partially ☐ No ☐ Unclear

(ii) progressive loaded exercise programme

☐ Yes ☐ Partially ☐ No ☐ Unclear

(iii) self-management advice

☐ Yes ☐ Partially ☐ No ☐ Unclear

A11. offers the patient a follow-up appointment

☐ Yes ☐ No ☐ Unclear

SECTION B: OTHER OBSERVATION PRACTICES

Setting description:

Length of consultation:

Other shoulder treatments provided:

Resources used (when, how discussed, reactions):

Specific advice given/language used:

Interactions/emotions:

Challenges identified to discuss:

Areas of good practice identified to discuss:

Anything unexpected to discuss:

SECOND APPOINTMENT WITH THE PHYSIOTHERAPIST

SECTION C: INTERVENTION FIDELITY

C1. Date of appointment: ☐☐/☐☐☐/☐☐☐☐ e.g. 01 / JAN / 2018
D D M M M Y Y Y Y

Is there evidence from the video observations that the physiotherapist:

C2. discusses the patient's progress, including barriers, in terms of:

(i) their shoulder-specific rehabilitation

☐ Yes ☐ Partially ☐ No ☐ Unclear

(i) their health behaviour change

☐ Yes ☐ Partially ☐ No ☐ Unclear

C3. tailors any further health behaviour conversations including, where appropriate, building motivations to change, building self-efficacy, positive feedback

☐ Yes ☐ Partially ☐ No ☐ Unclear

C4. assesses the patient to determine progression/regression of shoulder-specific exercises

☐ Yes ☐ Partially ☐ No ☐ Unclear

SECTION D: OTHER OBSERVATION PRACTICES
Setting description: Length of consultation: Other shoulder treatments provided: Resources used (when, how discussed, reactions): Specific advice given/language used: Interactions: Emotions: Challenges identified to discuss in interview: Areas of good practice identified to discuss in interview: Anything unexpected to discuss:

Appendix N: Interview topic guide (Patient) – Usability study

Interview guide (Patient)

Objectives of the study

To investigate the usability, acceptability, and feasibility of The COMBINED approach:

- To explore patient's user experience of The COMBINED approach.
- To identify key recommendations for refinements to The COMBINED approach.
- To determine intervention fidelity.
- To identify the strengths and limitations of remote data collection.

Preamble

- Confirm happy to proceed as per consent and permission to record

Start recording

Section 1 - Introductions

- Researcher introduces themself and provides an overview of their role within the project.
- Set expectations for how long the interview will last.
- Assurances of confidentiality/anonymity.

Section 2 – The consultation

- You were invited to attend this treatment session today with the physiotherapist, can you tell me about what you thought was going to happen?

  Prompts:

  - Can you tell me what you were expecting from today's treatment session?
  - Did anything happen in the treatment session that you were not expecting or that you were surprised about? (if so, what?)
- I'd like to explore your experience of attending for physiotherapy today for your shoulder pain. Can you tell me how you found the treatment session?

  Prompts:

- What, if anything, did you like about the treatment session?
- What, if anything, did you not like about the treatment session/caused you frustration?

- I'd like to explore your views about specific things that may have been discussed in the treatment session in relation to X (smoking, weight, physical activity levels). How did you feel about being asked about these things by the physiotherapist today?

  Prompts:

  - Did the physiotherapist explain why they were asking you about these things (smoking, weight, physical activity levels)? Yes - Can you expand on this?
  - Did you understand why you were being asked questions about X (smoking, weight, physical activity levels)? Yes - Can you expand on this?
  - Do you understand the links after today between your shoulder pain and X (smoking, weight, physical activity levels)? Yes - Can you expand on this?
  - Do you think these things (smoking, weight, physical activity levels) are an important part of your treatment for your shoulder pain? Yes/No - In what way?
  - Do you feel motivated to do anything in particular from today? (If so, what?)
  - Do you feel confident to do anything in particular from today? (If so, what?)
- Have you made a follow-up appointment? Yes/No – can you tell me why?

<u>Section 3 - Resources</u>

- Did the physiotherapist use any additional booklets/information today? Can you tell me about these?
- What did you think about the 1) Infographic; 2) Activity workbook; 3) Signposting information for further support?

  Prompts:

  - What did you like?
  - What did you not like?
  - Was this easy to understand/follow?
  - What was particularly useful?
  - What did you think about the layout/content/language?
  - Do you think it has helped you understand the links between your shoulder and x (specific to the infographic)?

    - Do you think it will help you to X (stop smoking, achieve a healthy diet, increase your physical activity levels)?
- Is there anything else that would have been helpful that wasn't included?

Section 4 – Recommendations to inform refinements

- Can you think of anything that might have improved the experience today?
    - What, if anything, would you change?
    - What else do you think would help to further improve your experience?
    - How could you be better supported to make these changes (stop smoking, achieve a healthy diet, increase your physical activity levels)?

Section 5 – Remote data collection

- We are looking for feedback on conducting these interviews online, instead of face-to-face. Can you tell me how this experience of an online interview has been for you today?
    - What, if any, have been the benefits of having an online interview?
    - What, if any, have been the challenges of having an online interview?
    - Is there anything we could have changed to further improve your experience?

Section 6 – Close

- Is there anything else that we have not covered that you would like to discuss with me?
- Have you got any questions for me?
- Reiterate confidentiality/anonymity
- Thank them for their time

End recording

Appendix O: Interview topic guide (Clinician) – Usability study

Interview guide (Clinician)

Objectives of the study

To investigate the usability, acceptability, and feasibility of The COMBINED approach:

- To explore clinician's user experience of The COMBINED approach.
- To identify key recommendations for refinements to The COMBINED approach.
- To determine intervention fidelity.
- To identify the strengths and limitations of remote data collection.

Preamble

- Confirm happy to proceed as per consent and permission to record

Start recording

Section 1 - Introductions

- Researcher introduces themself and provides an overview of their role within the project.
- Set expectations for how long the interview will last.
- Assurances of confidentiality/anonymity.

Section 2 - Opening questions/preliminary info

- From the information already collected, can you just summarise for the recording what your main role is? - What area do you work in and what type of patients do you see?

Section 3 – The training workshop

- I'd like to explore your experience of attending the training workshop. Can you tell me what this was like for you?
    - What did you like? Why? (content, format, delivery)
    - What did you not like? Why? (content, format, delivery)
    - Was it useful?
        - What skills did it add?
        - What knowledge did it add?

        - How confident did you feel afterwards about having to deliver the intervention in practice?
- Is there anything else that would have been helpful that wasn't included to better support you to deliver the intervention?
- Do you have any suggestions to improve the training workshop?

<u>Section 4 – The consultation</u>

- I'd like to explore your experience of delivering The COMBINED approach in clinical practice. Can you tell me what it was like for you?

    Prompts:

    - What did you like about delivering the intervention? (Refer to specific aspects: delivering usual care, asking about the health behaviours, explaining the links, exploring motivation to change, signposting, combining all this in a routine consultation)
    - What did you not like about delivering the intervention? (Refer to specific points above)
    - How does this compare to your current clinical practice? In what way is it similar/dissimilar?
- How did you feel about delivering a brief intervention within this consultation e.g., initiating the conversations around the health behaviours, raising awareness of the links between their shoulder pain and the health behaviours, exploring the patient's motivation to change and signposting to further support services?

    Prompts:

    - How confident did you feel to do this? - Why/why not? What helped with this?
    - Did you feel you had the skills to do this? - Why/why not? What helped with this?
    - Did you feel you had the knowledge to explain the links between the health behaviours and shoulder pain to patients? - What helped with this?
- Can you tell me about any challenges that you found to delivering the intervention?
    - Use examples from previous stakeholder workshops e.g., others have previously mentioned concerns about affecting therapeutic alliance/threat to identity/lack of time, what are your thoughts about that?

    - Use observations from video-recordings e.g., I noticed x, can you tell me more about this? Can you tell me what guided your decision when you did y?
- How do you think the intervention was received by patients?
    - Use examples from previous stakeholder workshops e.g., others have previously mentioned concerns about it not meeting patient's expectations/patients not being motivated to change/they won't understand these links between the health behaviours and their shoulder pain, what are your thoughts about that?
    - Use observations from video-recordings e.g., I noticed this when you discussed x, can you tell me more about that?

<u>Section 5 - Resources</u>

- What resources did you use during the consultation?

  Prompts:

    - Can you tell me more about why you chose to use/not use this particular resource?
    - Use observations from video-recordings e.g., I noticed you used/didn't use x during the consultation can you tell me what guided your decision about that?
- What do you think about the 1) Infographic; 2) Activity workbook; 3) Signposting information; 4) Scripts/prompts?

  Prompts:

    - What was particularly useful? Why?
    - What did you like about this? Why?
    - What did you not like about this? Why?
    - Was this easy to understand/follow? Why?
    - What did you think about the layout/content/language? Why?

<u>Section 6 – Recommendations to inform refinements</u>

- Are there any changes you would recommend to The COMBINED approach?
    - If you were to do this again, would you do anything differently? Why would that be needed?
    - How could you be better supported to deliver this intervention?
- What are your thoughts about this being implemented into clinical practice?

- What would need to happen for it to be successfully implemented into practice?
- What do you see as the benefits/advantages of this approach?
- What problems do you foresee, if any, in implementing this into practice?
- What would you recommend to others in delivering this approach?

Section 7 – Remote data collection

- We are looking for feedback on conducting these interviews online, instead of face-to-face. Can you tell me how this experience of an online interview has been for you today?
  - What, if any, have been the benefits of having an online interview?
  - What, if any, have been the challenges of having an online interview?
  - Is there anything we could have changed to further improve your experience?

Section 8 – Close

- Is there anything else that we have not covered that you would like to discuss with me?
- Have you got any questions for me?
- Reiterate confidentiality/anonymity
- Thank them for their time

End recording

Appendix P: Ethics approval – Usability study

Manchester Metropolitan University

20/12/2021
Project Title: Usability testing of an intervention 'The COMBINED approach' to optimise current treatments for people with a rotator cuff disorder

EthOS Reference Number: 37460

Ethical Opinion

Dear Julie Bury,

The above application was reviewed by the Health, Psychology and Social Care Research Ethics and Governance Committee and, on the 20/12/2021, was given a favourable ethical opinion. The approval is in place until 30/06/2022 .

Conditions of favourable ethical opinion

Application Documents

Document Type	File Name	Date	Version
Additional Documentation	COMBINED_UsabilityTesting_Manchester Movement Unit_letter of support_signed	06/10/2021	1.0
Information Sheet	COMBINED_UsabilityTesting_Infographic_final	04/11/2021	1.0
Consent Form	COMBINED_UsabilityTesting_Consent-form_Patients&Clinicians_V1.0_11th Nov 2021	11/11/2021	1.0
Information Sheet	COMBINED_UsabilityTesting_Participant-Information-Sheet_CLINICIAN_V1.0_11thNov2021	11/11/2021	1.0
Information Sheet	COMBINED_UsabilityTesting_Participant-Information-Sheet_PATIENT_V1.0_11thNov2021	11/11/2021	1.0
Information Sheet	COMBINED_UsabilityTesting_Patient-level_intervention_v1.0_11 Nov 21	11/11/2021	1.0
Information Sheet	COMBINED_UsabilityTesting_Patient Signposting information_v1.0_11 Nov 21	11/11/2021	1.0
Information Sheet	COMBINED_UsabilityTesting_Patient-workbook_active-lifestyle	11/11/2021	1.0
Information Sheet	COMBINED_UsabilityTesting_Patient-workbook_healthy-diet	11/11/2021	1.0
Information Sheet	COMBINED_UsabilityTesting_Patient-workbook_Smoking-Cessation	11/11/2021	1.0
Information Sheet	COMBINED_UsabilityTesting_PA-Diary-1	11/11/2021	1.0
Additional Documentation	COMBINED_UsabilityTesting_Focus group topic guide_clinician_v1.0_15 Nov 21	15/11/2021	1.0
Recruitment Media	COMBINED_UsabilityTesting_Email Invitation_Clinician Recruitment_V1.0_16 Nov 21	16/11/2021	1.0
Recruitment Media	COMBINED_UsabilityTesting_Patient advert_v1.0_16Nov2021	16/11/2021	1.0
Additional Documentation	COMBINED_UsabilityTesting_Data sharing contract_transcription company	16/11/2021	1.0
Information Sheet	COMBINED_UsabilityTesting_Script_1 Minute Conversation	16/11/2021	1.0
Information Sheet	COMBINED_UsabilityTesting_Script_5 Minute Conversation	16/11/2021	1.0
Additional Documentation	COMBINED_UsabilityTesting_Interview guide_Patient_v1.0_17 Nov 21	17/11/2021	1.0
Additional Documentation	COMBINED_UsabilityTesting_Interview guide_Clinician_v1.0_17 Nov 21	17/11/2021	1.0
Project Protocol	COMBINED_UsabilityTesting_Protocol_v1.1_14 Dec 21	14/12/2021	1.1
Additional Documentation	14 Dec 21_Reviewers_response_letter	14/12/2021	1.0

The Health, Psychology and Social Care Research Ethics and Governance Committee favourable ethical opinion is granted with the following conditions

Adherence to Manchester Metropolitan University's Policies and procedures

This ethical approval is conditional on adherence to Manchester Metropolitan University's Policies, Procedures, guidance and Standard Operating procedures. These can be found on the Manchester Metropolitan University Research Ethics and Governance webpages.

Amendments

If you wish to make a change to this approved application, you will be required to submit an amendment. Please visit the Manchester Metropolitan University Research Ethics and Governance webpages or contact your Faculty research officer for advice around how to do this.

We wish you every success with your project.

HPSC Research Ethics and Governance Committee

HPSC Research Ethics and Governance Committee

For help with this application, please first contact your Faculty Research Officer. Their details can be found here

Appendix Q: Revised TIDieR checklist

Green = added to the revised checklist; Red = removed from the revised checklist

Name	The COMBINED approach
Why	The COMBINED approach seeks to (1) help patients improve their shoulder pain by assessing and addressing the lifestyle factors associated with the onset and persistence of a rotator cuff disorder through the delivery of a brief intervention within a routine physiotherapy consultation; (2) enable and support physiotherapists through an implementation toolkit to effectively integrate a brief intervention within a routine consultation for people with a rotator cuff disorder.
What	*Materials:* The COMBINED approach involves two levels 1) a brief intervention integrated within a routine consultation targeting patient behaviour change with respect to the relevant lifestyle risk factors and 2) an implementation toolkit as a strategy to support delivery by physiotherapists. Materials used for each level will be: 1. Patient-level intervention a. Workbook for each relevant lifestyle factor (smoking cessation, healthy diet, physical activity) which includes assessing confidence and personal importance of behaviour change, setting goals and action planning –adapted from movingmedicine.ac.uk b. Self-monitoring diaries for each relevant lifestyle factor (smoking cessation, healthy diet, physical activity) - adapted from movingmedicine.ac.uk 2. Clinician-level implementation strategy (toolkit) a. PowerPoint training slides b. Role play videos c. Videos on motivational interviewing d. Video from an internationally renowned shoulder expert endorsing The COMBINED approach

	e. Signposting to the Moving Medicine website (movingmedicine.ac.uk) f. Step-by-step guide to delivering The COMBINED approach g. Scripts h. Infographic highlighting links between the lifestyle factors and shoulder pain to display as posters in patient waiting areas and as an aid for discussion in the consultation i. Signposting information to national support services/websites *Procedures:* *1.* Patient-level intervention Patients will attend one initial physiotherapy consultation, and offered one follow-up consultation, where they will receive The COMBINED approach intervention. The intervention consists of: a. A brief intervention based on the Moving Medicine resource to identify, assess and target the key lifestyle factors smoking, overweight/ obesity, and physical inactivity (moving medicine.ac.uk) b. A shoulder assessment and treatments based on the principles of the Best Practice Advice intervention from the GRASP trial (Hopewell et al 2021) c. Patient resources to support behaviour change (Workbook and self-monitoring diaries) 2. Clinician-level implementation strategy (toolkit) Clinicians will receive the clinician-level implementation toolkit, before delivering The COMBINED approach to patients as described above. The toolkit is a multi-faceted implementation strategy and aims to ensure that clinicians are provided with the support to effectively deliver the patient-level intervention as intended. The multi-faceted strategy will consist of: a. A theoretically informed training package including a practical, skill-based workshop and an optional online top-up training session b. Resources as described under materials c. Audit and feedback – clinicians will be observed delivering The COMBINED approach and provided with feedback to improve the delivery of The COMBINED approach as intended d. Regular communication and support from the Chief Investigator

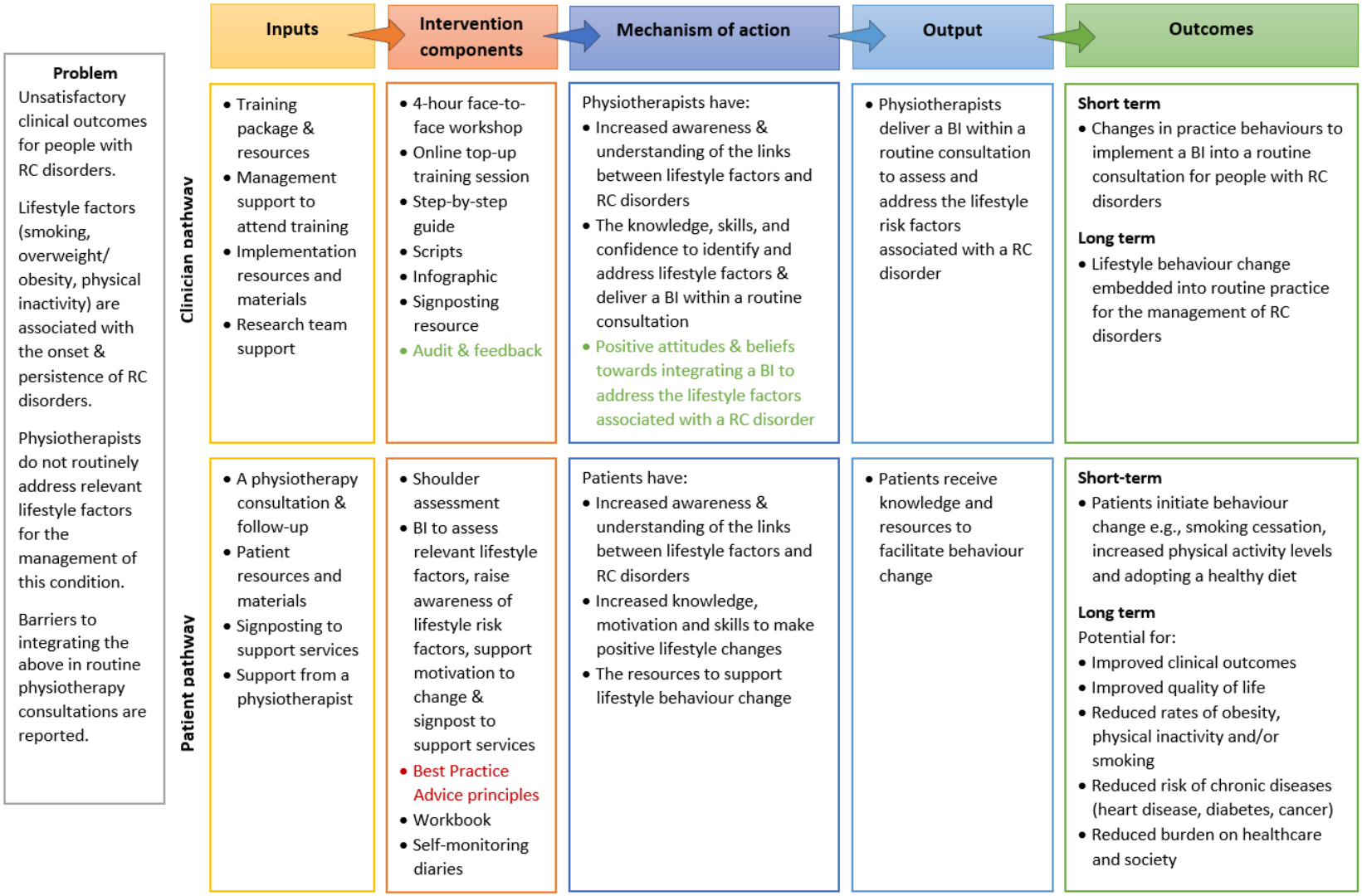
Who provided	1. Patient-level intervention: The patient-level intervention will be delivered by HCPC registered physiotherapists who treat this patient population. Physiotherapists will be invited to participate in the study, consented and participate in the training before delivering The COMBINED approach in practice. 2. Clinician-level implementation strategy: The training will be delivered, and the supporting resources distributed, by the research team. The research team delivering the training are physiotherapists by background and have expertise in the management of rotator cuff disorders and in the development of The COMBINED approach intervention.
How	1. Patient-level intervention: The patient-level intervention will be delivered individually at a face-to-face physiotherapy consultation 2. Clinician-level implementation strategy (toolkit): The training workshop and supporting resources will be delivered to physiotherapists in a face-to-face group session. The online top-up training session will be delivered in a group session, although this may include smaller groups to deliver the training in-line with individual site set-up and recruitment as the purpose of this training is to bridge the gap between the training workshop and delivery of the intervention to the first recruited patient participant.
Where	1. Patient-level intervention: The patient-level intervention will be delivered within a musculoskeletal physiotherapy department at the participating sites. 2. Clinician-level implementation strategy (toolkit): The training workshop will be delivered at a university building or at the participating NHS site. The online top-up training will be delivered via Microsoft Teams.
When and how much?	1. Patient-level intervention: The patient-level intervention will be delivered within an initial physiotherapy consultation lasting up to 60 minutes, and at a follow-up consultation lasting up to 30 minutes.

	2. Clinician-level implementation strategy (toolkit): The training workshop will be delivered once over a 3–4-hour session. The online top-up training will last up to 60 minutes.
Tailoring	1. Patient-level intervention: The patient-level intervention will be standardised with a step-by-step guide and materials provided to the clinicians, however delivery of the brief intervention by clinicians may need to be tailored according to individual patient needs. For example, some patients may not want to discuss lifestyle factors within the consultation and not all aspects of The COMBINED approach will be delivered, others may want to spend longer discussing the role of lifestyle factors in the management of their rotator cuff disorder. Integration of The COMBINED approach within the consultation can be tailored as this will depend on how the conversation naturally occurs and certain cues received form the patient about their lifestyle. It is also acknowledged that within the consultation unforeseen issues may arise which clinicians may have to deal with as a priority, preventing the delivery of The COMBINED approach. 2. Clinician-level implementation strategy (toolkit): Training will be standardised using pre-developed PowerPoint slides, videos, and resources to ensure consistency of the clinician training and of the patient-intervention delivery. The practical role-play sessions, discussions and top-up training will be tailored to clinician's needs.
Modifications	N/A as intervention not delivered yet Following early usability testing, the following modifications were made: 1. Patient-level intervention: a. Removal of the Best Practice Advice intervention based on the GRASP trial (Hopewell et al 2021) – the brief intervention will be integrated with usual care 2. Clinician-level implementation strategy (toolkit): a. An enhanced training package – including a facilitated discussion to explore personal beliefs and biases that would limit engagement with The COMBINED approach, more practical sessions, mandatory top-up training session, electronic training pack and resources, optional references related to underpinning systemic inflammatory mechanisms b. A more simple, prescriptive approach – including the removal of Best Practice Advice as a component of The COMBINED approach described

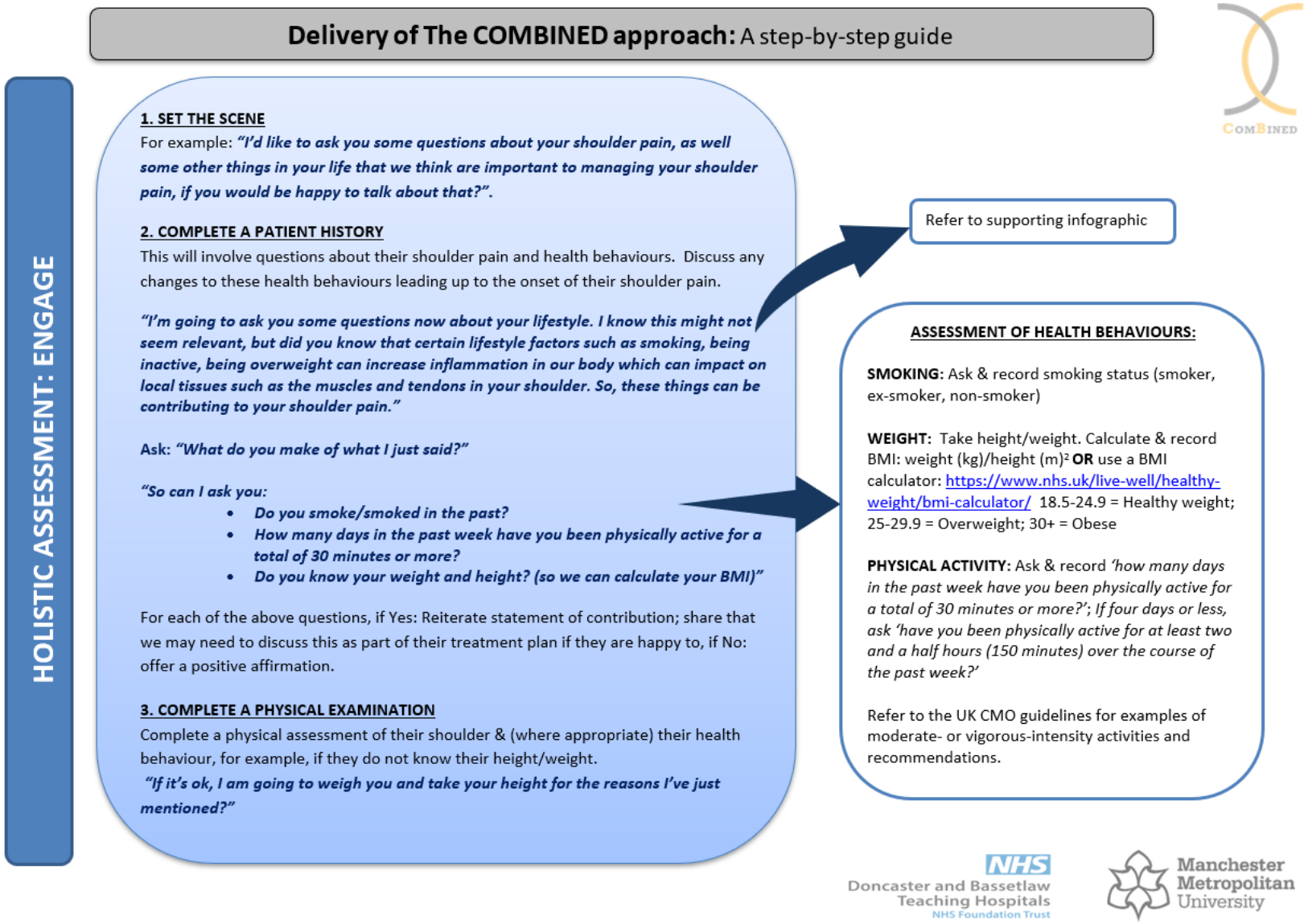
	above, more guidance on the integration of The COMBINED approach within usual processes, a more detailed infographic to explain the underpinning systemic inflammatory mechanisms c. Inclusion of audit and feedback
How well	Planned: Intervention fidelity will be assessed. Intervention fidelity and the key factors influencing the implementation of The COMBINED approach among physiotherapists will be assessed. Actual: Early usability testing: The fidelity assessment showed that overall, 40% of the aspects of the intervention were delivered as intended in line with the training. Feasibility study: The fidelity assessment showed that overall, 82% of the aspects of the intervention were delivered as intended in line with the training. Key factors influencing implementation of The COMBINED approach included the domains (from the theoretical domains framework) beliefs about capabilities, goals, behavioural regulation, environmental context and resources and emotion.

Appendix R: Revised Logic model

Green = added to the revised checklist; Red = removed from the revised checklist



Appendix S: Revised step-by-step guide to The COMBINED approach



HOLISTIC MANAGEMENT : EXPLORE

1. DISCUSS TREATMENT OPTIONS

For example: ***"One way to help you manage your condition is with exercises for your shoulder. The other way is to think about other things in your life that could be influencing your shoulder pain and supporting you to change these".***

2. EXPLAIN THE LINKS: HEALTH BEHAVIOUR(S) AND THEIR CONDITION

- Find out what they already know, for example, ***"What do you know about the benefits of [stopping smoking/being more active/incorporating a healthy diet to lose weight] in people with shoulder pain?"***
- Ask: ***"Can I share with you some other information you may find beneficial?"***
- Share: ***"We think that by addressing these lifestyle factors [in your case to stop smoking/be more active/incorporate a healthy diet to lose weight] combined with usual treatments for shoulder pain, it will help to reduce the inflammation in your body to better manage your shoulder pain".***
- Ask: ***"What do you make of what I have just said?" or "would you be interested in discussing support to stop smoking/being more physically active/incorporating a healthy diet to lose weight?"***

3. EXPLORE:

- Personal motivations to change their health behaviour

Refer to supporting infographic

If they decide they are NOT ready to change:

- Thank them for taking the time to talk with you
- Offer an opportunity to review the conversation
- Reassure them that help is available when they feel ready to change
- Offer further information to read

If they decide to change:

- Move onto planning and support

PLANNING & SUPPORT: DECIDE

1. SUMMARISE AND ASK THE KEY QUESTION:

- ***"What do you think you will do?"***

2. AGREE A PLAN:

Share options that might be helpful when making a plan:

- Setting some goals
- Using a diary
- Using an app or following a specific plan

3. SIGNPOST:

- To relevant support organisations

4. ARRANGE FOLLOW-UP:

"How would you feel about coming back another time to build on the thoughts and ideas you've shared with me today?"

Refer to the workbook and relevant resource pack

FOLLOW-UP APPOINTMENT TO:

Discuss progress in terms of shoulder pain & health behaviour change

- Go through patient resources previously given to the patient, e.g. action planner workbook or diary
- Assess any barriers to change
- Build on their motivations and self-efficacy to change
- Invite patients who weren't ready to change if they would like to discuss this further

ComBined

NHS Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Manchester Metropolitan University

Appendix T: Participant Information Sheet (Clinician) – Feasibility study

NHS
Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Manchester Metropolitan University

ComBined

Participant Information Sheet (Clinician)

Combining Treatments for Shoulder Pain
The COMBINED study

1. Invitation to take part in a research study

My name is Julie Bury and I am a Physiotherapist at Doncaster and Bassetlaw Teaching Hospitals and a PhD student at Manchester Metropolitan University. I am the lead researcher on this project.

We would like to invite you to take part in a research study, called the COMBINED study. Our research project is looking at how we can improve current treatments for people with shoulder pain, who have been diagnosed with a rotator cuff disorder.

Before you decide if you would like to take part, please take some time to read the following information to understand why the research study is being done and what it will involve. If anything is not clear, or you would like more information, please contact me (you will find my details at the end of this leaflet).

2. Background to the study

Routine treatments for a rotator cuff disorder include advice, exercise, steroid injections and surgery. However, information from studies testing these treatments suggest they offer only small to moderate benefits at best. Also, some patients don't always get better with these treatments and still report shoulder pain 12 months later.

Research also suggests a link between certain lifestyle factors and the onset and persistence of rotator cuff problems. These factors are smoking, being overweight, and low physical activity levels. A 'brief intervention' that includes advice, encouragement and support can be used as an effective way to help patients change the health behaviour linked to this factor, for example to stop smoking, to achieve a healthy diet or to increase physical activity levels.

We have designed and tested an intervention with the help of patients and clinicians called 'The COMBINED approach'. Physiotherapists can use this new approach within a treatment session for people with a rotator cuff disorder that combines the assessment of the lifestyle factors and, where appropriate, a brief intervention to target the health behaviours as described, together with current treatments, such as exercises for strengthening the

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muscles and tendons of the shoulder. It also includes training and support for the physiotherapists to deliver this.

We would like to find out if this treatment approach can be delivered within the NHS and to identify ways to improve how physiotherapists deliver the new treatment approach. Your thoughts and opinions will help us to improve it further before testing it in a larger study.

3. Why have I been invited?

You have been invited to take part as you are a qualified physiotherapist working in a musculoskeletal service in the NHS and may treat people who have a rotator cuff disorder.

4. Do I have to take part?

It is your decision if to take part or not. We will ask you to consider the information given in this sheet and if you would like to take part, express interest by return email. You will have the opportunity to discuss this information and ask any further questions.

You will then be invited to a brief meeting with the site principal investigator to check that you meet the criteria for taking part in the study. We will then go through a consent form with you to show you have agreed to take part and take some personal information from you, such as your job role and how many years of experience you have. The purpose of collecting this information is to enable us to describe who took part in the research and to make a judgement about if the findings of this research can be applied in other contexts.

You are free to withdraw at any time, without giving a reason, by contacting the lead researcher (details at the end of the leaflet). We will store any information we have already collected about you in line with our data storage procedures.

5. What will I be asked to do?

If you agree to take part, you will be asked to attend a half-day (3-4 hours) training workshop at an agreed convenient time and location (either NHS or university premises) during working hours. This will introduce you to the study and provide you with the knowledge and skills to deliver The COMBINED approach to patients. You will be asked to complete a short survey following this (up to 15 minutes to complete). You will be reimbursed for any travel expenses in relation to attending the training and catering will be provided.

After the training, we will ask you to deliver The COMBINED approach to patients with a rotator cuff disorder as part of a routine consultation and, where appropriate, during a follow-up consultation. We will ask you to audio-record the treatment sessions with patients (following consent) for the purpose of checking what aspects of The COMBINED approach

were delivered in the session. This will be determined using a checklist. We will not report individual discussions, and this is not an assessment of your clinical performance.

The lead researcher (Julie Bury) may request, with your and the patient's consent, to observe a few of these consultations. The purpose of this is to identify any early challenges to delivering The COMBINED approach and help us to make any changes where we can. At the end of the study, we will ask you to complete another short survey (up to 15 minutes to complete).

The findings from this study will be used to make any necessary changes to improve The COMBINED approach intervention, including the training workshop. Where applicable, changes may be made to the COMBINED approach intervention during the study, particularly where this may improve the delivery of The COMBINED approach. Other changes will be made after the analysis.

6. Are there any risks if I take part?

There are no anticipated risks associated with taking part in this research study. If new information comes to light that questions the validity of the study, then this information will be provided to participants, and you would have the option to withdraw or re-consent to different procedures.

The COMBINED study is being sponsored by Manchester Metropolitan University who have arrangements in place to provide compensation in the extremely unlikely event that you suffer lasting harm from participation in the study.

7. Are there any advantages if I take part?

If you agree to take part in this study you will receive a training workshop which will include current evidence regarding the management of rotator cuff disorders.

By taking part you will be helping us to further develop The COMBINED approach with the aim of providing better care for patients with a rotator cuff disorder in the future.

8. How will we use information about you?

Manchester Metropolitan University (we) are the sponsor for this study. We will need to use information from you for this research project.

This information will include your:

- Name
- Contact details (telephone number, email)

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. Access to the research data will be restricted to the research team and a minimum number of individuals necessary for quality control, audit, and analysis.

We will keep all information about you safe and secure. If any research data is required to be transferred between NHS sites then the security mechanisms for this will be in line with the policies and procedures for transferring patient clinical data. Some of this data will be anonymised using a code number, such as the treatment log (participant contact form), but some will contain identifiable information, such as the consent forms. Audio recordings of the consultation will be on a password-protected device. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

9. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

10. Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from **www.hra.nhs.uk/patientdataandresearch**
- by sending an email to ethics@mmu.ac.uk

11. What will happen to the results of the research study?

Research data collected will be securely stored and kept for 10 years after the study has finished. Some data that we will store includes information that will be identifiable to you, for example, it will include your name on it. Other data will be anonymised using a code number, which means you will not be able to be identified from this. Specific examples are:

- Consent forms – these will be identifiable to you
- The survey data – these will be anonymised using a code number
- Screening logs – these will include demographic information about you such as your job role, but people will not be able to see your name or contact details

- Case report forms to check the delivery of the intervention - these will be anonymised using a code number.

A fully anonymised version of the data may be deposited in an Open Access repository so that it can be used to support future research and learning.

The results of the research study will be used to inform further development of The COMBINED approach that will then be tested in a clinical trial. The results of this trial may inform future grant applications.

The information may also be published in scientific journals and presented at scientific conferences describing this intervention development process. Anything you say in the audio-recordings will not be used.

If you would like to be informed about the results of this study, you can contact the lead researcher via the details provided below.

12. Who has reviewed this research project?

This research project has been reviewed by academic supervisors, by Manchester Metropolitan University as the study sponsor and patient representatives (as part of patient and public involvement activity).

It has been reviewed by West of Scotland Research Ethics Committee 4 and the Health Research Authority.

This work is funded by the National Institute for Health Research as part of a Clinical Doctoral Research Fellowship and has been reviewed by independent expert panel members.

13. Who do I contact if I have concerns about this study or I wish to complain?

Should you have any general questions about the research study or information contained within this information sheet, please contact the lead researcher in the first instance:

Julie Bury
Lead researcher
Email: julie.bury@stu.mmu.ac.uk

If you wish to complain or have any concerns about any aspect of the study or the way you have been approached or treated during the course of this study, please contact the Principal Supervisor:

Dr Gill Yeowell
Reader in Musculoskeletal Health and Wellbeing
Faculty of Health and Education
Department of Health Professions
Manchester Metropolitan University
Brooks Building, 53 Bonsall Street, M15 6GX
Email: g.yeowell@mmu.ac.uk

Or, you can contact the Research Ethics and Governance team:

The Research and Knowledge Exchange Directorate
Room 1.25, Cavendish North Building
Manchester Metropolitan University
Cavendish Street
Manchester, M15 6BG
Tel: 0161 247 2000
Email: ethics@mmu.ac.uk

If you have any concerns regarding the personal data collected from you, our Data Protection Officer can be contacted using the legal@mmu.ac.uk e-mail address, by calling 0161 247 3331 or in writing to: Data Protection Officer, Legal Services, All Saints Building, Manchester Metropolitan University, Manchester, M15 6BH. You also have a right to lodge a complaint in respect of the processing of your personal data with the Information Commissioner's Office as the supervisory authority. Please see: https://ico.org.uk/global/contact-us/

THANK YOU FOR CONSIDERING PARTICIPATING IN THIS PROJECT

This research is funded by the National Institute for Health & Care Research (NIHR)'s Clinical Doctoral Research Fellowship Programme (Ref: NIHR300541).

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Appendix U: Consent Form (Clinician) – Feasibility study

NHS
Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Manchester Metropolitan University

Clinician Consent Form

Site:

Study ID Number:

Title of Project: Combining brief interventions for modifiable health behaviours within a physiotherapy consultation for people with a rotator cuff disorder (COMBINED)

Name of Researcher: Julie Bury

Please initial box

1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my legal rights being affected. If I withdraw I understand information already collected about me will be retained in line with data storage procedures. ☐
3. I agree to my participation being audio recorded for analysis. ☐
4. I understand that the lead researcher may request to observe the treatment session. ☐
5. I understand that the information held and maintained by Manchester Metropolitan University may be used to help contact me about this study. All personal information will remain confidential and handled and stored securely at all times in line with the General Data Protection Regulation (GDPR). ☐
6. I give permission for the researchers named in the participant information sheet to contact me in the future about this research or other research opportunities. ☐
7. I give permission for a fully anonymised version of the data I provide to be used in reports and study publications. Data will be securely stored and kept for 10 years after the study has finished. ☐
8. I give permission for a fully anonymised version of the data I provide to be deposited in an Open Access repository so that it can be used for future research and learning. ☐
9. I wish to be informed of the outcomes of this research. I can be contacted at: ☐
10. I agree to take part in the above study to the extent of the activities described to me in the above participant information sheet. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

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COMBINED is funded by the NIHR Clinical Doctoral Fellowship Scheme (ref: NIHR300541).

When completed: 1 for participant; 1 for researcher site file.

COMBINED

Appendix V: Participant Information Sheet (Patient) – Feasibility study

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Manchester Metropolitan University

Participant Information Sheet (Patient)

Combining Treatments for Shoulder Pain
The COMBINED study

1. Invitation to take part in a research study

My name is Julie Bury and I am a Physiotherapist at Doncaster and Bassetlaw Teaching Hospitals and a PhD student at Manchester Metropolitan University. I am the lead researcher on this project.

We would like to invite you to take part in a research study, called the COMBINED study. Our research project is looking at how we can improve current treatments for people with shoulder pain, who have been diagnosed with a rotator cuff disorder. The rotator cuff is a group of muscles and tendons which move and stabilise the shoulder joint, and problems with these muscles and tendons can result in pain and difficulty doing everyday tasks.

Before you decide if you would like to take part, please take some time to read the following information to understand why the research study is being done and what it will involve for you. If anything is not clear, or you would like more information, please contact me (you will find my details at the end of this leaflet).

2. Background to the study

Routine treatments for a rotator cuff disorder include advice, exercise, steroid injections, and surgery. However, information from studies testing these treatments suggests people don't always improve much in terms of their pain and function and can still report shoulder pain 12 months later. Research also suggests a link between certain lifestyle factors and the onset and persistence of rotator cuff problems. These factors are smoking, being overweight, and low physical activity levels.

We have designed and tested a new treatment approach with the help of patients and clinicians called The COMBINED approach. Physiotherapists can use this new approach within a treatment session for people with a rotator cuff disorder that combines the assessment and

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management of the lifestyle factors together with current treatments, such as exercises for strengthening the muscles and tendons of the shoulder.

The main aim of this study is to find out if this treatment approach can be delivered within the NHS and to identify ways to improve how physiotherapists deliver the new treatment approach. Your thoughts and opinions will also help us to improve it before testing it in a larger study.

3. Why have I been invited?

You have been invited to take part as you may have a rotator cuff disorder.

4. Do I have to take part?

It is your decision if to take part or not. We will ask you to consider the information given in this sheet. The physiotherapist will then contact you and you will have the opportunity to discuss this information and ask any further questions.

If you would like to take part, a physiotherapist will firstly check that you meet the criteria for taking part in the study. This will include asking you some questions (usually over the telephone) about your shoulder problem to check if we think this may be a rotator cuff disorder. If you meet the initial eligibility checks for the study, you will then be offered an appointment with a physiotherapist. At this appointment we will need to carry out an examination of your shoulder to confirm that you have a rotator cuff disorder in order for you to take part in the study.

If you are eligible, and willing to take part, we will go through a consent form with you at this appointment to show you have agreed to take part before commencing any treatments as part of the study. We will also take some personal information from you, such as your gender and ethnicity. The purpose of collecting this information is to enable us to describe who took part in the research and to make a judgement about if the findings of this research can be applied in other contexts.

If we find at this appointment you do not meet the criteria, you will continue with physiotherapy treatment as per standard care, but not as part of this study. Care will be processed as usual in this study and normal waiting times will apply. You are free to withdraw at any time up to and during treatment, without giving a reason, by contacting the lead researcher (details at the end of the leaflet) or discussing with your physiotherapist. If you choose to withdraw your consent to be part of this study, or you lose the capacity to consent, this will not affect any routine NHS care and you will continue with your physiotherapy treatment on the normal pathway as per standard care. We will store any information we

have already collected about you in line with our data storage procedures (see section 9 for further information).

5. What will I be asked to do?

If you agree to take part, and meet the criteria, you will be asked to attend up to two treatment sessions for your shoulder pain (up to one hour each) with a qualified physiotherapist.

During this treatment session you will be asked some questions about your shoulder pain and other things that could be influencing your shoulder pain, such as if you smoke, your weight and how active you are. Where applicable, the physiotherapist may also measure your height and weight during the consultation. You will also have an examination of your shoulder. Different treatment options will then be discussed with you. This will be very similar to what you would expect in a normal physiotherapy appointment. The treatment sessions will be audio-recorded, but only for the purpose of checking what information and treatment was delivered by the physiotherapist in the session. The lead researcher (Julie Bury) may also request, with your consent, to observe one of the treatment sessions. The purpose of this is to identify ways to improve how physiotherapists deliver the new treatment approach.

A follow-up appointment will be discussed between yourself and the treating physiotherapist. If you attend this session, this will also be audio-recorded.

After your appointment(s) we may ask you to take part in an optional short interview about your views and experience of the treatment session. The information from the interviews will be used to make any necessary changes to improve The COMBINED approach before a larger study. This would be done over the telephone and would last up to 20 minutes. We will ask you at your first appointment if you would be happy to be contacted regarding this. If you do not wish to take part in an interview, you can still take part in the study.

If you require any further treatment for your shoulder beyond these two treatment sessions, this will be discussed with your physiotherapist as part of your ongoing care, but it will not be part of this research study.

6. Are there any risks if I take part?

There are no anticipated risks associated with taking part in the COMBINED study. If new information comes to light that questions the validity of the study, then this information will be provided to participants and you would have the option to withdraw or re-consent to different procedures.

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The COMBINED study is being sponsored by Manchester Metropolitan University who have arrangements in place to provide compensation in the extremely unlikely event that you suffer lasting harm from participation in the study. NHS indemnity operates in respect of the clinical treatment you receive.

7. What are the advantages to me if I take part?

If you agree to take part in this study, we cannot guarantee any specific treatment benefits, but you will be helping us to further develop The COMBINED approach with the aim of providing better care for patients with a rotator cuff disorder in the future.

8. How will we use information about you?

Manchester Metropolitan University (we) are the sponsor for this study. We will need to use information from you and from your medical records for this research project.

This information will include your:

- Name
- Contact details (address, telephone number, email)

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. Access to the research data will be restricted to the research team and a minimum number of individuals necessary for quality control, audit, and analysis.

We will keep all information about you safe and secure. If any research data is required to be transferred between NHS sites then the security mechanisms for this will be in line with the policies and procedures for transferring patient clinical data. Some of this data will be anonymised using a code number, such as the treatment log (participant contact form), but some will contain identifiable information, such as the consent forms. Audio-recordings of the consultation will be on a password-protected device. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

9. What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason and without this impacting on your clinical care, but we will keep information about you that we already

have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you choose to withdraw from the study every effort to ensure your specific wishes regarding further involvement in the study will be defined and documented. This will include the option to completely withdraw from the trial and not use any data in the analysis, or to withdraw from the treatments but to still agree for us to use your data collected in the analysis and to have the option, if willing, to participate in an interview (if applicable).

10. Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by sending an email to ethics@mmu.ac.uk

11. What will happen to the results of the research study?

Research data collected will be securely stored and kept for 10 years after the study has finished. Some data that we will store includes information that will be identifiable to you, for example, it will include your name on it. Other data will be anonymised using a code number, which means you will not be able to be identified from this. Specific examples are:

- Consent forms – these will be identifiable to you
- Screening logs – these will include demographic information about you such as your gender and ethnicity, but people will not be able to see your name or contact details
- Interview reports (transcripts) – these will be anonymised using a code number.

A fully anonymised version of the data may be deposited in an Open Access repository so that it can be used to support future research and learning.

The results of the research study will be used to inform further development of The COMBINED approach that will then be tested in a clinical trial. The results of this trial may inform future grant applications.

The information may also be published in scientific journals and presented at scientific conferences describing this intervention development process. Anything you say in the audio-recordings will not be used.

If you would like to be informed about the results of this study, you can contact the lead researcher via the details provided below.

12. Who has reviewed this research project?

This research project has been reviewed by academic supervisors, by Manchester Metropolitan University as the study sponsor and patient representatives (as part of patient and public involvement activity).

It has been reviewed by West of Scotland Research Ethics Committee 4 and the Health Research Authority.

This work is funded by the National Institute for Health Research as part of a Clinical Doctoral Research Fellowship and has been reviewed by independent expert panel members.

13. Who do I contact if I have concerns about this study or I wish to complain?

Should you have any general questions about the research study or information contained within this information sheet, please contact the lead researcher in the first instance:

Julie Bury
Lead researcher
Email: julie.bury@stu.mmu.ac.uk

If you wish to complain or have any concerns about any aspect of the study or the way you have been approached or treated during the course of this study, please contact the Principal Supervisor:

Dr Gill Yeowell
Reader in Musculoskeletal Health and Wellbeing
Faculty of Health and Education
Department of Health Professions
Manchester Metropolitan University
rooks Building, 53 Bonsall Street, M15 6GX
Email: g.yeowell@mmu.ac.uk

Or, you can contact the Research Ethics and Governance team:

The Research and Knowledge Exchange Directorate
Room 1.25, Cavendish North Building
Manchester Metropolitan University
Cavendish Street
Manchester, M15 6BG
Tel: 0161 247 2000
Email: ethics@mmu.ac.uk

If you have any concerns regarding the personal data collected from you, our Data Protection Officer can be contacted using the legal@mmu.ac.uk e-mail address, by calling 0161 247 3331 or in writing to: Data Protection Officer, Legal Services, All Saints Building, Manchester Metropolitan University, Manchester, M15 6BH. You also have a right to lodge a complaint in respect of the processing of your personal data with the Information Commissioner's Office as the supervisory authority. Please see: https://ico.org.uk/global/contact-us/

THANK YOU FOR CONSIDERING PARTICIPATING IN THIS PROJECT

This research is funded by the National Institute for Health & Care Research (NIHR)'s Clinical Doctoral Research Fellowship Programme (Ref: NIHR300541).

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Appendix W: Consent Form (Patient) – Feasibility study

NHS
Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Manchester Metropolitan University

Patient Consent Form

Site:

Study ID Number:

Title of Project: Combining brief interventions for modifiable health behaviours within a physiotherapy consultation for people with a rotator cuff disorder (COMBINED)

Name of Researcher: Julie Bury

Please initial box

1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. If I withdraw I understand information already collected about me will be retained in line with data storage procedures. ☐
3. I agree to my participation being audio recorded for analysis. ☐
4. I understand that the lead researcher may request to observe the treatment session. ☐
5. I understand that the information held and maintained by Manchester Metropolitan University may be used to help contact me about this study. All personal information will remain confidential I and handled and stored securely at all times in line with the General Data Protection Regulation (GDPR). ☐
6. I give permission for the lead researcher to contact me after completion of the treatment to see if I would be willing to discuss my experience. ☐
7. I give permission for the researchers named in the participant information sheet to contact me in the future about this research or other research opportunities. ☐
8. I give permission for a fully anonymised version of the data I provide to be used in reports and study publications. Data will be securely stored and kept for 10 years after the study has finished. ☐
9. I give permission for a fully anonymised version of the data I provide to be deposited in an Open Access repository so that it can be used for future research and learning. ☐
10. I wish to be informed of the outcomes of this research. I can be contacted at: ☐
11. I agree to take part in the above study to the extent of the activities described to me in the above participant information sheet. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

NIHR National Institute for Health Research

COMBINED is funded by the NIHR Clinical Doctoral Fellowship Scheme (ref: NIHR300541)

When completed: 1 for participant; 1 for researcher site file; 1 to be kept in medical notes.

Appendix X: Qualitative Interview Information Sheet (Patient) – Feasibility study

NHS Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Manchester Metropolitan University

Patient Qualitative Interview Information Sheet

Combining Treatments for Shoulder Pain
The COMBINED study

Thank you for taking part in the COMBINED study. After your physiotherapy treatment session, you said you would be happy to receive further information about the related interview study. Here is that information.

The interview study includes an informal discussion (interview) with a researcher about your experiences of the COMBINED study.

Before you decide whether to take part in the interview, it is important for you to understand why the interview is taking place and what it will involve. Thank you for taking the time to read the following information.

1. What is the purpose of the study interviews

The purpose of this part of the study is to conduct an interview to find out your views and experiences of the COMBINED study and the treatment you received.

We hope that the results of the interviews will help us plan future research and also help us improve treatments for people who have shoulder pain involving their shoulder muscles and tendons.

2. Why have I been invited?

You have been invited because you took part in the COMBINED study and then agreed that we could send information about the interview study to you.

3. What does taking part in an interview involve?

Shortly, you will be contacted by the lead researcher, Julie Bury, to discuss taking part. If you agree to take part in a telephone interview, she will ask you to confirm that you are happy to be interviewed and then arrange for the interview to be carried out at a time that is convenient for you.

The interview will be conducted by the lead researcher, Julie Bury, and will last up to **20 minutes,** which will focus on your views and experiences of the COMBINED study. As we are interested in your views and experiences, there are no right or wrong answers. No preparation for the discussion is necessary. No further involvement is required following the interview.

We will record the interviews using a digital recorder and will confirm this with you at the start of the interview.

During the discussion, you can choose not to answer questions, or stop the discussion at any time without giving a reason. You will be asked at the end of the discussion if you are still happy to be included in the study. If you decide that you are no longer happy to do so, the recording of the discussion will be deleted.

4. Do I have to take part in an interview?

No. Taking part in an interview is entirely voluntary. If you decide not to take part, the care you receive now and, in the future, will not be affected.

If you decide to take part in the interview, you are free to stop the interview at any time or withdraw from the interview study for up to one week after the interview. Again, withdrawing will not affect the care you receive now or in the future. You can withdraw by contacting Julie Bury by email: julie.bury@stu.mmu.ac.uk quoting the COMBINED study and we will delete the discussion we had during the interview.

5. What are the possible risks and benefits to taking part?

We do not foresee any risk in taking part in an interview for the COMBINED study. The only burden is on your time in undertaking the interview. If new information comes to light that questions the validity of the study, then this information will be provided to participants and you would have the option to withdraw or re-consent to different procedures.

Although there may not be any direct benefit to you, your participation will help us plan future research and also help us improve treatments for people with shoulder pain involving their shoulder muscles and tendons.

The COMBINED study is being sponsored by Manchester Metropolitan University who have arrangements in place to provide compensation in the extremely unlikely event that you suffer lasting harm from participation in the study. NHS indemnity operates in respect of the clinical treatment you receive.

6. What will happen with the information I provide?

We will need to use information from you and from your medical records for this research project. This information will include your:

- Name
- Contact details (address, telephone number, email)

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Access to the research data will be restricted to the research team and a minimum number of individuals necessary for quality control, audit, and analysis.

If you agree to take part in an interview, the audio-recording will be typed out to make a paper copy of the discussion (called an interview transcript). This will be carried out by Julie Bury, the lead for this study. The transcript will then be pseudonymised, stored securely and the audio-recording will be deleted. A fully anonymised version of the interview data you provide may be deposited in an Open Access repository so that it can be used for future research and learning. The anonymised interview data will be kept for 10 years after the study has finished.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

7. What will happen to the results of the research study?

After the study has finished and we have reviewed the results, the main findings from the study will be shared with the hospital sites and a written summary will be available to patients who have taken part.

The results of this study will also be shared at medical conferences and through publication in academic journals which are read by a large number of health professionals. Quotations from the discussion may be used in reports of this study. Your identity (name, address and any personal information) will not be revealed in any such report, so that your personal details will not be shown.

If you would like to be informed about the results of this study, you can contact the lead researcher via the details provided below.

8. Who has reviewed this research project?

This research project has been reviewed by academic supervisors, by Manchester Metropolitan University as the study sponsor and patient representatives (as part of patient and public involvement activity).

It has been reviewed by the West of Scotland Research Ethics Committee 4 and the Health Research Authority.

This work is funded by the National Institute for Health Research as part of a Clinical Doctoral Research Fellowship and has been reviewed by independent expert panel members.

9. Who do I contact if I have concerns about this study or I wish to complain?

Should you have any general questions about the research study or information contained within this information sheet, please contact the lead researcher in the first instance:

Julie Bury
Lead researcher
Email: julie.bury@stu.mmu.ac.uk

If you wish to complain or have any concerns about any aspect of the study or the way you have been approached or treated during the course of this study, please contact the Principal Supervisor:

Dr Gill Yeowell
Reader in Musculoskeletal Health and Wellbeing
Faculty of Health and Education
Department of Health Professions
Manchester Metropolitan University
rooks Building, 53 Bonsall Street, M15 6GX
Email: g.yeowell@mmu.ac.uk

Or, you can contact the the Research Ethics and Governance team:

The Research and Knowledge Exchange Directorate

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Manchester Metropolitan University

Room 1.25, Cavendish North Building
Manchester Metropolitan University
Cavendish Street
Manchester, M15 6BG
Tel: 0161 247 2000
Email: ethics@mmu.ac.uk

If you have any concerns regarding the personal data collected from you, our Data Protection Officer can be contacted using the legal@mmu.ac.uk e-mail address, by calling 0161 247 3331 or in writing to: Data Protection Officer, Legal Services, All Saints Building, Manchester Metropolitan University, Manchester, M15 6BH. You also have a right to lodge a complaint in respect of the processing of your personal data with the Information Commissioner's Office as the supervisory authority. Please see: https://ico.org.uk/global/contact-us/

THANK YOU FOR CONSIDERING PARTICIPATING IN THIS PROJECT

This research is funded by the National Institute for Health & Care Research (NIHR)'s Clinical Doctoral Research Fellowship Programme (Ref: NIHR300541).

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Appendix Y: Qualitative Interview Consent Form (Patient) – Feasibility study

NHS Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Manchester Metropolitan University

Qualitative Interview Consent Form

Title of Project: Combining brief interventions for modifiable health behaviours within a physiotherapy consultation for people with a rotator cuff disorder (COMBINED)

PLEASE READ THE FOLLOWING OUT AND CONFIRM CONSENT BY PLACING INITIALS OF THE PERSON TAKING CONSENT IN THE BOX

	Please initial box
1. The participant confirms that they have read and understand the COMBINED Qualitative Interview Information Sheet (v _date) and have had the opportunity to ask questions.	☐
2. The participant understands that their participation is voluntary, that they can refuse to answer a question or stop the interview at any time.	☐
3. The participant understands that the interview will be audio-recorded, transcribed by the researcher, and understands that the anonymised transcripts will be securely stored and will be kept for 10 years after the study has finished.	☐
4. The participant consents to audio-recording of the interview and agrees that their words may be quoted anonymously in reports and study publications.	☐
5. The participant understands that relevant sections of my data collected during the study, may be looked at by individuals from Manchester Metropolitan University, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. The participant gives permission for these individuals to have access to my records.	☐
6. The participant understands that a fully anonymised version of the data they provide may be deposited in an Open Access repository so that it can be used for future research and learning.	☐
7. The participant agrees to take part in the above study.	☐

Name of Participant	Study ID	
Name of Person taking audio consent	Date	Signature

I CONFIRM THAT AN AUDIO RECORDING OF THIS CONSENT DISCUSSION HAS BEEN COMPLETED. ☐

NIHR | National Institute for Health Research

COMBINED is funded by the NIHR Clinical Doctoral Research Fellowship Scheme (Ref: NIHR300541)

Appendix Z: Case Report Form (Participant Contact Form) – Fidelity study

The COMBINED study – Participant Contact Form

This form is to be completed for every study participant by the treating physiotherapist.

Patient Study ID number:
Site:

FIRST APPOINTMENT WITH THE PHYSIOTHERAPIST

SECTION A *This section is to be completed for all participants*

A1. Date of appointment: ☐☐/☐☐☐/☐☐☐☐ e.g. 01 / JAN / 2018
D D M M M Y Y Y Y

A2. Tick if the participant did not attend (if YES, no further details to complete) ☐

A3. I have turned on the digital recorder
☐ Yes ☐ No

A4. The patient has the following lifestyle factors (tick all that apply):
☐ Smoker ☐ Overweight/obese ☐ Physically inactive ☐ No lifestyle factors

A5. I have set the scene for the consultation (introduced the lifestyle factors/ask permission)
☐ Yes ☐ No

A6. I have taken a patient history including:
(i) questions about their shoulder pain
☐ Yes ☐ No
(ii) questions relating to the lifestyle factors (smoking, weight, and physical activity levels)
☐ Yes ☐ No

A7. I have completed a physical examination including:
(i) a shoulder examination
☐ Yes ☐ No
(ii) assessment of any relevant lifestyle factors (e.g., BMI)
☐ Yes ☐ No ☐ N/A

SECTION B *This section is only to be completed for participants with an identified lifestyle factor*

B1. I have discussed treatment options in relation to both shoulder-specific rehabilitation and supporting health behaviour change
☐ Yes ☐ No

B2. I have discussed the links between the patient's shoulder condition and the identified lifestyle factor(s)
☐ Yes ☐ No

B3. I have explored the patient's motivations to change relevant to their health behaviour
☐ Yes ☐ No

ONE COPY TO BE RETAINED IN THE INVESTIGATOR SITE FILE; ONE COPY TO BE TRANSFERRED TO THE CI
COMBINED_Participant Contact Form_V1.0_06/03/23

B4. I have agreed a plan with the patient

☐ Yes ☐ No

B5. I have signposted the patient to further support services

☐ Yes ☐ No

B6. I have offered the patient a follow-up appointment

☐ Yes ☐ No ☐ N/A **Date:** ☐☐/☐☐☐/☐☐☐☐

D D M M M Y Y Y Y

B7. I have given the patient a resource pack (with relevant health behaviour specific resources e.g. patient activity workbook, and/or diary)

☐ Yes ☐ No ☐ N/A

SECTION C: OTHER INFORMATION

Length of consultation:

Other shoulder treatments provided:

Resources used/comments (e.g., infographic, signposting information, action-planner, diary):

What worked well:

Challenges identified:

Any other comments (please comment why not if answered 'No' in section A or B):

FOLLOW-UP APPOINTMENT WITH THE PHYSIOTHERAPIST

This section is only applicable for participants with an identified lifestyle factor

D1. Date of appointment: ☐☐/☐☐☐/☐☐☐☐ e.g. 01 / JAN / 2018
D D M M M Y Y Y Y

D2. Tick if the participant did not attend (if YES, no further details to complete) ☐

D3. I have turned on the digital recorder

☐ Yes ☐ No

D4. I have discussed the patient's progress, including barriers, in terms of:

(i) their shoulder-specific rehabilitation

☐ Yes ☐ No

(i) their health behaviour change

☐ Yes ☐ No

D5. I have completed/reviewed the patient activity workbook and/or diary

☐ Yes ☐ No ☐ N/A

D6. I have tailored any further health behaviour conversations including, where appropriate, building motivations to change, building self-efficacy, positive feedback

☐ Yes ☐ No

SECTION E: OTHER INFORMATION

Length of consultation:

Other shoulder treatments provided:

Resources used/comments (e.g., infographic, signposting information, action-planner, diary):

What worked well:

Challenges identified:

Any other comments (please comment why not if answered 'No' in section D):

Signed (treating physiotherapist):.....

Name (print in capitals):.....

Appendix AA: Clinician Survey based on the Theoretical Domains Framework

Clinician Survey

Study ID No:

The following survey is designed to explore what makes it easy or difficult for you to implement The COMBINED approach in your routine clinical practice.

Please read the following statements and indicate your level of agreement to each statement.

Please circle a response between 1 (strongly disagree) to 7 (strongly agree).

	Strongly disagree	***Disagree***	***Slightly Disagree***	***Neutral***	***Slightly Agree***	***Agree***	***Strongly Agree***
KNOWLEDGE							
1. I am aware of the objectives of The COMBINED approach	1	2	3	4	5	6	7
2. I am familiar with the content of The COMBINED approach	1	2	3	4	5	6	7
3. I know how to deliver The COMBINED approach	1	2	3	4	5	6	7
SKILLS/TRAINING							
4. I have received enough training to know how to deliver The COMBINED approach	1	2	3	4	5	6	7
5. I have the skills to deliver The COMBINED approach	1	2	3	4	5	6	7
6. During the training, I have had enough opportunity to practice delivering The COMBINED approach	1	2	3	4	5	6	7
PROFESSIONAL ROLE							
7. Delivering The COMBINED approach in routine consultations with	1	2	3	4	5	6	7

patients is part of my work as a healthcare professional							
8. As a healthcare professional, it is my job to implement The COMBINED approach	1	2	3	4	5	6	7
9. Delivering The COMBINED approach with my patients is consistent with my healthcare profession	1	2	3	4	5	6	7
BELIEFS							
10. I am confident that I can deliver The COMBINED approach even when my patients are not motivated	1	2	3	4	5	6	7
11. I am confident that I can deliver The COMBINED approach when there is little time	1	2	3	4	5	6	7
12. For me, delivering The COMBINED approach with my patients seems/is easy	1	2	3	4	5	6	7
13. I am optimistic about the benefits of delivering The COMBINED approach	1	2	3	4	5	6	7
14. With regard to delivering The COMBINED approach I'm always optimistic about the outcomes	1	2	3	4	5	6	7
15. With regard to delivering The COMBINED approach I hardly ever expect things to go well	1	2	3	4	5	6	7
16. I believe that delivering The COMBINED approach is a good idea	1	2	3	4	5	6	7
17. If I deliver The COMBINED approach, it will benefit my patients' health	1	2	3	4	5	6	7
18. If I deliver The COMBINED approach it might damage my relationship with my patients	1	2	3	4	5	6	7

19. If I deliver The COMBINED approach, I would feel like I am making a difference to patients	1	2	3	4	5	6	7
20. If I deliver The COMBINED approach, I feel my patients would appreciate it	1	2	3	4	5	6	7
PLANS & ACTIONS							
21. I have a clear plan of how I will deliver The COMBINED approach	1	2	3	4	5	6	7
22. Generally, other aspects of care take precedence over delivering The COMBINED approach	1	2	3	4	5	6	7
23. Generally, there are more urgent priorities than delivering The COMBINED approach	1	2	3	4	5	6	7
24. Delivering The COMBINED approach is something I can do automatically	1	2	3	4	5	6	7
25. I (will) keep track of how well I'm doing with regard to the delivery of The COMBINED approach	1	2	3	4	5	6	7
CLINICAL ENVIRONMENT							
26. It is possible for me to prioritise delivering The COMBINED approach	1	2	3	4	5	6	7
27. Delivering The COMBINED approach is a good fit with routine clinical practice	1	2	3	4	5	6	7
28. It is possible for me to adapt the delivery of The COMBINED approach in routine clinical practice to my patients' needs	1	2	3	4	5	6	7
29. In the organisation I work in, supporting health behaviour change with patients is routine	1	2	3	4	5	6	7

30. In the organisation I work in, there is sufficient time to deliver The COMBINED approach	1	2	3	4	5	6	7
31. There is sufficient implementation support provided for delivering The COMBINED approach	1	2	3	4	5	6	7
MY FEELINGS TOWARDS DELIVERING THE COMBINED APPROACH							
32. I generally feel positive about delivering The COMBINED approach	1	2	3	4	5	6	7
33. I generally feel nervous about delivering The COMBINED approach	1	2	3	4	5	6	7
34. Having to deliver The COMBINED approach adds to my feelings of stress at work	1	2	3	4	5	6	7

35. In your own words, please briefly list the top three things that make it easier to deliver The COMBINED approach (if applicable)

1

2

3

36. In your own words, please briefly list the top three things that make it difficult to deliver The COMBINED approach (if applicable)

1

2

3

37. If you have any further comments regarding your experiences of delivering The COMBINED approach, please share these below:

Thank you for completing this survey.

Appendix BB: Fidelity Checklist – Feasibility study

The COMBINED study – CI Fidelity Checklist

Site: Patient study ID No: Clinician study ID No:

FIRST APPOINTMENT WITH THE PHYSIOTHERAPIST

SECTION A: INTERVENTION FIDELITY – to be completed for all participants

A1. Date of appointment: ☐☐ ☐☐☐ ☐☐☐☐ e.g. 01 / JAN / 2018
D D M M M Y Y Y Y

A2. The patient has the following lifestyle factors (tick all that apply):
☐ Smoker ☐ Overweight/obese ☐ Physically inactive ☐ No lifestyle factors

Is there evidence from the recording that the physiotherapist:

A3. sets the agenda for the consultation (introduces the lifestyle factors/asks permission)
☐ Yes ☐ Partially ☐ No

A4. takes a patient history including:

(i) questions about their shoulder pain
☐ Yes ☐ Partially ☐ No

(ii) questions relating to the lifestyle factors (smoking, weight, and physical activity)
☐ Yes ☐ Partially ☐ No

A5. completes a physical examination including:

(i) a shoulder examination
☐ Yes ☐ Partially ☐ No

(ii) assessment of any relevant lifestyle factors (e.g., BMI)
☐ Yes ☐ No ☐ N/A

SECTION B: *To be completed for participants with an identified lifestyle factor*

B1. discusses treatment options in relation to specific shoulder rehabilitation and supporting health behaviour change
☐ Yes ☐ Partially ☐ No

B2. (i) discusses the links between patient's shoulder condition and any lifestyle factors
☐ Yes ☐ Partially ☐ No

(ii) the infographic was used
☐ Yes ☐ Partially ☐ No

B3. explores patient's motivations relevant to health behaviour change
☐ Yes ☐ Partially ☐ No

B4. agrees a plan using:

(i) the patient activity workbook and/or diary
☐ Yes ☐ Partially ☐ No

B5. signposts the patient to further support services

☐ Yes ☐ Partially ☐ No

B6. offers the patient a follow-up appointment

☐ Yes ☐ No

SECTION C: OTHER OBSERVATION PRACTICES

Length of consultation:

Other shoulder treatments provided:

Resources used/comments (e.g., infographic, signposting information, action-planner, diary):

Challenges identified:

Areas of good practice identified:

Any other comments (comment why not if answered 'Partially' or 'No' in section A or B):

FOLLOW-UP APPOINTMENT WITH THE PHYSIOTHERAPIST

SECTION D: INTERVENTION FIDELITY

D1. Date of appointment: ☐☐/☐☐☐/☐☐☐☐ e.g. 01 / JAN / 2018
D D M M M Y Y Y Y

Is there evidence from the recordings that the physiotherapist:

D2. discusses the patient's progress, including barriers, in terms of:

(i) their shoulder-specific rehabilitation

☐ Yes ☐ Partially ☐ No

(i) their health behaviour change

☐ Yes ☐ Partially ☐ No

D3. completes/reviews the patient activity workbook and/or diary

☐ Yes ☐ Partially ☐ No

D4. tailors any further health behaviour conversations including, where appropriate, building motivations to change, building self-efficacy, positive feedback

☐ Yes ☐ Partially ☐ No

SECTION D: OTHER OBSERVATION PRACTICES

Length of consultation:

Other shoulder treatments provided:

Resources used/comments (e.g., infographic, signposting information, action-planner, diary):

Challenges identified:

Areas of good practice identified:

Any other comments (please comment why not if answered 'Partially' or 'No' in section D):

Appendix CC: Audit and Feedback (RREAL Sheet) – Feasibility study

Topic	Main Findings	Resulting changes made (if possible) – with justification
Components delivered as intended		
Components not delivered as intended		
Barriers/challenges faced to delivery as intended (why not delivered as intended/what doesn't work?)		
Facilitators to delivery as intended – (what worked well?)		
Physiotherapists' experience of delivering The COMBINED approach		
Areas of good practice/ positive comments		
Recommended changes to components / areas for improvement or that could be done differently /		

what could make it better now		
Lessons learnt / things they would do differently / anything to share		
Changes that need to happen in the future / factors to consider for trial scale-up and embedding into routine clinical practice		
Miscellaneous / additional comments		
Overall feedback to implementers to improve delivery as intended		

Appendix DD: Interview topic guide (Patient) – Feasibility study

Patient Interview Topic Guide

Objectives of the study

- To explore the patient's experience and views of receiving The COMBINED approach.
- To identify and make any refinements to The COMBINED approach.

1 - Introductions

- Confirm patient is happy to proceed as per consent and permission to audio record.

START RECORDING

- Thank participant for agreeing to take part.
- Researcher introduces themself and provides an overview of their role within the project.
- Set expectations for how long the interview will last.
- Assurances of confidentiality/anonymity.
- Any questions?

2 – The Consultation

I'd like to explore your experience and views of the physiotherapy consultation you attended for your shoulder pain.

TOPIC: PERCEPTIONS AND KNOWLEDGE & UNDERSTANDING

- In your physiotherapy consultation, were you asked about any of the following: If you smoke, your weight and how active you are? If Yes:
    - How did you feel about that?
    - Did this surprise you? Was it unexpected?

- Were you assessed in relation to these e.g., did the physiotherapist measure your height/ weight? If Yes:
    - How did you feel about that?

- What do you understand about why you were asked these questions in the consultation about If you smoke, your weight and how active you are?

- What do you understand about the role of these factors in managing your shoulder pain?

TOPIC: ENGAGEMENT & IMPACT

- What was the impact of this discussion on you?
    - Will you do anything differently/Have you done anything differently (for those after a follow-up consultation) after your treatment session with regards to any identified additional factors in helping to manage your shoulder pain (e.g., stop smoking, increase physical activity levels, adopt a healthy diet)?
    - How confident/motivated are you that you will do anything differently?
    - How important do you think these things are as part of your treatment for your shoulder pain? In what way?

- Were you given any additional leaflets/resources in your consultation? If Yes:
    - What are your thoughts on these?
    - What do you like/not like?
    - Do you think they will be useful? Have these been useful? (for those after a follow-up consultation) In what way?

- Did this consultation meet your expectations? In what way?
    - Was there anything that wasn't addressed/missing from the consultation that you think would have helped you?

TOPIC: REFINEMENTS

- Do you have any other comments that may help us to improve the consultation? (Specifically, regarding any discussions or information you were given about smoking/weight/activity levels in relation to your shoulder pain)

Section 3 – Close

- Is there anything else that we have not covered that you would like to discuss with me?
- Have you got any questions for me?
- Thank them for their time.

***END RECORDING**

Appendix EE: Ethics approval (West of Scotland REC 4) – Feasibility study

WoSRES

West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Mrs Julie Bury
Specialist Physiotherapist / Research Fellow
Doncaster & Bassetlaw Teaching Hospitals
Physiotherapy Department
Doncaster Royal Infirmary, Armthorpe Road
Doncaster
DN2 5LT

West of Scotland REC 4
Research Ethics
Ward 11, Dykebar Hospital
Grahamston Road
Paisley
PA2 7DE

Date 07 June 2023
Direct line 0141 314 0213
E-mail WoSREC4@ggc.scot.nhs.uk

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

Dear Mrs Bury

Study title:	**COmbining brief interventions for Modifiable health Behaviours withIN a physiotherapy consultation for pEople with a rotator cuff Disorder: development and testing in a single-arm feasibility study (COMBINED)**
REC reference:	**23/WS/0073**
Protocol number:	**EthOS ID: 51451**
IRAS project ID:	**322325**

Thank you for your letter of 23 May 2023, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC. A list of the Sub-Committee members is attached.

Confirmation of ethical opinion

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

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies

2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

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

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

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

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

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:
https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

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

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at
https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites (as applicable)

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

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

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter]		20 March 2023
Covering letter on headed paper [Covering letter]		23 May 2023
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor Insurance]		
Interview schedules or topic guides for participants [Patient interview-Topic Guide]	1.0	06 March 2023
IRAS Application Form [IRAS_Form_17042023]		17 April 2023
Letter from funder [Grant letter]		09 January 2020
Letter from sponsor [Sponsor letter]		29 March 2023
Letters of invitation to participant [Clinician-Invitation]	1.0	06 March 2023
Non-validated questionnaire [Clinician Survey]	1.0	06 March 2023
Other [Patient Workbook (Smoking Cessation)]	1.0	06 March 2023
Other [Patient Workbook (Physical Activity)]	1.0	06 March 2023
Other [Patient Workbook (Healthy Diet)]	1.0	06 March 2023
Other [Patient Diary (Physical Activity)]	1.0	06 March 2023
Other [Clinician screening log]	1.0	06 March 2023
Other [Patient screening log]	1.0	06 March 2023
Other [Patient Diary (Healthy Diet)]	1.0	06 March 2023
Other [Patient Diary (Smoking Cessation)]	1.0	06 March 2023
Other [Patient infographic 1]	1.0	06 March 2023
Other [Patient infographic 2]	1.0	06 March 2023
Other [Patient signposting information]	1.0	06 March 2023
Participant consent form [Clinician-Consent Form]	1.1	23 May 2023
Participant consent form [Patient-Consent-Form]	1.1	23 May 2023
Participant consent form [Patient-Qual-Consent-Form]	1.1	23 May 2023
Participant information sheet (PIS) [Clinician-PIS]	1.1	23 May 2023
Participant information sheet (PIS) [Patient-PIS]	1.1	23 May 2023
Participant information sheet (PIS) [Patient-Qual-PIS]	1.1	23 May 2023
Research protocol or project proposal [Protocol]	1.1	23 May 2023
Summary CV for Chief Investigator (CI) [CI CV]	1.0	09 January 2023
Summary CV for supervisor (student research) [CV GY]	1.0	10 January 2023
Summary CV for supervisor (student research) [CV CL]	1.0	16 January 2023
Summary CV for supervisor (student research) [CV CJ]		01 February 2023

Statement of compliance

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 322325	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Abibat Ackwumi

On behalf of
Dr Michael Fail
Chair

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers"

After ethical review guidance for sponsors and investigators – Non CTIMP Standard Conditions of Approval]

Copy to: Alison Lloyd

Lead Nation England: approvals@hra.nhs.uk

West of Scotland REC 4

Attendance at Sub-Committee of the REC meeting

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Wendy Cohen	Speech & Language Therapist (Vice Chair)	Yes	Chair of Meeting
Dr Niamh Davies-Branch	Medical Registrar	Yes	
Ms Patricia Young	Retired Business Manager	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Abibat Adewumi-Ogunjobi	REC Manager

Appendix FF: Ethics approval (Health Research Authority) – Feasibility study

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Mrs Julie Bury
Specialist Physiotherapist / Research Fellow
Doncaster & Bassetlaw Teaching Hospitals
Physiotherapy Department
Doncaster Royal Infirmary, Armthorpe Road
Doncaster
DN2 5LT

Email: approvals@hra.nhs.uk

14 June 2023

Dear Mrs Bury

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**COmbining brief interventions for Modifiable health Behaviours withIN a physiotherapy consultation for pEople with a rotator cuff Disorder: development and testing in a single-arm feasibility study (COMBINED)**
IRAS project ID:	**322325**
Protocol number:	**EthOS ID: 51451**
REC reference:	**23/WS/0073**
Sponsor	**Manchester Metropolitan University**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** 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, in 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 IRAS Help 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 obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who 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 **322325**. Please quote this on all correspondence.

Yours sincerely,
Juliana Araujo

Approvals Specialist

Email: **INSERT for nation of sender** approvals@hra.nhs.uk

Copy to: *Alison Lloyd*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter]		20 March 2023
Covering letter on headed paper [Covering letter]		23 May 2023
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor Insurance]		
Interview schedules or topic guides for participants [Patient interview-Topic Guide]	1.0	06 March 2023
IRAS Application Form [IRAS_Form_17042023]		17 April 2023
Letter from funder [Grant letter]		09 January 2020
Letter from sponsor [Sponsor letter]		29 March 2023
Letters of invitation to participant [Clinician-Invitation]	1.0	06 March 2023
Non-validated questionnaire [Clinician Survey]	1.0	06 March 2023
Organisation Information Document [Organisation Information Document]		29 March 2023
Other [Patient Workbook (Smoking Cessation)]	1.0	06 March 2023
Other [Patient Workbook (Physical Activity)]	1.0	06 March 2023
Other [Patient Workbook (Healthy Diet)]	1.0	06 March 2023
Other [Patient Diary (Physical Activity)]	1.0	06 March 2023
Other [Clinician screening log]	1.0	06 March 2023
Other [Patient screening log]	1.0	06 March 2023
Other [Patient Diary (Healthy Diet)]	1.0	06 March 2023
Other [Patient Diary (Smoking Cessation)]	1.0	06 March 2023
Other [Patient infographic 1]	1.0	06 March 2023
Other [Patient infographic 2]	1.0	06 March 2023
Other [Patient signposting information]	1.0	06 March 2023
Participant consent form [Clinician-Consent Form]	1.1	23 May 2023
Participant consent form [Patient-Consent-Form]	1.1	23 May 2023
Participant consent form [Patient-Qual-Consent-Form]	1.1	23 May 2023
Participant information sheet (PIS) [Clinician-PIS]	1.1	23 May 2023
Participant information sheet (PIS) [Patient-PIS]	1.1	23 May 2023
Participant information sheet (PIS) [Patient-Qual-PIS]	1.1	23 May 2023
Research protocol or project proposal [Protocol]	1.1	23 May 2023
Research protocol or project proposal [Protocol]	1.0	20 March 2023
Schedule of Events or SoECAT [SoECAT]	1.0	27 March 2023
Summary CV for Chief Investigator (CI) [CI CV]	1.0	09 January 2023
Summary CV for supervisor (student research) [CV GY]	1.0	10 January 2023
Summary CV for supervisor (student research) [CV CL]	1.0	16 January 2023
Summary CV for supervisor (student research) [CV CJ]		01 February 2023

Appendix GG: Ethics approval (Faculty of Health and Education REC, Manchester Metropolitan University) – Feasibility study

Manchester Metropolitan University

03/07/2023

Project Title: Combining brief interventions for modifiable health behaviours within a routine physiotherapy consultation for people with a rotator cuff disorder (COMBINED): Feasibility Study

EthOS Reference Number: 51451

Certification

Dear Bury,

The above application was reviewed by the Research Ethics and Governance Team and on the 03/07/2023, was certified. The certification is in place until the end of your HRA approval and is based on the documentation submitted with your application.

Application Documents

Document Type	File Name	Date	Version
External Approval Supporting Information	LetterOfIntent-NIHR300541	09/01/2020	1.0
External Approval Supporting Information	JB_MMU-Research-Insurance-Checklist amended 13.06.18	09/01/2023	1.0
External Approval Supporting Information	JB_CI-Internal-Agreement v2.0_updated Oct'18	09/01/2023	2.0
External Approval Supporting Information	Brief HRA CV_Julie Bury v1.0 09 Jan 2023	09/01/2023	1.0
External Approval Supporting Information	Brief HRA CV_Gill Yeowell v1.0 10 Jan 2023	10/01/2023	1.0
External Approval Supporting Information	Brief HRA CV_Chris Littlewood v1.0 16 Jan 2023	16/01/2023	1.0
External Approval Supporting Information	Brief HRA CV_Clare Jinks 01 Feb 2023	01/02/2023	1.0
External Approval Supporting Information	COMBINED_Patient Interview Topic Guide_V1.0_06 Mar 2023	06/03/2023	1.0
External Approval Supporting Information	COMBINED_Clinician Recruitment Email Invitation_V1.0_06 Mar 2023	06/03/2023	1.0
External Approval Supporting Information	COMBINED_Clinician Survey_V1.0_06 Mar 2023	06/03/2023	1.0
External Approval Supporting Information	COMBINED_Patient-workbook_active-lifestyle_v1.0_06 Mar 2023	06/03/2023	1.0
External Approval Supporting Information	COMBINED_Patient workbook-Smoking Cessation_v1.0_06 Mar 2023	06/03/2023	1.0
External Approval Supporting Information	COMBINED_Patient workbook-healthy diet_v1.0_06 Mar 2023	06/03/2023	1.0
External Approval Supporting Information	COMBINED_Patient Diary-Smoking_v1.0_06 Mar 2023	06/03/2023	1.0
External Approval Supporting Information	COMBINED_Patient Diary-Healthy Diet_v1.0_06 Mar 2023	06/03/2023	1.0
External Approval Supporting Information	COMBINED_Patient Diary- Physical Activity_v1.0_06 Mar 2023	06/03/2023	1.0
External Approval Supporting Information	COMBINED_Clinician Screening-Demographic Log_v1.0_06 Mar 2023	06/03/2023	1.0

Document Type	File Name	Date	Version
External Approval Supporting Information	COMBINED_Patient Screening-Demographic Log_V1.0_06 Mar 2023	06/03/2023	1.0
External Approval Supporting Information	COMBINED_Infographic_Part1_v1.0 06 Mar 2023	06/03/2023	1.0
External Approval Supporting Information	COMBINED_Infographic_Part-2-V1.0_06 Mar 2023	06/03/2023	1.0
External Approval Supporting Information	COMBINED_Patient Support Services_v1.0_06 Mar 2023	06/03/2023	1.0
External Approval Supporting Information	Covering letter	20/03/2023	1.0
External Approval Supporting Information	COMBINED_Protocol_v1.0_20 Mar 2023	20/03/2023	1.0
External Approval Supporting Information	VALIDATED SoECAT COMBINED (1)	27/03/2023	1.0
External Approval Supporting Information	322325_SponsorLetter_V1.0_29March2023_signed	29/03/2023	1.0
External Approval Supporting Information	29 Mar 2023_Organisation_Information_Document_NonCommercial_v1_0_Localised_DBTH	29/03/2023	1.0
External Approval Supporting Information	Combined TWIMC Letter - Manchester Metropolitan University - NHE-07CA06-0013	30/03/2023	1.0
External Approval Application Form	IRASForm_snapshot (2)	17/04/2023	1.0
External Approval Supporting Information	REC review response cover letter_ 23 May 2023	23/05/2023	1.0
External Approval Supporting Information	COMBINED_Clinician Consent Form_V1.1_23 May 2023	23/05/2023	1.1
External Approval Supporting Information	COMBINED_Patient Consent Form_V1.1_23 May 2023	23/05/2023	1.1
External Approval Supporting Information	COMBINED_Qualitative Interview Consent Form_V1.1_23 May 2023	23/05/2023	1.1
External Approval Supporting Information	COMBINED_Clinician Participant Information Sheet_V1.1_23 May 2023	23/05/2023	1.1
External Approval Supporting Information	COMBINED_Patient Participant Information Sheet_V1.1_23 May 2023	23/05/2023	1.1
External Approval Supporting Information	COMBINED_Qualitative Interview Participant Information Sheet_V1.1_23 May 2023	23/05/2023	1.1
External Approval Supporting Information	COMBINED_Protocol_v1.1_23 May 2023	23/05/2023	1.1
External Approval Letter	322325 SL45_(Approval)_Letter_of_HRA_Approval	14/06/2023	1.0
External Approval Supporting Information	1635 COMBINED R&D CCC at CHFT (Maher)_30-06-2023	30/06/2023	1.0
External Approval Supporting Information	22 Mar 2023_OID_NonCommercial_v1_0_Localised_C&H_30-06-23	30/06/2023	1.0
External Approval Supporting Information	DBTH Authorisation Letter 30 June 2023	30/07/2023	1.0
External Approval Supporting Information	Organisation_Information_Document_NonCommercial_v1_0_22 Mar 2023_ Localised_DBTH	30/07/2023	1.0

Conditions of certification

The Research Ethics and Governance Team would like to highlight the following conditions

Adherence to Manchester Metropolitan University's Policies and procedures

This certification is conditional on adherence to Manchester Metropolitan University's Policies, Procedures, guidance and

Standard Operating procedures. These can be found on the Manchester Metropolitan University Research Ethics and Governance webpages.

Amendments

If you wish to make a change to this approved application, you will be required to submit an amendment in accordance with HRA guidelines. Please contact the Research Ethics and Governance team for advice around how to do this.

We wish you every success with your project.

Research Ethics and Governance Team