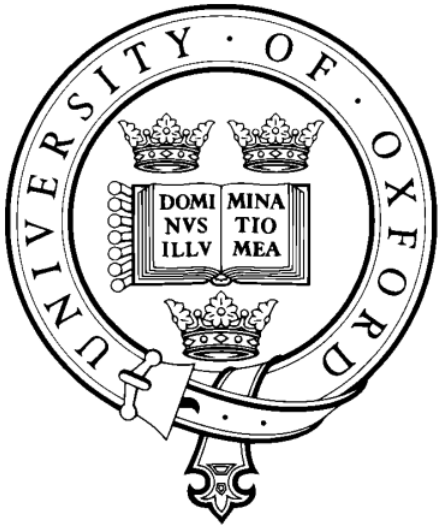
Rehabilitation After Ankle Fracture Treatment (RAAFT): Facilitating safe weight-bearing after ankle fracture surgery



Christopher Bretherton

Wolfson College

University of Oxford

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Abstract

For as long as orthopaedic surgeons have treated patients with ankle fractures, surgical dogma has enforced weight-bearing restrictions on patients postoperatively.

These restrictions have perpetuated patients' fear of pain, falls and re-injury, with subsequent muscle wasting, stiffness and delayed return to work and hobbies.

This thesis explored the behavioural influences which underpin this delayed return to weight-bearing and established the components of ankle fracture rehabilitation requiring advancement.

Firstly, a systematic review found that existing rehabilitation interventions to improve ankle fracture recovery lack a theoretical grounding. Some interventions employed "Education" and "Training" techniques, but few attempted to modify underlying beliefs and behaviour to improve adherence and engagement with recovery.

An exploratory analysis built on previous research in the upper limb, finding association between unhelpful pain beliefs and worse medium-term patient-reported outcomes after ankle fracture surgery.

The gaps, inconsistencies and needs in rehabilitation were explored through interviews with patients recovering from ankle fracture surgery and healthcare professionals who treat them. Patient anxieties, uncertainties, and variable-quality interactions with healthcare professionals were among many deficiencies identified and targeted during subsequent intervention design.

The components of a novel rehabilitation package were developed and prioritised through a series of online workshops and surveys. The findings were triangulated to establish theoretically congruent behaviour-change interventions. Surprisingly, the uncertainties and desires of patients were relatively simple. A small amount of information around swelling, weight-bearing and managing pain could be delivered with minimal additional healthcare professional resource.

Overall, this thesis challenges the dogma of weight-bearing restrictions and rehabilitation methods after ankle fracture surgery. It proposes methods for patients to self-manage their recovery, while highlighting some remaining barriers to implementation.

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Thank you to Caitlyn, for supporting me, for inspiring me and for your contagious kindness.

Declaration

I hereby certify that this thesis is the result of my own work except where otherwise indicated and due acknowledgement is given.

Permissions for the reproduction of figures used in this thesis are listed in Appendix G.3.

I certify that this thesis is 48,348 words long excluding the bibliography and appendices.

Impact of COVID-19

Fortunately, my thesis was not substantially impacted by the COVID-19 pandemic. Important limitations include:

- I returned to full-time clinical work in the NHS between April 2020 and July 2020 and was unable to work on my DPhil.
- The WAX trial paused recruitment between March 2022 and June 2020. This caused a delay beyond the 3-months of recruitment pause, as new sites in set-up faced further delays due to the prioritisation of COVID-19 studies by their research and development departments and a backlog thereafter.

This affected my DPhil in the following ways:

Chapter 2
I had to curtail plans for my systematic review and narrow the scope as discussed in Section 2.2.

Chapter 3

- 12-month follow-up data for OMAS and EQ-5D-5L were not available at the time of submission.
- Adverse events data were not available.
- Only the minimum data for all time points were available. This aligned with the statistician's workload and reduced the risk of unblinding me to treatment allocations in the WAX trial.
- Treatment allocations were not available to include in the exploratory analysis, nor was time to weight-bearing (risk of unblinding).

Chapters 4 and 5
I had initially planned to conduct some face-to-face interviews with patients and healthcare professionals. This changed to telephone or video-call only, and was a condition of my letter of access for most healthcare trusts included.

Chapters 6 and 7
I had planned to conduct three face to face workshops: one with patients, one with healthcare professionals and one with a mix. This was changed to a series of virtual workshops as described in the relevant chapters.

Abbreviations

β beta-coefficient

A&E Accident and Emergency department

ADLs activities of daily living

AI artificial intelligence

AIM Ankle Injury Management

AIR Ankle Injury Rehabilitation

APEASE Affordability, Practicability, Effectiveness/ Cost-effectiveness, Acceptability, Safety/ Side effects

App Application

BAME Black, Asian and Minority Ethnic

BCT Behaviour Change Technique

BCW Behaviour Change Wheel

BMI Body Mass Index

BOAST British Orthopaedic Association Standards for Trauma

BOFAS The British Orthopaedic Foot and Ankle Society

CBT Cognitive Behavioural Therapy

CDC Centre for Disease Control

CI confidence interval (95%)

COM-B Capability, Opportunities, Motivation-behaviour

COREQ Criteria for Reporting Qualitative Research

COVID-19 SARS-CoV-2

CRF case report form

CRN Clinical Research Network

CROSS Checklist for Reporting of Survey Studies

CRPS complex regional pain syndrome

DGH district general hospital

DOAC Direct Oral Anticoagulant

DVT Deep Vein Thrombosis

EQ VAS EQ visual analogue scale

EQ-5D-5L EuroQol 5 Dimensions 5L

EWB early weight-bearing (2 weeks post-op)

F2F face-to-face

GP General practitioner

GRADE Grading of Recommendations, Assessment, Development and Evaluation

GRAMMS Good Reporting of A Mixed Methods Study

HCP healthcare professional

HLCS Health Locus of Control Scale

IASP International Association for the Study of Pain

IQR interquartile range

LEFS Lower Extremity Functional Scale

LMWH Low Molecular Weight Heparin

mCCI modified Charlson comorbidity index

MRC Medical Research Council

MTC major trauma centre

NGT Nominal Group Technique

NHS National Health Service

NICE National Institute for Health and Care Excellence

NIHR National Institute for Health and Care Research

NWB non weight-bearing

OCTRU Oxford Clinical Trials Research Unit

OMAS Olerud and Molander Ankle Score

ORIF open reduction internal fixation

OUH Oxford University Hospitals Trust

P participant

PE Pulmonary Embolus

PI principal investigator

PIS participant information sheet

PPI patient and public involvement

PRIME Plans, Responses, Impulses, Motives and Evaluations

PRISMA Preferred Reporting Items for Systematic Reviews and Meta-analyses

PROM patient-reported outcome measure

PROMOTE Pain Management Intervention to Improve Recovery after Major Trauma

PROSPERO The International Prospective Register of Systematic Reviews

PSEQ-2 Pain self-efficacy questionnaire-2

R^2 coefficient of determination

RAAFT Rehabilitation After Ankle Fracture Treatment

RCT randomised controlled trial

REDCap Research Electronic Data Capture

RfPB Research for Patient Benefit

ROC receiver operating curve

RR risk ratio

S staff

SD standard deviation

SF-36 Short-Form 36

SIV site initiation visit

SMART Specific, Measurable, Achievable, Relevant and Time-bound

SMD Standardised Mean Difference

SOLO Search Oxford Libraries Online

STROBE Strengthening the reporting of observational studies in epidemiology

SWAT Study Within a Trial

TDF Theoretical Domains Framework

TiDier Template for intervention Description and replication

TSK-11 Tampa scale of kinesiophobia-11

UK United Kingdom

VTE Venous Thromboembolism

WAX Weight-bearing in Ankle Fractures

WB weight-bearing

WHO World Health Organisation

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CHAPTER 1

Introduction

1.1 Ankle fractures

1.1.1 Epidemiology

Each day approximately 180 patients sustain an ankle fracture in the United Kingdom (UK). This rate is predicted to rise, reflecting an ageing population [1]. There is a bimodal age distribution for these fractures, with one peak in young men sustaining high-energy sports and leisure injuries and another peak in older women sustaining fragility fractures after simple twists or falls [2].

1.1.2 Anatomy, classification and treatment

Ankle fractures are generally the result of rotational or twisting movements. There is an associated classification first proposed by Dr Lauge-Hansen, which has been part of orthopaedic education and treatment since the 1950s [3]. The rotational mechanism of ankle fractures differentiates them from intra-articular distal tibia fractures (Pilon fractures), which typically involve a higher energy transfer mechanism of injury with axial loading [4]. This distinction becomes important during the management and rehabilitation of these fractures.

An ankle fracture can involve three parts of the ankle: the fibular (lateral malleolus), the side of the tibia (medial malleolus) and the back of the tibia (posterior malleolus). All or just one of the malleoli can be broken and, depending on the fracture pattern, may or may not need surgery. More important than which parts are broken is whether the ankle is "stable" or "unstable". Definitions of ankle fracture stability vary, but the broadest meaning of stability is the ability to withstand physiological load without displacement [5]. In the ankle, a stable fracture is one where the talus remains under the tibia (See Figure 1.1).



Figure 1.1: Ankle anatomy

An unstable fracture is where the talus separates from the tibia, and the space between the medial malleolus and talus widens (medial clear space) [6], as indicated in Figure 1.2. Figure 1.3 shows an X-ray where the fibular has been fixed with plates

and screws, which has restored the ankle bones' alignment.



Figure 1.2: An ankle fracture with talar shift [6]



Figure 1.3: A surgically fixed ankle fracture [7]

About 40% of ankle fractures are unstable and require surgery to correct and then stabilise the alignment of the ankle bones [8]. An estimated 20,000 of these procedures are performed annually in the UK [8]. This represents a substantial burden with an average length of hospital stay of nine days and an associated mean NHS treatment cost of £4,491 per patient [9]. In patients aged over sixty years, this increases to a mean NHS cost of £6,648 and a mean societal cost of £7,684 per patient [10].

After ankle fracture surgery, the patient usually remains in a temporary plaster (backslab) to allow the swelling to settle and the wound to heal. After two weeks, the patient is then placed into a full plaster or provided with a removable orthotic boot for a further 4-6 weeks [8]. Recently, the Ankle Injury Rehabilitation (AIR) [11] randomised controlled trial (RCT) demonstrated no clinically significant difference

in outcomes between a plaster cast and a removable boot for ankle support in the two months post-ankle surgery. Therefore, decisions on postoperative ankle support can be undertaken as a shared decision-making process with patients based on their preferences. However, the qualitative component of the AIR study found that there was considerable uncertainty around weight-bearing in the postoperative period. This relates to variability in weight-bearing restrictions, difficulty adhering to instructions and the resulting loss of independence [12]. Weight-bearing remains the significant unanswered question around rehabilitation after ankle fracture surgery, discussed further in Section 1.2.

1.1.3 Outcomes

Immediate effects of an ankle fracture include pain, swelling and physical impairment. In the short term, patients experience a significant limitation in their function and activity and often become dependent on their social networks [13–15]. A systematic review from Beckenkamp et al. found that the mean patient-reported functional score on a 100-point scale was 31.9 one month after injury (best score = 100) [16]. This improved quickly in the months after surgery, reaching a mean of 78.3 at six months but plateaued after that, settling at 86.9 at 24 months post-injury. In patients over 60 years of age, the recovery is more modest, with a mean score of 79.4 three years after surgery [10].

While most patients can expect a recovery of 80-90% of their previous ankle function, there are many patients in whom pain and functional deficits persist, leading to prolonged work absence and, in the long-term, to post-traumatic arthritis and psychological consequences [13, 17]. In addition, just under a quarter (24%) will experience persistent pain affecting their daily life beyond 1-year post-injury [18].

It is unknown which patients are at risk of poor functional outcomes after ankle fracture surgery. Prospective studies and a systematic review have examined outcomes after ankle fracture. High Body Mass Index (BMI), diabetes, increasing age, female sex, poor pre-injury function and fracture severity have all been proposed as baseline predictors of negative outcomes [19–21]. However, there is a lack of agreement among studies, and a high-quality multicentre prospective study [21] was only able to account for 23-26% of the variability in patient-reported outcomes six months post-surgery, suggesting a need to study other patient, injury or treatment factors.

1.2 Weight-bearing after ankle fracture surgery

1.2.1 Current evidence and UK practice

The decision-making and operative strategies for unstable ankle fractures are well established and standardised [22]. Conversely, the best postoperative weight-bearing strategy after surgery is unknown [23]. Weight-bearing refers to the act of walking or putting bodyweight through an (injured) extremity or limb. Patients are often told to avoid walking on their affected leg for several weeks following surgery. Historically, this has been due to a fear that excessive loading could lead to a failure of the metal implants used to fix the ankle bones in place and that this could lead to revision surgery or early arthritis [24]. These weight-bearing restrictions have a significant impact on patients and healthcare services with increased social dependency and hospital stays [13–15]. The restrictions also prolong time off work with consequent personal and societal financial implications [13, 15, 25].

A 2012 Cochrane review reported on the evidence regarding rehabilitation strategies after ankle fracture, and in 2016 the National Institute for Health and Care Ex-

cellence (NICE) conducted a further review of postoperative weight-bearing; six and eight trials were identified respectively in these reviews [23, 26]. The reviews concluded that there is insufficient evidence to support or refute postoperative weight-bearing restrictions, and recommended determining the clinical and cost-effectiveness of weight-bearing strategies as a research priority. Since the publication of the Cochrane and NICE reviews, further trials investigating rehabilitation in ankle fractures have been conducted [27, 28]. These studies do not provide conclusive evidence for when to weight-bear post-operatively. I led a two-week prospective national audit of orthopaedic practice in 276 patients in 77 NHS hospitals, demonstrating that delayed weight-bearing is recommended to approximately 80% of patients postoperatively [8].

The WAX trial is a National Institute for Health and Care Research (NIHR) Research for Patient Benefit (RfPB) study that randomised patients to weight-bear early (at two weeks postoperatively) or wait till six weeks postoperatively, which is standard care [8, 29]. It aims to determine if early weight-bearing produces non-inferior functional outcomes to a delayed weight-bearing strategy and will also conduct a health economic analysis to determine the cost-effectiveness of the two weight-bearing strategies. The WAX trial has run parallel to my DPhil, commencing recruitment in December 2019 and finishing recruitment in October 2021, pausing due to the COVID-19 pandemic between March and June 2020. The WAX trial will be the largest, most robust clinical trial to examine the question of weight-bearing after ankle fracture surgery conducted globally to date. It is hoped that the WAX trial will provide high-quality evidence for when patients should begin walking after their surgery, but it will not provide evidence of what to tell patients regarding how to commence walking. The background to this second question is discussed in the

next section.

1.2.2 Patient experiences of non-weight-bearing and returning to weight-bearing

Recent qualitative studies have highlighted the burden for patients having to endure a period of non-weight-bearing [10, 12, 13]. For example, the Ankle Injury Management (AIM) trial compared close-contact-casting to operative fixation in patients over the age of 60 years with unstable ankle fractures and the AIR trial compared postoperative ankle immobilisation methods [10, 11]. They included a qualitative study of patients' experiences after ankle fracture. A common theme was struggling to cope during non-weight-bearing periods after surgery, with a marked loss of independence, sometimes avoiding showering or bathing altogether during their six-week non-weight-bearing period. Many patients struggled to adjust and found the experience to be a "nightmare" or "terrifying", saying, "I felt like a prisoner in my own home, I think for the first four weeks...". Often patients experienced pains in other areas of the body due to compensation and had fallen due to their inability to mobilise with walking aids safely.

Previous studies provide only brief insights into the commencement of weight-bearing. While patients often report difficulty with non-weight-bearing, how patients respond once advised to weight-bear is unknown [12]. Even if instructed to weight-bear, many patients are wary of pain, falls, and re-injury and avoid walking on their ankles for several weeks [13]. McPhail et al. conducted a qualitative study on the life impacts of ankle fracture [13]. The psychological effect of ankle fracture and uncertainty around commencing weight-bearing were common themes. Patients' comments about their ankle included: "I felt anxious about putting weight on it...even

after the doctor said I could" and "I was scared I was going to break it again." Interviews were mainly conducted beyond six months from injury with little exploration of the underlying beliefs and determinants of weight-bearing anxiety and behaviour.

We do not know how patients decide what is an acceptable level of discomfort when starting to weight-bear (whether this is undertaken early or late) or how they decide to stop using their postoperative splints or walking aids. There is little guidance for clinicians on advising patients and no rehabilitation package for patients themselves.

During my DPhil (Rehabilitation After Ankle Fracture Treatment (RAAFT)), I studied participants recruited to the WAX trial to investigate how patients can be supported to walk after their surgery (reported in Chapters 4 to 9).

1.2.3 Impetus for research

Weight-bearing after ankle fracture was ranked in the top five research priorities by the 2018 James Lind Alliance Priority Setting Partnership [30]. "What is most important to adults in their recovery" and "What information about recovery and in what form should be provided to patients" were also among the top ten priorities for lower limb fragility fracture research. These were shared priorities with a 50:50 split between healthcare professionals and patients and their carers, from a total of 365 respondents. This highlighted the need to investigate patients' perceptions, expectations and experiences after ankle fracture. My DPhil explored these questions and seeked to provide a blueprint for future rehabilitation materials for patients recovering from ankle fractures.

1.3 Pain beliefs

1.3.1 What are pain beliefs?

A vast array of scores and factors have been used to describe and quantify specific phenomena and experiences related to pain. These include pain catastrophising (exaggerating the seriousness of pain sensations [31]), kinesphobia (fear of movement [32]) and low pain self-efficacy (the inability to overcome problems and accomplish tasks whilst in pain [33]). These factors are highly correlated [34, 35] and in this thesis, I refer to "pain beliefs" as an encompassing term. The essence is that they describe states in which patients perceive pain in an unhelpful manner. That is, not as an evolutionary response to avoiding ongoing tissue damage. Fear of post-traumatic pain is instinctual, yet the fear of movement can lead to biological consequences of muscle wasting, joint contraction and osteopenia [23]. This cycle may lead to chronic pain, impairment and arthritis [23].

1.3.2 The scale of the problem after trauma

It is estimated that 20-25% of patients sustaining a fracture will suffer from depression, post-traumatic stress disorder or develop unhelpful pain beliefs [36, 37]. Psychological factors including pain catastrophising, fear of movement and re-injury, and pain self-efficacy have been used to study adverse pain beliefs in relation to musculoskeletal injury [34–36]. However, their impact has not yet been investigated in patients with lower limb fractures.

If unhelpful pain beliefs are prevalent, then targeting patients with these beliefs could be more clinically and cost-effective than spreading resources across an

entire population of patients recovering from ankle fracture surgery. A preliminary randomised controlled trial by Vranceanu et al. demonstrated the feasibility, acceptability and potential efficacy of cognitive-behavioural strategies in reducing pain and disability in patients with unhelpful pain beliefs [38]. Furthermore, the Pain Management Intervention to Improve Recovery after Major Trauma (PROMOTE) study is looking at the feasibility of using a psychological self-management intervention to help people manage pain after a major lower limb injury [39].

1.4 Behaviour change theory

1.4.1 Why we need theory

Understanding what influences weight-bearing may help facilitate it.

An intervention to encourage weight-bearing would be considered a "complex intervention" [40]. This is because techniques to change weight-bearing behaviour would include several interacting components, which may be related to those delivering (healthcare professionals) and those receiving the intervention (patients) [40].

1.4.2 Why use behaviour change theory?

There are many models used for seeking to understand disability, outcomes and self-management after injury [41, 42]. My DPhil proposed to design an intervention for recovery after ankle fracture surgery; accordingly, my chosen model aligns with processes that facilitate this: O'Cathain et al. provide guidance on designing complex interventions in healthcare [43]. The guidance was compiled through triangulation of evidence from a systematic review, qualitative interviews and an e-Delphi

study. Figure 1.4 provides a summary of the design process recommendations. Key considerations are ensuring the process is dynamic, iterative and considers how an intervention could be evaluated once implemented. Stakeholder engagement, evidence review and the use of suitable theory are further tenants of development.

This thesis focused only on the development, rather than evaluation of the intervention. Figure 1.5 lists an overview of approaches to intervention development. O'Cathain et al. acknowledge that there is a lack of evidence to support one strategy over another and encourages flexibility in design. For RAAFT, I used a combination of "2. Target-population centred" and "3. Theory and evidence based" approaches (see Figure 1.5). As the RAAFT intervention seeks to modify behaviour (and encourage weight-bearing after ankle fracture surgery), behaviour change theory is the theoretical framework which underpins the intervention design.

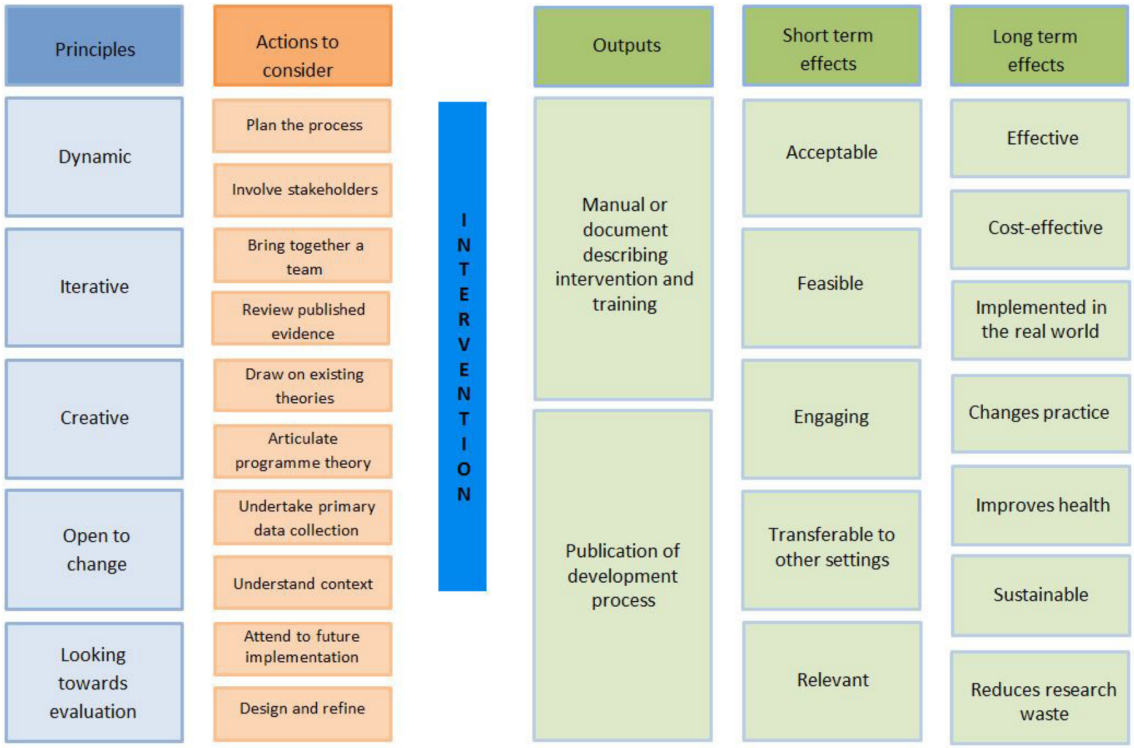


Figure 1.4: Logic model for intervention development [43]

Category	Definition	Examples of approaches*
1. Partnership	The people whom the intervention aims to help are involved in decision-making about the intervention throughout the development process, having at least equal decision-making powers with members of the research team.	Coproduction, cocreation, codesign; user driven; experience-based codesign; community-based participatory research
2. Target population centred	Interventions are based on the views and actions of the people who will use the intervention.	Person based; user centred; human-centred design
3. Theory and evidence based	Interventions are based on combining published research evidence and existing theories for example, psychological or organisational theories.	Medical Research Council Framework for developing and evaluating complex interventions; Behaviour Change Wheel; Intervention Mapping; Normalisation Process Theory; Theoretical Domains Framework
4. Implementation based	Interventions are developed with attention to ensuring the intervention will be used in the real world if found to be effective at the evaluation phase.	Reach, Effectiveness, Adoption, Implementation, Maintenance
5. Efficiency based	Components of an intervention are tested using experimental designs to determine active components and make interventions more efficient.	Multiphase Optimization Strategy
6. Stepped or phased	Interventions are developed through emphasis on a systematic and sequential set of processes involved in intervention development.	Six essential Steps for Quality Intervention Development; Five actions model; Obesity Related Behavioral Intervention Trials
7. Intervention specific	An intervention development approach is constructed for a specific type of intervention.	Digital (eg, Integrate, Design, Assess and Share); patient decision support aids
8. Combination	Published approaches to intervention development are combined.	Participatory Action Research based on theories of Behaviour Change and Persuasive Technology
9. Pragmatic	Developers use a self-selected set of actions.	Sometimes framed as mixed methods or formative evaluation

Figure 1.5: Different approaches to intervention development [43]

The Behaviour Change Wheel (BCW) is a model which builds on behaviour change theory; an extensive framework for understanding interventions in healthcare and describes a process for intervention design, summarised in Figure 1.6 [44]. The process begins with identifying a behavioural problem requiring modification and provides step-by-step guidance through evidence review, data generation and intervention selection and implementation. The BCW already has an extensive framework for understanding interventions in healthcare [44–46]. One of its strengths is that it is also compatible with various additional frameworks such as the Theoretical Domains Framework (TDF) and the PRIME theory of motivation [47, 48]. Incorpor-

ating TDF enables further granularity when breaking down behavioural influences into their component parts and later synthesising intervention functions to modify them [45]. Another advantage is that the BCW has been used to design and evaluate similarly complex rehabilitation interventions in chronic musculoskeletal conditions [46]. This framework allows the linkage of determinants of behaviour (e.g. pain beliefs or resource availability) to behaviour change techniques, which can be used to develop an intervention [44].

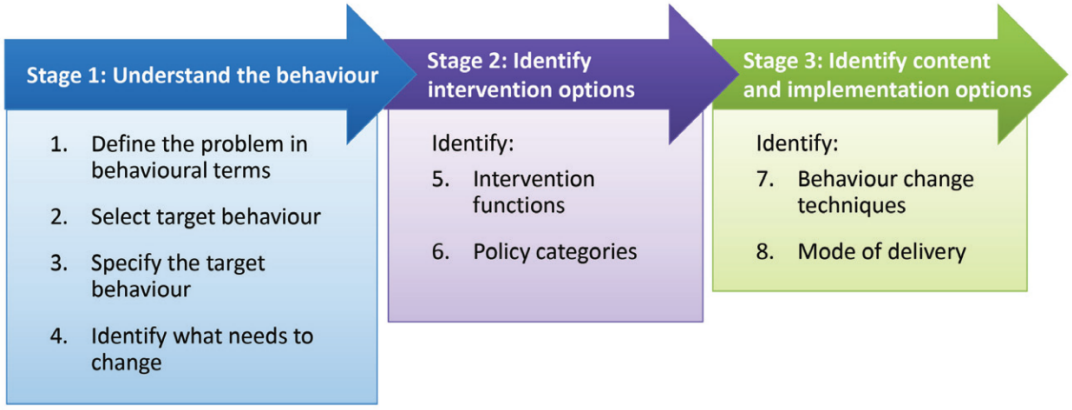


Figure 1.6: Behaviour change intervention design process [44]

The BCW method uses the Capability, Opportunities, Motivation-behaviour (COM-B) model of behaviour to understand and define behavioural problems (see Figure 1.7). The BCW is slightly deficient in considering patients' functional impairment and life roles, so I ensured these components were addressed during intervention development. Figure 1.8 shows how the BCW and COM-B model can be linked with relevant intervention functions and policy options.

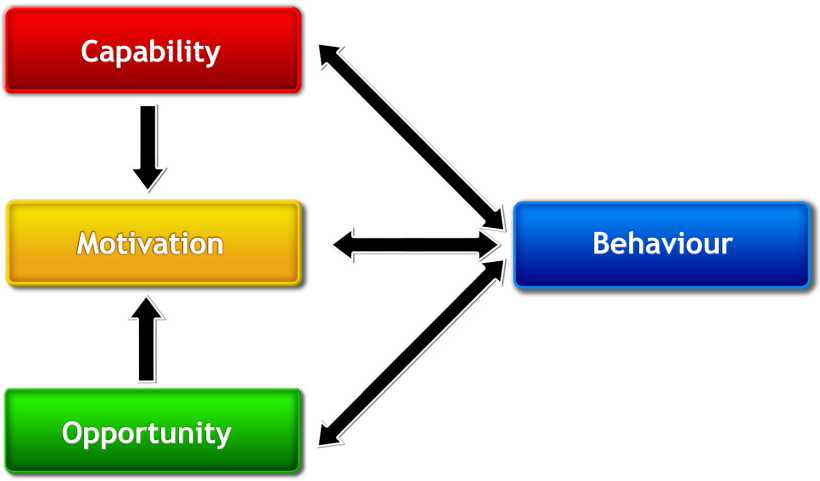


Figure 1.7: The COM-B system - a framework for understanding behaviour [44]

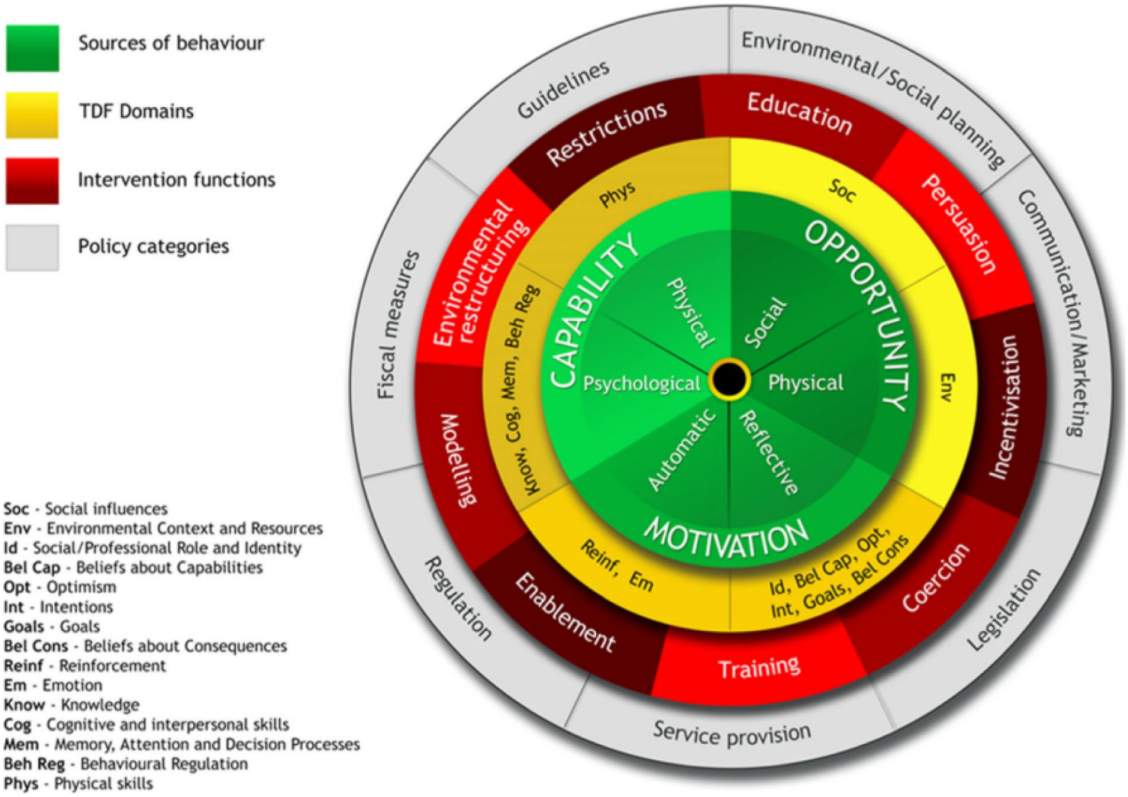


Figure 1.8: The Behaviour Change Wheel (BCW) [44, 49]

1.4.3 Summary

Ankle fractures are common, and the best postoperative weight-bearing strategy is unknown [23]. The WAX trial aims to determine when patients should start walking after surgery [29]. My DPhil thesis, RAAFT, builds on the WAX trial to investigate how patients can be supported to walk after their surgery.

We know patients find limiting their walking distressing [10, 12]. Conversely, some patients are wary of pain and fearful of causing damage when starting to walk on their ankle [13]. There is little research or advice to help them. My thesis developed this guidance for patients and healthcare professionals following the processes described by the Behaviour Change Wheel (BCW), which has been used to design a range of complex interventions in healthcare [44].

RAAFT explored the distribution of unhelpful pain beliefs in the ankle fracture population and investigated how they influence patients' functional outcomes. This will inform the design of future studies to direct resources to those in greatest need and potentially target pain in the acute phase before it becomes chronic and disabling.

1.5 Goals and objectives

1.5.1 Overarching goals

To understand how patients' experience of pain affects their functional recovery after ankle fracture surgery and co-design a rehabilitation package to facilitate weight-bearing.

1.5.2 Objectives

1. To determine existing published evidence about the effectiveness of rehabilitation interventions for patients with ankle fractures and what behaviour change techniques they are based on.

2. To investigate the distribution of unhelpful pain beliefs after ankle fracture surgery and their influence on functional recovery.

3. To explore patient experiences of commencing weight-bearing as well as general priorities for recovery after surgery for an ankle fracture.

4. To explore healthcare professionals' weight-bearing practice, including behavioural influences and priorities for improving rehabilitation after ankle fracture surgery.

5. To co-design a rehabilitation package to facilitate safe weight-bearing after ankle fracture surgery based on the Behaviour Change Wheel, informed by objectives 1 to 4.

1.6 Patient and public involvement

Two RAAFT patient representatives have helped design and pilot sections of my DPhil, in particular, Chapters 3 to 8. Both are experienced patient and public involvement (PPI) representatives. One is a white male with experience of lower limb fracture surgery (and has experienced periods of restricted weight-bearing), and the other is an Asian male who is a family carer for a disabled relative. Initially, it was planned they would not just help design the research but would undertake meth-

odological training and conduct the research, including qualitative interviews and analysis. Unfortunately, I was unable to secure funding for this but was pleased they were able to help facilitate the workshops described in Chapters 6 and 7. Their input throughout RAAFT was invaluable and is described further in the relevant chapters.

CHAPTER 2

A systematic review of the effectiveness of behaviour change techniques in rehabilitation interventions to improve functional recovery after ankle fracture

2.1 Introduction

The World Health Organisation (WHO) defines rehabilitation as "a set of measures that assist individuals who experience, or are likely to experience, disability to achieve and maintain optimal functioning in interaction with their environments" [50]. Rehabilitation for ankle fractures has focused chiefly on comparing devices, weight-bearing strategies and manual or exercise therapies [23]. In other words, therapies given or done to patients rather than with patients. A Cochrane review has found no evidence to support many of these interventions [23]. Yet, outcomes after ankle fracture vary widely, with a standard deviation (SD) of 20-25 for the patient-reported Olerud and Molander Ankle Score (OMAS) post-injury [10, 11, 23]. This equates to the difference between a patient having no pain in their ankle compared

to having constant and severe pain [51]. There is a growing acknowledgement that promoting self-management and adherence to physiotherapy interventions may improve and narrow the outcomes gap [52–54]. The central issue is that many perceive that physiotherapy treatment only occurs during the physiotherapy clinic; encouraging patients to engage and continue physiotherapy regularly at home remains a challenge [54].

Behaviour change theory has grown in popularity and is beginning to show efficacy in treating musculoskeletal conditions [46, 55, 56]. It has improved mobility and exercise adherence in patients with musculoskeletal disorders, but it has not been found to improve patient-reported outcomes. There has been limited investigation of behaviour change techniques in traumatic injury rehabilitation and none looking at ankle fracture recovery [57].

It is not only the aspiration of improved patient outcomes than has increased the use of behaviour change theory in healthcare interventions: The Medical Research Council (MRC) recommends using a theory-based approach for understanding and designing interventions [40]. The MRC recommends theoretical deconstruction of interventions into components to enable agreed variation in delivery across different contexts. Additionally, deconstruction assists in identifying mechanisms of behaviour change within interventions. Where a complex intervention is likely to involve multiple components, a theory-based approach allows deconstruction and evaluation of the effectiveness of the intervention. This subsequently aids faithful replication of the key elements of the intervention for future use [58]. However, it is unclear to what extent this approach is currently used to design rehabilitation treatments for patients recovering from fractures.

2.1.1 Objectives

1. To determine which behaviour change techniques (BCTs) have been most commonly used in studies comparing rehabilitation interventions after ankle fracture and determine which theories they are based on.

2. To determine which BCTs are most effective in improving patient-reported outcomes after ankle fracture.

2.2 Methods

Protocol and registration

A protocol for this systematic review was submitted to The International Prospective Register of Systematic Reviews (PROSPERO) on the 18th of March 2020 and was registered on the 9th of June 2020 (PROSPERO: CRD42020170462) [59]. Results were reported according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) checklist [60].

2.2.1 Eligibility criteria

Types of studies

Included:

- Prospective RCTs, including pilot studies.

Excluded:

- Non-randomised or quasi-randomised studies.

- Protocols or feasibility studies not reporting outcomes by treatment group.

- Observational studies with or without control groups.
- Cross-sectional studies.
- Case series and case reports.
- Abstracts, commentaries and expert opinion studies.

The review was limited to randomised studies because an evaluation of effectiveness was one of the review's objectives. It was anticipated that observational studies, even with controls, may compare a new intervention to historical or usual care, which may have contained BCTs not reported in the intervention description, leading to a dilution of effects. While it was anticipated there may be a lack of RCTs based on behavioural theory which explicitly listed BCTs in their intervention description, a review of the interventions to identify and code BCTs was planned.

Participants and population

Included participants were adults (aged 18 years and over) who sustained a fracture of the ankle or hindfoot treated operatively or non-operatively. The initial systematic review protocol registered on PROSPERO included all lower limb fractures, and the search strategy reflects this. However, a caveat was included, specifying that if an overwhelming number of studies were identified, the scope would be narrowed to include only ankle fractures. This was the case, and most studies focused on hip fracture care. Patients sustaining hip fractures are a different population, and even patients aged over 60 years are on average frailer than age-matched patients sustaining ankle fractures [61]. This frailty significantly impacts clinical outcomes, complications, and treatment priorities, in which survival is prioritised over joint-

specific functional outcomes [62]. Moreover, anxiety around weight-bearing and joint movement is less marked in hip fractures compared to ankle fractures [61].

The rehabilitative challenges related to weight-bearing anxiety were the reason the scope was limited to ankle and hindfoot fractures (or fractures in bony segments that articulate with the talus). Richardson et al. [61] found that the closer the injured segment was to the floor, the more weight-bearing restrictions patients faced, with 89% of ankle fracture patients compared to 4% of hip fracture patients receiving weight-bearing restrictions postoperatively. However, mid and forefoot fractures were not included in the scope because these patients are rarely given weight-bearing restrictions after injury [63]. Where studies included a mixture of lower-limb fractures, studies were eligible if the population consisted of >50% ankle or hindfoot fractures.

Operative and non-operatively managed fractures were included because although there is a trend to allow non-operatively managed patients to commence weight-bearing immediately after injury, some restrictions are still prescribed, and patients face similar anxieties and life impacts [8, 13].

Intervention(s)

The interventions were any rehabilitation method using BCTs to improve patient-reported functional outcomes after ankle fracture. The BCTs could target a range of behaviours as mediators for improving function, for example, promoting adherence to physical exercise or reducing catastrophising thoughts. Only BCTs that provided sufficient detail of the components to allow them to be identified from the BCT taxonomy were included [64]. Interventions had to encourage active engagement for patients to continue the behaviour and not rely on the continued physical presence

of a trainer or healthcare professional. The continued presence of peers or family support was permitted.

Comparator(s)/control

Studies comparing different rehabilitation regimes against each other or against "usual care" were included. The control group could include BCTs, but the intervention group needed to incorporate additional BCTs.

Main outcome(s)

The primary outcome was patient reported outcome measures (PROMs) of ankle or lower limb function. The secondary outcomes were quality of life and adverse events.

Information sources and searches

Medline, EMBASE, CINAHL, PsycINFO, AMED, CENTRAL, PEDRO and clinicaltrials.gov were searched from inception, using a search strategy developed with an information specialist. Searches were conducted on May 18th 2020 and repeated on April 8th 2022. The Medline search strategy is included in Appendix A.1 and was modified for the other databases under the direction of the information specialist. Reference lists of included studies were searched. Unpublished and grey literature were not searched due to the reporting detail required to accurately code BCTs, as discussed in Section 2.2.1.

Study selection

All titles and abstracts were imported to a reference manager database, and duplicates were removed. The remaining titles and abstracts were uploaded to Rayyan,

[65] and further duplicates were manually screened and removed. Two reviewers independently screened the titles and abstracts against the inclusion criteria, scoring studies as "include", "exclude", or "maybe". All studies scored as "include" by either reviewer went forward for full-text review, and those scored as "maybe" were resolved by discussion. A third reviewer adjudicated any disagreement.

Data extraction

Full texts were sought through multiple sources, including OVID, PubMed, Search Oxford Libraries Online (SOLO), Library Hub Discover and WorldCat. Full-text articles were reviewed against the inclusion criteria. The intervention descriptions were reviewed according to and after completion of the BCT taxonomy training package [66]. Supplementary materials, protocols and intervention development papers were reviewed to look for underpinning behavioural theory and intervention descriptions for BCT coding. Data were extracted using a bespoke form for studies meeting the inclusion criteria. Authors were contacted via email to obtain missing data.

Risk of bias assessment

The risk of bias was assessed using the Cochrane risk of bias tool [67]. This included assessment of: (1) sequence generation, (2) concealment of allocation, (3) blinding, (4) incomplete outcome data, (5) selective reporting, and (6) other sources [67].

2.2.2 Analysis

Synthesis

The review focused on describing the range of BCTs used and their effectiveness. Studies were summarised according to fracture location, management (operative

vs non-operative treatment) and additional, non BCT interventions (e.g. immobilisation or weight-bearing restrictions). Studies were grouped based on the BCTs employed (according to the BCT taxonomy [64]) and where possible, their underlying behavioural theory.

Summary measures and meta-analysis

Characteristics of studies were summarised as counts and percentages for categorical data and means and SDs for continuous data. The Standardised Mean Difference (SMD) for included studies with available effect sizes and SDs were calculated and pooled using a random-effects model. Heterogeneity was investigated using I^2, with an I^2 of equal to or under 75% used as the cut-off for proceeding with meta-analysis [68]. Meta-analyses were undertaken using RevMan v.5.4 (Cochrane Collaboration, Vienna, Austria) and reported following PRISMA guidance.

Certainty of evidence

The certainty of the evidence assessment was undertaken using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach and summarised using GRADEpro GDT Software [69, 70].

Additional analyses

A pre-planned sensitivity analysis included only studies at low risk of bias for the primary outcome. A further post-hoc sensitivity analysis was conducted to examine the risk of adverse events in operatively treated ankle fractures only. This analysis was driven by two factors: 1) There has been a reported increased risk of wound healing complications in operatively treated ankle fractures treated with

early-weight-bearing or a removable splint (instead of a plaster), but the studies were not sufficiently powered to detect a significant difference in complication rates [23, 24]. 2) During analysis, the rates of reported adverse events between studies varied widely, leading to further investigation of the types of events reported in each study. One study, with a disproportionately high complication rate reported relatively minor events (e.g. numbness) which were not reported in other studies, and might be considered an expected consequence of injury or treatment [11]. Therefore, a separate analysis including only operatively treated ankle fractures was conducted to mitigate the potential over-reporting of minor events.

2.3 Results

2.3.1 Study selection

The search results returned 32,759 items, with 19,517 remaining after removing duplicates. After the abstract screening, 154 full-text articles were sought. Sixteen full-text articles were unavailable; in all cases, the items were titles only and may have been excluded earlier in the searches if abstracts were available for review. Fifteen of the 16 unavailable items were published in non-English-language journals, and 14 of the 16 were published pre-1990. After exclusion criteria, nine studies remained and were included in the final review. Figure 2.1 shows a PRISMA flow diagram detailing the selection process, including reasons for exclusion at full-text review.

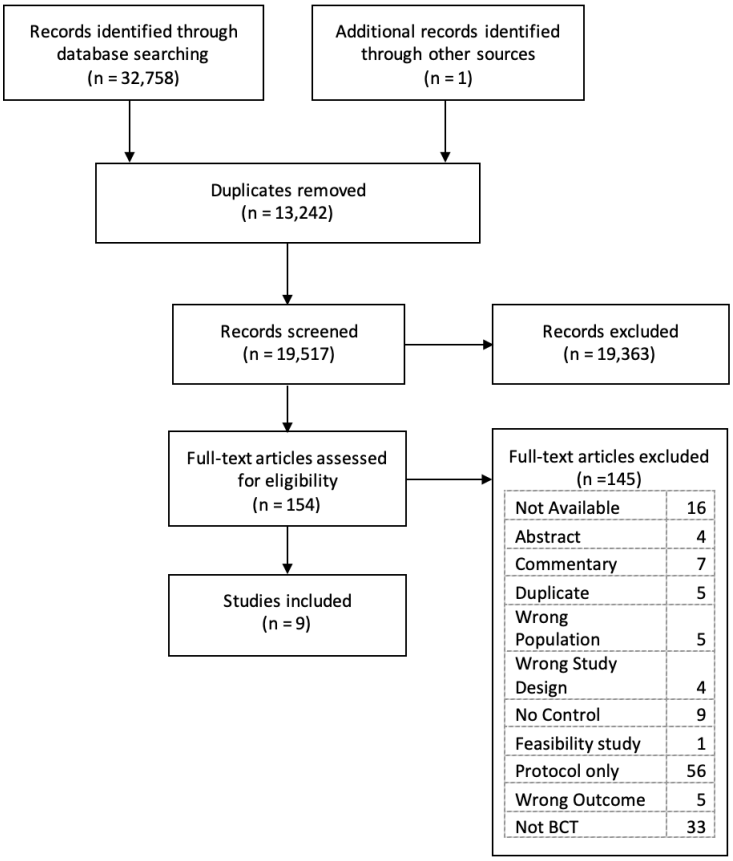


Figure 2.1: PRISMA flow diagram of study selection

2.3.2 Included studies and characteristics

Population and setting

Nine studies were included, which enrolled a total of 1,437 patients. Two took place in Australia [71, 72], two in Canada [73, 74], two in Sweden [75, 76], two in the UK [11, 77], and one in the Republic of Ireland [78]. Six studies focused only on operatively treated ankle fractures [73–78] and three on non-operatively and operatively treated ankle fractures [11, 71, 72]. No studies of hindfoot fractures met the inclusion criteria.

Behavioural theory and interventions

No studies referenced behavioural theory in their intervention design or description. Instead, BCTs were coded from the published articles and protocols as described in Section 2.2. The target behaviour in eight of the studies was ankle exercises [11, 72–78]. In addition to the BCTs used, five studies had additional, non-BCT interventions. In four studies, the intervention group received some form of removable splint, and the control group were immobilised in a plaster cast [11, 76–78]. In one study, the intervention group was permitted early weight-bearing in a removable splint and the control group had their weight-bearing restricted in a plaster cast [73].

Eight studies compared one intervention group to one control group [11, 72–78]. One study, Moseley 2005 [71], consisted of three groups: an exercise-only group, a short-duration stretch group (six minutes per day) and a long-duration stretch group (30 minutes per day). For the meta-analyses, just the long stretch group was compared to the control group due to data availability.

A summary of study characteristics is provided in Table 2.2.

Behaviour change techniques

A total of 34 BCTs were coded throughout the nine included studies, which included eight unique behaviour change techniques. Table 2.1 shows the most commonly coded BCTs, with percentages corresponding to the proportion of all studies using the stated BCT. Two studies [11, 77] used "1.1 goal setting (behaviour)" and "4.1 instruction on how to perform a behaviour", two studies [73, 78] combined these with "9.1 credible source". One study [74] combined "1.1 goal setting (behaviour)", "4.1 instruction on how to perform a behaviour" with "5.1 information about health

consequences". One study [76] used "4.1 instruction on how to perform a behaviour" alone.

In studies Dehghan 2016 [73], Dogra 1999 [77], Kearney 2021 [11], Mayich 2013 [74], Tropp 1995 [76], Vioreanu 2007 [78] "4.1 instruction on how to perform a behaviour" was coded as the intervention referred to a verbal or written instruction to perform ankle exercises. Dehghan 2016 [73], Dogra 1999 [77], Kearney 2021 [11] and Vioreanu 2007 [78] combined this instruction with a specific, numeric daily exercise repetition goal and thus, "1.1 goal setting (behaviour)" was coded in addition. Dehghan 2016 [73] and Vioreanu 2007 [78] reported that these instructions and goals were prescribed and delivered by a dedicated physiotherapist and so "9.1 credible source" was coded. Mayich 2013 [74] provided a leaflet which in addition to exercises, also included educational advice coded as "5.1 information about health consequences" as it emphasised the importance of activity to progress recovery and reduce the risk of blood clots.

In the remaining three studies, a wider range of BCTs were coded. Moseley 2005 [71] and Moselely 2015 [72] compared treatment groups in which the intervention and control groups contained BCTs: in both studies, treatment began after the removal of the cast. In Moselely 2015 [72], the target behaviour was performing ankle exercises. The control group received an exercise and advice leaflet provided by a physiotherapist in fracture clinic; accordingly, the BCTs coded were "1.1 goal setting (behaviour)", "4.1 instruction on how to perform a behaviour", and "9.1 credible source". The intervention group received the same advice leaflet and in addition undertook a supervised physiotherapy programme. The additional BCTs coded in the intervention group were "8.1 behavioural practise/ rehearsal" (practising the exercises at outpatient physiotherapy sessions), "8.6 generalisation of target behaviour"

(encouragement to perform the same exercises at home) and "8.7 graded tasks" (individualised exercise progression based on progress).

In Moseley 2005 [71], the target behaviour was passive ankle stretching, so while the control group received BCTs to encourage ankle exercises, they were not coded in relation to the target behaviour. Similar to Moseley 2015 [72], the coded BCTs included "1.1 goal setting (behaviour)", "4.1 instruction on how to perform a behaviour", "8.1 behavioural practise/ rehearsal", "8.6 generalisation of target behaviour", "8.7 graded tasks" and "9.1 credible source". While the patients were provided exercise diaries, these were used by the study team to analyse compliance rather than to influence patient behaviour, hence this was not coded as a BCT as per the taxonomy guidance [64].

In Nilsson 2009 [75], the target behaviour was performing ankle exercises after the removal of the plaster cast. Similar to the studies above, a physiotherapist-led training programme led to coding the BCTs "1.1 goal setting (behaviour)", "4.1 instruction on how to perform a behaviour", "8.1 behavioural practise/ rehearsal", "8.6 generalisation of target behaviour", "8.7 graded tasks" and "9.1 credible source". Additionally, the BCT "1.2 goal setting (outcome)" was coded, because, in addition to behavioural goals, specific functional outcome goals were encouraged (e.g. range of motion targets and the ability to perform one-legged heel raises). Finally, "5.1 information about health consequences" was coded as they emphasised the rationale and benefits of performing the exercises.

Table 2.1: Summary of coded behaviour change techniques in included studies

Behaviour Change Technique (BCT)	**N (%[1])**
4.1 Instruction on how to perform a behaviour [11, 71–78]	9 (100%)
1.1 Goal setting (behaviour) [11, 71–75, 77, 78]	8 (89%)
9.1 Credible source [71–73, 75, 78]	5 (56%)
8.1 Behavioural practise/ rehearsal [71, 72, 75]	3 (33%)
8.6 Generalisation of target behaviour [71, 72, 75]	3 (33%)
8.7 Graded tasks [71, 72, 75]	3 (33%)
5.1 Information about health consequences [74, 75]	2 (22%)
1.2 Goal setting (outcome) [75]	1 (11%)

[1] % of all included studies using this BCT: they are not mutually exclusive

2.3.3 Risk of bias

A summary risk of bias table for all nine included studies is provided in Figure 2.2

Random sequence generation and allocation

Kearney 2021 [11], Moseley 2005 [71] and Moseley 2015 [72] were judged at low risk of bias as they described an independent process for random sequence generation and used a web service, opaque sealed envelopes and a telephone service, respectively for allocation. Mayich 2013 [74] and Vioreanu 2007 [78] used the odd/ even hospital number and date of birth method respectively for allocation, and so were judged as high risk of bias. Dehghan 2016 [73] and Dogra 1999 [77] used opaque, sealed envelopes and so were judged at low risk of allocation bias but did not describe the sequence generation process and were deemed as unclear risk. Nilsson 2009 [75] described only "sealed" envelopes for allocation and Tropp 1997 [76] did not provide

any details, so both were judged as unclear risk of bias for sequence generation and allocation.

Blinding

All studies were judged as low risk of bias for blinding of participants and personnel because it was judged that the interventions (exercises and stretching) were unable to be blinded. Dogra 1996 [77], Kearney 2021 [11], Moseley 2005 [71], Moseley 2015 [72] and Nilsson 2009 [79] were deemed at low risk of detection bias as the outcome assessors were blinded and independent of the clinical and research delivery team. Vioreanua 2007 [78] stated that "one of the authors" assessed clinical outcomes, so this was judged to be at high risk of bias. Dehghan 1996 [73], Dogra 1999 [77] and Tropp 2007 [76] did not state who assessed outcomes and were deemed as unclear risk.

Outcome data and reporting

Tropp 1997 [76] and Viorena 2007 [78] did not clearly report the completeness of outcome data and so were judged as unclear risk of bias. Dehghan 2016 [73], Dogra 1999 [77], Mayich 2013 [74], Moseley 2005 [71] and Nilsson 2009 [75] had similar rates of dropout between groups and >85% follow-up rates and so were judged as low risk of bias for outcome data.

Moseley 2015 [72] had a 23% dropout in the control group and a 15% dropout in the intervention group. Kearney 2021 [11] had a 27% and 22% dropout in the control and intervention groups, respectively. However, both studies followed pre-planned methods, including multiple imputation to account for missing data and so were judged as low risk of bias for outcome reporting. The analysis plan for Moseley

2015 [72] and Kearney 2021 [11] matched their pre-published protocol and so were judged as low risk of selective reporting. The remaining studies did not publish a protocol and so were judged as unclear risk of selective reporting.

Other sources of bias

Kearney 2021 [11], Moseley 2005 [71] and Moseley 2015 [72] were judged as low risk as no other important sources of bias were identified. While Nilsson 2009 [75] had uncertainty around the randomisation process, there was adequate detail in the methods and reporting to judge the study as low risk of other sources of bias. The remaining studies were judged as unclear risk as there was limited reporting of baseline characteristics and outcomes to enable assessment.

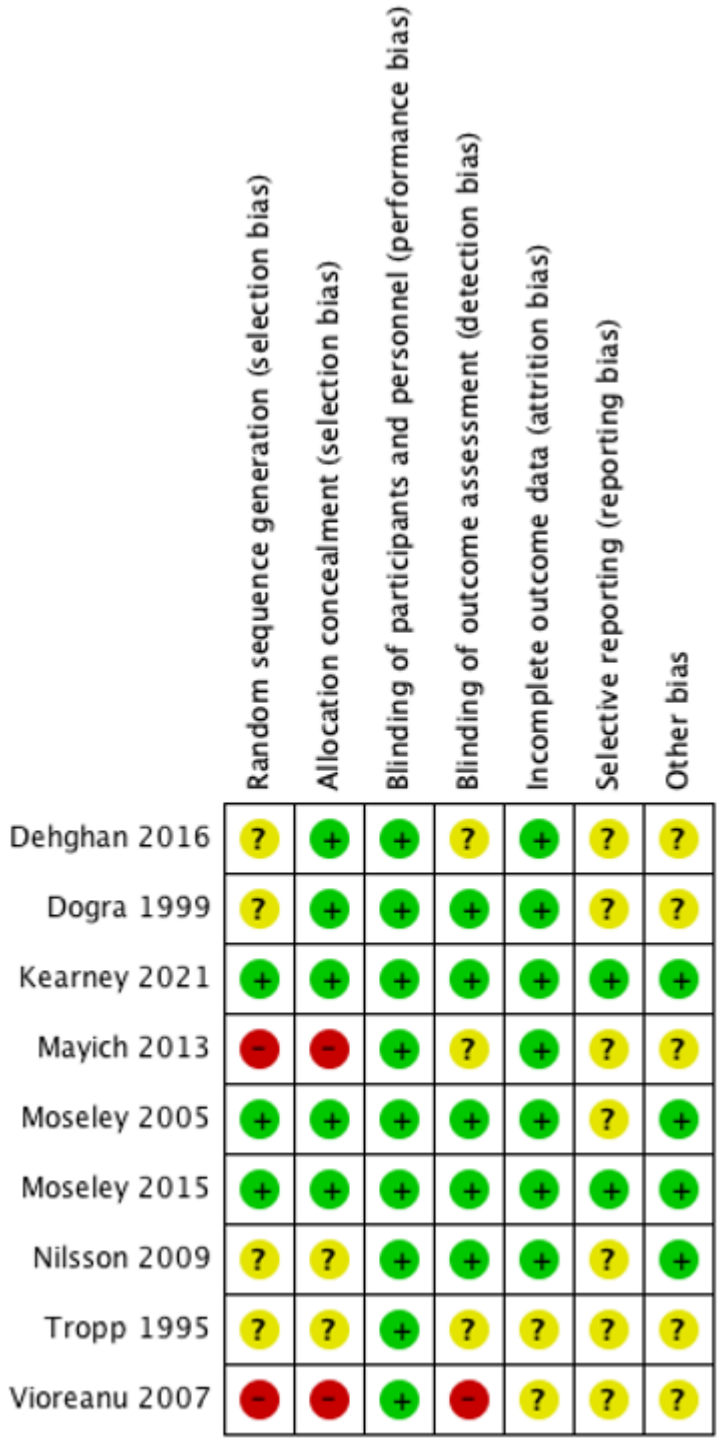


Figure 2.2: Risk of bias summary

Table 2.2: Summary of included studies

Study/ setting	Population	Target behaviour and time frame	Behaviour change techniques (BCTs)	Additional non-BCT intervention	PROM/ effect size
Dehghan 2016 Canada RCT	Operatively treated ankle fractures. Participants: ‡I: 56, †C: 54. Mean age: ‡I: 42.1 years, †C: 41.5 years.	Ankle exercises. 2-6 weeks post-operatively. Physiotherapist delivered.	‡I: 1.1 goal setting (behaviour), 4.1 instruction on how to perform a behaviour, 9.1 credible source. †C: nil.	‡I: Splint, EWB. †C: Plaster, DWB.	OMAS at 3 months. ‡I: 62 (SD 22). †C: 56 (SD 21). Effective: No. Mean diff: Not reported.
Dogra 1999 UK RCT	Operatively treated ankle fractures. Participants: ‡I: 26, †C: 26. Mean age: 42.7 years.	Ankle range of motion exercises. From 24 hours postoperatively.	‡I: 1.1 goal setting (behaviour), 4.1 instruction on how to perform a behaviour. †C: nil.	‡I: Removable plaster. †C: Plaster.	OMAS at 3 months. ‡I: 46.2 (SD not reported). †C: 43.4 (SD not reported). Effective: No. Mean diff: Not reported.
Kearney 2021 UK RCT	Operatively and Non-operatively treated ankle fractures. Participants: ‡I: 335, †C: 334. Mean age: 46 years	Ankle exercises. First 6 weeks post-injury or surgery, for a minimum of 3 weeks. Educational handout.	‡I: 1.1 goal setting (behaviour), 4.1 instruction on how to perform a behaviour. †C: nil.	‡I: Removable brace. †C Plaster.	OMAS at 16 weeks. ‡I: 64.5 (SD 22.4). †C: 62.4 (SD 23.4). Effective: No. Mean diff: 2.1 (CI -1.9 to 6.2).
Mayich 2013 Canada RCT	Operatively treated ankle fractures. Participants: ‡I: 20, †C: 20. Mean age: ‡I: 39.9 years, †C: 34.8 years.	Educational handout and physiotherapy exercises. 2-6 weeks postoperatively. Physiotherapist delivered.	‡I: 1.1 goal setting (behaviour), 4.1 instruction on how to perform a behaviour, 5.1 information about health consequences. †C: nil.	N/A	OMAS at 3 months. ‡I: Not reported. †C: Not reported. Effective: No. Mean diff: Not reported.
Moseley 2005 Australia RCT	Operatively and Non-operatively treated ankle fractures. Participants: ‡I short: 49, ‡I long: 51, †C: 50. Mean age: ‡I short: 43 years, ‡I long: 47 years, †Cl: 49 years.	Supervised manual stretching program. After removal of plaster cast. Physiotherapist delivered.	‡I: 1.1 goal setting (behaviour), 4.1 instruction on how to perform a behaviour, 8.1 behavioural practise/ rehearsal, 8.6 generalisation of target behaviour, 8.7 graded tasks, 9.1 credible source. †C: The same BCTs were used for ankle exercises, but nil for stretching.	N/A	LEFS at 3 months. ‡I short: 67.4 (SD 11.1). ‡I long: 65.8 (SD 12.9). †C: 65.8 (SD 13.6). ‡I long vs †C: Effective: No. Mean diff: 0.9 (CI -4.7 to 6.6).
Moseley 2015 Australia RCT	Operatively and Non-operatively treated ankle fractures. Participants: ‡I: 106, †C: 108. Mean age: ‡I: 43.0 years, †C: 41.3 years.	Supervised exercise program. After removal of cast.	‡I: 1.1 goal setting (behaviour), 4.1 instruction on how to perform a behaviour, 8.1 behavioural practise/ rehearsal, 8.6 generalisation of target behaviour, 8.7 graded tasks, 9.1 credible source. †C: 1.1 goal setting (behaviour), 4.1 instruction on how to perform a behaviour, 9.1 credible source.	N/A	LEFS at 3 months. ‡I: 64.3 (SD 15.1). †C: 64.3 (SD 13.5). Effective: No. Mean diff: 0.4 (CI -3.3 to 4.1).
Nilsson 2009 Sweden RCT	Operatively treated ankle fractures. Participants: ‡I: 52, †C: 58. Mean age: Male: 37 years, Female: 48 years	Ankle exercises. After removal of cast (mean 43 days post-operatively). Physiotherapist delivered.	‡I: 1.1 goal setting (behaviour), 1.2 goal setting (outcome), 4.1 instruction on how to perform a behaviour, 5.1 information about health consequences, 8.1 behavioural practise/ rehearsal, 8.6 generalisation of target behaviour, 8.7 graded tasks, 9.1 credible source. †C: nil.	N/A	OMAS at 6 months. ‡I: 62.4 (SD 25.1). †C: 63.5 (SD 20.9). Effective: No. Mean diff: Not reported.
Tropp 1995 Sweden RCT	Operatively treated ankle fractures. Participants: ‡I: 15, †C:15. Mean age: 26 years.	Ankle exercises. First 6 weeks postoperatively. Physiotherapist delivered.	‡I: 4.1 instruction on how to perform a behaviour. †C: nil.	‡I: Brace. †C: Plaster.	OMAS at 10 weeks. ‡I: Not reported. †C: Not reported. Effective: No. Mean diff: Not reported.
Vioreanu 2007 Republic of Ireland RCT	Operatively treated ankle fractures. Participants: ‡I: 33, †C: 29. Mean age: ‡I: 37.2 years, †C: 34.9 years.	Ankle exercises. First 6 weeks Postoperatively. Physiotherapist delivered.	‡I: 1.1 goal setting (behaviour), 4.1 instruction on how to perform a behaviour, 9.1 credible source. †C: nil.	‡I: Removable plaster. †C: Plaster.	OMAS at 12 weeks. ‡I:93.2 (SD 8.8). †C: 81.1 (SD 9.6). Effective: Yes. Mean diff: Not reported.

‡I: Intervention group, †C: Control group, Mean diff: Mean difference (effect size)

2.3.4 Outcomes and synthesis

Patient reported outcomes

Six studies used a PROM of lower limb function as the primary outcome. The primary outcome used by Moseley 2005 [71] and Moseley 2015 [72] was the Lower Extremity Functional Scale (LEFS) at three months post-injury. The primary outcome for Kearney 2021 [11], Nilsson 2009 [75], Tropp 1995 [76] and Vioreanu 2007 [78] was the Olerud and Molander Ankle Score (OMAS) at 16 weeks, six months, 12 months and 12 weeks, respectively.

The primary outcome for Dehghan 2016 [73] was return to work, for Mayich 2013 [74] it was satisfaction with staff and for Dogra 1999 [77] the primary outcome was not stated. Dehghan 2016 [73] reported OMAS at six weeks and three, six and 12 months postoperatively. Dogra 1999 [77] and Mayich 2013 [74] reported OMAS at 12 weeks and three months post-operatively, respectively. Only Vioreanu 2007 [78] found a statistically significant difference in the patient-reported outcome measurements, favouring the BCT intervention group.

Meta-analysis of patient-reported functional outcomes

Four studies reported sufficient results to include and calculate SMDs for patient-reported functional outcomes. After contacting all authors, data for two further studies was obtained, bringing the total number of studies included in the meta-analysis to six. Heterogeneity was considerable, but within threshold when including all six studies ($I^2 = 75\%$). When removing Vioreauna 2007 [78], which was judged as high risk of bias, heterogeneity was reduced substantially ($I^2 = 0\%$). Of note, the mean OMAS in both treatment groups in Vioreanu 2007 [78] was considerably higher

and the SD substantially lower than in other published studies in this population [10, 11]. This can be seen in Table 2.2. This may indicate that the patient populations or conduct of the study were atypical.

The pooled SMD for Dehghan 2016 [73], Kearney 2021 [11], Moseley 2005 [71], Moseley 2015 [72], Nilsson 2009, [75] and Vioreanu 2007 [78] was 0.22 (CI -0.06 to 0.49), favouring the BCT group (non-significant). A forest plot is included in Figure 2.3. There remained an insignificant difference between the BCT (intervention) and non-BCT (control) groups when Vioreanu 2007 [78] was excluded: 0.07 (CI -0.06 to 0.20) in favour of the BCT group (non-significant).

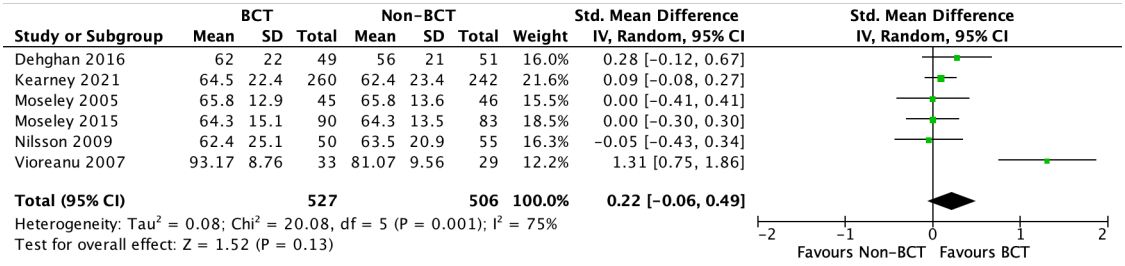


Figure 2.3: A forest plot comparing patient-reported functional outcomes

Meta-analysis of quality of life

Two studies reported a global quality of life score [11, 72]. Kearney 2021 [11] reported the EQ-5D-5L [80] at 16 weeks and Moseley 2015 [72] reported the Assessment of Quality of Life Instrument [81] at three months. Three studies [73, 75, 78] reported the Short-Form 36 (SF-36); this is split into a Mental and Physical component, and combining them into a global score for meta-analysis is not advised [82]. No significant differences were found in the studies that reported SF-36, and only Nilsson 2009 [75] reported the mean scores with SDs in each group (at 6 months) to enable inclusion in the meta-analysis. For the purposes of the meta-analysis, the physical component of the SF-36 was included, as physical quality of life was prioritised for

this review. The remaining studies did not report a quality-of-life score [71, 74, 76, 77]. The pooled standardised mean difference for Kearney 2021 [11], Moseley 2015 [72] and Nilsson 2009 [75] was 0.12 (CI -0.02 to 0.26) in favour of the BCT group (non-significant). Figure 2.4 shows the forest plot for quality of life.

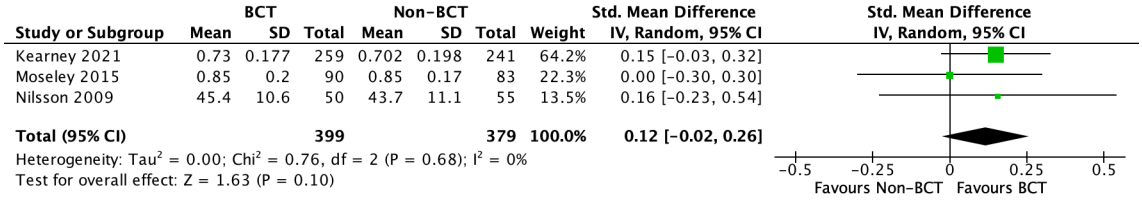


Figure 2.4: A forest plot comparing quality of life

Meta-analysis of adverse events - all

Complications were noted in eight studies, with Moseley 2005 [71] finding no complications in study participants. Dogra 1999 [77] reported a superficial wound infection, but it was not specified which treatment group this occurred in, so it was excluded from the meta-analysis. Commonly reported complications throughout the studies included Deep Vein Thrombosis (DVT) or Pulmonary Embolus (PE), infection or wound healing complications and re-operation. The results of all complications are displayed in Figure 2.5, reporting a non-statistically significant risk ratio (RR) favouring the control group of 1.11 (CI 0.89 to 1.40).

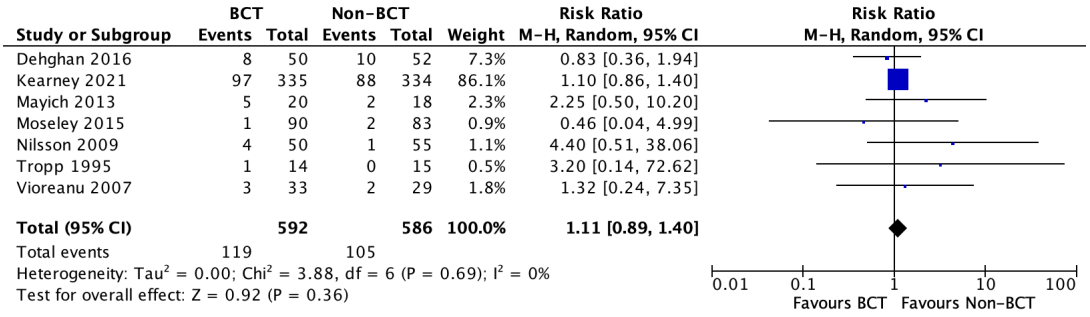


Figure 2.5: A forest plot showing the risk of adverse events

Post-hoc analysis: Meta-analysis of adverse events - operatively treated

During data extraction and analysis, it was noted that Kearney 2021 [11] contributed the largest number of participants but also reported a much higher incidence of complications (27.7%), which represented an 81.1% weighting in the meta-analysis of all adverse events. Over half of the reported complications in Kearney 2021 [11] were numbness of the side of the foot 93/185 (50.3%). Numbness was not reported in any other study and may not warrant inclusion in the meta-analysis for two reasons: it is likely a direct result of surgery (rather than having any association with the rehabilitation intervention), and it is a subjective measure, often considered a consequence of injury or treatment, rather than a complication. If numbness is excluded from the meta-analysis, the RR for experiencing a complication was 1.40 (CI 1.01 to 1.94, p=0.05) in favour of the control group.

Furthermore, on inspection of the complications in all studies (excluding numbness), 94/136 (69.1%) were complications unique to surgery, including infection, wound healing problems and re-operation. Kearney 2021 [11] reported complications unique to the surgical group, and so a revised meta-analysis including only surgical complications from this study is provided in Figure 2.6 (which also excludes Moseley 2015 [72], which reported operatively and non-operatively treated

patients together). Other complications that can occur in operatively treated and non-operatively treated patients were not included in the reporting. This is important to consider as these could have a higher incidence in the control group. However, these were similar in the BCT and non-BCT groups in Kearney 2021 [11], with identical rates of DVT, PE and complex regional pain syndrome (CRPS), with one extra non-union in the BCT group and four extra pressures sores in the non-BCT group. In the revised meta-analysis, the RR for a complication occurring was 1.70 (CI 1.16 to 2.50, p=0.007) for patients in the BCT group.

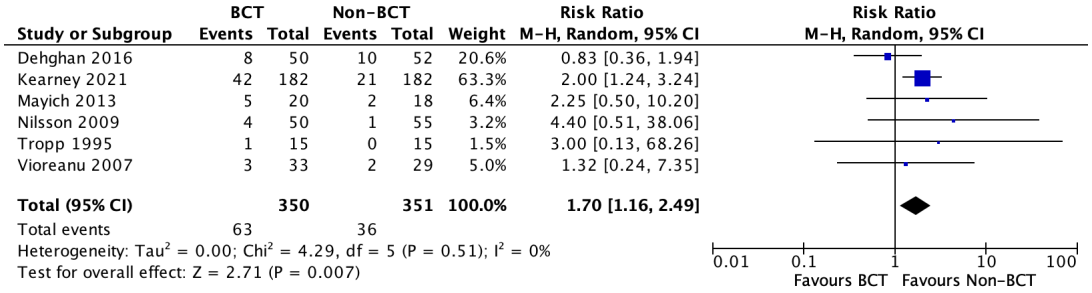


Figure 2.6: A forest plot showing the risk of adverse events for operatively treated ankle fractures only

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Certainty of evidence

Figure 2.7 provides an assessment of the certainty of the evidence for the reported outcomes using the GRADE approach [70].

Question: BCTs compared to non-BCTs in rehabilitation interventions to improve functional recovery after ankle fracture
Setting: Hospitals treating patients with ankle fractures
Bibliography: A systematic review of the effectiveness of behaviour change in rehabilitation interventions to improve functional recovery after ankle fracture

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	BCTs	non-BCTs	Relative (95% CI)	Absolute (95% CI)		
Patient Reported Functional Outcome												
6	randomised trials	not serious	not serious	very serious[a]	not serious	none	527	506	-	SMD **0.22 SD higher** (-0.06 lower to 0.49 higher)	⨁⨁◯◯ Low	
Quality of Life												
2	randomised trials	not serious	not serious	very serious[a]	not serious	none	349	324	-	SMD **0.11 SD higher** (-0.04 lower to 0.26 higher)	⨁⨁◯◯ Low	
Adverse Events												
6	randomised trials	serious[b]	not serious	very serious[a]	not serious	none	63/350 (18.0%)	36/351 (10.3%)	**RR 1.70** (1.16 to 2.49)	**72 more per 1,000** (from 16 more to 153 more)	⨁◯◯◯ Very low	

CI: confidence interval; **RR:** risk ratio; **SMD:** standardised mean difference

Explanations

a. Included studies did not use behavioural theory and contained substantial non-BCT components
b. Most included studies were at unclear risk of bisk.

Figure 2.7: GRADE summary of findings

2.4 Discussion

2.4.1 Summary of evidence

Behaviour change techniques

The performance of ankle exercises was the most commonly targeted behaviour in RCTs seeking to improve rehabilitation after ankle fracture. The most commonly used BCTs used were "4.1 instruction on how to perform the behaviour" (100%) and "1.1 goal setting (behaviour)" (89%), with other BCTs augmenting these. In essence, the interventions sought to teach participants how to perform ankle exercises and encourage them to practice them by setting targets and goals. "9.1 credible source" was coded in fives studies, where a dedicated physiotherapist provided the intervention training [71–73, 75, 78]. However, the use of a physiotherapist to deliver

the interventions was primarily to standardise exercise instructions rather than to persuade participants to engage with the behaviour.

Patient reported functional outcomes

There was low-certainty evidence from six studies [11, 71, 72, 75] that the use of BCTs did not significantly impact patient-reported functional outcomes after ankle fracture.

Quality of life

There was low-certainty evidence from two studies [11, 72] that the use of BCTs did not significantly impact participants' quality of life after ankle fracture.

Adverse events

There was very low-certainty evidence from six studies [11, 73–76, 78] that the use of BCTs significantly increased the risk of an adverse event after **operatively**-treated ankle fracture (RR 1.7 (CI 1.16 to 2.49)). This equates to 72 more complications per 1,000 patients treated (16 to 153). However, the level of certainty was downgraded because the studies had substantial non-BCT components, and five studies [73–76, 78] were at unclear or high risk of bias.

2.4.2 Strengths and limitations

This systematic review has used a comprehensive taxonomy to identify and code BCTs [64]. This will enable faithful replication of the behavioural components of the interventions during the design of the RAAFT rehabilitation package in later chapters of this thesis and for other researchers in the future. The broad search

strategy also provides confidence that all relevant studies, including a wide spectrum of possible rehabilitation interventions, have been included.

The central limitation of this review is that it has been unable to answer the research questions due to the lack of behavioural theory used in the design of the included study interventions, as discussed in Section 2.4.1. This limitation is the primary reason there is low certainty evidence for the outcomes examined: there were substantial non-BCT components testing different physiotherapy, immobilisation and weight-bearing strategies rather than discrete, theory-based BCTs. The interventions were designed to simply provide instructions rather than influence the psychological motivations of participants to engage with the behaviours.

Selection and publication bias

The Cochrane handbook discusses the non-publication of "negative" studies (no significant effect between interventions and control groups) as the primary source of publication bias in systematic reviews [67]. In this review, all but one study reported negative findings (which itself was at high risk of bias), and so publication bias was scored as "undetected" in the GRADE table (Figure 2.7). However, the design and conduct of this review may have introduced bias: only RCTs were included, and grey literature was not searched. This was because the coding of BCTs required a great level of detail in intervention reporting, generally lacking in observational and grey literature studies. It is possible that "positive" studies were missed due these limitations. However, the overall grading of evidence as "low" and "very low" certainty would not have changed, due to the inherent indirectness of the available studies to answer the review question, as discussed in Section 2.4.1.

Other sources of bias

The unavailability of full text-articles described in Section 2.3.1, mostly due to publication in non-English speaking journals is a source of bias that may limit the generalisability of the findings. Another potential source of bias was that only one reviewer screened the full-text articles (154) for inclusion. The primary reason for this was the availability of funding and time available for a second reviewer: meaningful coding of BCTs requires considerable training. Having undertaken >50 hours of BCT training provided by the authors of the BCW [66, 83], there is confidence that the coding reflects the specifications in the BCT taxonomy [64], yet this remains a potential source of bias. Using a second reviewer for the risk of bias and GRADE assessments would have added additional validity. Still, the use of established methods and regular discussions with a multi-disciplinary supervisory team provide confidence in these processes [67, 70].

Lastly, the choice of outcomes, with limitation to patient reported outcome measures (PROMs) may have narrowed the scope of included studies, and limited demonstration of effectiveness. Studies examining the use of BCTs in other areas of musculoskeletal care have found a benefit: Williamson et al. [55] found a combined physical and psychological group programme improved walking performance and reduced disability compared to best practice advise for patients with back pain. Systematic reviews by Room et al. [46] and Willet et al. [56] found BCTs improved exercise adherence in older persons and patients with lower limb osteoarthritis: both reviews included studies which were underpinned by behavioural theory. It may be that the RAAFT review found no benefit from BCTs because the included studies were not

based on behavioural theory, or because the outcome measures were misaligned to studies which use such theories.

2.4.3 Conclusions

The lack of behavioural theory used in the design of rehabilitation interventions after ankle fracture has limited the usefulness of this review to meet the objectives specified in Section 2.1.1. This review has demonstrated that the existing use of BCTs in this area has centred around conventional methods of physiotherapy delivery: instruction and encouragement to perform ankle exercises. While these BCTs did not significantly improve patient-reported outcomes in this context, the frequent use of the BCTs indicates they are likely to be familiar to patients and to healthcare professionals delivering interventions. These conventional BCTs are also being used in current musculoskeletal interventional studies [84, 85], reinforcing their likely acceptability and indicating they could form the baseline level of therapy in the design of future interventions in this area. Ankle fracture rehabilitation could seek to build on these and include a broader range of BCTs, which have proven efficacious in non-acute musculoskeletal conditions [46, 86].

This review provides an important and unexpected insight: BCT interventions may increase the risk of adverse events in operatively treated ankle fractures. For reasons listed in Section 2.4.1, this is unlikely to represent an issue with BCTs. However, it does highlight a broader consideration for the rehabilitation of patients after ankle fracture surgery. There is a trend toward promoting earlier movement and weight-bearing after ankle fracture surgery, with evidence suggesting this leads to an earlier return to work and hobbies [27, 73]. These early functional improvements may obscure an increased rate of complications, particularly wound healing problems

and infection. Most studies have been powered to detect a change in PROMs, not complications [10, 11]. Thus, they may be insufficiently powered to detect significant differences in adverse events. One study comparing different immobilisation and weight-bearing strategies even stopped recruitment early due to superior PROMs in the early movement and weight-bearing group [27]. The largest single study in this area inadvertently masked this issue by combing operative and non-operatively treated populations [11], as discussed in Section 2.3.4. Future studies using BCTs to promote early movement should look carefully at the risk of wound healing complications and consider including additional BCTs to enable monitoring, detection and avoidance of these complications. These insights guide the development of the rehabilitation package in the remainder of this thesis.

CHAPTER 3

An embedded exploratory study investigating the impact of pain beliefs and demographic characteristics on patients with surgically managed ankle fractures

3.1 Introduction

Evidence suggests that patient characteristics may be more important for predicting patients' recovery after musculoskeletal injuries than injury-related or surgical factors alone [19–21, 34, 87]. Additionally, the interaction between psychosocial factors and outcomes in musculoskeletal disorders is becoming established. Initially studied in chronic musculoskeletal conditions such as back pain [88], their importance in mediating recovery after trauma is gaining interest. In a single-centre study, Jayakumar et al. found that low pain self-efficacy and fear of movement were the most significant predictors of poor functional outcomes and ongoing pain after upper limb fracture [34, 35]. These pain beliefs were measured at under one week and two to four weeks from injury. Scores at both time points were correlated with patient-

reported outcomes at six to nine months post-injury. However, there has been no published study of the impact of patients' pain beliefs on outcomes in an ankle fracture population. Pain beliefs are discussed further in Section 1.3.

The hypothesis is that if certain patient groups or those with at-risk characteristics can be identified early after injury, further support or modification of risk-factors for poor recovery could be provided [38, 39]. This chapter seeks to identify these at-risk factors via a prospective, multi-centre observational study.

3.1.1 Objectives

1. To determine the distribution of unhelpful pain beliefs in patients after ankle fracture surgery.

2. To investigate the impact of unhelpful pain beliefs and other demographic characteristics on recovery after ankle fracture surgery.

3.2 Methods

3.2.1 Study design

An observational cohort study of patients undergoing operative management of an unstable ankle fracture, with an exploratory analysis was conducted, and reported in accordance with the Strengthening the reporting of observational studies in epidemiology (STROBE) checklist [89].

3.2.2 Source of data and approvals

Data for this exploratory analysis were collected through the WAX trial [29]. WAX is a multicentre, prospective, randomised, non-inferiority trial using a two-arm parallel-group design. Participants were recruited from the routine fracture clinic two weeks post-surgery and randomised in a 1:1 ratio to either early weight-bearing or delayed weight-bearing. The details of the WAX trial interventions are described in the WAX trial protocol (Appendix H.1) and are beyond the scope of this thesis. The protocol for the WAX trial has been published [29] and the study was registered on 2nd December 2019, Ref ISRCTN12883981 [90]. Patients were recruited between 5th February 2020 and 29th October 2021.

The entire WAX cohort were sampled for the RAAFT exploratory analysis, hereafter referred to as the RAAFT cohort. RAAFT was embedded as a Study Within a Trial (SWAT), and the SWAT protocol is included as a supplemental file in the WAX trial protocol [29]. The SWAT protocol covers Chapters 3 to 8 of this thesis. The SWAT was submitted as an amendment (05) and received a favourable opinion from the South Central - Oxford A Research Ethics Committee on 23rd March December 2021 - Ref Reference 19/SC/0566 (Appendix G.1).

Recruitment and consent

All sites registered the study with their local research and development departments and were eligible for support from their local Clinical Research Network (CRN). All sites had a site initiation visit (SIV), attended by a local principal investigator (PI) and relevant members of the clinical and research team. Team members were required to undertake training and enrol on the delegation log, with PI sign-off before

recruiting patients. Where possible, patients were approached during their index hospital stay and provided with a participant information sheet (PIS). All patients were non-weight-bearing in the first two weeks postoperatively. When they returned for their two-week clinical check-up, a member of the clinical or research team discussed the study and obtained consent for study enrolment. Once completed, a copy of the signed consent form was emailed to the participant. A copy of the PIS and participant consent form is provided in Appendix B.1. The first patient was recruited on 5th February 2020 and the last on 29th October 2021. After the initial COVID-19 wave in Spring 2020, virtual consent forms were also introduced to allow recruitment asynchronously from clinical visits. Screening data were recorded for patients that were ineligible or declined study participation (Figure 3.3). Participants were free to withdraw from the study at any time without giving reasons. If a patient withdrew, their data up until the point of withdrawal was retained for analysis, as specified in the PIS.

3.2.3 Participants

Participant eligibility

Inclusion criteria

- They were aged 18 years and older.
- They had undergone operative fixation for an unstable ankle fracture.
- Surgery was performed within 14 days of the injury.
- In the opinion of the treating surgeon, the patient might have benefited from early weight-bearing.

Exclusion criteria

- They had cognitive impairment or could not speak English.
- They lacked protective sensation (e.g. peripheral neuropathy).
- They had received a hindfoot nail to treat the index fracture.
- They had bilateral operatively treated ankle fractures.

Several of these criteria relate to practical considerations for patients being able to consent to participate in the study and completing the follow-up questionnaires (cognitive impairment and English-speaking). Only adults were included because children and adolescents sustain different patterns of fracture, which often do not require surgical incisions and internal fixation. Decision-making around children's fractures remains controversial and is the topic of an ongoing RCT [91].

Ankle fracture classification and stability are discussed in Section 1.1.2. The concept that only "unstable" fractures require surgery is relatively new and was confirmed in the 2017 CROSSBAT study by Mittal et al. [92]. This inclusion criterion was added to ensure the study population reflected contemporary, not historical practice.

If the decision to operate is made, British Orthopaedic Association Standards for Trauma (BOAST) and NICE guidelines recommend surgery on the day of injury or the day after [26, 93]. Occasionally, surgery can be delayed due to patient, injury or logistical factors, or patients may have an initial trial of non-operative treatment [10]. There is evidence to suggest patients undergoing delayed open reduction internal fixation (ORIF) have adverse outcomes [94] and 14 days was felt to be a reasonable balance between ensuring a comparable study population and maximising recruitment within the resources of the NHS.

Some surgeons believe patients with diabetes, open fractures or other factors are unsuitable for early weight-bearing and individual equipoise varies widely [8, 95]. Therefore, a pragmatic approach was taken for inclusion with an encompassing phrase: "In the opinion of the treating surgeon, the patient might benefit from early weight-bearing".

Patients without protective sensation (e.g. peripheral neuropathy) were excluded because a principle theory in allowing early weight-bearing is that if early walking is causing harmful tissue damage, patients will self-regulate and stop walking if it is painful. There is little clinical evidence to prove this concept, but it is investigated in later chapters of this thesis.

Conversely, patients with peripheral neuropathy or low functional demands with high risks of complications are sometimes treated with a hindfoot nail: this is a metal nail introduced through the heel, across the ankle joint, and into the tibia. One of the key purposes of this procedure is to allow early weight-bearing and mobility: survival is prioritised over ankle function, a similar strategy taken in frail patients with hip fractures [96]. Accordingly, patients treated with hindfoot nails were excluded, as they would usually weight-bear immediately and be unable to move their ankle joint (skewing several sections on the OMAS).

Patients with bilaterally operatively treated ankle fractures were excluded because if they were permitted to weight-bear on one ankle but not the other, this would be difficult for them to manage and would bias their quality of life scores.

3.2.4 Outcomes/ dependant variables

Functional outcome - OMAS

The OMAS is a region-specific patient-reported functional outcome measure - the Olerud and Molander Ankle Score (OMAS). It has three domains related to ankle symptoms, lower limb-related activities and overall function. It has nine (asymmetrically weighted) items that add to give a score of 0 (worst) to 100 (best) (see Appendix B.2). Its reliability and validity have been published [79], and it is used as the primary outcome for most previously published ankle fracture studies [10, 11, 23]. It was collected at baseline (pre-injury), six weeks, four months and 12 months post recruitment, as function has been shown to improve quickly in the first three months from surgery, improve little between three and six months and plateau thereafter [16].

Health-related quality-of-life - EQ-5D-5L

The EuroQol 5 Dimensions 5L (EQ-5D-5L) is a validated, generalised and standardised health status instrument consisting of a five-level response (no problems, some problems, moderate problems, severe problems and unable) for five domains related to daily activities; (i) mobility, (ii) self-care, (iii) usual activities, (iv) pain and discomfort, and (v) anxiety and depression [97]. Responses to the health status classification system were mapped on the EQ-5D-3L value set and converted into an overall index score using a published utility algorithm for the UK population [98], as recommended by NICE [99]. The second component is the EQ visual analogue scale (EQ VAS) which gives self-rated health on a scale where the endpoints are labelled "best imaginable health state" (100) and "worst imaginable health state" (0) (Ap-

pendix B.2). For the exploratory analysis, only the EQ5D index was a dependent variable in the model.

3.2.5 Exposures/ independent variables

The criteria for variable selection were based on three principles:

- Data available from the WAX trial, without over-burdening participants, as piloted with two patient and public involvement representatives.
- The use of baseline demographic factors, which have previously been shown to correlate with the outcomes of interest.
- Potentially modifiable factors, which could be screened for early during recovery from ankle fracture surgery, or socioeconomic factors which may demonstrate health in-equity.

Age in years: As a continuous measure. Increasing age has been previously associated with poorer functional outcomes [19, 20].

Gender: Coded as a binary categorical variable. Gender was included as being female has been associated with poorer outcomes in a previous study, albeit this was only in patients aged over 60 years [21]. Gender was used, rather than sex, because it was felt there was no scientific requirement to study biological sex, and the RAAFT PPI representatives felt asking patients to report their gender would widen study appeal and participation.

Body Mass Index (BMI): As a continuous measure. This was calculated from participants' reported weight and height. BMI was chosen rather than weight and

height, as it has proven to be a more reliable predictor of outcome based on previous studies [19, 20, 100].

Injury mechanism: Coded as a binary categorical variable; high vs low energy transfer mechanism. This was chosen to represent the degree of soft tissue damage and injury severity previously correlated with poorer outcomes [21]. Low energy injuries included falls from standing height, or falls while running or during non-contact sports. High energy injuries included falls from greater than standing height, road traffic accidents and contact sports.

Pre-injury ankle function score: OMAS and **Pre-injury health state** EQ5D index as a continuous measure for their respective models. Pre-injury scores have been correlated with post-injury scores and account for a range of other potential variables (e.g. previous mobility) [21].

Educational attainment: This was coded as sequential levels of education attainment from secondary school to a university degree. It was coded as an ordinal categorical variable from 1-5. Educational attainment was included as a proxy measure for examining how social status may influence patients' recovery after ankle fracture surgery, either directly or by changing how they engage with healthcare services or rehabilitation resources.

Occupation: Coded as a categorical variable: labour, non-labour (sedentary or intermediate) and not employed (student, unemployed or retired). These are explored with the hypothesis that patients that work in manual labour occupations may

recover differently, either because the physical nature of their work mandates an increased level of activity (and associated ankle exercise) or because this physical activity raises their functional requirements and makes them more aware of their limitations.

Comorbidity score: The modified Charlson comorbidity index (mCCI) [101] gives an age-adjusted numerical (continuous) score based on a range of comorbidities and is predictive of one-year mortality. The best possible score is 0, and the worst is 20 (Appendix B.2).

Pain beliefs

The following measures were selected to explore if pain beliefs are associated with outcomes after ankle fracture surgery. These measurements were chosen for two reasons: 1) They have been shown to be the strongest predictors of functional outcomes after upper limb fracture [34, 35]. 2) They are abbreviated scores; if they are to be used in clinical practice for screening purposes, brevity will be desired.

Fear of movement: The Tampa scale of kinesiophobia-11 (TSK-11) is a brief, reliable, and valid measure of fear of movement/(re)injury for patients with chronic painful conditions [102] (Appendix B.2). It is a continuous score from 11 (best) to 44 (worst). Fear of movement was chosen over other measures of pain belief's due to the perceived importance of early movement after musculoskeletal injury as found in Chapter 2.

Pain self-efficacy: The Pain self-efficacy questionnaire-2 (PSEQ-2) is a validated, abbreviated measure of an individual's confidence in their ability to accomplish tasks, overcome problems and live a normal life despite pain. Low levels of self-efficacy are associated with less optimal health behaviours [33] (Appendix B.2). It is a continuous score from 0 (worst) to 12 (best).

3.2.6 Blinding and missing data

Patient-reported baseline and follow-up data were entered directly onto the central trial database: Research Electronic Data Capture (REDCap) [103] (Vanderbilt University Medical Center, Nashville, USA), hosted by Oxford Clinical Trials Research Unit (OCTRU) without influence from the clinical or research team. Participants were contacted for follow-up using email and/or text message prompts and invited to complete questionnaires through a secure (encrypted) unique online link or on paper if the participant preferred. The blinded central research team called patients that did not reply to these prompts to input the follow-up data.

There were no missing data for baseline questionnaires; this is because all inputs were electronic via REDCap, where it was not possible to progress through sequential case report forms (CRFs) until all data fields were complete. Complete case analyses were conducted as there were no missing data other than the follow-up dependant outcome variables (see Figure 3.1) [104–106]. Thus participants that did not complete the relevant dependent outcome measure were excluded from analysis.

3.2.7 Sample size

The sample size calculation for the WAX trial assumed a 10% loss to follow-up rate. Therefore, it was anticipated that 392 participants would provide follow-up data at

four months. With 80% power and a significance level of 0.05, a model with 392 patients and ten predictor variables would be able to account for 4% of the variability in OMAS at four months (R^2=0.041; calculations performed using G*Power 3.1.9.4) [107]. This is much lower than the expected adjusted R^2 based on previous studies [34, 35]. Hence the available data were deemed sufficient to answer the research question.

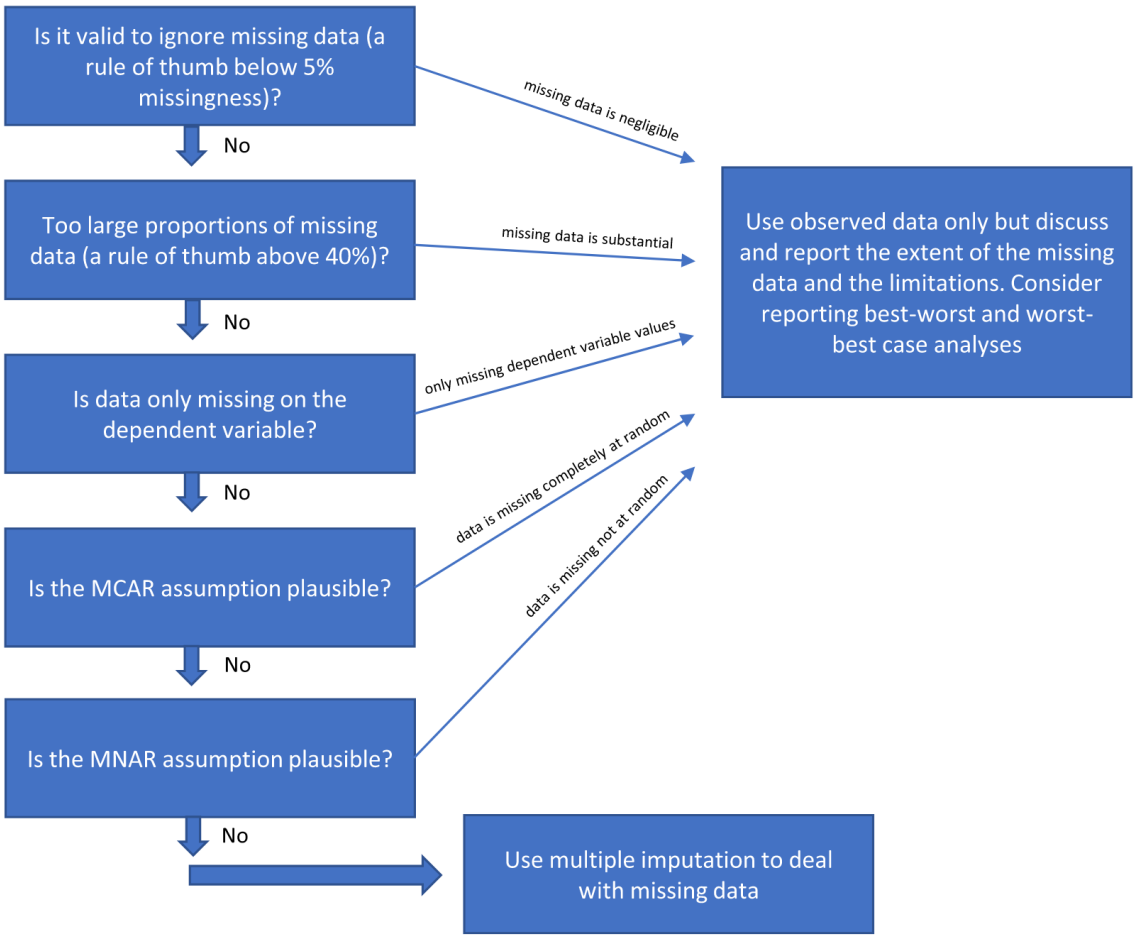


Figure 3.1: Flowchart: when should multiple imputation be used to handle missing data [104]

Changes due to COVID-19

Due to delays caused by the COVID-19 pandemic, several changes were made, as listed on page iv. 12-month data were not available for OMAS or EQ-5D-5L, and the minimum required data were released, e.g. only the primary outcome (four-month) data. A model exploring the risk of adverse events was planned. However, most sites screen their hospital records at 12 months to check for adverse events in the previous year, so accurate adverse event data for the four-month time-point were not available. Participants' weight-bearing allocation group (early or delayed weight-bearing) had been a planned variable to include in the exploratory analysis, but this was not available due to the risk of unblinding before the publication of the WAX trial results. Similarly, a mediation analysis was planned to explore the logic model shown in Figure 3.2. The logic model shows two potential pathways:

Pathway A) There will be a direct causal relationship between pain beliefs and functional outcome (OMAS).

Pathway B) Pain beliefs will mediate patients' behaviour to start weight-bearing (particularly if they have pain when walking). Walking sooner will then have a direct causal relationship with functional outcome (OMAS).

The WAX trial asked participants to self-report (via a weekly text message) when they started to weight-bear on their injured ankle. A mediation analysis had been planned to explore Pathway B. Unfortunately, due to COVID-19 delays, the weekly weight-bearing data were not available (risk of unblinding). So instead, only Pathway A was explored.

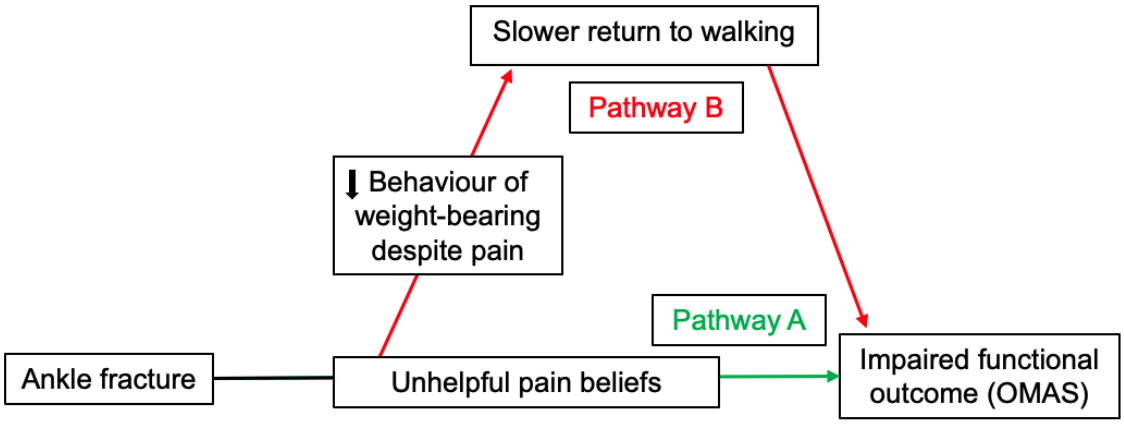


Figure 3.2: Logic model of pain beliefs, weight-bearing and functional outcome

3.2.8 Analysis

Analysis was conducted in R [108]. Patient baseline characteristics, and outcome values were summarised as frequencies and percentages for categorical data, means and SDs for parametric continuous data, and medians and interquartile ranges (IQRs) for non-parametric continuous data.

Dependant variables for the exploratory analysis were continuous, so only linear regression was undertaken. Two models were created; one for OMAS and one for the EQ5D index at four-month follow-up. For multivariable analyses, a Pearson's rank correlation was conducted for testing associations between parametric independent and dependent variables and a Spearman's rank correlation for non-parametric data. For analysis of the associations between categorical variables and the continuous outcome variables, analysis of variance was used for parametric data and the Kruskal-Wallis test for non-parametric data.

Variable selection

There are many methods for variable selection reported in the literature. Methods include selection by univariable analysis, removal based on collinearity, or stepwise (forwards or backwards) selection. However, collinear or non-significant variables from the univariable analysis may have positive or negative effects on other variables and the model as a whole [109]: with the use of pre-specified, literature-informed variable selection employing clinical rationale, statistical methods for variable selection are not required [110]. All variables were pre-specified in the WAX SWAT protocol (Appendix H.2) and justified in Section 3.2.5 and so no variable selection or testing for collinearity were conducted.

Model performance and validation

This was an exploratory analysis to identify individual variables that may be associated with patient outcomes after ankle fracture. The primary purpose was to identify factors which could be used for screening (not for diagnosis or prediction); therefore the performance of the model as a whole was of secondary interest. Models and variables therein were reported with univariable and multivariable analyses. The beta-coefficient (β) for each variable was presented with CIs and p-values. β indicates the degree of change in the outcome (dependent) variable for every unit of change in the exposure (independent) variable. Each variable in the model is measured on a different scale, e.g. TSK-11 from 11-44 and the mechanism of injury is binary (low or high energy). Therefore, β alone does not indicate the most important explanatory variables or allow comparison between them; the partial R^2 can aid interpretation. The R^2 were provided for each variable within the univariable analysis and an overall adjusted R^2 for the multivariable model as a whole. The R^2 indic-

ates the proportion of variability in the dependant (outcome) variable explained by the independent variable(s). A value of 1.0 suggests that the model explains all the variability in the dependant variable, and a value of 0.0 indicates that none of the variability is accounted for by the independent variable(s) [111].

Post-hoc analyses

Post-hoc analyses were conducted to explore associations with variables that were strongly associated with functional outcomes. Characteristics by gender, mechanism of injury and occupation were compared. Comparisons were made using a Welch two-sample t-test for parametric continuous data and a Mann-Whitney U test for non-parametric continuous data. Categorical data were compared using Pearson's Chi-squared test.

Uni and multivariable analyses were conducted to explore the association between occupation type and functional outcome: self-employed vs not self-employed. This was to explore the potential social implications concerning rehabilitation and how self-employment status might interact with recovery.

3.3 Results

3.3.1 Participants

Two thousand one hundred eighty-seven patients with operatively treated ankle fractures were screened for inclusion from 23 participating hospitals. Seven hundred sixty-six patients were deemed eligible for inclusion, of which 562 were recruited to the study. Figure 3.3 shows the participant flow diagram with reasons for exclusion. Twenty three sites recruited patients into the study. These were all hospitals

which regularly treated patients with ankle fractures, and there was a mix of major trauma centres (MTCs) and district general hospitals (DGHs). Table 3.1 indicates the participating hospitals and the number of recruits per site.

The mean age of recruited participants was 48 years (SD 16), and 359 (64%) were female. By comparison, of patients that were screened but not recruited, the mean age was 51 years (SD 18) and 1,030 (63%) were female. Table 3.2 shows the participant characteristics listed for all recruits at baseline and those that completed four-month follow-up data for the primary outcome: the included sample with 4 months outcome data was representative of the overall recruited population.

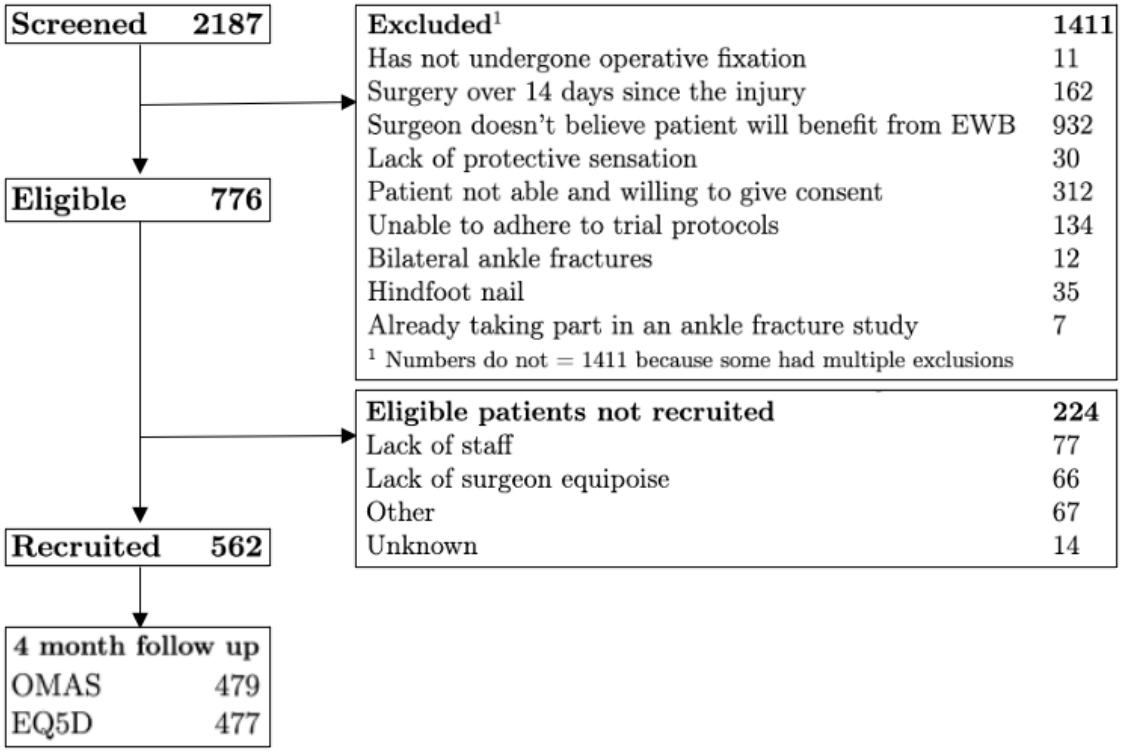


Figure 3.3: Participant flow diagram

Table 3.1: Recruits per site

Site	**N**	**Site**	**N**
The Princess Alexandra Hospital Harlow	82	Leicester Royal Infirmary	15
Royal Victoria Hospital Belfast	61	Craigavon Area Hospital	11
Royal United Hospitals Bath	58	Queens Medical Centre Nottingham	11
Conquest Hospital	49	The Royal Cornwall Hospital	11
Basingstoke and North Hampshire Hospital	39	Southampton General Hospital	9
Queen Alexandra Hospital Portsmouth	35	Royal Derby Hospital	8
East Surrey Hospital	34	Dorset County Hospital	7
William Harvey Hospital	29	Kings College Hospital Trust	6
Maidstone and Tunbridge Wells Hospital	27	Salisbury District Hospital	6
Cardiff and Vale University Health Board	24	University Hospital Coventry	5
Royal Berkshire Hospital Reading	16	University Hospital Lewisham	3
Royal Preston Hospital	16	**Total**	562

Table 3.2: Participant characteristics for all recruited and those with complete outcome data at four-month follow-up

Characteristic	All recruited N = 562[1]	4 month follow-up N = 479[1]
Age	48 (16)	50 (16)
Gender		
Male	203 / 562 (36%)	157 / 479 (33%)
Female	359 / 562 (64%)	322 / 479 (67%)
Prefer to self-describe	0 / 562 (0%)	0 / 479 (0%)
BMI (kg/m2)	29.0 (6.1)	29.1 (5.9)
Diabetic	20 / 562 (3.6%)	18 / 479 (3.8%)
Osteoporosis	19 / 562 (3.4%)	19 / 479 (4.0%)
mCCI	1.04 (1.28)	1.11 (1.29)
Smoker	112 / 562 (20%)	80 / 479 (17%)
Mechanism of injury		
Low Energy	422 / 562 (75%)	372 / 479 (78%)
High Energy	140 / 562 (25%)	107 / 479 (22%)
Educational attainment		
Secondary school	146 / 562 (26%)	121 / 479 (25%)
Sixth form/ college	130 / 562 (23%)	104 / 479 (22%)
Formal qualification(s) through training at work	56 / 562 (10.0%)	49 / 479 (10%)
Qualification (other than degree) from college or university	88 / 562 (16%)	73 / 479 (15%)
Degree from college or university	142 / 562 (25%)	132 / 479 (28%)
Employment status		
Full-time	219 / 562 (39%)	181 / 479 (38%)
Part-time	79 / 562 (14%)	69 / 479 (14%)
Self-employed	73 / 562 (13%)	59 / 479 (12%)
Unemployed	59 / 562 (10%)	44 / 479 (9.2%)
Voluntary work	2 / 562 (0.4%)	2 / 479 (0.4%)
Full time student	12 / 562 (2.1%)	12 / 479 (2.5%)
Retired/ looking after home	118 / 562 (21%)	112 / 479 (23%)
Occupation		
Corporate management or director	28 / 373 (7.5%)	26 / 311 (8.4%)
Professional occupation (medicine, law, accountancy, engineering, teaching)	80 / 373 (21%)	74 / 311 (24%)
Associate in a profession/ technical role (healthcare, technology, media or sports)	25 / 373 (6.7%)	22 / 311 (7.1%)
Administrative or secretarial occupation	61 / 373 (16%)	53 / 311 (17%)
Skilled trade	71 / 373 (19%)	48 / 311 (15%)
Caring, leisure or other service occupation	58 / 373 (16%)	49 / 311 (16%)
Process, plant or machine operatives including driver	20 / 373 (5.4%)	14 / 311 (4.5%)
Elementary occupation (cleaner, kitchen assistant, bar worker, unskilled labourer)	30 / 373 (8.0%)	25 / 311 (8.0%)
Not employed	189	168
Occupation type		
Labour	125 / 373 (34%)	92 / 311 (30%)
Intermediate	126 / 373 (34%)	112 / 311 (36%)
Sedentary	122 / 373 (33%)	107 / 311 (34%)
Not employed	189	168
TSK-11 score	27 (6)	27 (6)
PSEQ-2	8.1 (3.5)	8.1 (3.5)
EQ VAS baseline score	84 (15)	85 (14)
OMAS baseline score	97 (10)	97 (10)
EQ5D index baseline score	0.92 (0.14)	0.93 (0.13)

[1] Mean (SD); n / N

3.3.2 Pain beliefs

For the recruited population the mean PSEQ-2 score was 8.1 (SD=3.5). The mean TSK-11 was 26.6 (SD=6.4). There were no statistically significant differences in the distribution of pain beliefs based on gender, mechanism of injury, educational attainment or occupation type.

3.3.3 Variable/ model performance

Functional outcome

Table 3.3 shows the results of the univariable and multivariable analyses associating the explanatory variables with OMAS at four-month follow-up. Variables that had a statistically significant positive association with OMAS in univariable and multivariable analyses included male gender and PSEQ-2. Variables that were associated with poorer OMAS scores in univariable and multivariable analyses included higher BMI, manual labour occupation and higher TSK-11 scores. After adjustment in the multivariable analyses, increasing age was negatively associated with functional outcome and increasing mCCI was positively associated with functional outcome at four-month follow-up. High energy mechanism of injury and baseline OMAS were positively associated with OMAS at four months, but this became statistically non-significant after adjustment during multivariable analysis. The adjusted R^2 for the model as a whole was 0.14, indicating that the model predicted 14% of the variability in functional outcome, suggesting other unexplored factors have a role to play. Figure 3.4 shows a plot demonstrating the vector of association with CIs for the adjusted multivariable analysis.

Table 3.3: Linear regression model for OMAS at four months

	Univariable				Multivariable		
Variable	β	**CI**	**p-value**	**Partial R^2**	β	**CI**	**p-value**
Age	-0.092	-0.218 to 0.034	0.151	0.004	-0.289	-0.502 to -0.076	**0.008**
Gender							
Female	—				—		
Male	8.93	4.69 to 13.2	**<0.001**	0.035	7.58	3.36 to 11.8	**<0.001**
BMI	-0.592	-0.929 to -0.254	**0.001**	0.024	-0.473	-0.798 to -0.148	**0.004**
mCCI	0.258	-1.31 to 1.82	0.747	0.001	3.27	0.509 to 6.03	**0.020**
Mechanism of injury							
Low energy	—				—		
High energy	6.36	1.53 to 11.2	**0.010**	0.014	3.30	-1.43 to 8.04	0.171
Educational attainment	0.96	-0.319 to 2.25	0.140	0.005	0.680	-0.553 to 1.91	0.279
Occupation type							
Not employed	—				—		
Labour	-5.95	-11.7 to -0.22	**0.042**	0.009	-6.90	-12.6 to -1.16	**0.019**
Not labour	0.75	-3.77 to 5.28	0.744	<0.001	-0.29	-4.98 to 4.39	0.902
TSK-11	-0.815	-1.12 to -0.509	**<0.001**	0.054	-0.562	-0.884 to -0.239	**0.001**
PSEQ-2	1.40	0.829 to 1.96	**<0.001**	0.047	0.831	0.236 to 1.43	**0.006**
OMAS baseline	0.222	0.027 to 0.418	**0.026**	0.010	0.157	-0.031 to 0.345	0.101

Number in model = 479, Adjusted R^2 = 0.14, — = Index reference for comparison, Significant finds are in **bold**

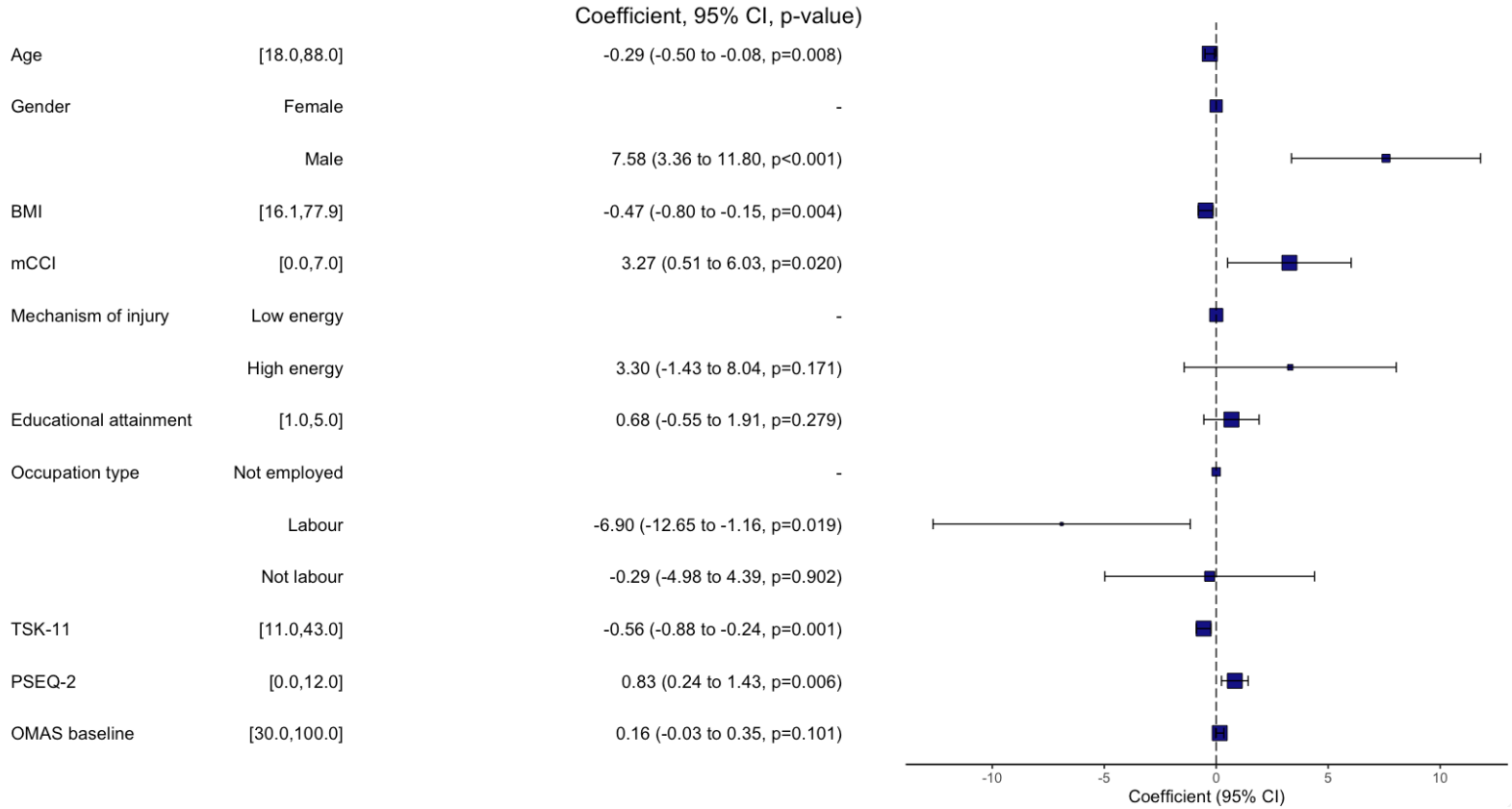


Figure 3.4: A plot demonstrating the vector of association for the adjusted multivariable analysis for the four-month OMAS model

Post-hoc analysis

Baseline factors that differed significantly between gender included age (females were a mean of 6.1 years older, CI 3.0 to 9.2, p<0.001), mechanism of injury (271 (84%) of females had a low energy mechanism compared to 101 (64%) of males p<0.001), occupation type (50 (16%) of females were in working in manual labour occupations compared to 42 (27%) of males p<0.001). The mean mCCI for females was higher by 0.27 (CI 0.03 to 0.52, p=0.031), though this may reflect the increased mean age of females, which is included in the mCCI score calculation.

Patients sustaining lower energy mechanisms of injury were on average older (mean difference 7.2 years, CI 3.9 to 11, p=<0.001), had a higher BMI (mean difference 1.6kg/m^2, CI 0.41 to 2.8, p =0.009) and had a higher mCCI (mean difference 0.44, CI 0.18 to 0.70, p=0.001). Patients in manual labour occupations were younger (mean difference -5.9 years, CI -8.9 to -2.4, p<0.001) than those not employed or in non-labour occupations. Self-employed participants had a lower mean OMAS in univariable but not adjusted multivariable analyses (β=-7.68, CI -13.81 to -1.56, p=0.014, partial R^2=0.013).

Quality of life

Table 3.4 shows the results of the univariable and multivariable analyses associating the explanatory variables with the EQ5D index score at four-month follow-up. Factors that had a statistically significant association with the EQ5D index did so in both the univariable and adjusted multivariable analyses. Factors positively associated with the EQ5D index at four months included mCCI, PSEQ-2 and EQ5D index at baseline. Variables that were associated with a lower EQ5D index included higher BMI, manual labour occupation and higher TSK-11. The adjusted R^2 for the

model as a whole was 0.15, indicating that the model predicted 15% of the variability in quality of life. Figure 3.5 shows a plot demonstrating the vector of association for the adjusted multivariable analysis for the four-month EQ5D index model.

Table 3.4: Linear regression model for EQ5D index at four months

	Univariable				Multivariable		
Variable	β	**CI**	**p-value**	**Partial R^2**	β	**CI**	**p-value**
Age	0.001	0.000 to 0.002	0.095	0.006	-0.002	-0.004 to 0.000	0.083
Gender							
Female	—				—		
Male	0.026	-0.012 to 0.064	0.184	0.004	0.022	-0.016 to 0.060	0.255
BMI	-0.004	-0.007 to -0.001	**0.006**	0.016	-0.003	-0.006 to 0.000	**0.045**
mCCI	0.019	0.005 to 0.033	**0.007**	0.015	0.029	0.005 to 0.054	**0.017**
Mechanism of injury							
Low energy	—				—		
High energy	0.026	-0.070 to 0.017	0.228	0.003	-0.034	-0.076 to 0.008	0.108
Educational attainment	0.006	-0.005 to 0.018	0.266	0.003	0.003	-0.008 to 0.014	0.613
Occupation type							
Not employed	—				—		
Labour	-0.084	-0.135 to -0.034	**0.001**	0.022	-0.062	-0.113 to -0.011	**0.017**
Not labour	-0.008	-0.048 to 0.032	0.709	<0.001	-0.003	-0.045 to 0.039	0.884
TSK-11	0.006	-0.009 to -0.004	<**0.001**	0.041	-0.004	-0.007 to -0.001	**0.011**
PSEQ-2	0.011	0.006 to 0.016	<**0.001**	0.039	0.007	0.002 to 0.013	**0.007**
EQ5D index baseline	0.413	0.280 to 0.547	<**0.001**	0.072	0.372	0.239 to 0.504	<**0.001**

Number in model = 477, Adjusted R^2 = 0.15, — = Index reference for comparison, Significant finds are in **bold**

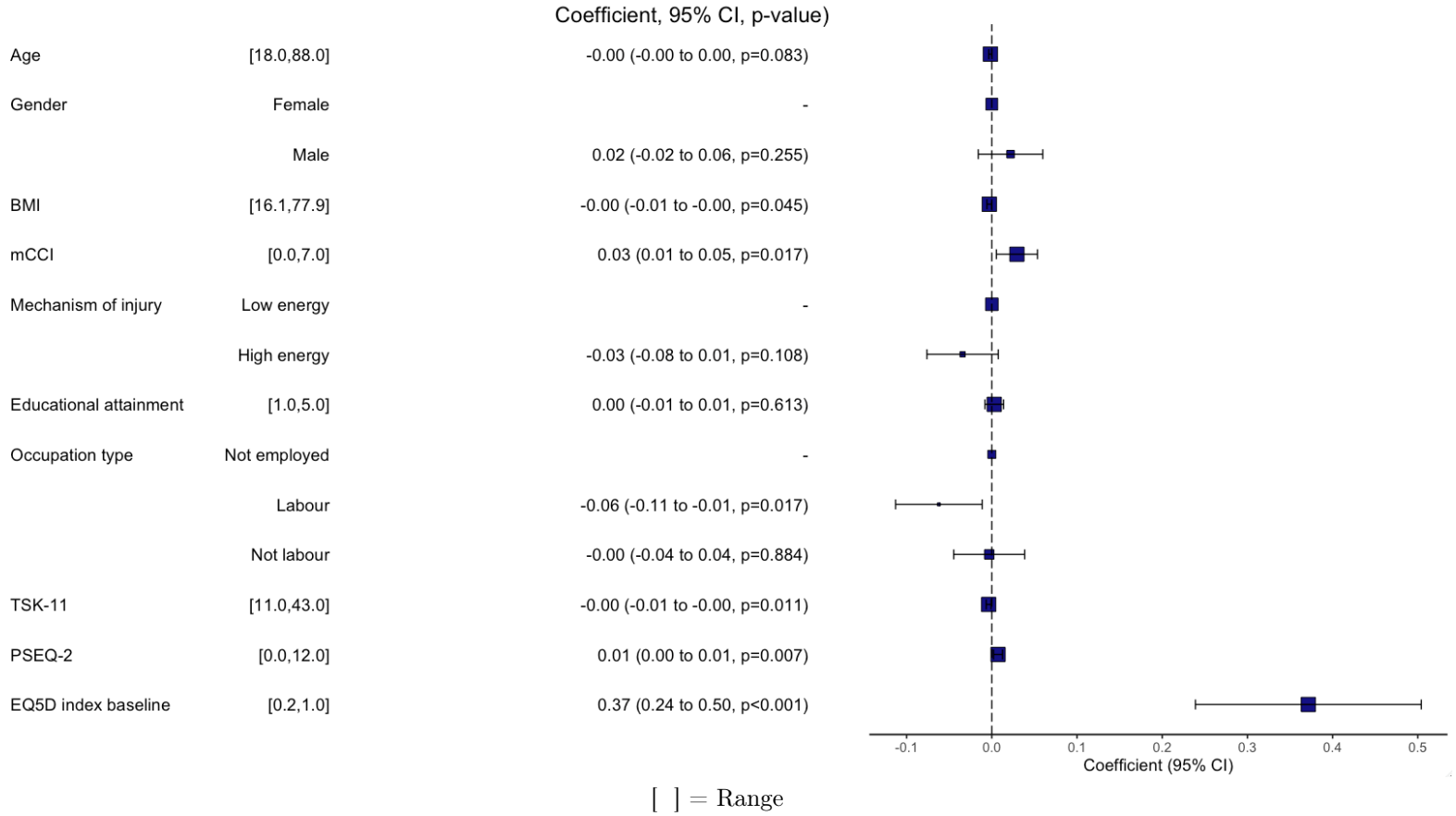


Figure 3.5: A plot demonstrating the vector of association for the adjusted multivariable analysis for the four-month EQ5D index model

Summary of strongest associations

Across functional outcome and quality of life, BMI, occupation type, fear of movement and pain self-efficacy had the strongest and most consistent association with outcomes. A higher BMI was associated with poorer outcomes (OMAS Partial R^2 = 0.024, p=0.001, EQ5D Partial R^2 = 0.016, p=0.006). Manual labour occupation (OMAS Partial R^2 = 0.009, p=0.042, EQ5D Partial R^2 = 0.022, p=0.001) and increasing fear of movement (TSK-11) (OMAS Partial R^2 = 0.054, p<0.001, EQ5D Partial R^2 = 0.041, p<0.001) were associated with worse outcomes. High levels of pain self-efficacy (PSEQ-2) were associated with better outcomes (OMAS Partial R^2 = 0.047, p<0.001, EQ5D Partial R^2 = 0.039, p<0.001).

3.4 Discussion

3.4.1 Interpretation

Pain beliefs

Pain beliefs at two weeks postoperatively were associated with functional outcome and quality of life four months after ankle fracture surgery. TSK-11 and PSEQ-2 accounted for double the variability in outcomes compared to other factors examined (excluding baseline EQ5D index in the EQ5D model and gender in the OMAS model). They were similarly associated with OMAS and EQ5D index. This is the first study to demonstrate this association in the ankle fracture population. However, the partial R^2 for these scores was substantially lower than those reported in the upper limb fracture population, which reported partial R^2s of 0.07-0.38 for TSK-11 and PSEQ-2 compared to 0.04-0.05 in the present study [34, 35]. This may be because the upper limb studies reported results from a single centre: there is

likely to be greater variability in population and healthcare factors across the 23 sites in this study.

Other variables

Age

Age was significantly associated with ankle function (OMAS in the multivariable analysis, but not in the univariable analysis). Age was not significantly associated with quality of life. This reinforces findings from previous studies [19, 20] that older patients have worse outcomes after ankle fracture surgery. However, the lack of association with quality of life may indicate that older patients are content to place less demand on their ankle for activities of daily living.

Gender

Male gender was positively associated with ankle function, but not quality of life. This association builds on the results from Keene et al [21] who had similar findings in patients aged 60 years and over. There was no clear association between pain beliefs or other demographic factors with gender, other than females were on average older, which may partly explain their lower functional scores.

BMI

Increasing BMI was associated with poorer outcomes, though this was less marked for the multivariable EQ5D index analysis than for the OMAS analysis. This may be because BMI has a greater association with baseline quality of life than it does with baseline ankle function: a patient with a high BMI should still be able to score highly or perfectly on the OMAS but may score lower on domains of the EQ-5D-5L,

either due to direct difficulties or due to indirect problems caused by comorbidities associated with higher BMI [100, 112]. Cardoso et al. [100] recently reported a 16-year retrospective cohort study that found that a higher BMI at the time of surgery correlated negatively with ankle function scores at an average of 11 years postoperatively (23% follow-up). Interestingly, BMI at surgery had a much stronger predictive effect than BMI at follow-up, suggesting this may have limited potential as a modifiable factor after injury.

Injury mechanism

Patients that sustained high energy transfer mechanisms of injury had significantly higher OMAS scores in the univariable analysis, but this trend reversed in the multivariable model (non-significant), likely because of the strong correlation with younger, fitter patients engaging in more high-energy activities.

Educational attainment

Educational attainment was not associated with functional outcomes or quality of life after ankle fracture surgery.

Occupation type

Working in a manual labour occupation was negatively associated with functional outcomes and quality of life. This is despite patients from manual occupations being younger and a higher proportion being male (factors which were positively associated with outcomes). No other factors explained this correlation, suggesting it is an independent risk factor for poor outcomes or that further factors need to be explored. This is the first study in the literature to report this association, though

a study by De las Heras Romero et al. [113] found that being self-employed correlated with poorer outcomes after ankle fracture surgery. A post-hoc analysis of the RAAFT cohort found that being self-employed was negatively associated with functional outcomes.

One theory could be that there is a socioeconomic disparity in ankle fracture outcomes, though this is not supported by the lack of correlation between educational attainment and functional outcome. Another possible explanation is that patients in manual labour occupations place greater demands on their ankle and are more aware of pain and impairments. This may particularly be true as their recovery may not be complete by the four-month time-point used as the dependent variable in these analyses.

These findings are contrary to those in the upper limb, where being retired or engaging with less occupational activity was associated with worse outcomes. However, Jayakumar et al. [34, 35] looked at the effect of workers' compensation claims and found a negative association with clinical outcomes, as supported by other studies in the literature [114, 115]. The RAAFT exploratory analysis did not collect data on worker's compensation or whether participants returned to their pre-injury occupation. In addition, occupational injuries are more common in manual labour occupations, which could interact with patient outcomes [116].

Comorbidities

Increasing mCCI was associated with improved functional outcomes and quality of life at follow-up. This contrasts to studies in the hip fracture population where mCCI has been associated with poorer outcomes [117].

3.4.2 Strengths and limitations

The key strengths of this study were the multi-centre recruitment and prospective data collection. This increases the external validity of the results and reinforces the findings from previous single-centre studies examining the impact of pain beliefs on musculoskeletal outcomes [34, 35].

However, only 26% of patients screened were recruited to the study. Of those not included, 932 (57%) were excluded due to the surgeon not believing the patient would benefit from early weight-bearing. Practically, this means that they had concerns that the ankle fracture fixation was not robust enough due to patient or operative factors, as discussed in Section 3.2.3. Those in the screening group had a similar gender mix but were older than the recruited population. This aligns with clinical practice, where poor bone quality is a common reason for not permitting early weight-bearing after ankle ORIF [8]. This may limit the generalisability of the findings, but in practice, this reflects the pragmatic, multicentre nature of the study, which should be considered a strength.

Of those recruited, there was a 15% loss to follow-up rate for the 4 month outcome, which was higher than the anticipated 10%. This compares favourably to another contemporary large pragmatic, multicentre study in the ankle fracture population that reported a 25% drop-out rate for four-month follow-up [11]. The power of the study was not affected as it over-recruited by more than the additional loss to follow-up, but this could potentially introduce bias as the loss to follow-up population could have been different to those included in the analyses. However, there were no differences in the baseline demographics of all recruited participants compared to only those that completed four-month follow-up. Patients lost to follow-up were

younger and more likely to be male and smokers, similar to findings from previous studies [118].

The overall model accounted for only 15% of the variability in outcomes, which indicates many other factors have not been considered. These might include injury classification, treatment factors, complications and weight-bearing status/ behaviour, as discussed in Section 3.2.7. Additionally, no internal or external validation of the models were performed. However, the purpose of this study was to explore individual factors useful for screening or modification rather than to create a full prediction model.

The choice of instruments to measure pain beliefs were abbreviated scales to limit participant burden. It is unknown if other or full scales would have yielded different or stronger associations. Reassuringly, however, there appeared to be good agreement between the TSK-11 and PSEQ-2 scores and their association with four-month outcomes.

Before PSEQ-2 or TSK-11 can be used as a screening tool, an agreed "pathological" cut-off needs to be established. These instruments have been used in the context of chronic painful conditions, for which several cut-offs have been proposed, mostly for full versions of the scores [119–121]. Jayakumar et al. [122] proposed a cut-off of ten for the PSEQ-2, which when combined with other clinical cues, had greater than 80% sensitivity (but low specificity) for detecting symptoms of depression and psychological trauma. However, this was in an elective upper limb setting, where the pain had likely plateaued rather than in an acute, traumatic setting, where symptoms usually improve [16]. Had a cut-off of ten been used in the RAAFT exploratory analysis, 319 (57%) of participants would have been considered to have unhelpful pain beliefs: this threshold may be impractical for screening and resource allocation

purposes. A number of methods are described for determining clinical cut-offs, including receiver operating curve (ROC) analysis or Bayesian methods, which may be useful approaches for future work in this area [123]. Additionally, determining the most suitable time point and setting for screening needs to be established, which is explored in Chapters 4 to 8 of this thesis.

As discussed in Section 3.2.7, it was not possible to include patients' weight-bearing group allocation or mediate for their self-reported weekly weight-bearing responses. Were this possible, this could have helped elucidate the mechanism by which unhelpful pain beliefs impact recovery, though this is explored qualitatively in Chapters 4 and 5.

3.4.3 Conclusions

Unhelpful pain beliefs collected at two weeks after ankle fracture surgery are negatively associated with patient outcomes at four-month follow-up. The strong and consistent association supports pain beliefs as a potential target for screening and modification. This research adds to a body of literature that advocates the use of abbreviated scales to measure pain beliefs [34, 35]. In turn, this increases their utility as potential screening tools that could be used in routine clinical practice. Biopsychosocial interventions are already in development to modify unhelpful pain beliefs in other areas of orthopaedic trauma [39, 124, 125]. This research suggests there may be utility in expanding to include patients recovering from ankle fracture surgery.

The other factors consistently associated with negative outcomes were BMI and occupation type. The correlation with BMI is clinically intuitive and may have limited scope for modification [100]. However, the finding that working in a manual

labour occupation is associated with poorer outcomes is a novel finding requiring further exploration. Several explanatory theories are discussed in Section 3.4.1, but discerning if this association is related to inequity in access to healthcare resources should be a priority as a potentially modifiable factor.

Chapters 4 to 6 investigate how patients' pain beliefs and social environments influence their behaviours after ankle fracture surgery. Their fears and uncertainties are explored to provide a more granular understanding of how factors such as pain beliefs and occupation influence their recovery and which elements could be supported or modified.

CHAPTER 4

Semi-structured interviews with patients after ankle fracture surgery

4.1 Introduction

Qualitative research in surgery and orthopaedic trauma is relatively sparse [126]. There are some notable examples within the last decade, often linked to large RCTs comparing a range of interventions, from surgical devices and strategies to different rehabilitation techniques [127–129]. Most of this research seeks to explore recruitment patterns, clinical equipoise and participants' experiences of interventions, with phenomenology and grounded theory being the most common analytic approaches [126]. Phenomenology aims to understand patients lived experiences of the world, and grounded theory centres on an inductive process which generates themes during analysis [130–132]. That is, these qualitative studies have aimed to describe and explore experiences rather than develop an intervention.

Atkins et al. provide a detailed framework for conducting behaviour change implementation research [45]. Behaviour change theory has grown in popularity, featuring in the MRC framework for developing complex interventions [40] and being used to develop and evaluate a wide range of healthcare interventions [133–135].

The qualitative methods used in BCW research often follow deductive or mixed approaches. This promotes identifying the target behaviour and then systematically identifying barriers and facilitators to change, which can be linked to intervention strategies through the BCW.

Qualitative and mixed methods research can help explore areas and theories that quantitative analysis alone cannot. An example pertaining to RAAFT is exploring patients' experience of returning to weight-bearing: quantitative research can ask if patients are in pain or even what time of day they are in pain, but a qualitative approach can probe deeper. For example, there is an anecdotal theory that it is painful when starting to walk after ankle fracture surgery [12]. However, the degree to which pain limits commencing weight-bearing and rehabilitation is unknown and, at present, remains an assumption. Throughout this chapter, these assumptions are challenged and investigated to understand what it is really like to recover from ankle fracture surgery and determine the barriers and facilitators to returning to everyday life.

4.1.1 Objectives

1. To explore patients' experiences of commencing weight-bearing after ankle fracture surgery.

2. To explore patients' priorities for recovery after ankle fracture surgery to inform a new rehabilitation intervention.

4.2 Methods

4.2.1 Study design

Qualitative semi-structured interviews with patients after ankle fracture surgery were conducted and reported in accordance with the Criteria for Reporting Qualitative Research (COREQ) checklist [136].

Researcher characteristics

I conducted all interviews, hereafter described as "the interviewer". Originally, it was planned for two RAAFT patient representatives to undertake training and conduct qualitative interviews also. This was to gain a broader range of perspectives and, in particular, to discuss topics that patients might not feel comfortable discussing with a surgeon, such as questions regarding trust in their surgeon and healthcare team. Unfortunately, full funding was not available, so this could not happen.

The interviewer was a white male undertaking a DPhil in musculoskeletal sciences at the University of Oxford, having taken time out from a trauma and orthopaedic training programme. At the time of the interviews, he had undertaken eight years of post-graduate medical training and continued to work clinically alongside his DPhil. The interviewer undertook formal training in qualitative research methods, undertaking a 5-day course, including mock interview practice. There were no personal or professional relationships between the interviewer and the participants, but the participants knew he was a trauma and orthopaedic surgery registrar undertaking a DPhil. There were no attempts to distance his clinical expertise, and informal clinical advice was given to patients who asked for it during the interviews.

Setting and sampling

All patients were recruited through the WAX trial; the eligibility criteria are discussed in Section 3.2.3. During recruitment to the WAX trial, participants were asked to indicate if they were happy to be contacted for a qualitative interview (Appendix B.1). Additionally, patients who were eligible but declined randomisation into the WAX trial were invited to complete a consent to contact form for a qualitative interview: this was to ensure the sample was maximally representative of an ankle fracture population. Additionally, patients who did not speak English as their first language, alongside an English-speaking relative, were invited to interview and provided with a £10 shopping voucher incentive to participate. This was to explore any health inequity non-English speakers may face and identify considerations for rehabilitation intervention design.

Patients who consented to contact were contacted by email and provided another PIS specific to the qualitative study. Interviews were conducted over the telephone or video call based on participant preference. A consent form was emailed to participants in advance and completed over the phone. Examples of the PIS and consent forms are included in Appendix C.1 and Appendix C.2.

Participants were invited to interview approximately eight weeks after surgery, shortly after they completed their six-week post-recruitment follow-up questionnaires. This was for three reasons: 1) By this time, it was anticipated that all patients would have returned to full weight-bearing and could discuss their experiences of doing so, yet it would be early enough to capture insights about their hospital treatment and experiences whilst non-weight-bearing. 2) It would not bias responses to patients' eight-week follow-up questionnaires. 3) Participants could be asked about

their experience of completing the eight-week follow-up questionnaire, using this as a chance to reflect on any other important outcomes they felt had not been captured. There was a risk that this could bias the four-month follow-up questionnaire responses; however, this was balanced against the risk of patients forgetting about their earlier experiences by four months. The proportion of patients interviewed was also expected to be under 10% of the total and balanced between treatment groups.

A purposive, maximum variation sampling strategy was used to ensure the spread of participant characteristics. The sampling strategy mirrored the predictors selected for the exploratory analysis discussed in Section 3.2.5:

- **Age:** Patients aged 60 years and over vs patients aged under 60 years.
- **Gender:** Male vs female.
- **Occupation:** Labour vs non labour occupation.
- **Pain beliefs:** PSEQ-2 scores of equal to or higher than eight vs scores lower than eight, based on mean results from previous studies [34, 35].
- **Site:** A spread of hospital sites to investigate differences in treatment and healthcare provision.

Interviews continued until two criteria were met: 1) thematic saturation was achieved and 2) an adequate sample accounting for the above variables was achieved. Therefore, ten interviews was the pre-specified minimum, with three further interviews conducted until no new themes were generated. Additionally, a minimum of three interviews per stratification factor were pre-specified (i.e. at least three participants over age 60 years, three male participants, three participants with manual labour occupations, three participants with PSEQ-2 scores equal to eight or over

eight and vice versa). There was no minimum number of participants per site, only as diverse a spread as possible whilst balancing the other stratification factors. This was in accordance with recommendations for conducting theory-based interviews [45, 137].

It was anticipated that interviews would be spread evenly throughout study recruitment. However, due to the COVID-19 pandemic and the study pause in March 2020, it was unknown if or when the WAX trial would re-open, so all eligible patients recruited before the COVID-19 pause were invited to interview. Practically, this is unlikely to have caused a problem because it allowed subsequent patients to be selected based on the maximum variation sampling strategy. A list of participant characteristics is provided in Table 4.3. Patient interviews were conducted between 31st March 2020 and 19th November 2021.

Approvals

Ethical approvals were obtained as described in Section 3.2.3 (Appendix G.1). The interviewer held an honorary contract with Oxford University Hospitals Trust (OUH) and obtained a research passport. The research passport was used to obtain a letter of access for participating sites. A list of approvals is included in Appendix G.2.

Data collection methods

An interview schedule was designed in three phases: 1) Initial questions were drafted with a research team, including an expert qualitative researcher with experience interviewing patients after ankle fracture. 2) Questions were piloted with two RAAFT PPI representatives. 3) Questions were mapped to TDF domains by the interviewer and reviewed by an academic health psychologist. Mapping interview questions to

the TDF helped ensure broad domain coverage and facilitated later coding and pairing of barriers and facilitators to intervention functions using the BCW.

During piloting with RAAFT PPI representatives, they recommended further exploration of participants' thoughts and concerns for the future and the influence of their family, friends and peers in their recovery. Table 4.1 shows the questions on the interview schedule mapped to TDF domains. The numbered domain labels correspond to the validated version of the TDF and are provided for ease of coding and recognition [47].

There was good agreement between questions and corresponding TDF domains between researchers. However, one area of uncertainty was "3. Social/ professional role and identity": originally, the question "What were your thoughts and feelings following the discussion with the surgeon/research staff?" had been coded to this domain. However, after discussion, this was instead coded to "11. Environmental context and resources", and it was agreed that "3. Social/ professional role and identity" was not relevant to behaviours in the context of returning to walking after ankle fracture surgery. Therefore, topics surrounding return to work or other social roles were instead coded into the "12. Social influences" or "9. Goals" domains (e.g. if patients' set themselves a goal or time-frame to return to work).

The interview schedule was updated iteratively to explore new themes generated during analysis; a copy is provided in Appendix C.3.

Recording

All interviews were audio-recorded using a password-protected recorder, anonymised and transcribed verbatim by the interviewer. In addition, field notes and a reflexivity diary were kept. Transcripts were not sent back to participants for comment. This

Table 4.1: Patient interview schedule mapped to TDF/COM-B domains

Domain	Description	Sample interview questions
Capability - Physical		
2. Skills	Ability or proficiency acquired through practice	What has helped you start weight-bearing? Prompts: strength/fitness How is learning to use the crutches/ zimmer frame?
Capability - Psychological		
1. Knowledge	An Awareness of something	Is there anything you would like to have known more about at that time or that you might tell someone else that has injured their ankle?
10. Memory, attention and decision processes	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives	What do you remember about what the research team told you about putting weight on your injured leg and the instructions you were given? How did that make you feel?
14. Behavioural regulation	Anything aimed at managing or changing objectively observed or measured actions	How do you monitor your recovery progress?
Opportunity - Physical		
11. Environmental context and resources	Circumstances of a person's situation/environment that affect behaviour	Have you experienced any difficulty in weight-bearing? What has made it difficult? What were your thoughts and feelings following the discussion with the surgeon/research staff?
Opportunity - Social		
12. Social influences	Interpersonal processes that can cause individuals to change thoughts/feelings/behaviours	What has helped you in your recovery? Prompt: Family
Motivation - Reflective		
3. Social/professional role and identity	Set of behaviours and qualities of an individual in social or work setting	Not applicable
6. Beliefs about consequences	Acceptance of the truth, reality or validity about outcomes of a behaviour in a given situation	Do you get pain when you weight-bear? How do you respond to that?
5. Optimism	Confidence that things will happen for the best or that desired goals will be attained	How do you feel you will progress in the future?
8. Intentions	Conscious decision to perform a behaviour or resolve to act in a certain way	How did you progress exercises?
4. Beliefs about capabilities	Views about one's ability/talent/capability to perform the target behaviour(s)	What has it been like getting back to putting weight on your injured ankle since your injury? What stopped you walking straight away?
9. Goals	Mental representation of outcomes or states that an individual wants to achieve	What activities do you hope to get back to?
Motivation - Automatic		
13. Emotion	Complex reaction pattern by which individuals attempt to deal with a personally significant matter or event	Were you worried about anything when you started to weight-bear or during your recovery?
7. Reinforcement	Increasing the likelihood of a behaviour being performed by establishing an association between performing a behaviour and a given stimulus or cue	What has helped you in starting to weight-bear and your recovery? Prompts: Physio/ encouragement

The shaded rows correspond to the COM-B domains. The numeric labels correspond to the TDF domains.

was primarily to reduce the burden on participants, who would continue to complete the WAX trial follow-up questionnaires and later be invited to a discussion workshop.

4.2.2 Analysis

Qualitative data were managed using NVIVO [138]. Data were analysed using a combined deductive and inductive approach based on the framework approach [139]. This approach has been used extensively in previous BCW research and facilitates the translation of interview responses to implementation options during subsequent intervention design [45, 83].

Deductive coding

The interviewer reviewed each transcript and broke paragraphs down into individual utterances, defined as a phrase or chain of dialogue expressing a single concept. Utterances were deductively coded into the COM-B and TDF domains they most closely represented. The coding framework was reviewed and amended by an academic health psychologist to assist in robust coding according to the TDF. A third researcher independently coded a 10% sample of transcripts to assess coding reliability. Disagreements were settled by discussion, and the coding framework was updated accordingly.

Inductive coding

A thematic analysis was then undertaken using established methods described below [45, 140]. Utterances which had been deductively coded into their respective COM-B and TDF domains were reviewed and grouped into inductively labelled themes or "belief statements". A belief statement is "a collection of responses with a similar

underlying belief that suggests a problem and/or influence of the beliefs on the target implementation problem" [45]. Belief statements were presented as barriers or facilitators to the target behaviour; returning to weight-bearing and progressing with recovery after ankle fracture surgery. Statements were presented with frequencies related to the number of individual patients that gave an utterance coded into the respective belief statement. This was not intended to provide precise quantitative measurement for analysis because the interview guide was flexible, and not every patient was asked the same set of questions. Quotes were provided to illustrate themes with their corresponding participant (P) number [141].

Target themes and beliefs for future intervention development were selected based on three criteria: (1) frequency of specific themes/beliefs, (2) presence of conflicting beliefs, and (3) evidence of strong beliefs that may affect the target behaviour [45, 142].

4.3 Results

4.3.1 Interview participants

506/562 (90.0%) of recruited patients consented to be contacted for a qualitative interview. Forty-two were invited to interview, of which 25 agreed. Twenty-five patients that declined participation in the WAX trial consented to contact for a qualitative interview. Of these, ten were invited to interview, and four agreed. Overall, 29 patients were interviewed. Occupation and PSEQ-2 scores were unavailable for the four patients not enrolled in the WAX trial. Interviews were conducted with patients from 13 different sites; a summary is provided in Table 4.2. The mean age of participants was 49 years (SD 14), and 18/29 (59%) were female. 15/25 (60%)

Table 4.2: Patient interview sites

Site	**N = 29**
Maidstone and Tunbridge Wells Hospital	6 (21%)
Royal Berkshire Hospital Reading	4 (14%)
Royal Victoria Hospital Belfast	4 (14%)
Royal United Hospitals Bath	3 (10%)
East Surrey Hospital	3 (10%)
Dorset County Hospital	2 (6.9%)
Cardiff and Vale University Health Board	1 (3.4%)
Royal Derby Hospital	1 (3.4%)
Royal Preston Hospital	1 (3.4%)
Southampton General Hospital	1 (3.4%)
The Princess Alexandra Hospital Harlow	1 (3.4%)
The Royal Cornwall Hospital	1 (3.4%)
University Hospital Coventry	1 (3.4%)

were employed, of which 3/15 (20%) were in manual labour occupations. The mean PSEQ-2 score was 7.6 (SD 3.7) and 14/25 (56%) had a PSEQ-2 score of eight or higher. Interviews took place a mean of 64 days post-surgery (SD 7) and lasted a mean of 32 minutes (SD 7). A summary of interview participant characteristics is provided in Table 4.3, the site is omitted to preserve anonymity.

Table 4.3: Interview participant characteristics (Patients)

Interview ID	WAX participant?	Age (years)	Gender	PSEQ-2 score	Occupation	Days post-surgery	Interview duration (mins)
1	Yes	30	Female	12	Sedentary	73	21
2	Yes	34	Female	12	Sedentary	65	30
3	Yes	34	Female	10	Sedentary	72	26
4	Yes	30	Female	4	Sedentary	65	24
5	Yes	60	Male	11	Not employed	64	35
6	Yes	68	Female	4	Not employed	60	34
7	Yes	50	Female	3	Sedentary	63	35
8	No	44	Female	NA	NA	66	30
9	No	20	Female	NA	NA	63	36
10	Yes	63	Female	10	Intermediate	61	36
11	Yes	37	Male	9	Not employed	66	46
12	Yes	41	Female	0	Intermediate	60	33
13	Yes	32	Male	8	Intermediate	63	32
14	Yes	63	Male	2	Not employed	62	36
15	Yes	41	Male	4	Sedentary	60	24
16	Yes	47	Female	6	Intermediate	59	25
17	Yes	67	Male	12	Not employed	62	32
18	Yes	68	Female	8	Not employed	68	39
19	No	59	Male	NA	NA	57	43
20	Yes	65	Female	12	Not employed	63	32
21	Yes	35	Male	12	Labour	69	24
22	Yes	69	Female	5	Not employed	56	39
23	Yes	56	Male	8	Sedentary	74	42
24	Yes	52	Female	6	Intermediate	69	22
25	Yes	43	Female	4	Not employed	63	25
26	Yes	68	Female	10	Not employed	64	40
27	Yes	42	Male	12	Labour	76	36
28	No	37	Male	NA	NA	85	26
29	Yes	57	Male	6	Labour	49	19

4.3.2 Deductive coding to the COM-B and TDF

This section discusses the results for the deductive coding of interview utterances to the COM-B and TDF domains.

Double coding

The Kappa value for the double coding was 0.54, showing moderate agreement between researchers for the coding of utterances into TDF domains [45, 143]. The most prominent areas of discrepancy in coding are discussed below. The discussion of discrepancies is intended to provide transparency in coding and reporting [45]. The numeric domain labels correspond to the validated version of the TDF [47].

Coding discrepancies related to the "2. Skills" domain

One of the most common difficulties when using the TDF is that it lacks an explicit category for symptoms or physical experiences. This has perhaps been less obvious in previous healthcare literature using TDF because most have explored healthcare professionals' behaviours, rather than patients' behaviours, as reflected in the examples quoted in the guide by Atkins et al. [45, 133]. The inflexibility of the TDF has also been noted in a rapid review by McGowan et al., highlighting the importance of remaining flexible during coding to ensure all relevant content is coded [144]. Accordingly, the solution was to code physical symptoms into "2. Skills", this was because when the TDF is mapped onto the COM-B model, "2. Skills" is mapped under the "Capabilities - Physical" domain of COM-B. Discrepant examples regarding the "2. Skills" domain included the following:

6. Beliefs about consequences

The quote 'I think weight-bearing helps take off the strain from your arms and your hands on the crutches' (P2) was recoded as "2. Skills". This is because while the patient felt there was a causal relationship between weight-bearing and strain elsewhere, it was the activity and the change in physical symptoms that was the dominant aspect of the utterance. Examples of statements coded to "6. Beliefs about consequences" are given in Table 4.7.

7. Reinforcement

Similar causal confusion occurred in the "7. Reinforcement" domain. For instance, it could be interpreted that the quote 'I think five or ten minutes was the maximum amount of time I could stand up and walk around before I had to sit down and elevate again' (P2) represents a reinforcement that the behaviour of walking causes discomfort and the need to sit. In this context, it was agreed to code it as "2. Skills", because the quote conveyed more of an issue with physical limitations or "Capability - Physical" as per the COM-B. An example of "7. Reinforcement" would constitute the finding that the behaviour of increasing walking improved mood.

8. Intentions

The second researcher coded the quote 'So I walked out and said I'm comfortable now so let's go' (P9), as "8. Intentions". It was felt that this quote related to the patient's experience of their symptoms, rather than intentions. Intentions might relate to a plan to perform a certain activity or behaviour, in order to achieve a goal.

13. Emotion

In some cases, there was disagreement between patients' responses to symptoms. A quoted example included 'I used to get quite bad pins and needles in my toes with all the nerves were coming back in' (P9). It was felt this was better coded as "2. Skills" than "13. Emotion", because it discussed the symptoms, rather than the emotional effect they had on the patient.

Coding discrepancies related to other domains

3. Social/ professional role

As discussed in Section 4.2.1, "3. Social/ professional role" was felt to be rarely relevant to a patient's recovery. Originally, the second researcher coded 'I play hockey so going back and ready for Hockey season is one of my own main aims' (P9) into this domain, but it was felt this related better to the "9. Goals" domain.

There was debate around the quote 'Because I'm wanting to see a proper physio at some point' (P5). It was felt this did not refer to the patient's social or professional role, but instead was a reference to the healthcare team, which was better coded as "11. Environmental Context/ resource", as discussed in Section 4.2.1.

12. Social influences

There was debate around statements when patients discussed their ability to navigate their work or home environments. For example, 'I said I can't live without my foot for another six weeks. Especially at University. Because I live on the third floor of my house and it was just getting a bit complicated' (P9). It was felt such statements corresponded better to the physical environment rather than the social environment and so were coded as "11. Environmental context/ resource".

4.3.3 Belief statements

The belief statements in this section are summarised under their respective TDF and COM-B domains.

Capability - Physical

Table 4.4 shows the belief statements and frequencies within the Capability - Physical domain.

2. Skills

Physical concerns

Patients expressed a range of physical concerns. The most common concerns were swelling around the ankle and ankle stiffness. Other common concerns were wound healing problems and tingling around the wound: 'I was having sort of strange symptoms sort of I think it was nerve tingling in the wounds. Every time I flex my ankle I was getting sort of nerve tingling' (P14). Two patients reported delays in receiving medical attention for a wound infection and described the toll of the physical and psychological setbacks:

> So when it was red, shiny and puffy and I thought you know, I'll speak to the doctor. But it just took me a long time to get an appointment to be honest. I did try on the Friday. And then on Monday and then I think finally got to see someone on Wednesday. (P21)

> I actually managed to open the wound up again, and I got an infection...So it really set me back to almost as bad if not worse as the day after the operation to be honest. The infection was really really tough. (P28)

Two patients expressed concerns about other injuries, referring to concomitant or existing injuries.

> My only, it's probably nothing to do with your particular field, but my only slight issue. Is because of how I broke the ankle. I've done many years of road running and I have a bit of a dodgy knee and it collapses. It collapses a few times and then I broke my ankle (P17).

One patient was concerned about intermittent discolouration of their ankle.

> The only problem I had was not swelling as such, but I need to keep my foot in the air otherwise my toes go purple but that only lasted probably about ten days after the cast was removed (P12).

Pain experience

Patients were asked if they got pain at the precise moment their foot made contact with the ground and their body weight went through their ankle: a higher proportion of patients reported that they did not. Similarly, in most cases, pain was not a prominent feature that limited patients' rehabilitation progress. There were, however, exceptions, with patients struggling with pain: 'Yes significantly more painful. I couldn't walk. It's more painful if the leg is down. If it's elevated that takes away the pain' (P7). 'Yeah, it's the pain that is stopping me. Stopping me walking properly' (P22). Two patients found pain at night was a prominent feature.

Weight-bearing experience

The majority of patients had a preference to commence weight-bearing earlier. Participants typically had negative experiences with non-weight-bearing, and it even brought on 'a bout of depression' (P21) in some. A loss of independence was common, and reliance on crutches also produced aches elsewhere in the body, such as the hands and back. Often patients lacked the strength to use crutches and had to use a wheelchair during their non-weight-bearing period. In many cases, they felt it

was safer to walk without using crutches. Some patients reported an episode where their crutches would slip, and they would land heavily on their injured ankle.

> One day I slipped on the crutch. I had to stop myself with my broken ankle so my right leg. Which annoyed me and that was when I bought the wheelchair to be honest. (P21)

> I was really unsteady on my crutches...I didn't feel safe at all. (P24)

Participants reported balance difficulties which made activities of daily living (ADLs) difficult: 'I was quite scared at the start. I was very aware. With falling with doing that. And I was a bit wobbly' (P18). The simple act of putting their foot down lightly for balance made life easier for many: 'I might have put my foot down like when I was brushing my teeth and standing at the sink' (P19).

Most found that once permitted to weight-bear, it was a relatively straightforward and intuitive process. A common theme, from advice patients received from healthcare professionals (HCPs) and reflections from their own experience, was that building up weight-bearing gradually over time was the best way to approach it. However, many felt they would have liked more advice, skills training or resources to support them:

> The first couple of days I didn't do much because I didn't really know how much, I didn't really know how to go about weight-bearing. (P16)

> I remember thinking after that two-week appointment I probably should have been given more information and what I should have done is even try some partial weight-bearing there. (P11)

Another theme was the feeling that the longer patients spent non-weight-bearing, the harder it was to commence walking normally:

> Obviously coming to the sixth week of being immobile and then not moving at all to then start moving was harder than if I've been weight-bearing all the way through. (P13)

> Trying to coordinate yourself I think isn't easy when you've got used to not using the foot. (P2)

Patients generally found that returning to driving was a straightforward process:

> Driving was much easier than walking for me, because one of the exercises...Well I would call them good toes, naughty toes, with light pointing and then raising your toes and then I could do that no problem. So driving was a breeze really. (P3)

Table 4.4: Beliefs statements mapped to the TDF/COM-B domains: Capability - Physical

Barriers	Count	Facilitators	Count
CAPABILITY - PHYSICAL - 29			
2. Skills - 29			
Physical Concerns			
Swelling	22		
Stiffness	11		
Nerve tingling	4		
Wound healing problems	4		
Muscle wasting	2		
Other injuries	2		
Athletes foot	1		
Skin colour changes	1		
Pain experience			
Pain related to weight-bearing	3	Pain not related to weight-bearing	19
Pain limiting rehabilitation progress	7	Pain not limiting rehabilitation progress	18
Pain at night	2		
Weight-bearing (WB) experience			
Difficulty NWB - loss of independence	14	Patients experienced a gradual build-up of WB and exercises	19
Would have liked additional skills training for increasing WB	13	Increasing WB was quick & straight forward	17
Prolonged NWB makes WB harder once allowed	8	It's easier & safer to walk without using crutches	14
Limited standing & walking time	6	Re-learning to drive is easier than walking	12
NWB produces aches elsewhere in the body	8	Told to WB for balance which was helpful	6
Balance difficulties	7	Patients are able to adapt to NWB	2
Patients had to "learn to walk again"	3	Important to stay active whilst NWB	1
No strength to use crutches	5		
NWB causing depression or low mood	2		
Preference for delayed weight-bearing (6 weeks post-op) (DWB)	2	Preference for early weight-bearing (2 weeks post-op) (EWB)	25
A preference for neither WB group, prefer to find own way	1		

Capability - Psychological

Table 4.5 shows the belief statements within the Capability - Psychological domain.

1. Knowledge

A prominent uncertainty was knowing if symptoms that patients were experiencing were a normal part of recovery or a cause for concern: 'It sort of goes a red and pink mottled colour I'm not sure if that is normal' (P14). 'It would have been helpful to know that if you develop complications, then here's someone you can contact; these things are normal and to be expected or not so' (P2). Similarly, not knowing what to expect during their recovery was an issue for many patients.

> I wasn't really told, the doctors were obviously incredible at the hospital but given that they can't really give you any like sure sure advice I just had no idea what the recovery would be like. (P1)

Many patients could draw on knowledge from previous injuries and family and friends. A common finding was that when patients were provided with information resources, they found them of limited benefit because they did not know if the resources were specific and suitable for their individual circumstances.

> The funny thing is, is it there are people who break their ankle who are in their eighties that might be quite frail and then my people that are young and they may have different needs. (P11)

> I've read that, but I'm just nowhere near when they say week five or week six. You can do this and that. I'm just nowhere near that. (P24)

Many expressed a desire to be provided with times-frames for when to start weight-bearing, exercises and returning to life roles. Some specific areas of uncertainty were not understanding what weight-bearing means:

> I had a question about how much weight can I put on for me. And I wasn't really given a really good answer on it. (P2)

> I didn't know what walking on it means. Walking on it with crutches can mean. You know? How much weight do you put on it? I had no idea. And that's why I didn't do it. I literally had almost no guidance on what I should, or I shouldn't do...And the other thing was it wasn't clear to me about what was meant by weight-bearing so I just took that to mean basically putting any weight on your foot, not necessarily getting your foot completely flat to the floor or weight-bearing without your crutches. So just yeah I assume that to mean assisted weight-bearing if that makes sense. Yeah, it was a bit ambiguous. I feel like other people's interpretation of what that means would be different. (P28)

Another area of uncertainty was about knowing when to progress rehabilitation exercises, particularly when exercises were painful.

> What I'd kind of like to know and I might give the physio a ring: should I endure that pain and work at it or should I obey pain and stop working at it if you see what I mean? (P5)

10. Memory, attention and decision processes

Some patients felt overwhelmed when they were given information in clinic.

> I wasn't really completely paying attention, or I can't actually remember many instructions that I was given in terms of weight bearing. I don't think I actually asked enough questions because obviously, I was still in a bit of shock. So I probably just didn't think to ask enough questions myself. (P8)

Others remarked that providing information on the hospital ward, pre or postoperatively was an excellent time to give written information because they 'didn't have much else to read at the time' (P9).

Most interview participants received a paper WAX exercise booklet with a Specific, Measurable, Achievable, Relevant and Time-bound (SMART) diary at the

back. This feature was intended to help patients track their recovery and plan and attain their goals. While some patients initially engaged with the diary, few participants continued.

> Oh yeah, yeah I never used the diaries and things - Two days I was pretty good about ticking off everything and then it sort of drifted because I was busy doing other stuff. Once I was, you know, getting about. (P20)

> Well I did start it if I'm honest, but no, I didn't get very far, and I think I can't go back and find this piece of paper every time; I'll do it on my phone. (P26)

Many patients struggled to remember to do their daily physiotherapy exercises; some found that associating it with parts of their daily routine was helpful: 'I started to do the exercises then when I was standing to brush my teeth' (P3).

14. Behavioural regulation

When it came to judging how and when to start weight-bearing, more than anything else, it was patients' trust in their own body that helped regulate their behaviour: 'I just think the body tells you. The body tells you when you're ready' (P10).

Table 4.5: Beliefs statements mapped to the TDF/COM-B domains: Capability - Psychological

Barrier	Count	Facilitator	Count
CAPABILTIY – PSYCHOLOGICAL - 29			
1. Knowledge - 28			
Uncertainty if resources are patient-specific	16	Patients would like timeframes for weight-bearing (WB) & exercises	6
Not knowing what to expect	10	Knowledge from family & friends	6
"Is this normal?" e.g. their experience of recovery/ swelling etc	8	Knowledge from previous injuries	5
Should patients push through pain or not during rehab?	8	Knowledge from healthcare professionals	1
Uncertain what weight-bearing (WB) means	7		
Unsure when to use the orthotic boot	4	.	
Lack of additional advice (e.g around swelling or wound management)	4		
When to start driving	3		
Airport metal detectors	2		
When to take analgesia	1		
When to return to work	1		
When will syndesmosis screw break	1		
Lack of weight-bearing (WB) advice – it's up to the patient	1		
10. Memory, attention and decision processes - 15			
Didn't use or got bored of the SMART diary (in the exercise booklet)	11		
Struggled to remember to do physio exercises	4	Doing physio as part of a routine (e.g. brushing teeth)	2
Information overload during appointments	3	Give information postop on the ward - lots of time to read	1
14. Behavioural regulation - 14			
		Trust your body	14

Motivation - Automatic

Table 4.6 shows the belief statements within the Motivation - Automatic domain.

13. Emotion

When coding emotions that influenced weight-bearing behaviour after ankle fracture, negative emotions of fear and anxiety were the most prevalent. The most common area of anxiety related to a fear of damaging the ankle, resulting in long-lasting disability or the need for further surgery: 'I was absolutely terrified I would slip or fall and do some further damage' (P12). 'Being through an operation and if you've got through a healing process and you're like ohh well I don't want to go through this again' (P8).

In many cases, it was not pain itself but the fear of pain that limited weight-bearing in the early stages of recovery: 'It's just getting over the psychological, and possibly more the psychological and also the fear of pain, of course.' (P26). The longer the period of non-weight-bearing, the greater the anxiety in some cases:

> It was quite frightening at first. When you've been in the cast for a few weeks and then you get transferred into the boot...it is quite frightening because it's been protected and you know your ankle has been fixed, but you feel worried. (P25)

Patients reported fear of re-injury when in the same situation as their original injury:

> I was reluctant to get up and go to the toilet for three or four weeks. Partly because of the fall I had. Because it was actually when I was going to the toilet that I fell. I just don't want to do it again... Without overcooking it I've got a little bit of mini-PTSD and every time I walk through that door into the lounge I'm having flashbacks. (P5)

Along a similar theme, many patients were anxious about being outside the safety of their house: 'I don't want to go out on a walk and get stuck halfway and

realise I can't get home' (P9).

7. Reinforcement

Reinforcement relates to the outcome of a behaviour giving positive feedback to promote further performance of the behaviour, in this case, weight-bearing and ankle exercises: 'It was actually quite satisfying feeling my foot having a bigger and bigger range of movement' (P11).

Table 4.6: Beliefs statements mapped to the TDF/COM-B domains: Motivation - Automatic

Barrier	Count	Facilitator	Count
MOTIVATION – AUTOMATIC - 20			
	7. Reinforcement - 2		
		Reinforcement of progress	2
	13. Emotion - 20		
Anxiety of causing damage to ankle & re-operation	13		
Anxiety rather than pain is a limitation to WB	10		
Anxiety of WB after some time	6		
Fear of re-injury in the same situation	6		
Fear of being away from a safe environment	4		
Fear of not knowing what's normal e.g. pain	3		
Anxiety about going home	1		
Fear of falling	1		
Fear of ongoing pain	1		

Motivation - Reflective

Table 4.7 shows the belief statements within the Motivation - Reflective domain.

3. Social and professional role and identity

As discussed in Section 4.3.2, no utterances were coded into the social and professional role and identity domain.

4. Beliefs about capabilities

Ability to judge when to progress rehabilitation

The most common finding was that patients felt that it was confidence that was the primary barrier to commencing weight-bearing:

> I know once I got over the initial apprehension of putting my foot down expecting it to hurt and know it was fine, absolutely fine... It's probably a confidence thing. (P22)

Several patients reported "Eureka" moments when they found themselves inadvertently weight-bearing, often in the shower, which then gave them the confidence to try in other situations.

> For instance, I had my first shower, which was the first time I actually stood up on both feet without any shoes or anything on. And I was like oh okay I can put weight on both feet, and I don't feel like I'm overcompensating on one foot or anything. So let's see if I can start walking without the crutches. I think that was kind of the given moment when I sort of stood up in the shower and realised I could comfortably stand on both feet. (P9)

For progressing rehabilitation beyond the initial decision to commence weight-bearing, patients felt that it was often self-efficacy that drove their progress; 'mind over matter I think' (P6). There was a feeling that pain was to be expected during recovery but to optimise recovery 'it is important to push yourself a little bit' (P12). However, many patients felt that they lacked the capability to make this judgement: 'Because I didn't know whether I was causing more damage or not doing enough' (P27).

Interaction with healthcare professionals (HCPs)

There were various examples where the behaviour and comments from HCPs influenced the patient's beliefs in their capabilities. For example, pessimistic or off-the-cuff comments from HCPs about the severity of patients' injuries could often limit their expectations and their ability to progress their recovery:

> Because my break was a particularly bad one...The orthopaedic surgeon that fixed my leg kindly phoned to see how I was getting on. And that was during the sixth week he rang. And I said to him that I was frustrated that it wasn't getting better and that I wasn't fully able to move. And he said that he wasn't surprised with my particular break. He said that it could take up to three months in total. (P7)

Conversely, when HCPs made optimistic or encouraging comments, this often bolstered patients' belief in themselves.

> They said no no carry on no this is good, this is good and it is strong fixation, it will be fine. So again it was just a confidence thing in my head. So I was like okay, I trust you, I will do this. (P19)

There also appeared to be a perceived benefit of being shown their X-rays. Patients seem to respond positively to seeing and understanding the metalwork that was holding their ankle bones in place, demystifying and quelling the anxiety of the unknown: 'It was reassuring to have the X-ray...seeing that it was all in place gave me confidence, the confidence not to worry about it' (P12).

5. Optimism

Most patients felt optimistic about their recovery and that, in time, they would make a good recovery: 'I feel confident that my ankle will get back completely to normal' (P1).

6. Beliefs about consequences

Beliefs

Patients held a range of beliefs about the consequences of their behaviours. A common belief was that excess weight-bearing or activity could cause further damage to their ankle: 'I'm far too scared to go out and just run, to think that I would mess it up completely' (P9). Similarly, there was a feeling that non weight-bearing (NWB) allows the ankle to settle and heal: 'I was quite relieved that I was in the delayed group just because my preconceived ideas of you should really leave it' (P25). Conversely, some felt that early weight-bearing (2 weeks post-op) (EWB) improves healing and reduces stiffness:

> With weight-bearing and I think I've recovered quicker and I have. I think if I had been non-weight-bearing the movement will have been pretty much; it was obviously quite stiff to start off with, but I can't imagine what it would have been like. I mean, it would have taken a lot longer. (P27)

Expectations

Not knowing what to expect during recovery was a common theme and most patients felt that their weight-bearing and rehabilitation progress was slower than they had expected: 'It's a lot slower than I thought it would be' (P16). Where HCPs had given advice about what to expect, this was usually welcomed and reassuring for patients:

> When I started to weight-bear, it did swell a lot more than it had been. But actually, the consultant in the hospital did say it would swell, and just to elevate it. So I took some guidance from that. (P25)

8. Intentions

There were no utterances coded into the intentions domain. This is potentially because of overlap with the goals domain.

9. Goals

The desire to return to sports and hobbies was the most common goal that patients would work towards. Returning to work and driving were also common shorter-term goals. Many patients integrated exercises into their daily routine as a means to reach their goals and some used technology to assist them:

> The exercises I'm doing. I'm doing three times a day. And I'm walking without the crutches now for 20 minutes or so. And I do that five times a day. I've got it on my phone. It pings me if I haven't done it. (P26)

Breaking goals into smaller steps and increasing gradually was also common:

> I'm trying my best to set little goals for myself like this week, I was trying to do more only using one crutch and then maybe doing a few steps without any crutches. (P25)

Having an exercise booklet with graded tasks over time was helpful for many: 'You can see what you need to be doing and what your targets are' (P7). Conversely, some patients were in no rush to push their recovery as they had no specific goals to achieve:

> I'm 69, so I have no burning need to get back to any work. You know, for instance, and I haven't gotten any, I've got no children that I'm running around after, so my circumstances are such that I haven't had any great push to get on and get things done quicker other than just really wanting to get back to a normal life. (P26)

Table 4.7: Beliefs statements mapped to the TDF/COM-B domains: Motivation - Reflective

Barrier	Count	Facilitator	Count
MOTIVATION - REFLECTIVE - 27			
3. Social & professional role and identity - 0			
4. Beliefs about capabilities - 27			
Ability to judge when to progress rehabilitation			
Confidence as the main barrier to WB	17	Self-efficacy driving rehabilitation progress	12
Lacking capability to balance the risk of making worse with excessive rehabilitation	4	Eureka WB confidence moment (e.g. standing in the shower)	5
Setbacks hindering confidence for progress	2	Knowing what to expect helped recovery	1
Tendency to overdo it	2		
Being too cautious with rehabilitation	1		
Frustrated by pain impairing progress	1		
Interaction with healthcare professionals			
Pessimistic comments from HCPs negatively affecting capabilities	11	Value in seeing their own X-rays	12
Indifferent to seeing their X-rays	1	Positive affirmations from HCPs encouraging patients	7
5. Optimism - 7			
Unrealistic optimism/ expectations	1	Optimism for recovery	5
Pessimism	1		
6. Beliefs about Consequences - 17			
Belief that behaviour will cause damage to ankle	6	Belief that NWB allows more healing	2
Belief that NWB worsens stiffness	3	Belief that EWB speeds bone healing	1
Belief that long-term swelling will impede future function	1		
Expectations			
Slower WB progress than expected	6	WB sooner than expected	1
Slower rehabilitation progress than expected	4	Resources guiding expectations	2
No expectations	2	Knowing what to expect from HCPs is helpful	1
Not knowing what to expect	1		
8. Intentions - 0			
9. Goals - 11			
How to reach goals			
		Routines to reach goals	6
		Seeing future exercises in a resource to set as a goal	3
		Small step by step goals	3
		Setting progressive distance goals	1
Important goals			
In no rush to push recovery	1	Return to sport & hobbies as a long-term goal	14
		Commuting to work	4
		Getting back to driving	2

Opportunity - Physical

Table 4.8 shows the belief statements within the Opportunity - Physical domain.

11. Environmental context and resources

Difficulties with activities of daily living (ADLs) whilst NWB

The most common problems people faced were preparing and carrying food and drink, aswell as showering: 'You couldn't carry anything and cooking was obviously a nightmare' (P28). 'Frankly, I didn't actually shower for about three weeks. I just did a flannel wash coz I couldn't get in the shower' (P26). Difficulty with stairs and feeling unsteady on uneven ground were also common problems.

Patients came up with various solutions and adaptions to make tasks easier and aid their recovery, from purchasing bed pans and wheelchairs to exercise bikes and stretching aids. Organisation was also key:

> And kind of simple things probably it's more around the layout of your house is actually just getting the stuff, the right stuff you need. Enough pillows to elevate your foot. And the simplest things were the most challenging I think. (P8)

Some patients struggled to obtain the equipment they needed:

> Getting the wheelchair. I tried to rent one and. Because I didn't have any ID. What are the charities like the Red Cross? And mobility places. None would rent me because I didn't have any ID. (P21)

Orthotic boot experience

Most patients preferred the freedom of being placed into a boot rather than a plaster cast. Though some, particularly older patients liked the security of a plaster: 'Now the plasters off. I'm very... very fragile. I'm worried about doing it again, to be honest' (P5). Other issues with the boot were that it seemed excessively heavy and caused problems with unequal foot heights when walking:

> I quickly realised the issue was that my boot itself had quite a thick sole. And my shoe on the other foot was quite kind of normal, so it was sort of if one shoe was much you know, kind of one leg was longer than the other. So I think that stopped me being able to put my left foot as far forward as I would otherwise have done. So I actually did look up on the Internet and found there are companies that sell this thing called well I think there are different ones, but the one I got was the brand name was "even out". It's something you can put on the bottom of your other shoe, so it sort of straps onto your shoe and just makes it better. So I bought that, it was only £15 or something and it made things much much easier. (P11)

Some patients also found that the boot irritated their surgical wound or made their foot sweat, particularly in hot weather. One patient reported removing all supports and starting to walk in bare feet within two weeks postoperatively.

Information resources

Patients found the WAX advice booklet helpful and often they were happy to forgo additional clinical visits as a result:

> If I hadn't had the booklet I would have wanted, I would have felt frustrated that I didn't know what I was doing in order to make you know have the full potential of rehabilitation. I think instead of the booklet I would have wanted to see a physio. But actually given the choice, if someone said well here's a booklet, I would have been, and particularly the booklet that I was given: that makes far more sense than going to weekly physio appointments. That you have the instructions there with you. (P7)

Patients that didn't receive a booklet felt a desire for additional information: 'Even just a little leaflet would be good. A little leaflet. To say you're getting back on your feet, the does and don'ts' (P28).

The Internet was a common source of additional information, but many patients felt wary about online blogs and videos and had a desire for credible online resources:

> I had a quick look on the Internet really, but I'm a bit worried about Internet things that you see on the Internet about exercises, and then you know how reliable they actually are. (P22)

Despite a desire for additional support, many felt the need to cope 'without wanting to pester the NHS at this time' (P8). COVID-19 may have contributed to this feeling, but the idea of not wanting to overburden NHS resources remained a prevalent finding. Some patients were already using mobile phone Applications (Apps) for various reasons, most commonly to track exercise activity and give reminders. There was also a desire for a bespoke recovery App:

> I think again with the App that would be such a good idea...Because that's what we're doing now, even with all sorts of lessons online and I know if I'm unsure about doing anything, I YouTube it...Rather than reading through stuff, it is easier if they are showing you. I think that would be a brilliant idea. (P7)

Some patients also suggested that facilitating a peer-support network through an App would be helpful:

> I've kept in touch with a lady on the ward who had the exact same as me. We've kept in touch, sort of with our progress, which has helped tremendously. You know we text one another to see how we're getting on, and she's sort of in the same boat as me. (P24)

Some patients expressed concerns with reliance on technology: 'I'm at the age where I don't bother with Apps and I haven't got a smartphone or anything.' (P14)

Healthcare professional (HCP) resources

There was variability in access to healthcare professionals, in particular physiotherapists. In some hospitals, there was consistent and ready access to physiotherapists,

which patients highly valued: 'it's very difficult to beat spending time with a trained professional, trained physio' (P19). In others, no physiotherapy was offered, and comments such as this were common: 'I'd heard that waiting lists can be reasonably long, so I just had it privately' (P28). For certain patients, they felt physiotherapy was not required, and they were happy to work on their recovery independently: 'I have had physio and that advice but no, I mean I was offered it but didn't need it' (P21). In some cases, patients did not feel the need for advice on specific exercises but more for generic advice: 'I just thought. I just did. Just want to know the do's and don'ts' like am I making it worse?' (P27).

Professional trust was a common theme, with a reliance on HCP advice to guide behaviour:

> I think I kind of go off the recommendations of what people who have learned about this and have got a degree in Doctors and bones rather than me deciding that one day I'll go for a run because it feels it was okay. (P9)

Lack of information between appointments and this hampering recovery was a common theme:

> I just feel like sort of once you've had your appointment and you're just left to it...I haven't heard anything. I'm waiting for my next appointment at the hospital, and I haven't heard anything. (P24)

> Because I had the booklet from the WAX trial which had a couple of the exercises in, but a lot of it was sort of, refer to your consultant to make sure that they are happy with certain progress and so on but without having another check-up for another four weeks...Like in that four weeks I progressed quite a lot, and I wasn't sure whether I should be trying to walk without the boot or without the crutches when actually I felt I was pretty comfortable too. And that sort of information would have been quite good. (P4)

Another common finding was that patients often felt rushed by surgeons during their clinic appointments, which was often just 'a 2-minute conversation' (P9):

> I briefly saw the surgeon. (P2)

> I've been seeing the same surgeon every time. He seems to be spread very thinly...you can tell that he's not got much time between each person. (P21)

> He saw me another four weeks after. He literally just went in. He said yeah you're fine, off you go. (P21)

Tied to this concept of the value of coming back for surgical follow-up appointments is the effort involved in attending appointments. Some patients had the sentiment 'it's a hassle for me to get to there. I still don't like going' (P21), whereas others were happy to make the trip, often if they were not working or lived close to the hospital.

Some patients preferred to see the same HCP at each visit.

> As if it's been a sort of continuous process rather than having to explain everything all over again, which is always a frustration. (P20)

A similar proportion of patients were indifferent to seeing the same HCP as long as advice was not conflicting. Disinformation between HCP roles was also an issue:

> I saw the GP. And then when I saw the surgical team after my six-week check they said you really should have come to see us about that, and the GP should have referred you back to us for us to see you. The GP and the NHS. I mean once you see the doctor, the right doctor it's great, but I'm not criticising it, but it's just the logistics and communication is kind of where the NHS - is the NHS's Achilles heel. (P28)

Virtual consultations were discussed as solutions to some of the above difficulties, for which there were mixed opinions.

> I would find it very difficult because obviously I can't drive and to go to an appointment and relying on other people for lifts and things. So this telephone appointment will be better for me, and it was talked about if needed, a video call, and that would be very useful if needed, so that works well. (P25)

Others had less favourable views of telephone or virtual appointments, ranging from technical issues to feeling less confident in the HCPs ability to make a thorough assessment:

> Because over the phone it was just kind of like keep the boot on for another six weeks. We'll see you in four weeks. And so they couldn't personally examine every, anything. (P9)

Despite the difficulties with surgical follow-up discussed in this section, there was a sense that the trust in the surgeon that actually did the patient's operation remained the gold standard for providing confidence in HCP advice: 'I had a face to face contact with the surgeon who did the operation who gave me good advice' (P5).

Table 4.8: Beliefs statements mapped to the TDF/COM-B domains: Opportunity - Physical

Barrier	Count	Facilitator	Count
OPPORTUNITY – PHYSICAL - 29			
11. Environmental context and resources - 29			
Difficulties with activities of daily living whilst non weight-bearing (NWB)			
Can't carry anything e.g. food and drinks	15	Crutches for longer walks and confidence	8
Difficulty showering	15	Wheelchair	6
Difficulty with steps	13	Optimising layout of house	5
Difficulty with uneven ground	8	Bedpan & toilet frame	5
Difficulty with public transport	1	Zimmer frame	4
		Support whilst cooking	4
		Shower aids	4
		Scooter trolley	3
Orthotic boot experience			
Boot irritating wound	5	Boot helpful	10
Unequal foot height in boot	4	Don't need a boot to WB	1
Feeling fragile without plaster	3		
Boot heavy	3		
Information resources			
Desire for credible online resources	7	The rehab booklet is useful in place of HCP advice	14
Not wanting to bother the NHS	7	A rehabilitation App would be useful	13
Too old for Apps	2	Youtube & internet videos	4
		Internet resources	6
		Peer support	2
		NHS websites	1
Useful physical rehabilitation resources			
		Exercise bike	3
		Ankle support splint	2
		Balance ball & resistance bands	2
		Cycling	2
		Wide shoe for swelling & ankle brace	2
		Stretching aids	1
		Swimming	1
		Foot elevation resources	1
		Massaging wound with cream	1
		Outdoor space near home	1
Healthcare professional resources			
Lack of information between appointments	16	Virtual consultations are helpful/ preferable	6
Conflicting advice between HCPs	11	Don't mind seeing different HCPs at follow up	6
Feeling rushed by the surgeon during appointments	11	Patients didn't need physio	6
Less confidence with virtual consultations	8	Valued physio access	6
Hassle getting to appointments	7	Not a hassle getting to appointments	2
Want to see the same HCP at follow-up	5	Valued physio general advice rather than exercises	1
No access to physio	5	Used private healthcare	4
Variable time off work	3		
Can't assess wounds virtually	1		
Can't get two-way physio feedback virtually	1		
Had technical issues virtually	1		
Would like to book into physio immediately post-op	1		

OPPORTUNITY - SOCIAL

Table 4.9 shows the belief statements within the Opportunity - Social domain.

12. Social influences

Social support from family and friends was crucial for patients after ankle fracture surgery, particularly during the non-weight-bearing phase: 'Obviously you can't live on your own. You have to have somebody to help you' (P10).

Patients commonly used social comparisons to frame their injury and recovery and to gauge their progress:

> I think being an older person I think it's really important that we are encouraged to get better as I think in parts older people are more scared of an injury like this than the younger person who would take it in their stride. (P6)

Table 4.9: Beliefs statements mapped to the TDF/COM-B domains: Opportunity - Social

Barrier	Count	Facilitator	Count
OPPORTUNITY – SOCIAL - 13			
12. Social influences - 13			
		Social support	9
		Social comparisons	7

4.3.4 Target belief statements

Table 4.10 shows the target themes and beliefs prioritised for future intervention development and their corresponding TDF domains, using the selection criteria described in Section 4.2.2.

Table 4.10: Target TDF domains and themes/ beliefs for the RAAFT intervention

TDF Domain	**Theme/ belief**
1. Knowledge	Patient-specific knowledge
	Not knowing what to expect/ set expectations early
	Provide timeframes for recovery
2. Skills	Swelling
	Wound concerns
	Gradual build-up of WB
	Pain limiting/ not limiting progress
	It's easier to WB if allowed to touch foot down for balance
4. Beliefs about capabilities	Conflicting advice between HCPs
	Anxiety limiting WB, not pain
	Self-efficacy driving progress
	HCP trust
	Value of seeing X-rays
9. Goals	Hobbies
	Work
	Seeing future exercises
11. Environment context and resources	Conflicting advice between HCPs
	Lack of information between appointments
13. Emotion	Fear of redamaging ankle
	Anxiety limiting WB
	Fear of not knowing what is normal
	Difficulty WB after some time
	The need for a safe environment

4.4 Discussion

The patient interviews and analysis have generated a range of themes with regard to patients' experience of ankle fracture recovery. The burden of non-weight-bearing periods has been highlighted with a loss of independence and reliance on family and social networks. The anxiety of the unknown, fear of re-injury and a lack of expectations added additional emotional suffering to an already traumatic time. Once patients were permitted to weight-bear, they often found this a straightforward process. Variability in access to healthcare professionals and consistent advice was a common source of frustration and a potential area to target for improvement.

4.4.1 Interpretation

Capability - Physical

Several themes corroborate findings from other qualitative studies examining the ankle fracture population. A loss of independence and difficulties with adhering to weight-bearing restrictions were common [10, 12]. Physical symptoms, notably swelling, was a consistent complaint among patients in RAAFT as well as in previous studies [10, 12, 13, 145]. Difficulty with activities of daily living, in particular washing and showering, was also a persistent finding [10, 145]. While the finding that patients struggle to perform ADLs is not new, the safety and convenience benefit afforded by being able to rest the injured foot down for balance is stark and is explored further in Chapter 5.

Capability - Psychological

Previous studies shared findings that patients have diverse functional goals and

desire individualised rehabilitation advice and time-frames to return to work and hobbies [12, 145]. For many patients, having sight of goals and the next steps in their rehabilitation (such as which exercises to progress to) was a powerful source of motivation. McKeown et al. also found that patients value seeing their own X-rays [12]. Jensen et al.[145] shared the findings from RAAFT that patients often had explicit trust in their operating surgeon: harnessing that relationship within available resources could be useful.

Motivation - Automatic

Anxiety around causing further damage to the ankle and an inability to judge what pain to "push through" during rehabilitation was a common finding. Wound management is a concern unique to operatively treated ankle fractures and remains a diagnostic challenge for both patients and HCPs. Knowing what spectrum of swelling, skin colour changes and pain is normal and when to seek medical attention is an emotive area for which patients require more support.

Motivation - Reflective

Chapter 3 found quantitatively that patients' beliefs and responses to pain vary widely. Chapter 4 corroborates these findings qualitatively but probes deeper, finding that in most patients, pain is independent of the act of weight-bearing. The anticipation of pain and the assumption that being told not weight-bear for at least two weeks means that weight-bearing must be a painful and potentially damaging process appears to be a far more potent barrier to weight-bearing than pain itself. Often "Eureka" moments and the realisation that weight-bearing is not painful are all patients need to rapidly progress their recovery and regain their independence.

This ties to findings in upper limb research [35, 87] that self-efficacy is the key driver of progress, and patients that took responsibility for their rehabilitation had better experiences and a swifter return to independence and life roles.

Opportunity - Social

The benefit of support from family and friends cannot be overstated, and patients without this often had a very difficult and even depressing experience. Peer support is a potential alternative, with several patients stating the value of being able to share experiences and practical tips for recovery with patients in similar situations. Peer support has a broad evidence base for mental health conditions but is a relatively new concept in musculoskeletal health [146, 147].

Opportunity - Physical

Wide variability in physiotherapy provision and lack of information between appointments have been highlighted as targets for meaningful improvement in NHS ankle fracture rehabilitation. Preferences for alternative methods of healthcare provision, including virtual consultations and patient-directed follow-up have been explored. While key tenants such as reducing conflicting advice between HCPs have been established, the findings from this chapter have reinforced the message from previous studies that one size is unlikely to fit all for ankle fracture rehabilitation [12, 145].

4.4.2 Strengths and limitations

RAAFT included interviews with double the number of operatively treated ankle fractures compared to any other individual study, most of which interviewed a balanced mix of operative and non-operatively treated patients [10, 12, 13, 145]. The

previous studies cited interviewed participants from one or two hospitals (or did not say), compared to 13 in this study. Additionally, the largest study of 36 patients (15 treated with ORIF) included only patients aged 60-80 years [10]. Accordingly, RAAFT provides new insights into recovery from ankle fractures, exploring in greater depth the behaviour of returning to weight-bearing and the provision of healthcare from a wide variety of settings.

While this study achieved a comprehensive geographic and demographic sample of participants, some important population groups were not included. No non-English speaking participants were successfully recruited, and data on ethnicity were not collected or analysed due to demographic data being sourced from WAX trial CRFs.

Due to the COVID-19 pandemic, all interviews were conducted remotely: this enabled a large number of participants from a wide range of hospitals. However, the lack of face-to-face (F2F) interaction may have limited some of the psychological insights gleaned in other studies [10, 13]. Repeatedly in the reflexivity diary, it was noted that there was a limit to the depth of discussion around certain topics, such as belief and trust in the treating HCPs and patients' opinions of the outcome measures used to assess recovery. The positionality of the interviewer as a surgeon may have also posed a barrier to the discussion of these more sensitive topics that a researcher or patient representative, independent from a healthcare role may have been able to explore more candidly. However, the mean interview duration of 32 minutes in this study is similar to that reported in previous qualitative studies in this field [10, 13, 145].

The moderate agreement in the double-coding sample (kappa 0.54) may limit the reliability of the coding into TDF domains. Guidance indicates that kappa values

>0.6 indicate acceptable agreement and previous healthcare studies using the TDF have achieved kappa values of 0.67 [148] - 0.84 [142]. Studies achieved higher agreement when coders had jointly designed the interview schedule, undertaken dedicated BCT taxonomy training or conducted repeat rounds of coding after re-discussion [45, 56, 142]; this would have improved the reliability of the coding in the present study, had time and funding allowed.

The single-time frame for interviews (approximately two months post-surgery) limits insights into the longer-term experiences and challenges faced, in particular the return to manual labour occupations, which was found to be associated with poor functional outcomes in Chapter 3.

4.4.3 Conclusions

Patients experienced recovery from ankle fractures in many different ways. Some harnessed their physical strength, social networks and self-efficacy to navigate decisions and challenges they faced, making their recovery relatively straightforward. Others dealt with uncertainty, loneliness and surgical complications that made recovery a nightmare. The needs and preferences of patients varied widely, and they desired information and services unique to their circumstances.

This chapter has found themes and beliefs to target during intervention development. It has also begun to build a repertoire of barriers and facilitators to recovery that can be incorporated and addressed with future resources. Chapter 5 goes on to explore what healthcare professionals believe is important to patients and consider behaviours that would be helpful to encourage among patients and HCPs.

CHAPTER 5

Semi-structured interviews with healthcare professionals (HCPs)

5.1 Introduction

Qualitative studies have focused on patients' experiences after ankle fracture [10, 12, 145]. McPhail et. al interviewed six HCPs in addition to 12 patients, however, the HCP interviews were coded within the same framework as patients. That is, the focus of the interviews was to describe patients' experiences rather than reflect on the behaviours of the HCPs themselves. Rydberg et al. looked at physicians' experiences, but this was in relation to the usability of a fracture registry, rather than directly treating patients with ankle fractures [149].

Much of BCW research has focused on changing HCP behaviours, so the model is well suited for this purpose [45, 83]. However, most studies have examined HCPs behaviour regarding their engagement with organisations, systems or processes [133, 135, 148]. This chapter focuses less on processes, but on factors that influence HCPs decision-making and interactions with individual patients. The purpose is to explore topics where there is known variability in practice as well as new concepts found in Chapter 4. Existing topics include weight-bearing practice and instructions

[8], healthcare delivery and provision [150, 151], and patients' experience of pain postoperatively [152, 153].

Understanding HCPs' beliefs around ankle fracture rehabilitation, particularly where they differ from patients' beliefs, will help identify areas for intervention.

5.1.1 Objectives

1. To explore healthcare professionals' perspectives of patients' experiences of commencing weight-bearing and recovery after ankle fracture surgery.

2. To explore healthcare professionals' behaviours with respect to treating patients with surgically managed ankle fractures, to inform a new rehabilitation intervention.

5.2 Methods

5.2.1 Study design

Qualitative semi-structured interviews with healthcare professionals were conducted and reported in accordance with the COREQ checklist [136]. The methods and analyses follow those described in Chapter 4. Only where there are differences are they described below.

Researcher characteristics

The researcher characteristics and training are the same as in Chapter 4. In contrast to the interviews with patients, there was an existing personal or professional relationship between the interviewer and the participants in many cases. There were

no attempts made to disguise the interviewer's role as a trauma and orthopaedic surgery registrar.

Setting and sampling

HCP participants were recruited through existing professional networks and the WAX trial. They were contacted by email and provided with a PIS. Interviews were conducted over the telephone or video call, based on participant preference. A consent form was emailed to participants in advance and completed over the phone. Examples of the PIS and consent forms are included in Appendix D.1 and Appendix D.2.

Staff were invited to interview after 15 patient interviews had been conducted. This allowed themes from patient interviews to be explored in HCP interviews, but also enabled subsequent patient interviews to explore themes generated during staff interviews. Staff interviews were conducted between 28th July 2021 and 3rd December 2021.

A purposive maximum variation sampling strategy was used to obtain a spread of staff treating patients with ankle fractures in different roles and regions. Three groups were sought: 1) Physiotherapists, (2) Consultant trauma and orthopaedic surgeons, and 3) Trainee trauma and orthopaedic surgeons. These groups were chosen as the key decision-makers for patients recovering from ankle fractures. It was hypothesised that trainees may have different views from consultants and one objective of the interviews was to understand what influences HCPs' behaviour, namely do they simply follow their seniors' instructions?

Approvals

Approvals were obtained as described in Chapter 4.

Data collection methods

A new interview schedule for the HCP interviews was designed using the methods described in Section 4.2.1. Table 5.1 shows the questions on the interview schedule mapped to TDF domains (TDF descriptors are included in Chapter 4, Section 4.2.1). There was good agreement between questions and corresponding TDF domains between researchers. There was discussion around ensuring questions were situation-specific. For instance, for "4. Beliefs about capabilities", there are separate questions in the interview schedule regarding the patient's beliefs in their capabilities to commence weight-bearing and questions relating to encouraging HCPs to allow and promote early weight-bearing. The interview schedule was updated iteratively to explore new themes generated during analysis, a copy is provided in Appendix D.3

All interviews were audio-recorded using a password-protected recorder, anonymised and transcribed verbatim by the interviewer as per Chapter 4.

Table 5.1: Staff interview schedule mapped to TDF/COM-B

Domain	Sample interview questions
Capability - Physical	
2. Skills	[1]Are there any aspects of starting WB patients struggle with?
Capability - Psychological	
1. Knowledge	[1]Are there any particular areas patients are confused about or ask lots of questions about?
10. Memory, attention and decision processes	[1]Do patients understand the plan for weight-bearing? [2]Is there anything you do to help them remember to do their exercises?
14. Behavioral regulation	[1,2]How do you approach encouraging patients to WB or perform exercises if they are in pain?
Opportunity - Physical	
11. Environmental context and resources	[2]Some patients feel rushed in clinics, particularly by surgeons: Do you feel you have enough time in the NHS to give them all the information they need? [2]Do patients usually see the same surgeon at follow-up where you work? [1]Do you think they prefer continuity?
Opportunity - Social	
14. Social influences	[2]Do you feel confident in giving patients timeframes for their recovery? [2]How do you do this? Prompts: Comparisons to other patients?
Motivation - Reflective	
3. Social/professional role and identity	[2]Do you ever doubt the operating surgeon's weight-bearing instructions?
6. Beliefs about consequences	[2]Why do we worry about weight-bearing on ankle fractures vs hip and knee replacements where we get them straight up the next day?
5. Optimism	[2]How do you balance being optimistic vs defensive: e.g. saying "Oh it's a bad break – you'll have a slow recovery" vs "It's all fixed – you'll do fine"?
8. Intentions	[2]Do you make a point to act in a certain way – e.g. I'm going to be optimistic or not.
4. Beliefs about capabilities	[2]How can we encourage surgeons to change their weight-bearing practice? Prompts: Is it research studies? Operative teaching? Something else? [1]What do you think influences patients ability to start/ progress weight-bearing?
9. Goals	[1]Do patients tell you about goals they have?
Motivation - Automatic	
13.Emotion	[2]Do you have any key anxieties when helping patients progress their WB or recovery?
7. Reinforcement	[2]Is there anything you do to encourage patients to do their exercises at home?

[1] Patients' experience/ behaviour, [2] HCPs behaviour.
The shaded rows correspond to the COM-B domains. The numeric labels correspond to the TDF domains.

5.2.2 Analysis

The methods for qualitative data management and analysis were the same as for Chapter 4. The same combined deductive and inductive approach was used, however, the inductive frameworks were independent and created de novo for the staff interviews [45, 139]. Due to time and funding restraints, a third researcher was not available for independent coding of interview transcripts. Themes and belief statements were listed in the results tables as barriers or facilitators to the target behaviours. As there were behaviours relevant to both patients and HCPs, the barriers and facilitators listed correspond to the combined outcome of patients returning to weight-bearing and activities of daily living as soon as possible. Target themes and beliefs for future intervention development were selected based on similar criteria to Section 4.2.2. In addition, conflicting beliefs between patients and HCPs were summarised and prioritised for further intervention development [45, 142].

5.3 Results

5.3.1 Interview participants

Twenty-six HCPs were invited to interview, of which 18 (69%) replied and were able to partake in an interview. Interviews were conducted with HCPs from 13 different sites, a summary is provided in Table 5.2. Seven (38.9%) participants were physiotherapists, five (27.8%) were consultants, five (27.8%) were registrars, and one (5.6%) was a post-CCT fellow (pre-consultant grade). Thirteen (72.2%) were male, and five (27.8%) were female. A summary of staff interview participant characteristics is provided in Table 4.3, the site is omitted to preserve anonymity.

Table 5.2: Staff interview sites

Site	**N = 18**
Oxford University Hospitals Trust	6 (33.3%)
Royal United Hospitals Bath	1 (5.6%)
Barts and the London Hospital	1 (5.6%)
Conquest Hospital	1 (5.6%)
Leicester Royal Infirmary	1 (5.6%)
Maidstone and Tunbridge Wells Hospital	1 (5.6%)
Queen Alexandra Hospital Portsmouth	1 (5.6%)
Queens Medical Centre Nottingham	1 (5.6%)
Royal Victoria Hospital Belfast	1 (5.6%)
South Tees Hospital Trust	1 (5.6%)
Southampton General Hospital	1 (5.6%)
St George's Hospital London	1 (5.6%)
St Mary's Hospital London	1 (5.6%)

Table 5.3: Interview participant characteristics (Staff)

Participant ID	**WAX site?**	**Gender**	**HCP Role**	**Subspecialty**	**Interview duration (mins)**
1	Yes	Female	Physiotherapist	N/A	27
2	Yes	Male	Consultant	Trauma	31
3	Yes	Male	Consultant	Foot and ankle	34
4	Yes	Male	Physiotherapist	N/A	42
5	Yes	Female	Registrar	N/A	35
6	Yes	Female	Physiotherapist	N/A	32
7	Yes	Male	Consultant	Foot and ankle	33
8	No	Male	Registrar	N/A	26
9	No	Male	Consultant	Trauma	28
10	Yes	Female	Post-CCT Fellow	Foot and ankle	37
11	No	Male	Consultant	Trauma	35
12	No	Male	Physiotherapist	N/A	44
13	No	Male	Registrar	N/A	23
14	No	Male	Physiotherapist	N/A	22
15	No	Male	Registrar	N/A	20
16	No	Female	Physiotherapist	N/A	35
17	No	Male	Registrar	N/A	41
18	No	Male	Physiotherapist	N/A	50

5.3.2 Themes/ belief statements

Capability - Physical

Table 5.4 shows the belief statements within the Capability - Physical domain.

2. Skills

Coding here does not relate to the skills of the HCP (such as the operative skills of surgeons), but instead the physical factors of patients or their injuries that may influence HCPs' decisions to permit early weight-bearing.

HCP concerns

Before considering which factors might cause concern for HCPs, it is first important to consider what exactly they are concerned about. Barriers correspond to their concerns, including those specific to early weight-bearing and facilitators correspond either to areas for which they have little concern or those which they believed are minimised by employing an early weight-bearing strategy.

The most prevalent concern was wound healing problems and the potential spiralling crisis of 'wound infection, breakdown, recurrent operations and potentially amputations' (staff (S)8). This dictated weight-bearing practice for many HCPs:

> The six weeks non-weight-bearing or it's been two weeks for wound healing, and then they can weight bear after that...Wound healing around the foot and ankle is always slightly poorer. So particularly those first couple of weeks is important for wound healing and swelling. (S17)

The concern that the metalwork would fail was less common, but when compared to other lower limb surgery, such as hip or knee replacements, this remained a relative concern:

> Well, my general feeling about this is probably just because of a fear of the fixation failing. Ultimately, the construct may not be stable enough to withstand that load. And you are essentially just relying on the metalwork rather than the fracture is healed at that point. (S15)

Counter concerns included the risk of Venous Thromboembolism (VTE), prolonged stiffness and the associated life impacts of delayed weight-bearing and immobility. More general warning signs that HCPs felt required further assessment included pain which is disproportionate to the injury:

> I tend to tell them that if they are in significant pain from the weight bearing that they have carried out and if it's causing them significant pain, just to let us know and re-present to the hospital if it's very bad. (S15)

However, as discussed in Chapters 3 and 4, patients perceive pain in different ways and HCPs acknowledged that determining or advising on what is "disproportionate" pain remains a challenge.

While HCPs are wary of VTE, isolated ankle swelling was rarely a cause for concern, and was considered a normal part of recovery. As with pain, determining what is normal vs pathological swelling was stated as a challenge. One proposed indicator was 'as long as the swelling subsides overnight: if the swelling gets better the next morning, I wouldn't be so worried' (S15). Another concern for HCPs was complex regional pain syndrome (CRPS), and in particular the associated diagnostic challenges:

> I know about CRPS and I know some of the signs, some of this feeling that it doesn't belong to them. That pain is disproportionate to what you would expect. They can get sort of strange sort of nervous system responses when they can get redness or blotchy skin. So I know some of the signs, but I haven't had much experience of treating or managing it. (S16)

HCPs discussed their indications for removal of metalwork postoperatively and most felt this was only necessary if the patient reported persistent problems such as prominence or irritation.

Contraindications to early weight-bearing

There were a number of patient and fracture-related factors that HCPs viewed as contraindications to early weight-bearing, which they felt may be associated with the concerns discussed above. These included systemic factors which may interfere with wound healing such as diabetes, peripheral vascular disease and smoking. Another group were patient factors that might limit a patient's ability to self-regulate complications, such as those with ongoing substance misuse or peripheral neuropathy (no protective sensation). In these groups, some HCPs felt additional strategies are required beyond delayed weight-bearing instructions:

> The only ones that I've seen completely fall apart are the people who are substance misuse problems; they seem to walk off their fixation....they won't be able to comply with the protocols...they will get non-weight-bearing instructions in the full plaster knowing full well that they won't be non-weight-bearing, and you know their plaster might not make it for four weeks. (S3)

Other stated contraindications to early weight-bearing were fracture-related factors, such as posterior malleolus fractures, syndesmotic injuries, articular surface impaction and atypical fracture variants: the hypothesis being that the implants and bone unit are not strong enough to withstand axial loading. For some, obesity was a contraindication with the assumption that the fixation is subjected to excessive loads. Soft tissue injury, in particular patients sustaining open fractures, was stated as a contraindication, again due to wound healing concerns.

One of the most debated contraindications to early weight-bearing was patient frailty and the association with suboptimal 'quality of bone stock and quality of fixation' (S8). The counterargument was that frail patients are potentially those at the greatest risk of NWB and immobility:

> In the elderly, we may see a loss of independence and the functional decline associated with institutional and hospital stay and we know that from the hip fracture population that that is not always recoverable. We've got increased cost and length of stay in the hospital. (S11)

Another consideration was that 'a lot of people can't manage non-weight-bearing if they're frail, so it's unrealistic' (S11). Several of these concepts are discussed later in the "6. Beliefs about consequences" domain.

Pain experience

With respect to patients experiencing pain when weight-bearing, many HCPs stated 'a lot of them are actually surprised that they have less pain than they thought' (S2). This 'surprise' was a common theme, with an acknowledgement that patients 'might be apprehensive about it, but I can't think of many people that have not tolerated it because of pain' (S6).

There was an acknowledgement that some patients do experience pain and the response from most HCPs and all surgeons asked how they would approach a patient in unexpected pain would be to return to basic clinical and radiological assessment to exclude sinister causes such as infection or fixation failure. Once sinister causes have been excluded, HCPs explained there is a need to 'break the cycle' (S13) of stiffness, anxiety and pain related to disuse.

HCPs were rarely concerned about numbness or tingling around the scar: 'If that numbness is not associated with any motor deficit. Then I would say not to worry'

(S14). HCPs reinforced that swelling and wound concerns were the most common concerns usually discussed with them.

HCPs encouraging weight-bearing

Most HCPs explained returning to weight-bearing as a gradual process, directed by the patients' comfort and tolerance. However, some felt the use of scales or percentages were helpful:

> I normally would tell them to take a scale and then stand and then I will explain this to them physically and I tell them to stand on the operated leg with the frame. And they have a sense of what is ten kilos or what is five kilos. They would start with this sort of understanding. And I feel that is the way they understand, so it's sort of measurable. The way of explaining how to start weight-bearing. (S10)

There was variability in HCPs' opinions on whether non-weight-bearing patients could put their injured leg down for balance if needed. Most 'let them touch for transfers always, otherwise, people fall over' (S11). Others felt that 'it's a binary situation' (S13) and 'it's tempting then to start applying pressure' (S16). I.e. If patients are told they can put their foot down, they'll start walking on it.

Another rationale used to encourage patients that it is safe to weight-bear was explaining the rotational nature of ankle fractures:

> I've explained that the injuries they've had have largely got nothing to do with axial loading. I illustrate to them their ankle fractures are a rotational type movement. So I explain to them, that putting pressure through the heel and foot isn't a threat to ankle stability. It's safe to put their foot to the floor. (S9)

Simulating eureka moments was also thought to be helpful.

Table 5.4: HCP Beliefs statements mapped to the TDF/COM-B domains: Capability - Physical

Barriers	Count	Facilitators	Count
CAPABILITY - PHYSICAL - 18			
Skills - 18			
Healthcare professional (HCP) Concerns			
Wound breakdown	8	Swelling ok if subsides overnight	3
Infection	5	Removing metalwork only if concerns	3
Disproportionate pain	4	VTE risk if NWB	2
Fixation failure	3	Stiffness (so need mobilisation)	1
Prominent metalwork	2	Patient life impacts	1
CRPS (and difficulty in diagnosing)	2		
Revision surgery	1		
Contraindication to EWB		**Contraindication to DWB**	
Diabetic	5	Patients that are unable to DWB	4
Frailty	5	NWB risks (e.g. VTE)	3
Peripheral neuropathy	4	Discharge planning and hoist issues	1
Poor bone stock or comminution	4	Soft tissues heal better with stability	1
Dome impaction & pilon fractures	3		
Syndesmosis injury	3		
Just surgeon by surgeon	2		
Non-compliant patients	2		
Obesity	2		
Open injury or compromised soft tissues	2		
Deltoid injury	1		
Medial plate	1		
Partial fixation to avoid complications	1		
Posterior malleolus fractures	1		
Smokers	1		
Substance misuse	1		
Vascular disease	1		
Patients' pain experience			
Pain during WB	2	No pain during WB	4
Pain limiting progress	0	Pain not limiting progress	4
Explain some patients' pain pathways are different	3	Explain the balance between WB pain and disuse	2
Pain related to injury and disuse	2	Patient in pain - HCPs go back to basic assessment	5
		If WB pain, distract and work on ROM instead	2
Wound tingling after 3 months is a concern	1	Wound tingling is not concerning unless motor loss	4
		Wound tingling = reinnervation, which is good	1
(Extra) Patient areas of concern			
Swelling	3	Fear won't regain range of motion (ROM)	1
Wound concerns	3		
Falling	1		
HCPs encouraging weight-bearing			
		Do as you feel – It's a gradual process	11
Don't allow WB for balance: fear patients WB more than instructed	3	Allow WB for balance	12
Weighing scales unhelpful	4	Weighing scales or percentages helpful	4
Prolonged NWB makes WB harder once allowed	1	Fixation is strong, but it's a gradual process	4
		Allow axial loading, avoid rotational movements	3
		Simulate Eureka moments for WB	1
HCP preference for DWB	2	HCP preference for EWB	6
Patient preference for DWB	4	Patient preference for EWB	6

Capability - Psychological

Table 5.5 shows the belief statements within the Capability - Psychological domain.

1. Knowledge

As found in Chapter 4, HCPs acknowledged variation between the weight-bearing language used between professionals: 'My colleague has done a survey about what different weight-bearing strategy terminology means. And there is huge variation' (S12). Yet, HCPs generally felt that their own method of giving weight-bearing instructions was understandable to patients 'So yeah, just tell them to keep the weight off it. And most people understand what that means I think' (S12). There was also a feeling that there should be more communication between surgeons and physiotherapists: 'if the consultant has concerns then they should probably be discussed. And that should be made planning a bespoke way around that patient rather than carte blanche' (S16).

HCPs felt that setting expectations early is useful for patients:

> I try and tell them early on before clinic...After nine months you're still gonna know that this ankle is swollen and it will take three months before it even comes down from the post op swelling and for a long time they're going to have some kind of different shaped ankle because of the injury and the surgery so try and get them aware of that early on....I get involved as early as possible in that conversation. (S2)

Providing time-frames

When advising on timeframes for commencing activities such as weight-bearing or exercises, HCPs often used the criteria 'once [the wound] has fully healed' (S14), however when probed and asked what this means or how they would describe this to a patient, most were uncertain: 'I don't really know, to be honest. I know what in my head I would be looking at. But I don't know how I describe it' (S16). Some

recurrent descriptions included once ‘it’s dry’ (S14) with ‘no scabs’ (S17).

This "fully healed" criterion was also often used when providing patients with timeframes for getting their wound wet in the shower, soaking in the bath or massaging the wound. There was however variability in timeframes for when HCPs would allow these activities, mostly ranging from two to six weeks postoperatively. Several stated they ‘don’t really offer advice on scar massaging’ (S15).

There was a low level of confidence in providing patients with timeframes for returning to activities such as walking, running and driving, and often HCPs described being vague and deferring giving timeframes: ‘early on we normally kick the can down the road and just say, yeah, we’re not really sure at this stage, we will have to see how you’re getting on’ (S4). Most expressed a desire for better information around timeframes; ‘if there was good, reliable data for those things, that would be really useful’ (S12). Many felt that confidence increased with time: ‘I think I’ve become more confident after I’ve seen however many ankles over recruiting as a physio so I think I became more confident’ (S1). On the other hand, some felt that standardised timeframes are not achievable, and instead they focus on acknowledging that everyone is different:

> Everybody progresses at different rates and people recover at different rates. I make them not feel bad if they know someone that has recovered faster. I don’t give them absolute time points. (S2)

10. Memory, attention and decision processes

HCPs acknowledged that patients may struggle to retain all information given to them during clinic appointments:

> Nobody sort of explained to her what was going to happen next, and maybe somebody did explain which I do believe, but we have to bear

> in mind that the psychology of the patient and the role of the patient you know for any of us when we, in the role of the patient, whatever your education or your position is, we act. And we comprehend differently when it is our leg, hand or whatever. So you don't have that same understanding. (S10)

Several used an analogy or turn of phrase to reinforce key messages:

> I tell them to elevate for 45 minutes of every hour. To get up for tea, toast and toilet. To mobilise for necessity not for pleasure. When they're laying down they want their toes above their nose and then when they're sitting down the foot above their hip. (S3)

14. Behavioural regulation

Similar to patients' views in Chapter 4, trust in their body to regulate behaviour was a common theme among HCPs: 'their body will tell them whether or not they are happy to weight-bear on it' (S8).

A key issue identified by HCPs is that 'there are some patients very passive about their treatment and their recovery' (S15). Some patients 'think that physio is only done in the physio consultation as opposed to every day, several times a day' (S5). The ability to get patients to invest in their own recovery was perceived as a challenge: 'We need to put some responsibility on the patient' (S11). The concept of 'patient ownership' (S7) relates to patients taking responsibility for their recovery and progressing rehabilitation rather than waiting for guidance from HCPs at each stage. The counterargument to this is illustrated with the following analogy:

> It's a bit like people doing their homework right, when they know they're going to see somebody. Are you more likely to do your exercises because you know somebody is going to be asking about them and looking for your progress and looking over what you've achieved over the course of time? If no one is checking on you and no one is pushing you, do you do it? (S16)

This concept is discussed further in the "11. Environmental context and resources" domain.

Table 5.5: HCP Beliefs statements mapped to the TDF/COM-B domains: Capability - Psychological

Barriers	Count	Facilitators	Count
CAPABILITY - PSYCHOLOGICAL			
1. Knowledge - 6			
Variability and confusion between WB language	5	Early knowledge and expectations useful for patients	2
HCPs assume patients know what a fully healed wound is	4		
Should be more direct communication between surgeons and physios	1		
Providing timeframes			
Be vague and defer giving timeframes	8	HCPs would like to give time-frames	9
Variability when allowing to get wound wet or start wound massage	6	Everyone recovers at different rates	5
Variability in time given off work	1	Gradual build up attempts	3
Vague about driving advice	1	Confidence increases with exposure-volume	1
10. Memory, attention and decision processes - 5			
Information overload in clinic	1	Use WB Phrases to aid retention	4
14. Behavioural regulation - 9			
		Trust your body	4
Patients think physio only occurs in the physio clinic	3	Engage patients to take charge of their recovery	4

Motivation - Automatic

Table 5.6 shows the belief statements within the Motivation - Automatic domain.

13. Emotion

Reported sources of patient anxiety are 'anxiety around breaking the fixation' (S1) and that 'most people hop out of clinic, even if they can early weight-bear' (S5). This ties in with themes from Chapter 4 that patients prefer to first practise weight-bearing in a safe, calm and quiet environment, which clinic often is not.

7. Reinforcement

Reinforcement refers to increasing the likelihood of a behaviour being performed by establishing an association between performing a behaviour and a given stimulus or cue [45]. There were no utterances coded into the reinforcement domain.

Table 5.6: HCP Beliefs statements mapped to the TDF/COM-B domains: Motivation - Automatic

Barriers	Count	Facilitators	Count
MOTIVATION - AUTOMATIC			
13. Emotion - 4			
Patients fear for EWB - fixation failure	3		
More anxiety around trauma compared to elective surgeries	2		
Anxiety around trying to WB in clinic	2		
7. Reinforcement - 0			

Motivation - Reflective

Table 5.7 shows the belief statements within the Motivation - Reflective domain.

3. Social and professional role and identity

Themes in this domain related to how healthcare professionals viewed their roles and responsibilities for decision-making within the context of the NHS. A common theme among physiotherapists and registrars was deferring responsibility to senior colleagues, often saying 'just ask the consultant' (S1), and that they implicitly trust the surgeon's weight-bearing decisions. There was also a general apprehension about contradicting other consultants 'if it is a particular surgeon who was in the surgery, then very few people will go against that' (S4). Similarly, with regards to changing practice, there is apprehension: 'None of my colleagues have gone on to do that and so you don't want to be an outlier for something like that in case there any problems' (S3). However, once weight-bearing is permitted, surgeons were often happy to leave further decisions to physiotherapists: 'I would be happy for physios to take the lead role in terms of what they can and can't do' (S8).

Another concept was that surgeons may be anxious to allow early weight-bearing

because they do not always fix fractures optimally: that ankle fractures are often left to be fixed by junior colleagues, and if there is a problem, consultants 'usually they blame the registrar' (S7):

> I think some of my colleagues have said oh the bone quality is poor. I don't want to weight-bear, but I think that might be a surrogate for fixation quality is poor. (S3)

4. Beliefs about capabilities

Similar themes around anxiety as the main limitation for weight-bearing were present among HCPs:

> It's the apprehension, I think. It's not that they can't tolerate the weight bearing. They do tolerate it, but they are just too scared. (S6)

> Another element I normally consider is whether they're getting paid if they are off sick. It can be a very important motivation element for them to go back as soon as possible, and if I'm thinking in certain cases. You can slow them down a tiny bit. And so, I mean, the financial element is very important. (S14)

HCPs ability to change weight-bearing practice

Many HCPs noted a trend toward surgeons permitting early weight-bearing, but there remained substantial uncertainty among many. Most felt that the conventional practice of delaying weight-bearing was rooted in historical practice:

> I worry that the orthopaedic community has some kind of pathological disease of non-weight-bearing that is based on dogma and historical approaches to treating patients. And I suspect some of that came round through previous implant constructs, implant materials and surgical understanding and our techniques and tactics weren't as good as they are now. (S11)

Several of the surgeons felt that to enact change, 'we need to change the culture' (S7), and that this begins with a shift in the operative mindset:

> When we go to the operating theatre, in general orthopaedics, what I think is the wrong way around and I think what we do is, we go, we see an injury. We kind of go, OK, that's an ankle. So I fix ankles like this. We execute that operation and at the end, we sort of critique and make a judgement. Or you know that screw was a bit loose, so I didn't like that. And then we make our rehab prescription based on what our own subjective feeling of the operation was like. Whereas what we should be doing is saying there is an ankle fracture: I'm going to go to the operating theatre and they can't leave the theatre until I have created a weight-bearing construct. How do I get there?... What do I need to do above and beyond the norm or different to the norm to achieve that? And I think that is the cultural mental shift that we need to try and achieve in orthopaedics. (S11)

Better training and teaching were felt to be part of this: 'Intra-op teaching improves in this element. You will get more trainees, a lot more confident in taking the teachings forward' (S13). Thorough intra-operative screening was felt as another method to give surgeons confidence in allowing weight-bearing: 'At the end of procedure I will screen them and I'll see if there's any movement and when I screen I actually do it quite roughly' (S3).

Beyond this, there were several approaches discussed that could help change practice, including more basic science and cadaveric studies, randomised controlled trials, guidelines and tariffs:

> So there are RCTs that have been done in ankles, a couple in others, in other bits of the body. So we've got the benefit of RCTs. We've got the benefit of national guidance, which is a bit of pressure externally, but it seems to not always drive change unless it is associated with things like tariff. So hip fractures: Brilliant because there was money associated with it. (S11)

However, beyond evidence guiding practice, many acknowledged other behavioural factors that may influence practice. Comparison to peers was thought to be helpful:

> I think people would struggle to question stuff if they don't know the scope of the problem and if they don't know what the data is showing because they're only looking at their own individual silo. (S11)

Others felt that change had to come gradually, saying 'I think going from fixing it to two weeks later that might be the future, but I don't think I am ready for that yet' (S5).

A concern was that some HCPs felt that new advice can feel 'evangelical and pushed down our throats' (S9). Some felt disengaged and that RCT outcomes don't reflect what is important to them, and that 'there needs to be important outcome measures that can affect the surgeon doing the case' (S9).

Interactions with HCPs

Many felt that the interaction with HCPs influenced patients beliefs if their capability to progress with their recovery, in particular, 'what the surgeon says can be quite powerful' (S12). Many HCPs acknowledged there was a balance between pessimism and unrealistic optimism, with the two quotes below summarising the rationale behind both approaches:

> I think it is probably much more sensible as a surgeon to downplay outcomes after ankle fractures and then, if patients do better than that, it's great and if they don't, then that's kind of what they're expecting anyway. (S8)

> Yeah, so I think if you scare them and tell them ohh it was a really nasty break and it might take you ages to progress then I think that's going to affect people in the rehab. It's going to have a lot of psychological impact. (S4)

Others stated that they 'would probably skirt round it' (S4) and 'not set myself in such a strong position at that stage' (S12). Another approach was to 'tell them realistically where on the ankle spectrum their injury is' (S3) or frame their current condition in reference to how they were at previous follow-up visits.

Behavioural practices that HCPs felt enhanced patients' capabilities to weight-bear and progress their rehabilitation included the value of seeing their X-ray, comparison to their peers and professional trust, in particular, trust in the operating surgeon:

> If it's the surgeon that did the surgery, saw their fracture, fixed their fracture and they followed up the patient, that would give them a lot of reassurance. (S12)

Setting expectations and letting patients know it's 'OK to feel apprehensive' (S2) was felt to be helpful.

5. Optimism

The balance between pessimism and optimism is discussed above. A common strategy from HCPs was to say that 'your bone is broken, but it is fixed' (S6). That is to say that no matter where they were on the spectrum of injury severity, they have had the required treatment, and now they must engage with and progress their recovery.

6. Beliefs about consequences

HCP beliefs

A common belief was that surgeons should increase the level of their fixation in older persons, with poor bone quality:

> If you've got someone that has got poor bone quality then you are changing technique. You are maybe using pro tibial fixation to give that sort of lateral buttress to stop things swinging out posterolateraly. You're not just relying on standard fibular screws, and you make that decision in theatre that you increase your fix and your level of fixation. If you think the bone quality is too poor, standard fixation just on the fibular won't give you the confidence to let that patient weight-bear. (S2)

This followed the belief that most consultant surgeons interviewed were advocates of early weight-bearing and believed it speeds healing, reduces stiffness and reduces VTE: 'These are the forces it needs to give it the impetus to heal stronger... they've got to be weight-bearing to get it to heal better now' (S4). 'The longer they're off the leg, the more muscle weakness they will develop. And their ankle might become more stiff' (S12).

Conversely, non-consultants were less certain whether early weight-bearing is safe: 'The thing is, we don't really know, and that's why historically for six weeks everyone was kept non-weight-bearing' (S5). Medico-legal concerns were a common reason for not permitting early weight-bearing and for not changing the operating surgeon's instructions: 'you don't want to give any information that goes against that, probably from a medico-legal point of view' (S7).

> I think a lot of it, is because there is a reticence of surgeons protecting themselves...I think there's a misplaced belief that holding the foot off the ground. One can clear oneself of all potential complications, which is just nonsense, but I think that's what's held. (S9)

There was a perception that pushing for a faster recovery and slightly better ankle function was not worth the risk of a serious complication: 'If you've got a stiff, non-infected ankle with little metalwork in situ, it's much better than having a mobile ankle, but a dehisced wound with a shiny plate staring at you' (S5). In patients with poor bone and tenuous soft tissues, partial fixation, with additional external support and restricted weight-bearing was advocated by some:

> Partial fixations: we don't talk much about it, that is where you fix one side, and the ankle becomes reasonably stable. An 80-year-old. But you just have to strike, hit with common sense and put on a close contact cast on top. Then you will easily get away with it...they don't need you to get too aggressive with it. (S7)

The counterargument to this was 'there is a balance...soft tissues settle much better and rehabilitate much better if the underlying skeleton is inherently very stable, so partial fixation leaves the fractures unstable' (S11).

Other concerns from surgeons were that if they allow immediate weight-bearing, physiotherapists will push patients too far and too fast and risk complications: 'I don't want the physios trying to take you and turn you into some athlete' (S11). This view was not shared by physiotherapists, who felt that experienced musculoskeletal physiotherapists understand the need for balance and that less experienced physiotherapists would usually have a cautious or conservative approach.

Another widely held belief was that permitting early weight-bearing is safe because even if permitted to weight-bear, patients will not do this until it is safe, as pain will limit them:

> So I think that if there's going to be some subtle movement or potential harm that would happen from loading because they are not peripheral neuropathy, they will have pain and they will have pain inhibition...So

> that reassures me that it's not so much my fixation that's going to take it, but the patient is going to have a sort of pain threshold that's going to stop them from doing anything too crazy. (S3)

There was a feeling that patients who lack this protective pain feedback mechanism (due to physiological or cognitive reasons) should have their weight-bearing restricted for longer, though many felt this was futile: 'Telling a non-compliant patient not to weight-bear...they weight-bear anyway' (S9).

8. Intentions

There were no utterances coded into the intentions domain.

9. Goals

HCPs felt it was important to establish patients' goals as part of their rehabilitation. They felt most goals centred around returning to driving, work and leisure activities:

> We normally want to know what the person's goals are. Particularly long, short, clear the long term goals and then basically quickly agree the short-term goals which are often related to driving, and returning to work. What level sport or they need to do, so that those things. (S4).

> When they've had an injury and had surgery they are just generally apprehensive about how they are going to get back to pre-injury level of activity. (S2)

Table 5.7: HCP Beliefs statements mapped to the TDF/COM-B domains: Motivation - Reflective

Barriers	Count	Facilitators	Count
MOTIVATION - REFLECTIVE			
3. Social + Professional role and identity - 11			
Let seniors' take responsibility	4	Physios trust in surgeons WB status	4
Don't want to be a surgeon outlier with innovation	3		
Leave WB progression to physios	3		
Not wanting to contradict another consultant	3		
Ankles fixation left to Registrars	1		
Bone quality is a synonym for poor fixation	1		
4. Beliefs about capabilities - 6			
Patient anxiety as the main barrier to WB	5		
Patients getting sick pay may have less urgency to return to WB	1		
HCPs ability to change practice			
Surgeons follow historic practice	9	RCTs guide practice	7
Change requires a culture change	4	Rough intra-op screening improves confidence in fixation	6
Historic fixation methods were less robust	3	Practice follows guidelines	3
Change needs to be step by step	2	Helpful to compare to peers	2
Cadaveric studies helpful	1	Practice guided by literature	2
Change operative culture to rehab	1	Want to know more about long-term outcomes	2
CT scan improves operative planning/ ability	1	Surgeon important outcomes including service delivery	1
More operative planning is needed	1	Tarif's help change practice	1
Risk of forcing WB down throat	1	Pragmatic discussion with physio	1
		Value of operative teaching	1
		Practice guided by basic science	1
		Practice follows eminent figures	1
Interaction with HCP's			
Injury severity comments from HCPs influencing capability	9	Patient trust in operating surgeon	5
Negative comments influencing patients	5	Value of seeing X-rays	5
Balance between professional optimism vs risk	3	Patients engage more if exercises are personalised to them	3
Skirt around if it's a bad injury	2	Set expectations - normal to feel anxious	2
Can't tell who will do well	1	Helpful to compare to peers	2
NWB is tied to surgical success	1	Explain where they are on a spectrum	2
Pessimism or defensiveness from less experienced staff	1	Use previous comparisons to frame progress	1
HCP define "bad injuries" differently	1	Professional trust	1
5. Optimism - 9			
Expectations			
Avoid unrealistic optimism	2	Optimistic language helpful	5
Use pessimistic or neutral language	2		
6. Beliefs about Consequences - 6			
HCPs beliefs			
Medico-legal concerns	5	Increase fixation to allow EWB	6
Disparity between HCPs fixation	4	VTE is related to WB and exercises	4
We just don't know if EWB is safe	4	Pain as limitation of damage	4
Prolonged NWB causes more weakness & stiffness	3	Experience guiding beliefs in fixation	2
Better to have stiff non-infected ankle	2	Surgeons fear physios will push patients too fast & far	2
Use minimal fixation to respect soft tissues	2	More trust if own surgery	1
Rule out complications, not worried about anything else	2		
Non-compliant patients will WB anyway	1		
HCP assume immediate WB will be too painful	1		
8. Intentions - 0			
9. Goals - 12			
Relieve pain	1	Return to driving	6
Physio doesn't cater to high-demand goals	1	Return to work	4
		Establish goals	3
		Long walks	1
		Running	1
		Swimming	1

Opportunity - Physical

Table 5.8 shows the belief statements within the Opportunity - Physical domain.

11. Environmental context and resources

Orthotic boot vs cast

There was variability in boot use, with some placing patients in boots immediately postoperatively, though others were wary of this:

> When I first started as a consultant I put people into their air cast boot straight away from theatre and then I found that wasn't a good idea and that's why I put them in the backslab for about a week...I was getting wounds that were coming back quite angry looking in that first appointment. So I stayed away, and I know other people have had that same experience. So that they don't think it's a good idea to put it in the air cast boot from actual theatre (S4).

Many recommended a boot because it's easier to walk on than a plaster: 'If you've got something that looks like a shoe on your foot you're going to think "Oh well I might as well walk on it"' (S1) and 'it's relatively available and it's right there' (S4).

Many felt it was OK to remove the boot at night, though some felt it was helpful to keep the ankle in a good position at night. There was variability for when patients should remove their boot and start walking without it, though again, advice was often guided by patient comfort: 'If you feel you can walk on it comfortably in a few weeks, then you can take the boot off and walk on it' (S6).

HCP resources

Changes in healthcare provision due to COVID-19 enabled the discussion of a wide range of methods for patient follow-up. A recurrent message was that patients re-

ceived less F2F follow-up during the first COVID-19 wave. This stimulated discussion around what follow-up is needed:

> I mean I think they should only be coming back if there is a need for surgical review. If there is not, it's not the most efficient use of services. So as long as they don't need to come back, they shouldn't come back. (S12)

> To sit there in the clinic room just to tell me that you're fine, I think that's really unfair on our healthcare resources. (S11)

Several reported having earlier consultant input to facilitate 'sensible decisions on discharge and follow up, reducing the burden on clinic and the patient. And means that every patient gets consultant-level input' (S11). Many surgeons stated that they discharge patients early and 'say if they have any concerns they are normally left with the patient-initiated follow-up' (S11), that is, an easy method of representing to clinic if they have concerns. However, many felt it was important to have 'a robust method for the patient getting back in touch and having an expeditious appointment' (S11) if they had concerns, particularly with their wound, rather than having to go via their General practitioner (GP).

Many felt some patients are also dissatisfied with repeat follow-up visits and find it a hassle to get to clinic:

> I think a lot of patients struggle, especially in the [blinded] to get into park and patients come from a long way away. (S8)

> Trauma clinics aren't the most efficient in terms of patients, so they can end up waiting several hours for an appointment, that could last a few minutes... So I think they find it is very unsatisfactory. (S12)

The briefness of clinic encounters was a common finding, and HCPs felt that surgeons are 'always rushed in the NHS' (S8). Conversely, physios rarely reported this: 'I feel

that mostly physios have a lot more time to explain and talk and usually have autonomy over how much you see someone and how often' (S12).

Another theme was that patients had a lack of access to information between appointments:

> They want you to explain, and you know they need further explanation and you know that if you were on the other side, you would want further explanation, but there is no time because in the waiting room there are loads of other patients, so it's really uncomfortable. And unsafe, but that's the situation. (S10)

Some hospitals were employing digital methods to provide support 'we have a lot of, we have QR codes on the wall and websites that they can go to and look for reference' (S5).

Other surgeons were anxious about early discharge:

> We shouldn't be using this as a way to save money. It should be a way of getting patients better rehabilitation. There will be worries that you fix them and then you can weight-bear them: I don't want that to mean you can fix them and discharge them immediately to the physio. (S2)

Continuity of care

HCPs felt that continuity of care was preferable to patients: 'I've worked in places where the patient very rarely saw, they were seeing a different person every week and it was very frustrating for the patient' (S5). One of the main issues stated with a lack of continuity was patients receiving conflicting advice:

> They get different information from people telling them if they're not sure if they're allowed to weight-bear: then there comes the apprehension. The person they see in A&E versus the person that operates on them and the person that they then see in clinic aren't always the same so they may have been given different opinions. (S6)

Continuity was also helpful to reference earlier discussions with patients:

> So if you're the person they had the conversation with, and you say "remember I told you it's going to be swollen for this couple of months", so it makes it easier if they're the person that they have seen at the first, as everybody is different in language, even though they're just trying to say the same thing because of the different vocabulary that sounds different and gives mixed messages. (S2)

However, many acknowledged that delivering continuity of personnel can be logistically difficult and 'it's more important that people sing from the same hymn sheet' (S3). To aid this, there was a desire for standardisation of rehabilitation advice; 'having national guidance would be really useful' (S6):

> There's a lot of variation in practice...I would imagine that a good service which is what we've been trying to deliver in my hospital is more consistent. You know so whoever you see isn't a variable in your treatment. It's your injury that is the variable. (S3)

Some felt that when patients are made aware up-front, they are usually happy:

> We now say that as an introduction you'll be being seen by the gym team, otherwise, they think they should always see the same person. (S6)

Beyond the perceived benefit to patients, some surgeons 'want to see the outcomes of [their] own surgeries' (S3). This also tied into a feeling that there should be 'close scrutiny of your own data' (S7), and that electronic registries may be a way to facilitate this.

The value of physiotherapy

There was discrepancy in the role seeing a physiotherapist played in rehabilitation after ankle fracture surgery. Some felt physiotherapy is not required:

> I can't say that I routinely refer my ankle fractures to physiotherapy. I see them at two weeks, I get their cast off and I begin mobilising them...at six weeks when they begin weight-bearing at that point they typically have a very good range of motion, and I give them an information leaflet, and I tell them to get on with it. (S15)

Others felt it is crucial:

> Almost entirely being seen by a surgical set up in the early part of recovery before physiotherapy is allowed to do anything, I think it's the wrong way around. So our patients routinely see physios at the same clinic. And they prefer to see the physio than the surgical team. (S15)

Some surgeons felt it is important to give specific instructions to physiotherapists for what rehabilitation activities to do, yet most physiotherapists said 'Just tell me when they had the operation and when they can weight-bear and I'll do the rest' (S15).

When discussing the value of seeing a physiotherapist, this went beyond the prescription and instruction of exercises, but also rapport:

> It's just that rapport. Maybe it's someone to relay their concerns to. Who can maybe reassure them about the symptoms they are feeling and guide them through their recovery. Probably, rather than prescribing a specific exercise for the average person. (S12)

Many HCPs acknowledged it is 'quite difficult to access physiotherapy' (S12) because 'there are huge therapy shortfalls at the moment... there's just not enough posts for the amount of therapy that is required' (S14).

Considering the challenges described above, alternative care pathways were explored, as discussed below.

Virtual follow-up

Many had positive experiences with virtual follow-up:

> We did a little study about foot ankle clinic follow-ups in COVID times and actually, 80% of patients were happy with remote follow-up. They didn't need to necessarily come into hospital and they were happy. (S8)

Though many concerns were stated, ranging from technology and connection issues to logistic issues with booking appointments. Particularly for physiotherapy telephone calls, there was discontent:

> I can tell you that most of the patients are unhappy with the telephone, all age, all age groups, telephone calls. They don't feel they were sort of considered, and I feel a lot of frustration on the side of the patient. (S10)

The creation and use of an App-based physiotherapy service was discussed, where patients could message a physiotherapist via an App and arrange virtual appointments if needed. Many HCPs felt this would be useful:

> Enabling information early. Enabling access permissively. And you know, so it's not shoved down their throat, but they can access information about care...I think has massive positives, so that makes sense. (S9)

Some felt that such a service may be run better if it were delivered by local HCPs, or was begun after an initial F2F visit. Some HCPs raised concerns over workload:

> The main problem because you get a rush of patients at one time and then it could be no one for awhile. And how do you manage that load if it's unpredictable when they're going to call you? (S16)

Other concerns were that it may exclude groups without access or experience with the technology and there were concerns with whom liability would lie if any

patients suffered harm. Another consideration was the transfer and availability of medical records using an App-based service.

Wound review

HCPs and physiotherapists in particular were apprehensive about conducting patient wound reviews over a virtual consultation. Poor connection and picture quality were areas of concern. Beyond this, physiotherapists felt this was beyond their usual role and that assessing a troublesome wound was best done by a surgeon. Most felt they would be happy to give reassurance about a healthy wound but 'if there's any ambiguity then you probably do want to see it face to face' (S17). Another suggestion to improve HCP wound assessment was that 'if you take a photo every time, and then you compare and you upload that to the system that would help you for the future' (S16). Other considerations were that 'sometimes patients may not like how their scar looks' (S14) and so they may be uncomfortable taking videos or photos of it.

OPPORTUNITY - SOCIAL

Table 5.9 shows the belief statements within the Opportunity - Social domain.

12. Social influences

Comparisons to other patients were sometimes felt to be helpful. The merit of having dedicated time to see a physiotherapist may also be useful:

> If you're at work, have got a busy life. If you've got a physio appointment that is protected by their employer because it's an appointment. And they know that you're under treatment. That gives you permission. That gives you the right to do your rehab, and I think that's really important. (S16)

Table 5.8: HCP Beliefs statements mapped to the TDF/COM-B domains: Opportunity - Physical

Barriers	Count	Facilitators	Count
OPPORTUNITY – PHYSICAL - 18			
11. Environmental context and resources - 18			
	Orthotic boot use		
Wear boot at night	2	Don't wear boot at night	2
Early boot affecting wound	1	Could discard boot at 2 weeks postop	2
		More likely to WB in a boot	2
		Use a Boot as less follow-up required	1
		Use a boot immediately postop	1
		Use a boot because it's available	1
	HCP resources		
	Patient follow-up		
Patients feeling rushed by surgeons in clinic	12	Less follow-up during COVID-19	14
Desire for consistent Rehab	4	More Virtual & Telephone follow-up during COVID-19	6
Hassle for patients to get to clinic	7	No Hassle for patients to get to clinic	0
Want a way for rapid review safety net	4	Patient-initiated follow-up	5
Unhappy with telephone follow-up	3	Desire to stratify at-risk patients	4
Shouldn't use EWB as a cost-saving measure to discharge patients early	3	Physios don't feel rushed	3
Lack of access between appointments	3	QR code for information in clinic	2
Surgeon anxiety with early discharge	1	Happy to defer advice to a booklet or App	2
Patient's don't like long waits	1	Extra follow-up is a bad use of resources	2
Things reverting to traditional approaches after COVID-19	1	Have more consultant input in clinic to enable early decisions	1
Avoid aggressive rehab and offer a regime which is safe for everyone	1	Having a contact is reassuring, even if patients don't use it	1
		Group therapy classes are useful	1
		Trauma is personnel heavy	1
	Continuity of care		
Lack of continuity is frustrating for patients	4	Consistent advice is more important than continuity of personnel	5
Surgeons wants to monitor their outcomes	3	It's useful to reference earlier talks	2
Mixed messages and conflicting advice between HCPs	2	Acknowledge variety in clinic set up	2
Patients feel short-changed seeing juniors in clinic	1	Continuity more important for complex injuries	1
		Reference patients will be seen by "the team"	1
	Value of physiotherapy		
Lack of physio access	4	Physio value is rapport and reassurance	3
Perception ankles get better without physio	2	Physios want more gym access	1
Surgeons leave instructions up to physios	1	Physio value is to keep patients progressing	1
Surgeons should give specific instructions to physios	1	Physios are more helpful than surgeons once the wound has healed	1
	Virtual follow-up		
Communication and integration issues	4	An App would be useful	7
Must allow physio to liaise with surgeons	3	Virtual fracture clinic is useful	5
Not so good for elderly	3	Set patient expectations early	2
Poor previous experience with Tele follow-up	3	Good to have a pool of clinicians for queries	1
Concerns for physio workload balance	2	Inpatient physio can make the App referral	1
Some physios might not like App	2	Some physios do all remote work already	1
What information would physio need - letter, X-ray etc	2	Pick the right patient	1
Ironic that the elderly could benefit the most	1	A Drop-in service would be useful	1
F2F physio instructions with feedback is superior	1	Better if locally run and able to offer F2F sessions	1
Referral process could be cumbersome	1	F2F first is better to establish a relationship	1
Liability concern with virtual follow-up	1	NHS videos would be useful	1
Patients don't know what they are missing if they receive no physio	1	An App could be used to monitor patient outcomes	1
		HCPs would like a national and local registry	1
	Virtual wound review		
HCPs perceive issues with virtual wound reviews	4	HCPs think this would work ok	4
Some patients don't like to look at wounds	1	Taking baseline photos for comparison would be helpful	1

Table 5.9: HCP Beliefs statements mapped to the TDF/COM-B domains: Opportunity - Social

Barriers	Count	Facilitators	Count
OPPORTUNITY - SOCIAL - 2			
12. Social influences - 3			
Social comparisons	2	Use past patients as examples	1
Employer time allowance for physio	1		

5.3.3 Target beliefs and discrepancies between HCPs and patients

Table 5.10 shows the target beliefs statements and discordant beliefs between patients and HCPs, as well as common discordant beliefs between HCPs.

Table 5.10: Target beliefs and discordant beliefs between patients and HCPs

Patient beliefs	Discordant HCP beliefs	Other HCPs beliefs
	1. Knowledge	
Don't understand what a "fully healed" wound is.	Use the criteria of a "fully healed wound" to advise on timeframes such as bathing and wound massage.	
Patients would like timeframes for returning to recovery.	HCPs are not confident about giving timeframes for recovery and are often vague or defer giving advice.	
	2. Skills	
Swelling and wound numbness are a major concern.	Rarely concerned about swelling or wound numbness, even dismissive.	There is diagnostic uncertainty around CRPS and when this should be assessed.
It can be safer to walk without crutches (less chance of crutches slipping and falling), or at least put their foot down for balance.	HCPs restrict patients' weight-bearing, believing the minor inconvenience to patients outweighs the theoretical risk of putting strain on the operative fixation.	Other HCPs believe the risk of non-weight-bearing (e.g. VTE and sarcopenia) outweigh even the risks of metalwork failure and revision surgery. Hence fixation should be supplemented and tested if required.
Find using weighing scales or percentages confusing and unhelpful for progressing weight-bearing. Just "trust your body".	Think that advising absolute values for weight or percentages of bodyweight help patients to weight-bear.	Think that allowing patients to weight-bear as comfortable is the best way to progress weight-bearing and pain is a limitation to damage.
Pain during the act of weight-bearing is relatively uncommon, it is usually anxiety that limits their weight-bearing.	Some believe patients have pain during weight-bearing.	
	14. Behavioural regulation	
Patients value seeing a physiotherapist to practice exercises.	Think that patients only do physiotherapy exercises when at physiotherapy appointments.	Think that patients need regular physiotherapy appointments to monitor and motivate them.
	4. Beliefs about capabilities	
HCPs comments about the severity of a patient's injury can influence their ability to progress their rehabilitation.	Providing pessimistic expectations safeguards against disappointment and medico-legal repercussions.	Making an effort to be optimistic will boost patients' capabilities to progress their recovery.
	11. Environment context and resources	
Uncertainty about when to use their boot.	Some suggest using the boot at night.	Suggest removing the boot at night, using it only whilst walking.
Find the boot causes issues with walking (unequal foot height) and irritates their wound.	Think the boot is excellent to help with walking, especially compared to plasters.	Allow patients to discard their boot within the first 2 weeks postoperatively.
Don't want to bother the NHS with minor concerns.	Advocate for early discharge and "patient-initiated follow-up".	
There is variability and no strong desire to see the same HCP at follow-up.	Strongly believe that continuity of personnel is paramount and that patients prefer it.	Believe that consistency of advice is more important than continuity of personnel. Advocate for standardised rehabilitation pathways.
Patients feel rushed by surgeons in clinic.	Surgeons feel rushed in clinic.	Physiotherapists generally don't feel rushed in clinic.
	Some feel physiotherapy is fundamental and more important than seeing a surgeon postoperatively.	Some believe physiotherapy is rarely needed.
Are happy to attend appointments, only some find attending a hassle.	Think that patients generally find it a hassle to travel to appointments.	

5.4 Discussion

Healthcare professionals shared many of the same beliefs as patients with regard to commencing weight-bearing after ankle fracture surgery: "trusting your body" and gradually building up weight-bearing were commonalities between groups. There were notable discrepancies surrounding the significance of swelling post-operatively and the interpretation of numbness or tingling around surgical wounds. The belief among healthcare professionals that non-weight-bearing is safer for patients and reduces the risk of complications was in contrast to patients' experiences, who often felt unsteady and vulnerable when using crutches. The challenges and imbalances in surgical follow-up were unearthed, exploring overstretched resources and the dependent relationship that conventional follow-up and therapy models may establish.

5.4.1 Interpretation

Capability - Physical

Chapter 4 found that swelling and changes in ankle appearance and sensation are all prominent concerns for patients, and this is an area that causes a lot of anxiety and uncertainty. However, unless associated with infection or VTE, HCPs were unconcerned and even dismissive of swelling. HCPs viewed swelling as a routine part of patients' injury, treatment or recovery and were rarely concerned about burning or numbness around the ankle unless there was a corresponding motor loss. This marked discrepancy provides an opportunity: establishing a consensus around what symptoms are expected and which require HCP review should be achievable and providing patients with simple advice around this area could relieve a lot of anxiety. With regards to what does cause HCPs cause for concern, wound prob-

lems and infection, rather than fixation failure was the prime concern. Considering a problematic wound is tangible and should be externally assessable (as opposed to X-ray assessment), this is a potentially meaningful warning sign around which patient advice can be based. Further patient education around wound assessment with descriptors or pictures could also be helpful, as wound description was another area of discrepancy between patients and HCP: a healthy or "healed" wound was often the basis on which HCPs made rehabilitation recommendations (e.g. wound soaking or massaging), yet this term was poorly understood by patients.

Echoing the results of Chapter 4, HCPs acknowledged the variability around weight-bearing language and instructions, as found in previous research [8, 154, 155]. Though many acknowledged the variability, few HCPs appreciated the confusion and uncertainty that patients had around weight-bearing terms. Many aligned with patients in believing that returning to weight-bearing is a gradual process and "trusting your body" is the best strategy to increase weight-bearing safely. However, several recommended other methods such as increasing according to prescribed percentages of body weight, so achieving consensus on this matter could be useful. The concept of permitting patients to put their foot down for balance during non-weight-bearing periods was discussed, and a majority of interviewed HCPs felt this was reasonable. Agreeing to a consensus on this statement could also be very useful for patients in the early phases of their recovery.

Capability - Psychological

HCPs found it difficult to give patients timeframes for recovery and often gave vague or deferred responses. Patients were often surprised by this vagueness, though there is limited guidance in medical literature for timeframes for returning to ADLs and

life roles, with most previous studies measuring PROMs or radiographic changes [16, 156]. Accurate timeframes were wanted by patients and HCPs alike, and beyond the benefit to the individual patient, many HCPs felt that the comparison of return to life roles would be useful measurements to report in future research studies, potentially increasing uptake of the results by HCPs.

HCPs shared patients' beliefs that self-efficacy is paramount for recovery. This aligns with research in other body areas such as the hip and upper limb [157, 158]. In a systematic review Connolly et al. [159] found that self-efficacy was beneficial for recovery across a range of injury locations, but often this was an innate characteristic, potentially related to level of education and few interventions were able to enhance individuals' self-efficacy. A mixed methods study by Stern et al. [158] found that patients with high-self efficacy reported better outcomes after distal radius fracture and engaged more with self-management strategies. In addition, they found that patients with high self-efficacy would pro-actively seek information and problem solve, where as those with low self-efficacy were passive recipients and put greater emphasis on "following medical advice" [158]. During RAAFT interviews, this concept was probed deeper, with HCPs believing that if patients create a dependency on HCPs, they fail to transfer responsibility for their rehabilitation and outcome to themselves.

Motivation - Automatic

RAAFT is the first study to explore the root of anxiety around weight-bearing after ankle fracture surgery. For patients, some reported a public perception, sometimes reinforced from their own, or relative's past experiences, that patients should not weight-bear after an ankle fracture. HCPs theorised that this anxiety is more pronounced after trauma surgery than elective surgery, most likely because trauma

patients will be told to restrict their weight-bearing pre-operatively while their bones are unstable and it takes time to reverse this message, particularly if these weight-bearing restrictions are continued postoperatively. The rushed environment of fracture clinic was acknowledged as a non-ideal place to first practise weight-bearing, yet the presence of a HCP to simulate "eureka" moments was thought to be helpful, with most agreeing with patients that it is anxiety rather than pain that is the principal barrier to commencing weight-bearing.

Motivation - Reflective

A finding throughout was that most HCPs deferred decisions around weight-bearing to senior or consultant colleagues and even consultants would be unlikely to contradict the advice of another HCP. Anxiety around weight-bearing was felt to follow historic practice, for which the origin is unclear or anecdotal. There was a paradox between many of the contraindications to early weight-bearing: frailty and poor bone stock were quoted, yet these patients are those that face the greatest risks of prolonged periods of non-weight-bearing and immobility. This relates not just to sarcopenia [160, 161] and greater institutionalisation [14, 15], but to venous thromboembolism and cardiovascular complications [162, 163]. Additionally, as found by Eickhoff et al. older patients had more difficulty in complying with weight-bearing instructions [164]. A paradigm shift in the operative planning and fixation techniques was proposed to promote early weight-bearing, but many HCPs remain cautious. There was a sense that the "minor inconvenience" of non-weight-bearing outweighs the potentially catastrophic risks of wound infection and fixation failure. Several stated fear of medico-legal repercussions as a reason for not permitting early weight-bearing, feeling the body of medical evidence is not currently in their favour. This

sentiment was also reflected in some HCPs practising defensively and tending to be pessimistic when communicating with patients to avoid later dissatisfaction. Others recognised the detrimental effects pessimism could have on patients' self-efficacy and beliefs in their capabilities as discussed in Chapter 4.

Opportunity - Physical

The COVID-19 pandemic re-framed the expectations for delivery of healthcare follow-up, serving as a catalyst to embrace emergent technology [165, 166]. Many HCPs have reported at least some shift back to conventional methods, but there remains an opportunity to address long-standing issues of an overburdened healthcare system. HCPs agreed that surgeons feel rushed in clinic, which often leaves patients wanting. Many felt that after the early post-operative phase, seeing a physiotherapist is more beneficial than repeated surgical follow-ups, though a mechanism for timely clinical review of problems was paramount. However, physiotherapy provision is variable and regional variation is not explained by clinical need [167].

Several HCPs had experience with virtual follow-up, often with mixed experiences, as supported by Gilbert et al. [168]. Some felt that it solved unnecessary travel, parking and waiting times, which HCPs perceive as a disproportionate nuisance for patients, especially those with limited mobility or social support. Others found that patients felt short-changed, particularly by telephone follow-up, and that technical issues limited the usefulness of virtual follow-up.

While the introduction of virtual follow-up may be limited and dictated by the availability and usability of technology, other aspects of ankle fracture recovery may be amenable to improvement by consensus. HCPs felt favourable about using an orthotic boot in ankle fracture recovery, particularly after equivalence to plaster

cast treatment was reported in an RCT by Kearney et al. [11]. However, as found in Chapter 4, there was inconsistency for when and for how long the boot should be used in the post-operative phase. Standardisation of advice may be achievable by consensus and solve one source of uncertainty for patients, who were not as unanimously enthusiastic about walking in an orthotic boot.

Other themes around continuity were generated, with HCPs generally feeling that continuity of care relates to continuity of personnel and that this represents a gold standard of healthcare provision. Haggerty et al. [169] describe a trio of continuity: 1) Informational continuity, 2) Management continuity and 3) Relational continuity. As care circles enlarge and multi-disciplinary involvement widens, there is an acknowledgement that maintaining continuity of care can be challenging [170]. However, patients in Chapter 4 placed greater importance on informational and management continuity rather than relational continuity, which HCPs assumed was paramount.

Opportunity - Social

While patient self-management was perceived as useful, some patients struggled to keep up with their exercise regimen, particularly once back at work. Therefore, providing patients a dedicated period away from work with a physiotherapist to complete their exercise program was viewed as an underappreciated benefit of physiotherapy appointments.

5.4.2 Strengths and limitations

This is the first qualitative study in the literature to explore HCPs beliefs around rehabilitation after ankle fracture surgery. Mcphail et al. [13] interviewed one or-

thopaedic surgeons, three physiotherapists, one occupational therapist and one podiatrist, but focused only on patient perspectives and life experiences. Conversely, Rydberg et al. [149] interviewed only doctors and focused entirely on the usability of a new fracture registry system, without reference to patient experiences. RAAFT has compared HCPs priorities and beliefs around ankle fracture recovery with patients' own experiences, identifying discrepancies and potential areas for harmonisation and advancement.

Similar limitations discussed in Chapter 4 regarding a single interviewer and the conduct of virtual interviews apply to the HCP interviews. In most cases there was an existing professional relationship between interviewer and interviewee, and so the lack of F2F interaction is unlikely to have been a substantial barrier to rapport and faithful discussion. However, this prior relationship is a primary limitation as participants may have been uncomfortable disclosing more contrary or sensitive views or may have modified responses to align more closely with the interviewer's perspective [171, 172].

Only two groups of HCPs were invited to interview, and so this limits the full perspective of HCPs whom patients may interact with during their rehabilitation journey. Originally, interviews with nurses and plaster technicians were planned; however, during early interviews with physiotherapists, it quickly became evident that decision-making was deferred to doctors. Therefore, as behaviours influencing decision-making, particularly in the outpatient setting were the priority topic, interviews were limited to doctors and physiotherapists, for which there was a good spread of representation.

5.4.3 Conclusions

The behaviours of HCPs caring for patients with operatively-treated ankle fractures have been explored. Key discrepancies between patient and HCP perceptions, and areas for consensus and improved care have been established. These related to physical symptoms of swelling and numbness, when they should be investigated, and when to begin wound soaking and massage. In addition, findings from previous quantitative studies have been verified regarding variability around weight-bearing language and advice, with a new paradigm of permitting weight-bearing for balance proposed. Historical practice and medico-legal concerns were the prime sources of HCPs anxieties around early weight-bearing after ankle fracture surgery, yet the significant life impacts and potential long-lasting complications of non-weight-bearing have been brought to light.

A central concept explored was patients' self-efficacy and engagement with their own recovery and how interactions with HCPs may actually reduce their ability to self-manage. Alternative options for follow-up such as virtual consultations have been explored, yet the proposed theory is not that this is a cost saving or convenience measure, but a method for shifting the responsibility for patients' recovery from HCPs to patients. The following chapters now explore what knowledge and services patients need and want to self-manage their recovery and seek to gain consensus among HCPs and enable standardisation of rehabilitation information and pathways.

CHAPTER 6

Co-design of rehabilitation intervention - Patients

6.1 Introduction

Co-design or co-production refers to the process of researchers, practitioners and the public working together, sharing power and responsibility to deliver research [173]. Increasing co-production in research has been part on the strategic vision of the NIHR, primarily to ensure research outputs are relevant and applicable to service users [173, 174].

As discussed in Chapter 1, various theories and frameworks can be used to design a healthcare intervention. Core tenants for intervention development include using suitable theory, understanding context, establishing key uncertainties and stakeholder engagement [58]. In some cases, existing interventions can be adapted to suit a new context and evaluated. As identified in Chapter 2, there are no behaviourally-based effective interventions in the field of ankle fracture rehabilitation. Furthermore, there was significant uncertainty around the beliefs and behaviours of patients and HCPs with respect to weight-bearing. Hence adapting an existing intervention was not suitable.

The Behaviour Change Wheel (BCW) is ideally placed to co-design an intervention de novo [49, 83]. It begins by deconstructing the problem or need, defining it in its base behavioural components and follows a systematic process for addressing the need. The three core phases of the BCW are:

1. Understand the behaviour
2. Understand the intervention options
3. Understand the content and implementation options

The BCW is described in Chapter 1, Figure 1.6. Once the behavioural problem has been identified, the most common methodology used in phases two and three of the BCW is a qualitative approach in which interviews and or workshops are used to gain in depth data to help define behavioural problems and develop solutions with stakeholders [49, 175, 176]. Roberts et al. combined qualitative and quantitative approaches to identify significant barriers and facilitators to implementing a Sepsis Six care bundle in hospitals [133]. They used analysis of semi-structured interviews to generate belief statements which informed a questionnaire to determine the generalisability of belief statements among a wider group of stakeholders. Chapters 6 and 7 follow a similar approach but add in an intermediate step of the generation of behavioural intervention bundles to facilitate discussion at stakeholder workshops, as proposed by Shallcross et al. [135].

6.1.1 Objectives

1. To determine intervention options for a rehabilitation package.

2. To identify content and implementation options through consultation with patients.

6.2 Methods

6.2.1 Study design

Informed by Chapters 1 to 5, a rehabilitation strategy was co-designed using the three phases of the BCW [83].

Phase one of the BCW, "Understand the behaviour" was done by assessing participants' capability, opportunity and motivation to engage with the behaviour (weight-bearing) in Chapters 4 and 5. Phases two and three are the subject of Chapters 6 and 7, as described below.

Understand the intervention options

Key barriers, enablers, and areas needing change (as established in Chapters 4 and 5) were mapped onto the nine intervention functions of the BCW [44]. A list of candidate behaviour change intervention bundles was generated [135] using analysis methods described in Section 6.2.2.

Understand the content and implementation options

This was done using the Affordability, Practicability, Effectiveness/ Cost-effectiveness, Acceptability, Safety/ Side effects (APEASE) criteria [83]. A modified online Nominal Group Technique (NGT) patient workshop and survey were conducted and reported in accordance with the Checklist for Reporting of Survey Studies (CROSS) [177].

The formulated behaviour change intervention bundles were presented and discussed at a workshop attended by ten patients recovering from ankle fracture surgery. All participants were then sent a survey, asking them to rank the importance of different aspects of the intervention bundles and content.

Setting and sampling

Recruitment to the patient workshop followed the same process described in Chapter 4. Examples of the PIS and consent form are provided in Appendix E.1 and Appendix E.2. A maximum variation sample of patients from different geographical, demographic and socio-economic backgrounds at different stages in recovery from their ankle fracture were recruited. Participants were offered a £75 shopping voucher as an incentive to participate. Patients were provided with a PIS specific to the workshops. The workshop was conducted virtually, and patients completed an online consent form before the workshop.

Approvals

Approvals were obtained as described in Chapter 4.

Data collection methods

An online Nominal Group Technique (NGT), adapted from Bateman et al. [178] and Fisher et al. [179] was used. Figure 6.1 outlines the stages of the NGT. The workshop took place between 10 am - 4 pm on December 13th 2021. Participants were split into three break-out groups, facilitated by the lead researcher and two RAAFT patient representatives, whose characteristics are described in Section 4.2 and Section 1.6 respectively.

All participants completed pre-workshop tasks, including watching an explanatory video and completing a worksheet (see Appendix E.3). The worksheet included separate sections for different intervention bundles (see Section 6.2.2). Participants were presented with an illustrative quote from the interviews in Chapters 4 and 5 and asked to consider if they could relate or identify with the quote which expressed a particular concern, struggle or need. They were then asked to consider what additional content would be helpful to address their concern or need and how they would like that support or content delivered. Additionally, they were asked to consider any potential drawbacks of this new service and if any particular groups of patients might be excluded or find the new service challenging to engage with.

During the workshop, participants progressed through the worksheet discussing intervention bundles corresponding to different COM-B domains. All break-out groups were recorded. After the workshop, all recordings were reviewed, and notes from facilitators were compiled to create content for the survey.

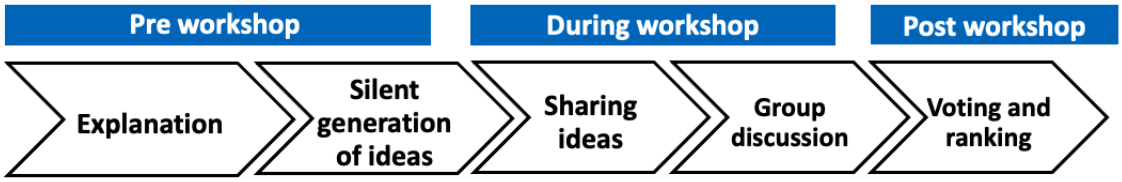


Figure 6.1: Online Nominal Group Technique (NGT)

Survey

An online survey was compiled using data from the workshop. The online survey link was emailed to participants and completed within two weeks of the workshop. Participants were asked to indicate how helpful various advice and support would be for their recovery by ranking statements on a 5-point Likert scale from "very unhelpful" to "very helpful".

6.2.2 Analysis

Generation of intervention bundles

Intervention bundles were generated by mapping target themes/ belief statements generated during Chapters 4 and 5 to intervention functions from the Behaviour Change Wheel (BCW) [83]. "Intervention functions" relate to a range of methods that can be used to change behaviour. NICE first issued the principles for selecting and evaluating behaviour change interventions [180]. Later, Michie et al. conducted a systematic review of intervention functions and produced mapping matrices to link COM-B domains to intervention functions that were most likely to bring about behaviour change (see Figure 6.2) [44].

Once target intervention functions were identified, these were mapped onto potential policy categories using further matrices shown in Figure 6.3. A list of definitions of intervention and policy options is provided in Appendix E.5. After establishing potential intervention functions and policy options, the corresponding behaviour change techniques (BCTs) were selected from the BCT taxonomy [64]. The taxonomy and a complete list of potential BCTs can be found in Appendix E.4. BCTs were chosen using the BCW guide, which lists the most suitable and commonly used BCTs for each of the nine possible intervention functions [83].

The resulting target behaviour, intervention function, policy category and corresponding BCT formed an "Intervention bundle", which was then presented to stakeholders during the workshop. For simplicity, no reference to behaviour change theory was used during the workshop. Instead, the intervention bundles were broken down into relatable concepts and categories as demonstrated in Appendix E.3 and discussed in Section 6.2.1.

Model of behaviour: sources	Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
C-Ph					√				√
C-Ps	√				√				√
M-Re	√	√	√	√					
M-Au		√	√	√			√	√	√
O-Ph						√	√		√
O-So						√	√		√

1. Physical capability can be achieved through physical skill development which is the focus of training or potentially through enabling interventions such as medication, surgery or prostheses.

2. Psychological capability can be achieved through imparting knowledge or understanding, training emotional, cognitive and/or behavioural skills or through enabling interventions such as medication.

3. Reflective motivation can be achieved through increasing knowledge and understanding, eliciting positive (or negative) feelings about behavioural target.

4. Automatic motivation can be achieved through associative learning that elicit positive (or negative) feelings and impulses and counter-impulses relating to the behavioural target, imitative learning, habit formation or direct influences on automatic motivational processes (*e.g.*, via medication).

5. Physical and social opportunity can be achieved through environmental change.

Figure 6.2: Matrix of links between COM-B and intervention functions [83]

	Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
Communication/ Marketing	√	√	√	√				√	
Guidelines	√	√	√	√	√	√	√		√
Fiscal			√	√	√		√		√
Regulation	√	√	√	√	√	√	√		√
Legislation	√	√	√	√	√	√	√		√
Environmental/social planning							√		√
Service Provision	√	√	√	√	√			√	√

Figure 6.3: Matrix of links between intervention functions and policy categories [83]

Analysis of survey responses

Analysis was conducted in R [108] and figures were compiled using the package Likert [181]. 75% was used as a threshold for consensus [182, 183].

6.3 Results

6.3.1 Intervention bundles

Table 6.1 shows the list of intervention bundles generated from the analysis of the results of Chapters 2 to 5. The intervention functions selected were "Education", "Training", "Environmental Restructuring", "Persuasion", and "Enablement". The policy category selected to modify patients' behaviour was "Service provision", and to modify HCPs behaviour, "Guidelines" was selected. Corresponding BCTs are listed in the last column of Table 6.1.

Table 6.1: COM-B Intervention bundles

COM-B/ TDF Domains	Intervention functions	Policy options	Behaviour change techniques (BCTs)
Capability – Physical **2. Skills** Uncertainty how to weight-bear or use crutches. Struggling to perform ADLs.	**Training** How to use walking aids and progress weight-bearing. How to perform ankle exercises. How to perform ADLs.	**Service Provision** An App/ website with instructional videos. Live chat to a physiotherapist.	4.1. Instruction on how to perform the behaviour. 6.1. Demonstration of the behaviour. 8.1. Behavioural practise/ rehearsal. 8.7. Graded tasks.
Capability - Psychological **2. Knowledge** What's normal? What to expect?	**Education** Timeframes for recovery, personalised to the patient. Pictures of normal and concerning wounds.	**Service Provision** An App/ website with explanations. Live chat to a physiotherapist. Collect information from patients about their recovery which can then be used to update the App timeframes information.	5.1. Information about health consequences. 7.1. Prompts/Cues. 2.3. Self-monitoring of behaviour.
10. Memory, attention and decision processes The perception that exercises only happen during physiotherapy clinic. Forgetting to do exercises.	**Environmental restructuring** Reminders to do physiotherapy	Exercise reminders via an App, with or without a diary.	7.1. Prompts/Cues. 2.3. Self-monitoring of behaviour.
Opportunity - Physical **11. Environment** Lack of access to physiotherapists. Lack of information between appointments. Uncertainty what aids would help or where to get them.	**Training** Which resources to use and how. **Environmental restructuring** Alternative access to HCPs (e.g. virtual).	**Service provision** An interactive website or App A national physiotherapist on-call 9-5pm to answer questions via the App or videoconference.	9.1. Credible source. 1.4. Action planning.
Opportunity - Social **12. Social influences** Peer support: sharing advice and experiences. Advice for family and friends.	**Environmental restructuring** Group physiotherapy. A method for providing peer support. **Education** Education resources for family and friends.	**Service Provision** Virtual group physiotherapy classes. A Peer support forum via an App.	3.1 Social support (unspecified). 3.2. Social support (practical). 6.2. Social comparison.
Motivation - Reflective **4. Beliefs about capabilities** Improve self-efficacy. Knowledge/ beliefs of benefits and lack of harm of walking and exercising. Reduce conflicting HCP advice. **9. Goals** Establish patient-specific goals.	**Persuasion** Persuade patients that they have the capability to walk/ exercise. **Education** What to expect during their recovery. Help patients identify red flag signs. **Enablement** Set goals and develop strategies for coping with pain.	**Service Provision** An App/ website with instructional videos. Live chat to a physiotherapist or virtual appointments. **Guidelines** Establish consensus for rehabilitation pathways and advice.	15.1. Verbal persuasion about capability. 5.1. Information about health consequences. 1.1. Goal setting (behaviour).
Motivation - Automatic **13. Emotion** Pain avoidance and fear of weight-bearing.	**Enablement** Set goals and develop strategies for coping with pain. **Education** What to expect during their recovery/ what's normal.	**Service Provision** An App/ website with instructional videos. Live chat to a physiotherapist.	9.1. Credible source. 15.1. Verbal persuasion about capability. 5.1. Information about health consequences.

6.3.2 Workshop and survey

Participants

Fifty participants were invited to participate in the workshop, of which ten (20%) agreed and attended. Participant sites and characteristics are shown in Table 6.2 and Table 6.3.

Table 6.2: Workshop participant sites (Patients)

Site	**N=10**
Royal United Hospitals Bath	3 (30%)
Dorset County Hospital	1 (10%)
East Surrey Hospital	1 (10%)
Maidstone and Tunbridge Wells Hospital	1 (10%)
Oxford University Hospitals	1 (10%)
Queen's Medical Centre Nottingham	1 (10%)
Royal Preston Hospital	1 (10%)

Table 6.3: Workshop participant characteristics (Patients)

Participant ID	**WAX participant?**	**Interview Participant?**	**Age**	**Gender**	**PSEQ-2 score**	**Occupation**	**Days post-surgery**
1	Yes	Yes	68	Female	4	Not employed	662
2	Yes	Yes	65	Female	12	Not employed	192
3	Yes	Yes	69	Female	5	Not employed	175
4	Yes	Yes	43	Female	4	Not employed	161
5	Yes	Yes	68	Female	10	Not employed	159
6	Yes	No	28	Female	2	Sedentary	105
7	Yes	No	45	Female	6	Intermediate	103
8	Yes	No	55	Female	10	Sedentary	88
9	Yes	No	40	Female	8	Sedentary	80
10	No	No	44	Male	NA	Labour	14

All participants completed the post-workshop survey. In addition, the two RAAFT patient representatives also completed the survey based on their personal experience

of injury or from caring for relatives with an ankle injury.

Survey results

The survey results show how strongly patients agreed with a variety of statements. The likert bar plots are displayed in Figure 6.4 to Figure 6.13. The percentages on the right side of the Likert bar plots correspond to the proportion of responses that were ranked "moderately helpful" or "very helpful, or "agree" or "strongly agree". The percentages on the left correspond to those ranked "moderately unhelpful" or "very unhelpful", or "disagree" or "strongly disagree", and the middle grey percentages to "neutral". Though 75% was stated as the level for consensus, in many cases regarding the content of a novel rehabilitation service, it was not the absolute percentage that was important, but instead it gives an indication of which content should be prioritised in futures stages of development.

Knowledge

Figure 6.4 shows the survey results within the Knowledge domain.

A wide range of knowledge was deemed helpful. Physical concerns included advice around swelling, skin colour changes and wound management. Providing expectations was also important, including time-frames for returning to driving, work, and hobbies, as well as expectations for a full recovery and the likelihood of suffering long-term functional restrictions or complications. There was also uncertainty about if and when patients would need removal of their ankle metalwork, and consistency of advice was desired.

Helpful additional advice desired included advice on available financial support, how to optimise the home layout and when to use or discontinue using their post-

operative boot and other resources. There was less enthusiasm for general psychological support, but all felt the need for credible information resources.

Skills

Figure 6.5 shows the survey results within the Skills domain.

Patients responded with the desire for additional skills training around weight-bearing, exercise and activities of daily living. They wanted skills training for mobilising on crutches and progressing with weight-bearing towards independence. Advice around ankle exercises, the use of exercise equipment, and how to perform non-ankle (e.g. upper body) exercises to keep fit was desired.

Several patients mentioned wound massage during the workshops, however, many were uncertain when and how to perform this and desired additional skills training in wound management. Patients also wanted extra advice on adjusting their orthotic boot and using injectable VTE prophylaxis.

Advice was desired around life skills that were particularly challenging whilst non-weight-bearing or using crutches, such as cooking, carrying drinks and showering. There was less interest in more general tasks of personal care or those where patients could sit down to perform tasks.

Knowledge and skills delivery

Figure 6.6 and Figure 6.7 show the results of the survey regarding the delivery of the Knowledge and Skills domains.

There were similar preferences for the delivery of advice. Most were open to receiving online advice, advice directly from a HCP or from a paper booklet. However, patients were less enthusiastic about receiving a series of emails week after week and

seemed to prefer the ability to dip into information at their own pace, as well as seeing what was to come in their recovery.

Reminders

Figure 6.8 and Figure 6.9 show the survey results for the Reminders and Reminders delivery domain.

Most patients would have liked a service that provided them with reminders to perform physiotherapy exercises and felt a structured program with inbuilt reminders would be helpful, as well as tips for building this into their daily routine.

Patients were less interested in using an exercise program for keeping a diary and tracking their progress, feeling that this might overburden them with tasks. There was also less desire for reminders to take VTE prophylaxis or analgesia. Most patients preferred such a reminder service to be delivered in the form of a booklet or a bespoke rehabilitation App rather than being given a generic list of existing Apps.

HCP Access

This section considered novel methods of interacting with HCPs. Figure 6.10 shows the survey results within this domain.

Regarding the organisation of care, there was a desire for the ability to make clinic bookings more easily and flexibly. Having a named contact available for queries was suggested. Additionally, some patients expressed frustration with having to wait in Accident and Emergency department (A&E) multiple times if injured away from their home region, and the majority agreed being referred directly to their local orthopaedic service would be preferable. Some patients had good experiences with

novel systems for requesting and receiving digital copies of their X-rays, and most agreed this would be useful. Having access to hospital records and clinic notes was also desired. Additionally, links to information on patients' injuries and treatments, including explanations of their X-Rays was desired.

With regard to physiotherapy, most would have liked earlier physiotherapy contact as an outpatient. Proposed helpful physiotherapy functions included videos of patients doing exercises or using different walking aids with feedback or virtual physiotherapy appointments to get direction and feedback. Several patients were interested in virtual group therapy classes, including yoga and pilates. Patients were enthusiastic about the ability to have a live messenger chat with a physiotherapist to answer questions, particularly if that physiotherapist had access to their relevant medical records. There was (mixed) interest in the ability to avoid additional surgical follow-up by instead sending pictures of their wounds and receiving virtual advice. There was an acknowledgement that different people had different needs and if offering alternative methods of healthcare interactions such as virtual consultations, these should be optional.

Social support

Figure 6.11 shows the survey results within the Social support domain.

Advice on where to procure additional rehabilitation equipment or a sharing message board was discussed, particularly as patients usually only needed equipment for short periods of time and didn't want to waste it. This concept of patients sharing information, experiences and advice was also seen as very helpful. Many found that even the opportunity to discuss with other people in similar situations with similar injuries during the patient workshop was valuable. Suggestions were that this peer

support could be organised in the form of a chatroom or virtual events. There was a consensus that having a HCP to moderate a forum and avoid misinformation would likely be useful.

Additional help accessing financial assistance, benefits and other social support was wanted. A booklet or video for families about how they can support patients was deemed helpful. There was less enthusiasm for engaging families in the peer support forum or giving routine life advice, e.g. cooking recipes.

Monitoring

Figure 6.12 shows the survey results within the Monitoring domain.

The idea of remotely monitoring patients' recovery was discussed. This was primarily to allow data to be used for research or surgeon feedback, and as long as this was secure and anonymised, all were happy with this. Patients were amenable to responding to questionnaires or providing this information via a text link on their phone or via email, as opposed to post or phone. Having weekly questionnaires in the early stages and tapering off thereafter was considered reasonable.

Patients also felt this function could be used to track their progress and motivate themselves and that the data could be used to identify patients that were recovering slowly or had poor scores, particularly if they could then be flagged for additional support or assessment. They could also compare themselves to other people with similar injuries.

The idea of screening patients that were at risk of depression or slow recovery (e.g. those with unhelpful pain beliefs) was discussed, and patients were amenable to this, but there was debate as to when this was best done: two weeks was considered too early by some, but most thought the six week time-point would be reasonable.

The patients were asked if they were concerned about "labelling" people at risk of depression, but this was generally not seen as a concern, particularly if those at risk could be offered additional support.

Overall delivery

Figure 6.13 shows the results of the survey with regard to the overall delivery of the rehabilitation package.

During the workshop and survey, patients were asked about their preferences for the overall delivery of the proposed additional support. Most felt it would be a valuable addition to their recovery that they would engage with, and that a website or App would be the ideal delivery method. Before and during the workshop, it was explained that cost savings may be needed elsewhere to justify the development of this new intervention and that reducing F2F follow-up might be one way of achieving this. Most patients felt that if they had access to the support discussed in the sections above, they would be amenable to this. Patients had mixed views about the usefulness of their six-week surgical follow-up visit and felt they would consider forgoing this appointment if they had access to the proposed rehabilitation App. Similarly, they would consider having less F2F physiotherapy if the virtual option was available. However, there was a consensus that even with the App, patients would still want to see a physiotherapist F2F at least once during their recovery.

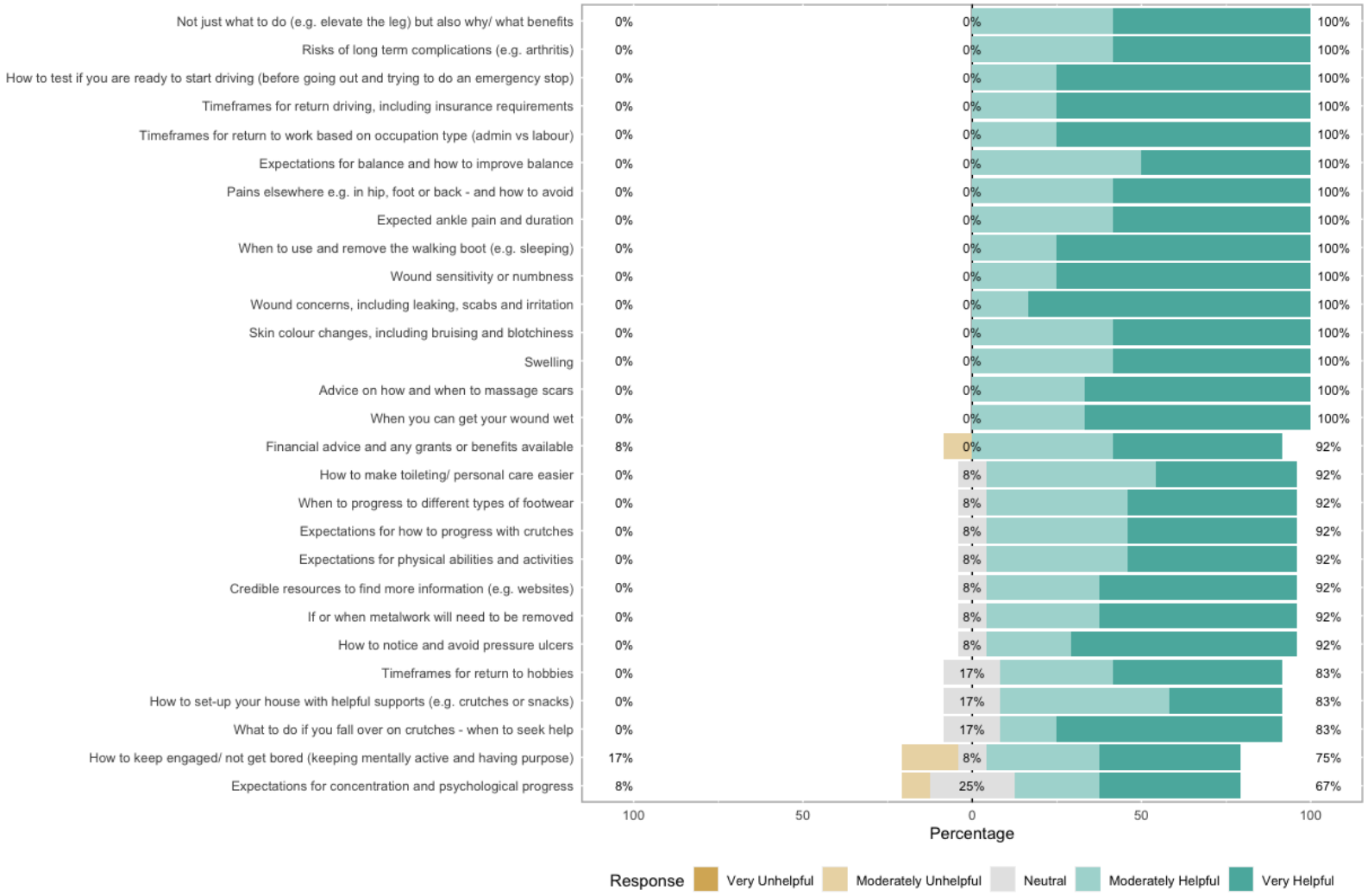


Figure 6.4: Patient survey - Knowledge

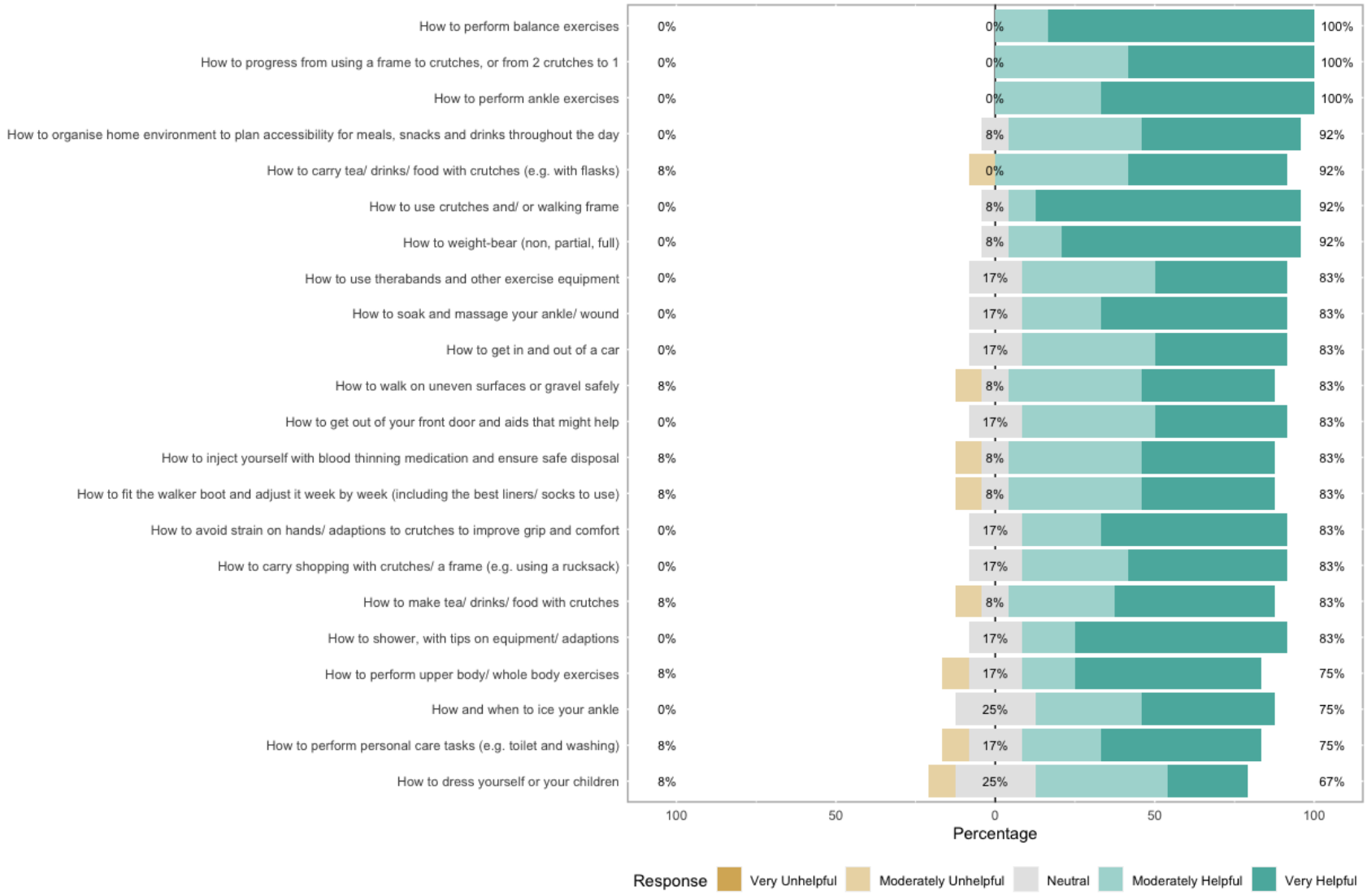


Figure 6.5: Patient survey - Skills

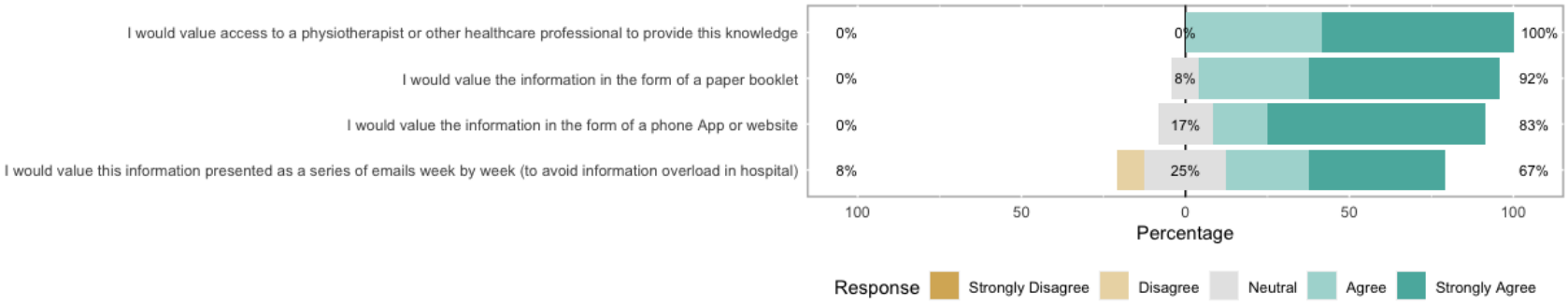


Figure 6.6: Patient survey - Knowledge delivery

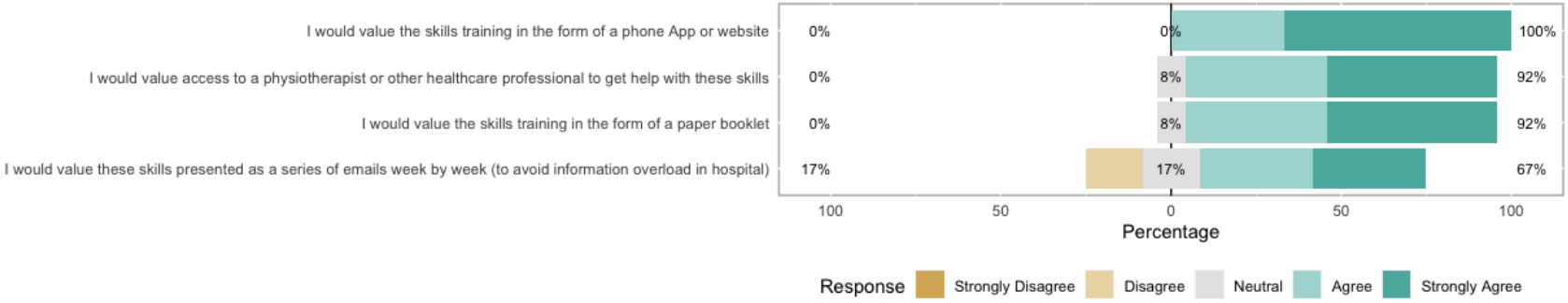


Figure 6.7: Patient survey - Skills delivery

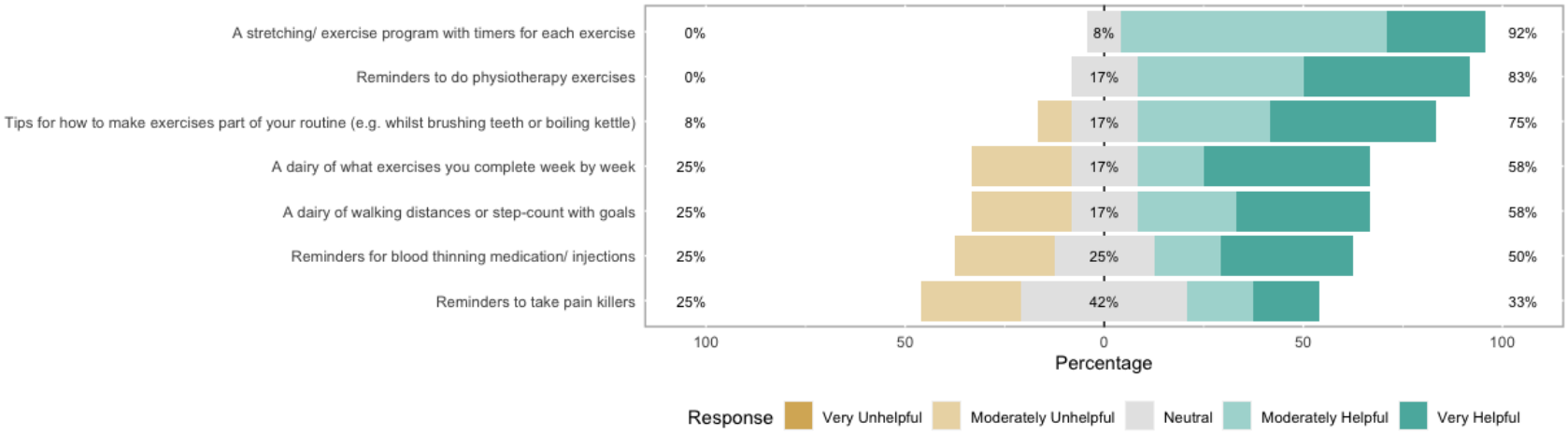


Figure 6.8: Patient survey - Reminders

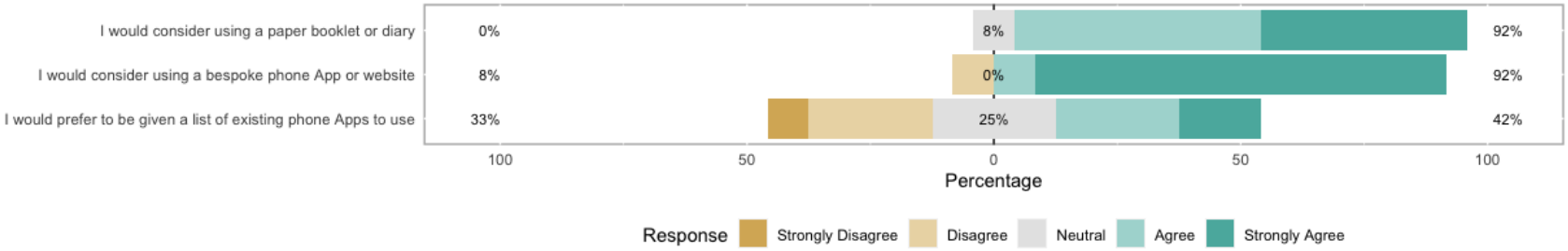


Figure 6.9: Patient survey - Reminders delivery

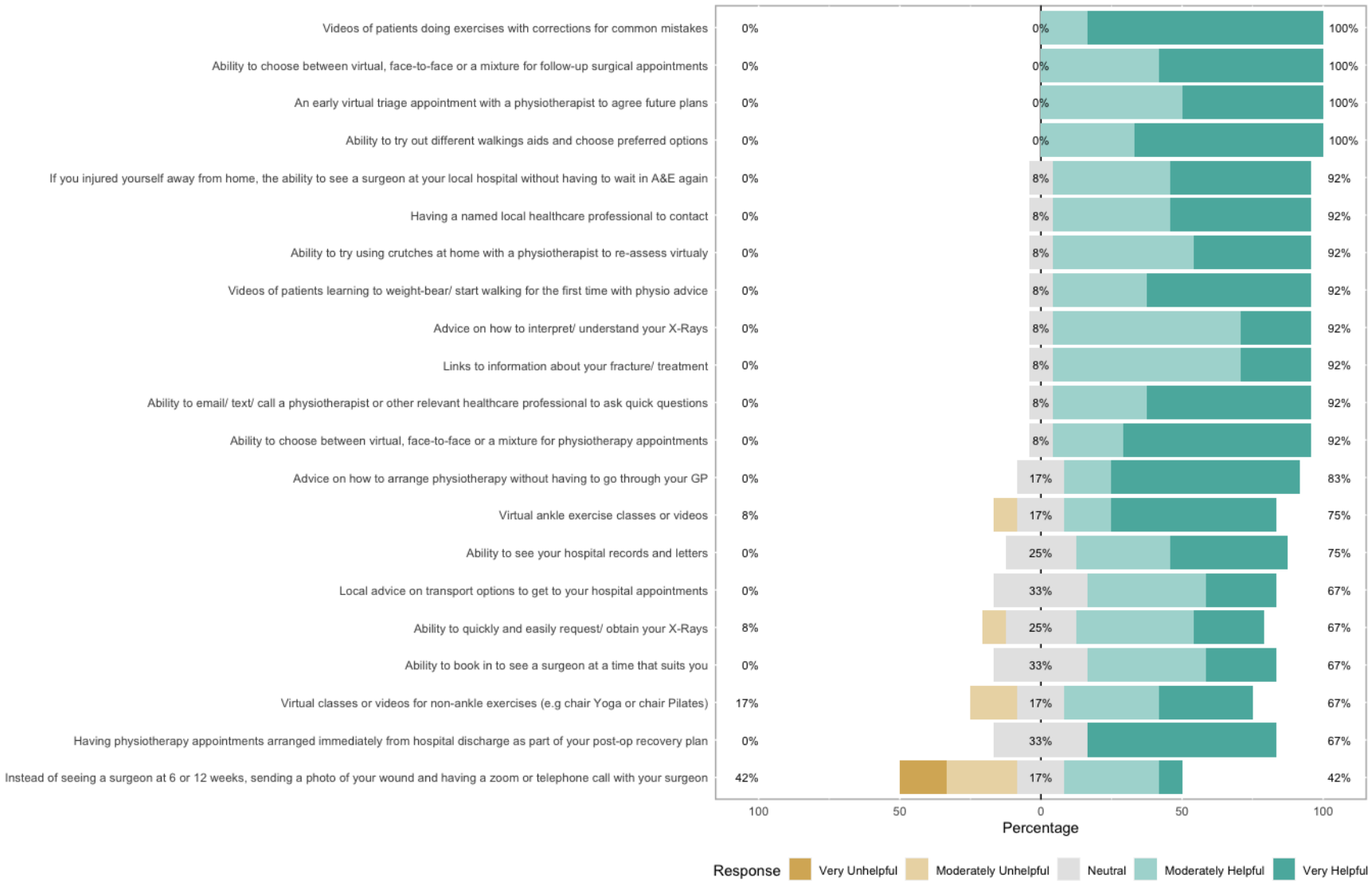


Figure 6.10: Patient survey - HCP access

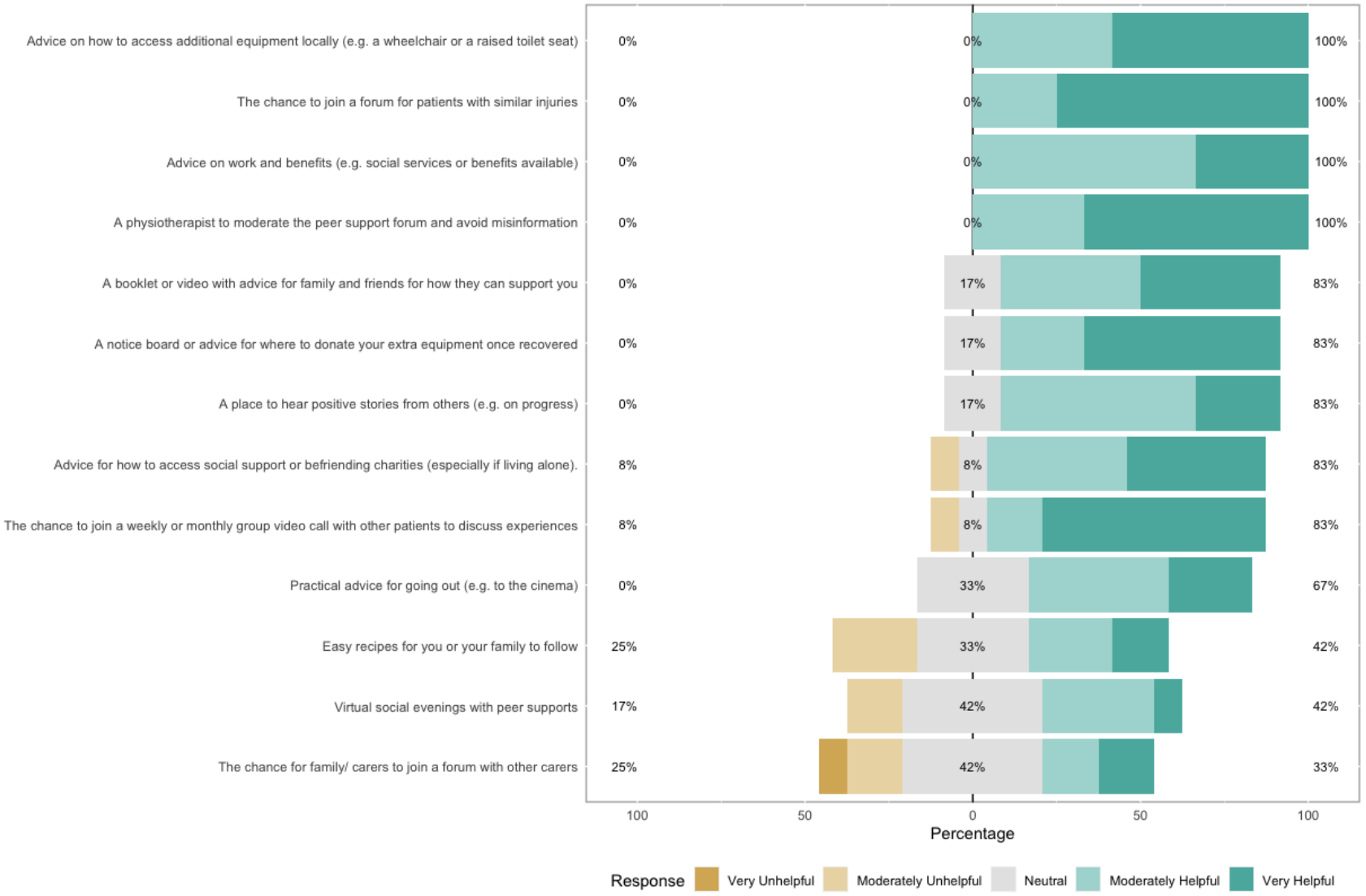


Figure 6.11: Patient survey - Social support

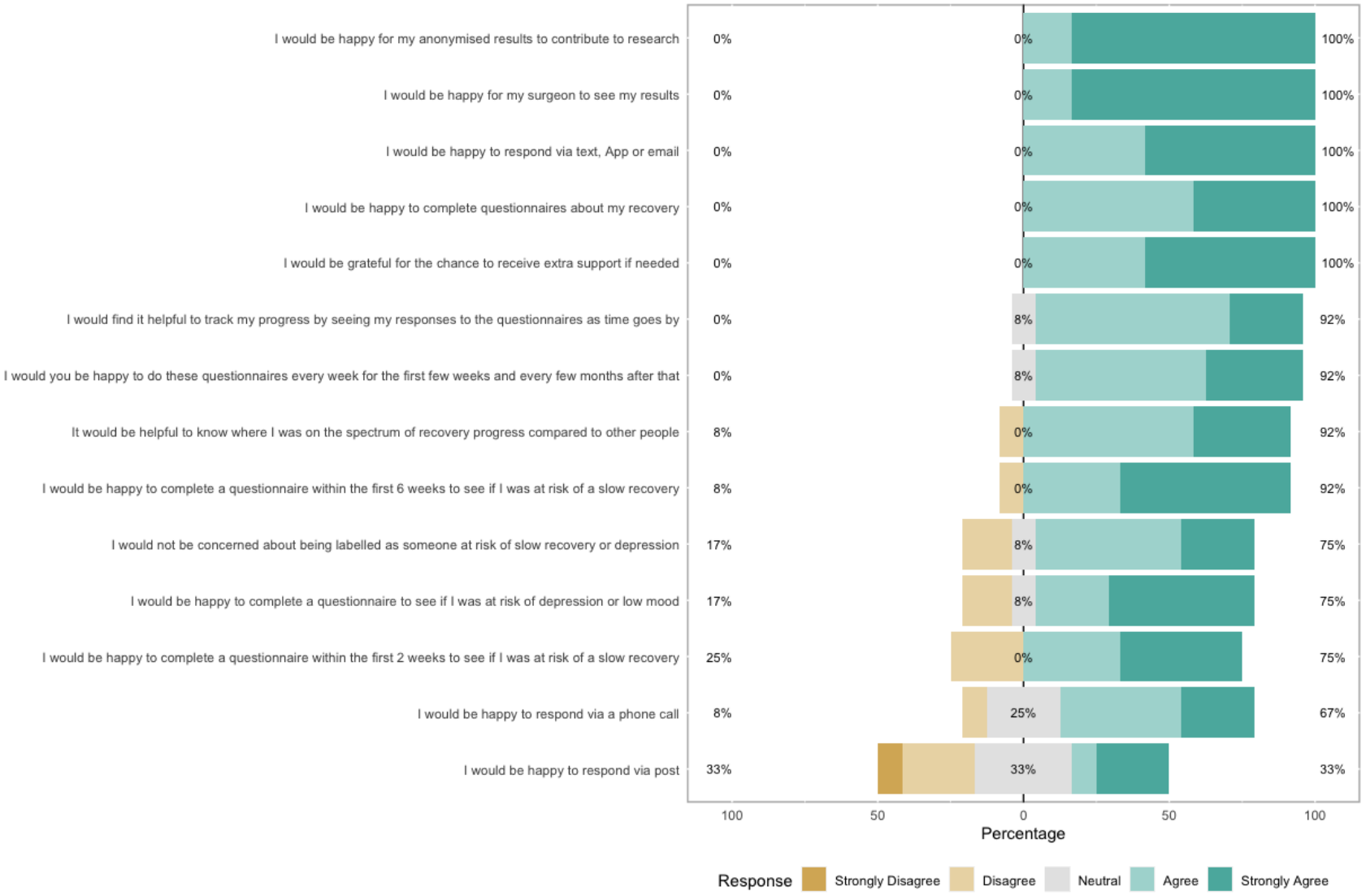


Figure 6.12: Patient survey - Monitoring

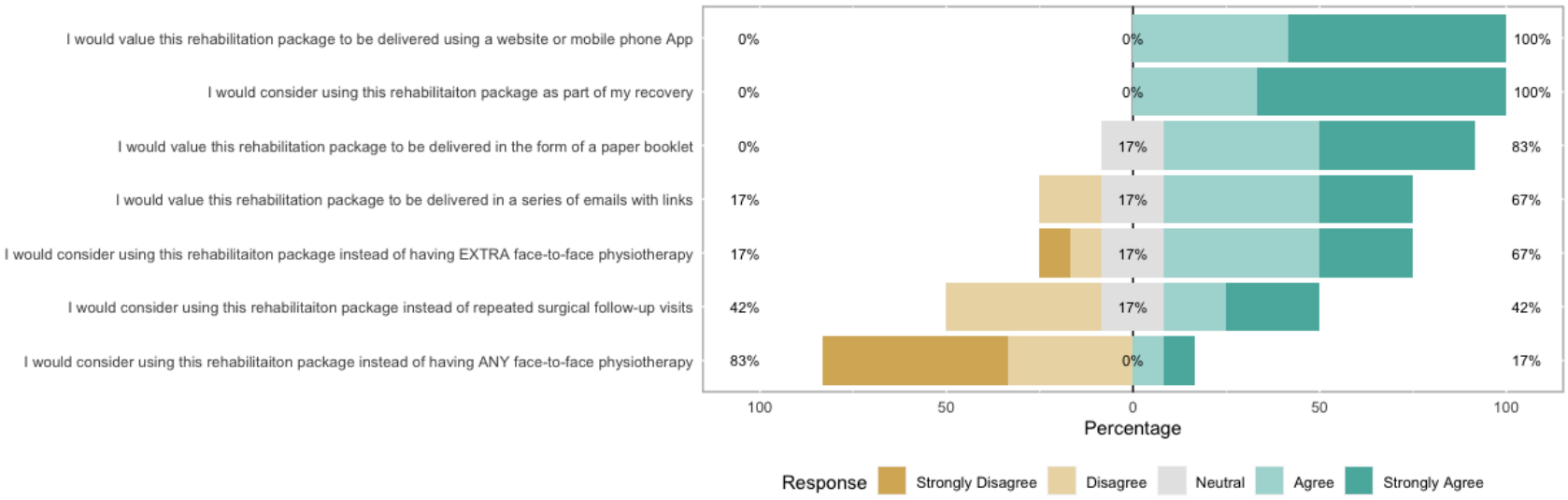


Figure 6.13: Patient survey - Overall delivery

6.4 Discussion

6.4.1 Interpretation

The Behaviour Change Wheel (BCW) has previously been used to systemically generate behaviour change intervention bundles for a range of health conditions, from sexual counselling to antibiotic stewardship [135, 184]. This is the first attempt to use the method in orthopaedic trauma. RAAFT has developed intervention bundles and defined the content and optimal delivery in collaboration with patients. A consensus of patients were enthusiastic about using the proposed rehabilitation package, with the strongest opinions suggesting it should be delivered in the form of a website or App.

The following presents key areas that require the generation of consensus advice from HCPs or consideration of how the bundles would be ideally delivered within the context of the NHS.

Skills

The critical area requiring HCP consensus is how patients should be advised to progress their weight-bearing and agreement about what activities patients can perform during their non-weight-bearing period.

Knowledge

Patients desired a range of information about their recovery, from knowledge about how to interpret their symptoms to when they should return to work. Patients would like information on their risk of complications and expected time-frames for return

to life roles. While individual research articles present rates of complications and mean PROMs at certain time periods, this is not in a risk-stratified or accessible format [16, 17, 185, 186]. A systematic approach for gathering and presenting these data would need to be developed, but first, a consensus for its importance among HCPs would need to be established to ensure engagement with the data collection process. There is literature which provides likely time-frames for returning to driving, though Burnham et al. showed that patients often returned to driving sooner, not based on advice or time-frames, but when they felt they were ready based on their self-assessment [187, 188]. A consensus around when or how HCPs advise people to return to driving will enable harmonisation of advice with recommendations from the literature.

RCTs and systematic reviews have been published comparing early vs delayed wound washing after surgery, with low-quality evidence suggesting that washing within 48 hours may be safe [189, 190]. However, these studies have been in heterogenous populations, primarily for minor procedures without retained metalwork. Considering the anxiety expressed by HCPs in Chapter 5, establishing a consensus opinion to guide patients is likely more suitable. Similarly, advice on when to use and remove the post-operative orthotic boot was variable and would require HCP consensus before providing standardised advice.

Virtual follow-up

Patients were open to alternative methods of clinical follow-up and were enthusiastic about being able to contact a physiotherapist as and when needed to discuss anxieties and concerns in real-time. Agreement on what symptoms patients can be reassured of, and which symptoms require further assessment must be established.

Furthermore, the feasibility and limitations of assessing patients virtually needs consideration.

A consensus among HCPs is required for when patients could be discharged from routine surgical follow-up to the proposed App. Additionally, the required minimum clinical information and notes for a physiotherapist delivering this service needs to be defined.

Social support

There was interest from patients regarding mechanisms for enabling and promoting peer support. However, the acceptability of this to HCPs needs to be established, and it remains to be determined if a peer-support forum would require moderation by a HCP.

Screening

Patients felt it would be acceptable to screen for unhelpful pain beliefs or other preexisting characteristics that might predispose them to a difficult or slower recovery. The optimal method for when, where and how this should take place is unclear and requires further investigation.

More broadly, achieving a consensus around the topics discussed above would help decrease conflicting advice and empower patients to progress their recovery independently.

6.4.2 Strengths and limitations

The use of the BCW to generate the template intervention bundles ensured that the proposed intervention and policy options were informed by relevant theory, based on techniques that have been effective in prior research [45, 83]. This method facilitated a focused discussion at the workshop and ensured the outputs were aligned with congruent theory. The systematic and transparent nature of the BCW method used also ensures that researchers will be able to trace the RAAFT interventions to their underlying BCTs for faithful replication or evaluation [58].

The design, facilitation and analysis of the patient workshops by RAAFT patient representatives tempered the limitations of previous chapters: a wider range of interpretation and less individual-researcher bias resulted. However, the demographic distribution of the population for the workshop and survey may not be representative. Ninety percent were female, and half were retired or not in employment. The population reflected one-half of the bimodal distribution of ankle fractures but not the other half, which occur in young men [2]. The under-representation of men in behavioural research has been reported elsewhere [191]. While efforts were made to include this population (fifty invites were sent), most were unable to attend an all-day workshop during working hours. Shorter, evening workshops could have increased attendance, but may have limited the usefulness of the outputs, due to the considerable introductory and explanatory content required at the start of the workshop.

Ten patients may not have provided a representative sample for the consensus survey. However, due to the complexity of the ideas discussed and the length of the survey, prior introduction to the survey concepts during the workshop was felt ne-

cessary. Ten patients is also a relatively high number for the design of BCW-based interventions compared to published studies. Many have focused on modifying HCP behaviour rather than patients' behaviour. Even when interventions have been focused on patients, discussion workshops have included fewer or a comparable number of patients to RAAFT [49, 176]. Furthermore, the use of the APEASE criteria encouraged a broader discussion, including the consideration of equity issues related to the proposed intervention functions, beyond participants that attended the workshop [83].

6.4.3 Conclusions

Chapter 6 has prioritised the intervention methods and content for facilitating weight-bearing and rehabilitation after ankle fracture surgery. Intervention bundles have been created to address the barriers and harness the facilitators found in Chapters 4 and 5. Patients have shown openness to engaging with HCPs through non-conventional methods, and the knowledge and skills required for patients to self-manage their recovery have been established. Chapter 7 aims to establish a consensus around key areas of advice and delivery of this self-management intervention.

CHAPTER 7

Co-design of rehabilitation intervention - HCPs

7.1 Introduction

The considerations for intervention design are discussed in Chapter 1 and Section 6.1. The intervention functions and content desired by patients were generated in Chapter 6. A consensus for the desired advice now needs to be established for inclusion in the intervention and wider patient-facing literature. An issue with patient-facing information leaflets is that they often require an advanced reading age and are generally not read by the HCPs that provide them [192, 193]. Where generic advice is provided, this may not cause harm, but patients in Chapter 4 expressed frustration that available patient-facing ankle fracture literature did not provide more specific advice, such as when to discontinue orthotic boot use. This is because there is no consensus around these topics, and advice for one patient, could be potentially unsafe for another. The indications for orthotic boot use have expanded rapidly over the last decade, and new evidence around fixation techniques and metalwork removal has begun to shift practice [194–197]. Now is an appropriate time to seek consensus around some of these topics for patient-facing advice so that

patients are no longer faced with uncertain, variable advice which may delay their recovery.

Additionally, as found in Chapter 5, peer opinion is an important modifier of HCP behaviour, in some cases preceding RCT evidence [198]. Hence, a consensus opinion will likely give HCPs the confidence to engage with the proposed RAAFT intervention and trust the advice within.

7.1.1 Objectives

1. To establish a consensus for advice for ankle fracture rehabilitation.
2. To identify content and implementation options for the RAAFT intervention through consultation with healthcare professionals.

7.2 Methods

7.2.1 Study design

A modified online NGT workshop and survey were conducted and reported in accordance with the CROSS [177]. Informed by Chapters 1 to 6, a rehabilitation strategy was co-designed, using the three phases of the BCW as discussed in Section 6.2.

Setting and sampling

Recruitment to the HCP workshop followed the same process described in Chapter 5. Examples of the PIS and consent form are provided in Appendix F.1 and Appendix F.2. The workshops were conducted virtually, and HCPs completed an online consent form before the workshop.

Approvals

Approvals were obtained as described in Chapter 4.

Data collection methods

An online NGT was used as described in Section 6.2.1.

Three two-hour workshops took place on April 25th, 29th and May 4th 2022. Two or three HCPs attended each workshop in addition to a RAAFT patient representative. All participants completed pre-workshop tasks, including watching an explanatory video and completing a worksheet. The purpose was to determine the content and phrasing of a consensus survey for surgeons and physiotherapists. A series of statements around different aspects of ankle fracture surgery were iteratively refined and updated. All break-out groups were recorded. After the workshop, all recordings were reviewed, and the statements and survey were iteratively updated, ready for the next workshop.

Survey

An online survey was compiled using data from the workshop. The REDCap survey link was emailed to all surgeons and physiotherapists on the WAX trial delegation log as well as disseminated via social media. A £10 shopping voucher was offered for survey completion. The survey was open from May 5th 2022 - July 13th 2022.

An online video and introduction page explained the purpose of the survey and how to complete it. Respondents were told that the survey aimed to create standardised concepts or phrases that can be given to patients to aid their recovery. The aim was to create advice that >75% of HCPs would be happy to provide to >75%

of their patients post-operatively. It was explained that if their patient were in the other 25%, their situation would somehow be atypical, and they would not be offered a generic rehabilitation programme.

Respondents were asked to indicate how strongly they agreed with various statements by ranking statements on a 5-point Likert scale from "strongly disagree" to "strongly agree". There was also an option to select "I can not comment in my role", as some questions were directed at specific groups of HCPs, and it was anticipated that some physiotherapists would not be comfortable making decisions for certain aspects of care (e.g. surgical decision-making). At the end of each section, a space for free-text comments was provided.

7.2.2 Analysis

Generation of provisional survey statements

The survey results from Chapter 6 were reviewed and cross-referenced against the results from Chapters 4 and 5. Where patients had prioritised advice around certain aspects of recovery, Chapters 4 and 5 were reviewed to see if there were discordant opinions or practices' among HCPs. Where a lack of agreement was evident, these aspects of recovery were prioritised for inclusion in the consensus survey. Additionally, aspects of intervention development were considered based on the Template for intervention Description and replication (TiDier) checklist, in particular where, when, how and by whom interventions could be delivered [199].

Analysis of survey responses

Analysis was conducted in R [108] and figures were compiled using the package Likert [181]. 75% was used as a threshold for consensus [182, 183].

7.3 Results

7.3.1 Workshop and survey participants

Sixteen HCPs were invited to the workshops, of which eight (50%) agreed and attended. Participant sites and characteristics are shown in Table 7.1 and Table 7.2. The survey was emailed to 177 HCPs on the WAX trial delegation log. A total of 79 HCPs responded from 38 different hospital trusts, but as there was also an open invitation via social media, a formal response rate was not calculated. The characteristics of survey respondents are provided in Table 7.3 and their employing hospital trusts in Table 7.4.

Table 7.1: Workshop participant sites (HCPs)

Site	**N=8**
Oxford University Hospitals	4 (50%)
Queens Medical Centre Nottingham	1 (12.5%)
Royal Victoria Hospital Belfast	1 (12.5%)
Southampton General Hospital	1 (12.5%)
St George's Hospital London	1 (12.5%)

Table 7.2: Workshop participant characteristics (HCPs)

Staff participant	WAX site?	Interview participant?	Gender	HCP Role	Subspecialty
1	No	Yes	Male	Physiotherapist	N/A
2	No	Yes	Male	Physiotherapist	N/A
3	No	Yes	Male	Consultant	Trauma
4	Yes	Yes	Male	Consultant	Trauma
5	Yes	Yes	Male	Physiotherapist	N/A
6	No	Yes	Male	Registrar	N/A
7	Yes	Yes	Female	Post-CCT Fellow	Foot and ankle
8	No	No	Male	Registrar	N/A

Table 7.3: Survey participant characteristics (HCPs)

Characteristic	**N = 79**
Job role	
Trauma and orthopaedic surgeon	53 (67%)
Physiotherapist	26 (33%)
Surgeon grade	
Registrar, Fellow or Trust grade equivalent to ST3+	32 (60%)
Consultant	21 (40%)
Consultant sub-specialty	
Foot and ankle	9 (43%)
Trauma	7 (33%)
Other	5 (24%)
Physiotherapist primary role	
Inpatients	12 (46%)
Outpatients	14 (54%)

Table 7.4: Survey participant sites (HCPs)

Hospital Trust	N	Hospital Trust	N
Royal Victoria Hospital, Belfast	9 (11%)	University Hospital Southampton	2 (2.5%)
Oxford University Hospital	7 (8.9%)	University Hospitals of Leicester	2 (2.5%)
East Surrey Hospital	4 (5.1%)	Altnagelvin Hospital	1 (1.3%)
East Sussex Hospitals	3 (3.8%)	Blackpool Teaching Hospitals	1 (1.3%)
Lancashire Teaching Hospitals	3 (3.8%)	Derriford Hospital	1 (1.3%)
Royal Cornwall Hospital	3 (3.8%)	Gloucestershire Hospitals	1 (1.3%)
Royal Preston Hospital	3 (3.8%)	Liverpool University Hospitals	1 (1.3%)
Salisbury NHS Foundation Trust	3 (3.8%)	Musgrave Park Hospital	1 (1.3%)
St George's Hospital, London	3 (3.8%)	Northern General Hospital	1 (1.3%)
Birmingham University Hospitals	2 (2.5%)	Nottingham University Hospitals	1 (1.3%)
Cardiff and Vale Hospitals	2 (2.5%)	Royal Berkshire Hospital, Reading	1 (1.3%)
East Kent Hospitals	2 (2.5%)	Royal Derby Hospital	1 (1.3%)
Hampshire Hospitals	2 (2.5%)	Royal Devon & Exeter hospital	1 (1.3%)
Maidstone & Tunbridge Wells Hospital	2 (2.5%)	Royal Sussex County Hospital	1 (1.3%)
Northern Care Alliance, Manchester	2 (2.5%)	St Mary's Hospital, London	1 (1.3%)
Princess Alexandra Hospital, Harlow	2 (2.5%)	UK Chandler Hospital	1 (1.3%)
Queen Alexandra Hospital, Portsmouth	2 (2.5%)	University Hospital Coventry and Warwickshire	1 (1.3%)
Royal London Hospital	2 (2.5%)	William Harvey Hospital, Kent	1 (1.3%)
Royal United Hospital, Bath	2 (2.5%)	Unknown	1 (1.3%)

7.3.2 Survey results

The results from Chapter 6 indicated a wide range of patient uncertainties and needs. The consensus survey focused not on giving expectations but on activities that patients usually seek advice or permission from HCPs about. That is "if or when" questions, rather than "how or why" questions.

The likert bar plots are displayed in Figure 7.1 to Figure 7.9. The percentages on the right side of the Likert bar plots correspond to the proportion of responses that were ranked "agree" or "strongly agree". The percentages on the left correspond

to those ranked "disagree" or "strongly disagree", and the middle grey percentages to "neutral". Where responses are labelled as "missing", this relates to respondents selecting that they "cannot comment in [their] role", all questions mandated a response.

Weight-bearing

Figure 7.1 shows the survey results for the weight-bearing (WB) statements. HCP workshop participants felt it was important first to establish if there was a perceived need for standardisation of language and pathways around WB and rehabilitation, which the survey found there was a consensus for. The survey attempted to find consensus for activities permitted during non-weight-bearing periods. HCPs agreed that patients could rest their foot on the floor whilst sitting during non-weight-bearing periods, but not for whether they could rest their foot down for balance while standing. HCP were in agreement that the best way to help patients increase and progress their weight-bearing was not to increase by set, defined amounts dictated by HCPs, but to increase gradually as their comfort allowed. A caveat was that giving patients warning signs to look out for (such as wound breakdown or redness) would be helpful.

As found in Chapters 4 and 5, it can be challenging to determine what amount of pain or swelling is cause for alarm. During the workshops, with the help of the RAAFT patient representatives, simple statements understandable to patients and HCPs were created to help this issue. The survey results indicated that as long as new pain or swelling settles by the following morning and doesn't worsen day after day, patients can continue weight-bearing and ankle exercises. Conversely, there was a consensus that if the wound starts leaking, opens or becomes red, patients should

stop weight-bearing and exercises and seek advice from a HCP.

The only consensus reached for driving was that patients should test if they are ready to start driving by getting into a stationary car and practising an emergency stop.

During the workshops, there was discussion about which aspects of care could be changed (or assumed if not previously stated on the operation note) without having to contact the operating surgeon. There was a consensus that HCPs would not usually contradict the operating surgeon's weight-bearing instructions without discussing with them first. This is relevant because sometimes there are discussions among HCPs around changing weight-bearing status, for instance, to facilitate discharge planning.

Orthotic boot use

The results from Chapters 4 and 6 found that patients were often uncertain when they should use their boot during the post-operative period, so the survey attempted to clarify this. Figure 7.2 shows the survey results for the orthotic boot statements. A consensus was established that patients do not need to wear their boot in bed at night if they do not want to. Additionally, there was a consensus that patients need only wear their boot when they are actually walking and can remove it when seated or to perform exercises, even during their non-weight-bearing period.

There was a consensus that when first starting to weight-bear without their boot, patients should do so gradually and avoid rotational movements to begin with. Chapters 4 to 6 found there was uncertainty about when patients could start attempting to weight-bear without their boot. The survey found that assuming patients had been permitted to weight-bear early, they could start trying to do so

without their boot any time from two weeks post-operatively, within the caveats of the findings above.

Wound management

While some HCPs in the discussion workshop had not considered advice on patients soaking or massaging their surgical wound, it was an area that patients desired advice on, as indicated in Chapter 6. Figure 7.3 shows the survey results for the wound management statements. Consensus was established, with HCPs indicating that patients could get their wound wet in the shower from two weeks post-operatively, and begin to soak and lightly massage their wound from three weeks post-operatively. This was with the caveat that the wound must be dry at this stage. The word "dry" was used instead of the word "healed", as this was a source of uncertainty found in Chapters 4 and 5, and dry was found to be acceptable to HCPs and understandable to patients.

A common concern from patients in Chapters 4 and 6 was numbness or tingling around their wound. Through the HCP workshops, the wording was chosen that as long as this did not become widespread or have a discrete motor loss, patients could be reassured this was normal and did not need HCP review. A consensus was achieved for this statement, however, the language to convey this to patients will need to be developed.

From Chapter 5, it was found that HCPs had uncertainty when numbness, tingling or burning sensations would herald complex regional pain syndrome (CRPS). It was proposed that an initial assessment or screening could be performed by a physiotherapist, with an onward referral if required. "Disproportionate" pain is one of the diagnostic criteria for CRPS [200], however, HCP workshop participants were

concerned that this overlapped with compartment syndrome, which requires urgent surgical assessment. Therefore a time-based caveat was included (after two weeks post-operatively) in the statement. A consensus was not achieved either for or against this suggestion. When reviewing free text comments from the survey, several respondents did not object to an initial assessment from a physiotherapist but felt a F2F assessment was more suitable.

Metalwork removal

Patients expressed uncertainty around if, when and why metalwork might need to be removed from their ankle. They were often given conflicting advice, so the survey sought to achieve a consensus. Figure 7.4 shows the survey results for the metalwork removal statements. There was a consensus that metalwork does not need to be removed routinely if patients are asymptomatic. Furthermore, if they do experience irritation, they should be monitored to see if this improves and wait until around nine months post-operatively to have this removed unless there is an urgent reason (e.g. infection). There was disagreement in the HCP workshops about when metalwork should be removed, primarily because surgeons want to be sure the bones have healed before removal. Respondents were asked how long they would usually wait before offering removal of metalwork for irritation alone; 89% and 70% would wait at least six or nine months, respectively, implying the consensus level is around the eight to nine month period. This does not mean this is when surgeons would be happy to remove the metalwork, but rather there is limited value in a patient presenting for assessment and requesting removal before then, as the majority of surgeons would not offer it. Additionally, several of the HCPs during the workshops said they would want radiological (X-ray or CT scan) evidence of bony healing be-

fore offering metalwork removal.

Additional support

Figure 7.5 shows the survey results for the additional support statements. There was a consensus that patients may face information overload and feel anxious about first attempting weight-bearing in clinic and that providing additional support at home would be helpful. Seventy-four percent of respondents felt that screening for depression, low self-efficacy or unhelpful pain beliefs would be useful, but there was no agreement on when or where this should be done. Only 15% felt that fracture clinic would be the best place to perform this screening, with physiotherapy appointments or a remote App being considered a better place to do this.

Follow-up

Figure 7.6 shows the survey results for the follow-up statements. There was a consensus that HCPs feel rushed during fracture clinic and that consistency of advice is more important than consistency of personnel during follow-up. Reducing unnecessary surgical follow-up was seen as a potential method for alleviating fracture clinic resources. There was a consensus that once the surgical wound has healed (this usually happens around two weeks post-operatively but can be longer if there are problems), seeing a physiotherapist was likely to be more beneficial than seeing a surgeon again.

During the workshops, there was variability in opinions around the need for radiographic follow-up before discharging patients from routine review after surgery. The results from the survey found equipoise around the need for either a six-week follow-up X-ray or an X-ray that shows signs of healing before discharge.

The survey asked respondents if they would consider discharging patients from clinic sooner than usual if the patient had access to credible recovery information and could book back into clinic quickly if they had problems. There was a consensus that HCPs would consider discharging patients with these provisions at six weeks, but only 43% of HCPs would consider this at two weeks post-operatively.

Patients in Chapter 6 expressed a desire to be referred directly to orthopaedic services if they were injured away from their home area, however, this was not a consensus opinion in the HCP survey. From the workshop discussion and free text survey responses, this appeared to be due to concerns around variability in fracture clinic organisation between regions and the fear that time-critical injuries could be missed or delayed, so re-presenting to a local A&E acts as a safety net.

Almost three-quarters of HCPs would like to review their aggregated patient outcomes via a national registry, though less wanted the ability to review their individual patient's outcomes remotely.

An App-based physiotherapy advice service.

A topic discussed in Chapters 4 to 6 was the creation of an App-based physiotherapy advice service to enhance patient rehabilitation and potentially decrease the requirement for F2F follow-up. The HCP survey sought to define the logistic requirements for such a service. Figure 7.7 shows the survey results for the App-based physiotherapy statements. The notes that accompanied the survey explained that an App-based physiotherapy advice service would involve access to a physiotherapist via an online chat service from 9 am to 5 pm, Monday to Friday (as discussed in the workshops) and with the assumption that relevant patient records could be shared in a secure, encrypted form. Within these confines, there was a consensus that such

a service should have access to the patient's discharge summary or rehabilitation prescription and recent clinic notes. There was a consensus that a physiotherapist providing this service should be able to communicate with the responsible surgical team within one week to seek advice or clarification. Additionally, 81% felt that patients should be able to be offered a F2F physiotherapy appointment within one week to assess problems or if virtual sessions were inadequate. The ability to arrange a fracture clinic review within one week was considered to be important but a consensus was not reached that it should be a mandatory feature.

Other suggestions that did not reach consensus were the need for an App-based physiotherapy advice service to have access to the patient's operation note, X-rays and hospital records, which from the workshops appeared not to form a routine or critical part of physiotherapy assessment. Similarly, the requirement to document intra-operative syndesmosis screening was not considered crucial.

A concept explored during Chapter 6 was the creation of a peer-support forum where patients could discuss their experiences with other patients. There was a suggestion that a HCP should monitor this to avoid misinformation, but this did not reach a consensus during the HCP survey.

As with the findings in the follow-up section, over 80% of HCPs would consider discharging patients to an App-based physiotherapy service at six weeks, but only 42% would consider this at two weeks post-operatively.

Virtual follow-up

The specific content and features of a virtual follow-up service were discussed. Figure 7.8 shows the survey results for the virtual follow-up statements. There was a consensus among surgeons that they would be happy for wound pictures from their

patients to be sent for them to assess remotely. However, during the workshops, some felt this would not be suitable. Results from the survey indicated that of the 11 surgeons that felt this was unsuitable, 64% felt they could not accurately assess wounds virtually, and 55% felt that they would not want notifications intruding on them while they were away from work.

Only 62% of surgeons felt confident in a physiotherapist virtually assessing wounds, but 77% felt it would be suitable for an App-based physiotherapist service to initially assess patients with problems and escalate to a surgeon as required. Physiotherapists were less happy about performing these functions, though they had more confidence in providing virtual exercise advice (assuming a good quality internet connection).

Another consideration was whether routine wound review was required at all or whether patients could identify their own wounds as problematic or not. Only 56% of HCPs felt patients could detect problems reliably themselves, suggesting a wound review service of some kind would be required.

Venous Thromboembolism (VTE) prophylaxis

This section explored equipoise around VTE prophylaxis, as several patients in Chapters 4 and 6 had expressed a preference for avoiding injection-based VTE prophylaxis if possible. Figure 7.9 shows the survey results for the VTE prophylaxis statements. Most physiotherapists felt they could not comment on this topic, but there was a consensus among surgeons for enrolling patients into a study which randomised patients to take a Direct Oral Anticoagulant (DOAC), Low Molecular Weight Heparin (LMWH) or aspirin as VTE prophylaxis post-operatively. However, only 46% of respondents would consider randomising a patient to take no phar-

macological VTE prophylaxis immediately post-operatively. There was a consensus that respondents would consider randomising patients to no pharmacological VTE prophylaxis once patients were permitted to weight-bear.

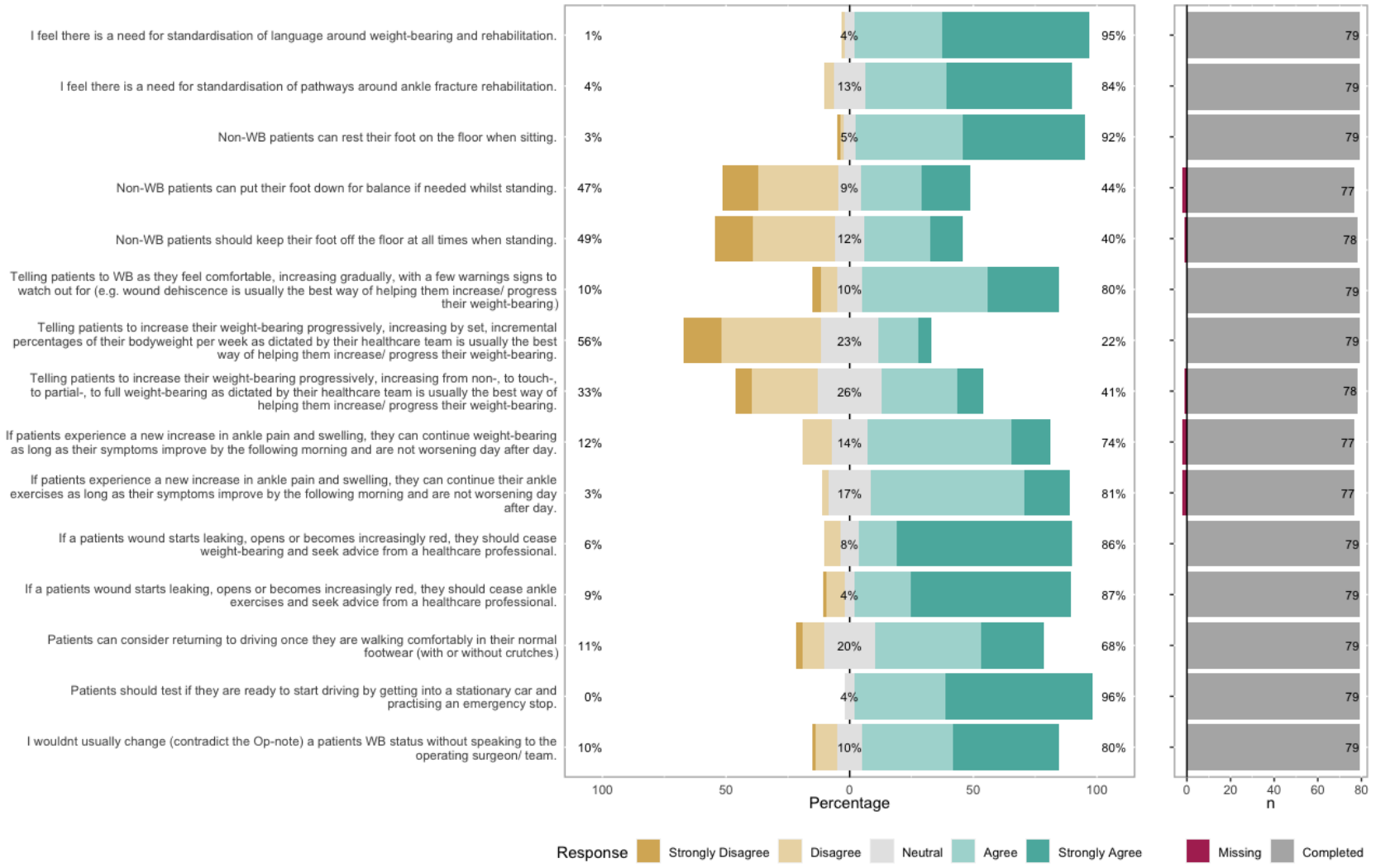


Figure 7.1: HCP Survey - Weight-bearing

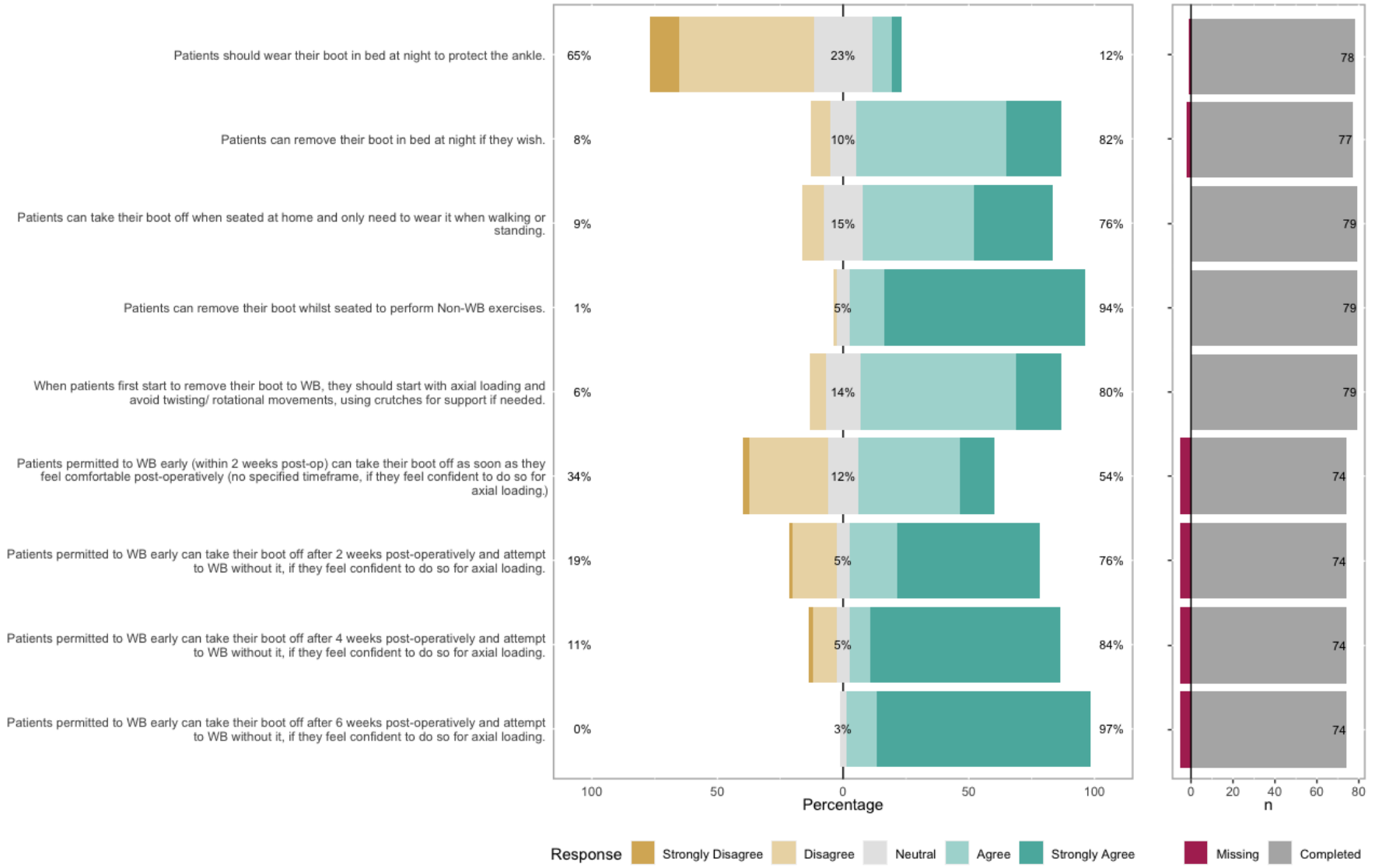


Figure 7.2: HCP Survey - Orthotic boot use

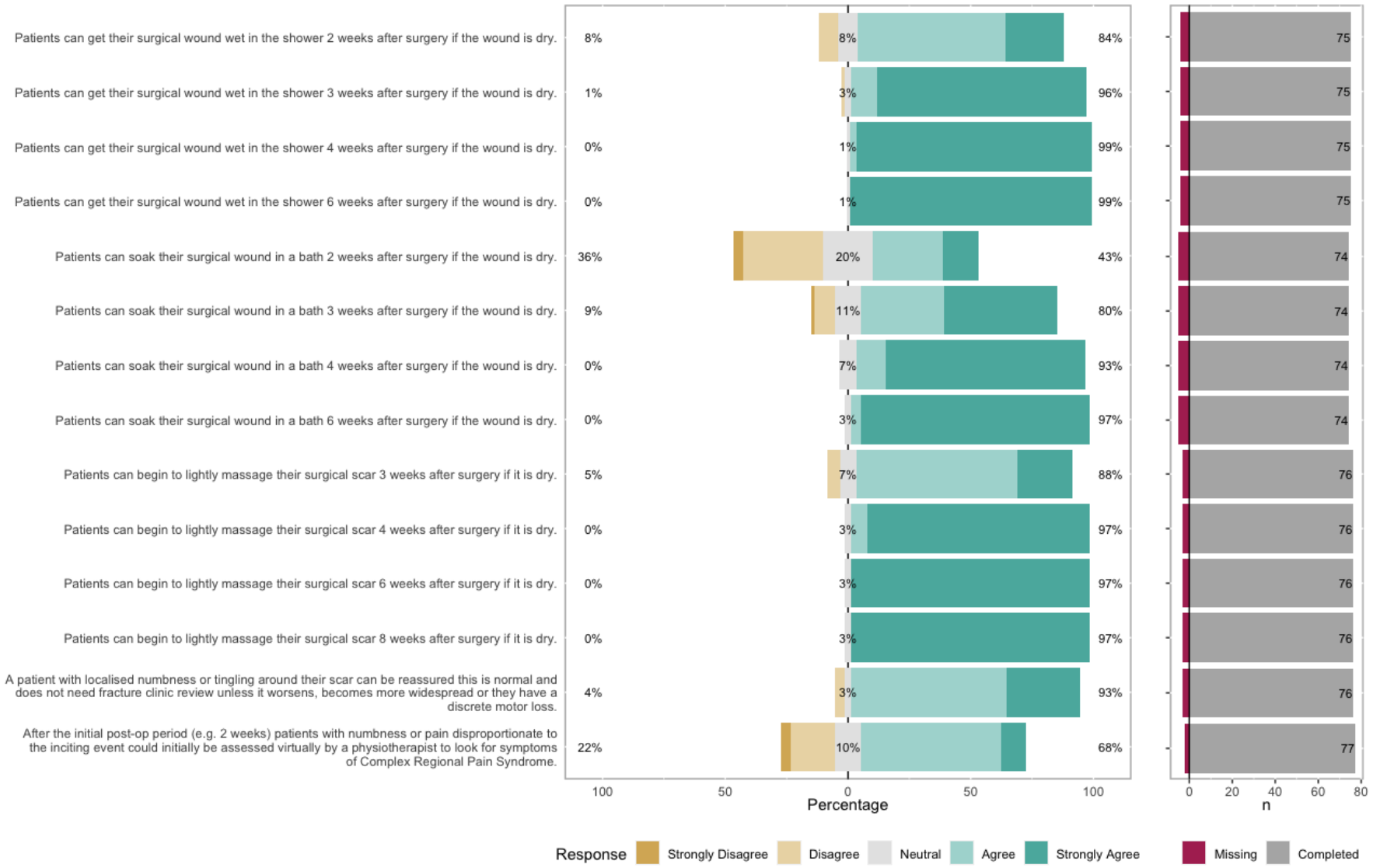


Figure 7.3: HCP Survey - Wound management

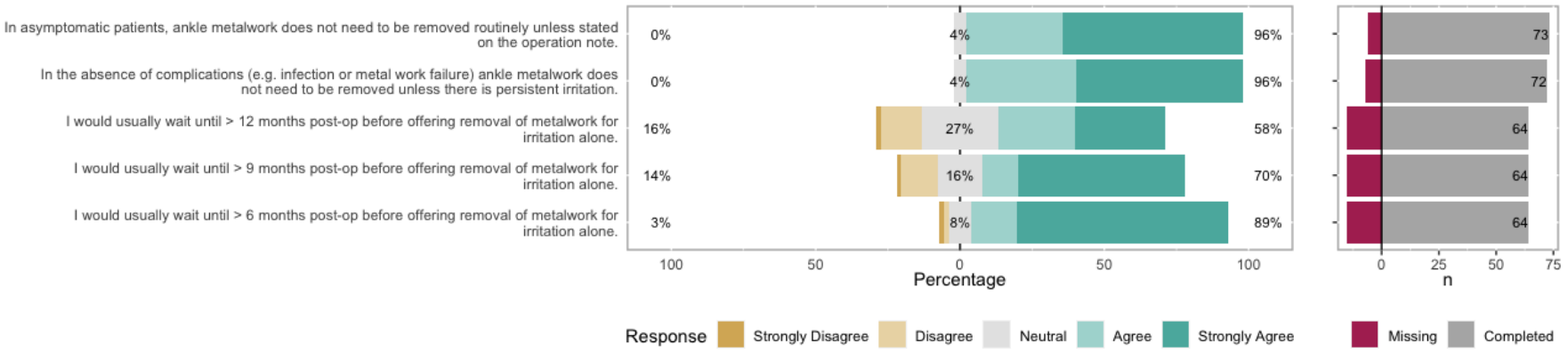


Figure 7.4: HCP Survey - Metalwork removal

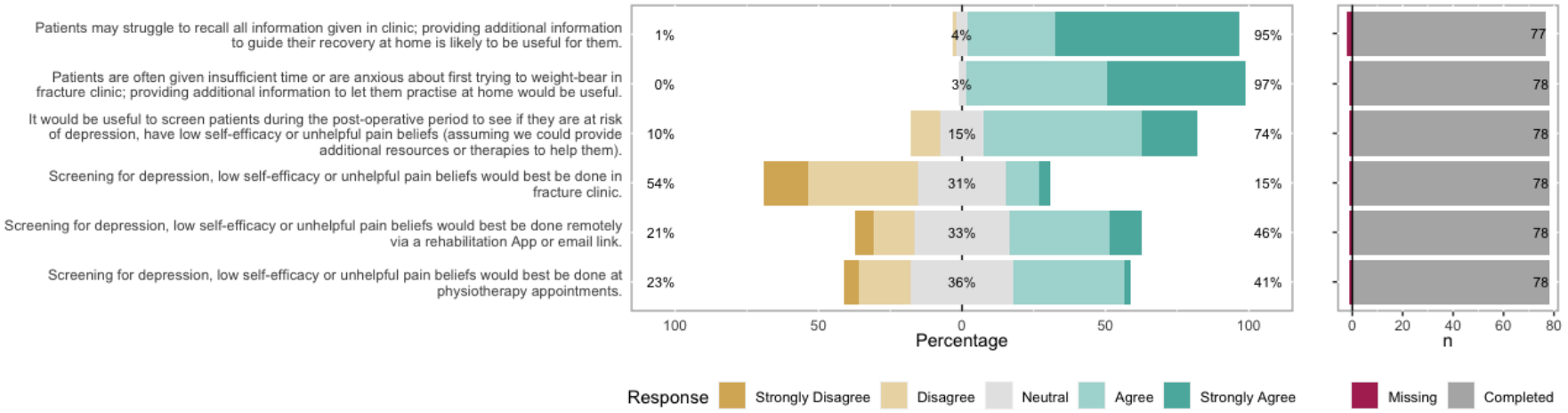


Figure 7.5: HCP Survey - Additional support

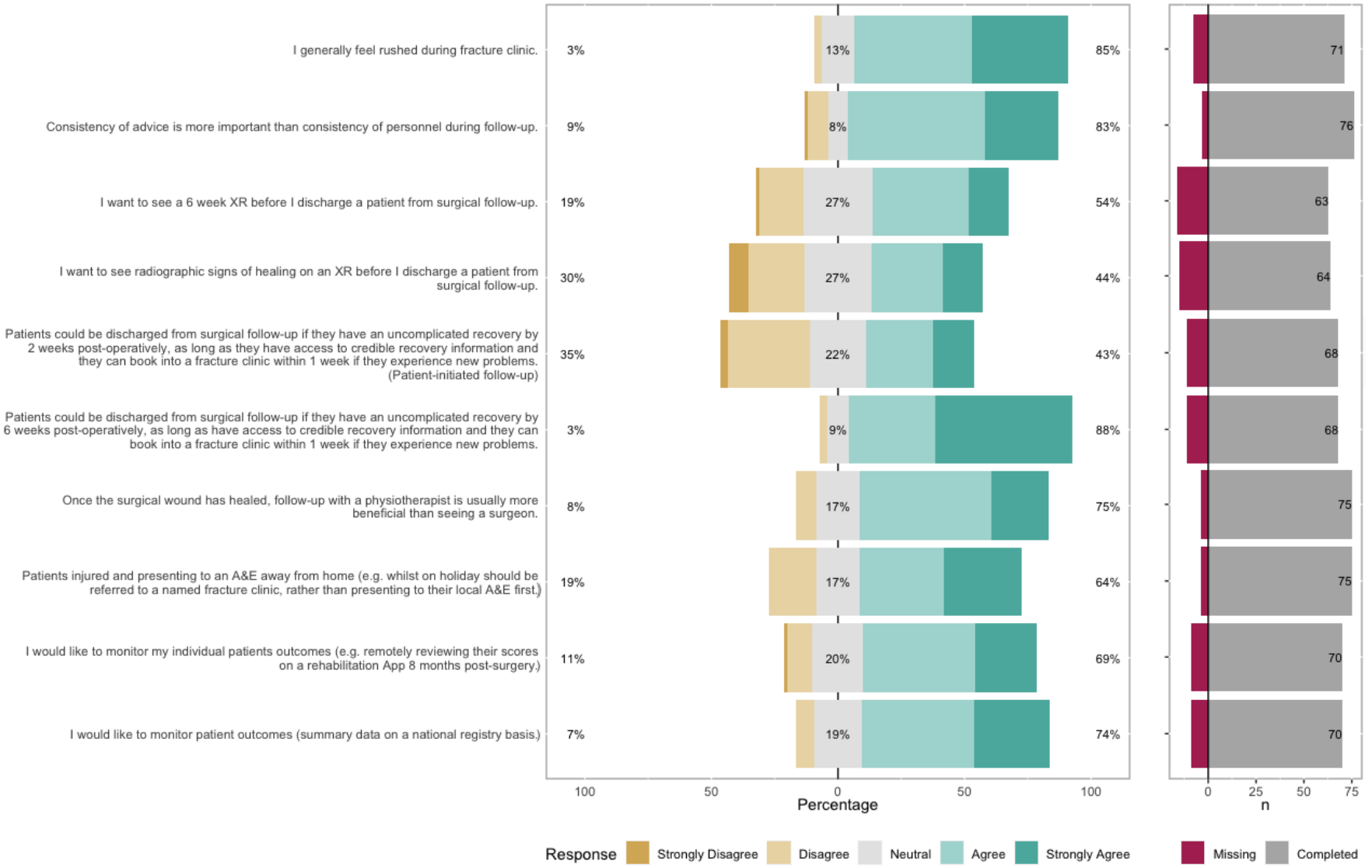


Figure 7.6: HCP Survey - Follow-up

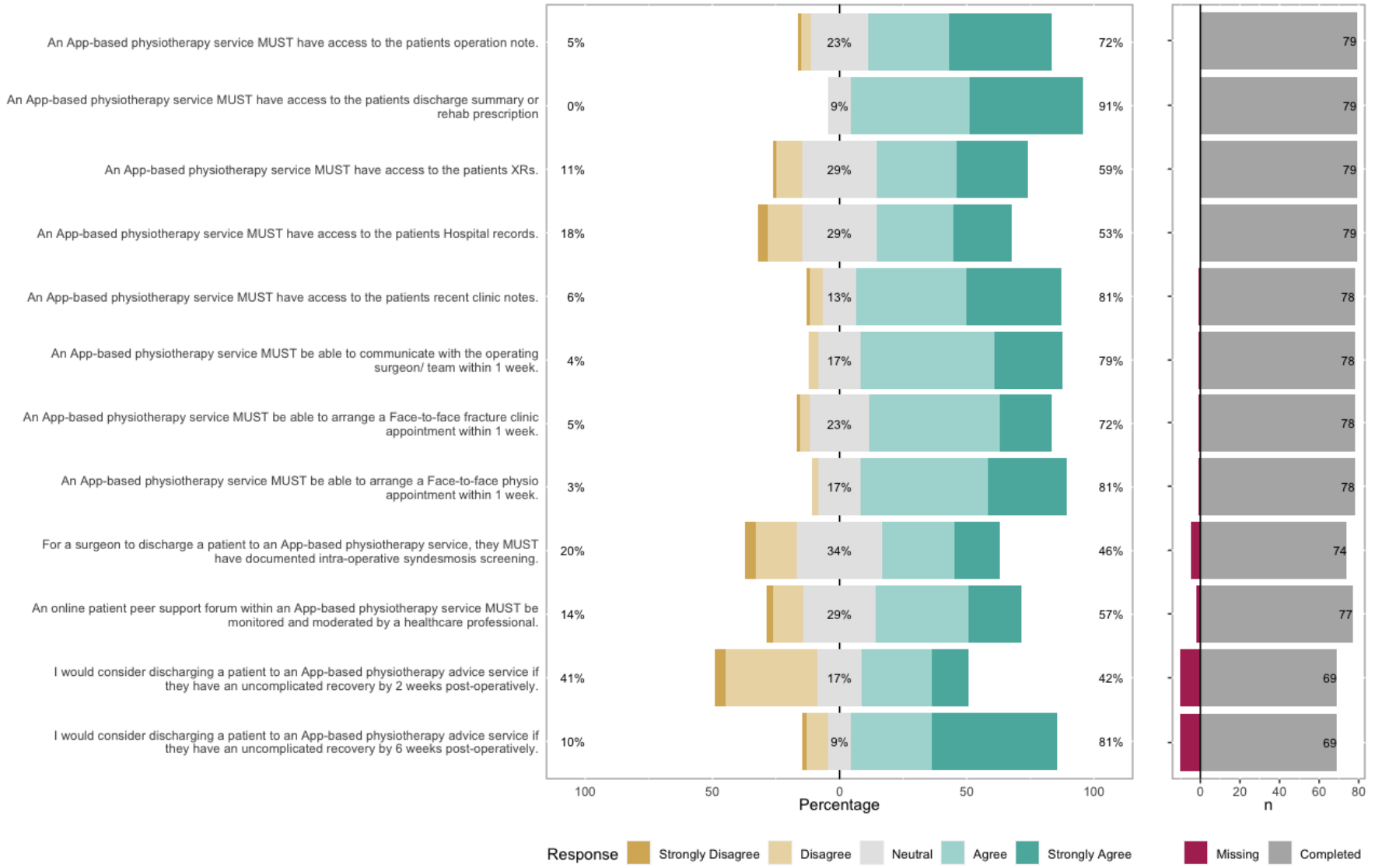


Figure 7.7: HCP Survey - An App-based physiotherapy advice service

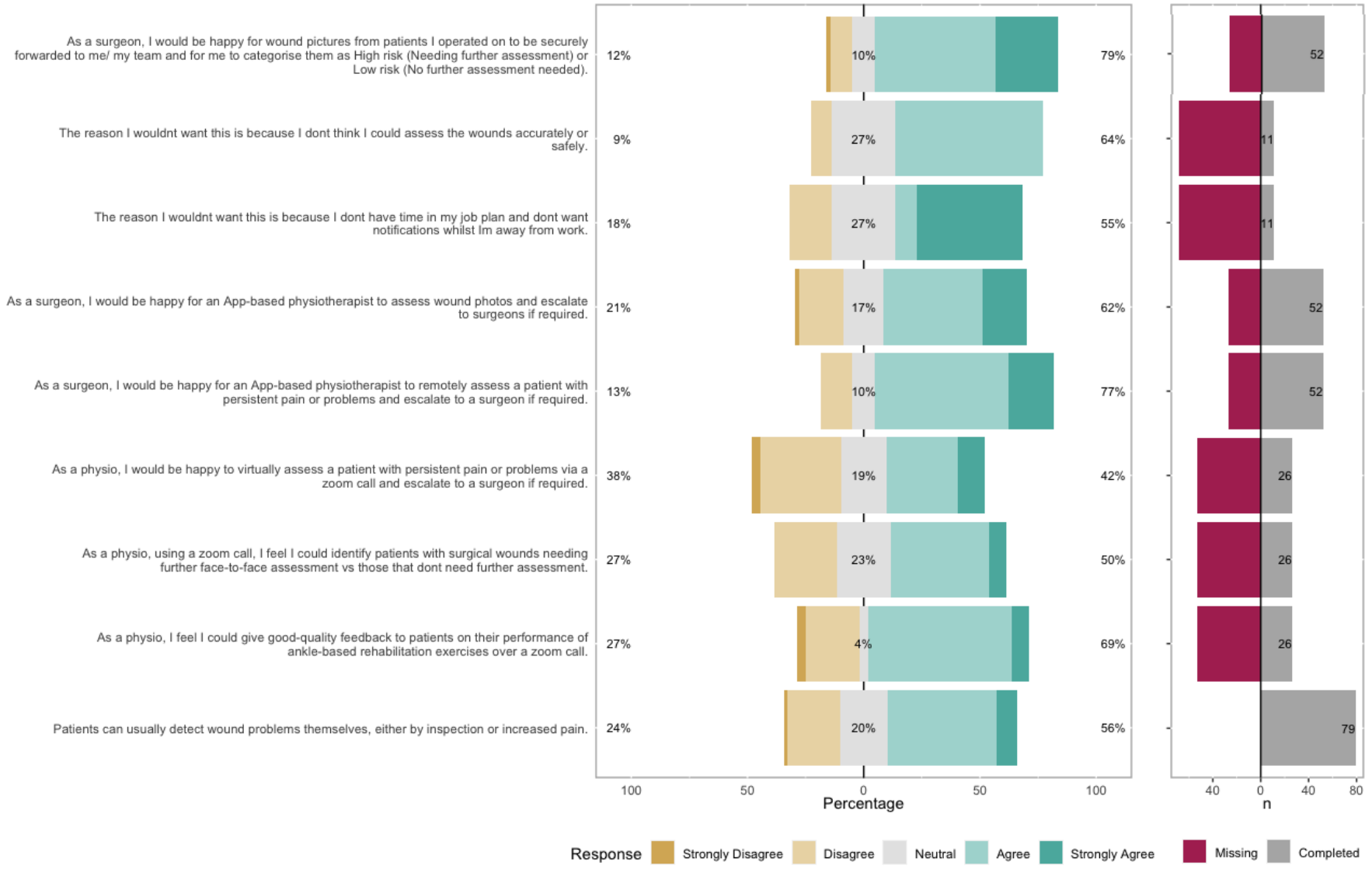


Figure 7.8: HCP Survey - Virtual follow-up

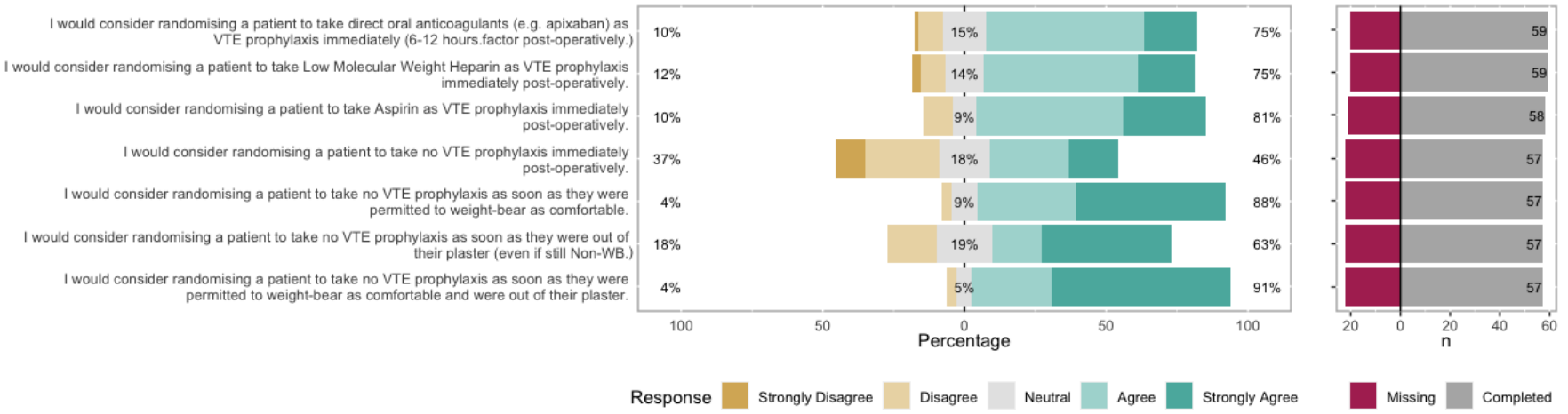


Figure 7.9: HCP Survey - VTE Prophylaxis

7.4 Discussion

7.4.1 Interpretation

RAAFT has established a consensus around several topics and identified other areas requiring further consideration. These include a consensus around the management of swelling and surgical wounds, weight-bearing recommendations and orthotic boot use. Additionally, novel methods of follow-up and monitoring were explored and preferences for their use in a future rehabilitation intervention were established. The specific areas of consensus are discussed under their respective heading below.

Swelling and surgical wounds

Results from the HCP workshops and survey provide further credence to the concept that the surgical wound can be a visible early indicator for alerting patients to seek medical attention. Training patients to assess their wound, using descriptors as well as pictures of "expected" and "concerning" wounds could help both sides of their recovery: if their wound looks healthy, they can be reassured about continuing their rehabilitation, and if not, they will know to seek help, potentially sending a photo to a HCP in the first instance. Bruce et al. [201] found a fair correlation between photographic and in-person assessment for surgical site infection in a lower-limb trauma population. Photographic assessment overestimated the surgical site infection rate compared to the Centre for Disease Control (CDC) criteria for surgical site infection (12% vs 6%). This indicates that remote photography is likely to be a safe screening tool for at-risk wounds, albeit not a tool to base treatment recommendations on.

HCPs did not agree on how to best assess patients with disproportionate pain, suspicious of CRPS. Guidance from the Royal College of Physicians states that patients should be assessed for the diagnosis using the Budapest/ International Association for the Study of Pain (IASP) criteria [200, 202]. The guidance suggests that physiotherapists and patients' GPs are well-placed to coordinate the diagnosis, assessment and instigate the four pillars of treatment (pain relief, physical and vocational rehabilitation, psychological intervention and patient education and self-management) [202]. The survey results suggested that if providing an initial assessment via a virtual physiotherapist, there should be a low threshold for a F2F review.

The pathogenesis of persistent ankle swelling after injury is poorly understood, and predicting which patients will experience it is difficult [203, 204]. Interventions to reduce ankle swelling after injury have had limited success, and none have pervaded in routine clinical practice [205]. The consensus achieved in RAAFT should at least decrease the uncertainty and anxiety patients expressed in Chapter 4 around ankle swelling and give them the confidence to continue with their rehabilitation in the face of transient increases in pain and swelling.

Weight-bearing and orthotic boot use

The use of orthotic boots for treating orthopaedic injuries around the ankle has been increasing, displacing the traditional dogma of immobilising patients in plaster casts for six to eight weeks [11, 194, 206]. There are situations, such as unstable ankle fractures treated without surgery, where external pressure is required to keep the ankle bones in place, and plaster immobilisation is still required [10]. However, once the decision to provide a patient with an orthotic walking boot has been made, this

usually means that external pressure is no longer required, and the orthotic boot is for comfort and ease of walking only. The recommendation to use the boot until the sixth post-operative week remains despite no evidence for this [8]. The six-week recommendation is likely a hangover from historical practice and also because some HCPs assume it is painful to weight-bear as found in Chapter 5. Kortekangas et al. found that in non-operatively treated ankle fractures, three weeks of boot use was non-inferior to six weeks [195], and Smeeing et al. found that early-weight-bearing without any boot support immediately post-operatively was superior to conventional treatment [27], but this strategy is rarely used in the UK [8]. RAAFT has established a consensus that the orthotic boot is only for comfort and ease of walking, and assuming patients are permitted to weight-bear, it can be discarded as soon as the second post-operative week. This finding is not only important because it will allow people to forgo the orthotic boot sooner, but it means there is one less restriction on patients from HCPs and patients are one step closer to having autonomy over their rehabilitation: this concept is discussed further in Section 8.4.1

While there was agreement that once permitted to weight-bear, patients should do this gradually based on their own comfort, starting with axial loading, a consensus around what activities they should do whilst non-weight-bearing (e.g. putting their foot down for balance) was not achieved.

Metalwork removal

Removal of metalwork is a controversial topic, particularly in the ankle. This is because unlike most other fractures, the historical practice had been that syndesmosis screws should be routinely removed two to three months post-operatively, due to the risk of screw breakage (by which time the syndesmosis will have healed) [207].

The syndesmosis is a ligament complex that holds the tibia and fibular together: it is injured, requiring fixation in around 20% of patients undergoing ankle fracture surgery [208]. However, it is often not known if the syndesmosis is injured until during the operation, and so many patients are told during the pre-operative consent process that they may need metalwork removing after surgery. More recently, two things have changed: 1) New devices (e.g. TightRope™) are being used to secure the syndesmosis, which are flexible and don't show X-ray signs of breakage [209] and 2) recent studies have found that even if broken, syndesmosis screws do not need to be removed unless they are causing patients irritation [196, 197].

During the HCP survey, a consensus was found that patients do not require routine removal of metalwork after ankle fracture surgery, and unless they experience complications, surgeons are unlikely to offer removal before nine months post-operatively. Taken with the above considerations, patients can be reassured that they do not routinely require metalwork removal. The only caveat is that patients with broken and irritating syndesmosis screws could have them removed before nine months, as the syndesmosis will have healed, even if the bones have not.

Discharge and monitoring

The proposed rehabilitation App may make repeated surgical follow-up visits obsolete, particularly as Chapters 4 and 6 found that patients perceive variable benefit from them. Technology will facilitate remote patient clinical assessment, but as yet, it will not enable remote radiological assessment. Several studies have examined the necessity of repeat X-rays, beyond the intra-operative or two-week X-rays, finding that there was no change in alignment or that any changes were not clinically meaningful [210, 211]. However, a large (but non-consensus) proportion of surveyed

HCPs in RAAFT wanted to see a six-week X-ray or signs of healing before discharging a patient from surgical follow-up. This is despite the fact that the mean time to radiographic healing is 82.2 days (SD 33.5) [210], well beyond even the 12-week follow-up visit. In contrast, 88% of HCPs would consider discharging patients from surgical follow-up after six weeks, though the same consensus was not achieved for discharge after two weeks. All surgeons interviewed in Chapter 5 would include a repeat X-ray as part of their assessment of patients that return with complications or new symptoms: this may be because it provides a measure of objectivity, but also due to the perceived value patients derive from seeing their X-rays, as found in Chapters 4 and 5. Furthermore, while Regan et al. found that 63% of patients had radiographic signs of arthritis a decade after their ankle fracture, this does not correlate clinically or dictate decisions for treatment [156].

With early discharge, a concern found in Chapter 5 was that surgeons wanted to follow-up their patients to monitor their outcomes. The survey results suggested a stronger desire to monitor aggregated data compared to a national average, than to monitor the outcomes of individual patients. The British Orthopaedic Foot and Ankle Society (BOFAS) have recently started a registry to provide this service, however, at present, it primarily relies on the completion of paper questionnaires at follow-up visits, and data completion and quality are variable [212]. Reducing the burden on individual HCPs, automating the PROMs collection and incentivising patients to complete the questionnaires by providing personalised progress monitoring could help combat the current issues with data quality.

The clinical and cost-effectiveness of pharmacological VTE prophylaxis is beyond the scope of this thesis. However, the survey results supported the perception that VTE risk is reduced once patients can weight-bear on their ankle [163]. The relevance

to rehabilitation is that if patients can forego injectable VTE prophylaxis and take an oral tablet which does not require monitoring, their reliance on HCPs will be further reduced, and responsibility for their own care internalised. Oral anticoagulants are not yet licensed for this indication in the UK, but research in this area is progressing [213].

7.4.2 Strengths and limitations

Several studies have attempted to gain consensus around weight-bearing and other areas of ankle fracture rehabilitation, though none have succeeded [154, 214]. This is likely because they have used a purely quantitative approach and not sought to understand behavioural influences around weight-bearing decisions. The success of RAAFT in generating a consensus was likely attributable to the iterative, multi-stage generation of the survey statements. The wording was refined to appeal to as many HCPs as possible while remaining specific enough to apply to the target population. A combined workshop with patients and HCPs was considered to ensure the wording and statements were understandable to patients. However, first creating clear statements for consensus among HCPs was the priority, with a plan for combined stakeholder review in future stages of the RAAFT intervention development.

The use of surveys for healthcare research has increased, particularly during the COVID-19 pandemic and survey fatigue is a problem [215, 216]. The balance between the number of responses desired, the range of topics covered and the complexity of questions asked was carefully considered. As funding was available (and may not be again), range and complexity were prioritised. A purposive sample was used to identify HCPs with direct experience in treating patients with surgically managed ankle fractures. Furthermore, the proportion of respondents who were unable to

comment on questions in their role was low and corresponded to physiotherapists being unable to comment on specific surgical questions. Guidance is sparse regarding the ideal sample size for consensus surveys, but considering the expert nature of respondents, the RAAFT survey sample is similar to other healthcare research [217, 218].

7.4.3 Conclusions

Chapter 7 has established a consensus for aspects of care around ankle fracture surgery rehabilitation. This will enable standardisation of advice around boot use, wound care and massage. Agreement around approaches to weight-bearing were established, reinforcing findings from Chapters 4 and 5 that "trusting your body" is the optimal way for patients to progress their rehabilitation, rather than waiting for HCPs approval or instructions. The design of a novel rehabilitation intervention has been considered and tailored to the desires of HCPs.

More important to the validity of the intervention development is not the absolute sample size or level of consensus achieved but the triangulation of themes and findings across data sources [219]. One purpose of establishing standardised guidance was to increase HCP engagement with the proposed RAAFT rehabilitation intervention. Therefore, a robust triangulation method was important to persuade HCPs of the validity of the intervention development as a whole: this is described in Chapter 8.

CHAPTER 8

Mixed methods integration

8.1 Introduction

The use of mixed methods research is becoming increasingly popular in medical research [220, 221]. The MRC recommends mixed methods for designing and evaluating complex interventions [58]. The primary reason for this is that quantitative methods, such as RCTs may be able to prove an intervention is effective, but they must also be implementable and scalable to benefit patients in the wider NHS.

Mixed methods research refers to studies which analyse quantitative and qualitative data within the same study [222]. Several designs can be used:

- **Explanatory sequential:** Quantitative data are collected and analysed first, with qualitative data then collected and analysed to help explain the quantitative data.
- **Exploratory sequential:** Qualitative data are collected and analysed first, with a quantitative approach then used to test and validate the qualitative findings and theories.
- **Parallel:** Qualitative and quantitative data are collected and analysed concurrently.

- **Nested:** The main design is either quantitative or qualitative, with an additional embedded study to answer a complementary question.

The mixed methods approach for this thesis was a nested design. The WAX trial sought to quantitatively determine the most clinically and cost-effective weight-bearing strategy after ankle fracture surgery and this thesis aimed to understand how patients can be supported to return to weight-bearing and daily living.

Chapters 1 to 7 of this thesis have demonstrated the complexity of an intervention to promote weight-bearing after ankle fracture surgery: that proving effectiveness would only modify the behaviours of HCPs (as opposed to patients directly), and only through one COM-B domain. The purpose of this mixed methods integration chapter is to define the individual components that are relevant to the behaviour of weight-bearing and progressing recovery after ankle fracture surgery and to assess their concordance across the empirical Chapters 2 to 7.

8.1.1 Objectives

1. To assess the concordance of the findings from Chapters 2 to 7.

2. To integrate the findings from Chapters 2 to 7 into a rehabilitation package.

8.2 Methods

8.2.1 Study design and methods

A triangulation protocol was generated and reported in accordance with the Good Reporting of A Mixed Methods Study (GRAMMS) checklist [223]. The sampling, data collection and analysis of each research component have been reported in the

respective chapters. The conduct and analysis were undertaken in chronological order of chapters. The findings from each successive chapter have iteratively informed the content of the later chapters and the design of the proposed rehabilitation intervention. This section describes the analysis methods for integration.

8.2.2 Mixed methods integration and analysis

The triangulation method was used for mixed methods integration. This was initially proposed by Farmer et al. [219] and has been used in subsequent mixed-methods healthcare research [224, 225].

A matrix was compiled listing key findings and themes from each chapter. Thereafter, the agreement between each chapter was compared using a convergence and completeness coding scheme [219, 224]. Convergence between themes was coded as follows:

- **Agreement:** the finding has been identified, and there was an agreement with the statement or in the case of the surveys >75% consensus was established.
- **Partial agreement:** the finding has been identified, but there is no consensus agreement with the statement.
- **Disagreement:** the finding has been identified, but there is disagreement with the statement, with >75% disagreement with the statement during the consensus surveys.
- **Silence:** the finding does not appear in the respective chapter.

Triangulation was undertaken by a single researcher and reviewed by a supervisory team.

8.2.3 Rehabilitation package design

Target intervention bundles were generated using the methods discussed in Section 6.2.2, using the Behaviour Change Wheel (BCW) [83]. An intervention bundle refers to a set of intervention functions, policy options and BCTs that work to modify a specified behaviour [45, 83, 135]. The content and delivery of these bundles were refined during Chapters 6 and 7, using the APEASE and TiDier criteria. These criteria assisted in determining the feasibility and acceptability of the intervention bundles to patients and HCPs, as well as how, where and by whom the interventions should ideally be delivered. The intervention bundles were then broken down into their component BCTs, to enable development and evaluation as recommended by the MRC [58].

8.3 Results

8.3.1 Convergence coding and assessment

Table 8.1 shows the triangulation coding results. Concepts or themes generated from Chapters 2 to 7 are presented and coded as for whether they are present in each chapter and whether there is convergence using the criteria described in Section 8.2.2. Discordance between Chapters 4 and 5 is discussed in Section 5.3.3 and so is not discussed here.

Behaviour change techniques (BCTs)

There was agreement throughout the chapters that "Education" and "Training" intervention functions and the "Credible source" and "Goal setting" BCTs should

form part of the proposed rehabilitation intervention. There was agreement that a new BCT-based rehabilitation intervention could increase the risk of complications such as infection or wound healing problems and that mechanisms to avoid, detect and monitor these complications should be in place. There was agreement that current rehabilitation strategies are rarely able to demonstrate improvement in PROMs, and therefore additional outcome measures such as cost and patient preference should be considered.

Populations

There was concordance that specific patient populations are at risk of poor or slow recovery after ankle fracture surgery, and therefore screening for these characteristics should be considered. Once identified, these characteristics should be modified if possible (such as unhelpful pain beliefs) or additional monitoring or support offered. Where characteristics are not modifiable, the provision of patient-specific information or expectations would be helpful.

Weight-bearing experience

There was agreement across chapters that non-weight-bearing reduces patients' independence and that often they have difficulty adhering to weight-bearing instructions. There was agreement that the act of weight-bearing itself is usually not painful, and it is anxiety that limits patients' ability to weight-bear in the initial phases. There was concordance that patients should view increasing their weight-bearing as a gradual process and should increase based on their comfort levels rather than set incremental percentages. There was agreement that seeing their X-rays can increase patients' capabilities for weight-bearing and progressing their rehabilitation.

There was partial agreement that it is safer to weight-bear early or that patients should be allowed to touch their foot to the ground for balance during non-weight-bearing periods.

Additional rehabilitation needs

There was a discrepancy between patients and HCPs that swelling and numbness are a concern during recovery, but agreement that the cross-over of these symptoms with early signs of CRPS can be a challenging diagnostic issue. There was agreement that knowing what pain is "normal" during recovery is also challenging.

There was agreement that physiotherapy access varies widely among regions, and there is a lack of reliable information for patients between appointments. Additionally, there was agreement that conflicting advice should be reduced, and standardised rehabilitation pathways could help this.

Table 8.1: Triangulation: Coding assessment

Concept/ theme	Chapter 2: Systematic review	Chapter 3: Exploratory analysis	Chapter 4: Patient interviews	Chapter 5: HCP interviews	Chapter 6: Patient workshop and survey	Chapter 7: HCP workshops and survey
Education and Training	✓	-	✓	✓	✓	✓
Goal setting	✓	-	✓	✓	✓	✓
Credible source	✓	-	✓	✓	✓	✓
Important to consider infection, wound healing problems and re-operation (detect, monitor, avoid)	✓	-	✓	✓	✓	✓
Current rehab strategies don't improve PROMs	✓	-	-	✓	-	-
Unhelpful pain beliefs should be screened for and extra therapy given	-	✓	✓	✓	✓	✓
Occupation (especially manual labour) could be a source of healthcare inequity, patients should be offered a range of ways to engage with HCPs	-	✓	✓	✓	✓	-
Other demographic factors (e.g. Age and BMI) could affect outcomes: information and expectations should be tempered accordingly	-	✓	✓	✓	✓	✓
It is helpful for patients to know what to expect during recovery	-	-	✓	✓	✓	-
Difficulty adhering to WB instructions	-	-	✓	✓	✓	✓
Patient preference for early WB	-	-	✓	✓	✓	✓
NWB causes difficulty with ADLs	-	-	✓	✓	✓	✓
Gradual build-up of WB as comfortable	-	-	✓	✓	✓	✓
Patient should be allowed to WB for balance	–	-	✓	P	✓	x
It's safer to be weight-bearing	-	-	✓	P	✓	P
Anxiety, not pain limits WB	-	-	✓	✓	✓	✓
Pain is independent from the act of weight-bearing	-	-	✓	✓	-	-
There is value in patients seeing their X-rays	-	-	✓	✓	✓	-
Conflicting advice should be reduced	-	-	✓	✓	✓	✓
There is lack of information between appointments	-	-	✓	✓	✓	✓
Swelling and numbness is a concern	-	-	✓	x	✓	x
How to push through pain during recovery	-	-	✓	✓	✓	✓
Diagnostic uncertainty around CRPS	-	-	-	✓	-	✓
Wide variety in physiotherapy provision	-	-	✓	✓	✓	-

✓= Agreement, x = Disagreement, P = Partial agreement, - = Silence/ not addressed

8.3.2 Components and content of the rehabilitation package

The BCTs and their respective COM-B/TDF domains, interventions functions and content are displayed in Table 8.2, 8.3 and 8.4. The numerical codes listed relate to the BCT Taxonomy [64], available in Appendix E.4.

The target behaviours were weight-bearing and progressing with rehabilitation after ankle fracture surgery. The BCTs only target the behaviours of patients, however, some of the components and content are included to increase the appeal and likely uptake of the rehabilitation intervention by HCPs. As such, the only policy option considered is "Service provision". Some intervention components, such as "4.1. Instruction on how to perform the behaviour", could be delivered individually in the form of a booklet. Here, however, a comprehensive intervention is proposed in the form of a rehabilitation App.

Table 8.2: Rehabilitation intervention: Goals, Feedback, Social support

BCT	COM-B/ TDF Domains	Intervention functions	Content
		1. Goals and planning	
1.1 Goal setting (behaviour) Set or agree on a goal defined in terms of the behaviour to be achieved.	**Motivation - Reflective** 9. Goals	**Enablement** Establish goals: Provide a selection of goals on a rehabilitation App and agree individual goals E.g. performance of ankle exercises ten repetitions, three times per day, or aim to walk one mile per day. Provide predicted timeframes based on patient characteristics. E.g. age and occupation.	Weight-bearing Discarding boot Discarding walking aids Ankle exercises
1.3 Goal setting (outcome) Set or agree a goal defined in terms of a positive outcome of wanted behaviour.	**Motivation - Reflective** 9. Goals	**Enablement** As per 1.1, but focus on outcomes, e.g. aim to be able to walk for one mile after four weeks.	Full body exercises Driving Work ADLs
1.4. Action planning Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity).	**Opportunity - Physical** 11. Environment context and resources	**Training, Enablement** As per 1.1, but with more detailed planning as routines change. E.g. Performing exercises after breakfast at home or during lunch break at work.	Running Hobbies
		2. Feedback and monitoring	
2.3. Self-monitoring of behaviour Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy.	**Capability - Psychological** 10. Memory, attention and decision processes	**Enablement, Incentivisation** Use a rehabilitation App to monitor the behaviours set in "1.1 Goal setting (behaviour)" E.g. keeping an exercise or walking diary.	
2.4 Self-monitoring of outcome(s) of behaviour Establish a method for the person to monitor and record the outcome(s) of their behaviour as part of a behaviour change strategy.	**Capability - Psychological** 10. Memory, attention and decision processes	**Enablement, Incentivisation** Use a rehabilitation App to monitor the outcomes set in "1.3 Goal setting (outcome)". Record responses to PROMs via the rehabilitation App. Self-monitor progression and improvements to provide motivation for continued performance of the behaviour.	Weight-bearing Ankle Exercises Discarding boot Discarding walking aids Driving Work
2.5 Monitoring outcome(s) of behaviour by others without feedback Observe or record outcomes of behaviour with the person's knowledge as part of a behaviour change strategy.	**Capability - Psychological** 10. Memory, attention and decision processes	**Enablement, Incentivisation** As per 2.4, but with the optional uploading of PROMs to a national database, so patients know their scores are monitored beyond their personal review. Additionally, with consent, collecting information from patients about their recovery which can then be used to update the App timeframes in "1. Goals and planning" iteratively.	Running Hobbies
2.7 Feedback on outcome(s) of behaviour Monitor and provide feedback on the outcome of performance of the behaviour.	**Capability - Psychological** 10. Memory, attention and decision processes **Motivation - Reflective** 6. Beliefs about capabilities	**Enablement, Persuasion** As per 2.4, but with the optional uploading of PROMs to a local database, allowing review at follow-up appointments or flagging up if poor progress.	
		3. Social support	
3.1 Social support (unspecified) Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues) or noncontingent praise or reward for performance of the behaviour.	**Opportunity - Social** 12. Social influences	**Enablement** Connect with peers via a rehabilitation App. Share experience with peers and gain motivation from others to continue with behaviours specified in "1.1 Goal setting (behaviour)".	A peer support forum, with or without HCP moderation. Virtual discussion meetings with peers. Group virtual exercise classes, led by a physiotherapist.
3.2. Social support (practical) Advise on, arrange, or provide practical help (e.g. from friends, relatives, colleagues) for performance of the behaviour.	**Opportunity - Social** 12. Social influences	**Enablement, Education** Educational resources for family and friends, including assistance they can provide to help patients with their ADLs and perform behaviours specified in "1.1 Goal setting (behaviour)".	Obtaining and donating additional equipment (e.g. wheelchair or bedpan). Meal preparation Home set-up

Table 8.3: Rehabilitation intervention: Knowledge, Consequences, Comparison of behaviour, Associations

BCT	COM-B/ TDF Domains	Intervention functions	Content
		4. Shaping knowledge	
4.1. Instruction on how to perform the behaviour Advise or agree on how to perform the behaviour.	**Capability - Physical** 2. Skills	**Training** A rehabilitation App with instructional videos, including examples of people receiving feedback on activities (e.g. exercises). A live chat to a physiotherapist on call 9am-5pm for queries and or virtual calls for feedback.	Weight-bearing Walking aids Adjusting walking boot Icing ankle Ankle exercises and stretching Full body exercises ADLs Balance Home set-up planning Wound cleaning and massage Blood thinning injections Driving
		5. Natural consequences	
5.1. Information about health consequences Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour.	**Capability - Psychological** 1. Knowledge **Motivation - Reflective:** 6. Beliefs about Consequences **Motivation - Automatic:** 13. Emotion	**Education** A rehabilitation App with educational content and explanations, including the benefits of performing specified behaviours. A live chat to a physiotherapist on call 9am-5pm for queries.	Weight-bearing Ankle exercises Whole body exercises Elevation Wound massage
		6. Comparison of behaviour	
6.1. Demonstration of the behaviour Provide an observable sample of the performance of the behaviour, directly in person or indirectly, e.g. via film, pictures, for the person to aspire to or imitate.	**Capability – Physical** 2. Skills	**Training, Modelling** A rehabilitation App with instructional videos, including examples of people receiving feedback on activities (e.g. exercises). A live chat to a physiotherapist on call 9am-5pm for queries and or virtual calls for feedback.	As per "4.1. Instruction on how to perform the behaviour".
6.2. Social comparison Draw attention to others' performance to allow comparison with the person's own performance.	**Opportunity - Social:** 12. Social influences	**Enablement, Environmental restructuring** Connect with peers via a rehabilitation App. Share experience with peers and compare progress, both informally, and via a tracking comparison function on the App.	A peer support forum, with or without HCP moderation. Virtual discussion meetings with peers. Group virtual exercise classes, led by a physiotherapist. A diary and progress tracker.
		7. Associations	
7.1. Prompts/Cues Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance.	**Capability - Psychological** 10. Memory, attention and decision processes	**Environmental restructuring** Use a rehabilitation App to remind patients to perform the behaviours set in "1.1 Goal setting (behaviour)". This can include an exercise schedule and timer, with or without a diary function.	Ankle exercises and stretching Analgesia Blood thinning injections

Table 8.4: Rehabilitation intervention: Repetition, Comparison of outcomes, Self-belief

BCT	COM-B/ TDF Domains	Intervention functions	Content
		8. Repetition and substitution	
8.1. Behavioural practise/ rehearsal Prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill.	**Capability - Physical** 2. Skills	**Training** A rehabilitation App with instructional videos, including examples of people receiving feedback on activities (e.g. exercises). A live chat to a physiotherapist on call 9am-5pm for queries and or virtual calls for feedback.	Weight-bearing Walking aids Adjusting walking boot Icing ankle Ankle exercises and stretching Full body exercises ADLs Balance Home set-up planning Wound cleaning and massage Blood thinning injections Driving
8.3 Habit formation Prompt rehearsal and repetition of the behaviour in the same context repeatedly so that the context elicits the behaviour.	**Capability – Physical** 2. Skills	**Training** As per 8.1, but with prompts to perform the behaviour in a specific context repeatedly. E.g. whilst brushing teeth.	
8.6 Generalisation of a target behaviour Advise to perform the wanted behaviour, which is already performed in a particular situation, in another situation.	**Capability – Physical** 2. Skills	**Training** As per 8.1, but with prompts to perform the behaviour outside of physiotherapy appointments.	
8.7. Graded tasks Set easy-to-perform tasks, making them increasingly difficult, but achievable, until behaviour is performed.	**Capability – Physical** 2. Skills 4. Beliefs about capabilities	**Training** As per 8.1, but with increasing complexity and intensity. E.g. a graded exercise regime.	
		9. Comparison of outcomes	
9.1. Credible source Present verbal or visual communication from a credible source in favour of or against the behaviour.	**Opportunity - Physical:** 11. Environmental context and resources	**Environmental restructuring** Providing an alternative method of interacting with HCPs. A live chat to a physiotherapist on call 9am-5pm for queries and or virtual calls for feedback. A booking and healthcare record storage facility on a rehabilitation App.	Contact a physiotherapist. Book a surgical or physiotherapy follow-up appointment. Access patient hospital records and X-rays.
		15. Self-belief	
15.1. Verbal persuasion about capability Tell the person that they can successfully perform the wanted behaviour, arguing against self-doubts and asserting that they can and will succeed.	**Motivation - Reflective:** 6. Beliefs about capabilities **Motivation - Automatic:** 13. Emotion	**Education, Persuasion, Environmental restructuring** Persuade patients that they have the capability to perform the behaviours specified in "1.1 Goal setting (behaviour)". A live chat to a physiotherapist on call 9am-5pm for queries and, or virtual calls for feedback, including sending ankle swelling and wound photos. An ability for rapid HCP advice and review.	Provide timeframes and consensus recommendations for: Weight-bearing Discarding boot Discarding walking aids Driving Work Running Hobbies Getting the wound wet Wound massage When to seek HCP support (e.g. for wound issues) Screen for unhelpful pain beliefs, low mood or depression and receive extra help accordingly.

8.4 Discussion

8.4.1 Interpretation

Concordance

The triangulation process found concordance across Chapters 2 to 7. The most promising BCTs and intervention functions from Chapter 2 were congruent with the findings from Chapters 4 to 7 and the theoretically relevant BCTs identified using the BCW mapping matrices (Figure 6.2 and 6.3).

Chapter 3 demonstrated that unhelpful pain beliefs and other patient characteristics are associated with poor outcomes, and there was agreement in Chapters 4 to 7 among patients and HCPs that it would be useful to screen for these. Many findings and beliefs were shared across the patient and HCPs interviews, workshops and surveys. Where there was congruence between the quantitative and qualitative components, this increases the validity and robustness of the findings and strengthens the hypotheses [219].

Through triangulation, it is apparent that several of the individual findings are part of a broader concept. That is, it would be helpful to enable patients to take greater responsibility for their own recovery. Wahl et al. [226] discussed the concept of "health locus of control", reporting results of a cross-sectional study of patients undergoing physiotherapy for musculoskeletal conditions in primary care. Patients with an internal locus of control perceive their own behaviours as the principal determinant of their outcome and life situation, whereas those with an external health locus of control place responsibility for their health and health behaviours on others (e.g. healthcare professionals). Wahl et al. [226] found that patients who attended

physiotherapy more regularly had lower levels of internal health locus of control and were less likely to engage with self-management strategies. Hamilton et al. [151] found in the context of a "therapy as required" service, patients that did not access physiotherapy after hip and knee replacement surgery had better postoperative outcomes. This is discussed further in Section 9.3.2.

Disagreement

The triangulation process did highlight areas of disagreement. If considering only the findings from interviews with patients and HCPs, one could determine or recommend, that patients should be allowed to weight-bear for balance for reasons of preference and safety during non-weight-bearing periods. However, quantification of these beliefs during the survey found that they were not shared by a consensus of HCPs, with 44% in direct disagreement. There are several theories for why this discordance may exist:

1) The interview participants may have modified their responses to mirror the interviewer's expectations and avoid social stigmatising [171, 172]. This may be particularly relevant as most interview participants had an existing professional relationship with the interviewer.

2) The interview sampling strategy may have attracted HCP with existing strong beliefs around early weight-bearing, as it was not possible to sample for negative or deviant cases as recommended by Safdar et al. [227].

3) The HCP survey was relatively long, and despite piloting, may have been confusing or complex and so HCPs may not have fully grasped the concept about which they were answering [227]. More likely, the results reinforce findings from other studies that there is variation and confusion around weight-bearing language and

practice that needs addressing [8, 61, 154].

Another area of disagreement identified prior to the triangulation process was the discrepancy between patients' and HCPs' perception of swelling and numbness. Prior identification enabled this discordance to be explored and remedied, as discussed in Chapter 7.

The results from RAAFT highlight that HCPs are aware that patients may be at risk of depression or unhelpful pain beliefs, but presently there is no consensus on how or what orthopaedic professionals' role is in addressing these.

8.4.2 Strengths and limitations

The strengths and limitations of the individual methods are discussed in their respective chapters. This section discusses the process of mixed methods integration.

The most common mixed methods research approach is the combination of qualitative interviews with quantitative surveys [221]. This thesis has supplemented these methods with participant workshops and data from an observational study (Chapter 3). Other methodologies could have enhanced the findings, such as ethnography, case studies and examination of patient diaries. However, considering this thesis has combined methodological approaches and explored this from the perspective of both patients and HCPs, the comprehensiveness of the mixed methods integration should be regarded as a strength.

The central limitation is that, while there has been good methodological and data source triangulation, there has been limited investigator triangulation. In addition to convergence and completion assessment, Farmer et al. [219] recommend two further steps:

1) Coding by multiple researchers and assessment of agreement between researchers.
2) Feedback to stakeholders, which might include interviews or survey participants.

These steps could have enhanced the validity of findings and reduced the biases of an individual researcher. While these steps were not feasible, a review of the results and interpretation from a multi-disciplinary supervisory team gives confidence that the findings can be translated into reliable outputs.

8.4.3 Conclusions

Many of the themes found in this thesis can be summarised as measures which promote an internal health locus of control. Chapter 2 found that existing, non-effective interventions mainly consisted of more HCP interaction, more physiotherapy and more adherence to prescribed goals and instructions. Chapter 3 found that patients with unhelpful pain beliefs have poorer outcomes, possibly because they cannot self-regulate their activity due to self-doubt and anxiety. Patients in Chapter 4 stated that self-efficacy was the primary driver for recovery, and uncertainty around not knowing "what is normal" was the primary barrier. Chapter 5 recognised that patients might rely too much on their HCPs and fail to take responsibility for their own recovery. In Chapters 6 and 7 priorities and consensuses were established to enable patients to self-manage their recovery. These themes and insights developed separately, and viewed in isolation, concepts such as "trust your body" and "do what you feel is comfortable" appear as rhetorical turns of phrase. Yet through the triangulation process, they can be seen to unite into a common concept: that the target behaviour for the intervention should not be to increase weight-bearing and progress rehabilitation. Instead, the target behaviour should be for patients to internalise their health locus of control. In doing so, the secondary objectives of earlier

weight-bearing, performing physiotherapy exercises and returning to work, hobbies, and life roles should follow.

CHAPTER 9

Summary and Conclusions

9.1 Introduction

9.1.1 Objectives

1. To summarise Chapters 2 to 8.

2. To set out conclusions and next steps.

9.2 Summary of empirical chapters

9.2.1 Chapter 2

Research question

Which behaviour change techniques (BCTs) have been most commonly used in rehabilitation interventions after ankle fracture, and which are the most effective?

Study design

A systematic review and meta-analysis of rehabilitation interventions after ankle fracture surgery.

Findings

The most common intervention functions were education and training. No random-

ised controlled trials comparing rehabilitation interventions for patients recovering from ankle fractures were based on behavioural theory. There is low certainty evidence that BCT do not improve patient-reported outcomes of ankle function or quality of life or reduce adverse events after ankle fracture. There is very low certainty evidence that for operatively-treated ankle fractures, BCTs may increase the risk of wound-related adverse events.

9.2.2 Chapter 3

Research question

What are the impacts of unhelpful pain beliefs and other demographic characteristics on recovery after ankle fracture surgery?

Study design

An observational cohort study of patients undergoing operative management of an unstable ankle fracture.

Findings

Unhelpful pain beliefs were negatively associated with patient-reported outcomes four months after ankle fracture surgery. Patients with a high BMI and those working in manual labour occupations had worse outcomes after surgery. Increasing patient comorbidity was associated with better patient reported outcomes. Age, gender, injury mechanism and educational attainment did not have a consistent association with outcome."

9.2.3 Chapter 4

Research question

What are patients' experiences of commencing weight-bearing and priorities for re-

covery after ankle fracture surgery?

Study design

Qualitative semi-structured interviews with patients after ankle fracture surgery.

Findings

Patients experienced a loss of independence and struggled to perform ADLs during non-weight-bearing periods after ankle fracture. For most patients, pain after ankle fracture surgery was independent of the process of weight-bearing. Anxiety was the primary barrier to weight-bearing, and providing knowledge and skills could help ease this. A primary uncertainty was not knowing what was "normal", particularly around swelling and sensations. In addition, there was variability in advice and access to HCPs in different regions, which patients found frustrating.

9.2.4 Chapter 5

Research question

How do HCPs perceive patients' experience of commencing weight-bearing, and what influences HCPs behaviours in the treatment of patients with surgically-managed ankle fractures?

Study design

Qualitative semi-structured interviews with HCPs.

Findings

There was a discrepancy between HCPs and patients' beliefs after ankle fracture surgery, particularly with regard to swelling, the risks of non-weight-bearing and responsibility for performing ankle exercises. HCPs were concerned about wound problems and the medicolegal implications of permitting early weight-bearing after ankle fracture surgery. There was substantial variation in the language and methods

used to facilitate patients to commence and progress weight-bearing. Surgeons felt rushed during fracture clinic and did not feel they provide patients with all the support they need.

9.2.5 Chapter 6

Research question

What are patients' priorities for the content and delivery of a rehabilitation intervention after ankle fracture?

Study design

A modified online Nominal Group Technique (NGT) patient workshop and survey.

Findings

Theoretically congruent behaviour-change intervention functions included education, training, persuasion, enablement and environmental restructuring. Patients desired information about what to expect after ankle fracture surgery, including when they should seek HCP advice and when they can return to hobbies and life roles. Patients were amenable to less F2F HCP follow-up if they could access credible rehabilitation resources remotely.

9.2.6 Chapter 7

Research question

What advice can be standardised for the content of a rehabilitation intervention for patients after ankle fracture, and what format would be acceptable to HCPs?

Study design

Modified online NGT HCP workshops and a survey.

Findings

A consensus was established for wound care, orthotic boot use and when patients should seek medical attention after ankle fracture surgery. Agreement was established for how patients should commence weight-bearing, but not for what activities should be permitted during non-weight-bearing periods. HCPs were amenable to discharging patients six-weeks after ankle fracture surgery to a rehabilitation App. The key components and information that a rehabilitation App should contain were established.

9.2.7 Chapter 8

Research question

What behaviour change techniques (BCTs) should a novel rehabilitation intervention for patients after ankle surgery fracture contain?

Study design

A mixed methods triangulation of the empirical chapters.

Findings

Facilitating patients to internalise their health locus of control should form the underlying basis of a new rehabilitation intervention. This should be facilitated by providing education, training and goal-setting from a credible source. Screening for patients with unhelpful pain beliefs or other risk factors for a slow recovery should be undertaken. Outcome monitoring could help patients progress their recovery and help HCPs appraise their practice, and facilitate research.

9.3 Conclusion

9.3.1 Weight-bearing in ankle fractures

The design of the rehabilitation intervention in this thesis has focused on an intervention for patients. Various BCTs have been identified and proposed to facilitate patients' weight-bearing sooner after ankle fracture surgery. However, perhaps the first step is to empower HCPs to permit patients to weight-bear sooner. There is significant variability and uncertainty around weight-bearing after lower limb fractures, particularly after ankle fracture surgery [8, 61]. A strong theme from Chapter 5 was that a change in culture will be required to persuade HCPs to discard the historic weight-bearing restrictions. Culture change will require a range of methods. These include cadaveric studies [228], RCTs [29], local and national guidelines [93] and persuasion from eminent figures [229].

A recent article issued "A call to arms" to start weight-bearing immediately after performing lower limb fracture surgery [229]. This strong messaging may lead to HCPs feeling they are having instructions "shoved down their throat" (S9). After reflection on the findings of Chapters 4 and 5, a different approach was explored. If HCPs cannot have their minds forcibly changed, perhaps a softer shift in practice could help. Patients found that it was not necessarily the ability to full weight-bear that enhanced their independence, but the ability to put their foot down to rest and for balance significantly improved their ability to undertake ADLs. However, a consensus was not achieved during the HCP survey, with 44% indicating patients could rest their foot on the ground for balance during non-weight-bearing periods and 47% indicating they should not. This differs from a study by Raza et al. [154], which

showed by comparison that only 6.5% of doctors and 2.2% of therapists considered non-weight-bearing to mean patients could put small amounts of weight through their ankle (0-20% of bodyweight). The same study showed much wider variation in interpretation of other weight-bearing terms such as touch, toe-touch, protected and partial weight-bearing. Furthermore, Thompson et al. [155] found HCPs were likely to overestimate the amount of weight they put through their leg. Conversely, Eickhoff et al. [164] found that particularly older patients and those with a high BMI underestimate and put more weight through their leg than instructed. Hence, simply asking HCPs to use different terminology is unlikely to solve the confusion, as found in Chapter 5. One interpretation of these findings, and a theme found in Chapter 5, is that HCPs fear their instructions will be interpreted as "binary". That is, if they allow some weight-bearing, they fear patients will walk at this level or exceed it in all their activities. This has prompted some HCPs to change their language, using phrases such as "weight-bear for transfers", "weight-bear for activities of daily living", and "weight-bear as required to survive".

While consensus was not achieved to allow patients to put their foot down for balance, it has highlighted the potential utility of this approach. Future efforts should consider discussing how allowing putting the foot down for balance during ADLs can result in a considerable improvement in patients' quality of life and independence, without the need to let them weight-bear on both feet whilst actually walking (when sometimes the un-injured leg will be off the ground during the gait cycle). Thereafter, pending the WAX trial results, HCPs should feel comfortable removing all weight-bearing restrictions and instructing patients to weight-bear as they feel comfortable and trust their body.

Furthermore, the inability to gain a consensus around this area indicates that

patients will continue to endure periods of non-weight-bearing. While there is increasing research into pressure sore management [230, 231], there is little research into other strategies to deal with the physical and psychological consequences of non-weight-bearing, particularly in vulnerable older persons [62]. The proposed RAAFT intervention will provide an opportunity to advise patients on coping strategies and monitor their outcomes during this time.

9.3.2 The future of rehabilitation after ankle fracture

There are broadly two schools of thought when it comes to delivering rehabilitation after Trauma:

1) Give more F2F time with therapists, whereby more therapy equals more repetitions and better outcomes. A systematic review [23] has found no evidence of benefit for delivering additional conventional physiotherapy sessions. Ongoing studies have supplemented F2F therapy sessions with additional, web-based information, yet the hypothesis remains; that the F2F dose to response relationship will result in better patient outcomes [84, 232].

2) The other approach, as found in Chapter 5, was that patients need to be empowered to take responsibility for their own rehabilitation and that waiting for another therapy session to progress to the next stage makes them a passive participant in their recovery.

The rehabilitation package proposed in this thesis aligns more closely with the latter approach, using BCTs that have proven effective in other health conditions

[55]. The discrete components of the proposed rehabilitation intervention are listed in Section 8.3.2. Broadly, the strategy is as follows:

1. Provide patients and their families with the knowledge and skills they require to progress their weight-bearing and rehabilitation independently, in an easily accessible format, in an environment of their choosing (usually at home).

2. Provide adjuncts to rehabilitation, including goal-setting, reminders and progress tracking.

3. Boost patients' beliefs in their capabilities to overcome uncertainties and challenges by having a physiotherapist available to rapidly reassure or review if required.

4. Provide a mechanism for identifying patients at risk of slow progress (e.g. with unhelpful pain beliefs) or that are progressing slowly to allow additional support to be provided.

These core functions have been co-designed with patients, for the benefit of patients, but secondarily also serve HCPs. It is anticipated that this rehabilitation package would be made widely available. This is because it seeks to provide standardised advice driven by an established consensus. It seeks to reduce surgical follow-up, which patients and HCPs have found at times unhelpful and even frustrating, and there-by may reduce in-hospital HCP workload, potentially making surgeons feel less rushed in NHS clinics.

Virtual wound follow-up

Al Salman et al. [233] found that confidence in remote wound evaluation and provision of exercise instructions were the primary determinants of surgeons' utilisation of virtual follow-up methods. Chapter 7 found a consensus that surgeons were confident in remote wound assessment, but physiotherapists were less comfortable. Mclean et al. [234] randomised emergency surgical patients to receive a digital wound assessment tool, or routine care, and demonstrated the safety, feasibility and decrease in community health visits associated with a remote wound assessment. In their trial, all wounds were screened by a senior clinician. However, an algorithm based on patient-reported symptoms and artificial intelligence (AI) assessment is currently under development and could assist less experienced HCPs in monitoring wounds remotely [234].

While virtual assessment has the potential to improve patient satisfaction, reduce costs and relieve the burden on out-patient services, Chapter 7 revealed an additional concern from HCPs: this related to workplace creep, with a concern that notifications and requests could encroach into HCPs personal lives, affecting their work-life balance.

Patients and HCPs had mixed opinions of virtual follow-up throughout Chapters 4 to 7. These correlate with findings from a systemic review and qualitative synthesis of nine studies using virtual consultations in an orthopaedic rehabilitation setting [168]. An additional key finding was that virtual consultations changed "the work of being a patient", which could be a barrier to access, or a benefit, with greater engagement in self-management activities. Patients used to F2F hands-on care had particular challenges with virtual care, where additional investment in the patient/HCP relationship was required [168].

Health locus of control

Several HCPs in Chapter 5 were sceptical of a remote rehabilitation App and virtual follow-up, fearing it was primarily a convenience and cost-saving measure. However, for the proposed rehabilitation intervention, these motives are secondary, with the primary aim to increase patients' engagement and responsibility for their own health. There are a variety of measures used to describe this concept. Jayakumar et al. [87] found that higher levels of patient engagement were associated with improved upper limb function six to nine months after injury. There was however, significant collinearity with other psychosocial factors, including pain self-efficacy and kinesphobia [87]. Health literacy refers to a patient's ability to understand health information and make informed health decisions [235]: higher levels have been found to correlate with patients' desire to be an active participant in their care, but not with their ability to achieve that goal [236].

However, the concept that most closely aligns with themes generated during this thesis is health locus of control, as discussed in Section 8.4.1. This alignment pertains to a commitment from patients and HCPs: HCPs in Chapters 5 and 7 appreciated that less direct HCP engagement can foster patients to adopt an internal health locus of control [226]. Internal health locus of control was first described by Rotter in 1954 [237] and has been found to correlate with improved outcomes in musculoskeletal health and even mortality [226, 238, 239]. These improved outcomes are thought to be mediated by improved health-related behaviours. Surprisingly, these concepts are mostly absent from behaviour change theory literature [44, 45]. Some studies discuss using the BCW to improve exercise adherence [46, 56], but few discuss health locus of control. One study by Morrison et al. [240] discusses health locus of control in

relation to digital healthcare interventions, suggesting that choice and flexibility help promote an internal locus of control and self-management. This flexibility and ability to personalise information and resources to individual patients has been a theme present throughout this thesis, and so has a strong theoretical and service-user agreement.

Figure 9.1 displays a summary of the beliefs, barriers and facilitators to weight-bearing and rehabilitation after ankle fracture surgery. The proposed App-based physiotherapy advice service is presented as the delivery method for internalising patients' health locus of control, which in turn is the unifying mechanism for addressing the barriers found throughout this thesis.

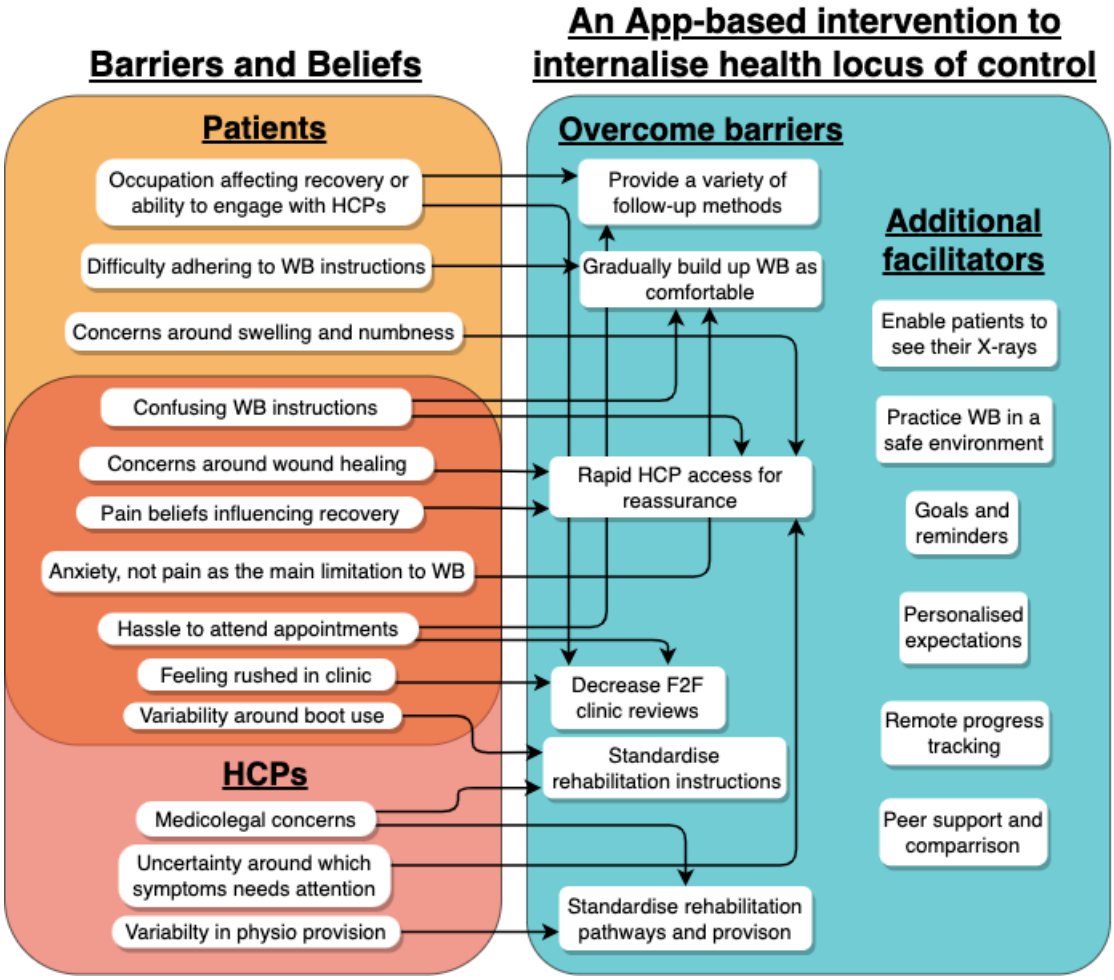


Figure 9.1: A logic model summarising the beliefs, barriers and proposed facilitators to weight-bearing and rehabilitation after ankle fracture surgery

Targets and exclusions

This rehabilitation App is specifically designed for patients for whom standard treatment methods have been used and where standardised rehabilitation pathways are suitable. As identified in Chapters 4 to 6, there are groups of patients for whom this will be unsuitable or undesired. For example, while 90% of UK adults own a smartphone [241], patients who do not speak English or those with limited access or experience with digital technology will be unsuitable. Other patients for whom

standardised advice may be unsuitable include patients without peripheral sensation who lack a self-regulatory mechanism to avoid and detect complications and patients who have already experienced complications that require regular review and tailored instructions.

Excluding minority or under-served groups is ethically problematic and is directly at odds with the NIHR ethos to better represent these groups [242]. However, the NIHR highlights that there are under-served groups at alternative risk of health care inequity, such as those in full-time employment, living in remote areas and others that struggle or do not regularly attend medical appointments. As found in Chapter 3, working in a manual labour occupation was associated with poorer patient-reported outcomes. Providing other options for HCP access may be one way of addressing this. Additionally, reducing the follow-up burden for patients who may not need it will free up HCP time and resources for under-served groups that cannot engage with the proposed rehabilitation package and may need extra support.

With appropriate investment, some of these exclusions could be overcome and enhance support for under-served populations. For example, the peer support component of the proposed rehabilitation App could help young people and those from Black, Asian and Minority Ethnic (BAME) backgrounds, who often do not engage with health services. Previous research has suggested that these groups are particularly receptive and value peer support over conventional HCP-delivered services [146, 147, 243].

Messaging and uptake

The proposed RAAFT rehabilitation App is designed to improve patient experience and outcomes after ankle fracture surgery. The cumulative sum of the individual components of the App can be seen to internalise a patient's health locus of control as illustrated in Figure 9.1. An alternative vantage would be that the App promotes or delivers a biopsychosocial model of healthcare [244, 245]. In turn, the biological (physical), psychological and social components of the biopsychosocial model align closely with the BCW and COM-B model [83]. While useful for design and research purposes, this labelling may create barriers for uptake among clinicians. The biopsychosocial model has been criticised as being generic and vague [246] and may be associated with negative branding among HCPs accordingly.

The findings from Chapter 5 and Chapter 7 indicate that while HCPs appreciate the important of psychological and social influences on patients, stronger influences on HCP behaviour included medico-legal considerations and resource availability. Thus, in presenting this new rehabilitation App to HCPs, the primary messaging would be that it provides a series of discrete, useful resources and interventions. The aim of which is to provide standardised advice to patients, improving their experience, whilst at the same time unburdening healthcare resources, rather than attempting to shift towards a healthcare model aligned with one of the above-stated theories.

9.4 Future work

This thesis has outlined the components of a rehabilitation intervention to support patients after ankle fracture surgery. Work is now needed to develop and test this

intervention. Figure 9.2 highlights the steps in the design of a complex intervention [58]. This thesis has established the core elements (in red), with development, feasibility testing, evaluation and implementation to follow. The obvious next step is to design and pilot the proposed rehabilitation App. However, there are other considerations, such as collinearity between pain beliefs and outcomes measures, as discussed below.

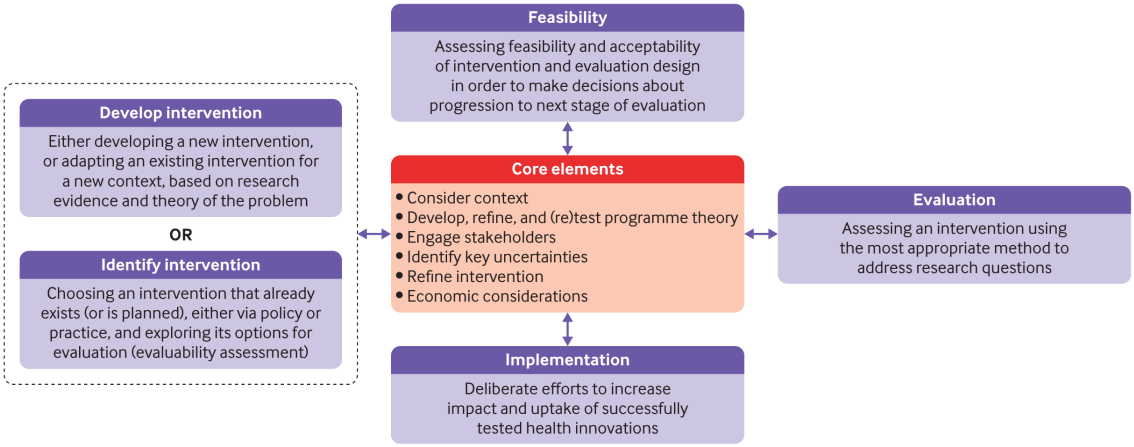


Figure 9.2: MRC Framework for developing and evaluating complex interventions [58]

Pain beliefs

This work adds to the findings from studies in the upper limb that pain beliefs are a potent mediator of patient outcomes after musculoskeletal injury [34, 35]. The question remains to what extent these beliefs are modifiable, or even preventable, if targeted early after injury. There was a consensus throughout this thesis that it would be helpful to identify patients with unhelpful pain beliefs, but the best timing and environment for screening patients remains uncertain. The results from Chapter 6 suggest that the two-week time-point used in Chapter 3 may not be

suitable, a finding supported and discussed in Section 3.4.1, whereby screening too early will decrease sensitivity and specificity and overwhelm healthcare resources. Additionally, once identified, it is unclear if patients would benefit from additional therapies such as Cognitive Behavioural Therapy (CBT) [38, 247] or whether the proposed provision of information, skills and HCP access will help patients overcome their unhelpful beliefs.

There is collinearity between measurement scales, [87] so the exact tool may not be important. However, finding the most acceptable and practical scale for assessing unhelpful pain beliefs in this context needs consideration. Furthermore, the most suitable outcome measure needs to be established for the ankle. Fortunately, Pearson et al. [248] are currently undertaking research to develop a core outcome set for this population. Lastly is the issue of collinearity between measures of unhelpful pain beliefs and PROMs: most PROMs include a pain rating, and even in those that do not, patients with unhelpful pain beliefs may simply be more pessimistic and rank themselves lower on PROMs domains. Interventions to alter pain beliefs may merely encourage patients to score themselves higher on PROMs. So, as found in Chapter 5, and broader range, and potentially more objective measures of outcome may be required.

Health locus of control

Several studies in the BCW literature have focused on intermediary outcomes, such as exercise adherence, rather than functional or quality of life outcomes as measures of effectiveness [46, 56]. There will be debate whether the proposed RAAFT rehabilitation intervention, designed to help internalise patients' health locus of control will need to demonstrate increased scores on the Health Locus of Control Scale (HLCS)

or just demonstrate improved quality of life PROMs. Considering the issues of collinearity discussed above, additional measures of healthcare utilisation and mediation analysis, including HLCS are likely to be useful during evaluation.

The final challenge will be to persuade patients and HCPs to engage with this new style of healthcare. They will need to soften their attachment to conventional models of patient/HCP interaction, shifting the locus of control towards the patient. It is hoped that the systematic and transparent approach used throughout this thesis will attune them to this new paradigm.

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Appendices

APPENDIX A

Chapter 2

A.1 Medline search strategy

Medline Search Strategy

1. exp Lower Extremity/
2. lower extremit*.ti,ab.
3. lower limb*.ti,ab.
4. foot.ti,ab.
5. feet.ti,ab.
6. (hip or hips).ti,ab.
7. (knee or knees).ti,ab.
8. (leg or legs).ti,ab.
9. (thigh or thighs).ti,ab.
10. (ankle or ankles).ti,ab.
11. forefoot.ti,ab.
12. (heel or heels).ti,ab.
13. exp "Bones of Lower Extremity"/
14. femur*.ti,ab.
15. femora*.ti,ab.
16. tibia*.ti,ab.
17. metatarsal*.ti,ab.
18. tarsal*.ti,ab.
19. ((toe or toes) adj3 phalan*).ti,ab.
20. patella*.ti,ab.
21. pelvi*.ti,ab.
22. acetabul*.ti,ab.
23. 1 or 2 or 3 or 4 or 5 or 6 or 7 or
    8 or 9 or 10 or 11 or 12 or 13 or 14 or
    15 or 16 or 17 or 18 or 19 or 20 or 21 or 22
24. exp Fractures, Bone/
25. fractur*.ti,ab.
26. (broke or broken or break*).ti,ab.
27. 24 or 25 or 26
28. 23 and 27
29. exp Rehabilitation/
30. rehab*.ti,ab.
31. exp Physical Therapy Modalities/
32. physiotherap*.ti,ab.
33. physical therap*.ti,ab.
34. exercis*.ti,ab.
35. physical activit*.ti,ab.
36. 29 or 30 or 31 or 32 or 33 or 34 or 35
37. 28 and 36

APPENDIX B

Chapter 3

B.1 Consent form and participant information sheet

Consent

1. I confirm that I have had an opportunity to review the trial information version [TBC] dated [TBC] for the above study.	Select one of: ☐ Check box if you agree
2. I understand that participation is voluntary and I am free to withdraw from the study at any time, without giving a reason and without my legal rights being affected.	Select one of: ☐ Check box if you agree
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the research team, regulatory authorities, the University of Oxford and from participating NHS organisations, where this is relevant to the participation in this study. I give permission for these individuals to have access to my medical records.	Select one of: ☐ Check box if you agree
I understand that copies of my completed questionnaires will be available to the research team at the hospital where I consented to the research.	Select one of: ☐ Check box if you agree
4. I understand and agree that the research team will store my identifiable details in order to contact me in future regarding this study. Identifiable details will be available only to the research team and stored securely.	Select one of: ☐ Check box if you agree
5. I understand that my demographic data will be collected as part of this study	Select one of: ☐ Check box if you agree
6. I understand that information held and managed by National Services Scotland / NHS Digital / NHS Wales Informatics Services / Health & Social Care in Northern Ireland (or equivalent) and other central UK NHS bodies may be used in order to provide information about my health status. To do this, I understand that my CHI number (Scotland) / NHS number (England & Wales) / H&C number (N Ireland), sex, date of birth and postcode will be shared with National Services Scotland/ NHS digital/ NHS Wales Informatics service/ Health & Social Care in Northern Ireland (or equivalent) and understand that the linkage file will be destroyed by National Services Scotland/ NHS digital/ NHS Wales Informatics Services/ Health & Social Care in Northern Ireland (or equivalent) once the linkage is complete.	Select one of: ☐ Check box if you agree
7. I understand how my personal data will be collected stored and processed.	Select one of: ☐ Check box if you agree
8. I agree to take part in the above study.	Select one of: ☐ Check box if you agree
9. I would like to receive occasional updates about the progress of the study.	Select one of: ☐ Yes ☐ No
10. I would like to be sent the results at the end of the study.	Select one of: ☐ Yes ☐ No
11. I agree to be contacted by a researcher from the WAX trial for an interview about my experience of my injury, treatment and taking part in the trial.	Select one of: ☐ Yes ☐ No

Full Name of Patient	
Signature of Patient	
Date of Consent	
  Sorry, consent is NOT valid, you will not be able to proceed 	
Name of Person Taking Consent	
Signature of Person Taking Consent	
Date of Consent	
Version and Date	V3.0 22Oct2020

[Trust Logo]

Weight Bearing in Ankle Fractures

Chief Investigator: Associate Professor Xavier Griffin

PATIENT INFORMATION SHEET

We would like to invite you to take part in a research study investigating rehabilitation following surgery for patients who have broken their ankles. The study is called WAX, which stands for Weight-bearing in Ankle fractures. Before you decide to participate in the WAX study, we would like you to understand why the research is being done and what it would involve for you. Someone from our team will go through the study information with you and answer any questions you might have.

1) WHAT IS THE PURPOSE OF THE WAX STUDY?

The WAX study aims to improve the rehabilitation of adults who have broken their ankle and have been treated with an operation. About one hundred and seventy people sustain this type of injury each day in the UK and many need to have an operation to fix it. After the operation, the advice patients receive about the best way to recover from the injury varies between doctors. Some doctors will allow their patients to start walking (weight-bear) on the injured leg two weeks after their operation, whereas others ask their patients to be careful to not weight-bear until six weeks after their operation. There are some risks and benefits to both ways of treating patients but not enough research has been done so far to work out whether one way is better than the other. With this study we hope to answer this question.

2) WHY HAVE I BEEN INVITED?

You have the type of ankle injury we are interested in investigating, and the doctors in your hospital would like to invite you to take part in the study. We expect approximately 20 hospitals across the country will be taking part in this study and we hope to recruit a total of 436 patients with a similar injury to yours.

3) WHAT WILL HAPPEN IF I DECIDE TO TAKE PART?

If you decide you would like to take part, you will be given a unique study identification number which will be used for all of the information we collect about you. This information will be transferred to, and stored at the University of Oxford, using a confidential, secure, encrypted web-based system.

A member of the team will ask you to complete:

1. A consent form.
2. A contact details form so we can contact you about your recovery.
3. A questionnaire with questions relating to your age, gender, occupation and other general information about you and your injury. We will also ask about any pain you have, your normal activities, feelings, and costs you may have incurred. This should take about 15 minutes.
4. A form to take part in an optional interview about your experience of your injury, treatment and experience of the study.

This study is funded by the National Institute for Health Research (NIHR Research for Patient Benefit PB-PG-1217-20029. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

FUNDED BY NIHR | National Institute for Health Research

After completing these forms we will then allocate you to one of the two treatment groups in the study. The only way to compare the treatments fairly is to create two groups of patients who are the same, by a process called randomisation. No-one can choose your treatment; not you, your family or a doctor or nurse. This ensures that the comparison at the end of the study is fair. When we have groups of patients who are as identical as possible, we can then compare them fairly in terms of how they respond to the treatment.

You will be allocated to one of the two treatments:

Early/Unrestricted weight-bearing:
If you are allocated to the early/ unrestricted weight bearing group you will be allowed to put as much weight through your affected leg as you feel comfortable and without causing pain. You will be informed that while you are allowed to walk on your operated leg, it does not mean you have to, or that you will feel able to immediately. You can continue to use the walking aids provided to you or discard them if you feel confident to walk without them at any point during the following 4 weeks.

Delayed/restricted weight-bearing:
If you are allocated to the delayed/ restricted weight bearing group you will be instructed to avoid putting any weight through your operated leg as you have already been doing. You will be asked to continue to use the walking aids provided to you.

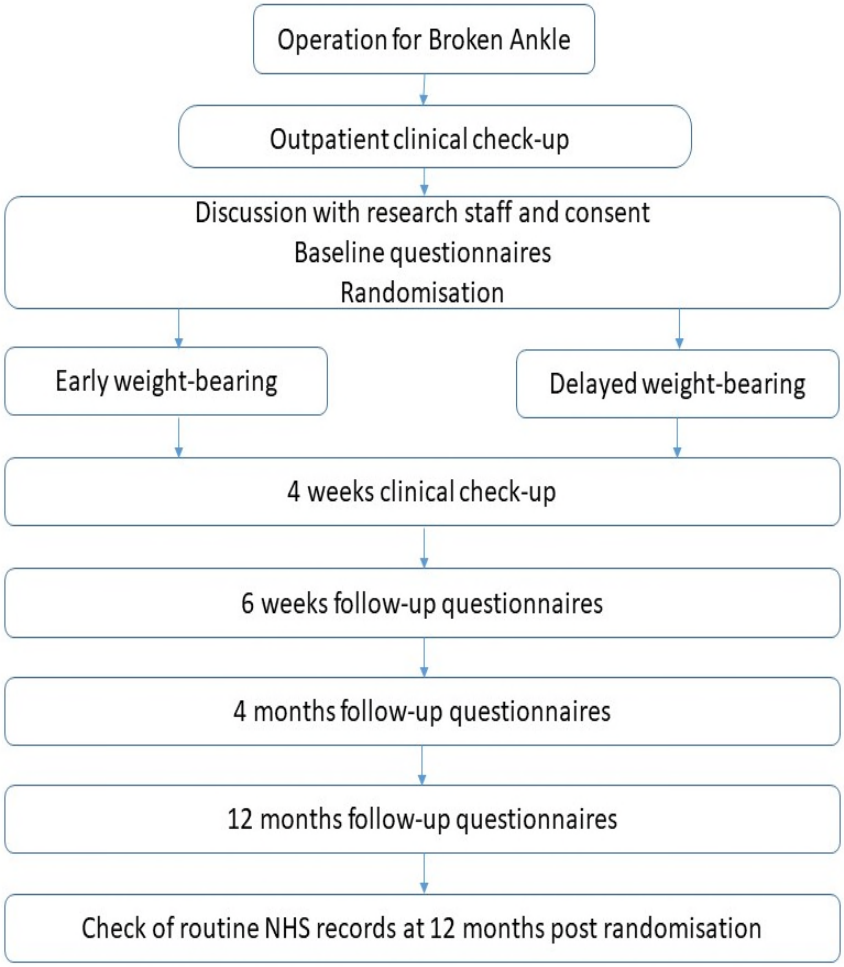
As part of your weight-bearing instruction, you will be given a rehabilitation booklet, this will give you some information on what to expect as you recover from your ankle fracture and advice on exercises you can do. Other than this instruction, you will be treated with the usual advice and methods by your doctor, who may refer you to physiotherapy.

During your initial recovery, we will have brief contact with you once a week for the first four weeks of the study to ask whether you have started to put weight through your ankle. Where possible we will do this follow up by text message or e-mail containing a unique hyperlink to a question or if this is not convenient we can phone you. Thereafter, we will follow you up through an electronic or postal questionnaire on three further occasions (Week 6, Month 4 and Month 12 after you are randomised into the study). We will ask questions about pain, activities, feelings, hospital attendances, and costs that you may have incurred in relation to this injury (i.e. days absent from work etc). The questionnaire will take approximately 15 minutes to complete. We may also contact you to clarify any information that you provide in these questionnaires if we are unsure of something. We may gather routine NHS information collected about you to see what the long-term outcomes are following your injury.

It is important that you try and complete the questionnaires as soon as possible after they are received. If a questionnaire is not completed, we will send you a reminder after a few days (by phone, text or e-mail based on your preference). If you would like a postal questionnaire a pre-paid envelope will be included for its return.

The study results will be published at the end of the study in medical journals and medical conferences. All results will be de-identified so no one can identify you from the results.

The flowchart below shows all the steps of your journey through the research study:



Flowchart: WAX Schedule

4) WILL THERE BE EXTRA TESTS?

No, there are no additional tests, the only additional thing we would ask you to do is to complete our questionnaires and offer you the choice to participate in an interview about your experience of the study.

5) ARE THERE ANY RISKS IN TAKING PART?

The study compares two treatments commonly used in the NHS. Each of these rehabilitation methods has potential advantages and disadvantages. The risks mentioned here are the same for all patients regardless of whether they are part of the WAX study.

Early weight-bearing, from two weeks after the operation, may reduce the inconvenience of having to use crutches and reduce immobility, length of hospital stay, and might lead to improved ability to walk, get back to work and what you enjoy. However, there is a small chance that putting weight through the ankle at an early stage may lead to the bone moving slightly or the skin around the injury and the incision made for the operation being damaged or causing infection, which might mean you need further treatment, such as an operation.

Delayed weight-bearing, for up to six weeks after the operation, may reduce the risk of the bones slipping out of place, the skin around the injury being damaged and as such a need for further operations. However it will be more inconvenient and it could lead to increased time off work and other activities. As you will not be using your calf muscle as much, you might lose some muscle mass and this means it might take longer after the initial 6 weeks to return to your usual strength and activities. Finally, although highly unlikely, there may be a slightly increased chance of getting a blood clot in your calf or lung, which could require additional blood thinning medication.

6) DO I HAVE TO TAKE PART?

It is entirely your decision as to whether or not you wish to take part. Your decision will not affect the level of care you will receive. Throughout the study you are still free to withdraw at any time and without giving a reason. Should you wish to withdraw, simply contact the study office on <insert telephone number> or email wax@ndorms.ox.ac.uk and a staff member will guide you through the withdrawal process. Alternatively, you may wish to contact your local research lead <<insert name of local researcher>> on <<insert telephone number>> who will assist you.

A decision to withdraw at any time or a decision not to take part will not affect the standard of care you receive. However, we will not be able to remove the data we have already collected prior to your decision to withdraw.

7) WHO IS INVOLVED WITH THE STUDY?

The study is funded by the National Institute of Health Research (NIHR). The University of Oxford is the lead centre for the study, and the day to day running of the study is being completed by Oxford Trauma & Emergency Care, a research group of the Nuffield Department of Rheumatology, Orthopaedics and Musculoskeletal Sciences (NDORMS).
The research team is qualified to do this study because they have all the specialties and skills needed. The team has a lot of experience in caring for patients with traumatic injuries and is active in health research. Patient representatives have also provided valuable insight into the development of this study.

Some of the research being undertaken will also contribute to the fulfilment of a doctoral thesis. However no identifiable data will be included in this educational research project.

8) WHAT WILL HAPPEN TO MY PERSONAL DATA?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest'. The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

The University of Oxford is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you, such as your contact details, for 12 months after the study has finished. We will store the de-identified research data and research documents with personal information, such as consent forms, securely at the University of Oxford for at least three years after the end of the study.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the

study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Your treating hospital will collect information from you and your medical records for this research study in accordance with our instructions. Your treating hospital will keep identifiable information about you from this study for a minimum of 12 months after the study has finished.

Your treating hospital will use your name, NHS/CHI/H&C number and contact details to contact you about the research study, to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Oxford and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your treating hospital will pass these details to the University of Oxford along with the information collected from you and/or your medical records. The only people in the University of Oxford who will have access to information that identifies you will be people who need to contact you to enable your follow-up in this study, or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number (or CHI number in Scotland/H&C number in Northern Ireland) or contact details.

Your data from the questionnaires will be sent to your trial team at the site where you were consented for the trial, in this way your doctor will have full oversight of the data in relation to your participation in the trial.

We will share limited personal information (e.g. your NHS number, gender, date of birth and postcode) with appropriate organisations (including, but not limited to, NHS Digital, Office of National Statistics, Clinical Practice Research Datalink) in order to link your trial data to specific records related to the research held in other databases. This will allow bodies such as NHS Digital to provide us with a dataset containing your data that will only identify you by your trial ID. Once the linkage is complete the linkage file will be destroyed. We will use the records from these databases to get information about any further treatments you have needed for your ankle, any complications you have suffered, to find out about other medical conditions so that we can take this into account when analysing the results of the study, and to look at the cost to the NHS. All information that is collected during the course of the research will be used and stored in accordance with the most up to date data protection legislation.

When you agree to take part in a research study, the de-identified information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information at www.waxstudy.org

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by South Central - Oxford A Research Ethics Committee on 1st December 2019.

The lawful basis for the processing of your personal data is governed by the General Data Protection Regulation (GDPR) Articles 6 & 9. The University of Oxford will not transfer your personal data to any third countries or international organisations.

9) Contacts for further information

If, at any time, you would like further information about this study you may contact the Trial Manager by telephoning <insert telephone number>. Or you can contact your local research lead <<insert name of local researcher>> telephone number <<insert telephone number>> or Associate Professor Xavier Griffin, who is the overall lead of this study on 01865 223116. For our full privacy notice you can also refer to the study website www.waxstudy.org

10) WHAT IF THERE IS A PROBLEM?

If you wish to discuss any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Xavier Griffin who is the overall study lead on +44 1865 223116 or at xavier.griffin@ndorms.ox.ac.uk, or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or the head of CTRG, email ctrg@admin.ox.ac.uk.

The University of Oxford is the Sponsor for this study and has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity covers any other clinical treatment with which you are provided.
For independent advice, ask your treating hospital for the contact details for the <<Patient Advice Liaison Service (PALS) or Patient Advice and Support Service (PASS)>>. <<PALS or PASS>> is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. <<PALS or PASS>> is unable to provide information about this research study. If you wish to contact the <<PALS or PASS>> team please contact <insert relevant NHS site phone number and email from the PALS website http://www.ouh.nhs.uk/patient-guide/pals.aspx or https://www.cas.org.uk/pass>.

B.2 Outcome measurements

Outcomes measurement licensing and registration

Outcome Measure	Version	Source and registration
OMAS	1984	Omas et al. [51] (Registration not required)
EQ-5D-5L	2020	www.euroqol.org (Registered (No. 32785), 2019)
PSEQ-2	2014	Bot et al. [33] (Registration not required)
TSK-11	2005	Woby et al. [102] (Registration not required)
mCCI	2015	Johnston et al. [101] (Registration not required)

Parameter	Degree	Score
I. Pain	None	25
	While walking on uneven surface	20
	While walking on even surface outdoors	10
	While walking indoors	5
	Constant and severe	0
II. Stiffness	None	10
	Stiffness	0
III. Swelling	None	10
	Only evenings	5
	Constant	0
IV. Stair-climbing	No problems	10
	Impaired	5
	Impossible	0
V. Running	Possible	5
	Impossible	0
VI. Jumping	Possible	5
	Impossible	0
VII. Squatting	No problems	5
	Impossible	0
VIII. Supports	None	10
	Taping, wrapping	5
	Stick or crutch	0
IX. Work, activities of daily life	Same as before injury	20
	Loss of tempo	15
	Change to a simpler job/ part-time work	10
	Severely impaired work capacity	0

Olerud and Molander Ankle Score (OMAS)

UK English Eq5d5l Redcap Self Complete Web

Please click the ONE box that best describes your health TODAY.

Please click the ONE box that best describes your health BEFORE your injury.

MOBILITY

◯ I have no problems in walking about
◯ I have slight problems in walking about
◯ I have moderate problems in walking about
◯ I have severe problems in walking about
◯ I am unable to walk about

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Please click the ONE box that best describes your health TODAY.

Please click the ONE box that best describes your health BEFORE your injury.

SELF-CARE

◯ I have no problems washing or dressing myself
◯ I have slight problems washing or dressing myself
◯ I have moderate problems washing or dressing myself
◯ I have severe problems washing or dressing myself
◯ I am unable to wash or dress myself

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Please click the ONE box that best describes your health TODAY.

Please click the ONE box that best describes your health BEFORE your injury.

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

◯ I have no problems doing my usual activities
◯ I have slight problems doing my usual activities
◯ I have moderate problems doing my usual activities
◯ I have severe problems doing my usual activities
◯ I am unable to do my usual activities

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Please click the ONE box that best describes your health TODAY.

Please click the ONE box that best describes your health BEFORE your injury.

PAIN / DISCOMFORT

◯ I have no pain or discomfort
◯ I have slight pain or discomfort
◯ I have moderate pain or discomfort
◯ I have severe pain or discomfort
◯ I have extreme pain or discomfort

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Please click the ONE box that best describes your health TODAY.

Please click the ONE box that best describes your health BEFORE your injury.

ANXIETY / DEPRESSION

◯ I am not anxious or depressed
◯ I am slightly anxious or depressed
◯ I am moderately anxious or depressed
◯ I am severely anxious or depressed
◯ I am extremely anxious or depressed

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EuroQol 5 Dimensions 5L (EQ-5D-5L)

We would like to know how good or bad your health is TODAY.

This scale is numbered from 0 to 100.

100 means the best health you can imagine.
0 means the worst health you can imagine.
Please click on the scale to indicate how your health is TODAY.

0 - The worst health you can imagine 50 100 - The best health you can imagine

(Place a mark on the scale above)

We would like to know how good or bad your health was BEFORE your injury.

This scale is numbered from 0 to 100.

100 means the best health you can imagine.
0 means the worst health you can imagine.
Please click on the scale to indicate how your health is was BEFORE your injury.

0 - The worst health you can imagine 50 100 - The best health you can imagine

(Place a mark on the scale above)

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EQ visual analogue scale (EQ VAS)

Hello [contact_details_arm_1][addressing_patient], please rate how confident you are that you can do the following things at present, despite the pain. To indicate your answer select one of the numbers on the scale under each item, where 0 = not at all confident and 6 = completely confident.

Remember, this question is not asking whether or not you have been doing these things, but rather how confident you are that you can do them at present, despite the pain.

		0	1	2	3	4	5	6
1)	1. I can still accomplish most of my goals in life, despite the pain.	○	○	○	○	○	○	○
2)	2. I can live a normal lifestyle, despite the pain.	○	○	○	○	○	○	○

Using likart scale for consistency of display over devices

Pain self-efficacy questionnaire-2 (PSEQ-2)

This is a list of phrases with other patients have used to express how they view their condition. Please select the number that best describes how you feel about each statement.

1. I'm afraid I might injure myself if I exercise.

◯ 1 Strongly disagree ◯ 2 Somewhat Disagree ◯ 3 Somewhat Agree ◯ Strongly Agree

2. If I were to try to overcome it, my pain would increase.

◯ 1 Strongly disagree ◯ 2 Somewhat Disagree ◯ 3 Somewhat Agree ◯ Strongly Agree

3. My body is telling me I have something dangerously wrong.

◯ 1 Strongly disagree ◯ 2 Somewhat Disagree ◯ 3 Somewhat Agree ◯ Strongly Agree

4. People aren't taking my medical condition seriously enough.

◯ 1 Strongly disagree ◯ 2 Somewhat Disagree ◯ 3 Somewhat Agree ◯ Strongly Agree

5. My accident/problem has put my body at risk for the rest of my life.

◯ 1 Strongly disagree ◯ 2 Somewhat Disagree ◯ 3 Somewhat Agree ◯ Strongly Agree

6. Pain always means I have injured my body.

◯ 1 Strongly disagree ◯ 2 Somewhat Disagree ◯ 3 Somewhat Agree ◯ Strongly Agree

7. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening.

◯ 1 Strongly disagree ◯ 2 Somewhat Disagree ◯ 3 Somewhat Agree ◯ Strongly Agree

8. I wouldn't have this much pain if there wasn't something potentially dangerous going on in my body.

◯ 1 Strongly disagree ◯ 2 Somewhat Disagree ◯ 3 Somewhat Agree ◯ Strongly Agree

9. Pain lets me know when to stop exercising so that I don't injure myself.

◯ 1 Strongly disagree ◯ 2 Somewhat Disagree ◯ 3 Somewhat Agree ◯ Strongly Agree

10. I can't do all the things normal people do because it's too easy for me to get injured.

◯ 1 Strongly disagree ◯ 2 Somewhat Disagree ◯ 3 Somewhat Agree ◯ Strongly Agree

11. No one should have to exercise when he/she is in pain.

◯ 1 Strongly disagree ◯ 2 Somewhat Disagree ◯ 3 Somewhat Agree ◯ Strongly Agree

Tampa scale of kinesiophobia-11 (TSK-11)

1) **Comorbidity (Choose all that are present)**

Assigned weights for each condition the patient has ( )

- **Ischemic heart disease (1)**
- **Congestive heart failure (1)**
- **Peripheral vascular disease (1)**
- **Cerebrovascular disease (1)**
- **Dementia (1)**
- **Chronic obstructive pulmonary disease (1)**
- **Chronic liver disease (1)**
- **Connective tissue disease (1)**
- **Diabetes (2)**
- **Non-haematological malignancy (2)**
- **Haematological malignancy (2)**

2) **Age**

* must provide value

Modified Charlson comorbidity index (mCCI)

APPENDIX C

Chapter 4

C.1 Patient interview PIS

Interview Information Sheet

A study about weight-bearing in ankle fractures

Background

The WAX study aims to find out more about when is best to weight-bear after an ankle fracture. Previously you agreed that we could contact you about participating in an interview. We would now like to invite you to take part in an interview with a member of our research team. This is so that we can hear about your experience of the study, your injury and its treatment.

Even if you chose not to take part in the WAX study, we would still like to know your thoughts and feelings about the decision and your treatment. We are keen to hear the views from a large number of patients who were approached to take part.

This document explains what taking part in the interview would involve. *Please take time to read this information and discuss it with others if you wish.*

What happens if I say yes?

Interviews may be in-person, or on the telephone or videocall. If you decide to take part in an interview, you will be asked to sign a consent form or provide spoken consent (if using the telephone).

You will then be invited to discuss your experience in an open and relaxed way with an experienced interviewer. The interview will normally take about 30 minutes. The interviewer will contact you to arrange a convenient time. The interview will be audio recorded so that the researcher can remember what you say.

The interview will focus on how you felt about the WAX study, and what it has been like for you since the injury. The researcher may ask to interview you up to two times over the course of the study.

Do I have to take part?

No. It is entirely your decision whether to take part or not. You do not have to decide straight away. You are free to withdraw your consent at any time, without giving a reason. This will not affect the standard of care you receive.

Are there any benefits to taking part?

There are no specific benefits for taking part in an interview. Some people may feel pleased to have shared their experience with a researcher and to have contributed to a broader understanding of treating this injury.

Are there any risks to taking part?

For some people talking about their experience can bring back memories and feelings. If this should happen the researcher will provide support, offer you a break or to continue the interview at another time. You can choose not to answer any questions and you can stop the interview at any point.

Will my information be kept confidential?

The University of Oxford is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Oxford will keep identifiable information about you for 12 months after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Your local hospital will collect your name and contact details and will pass these details to The University of Oxford. The only people in the University of Oxford who will have access to information that identifies you will be people who need to contact you for an interview or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

All of your information will be stored securely at the University of Oxford. A professional transcriber will type the interviews up with your personal details removed so that you cannot be identified. Quotes from the interviews may be used in the reporting of this study. Any quotes will be anonymised so it will not be possible to identify you. Copies

of the transcripts will be stored at the University of Oxford for a maximum of five years and then will be destroyed. Audio recordings will be deleted at the end of the study.

People from the University of Oxford and Regulatory Authorities may have access to your data so they can ensure the study is being carried out according to regulations.

Anonymised data may be provided to researchers running other research studies in this organisation and/or other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

What will happen to the results of the study?

When we have analysed the interviews, reports will be published in academic journals and presented at conferences. We will not identify anyone by their name; any study data to be made publicly available will be de-identified.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by South Central - Oxford A Research Ethics Committee on 1st December 2019.

What happens if something goes wrong?

The University of Oxford is the Sponsor for the study and has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial. If you wish to discuss any aspect of the way in which you have been approached or treated during the course of this study, you should contact

Associate Professor Xavier Griffin who is the overall lead of this trial on 01865 223114; or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or email ctrg@admin.ox.ac.uk. NHS indemnity covers any other treatment with which you are provided.

For independent advice, ask your treating hospital for the contact details for the Patient Advice Liaison Service (PALS). This is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. However, PALS cannot provide information about this research study.

Further Information and Contact details

If you have any questions about the interviews please contact the lead researcher*: Mr Christopher Bretherton* by telephone on <insert contact details> or email at christopher.bretherton@ndorms.ox.ac.uk.

Some of the research being undertaken will also contribute to the fulfilment of a doctoral thesis. No identifiable data will be included in this educational research project.

You may also contact the WAX team via email at wax@ndorms.ox.ac.uk or telephone <insert contact details>.

Thank you for reading this information and considering taking part in our study.

Interview Information Sheet

A study about weight-bearing in ankle fractures

Background

The WAX study aims to find out more about when is best to weight-bear after an ankle fracture. Previously you agreed that we could contact you about participating in an interview. We would now like to invite you to take part in an interview with a member of our research team. This is so that we can hear about your experience of the study, your injury and its treatment.

We are particularly interested in hearing the views of Non-English Speakers. For this reason, we asked you to provide the details of an English-speaking relative, carer or friend, to whom we have also sent this information sheet. We hope this person will be able to help you understand the information and make a decision whether to take part.

Even if you chose not to take part in the WAX study, we would still like to know your thoughts and feelings about the decision and your treatment. We are keen to hear the views from a large number of patients who were approached to take part.

This document explains what taking part in the interview would involve. *Please take time to read this information and discuss it with others if you wish.*

What happens if I say yes?

Interviews may be in-person, or on the telephone or videocall. If you decide to take part in an interview, you will be asked to sign a consent form or provide spoken consent (if using the telephone). We will either ask your English-speaking relative/ carer/ friend to be present during the interview, or we will call you via a professional translator, depending on your preference.

You will then be invited to discuss your experience in an open and relaxed way with an experienced interviewer. The interview will normally take about 30 minutes. The interviewer will contact you to arrange a convenient time. The interview will be audio recorded so that the researcher can remember what you say.

The interview will focus on how you felt about the WAX study, and what it has been like for you since the injury. The researcher may ask to interview you up to two times over the course of the study.

Do I have to take part?

No. It is entirely your decision whether to take part or not. You do not have to decide straight away. You are free to withdraw your consent at any time, without giving a reason. This will not affect the standard of care you receive.

Are there any benefits to taking part?

There are no specific benefits for taking part in an interview. Some people may feel pleased to have shared their experience with a researcher and to have contributed to a broader understanding of treating this injury.

We understand that participating in the interview as a non-English-speaker may pose additional challenges. For this reason, we would like to offer you and your English-speaking relative/ carer/ friend a £10 Love to shop voucher to say thank you.

Are there any risks to taking part?

For some people talking about their experience can bring back memories and feelings. If this should happen the researcher will provide support, offer you a break or to continue the interview at another time. You can choose not to answer any questions and you can stop the interview at any point.

Will my information be kept confidential?

The University of Oxford is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Oxford will keep identifiable information about you for 12 months after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Your local hospital will collect your name and contact details and will pass these details to The University of Oxford. The only people in the University of Oxford who will have

access to information that identifies you will be people who need to contact you for an interview or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

All of your information will be stored securely at the University of Oxford. A professional transcriber will type the interviews up with your personal details removed so that you cannot be identified. Quotes from the interviews may be used in the reporting of this study. Any quotes will be anonymised so it will not be possible to identify you. Copies of the transcripts will be stored at the University of Oxford for a maximum of five years and then will be destroyed. Audio recordings will be deleted at the end of the study.

People from the University of Oxford and Regulatory Authorities may have access to your data so they can ensure the study is being carried out according to regulations.

Anonymised data may be provided to researchers running other research studies in this organisation and/or other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

What will happen to the results of the study?

When we have analysed the interviews, reports will be published in academic journals and presented at conferences. We will not identify anyone by their name; any study data to be made publicly available will be de-identified.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been

reviewed and given a favourable opinion by South Central - Oxford A Research Ethics Committee on 1st December 2019.

What happens if something goes wrong?

The University of Oxford is the Sponsor for the study and has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial. If you wish to discuss any aspect of the way in which you have been approached or treated during the course of this study, you should contact Associate Professor Xavier Griffin who is the overall lead of this trial on 01865 223114; or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or email ctrg@admin.ox.ac.uk. NHS indemnity covers any other treatment with which you are provided.

For independent advice, ask your treating hospital for the contact details for the Patient Advice Liaison Service (PALS). This is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. However, PALS cannot provide information about this research study.

Further Information and Contact details

If you have any questions about the interviews please contact the lead researcher*: Mr Christopher Bretherton* by telephone on <insert contact details> or email at christopher.bretherton@ndorms.ox.ac.uk.

Some of the research being undertaken will also contribute to the fulfilment of a doctoral thesis. No identifiable data will be included in this educational research project.

You may also contact the WAX team via email at wax@ndorms.ox.ac.uk or telephone <insert contact details>.

Thank you for reading this information and considering taking part in our study.

C.2 Patient interview consent form

INTERVIEW CONSENT FORM

WAX- Weight-bearing in ankle fractures
Chief Investigator: Mr Xavier Griffin

A *multi-centre prospective randomised* non-inferiority clinical trial of weight-bearing following operatively treated ankle fracture.

Screening ID: WX- ☐☐☐ ☐☐☐☐

Interview ID: ☐☐☐

Please initial the box if you agree with the following statements

1.	I confirm that I have read and understood the Information Sheet dated DDMonYYYY version XX. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2.	I understand that participation is voluntary and I am free to withdraw from the study at any time, without giving a reason, and without my care or legal rights being affected.	☐
3.	I consent to the research team holding my contact details so that they can contact me about the study. I understand these details will be held securely and destroyed at the end of the study.	☐
4.	I give permission for anonymised written quotations from the interview to be used in reports, publications and presentations related to the trial.	☐
5.	I give permission for the interview to be audio recorded.	☐
6.	I understand that data collected during the study may be looked at by individuals from the research team at the University of Oxford, regulatory authorities and from participating NHS organisations, where it is relevant to me taking part in this research. I give permission for these individuals to have access to my records.	☐
7.	I agree to take part in an interview.	☐
8.	I understand that the information collected about me may be used in an anonymous way to support other research in the future. It will not be possible for me to be identified by it.	☐

Your Signature:	Your Full Name:

Date of Consent: D D / M O N / Y Y Y Y

Name of English-speaking relative, carer, friend or interpreter (if applicable):	Signature of English-speaking relative, carer, friend or interpreter (if applicable):

Date of Consent: D D / M O N / Y Y Y Y

Name of Person Taking Consent:	Signature of Person Taking Consent:

Date of Taking Consent: D D / M O N / Y Y Y Y

To be completed for telephone interviews:

Name of Person Verifying Consent:	Signature of Person Verifying Consent:

Date of Taking Consent: D D / M O N / Y Y Y Y

Date of Signature:

One copy to be kept in the investigator site file, one copy to be given to the participant and one copy to be kept in the participant's medical notes (medical notes not applicable for staff interviewees)

C.3 Patient interview schedule

Patient Interviews

Semi Structured Interview Guide

A study about weight-bearing in ankle fractures

Introduction

I'm Chris from the University of Oxford. I'm a trauma surgeon and part of the WAX trial team.

You were asked to be part of the WAX study that is researching two different forms of rehabilitation after surgery for an ankle fracture – trying to find out **when** people should start walking after surgery.
We're also interviewing people about their experiences, especially to find out about HOW we can help people to start walking after their ankle fracture and what is was like to be part of the research.

You are free to end the interview at any time. I'd like to audio-record the interview and then I'll type it up and remove your name and details from the written version.

Are you still interested in taking part in the project? *[Await confirmation].*

Great, Now I'll go through the consent form.

Do you have any questions and are you still willing to take part? [*Await confirmation]*

Great lets start. And just once again thanks for taking part and a reminder that you can skip any questions that you don't feel like answering.

- Explore barriers, facilitators and possible improvements throughout

The first section is about your Experience of getting back to walking

- What has it been like getting back to putting weight on your injured ankle since your injury?
  (Prompts: When, How much weight, how long, what are the consequences)
  Pain. What stopped you walking straight away? Do you get pain when you WB? How do you respond to that?
- What has helped you start weight-bearing/ in your recovery?
  (Prompts: mobility aids, layout of house, family, strength/fitness, physio, encouragement, bedpan)
  Did you get a choice of cast vs boot? How is learning to use the crutches/ zimmer frame?
- Have you experienced any difficulty/ What has made it difficult?
  (Prompts: pain, swelling, other injuries, strain on the rest of the body, concerns re ankle strength, frailty, strength/fitness)
- In the first 2 weeks before the trial, what else would you like to know?
- How do you feel you will progress in the future? Are you ok, do you think you'll be ok?
  (Prompts: concerns, practicalities, fear, confidence)
- What activities do you hope to get back to? Driving? How do you monitor/ judge your progress? Work?

Next section Is about the weightbearing instructions and about the information you given

- What do you remember about what the research team told you regarding putting weight on your injured leg and about the instructions you were given? Did you see the XR's?
- What do you think and feel about that information (information you were given)?
- Did it make sense to you?
- Were you worried about anything?
- What do you think about the information now you have had a go at putting weight on your injured leg?
- Have you had any conflicting advice in the past 8 weeks from HCP's?
- Is there anything you would like to have known more about at that time or that you might tell someone else that has recently injured their ankle? (Is there anything that would have helped you)
- How did you progress exercises?
- Did you get the paper exercise booklet, could that have been better? What if you hadn't had it (most don't).
- Would a phone call from a physio, or the ability to message one on the internet – did you ever feel that having to wait 4 weeks till your next appointment was hindering your progress? Or a peer support forum or app?

Next section – talking about being part of the trial (Trial Experience)

- What was it like being asked to be in the WAX study?
  (Prompts: Reasons for taking part: altruism, personal benefit, medical science)
- Did you have any thoughts about whether you would prefer to put weightbear on your leg earlier or later on?
- What do you think now?
- What were your thoughts and feelings following the discussion with the surgeon/research staff?
- (Prompts: Who did you talk to? What did they say? What did you think? What did you feel?)
- What do you feel helped you make the decision to take part?
  (Prompts: information, equipoise, degree of importance, trust in surgeon/staff)
- What do you feel would have stopped you taking part? Anything you weren't so sure about? We would like to understand any reasons, you don't have to tell us (Prompts: information, burden, lack of continuity of surgical staff)

Last few questions

- What was it like filling out the questionnaires? (Prompts: what helped? what was difficult? burden)
  What about the first questionnaires you did in the clinic when you started the study? Time? pain questions?
- Did you think anything was missing from the questionnaires? A part of your life that's been affected that we haven't really captured…
- And we don't do any measurements or strength tests? Do you think that is necessary? I supposed when you see the results and you are trying to decide – what difference between the treatments would you be most interested in?
- Is there something else you would like us to know or you'd like to discuss?

Wrap up / debrief

APPENDIX D

Chapter 5

D.1 Staff interview PIS

Staff Interview Information Sheet

A study about weight-bearing in ankle fractures

Background

You are invited to take part in an interview as part of the WAX study. We would like to speak to staff involved in the study to help us to identify potential barriers and facilitators to running this study. Before you decide whether or not to take part, we would like you to understand why we are doing these interviews and what it would involve. *Please take time to read this information and discuss it with others if you wish.*

What happens if I say yes?

If you decide to take part in an interview, you will be asked to sign a consent form or provide spoken consent over the telephone.

You will then be invited to discuss your experience in an open and relaxed way with an experienced interviewer. The interview will normally take 30 to 60 minutes, and may be face-to-face or on the telephone or videocall. The interviewer will contact you to arrange a convenient time. You may be interviewed on your own or, if you and your colleagues prefer, in a group. The interview will be audio recorded so that the researcher can remember what you say.

The interview will focus on things that help or hinder recruitment to the WAX study, the consent process, support for research within your team, any treatment preferences that you may have and your experience of treating patients with ankle fractures.

Do I have to take part?

No. It is entirely your decision whether to take part or not. You do not have to decide straight away. You are free to withdraw your consent at any time, without giving a reason. If you do decide to take part, you can choose not to answer any questions and you can stop the interview at any point.

Are there any benefits to taking part?

You are not likely to benefit from taking part in this interview. However, staff can value the opportunity to talk about their work, contribute to existing knowledge and provide guidance for conducting trials.

Are there any risks to taking part?

Interviews are confidential, however if you take part in group interviews there is a risk that other participants may discuss details of the interview.

Will my information be kept confidential?

The University of Oxford is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Oxford will keep identifiable information about you for 12 months after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Your local hospital will collect your name and contact details and will pass these details to The University of Oxford. The only people in the University of Oxford who will have access to information that identifies you will be people who need to contact you for an interview or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

All of your information will be stored securely at the University of Oxford. Your answers to the questions will be audio recorded, and later typed into a computer with all the personal details removed. Quotes from the interviews may be used in the reporting of this study. Any quotes will be anonymised so it will not be possible to identify you. Copies of the transcripts will be stored at the University of Oxford for a maximum of five years and then will be destroyed. Audio recordings will be deleted at the end of the study.

People from the University of Oxford and Regulatory Authorities may have access to your data so they can ensure the study is being carried out according to regulations.

Anonymised data may be provided to researchers running other research studies in this organisation and/or other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you. It will not be used to make decisions about future services available to you, such as insurance.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

What will happen to the results of the study?

When we have analysed the data from all the interviews, reports will be published in academic journals and presented at conferences. We will not identify anyone by their name; any study data to be made publicly available will be de-identified.

Who has reviewed this study?

This study has been reviewed and given a favourable opinion by South Central – Oxford A Research Ethics Committee.

What if there is a problem?

The University of Oxford is the Sponsor for this study. If you wish to discuss any aspect of the way in which you have been approached or treated during the course of this study, you should contact Associate Professor Xavier Griffin who is the overall study lead on 01865 223114 or at xavier.griffin@ndorms.ox.ac.uk; or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or email ctrg@admin.ox.ac.uk.

Further Information and Contact details

If you have any questions about the interviews please contact the lead researcher*: Christopher Bretherton* by telephone on <insert contact details> or email at christopher.bretherton@ndorms.ox.ac.uk

Some of the research being undertaken will also contribute to the fulfilment of a doctoral thesis. No identifiable data will be included in this educational research project.

You may also contact the WAX team via email at wax@ndorms.ox.ac.uk or telephone <insert contact detail>

Thank you for reading this information and considering taking part in our study.

D.2 Staff interview consent form

STAFF INTERVIEW CONSENT FORM

A study about weight-bearing in ankle fractures

Chief Investigator: Mr Xavier Griffin

A *multi-centre prospective randomised* non-inferiority clinical trial of weight-bearing following operatively treated ankle fracture.

Interview ID: ☐☐☐

Please initial the box if you agree with the following statements

1.	I confirm that I have read and understood the Information Sheet dated DDMonYYYY version XX. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily	☐
2.	I understand that participation is voluntary and I am free to withdraw from the study at any time, without giving a reason, and my legal rights being affected.	☐
3.	I consent to the research team holding my contact details so that they can contact me about the study. I understand these details will be held securely and destroyed at the end of the study.	☐
4.	I give permission for anonymised written quotations from the interview to be used in reports, publications and presentations related to the trial.	☐
5.	I give permission for the interview to be audio recorded.	☐
6.	I understand that data collected during the study may be looked at by individuals from the research team, regulatory authorities the University of Oxford, and from participating NHS organisations, where it is relevant to me taking part in this research.	☐
7.	I agree to take part in an interview	☐
8.	I understand that the information collected about me may be used in an anonymous way to support other research in the future. It will not be possible for me to be identified by it.	☐

Name of Participant	Your Signature:

Date of Consent:

D D / M O N / Y Y Y Y

Name of Person Taking Consent:	Signature of Person Taking Consent:

Date of Taking Consent:

D D / M O N / Y Y Y Y

To be completed for telephone interviews:

Name of Person Verifying Consent:	Signature of Person Verifying Consent:

Date of Taking Consent:

D D / M O N / Y Y Y Y

One copy to be kept in the investigator site file, one copy to be given to the parent/guardian and one copy to be kept in the patient's medical notes

D.3 Staff interview schedule

Staff Interviews

Semi Structured Interview Guide

A study about weight-bearing in ankle fractures

Introduction

I'm Chris from the University of Oxford. I'm a trauma surgery registrar and part of the WAX trial team.

The WAX study is trying to find out **when** people should start walking after surgery.
We're also interviewing people about their experiences, especially to find out about HOW we can help people to start walking after their ankle fracture.
We are looking at how we might be able to influence the behaviours of patients and encourage them to WB, do their exercises and progress their recovery – but also if there are any helpful behaviours to encourage amoung healthcare professionals – so questions may flip between both and seem a bit strange at times.

You are free to end the interview at any time. I'd like to audio-record the interview and then I'll type it up and remove your name and details from the written version.

Are you still interested in taking part in the project? *[Await confirmation].*

Great, Now I'll go through the consent form.

Do you have any questions and are you still willing to take part? [*Await confirmation]*

Great let's start. And just once again thanks for taking part and a reminder that you can skip any questions that you don't feel like answering.

The first section is about your usual weight-bearing practice:

- What are you/ your departments usual weight bearing after an Ankle ORIF?
- What factors influence decisions about weight-bearing?
- Do you find patients have a treatment preference?
- What are your usual instructions – NWB – do you let them WB for balance?
- What about when they can WB?
- Do patients understand the plan for weight bearing? Is there anything you do to help them remember to do their exercises?
- What do you think influences patients' ability to start/ progress weight-bearing?
- Are there any aspects of starting WB patients struggle with?
- How do you approach encouraging patients to weight-bear or perform exercises if they are in pain? Do you think pain when WB is common?
- What warning signs would make you tell a patient to stop WB/ exercises?
- How do you approach a patient with tingling or numbness around their scar – when do you worry/ further investigate them?
- When do you let them get the wound wet? Bath or massage it?
- Why do we worry about weight-bearing on ankle fractures vs hip and knee replacements where we get them straight up the next day?
- In the same way, many patients are worried about damaging their ankle/ the fixation failing – can you feel confident about reassuring them?
- Are there any particular areas patients are confused about or ask lots of questions about?
- Do you have any key anxieties when helping patient's progress their Weight-bearing or recovery?

Surgeon questions

- Is there anything you do, or you tell your trainees to make you feel – yes this is stable enough to resists the forces of weight-bearing?
- What about partial fixation in bad skin or do you increase fixation to allow EWB?
- Do you have any concerns that physios will push patients too hard if you allow them to WB early?
- How can we encourage surgeons to change their weight-bearing practice? Is it research studies? Operative teaching? Something else?

HCP Role

- Do you ever doubt the operating surgeon's weight-bearing instructions?
- What do you think is the intrinsic value of seeing a physiotherapist?
- Do you feel you have the knowledge/ confidence to answer their questions? Do you feel like you're just making your best guest/ what feels sensible?
- How do you balance how optimistic to be vs defensive - "Oh it's a bad break – you'll have a slow recovery" vs "It's all fixed – you'll do fine".
- Do you make a point to act in a certain way – E.g. I'm going to be optimistic or not…
- Some patients feel rushed in clinics, particularly by surgeons - Do you feel you have enough time in the NHS to give them all the information they need?
- Do patients usually see the same surgeon at follow-up where you work? Do you think they prefer continuity?
- Do patients tell you about goals they have, do you feel confident in giving them time-frames? How do you do this? Prompts: Comparisons to other patients.
- Before getting in their car to drive – is there anything you do to see if patients are ready for that?
- Who do you give VTE prophylaxis to? How long post-op?
- What are your indications for metalwork removal?

The Last Section is about future treatment/ service delivery:

- Has your department started doing things differently or innovatively since COVID?
- Are these good changes (e.g. virtual clinic)?
- How would you feel about having a centralised service that patients accessed for advice – e.g. virtual physio – with physios that had access to local notes? Any concerns about this?
- Would this be acceptable/ would any physios want this job?
- Would you feel confident assessing a surgical wound remotely via picture (High risk vs fine)?
- Do you think patients can detect wound problems themselves or any complications themselves?
- Would you feel confident giving patients exercise feedback via zoom?
- Anything else you think is lacking you think would be good to include.
- Thanks that's the end, is there anything else you'd like to discuss?

Wrap up / debrief

APPENDIX E

Chapter 6

E.1 Patient workshop PIS

WEIGHT-BEARING IN ANKLE FRACTURES

Workshop Information Sheet

A study about weight-bearing in ankle fractures

Background

The WAX study aims to find out more about when is best to weight-bear after an ankle fracture. We would like to invite you to take part in a group discussion workshop(s). This is so that we can design new treatments to help people recover from ankle fractures.

Even if you did not to take part in the WAX study, we would still like to know your thoughts about how we can improve treatment for ankle fractures.

This document explains what taking part in the interview would involve. *Please take time to read this information and discuss it with others if you wish.*

If anything is unclear or if you would like more information please contact the Chief Investigator, Christopher Bretherton:

Email: christopher.bretherton@ndorms.ox.ac.uk

What happens if I say yes?

We will invite you to come to one or two all-day meetings. Workshops will be conducted face-to-face, virtually via videoconference, or a combination of both. This will depend on social distancing guidelines in place at the time.

At the first meeting, we will discuss ways of helping people return to walking after ankle fracture surgery. We will select from a range of options to develop further. There will be approximately 10 patients or carers at the meeting.

At the second meeting, we will discuss the 1-2 options selected at the first meeting and discuss how best to deliver them to patients. There will be a mixture of patients, carers and healthcare professionals including surgeons, doctors, nurses and physiotherapists at this meeting.

You can decide if you wish to attend one or both meeting, or you can decide after the first meeting. You will also be invited to contribute by telephone or email after the workshops.

We will ask your permission to make an audio-visual recording of these meetings (for research purposes only).

Do I have to take part?

No. It is entirely your decision whether to take part or not. You are welcome to keep this leaflet and use it to help you make your decision. You do not have to decide straight away.

If you would like to take part then we will ask you to sign a consent form on the day if you come to a meeting. You are free to withdraw your consent at any time, without giving a reason. This will not affect the standard of care you receive.

Are there any benefits to taking part?

There are no specific benefits for taking part in the workshops. Some people may feel pleased to have contributed to a broader understanding of treating this injury.

Are there any risks to taking part?

Agreeing to help will take some of your time. We will send you documents to read before you come to the workshop. These documents may take up to 30 minutes to read.

For people who come to any face-to-face meeting, we will be able to pay your travel expenses for car mileage, standard class rail travel, parking charges and accommodation if needed.

Will my information be kept confidential?

The University of Oxford is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Oxford will keep identifiable information about you for 12 months after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that

we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Your local hospital will collect your name and contact details and will pass these details to The University of Oxford. The only people in the University of Oxford who will have access to information that identifies you will be people who need to contact you for an interview or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

All of your information will be stored securely at the University of Oxford. The workshop will be audio recorded, and later typed into a computer with all the personal details removed. Quotes from the workshops may be used in the reporting of this study. Any quotes will be anonymised so it will not be possible to identify you. Copies of the transcripts will be stored at the University of Oxford for a maximum of five years and then will be destroyed. Audio recordings will be deleted at the end of the study.

People from the University of Oxford and Regulatory Authorities may have access to your data so they can ensure the study is being carried out according to regulations.

Anonymised data may be provided to researchers running other research studies in this organisation and/or other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

What will happen to the results of the study?

When we have analysed the workshops, reports will be published in academic journals and presented at conferences. We will not identify anyone by their name.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by South Central - Oxford A Research Ethics Committee on 1st December 2019.

What happens if something goes wrong?

The University of Oxford is the Sponsor for the study and has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial. If you wish to discuss any aspect of the way in which you have been approached or treated during the course of this study, you should contact Associate Professor Xavier Griffin who is the overall lead of this trial on 01865 223114; or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or email ctrg@admin.ox.ac.uk. NHS indemnity covers any other treatment with which you are provided.

For independent advice, ask your treating hospital for the contact details for the Patient Advice Liaison Service (PALS). This is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. However, PALS cannot provide information about this research study.

Further Information and Contact details

If you have any questions about the workshops please contact*: Mr Christopher Bretherton* by telephone on <insert contact details> or email at christopher.bretherton@ndorms.ox.ac.uk.

Some of the research being undertaken will also contribute to the fulfilment of a doctoral thesis. No identifiable data will be included in this educational research project.

You may also contact the WAX team via email at wax@ndorms.ox.ac.uk or telephone <insert contact details>.

Thank you for reading this information and considering taking part in our study.

E.2 Patient workshop consent form

WORKSHOP CONSENT FORM

WAX - Study Within a Trial (SWAT):
Rehabilitation After Ankle Fracture Surgery (RAAFT)
Lead Investigator: Mr Christopher Bretherton

Facilitating safe weight-bearing after ankle fracture surgery

Screening ID: WX- ☐☐☐ ☐☐☐☐

Workshop ID: ☐☐☐

Please initial the box if you agree with the following statements

1.	I confirm that I have read and understood the Information Sheet dated DDMonYYYY version XX. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2.	I understand that participation is voluntary and I am free to withdraw from the study at any time, without giving a reason, and without my care or legal rights being affected.	☐
3.	I consent to the research team holding my contact details so that they can contact me about the study. I understand these details will be held securely and destroyed at the end of the study.	☐
4.	I give permission for the workshops to be audio/video recorded. I also give permission for anonymised written quotations from the workshops to be used in reports, publications and presentations related to the trial.	☐
5.	I understand that data collected during the study may be looked at by individuals from the research team at the University of Oxford, regulatory authorities and from participating NHS organisations, where it is relevant to me taking part in this research. I give permission for these individuals to have access to my records.	☐
6.	I agree to take part in this study	☐
7.	I understand that the information collected about me may be used in an anonymous way to support other research in the future. It will not be possible for me to be identified by it.	☐
8.	I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	**Yes** ☐ **No** ☐

Your Signature:	Your Full Name:

Date of Consent:

D D / M O N / Y Y Y Y

Name of English-speaking relative, carer, friend or interpreter (if applicable):	Signature of English-speaking relative, carer, friend or interpreter (if applicable):

Date of Consent:

D D / M O N / Y Y Y Y

Name of Person Taking Consent:	Signature of Person Taking Consent:

Date of Taking Consent:

D D / M O N / Y Y Y Y

One copy to be kept in the investigator site file, one copy to be given to the participant and one copy to be kept in the participant's medical notes

E.3 Patient workshop worksheet

Document C

WAX Workshop Participant Worksheet – pre-workshop exercise

This research aims to support people recovering from ankle fracture surgery and help them get back to walking, hobbies, and work sooner. This new support package is likely to be in the form of an app or website, a booklet, or a series of emails to patients.

During the workshop, you will be discussing each page in turn to help decide what options and functions the rehabilitation package should include.

Column 1. “Comments/ concerns/ needs & wants”, gives example quotes from patients about things they have struggled with during recovery (and some from healthcare professionals).

Column 2. “Content”, gives examples of information or support that could help overcome some of the difficulties from column 1.

Column 3. “Delivery method”, gives examples of how this information or help could be provided to patients in the future.

Column 4. “Acceptability/ practicability” asks you for suggestions for each function to make them as helpful as possible for patients.

Column 5. “Side effects/ equity” asks you to think about any drawbacks to delivering each option and if there are certain people that might struggle to use the new functions.

These examples are just suggestions to act as a guide – ultimately, we want YOU to decide what is important and included.

Before the workshop, please spend some time reading this list of options (around 5-10 minutes per page). Please make a note of any thoughts or comments in each box. You do not need to fill in every box and it’s OK if you feel some boxes don’t apply to you.

Please have this with you when you join the online workshop. You will **not** be asked to send it in: It just gives you a chance to consider the information beforehand and help guide the group discussion during the workshop.

WAX WEIGHT-BEARING IN ANKLE FRACTURES

UNIVERSITY OF OXFORD

Skills - Training

1. Comments/ concerns/ needs & wants	2. Content	3. Delivery method	4. Acceptability/ practicability	5. Side effects/ equity
"I don't know how to Weight-bear or use crutches safely"	<u>Walking tips</u> - How to weight-bear (none, partial, full) - How to use crutches	- Videos - Pictures	What other skills did you struggle with?	Can you think of any drawbacks to this?
"What am I allowed to do? Can I weight-bear gently to help me balance?"				
"I struggle with day-to-day activities like carrying a cup of tea or showering"	<u>Day-to-day tips:</u> - How to carry tea - How to shower	- Booklet	What other training or advice would be helpful?	Could it exclude certain people?
"Am I doing my exercises correctly?"				
	- Exercise instructions		How best would they be delivered?	How might these drawbacks or exclusions be avoided/ helped?

Knowledge – Education

1. Comments/ concerns/ needs & wants	2. Content	3. Delivery method	4. Acceptability/ practicability	5. Side effects/ equity
"What's normal – am I supposed to have this pain and swelling still? I don't know what to expect"	<u>What's normal/ what to expect/ when to seek help</u> - Swelling - Skin colour changes - Wound concerns - Managing pain	- Pictures in a booklet	Would these have answered most of your concerns? Are there any other concerns you had?	Can you think of any drawbacks to this?
"Are these exercises and advice suitable for me and my ankle – or are they designed for younger/ older people?"		- Pictures on an App/ website with explanations based on experiences week by week	What other timeframes for recovery would it be useful to know?	Could it exclude certain people?
"I'm not in too much pain; it's mostly confidence that stops me walking on my ankle"	- Timeframes for return to work, driving and hobbies based on age and fitness	- Live chat to a physiotherapist		How might this be avoided/ helped?
"I had conflicting advice from different healthcare professionals"		- Ability to take a picture of your wound to send to a physiotherapist	How best would this information be delivered?	

Improving access - Healthcare professional support

1. Comments/ concerns/ needs & wants	2. Content	3. Delivery method	4. Acceptability/ practicability	5. Side effects/ equity
“I don’t have access to a physiotherapist”	- A chat function to ask questions &/or send photos to a physiotherapist	- An interactive App or website	Would you consider using this service instead of seeing a face-to-face (F2F) physiotherapist or an extra surgical visit?	Could it exclude certain people?
"I have limited time to ask questions in the clinic and I have to wait 4 weeks till my next appointment to ask my new questions"	- Ability to schedule a virtual appointment	- A national physiotherapist on-call 9am-5pm to answer questions	If not, why? What parts of the F2F visit do you value?	How might this be avoided/ helped?
“I was nervous about practising walking on the hard clinic floors. I preferred to try at home later”	- Ability to book in to see a surgeon if needed – at a time that suits you	- See and upload your XR’s and operation note to a secure App	Can you think of any barriers to using it?	

Social support

1. Comments/ concerns/ needs & wants	2. Content	3. Delivery method	4. Acceptability/ practicability	5. Side effects/ equity
"Keeping in touch with a patient on the ward who also broke their ankle was really helpful"	- Peer support for questions and advice	- Peer support forum where you can chat to other patients with ankle fractures	Would you use these services?	Can you think of any drawbacks to this?
"My family and friends have been so helpful; I couldn't have done it without them"	- Tips for how family can help	- Group virtual physio sessions/ classes	Would your family members have liked this service/ information?	Might it put too much pressure on family members?
"I saw people with wheelchairs and other mobility aids – I'd like to have one, but I don't know where to get them"	- Where to rent/ purchase a wheelchair	- A website with local information on where to access additional resources	Would you feel awkward providing this list to your family?	Could it exclude certain people?
			What tips might you give to other people's family?	How might this be avoided/ helped?

Memory

1. Comments/ concerns/ needs & wants	2. Content	3. Delivery method	4. Acceptability/ practicability	5. Side effects/ equity
"Sometimes I just forget to do my exercises"	- A phone App with reminders - Stretching/ exercise program with timers for each exercise - A dairy of what you complete, with increasing goals	- Reminders on a phone App - A paper diary as part of a booklet	Would you use this service? Can you think of any barriers to using it? Other than exercises, are there any other reminders that might be helpful?	Can you think of any drawbacks to this? Could it exclude certain people?

Finding who will struggle

1. Comments/ concerns/ needs & wants	2. Content	3. Delivery method	4. Acceptability/ practicability	5. Side effects/ equity
"It might be useful to find a way of risk stratifying patients that will struggle with exercises at an early stage so they can be given extra support"	- A questionnaire that sees if you are likely to recover slowly - A physiotherapist could check in more regularly with these patients	-Performed in clinic at 2 weeks post-op -Or the questionnaire would be on the App	Would there be concerns with patients feeling "labelled"?	Can you think of any drawbacks to this? Could it exclude certain people?

Monitoring how people recover

1. Comments/ concerns/ needs & wants	2. Content	3. Delivery method	4. Acceptability/ practicability	5. Side effects/ equity
"Surgeons should monitor their patients' outcomes - every ankle fracture that has been fixed in the country should really go into a registry, and we would have much more meaningful outcomes than what we are seeing now"	-Asking patients how they recover with questionnaires -Allow surgeons to monitor how their patients are doing -Patients that are recovering slowly could be given extra support -The data could be fed back into the App to update the information and expectations for new patients.	-Phone/ email questionnaires	Would you be happy to do these questionnaires? Is every 2-3 months OK? How many reminders is reasonable to send people if they don't complete the first questionnaire? What might encourage you to respond?	Could this put people off using the App altogether? Would you want to Opt-in/ Opt-out of sharing your data?

Space for extra notes/ Is there anything else we could include?

E.4 Behaviour Change Technique (BCT) Taxonomy

Grouping and BCTs	Grouping and BCTs	Grouping and BCTs
1. Goals and planning 1.1. Goal setting (behaviour) 1.2. Problem solving 1.3. Goal setting (outcome) 1.4. Action planning 1.5. Review behaviour goal(s) 1.6. Discrepancy between current behaviour and goal 1.7. Review outcome goal(s) 1.8. Behavioural contract 1.9. Commitment **2. Feedback and monitoring** 2.1. Monitoring of behaviour by others without feedback 2.2. Feedback on behaviour 2.3. Self-monitoring of behaiour 2.4. Self-monitoring of outcome(s) of behaviour 2.5. Monitoring of outcome(s) of behaviour without feedback 2.6. Biofeedback 2.7. Feedback on outcome(s) of behaviour **3. Social support** 3.1. Social support (unspecified) 3.2. Social support (practical) 3.3. Social support (emotional) **4. Shaping knowledge** 4.1. Instruction on how to pe form the behaviour 4.2. Information about Antecedents 4.3. Re-attribution 4.4. Behavioural experiments **5. Natural consequences** 5.1. Information about health consequences 5.2. Salience of consequences 5.3. Information about social and environmental consequences 5.4. Monitoring of emotional consequences 5.5. Anticipated regret 5.6. Information about emotional consequences	**6. Comparison of behaviour** 6.1. Demonstration of the behaviour 6.2. Social comparison 6.3. Information about others' approval **7. Associations** 7.1. Prompts/cues 7.2. Cue signalling reward 7.3. Reduce prompts/cues 7.4. Remove access to the reward 7.5. Remove aversive stimulus 7.6. Satiation 7.7. Exposure 7.8. Associative learning **8. Repetition and substitution** 8.1. Behavioural practice/ rehearsal 8.2. Behaviour substitution 8.3. Habit formation 8.4. Habit reversal 8.5. Overcorrection 8.6. Generalisation of target behaviour 8.7. Graded tasks **9. Comparison of outcomes** 9.1. Credible source 9.2. Pros and cons 9.3. Comparative imagining of future outcomes **10. Reward and threat** 10.1. Material incentive (behaviour) 10.2. Material reward (behaviour) 10.3. Non-specific reward 10.4. Social reward 10.5. Social incentive 10.6. Non-specific incentive 10.7. Self-incentive 10.8. Incentive (outcome) 10.9. Self-reward 10.10. Reward (outcome) 10.11. Future punishment **11. Regulation** 11.1. Pharmacological support 11.2. Reduce negative emotions 11.3. Conserving mental resources 11.4. Paradoxical instructions	**12. Antecedents** 12.1. Restructuring the physical environment 12.2. Restructuring the social environment 12.3. Avoidance/reducing exposure to cues for the behaviour 12.4. Distraction 12.5. Adding objects to the environment 12.6. Body changes **13. Identity** 13.1. Identification of self as role model 13.2. Framing/reframing 13.3. Incompatible beliefs 13.4. Valued self-identify 13.5 Identity associated with changed behaviour **14. Scheduled consequences** 14.1. Behaviour cost 14.2. Punishment 14.3. Remove reward 14.4. Reward approximation 14.5. Rewarding completion 14.6. Situation-specific reward 14.7. Reward incompatible behaviour 14.8. Reward alternative behaviour 14.9. Reduce reward frequency 14.10. Remove punishment **15. Self-belief** 15.1. Verbal persuasion about capability 15.2. Mental rehearsal of successful performance 15.3. Focus on past success 15.4. Self-talk **16. Covert learning** 16.1. Imaginary punishment 16.2. Imaginary reward 16.3. Vicarious consequences

Labels of the BCTs within the taxonomy [83]

E.5 Definitions of BCW interventions and policies

Interventions	Definition	Examples
Education	Increasing knowledge or understanding	Providing information to promote healthy eating
Persuasion	Using communication to induce positive or negative feelings or stimulate action	Using imagery to motivate increases in physical activity
Incentivisation	Creating expectation of reward	Using prize draws to induce attempts to stop smoking
Coercion	Creating expectation of punishment or cost	Raising the financial cost to reduce excessive alcohol consumption
Training	Imparting skills	Advanced driver training to increase safe driving
Restriction	Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)	Prohibiting sales of solvents to people under 18 to reduce use for intoxication
Environmental restructuring	Changing the physical or social context	Providing on-screen prompts for GPs to ask about smoking behaviour
Modelling	Providing an example for people to aspire to or imitate	Using TV drama scenes involving safe-sex practices to increase condom use
Enablement	Increasing means/reducing barriers to increase capability or opportunity[1]	Behavioural support for smoking cessation, medication for cognitive deficits, surgery to reduce obesity, prostheses to promote physical activity
Policies		
Communication/marketing	Using print, electronic, telephonic or broadcast media	Conducting mass media campaigns
Guidelines	Creating documents that recommend or mandate practice. This includes all changes to service provision	Producing and disseminating treatment protocols
Fiscal	Using the tax system to reduce or increase the financial cost	Increasing duty or increasing anti-smuggling activities
Regulation	Establishing rules or principles of behaviour or practice	Establishing voluntary agreements on advertising
Legislation	Making or changing laws	Prohibiting sale or use
Environmental/social planning	Designing and/or controlling the physical or social environment	Using town planning
Service provision	Delivering a service	Establishing support services in workplaces, communities etc.

[1] Capability beyond education and training; opportunity beyond environmental restructuring

Definitions of interventions and policies [44]

APPENDIX F

Chapter 7

F.1 Patient workshop PIS

Staff Workshops Information Sheet

A study about weight-bearing in ankle fractures

Background

The WAX study aims to find out more about when is best to weight-bear after an ankle fracture. We would like to invite you to take part in a group discussion workshop(s). This is so that we can design new treatments to help people recover from ankle fractures.

Even if you did not to take part in the WAX study, we would still like to know your thoughts about how we can improve treatment for ankle fractures.

This document explains what taking part in the interview would involve. *Please take time to read this information and discuss it with others if you wish.*

If anything is unclear or if you would like more information please contact the Chief Investigator, Christopher Bretherton:

Email: christopher.bretherton@ndorms.ox.ac.uk

What happens if I say yes?

We will invite you to come to one or two all-day meetings. Workshops will be conducted face-to-face, virtually via videoconference, or a combination of both. This will depend on social distancing guidelines in place at the time.

At the first meeting, we will discuss ways of helping people return to walking after ankle fracture surgery. We will select from a range of options to develop further. There will be other healthcare professionals including surgeons, doctors, nurses and physiotherapists at this meeting.

At the second meeting, we will discuss the 1-2 options selected at the first meeting and discuss how best to deliver them to patients. There will be a mixture of patients, carers and healthcare professionals including surgeons, doctors, nurses and physiotherapists at this meeting.

You can decide if you wish to attend one or both meeting, or you can decide after the first meeting. You will also be invited to contribute by telephone or email after the workshops.

We will ask your permission to make an audio-visual recording of these meetings (for research purposes only).

Do I have to take part?

No. It is entirely your decision whether to take part or not. You are welcome to keep this leaflet and use it to help you make your decision. You do not have to decide straight away.

If you would like to take part then we will ask you to sign a consent form on the day if you come to a meeting. You are free to withdraw your consent at any time, without giving a reason.

Are there any benefits to taking part?

There are no specific benefits for taking part in the workshops. Some staff may feel pleased to have contributed to a broader understanding of treating this injury.

Are there any risks to taking part?

Agreeing to help will take some of your time. We will send you documents to read before you come to the workshop. These documents may take up to 30 minutes to read.

For people who come to any face-to-face meeting, we will be able to pay your travel expenses for car mileage, standard class rail travel and parking charges.

Will my information be kept confidential?

The University of Oxford is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Oxford will keep identifiable information about you for 12 months after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information www.waxstudy.org

Your local hospital will collect your name and contact details and will pass these details to The University of Oxford. The only people in the University of Oxford who will have access to information that identifies you will be people who need to contact you for the workshops or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

All of your information will be stored securely at the University of Oxford. The workshop will be audio recorded, and later typed into a computer with all the personal details removed. Quotes from the workshops may be used in the reporting of this study. Any quotes will be anonymised so it will not be possible to identify you. Copies of the transcripts will be stored at the University of Oxford for a maximum of five years and then will be destroyed. Audio recordings will be deleted at the end of the study.

People from the University of Oxford and Regulatory Authorities may have access to your data so they can ensure the study is being carried out according to regulations.

Anonymised data may be provided to researchers running other research studies in this organisation and/or other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you. It will not be used to make decisions about future services available to you, such as insurance.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

What will happen to the results of the study?

When we have analysed the workshops, reports will be published in academic journals and presented at conferences. We will not identify anyone by their name.

Who has reviewed this study?

This study has been reviewed and given a favourable opinion by South Central – Oxford A Research Ethics Committee.

What if there is a problem?

The University of Oxford is the Sponsor for this study. If you wish to discuss any aspect of the way in which you have been approached or treated during the course of this study, you should contact Associate Professor Xavier Griffin who is the overall study lead on 01865 223114 or at xavier.griffin@ndorms.ox.ac.uk; or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480 or email ctrg@admin.ox.ac.uk.

Further Information and Contact details

If you have any questions about the workshops please contact*: Christopher Bretherton* by telephone on <insert contact details> or email at christopher.bretherton@ndorms.ox.ac.uk

You may also contact the WAX team via email at wax@ndorms.ox.ac.uk or telephone <insert contact details>.

Thank you for reading this information and considering taking part in our study.

F.2 Patient workshop consent form

STAFF WORKSHOP CONSENT FORM

WAX - Study Within a Trial (SWAT):
Rehabilitation After Ankle Fracture Surgery (RAAFT)
Lead Investigator: Mr Christopher Bretherton

Facilitating safe weight-bearing after ankle fracture surgery

Workshop ID: ☐☐☐

Please initial the box if you agree with the following statements

1.	I confirm that I have read and understood the Information Sheet dated DDMonYYYY version XX. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily	☐
2.	I understand that participation is voluntary and I am free to withdraw from the study at any time, without giving a reason, and my legal rights being affected.	☐
3.	I consent to the research team holding my contact details so that they can contact me about the study. I understand these details will be held securely and destroyed at the end of the study.	☐
4.	I give permission for the workshops to be audio/video recorded. I also give permission for anonymised written quotations from the workshops to be used in reports, publications and presentations related to the trial.	☐
5.	I understand that data collected during the study may be looked at by individuals from the research team, regulatory authorities the University of Oxford, and from participating NHS organisations, where it is relevant to me taking part in this research.	☐
6.	I agree to take part in this study	☐
7.	I understand that the information collected about me may be used in an anonymous way to support other research in the future. It will not be possible for me to be identified by it.	☐
8.	I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	**Yes** ☐ **No** ☐

Name of Participant	Your Signature:

Date of Consent:

D D / M O N / Y Y Y Y

Name of Person Taking Consent:	Signature of Person Taking Consent:

Date of Taking Consent:

D D / M O N / Y Y Y Y

One copy to be kept in the investigator site file, one copy to be given to the participant and one copy to be kept in the participant's medical notes (medical notes not applicable for staff interviewees)

APPENDIX G

Approvals

G.1 Ethical approvals

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Prof Xavier Griffin
University of Oxford, NDORMS
Kadoorie Centre, Level 3
Oxford
OX3 9DU

Email: hra.approval@nhs.net
HCRW.approvals@wales.nhs.uk

2 December 2019

Dear Prof Griffin

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Weight Bearing in Ankle Fractures. A randomised clinical trial of weight-bearing following operatively treated ankle fracture.**
IRAS project ID:	**265559**
Protocol number:	**000000**
REC reference:	**19/SC/0566**
Sponsor	**University of Oxford/ Clinical Trials and Research Governance**

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 **265559**. Please quote this on all correspondence.

Yours sincerely,

Joanna Strickland
Approvals Specialist

Email: nrescommittee.southcentral-oxforda@nhs.net

Copy to: *CTRG, Oxford*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template [Model non-Commercial agreement]	1.0	04 October 2019
Covering letter on headed paper	1.0	07 October 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsors evidence of insurance]	N/A	01 August 2019
Interview schedules or topic guides for participants [Participant Interview Schedule]	1.0	04 October 2019
Interview schedules or topic guides for participants [WAX Staff Interview schedule]	1.0	04 October 2019
IRAS Application Form [IRAS_Form_10102019]		10 October 2019
IRAS Checklist XML [Checklist_10102019]		10 October 2019
Letter from funder [RfPB intent to fund letter]	N/A	15 November 2018
Letter from sponsor [University of Oxford confirmation of sponsorship]	1.0	07 October 2019
Letters of invitation to participant [Interview invitation]	1.0	04 October 2019
Non-validated questionnaire [Patient reported complications]	1.0	07 October 2019
Non-validated questionnaire [Patient contact details]	1.0	07 October 2019
Non-validated questionnaire [Patient contact details check]	1.0	07 October 2019
Non-validated questionnaire [6 week paper CRF]	1.0	07 October 2019
Non-validated questionnaire [4 month paper CRF]	1.0	07 October 2019
Non-validated questionnaire [12 Month paper CRF]	1.0	07 October 2019
Non-validated questionnaire [Resource use questionnaire]	1.0	07 October 2019
Non-validated questionnaire [Contact details change form]	1.0	07 October 2019
Non-validated questionnaire [Weekly questions delayed weight-bearing]	1.0	09 October 2019
Non-validated questionnaire [Weekly questions early weight-bearing]	1.0	09 October 2019
Non-validated questionnaire [Baseline Demographics]	1.0	07 October 2019
Non-validated questionnaire [Global Rating of Change]	1.0	13 August 2019
Non-validated questionnaire [Post-assessment questionnaire]	1.0	13 August 2019
Non-validated questionnaire [6week CRF section 1]	1.0	16 August 2019
Non-validated questionnaire [4 Month CRF section 1]	1.0	16 August 2019
Non-validated questionnaire [12 Month CRF section 1]	1.0	16 August 2019
Organisation Information Document [WAX Organisation Information Document]	1.0	27 September 2019
Other [Rehabilitation manual for participants Early Weight-bearing]	1.0	07 October 2019
Other [Rehab manual for participants Delayed Weight-bearing]	1.0	07 October 2019
Other [Example screen shots of surveys created by the database]	N/A	19 August 2019
Other [Support and ETC email]	N/A	
Other [Email and Text wording for Questionnaires]	1.0	04 October 2019
Other [Follow-up check within database]	1.0	16 August 2019
Other [Thank you after questionnaire]	1.0	16 August 2019
Other [WAX welcome email]	1.0	23 August 2019
Other [WAX Qualitative consent to contact email]	1.0	07 October 2019

Other [WAX LoneWorker]	1.0	25 November 2019
Other [WAX FE Agreement]	2/18	
Other [Questionnaire cover letter]	2.0	26 November 2019
Other [Questionnaire cover letter (TC)]	2.0	26 November 2019
Participant consent form [Interview consent form (Staff)]	1.0	04 October 2019
Participant consent form [Interview consent form (participants)]	1.0	04 October 2019
Participant consent form [Consent to Contact for qualitative interviews only]	1.0	13 August 2019
Participant consent form [WAX Consent form]	2.0	26 November 2019
Participant information sheet (PIS) [WAX Patient Information Sheet. Main Study]	2.0	26 November 2019
Participant information sheet (PIS) [WAX Interview Patient information sheet]	1.0	04 October 2019
Participant information sheet (PIS) [WAX Interview Patient information sheet (Staff)]	1.0	04 October 2019
Research protocol or project proposal [WAX Protocol]	1.0	04 October 2019
Schedule of Events or SoECAT [dated]	1	23 October 2019
Summary CV for Chief Investigator (CI) [Chief Investigators CV]	N/A	01 May 2019
Summary CV for student [Christopher Brethertons CV]	N/A	16 September 2019
Validated questionnaire [EQ5D-5L]	1.0	13 August 2019
Validated questionnaire [Work Productivity and Activity impairment questionnaire]	1.0	13 August 2019
Validated questionnaire [Olerud and Molander ankle score]	1.0	07 October 2019
Validated questionnaire [Tampa Scale of Kinesphobia-11]	1	08 October 2019
Validated questionnaire [Pain Self-efficacy Questionnaire 2]	1	13 August 2019

IRAS project ID	265559

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
There is one NHS site type acting as a full research site performing the local research activities as stated in the schedule of events.	Research activities should not commence at participating NHS organisations in England or Wales recruiting patients, prior to their formal confirmation of capacity and capability to deliver the study. Organisations will not be required to formally confirm capacity and capability to recruit NHS staff, and research procedures may begin 35 days after provision of the local information pack, provided the following conditions are met: • You have contacted participating NHS organisations (see	An Organisation Information Document has been submitted and the sponsor is intending to use a separate site agreement. The model NCA agreement is unmodified and will be used for NHS sites in England, Wales, Scotland and Northern Ireland.	External funding has been secured by the NIHR RfPB grant and funding is available to the NHS sites.	A local Principal Investigator (PI) is expected to be in place at the NHS site to oversee the local research activities.	Where arrangements are not already in place, staff undertaking any of the research activities listed in A18 or A19 of the IRAS form (except for administration of questionnaires or surveys), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health

	below for details) • HRA and HCRW Approval has been issued • The NHS organisation has not provided a reason as to why they cannot participate • The NHS organisation has not requested additional time to confirm. You may start the research prior to the above deadline if HRA and HCRW Approval has been issued and the site positively confirms that the research may proceed. You may now provide the local information pack for your study to your participating NHS organisations in England and/or Wales. If you have not already started to provide the local information packs to participating NHS organisations in Northern Ireland and/or Scotland please				clearance. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

	do so when you are ready. A current list of R&D contacts is accessible at the NHS RD Forum website and these contacts MUST be used for this purpose. The password to access the R&D contact list is Redhouse1.				

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
Training in trial intervention and conduct will be delivered by the sponsor; protocol adherence training, CRF completion, timelines for form returns, timelines for data query returns, how to report adverse events and serious adverse events will be provided at site initiation visits carried out at each site prior to the site activation. The Sponsor expects individuals involved in a study to be trained appropriately for their function.

NHS
Health Research Authority

South Central - Oxford A Research Ethics Committee

Ground Floor
Temple Quay House
2 The Square
Bristol
BS1 6PN

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

23 March 2021

Mr Christopher Bretherton
DPhil Student
University of Oxford
University of Oxford, NDORMS
Kadoorie Centre, Level 3
Oxford
OX3 9DU

Dear Mr Bretherton

Study title:	**Weight Bearing in Ankle Fractures. A randomised clinical trial of weight-bearing following operatively treated ankle fracture.**
REC reference:	**19/SC/0566**
Protocol number:	**000000**
Amendment number:	**Amendment 05**
Amendment date:	**21 January 2021**
IRAS project ID:	**265559**

The above amendment was reviewed at the meeting of the Sub-Committee held on 05 March 2021 by the Sub-Committee in correspondence.

Ethical opinion

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

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Completed Amendment Tool [265559_Amendment 05_.pdf]	Amendment 05_08Jan2021_Locked20Jan21_100240	20 January 2021
Copies of materials calling attention of potential participants to the research [RAAFT_PublicPoster_V1.0_21Jan2021.pptx]	1.0	21 January 2021
Letter from funder [Bretherton Funding letter]	1.0	22 October 2020
Letters of invitation to participant [WAX_InterviewInvitation_Non-EnglishSpeaking_V1.0_21Jan2021]	1.0	21 January 2021
Letters of invitation to participant [WAX_WorkshopInvitation_Non-EnglishSpeaking_V1.0_21Jan2021]	1.0	21 January 2021
Letters of invitation to participant [WAX_WorkshopInvitation_V1.0_21Jan2021]	1.0	21 January 2021
Letters of invitation to participant [WAX_ReplySlip_V1.0_21Jan2021]	1.0	21 January 2021
Other [WAX_Amemdent05_DocumentsList_V1.0_21Jan2021]	1.0	21 January 2021
Other [RAAFT_ParticipantResponseSpreadsheet_V1.0_21Jan2021]	1.0	21 January 2021
Participant consent form [WAX_WorkshopConsentFormStaff_V1.0_21Jan2021]	1.0	21 January 2021
Participant consent form [WAX_WorkshopConsentFormPatient_V1.0_21Jan2021]	1.0	21 January 2021
Participant consent form [WAX_QualitativeConsentToContact_Non-EnglishSpeaking_V1.0_21Jan2021]	1.0	21 January 2021
Participant consent form [WAX_QualitativeConsentToContact_V2.0_21Jan2021_Clean]	2.0	21 January 2021
Participant consent form [WAX_QualitativeConsentToContact_V2.0_21Jan2021_Tracked]	2.0	21 January 2021
Participant consent form [WAX_Consent_V4.0_21Jan2021_Tracked]	4.0	21 January 2021
Participant consent form [WAX_InterviewConsent_V2.0_21Jan2021_Clean.docx]	2.0	21 January 2021
Participant consent form [WAX_InterviewConsent_V2.0_21Jan2021_Tracked.docx]	2.0	21 January 2021
Participant consent form [WAX_Consent_V4.0_21Jan2021_Clean]	4.0	21 January 2021
Participant information sheet (PIS) [WAX_InterviewPIS_Non-EnglishSpeaking_V1.0_]	1.0	21 January 2021
Participant information sheet (PIS) [WAX_InterviewPIS_Staff_V3.0_21Jan2021_Clean]	3.0	21 January 2021
Participant information sheet (PIS) [WAX_InterviewPIS_Staff_V3.0_21Jan2021_Tracked]	3.0	21 January 2021
Participant information sheet (PIS) [WAX_InterviewPIS_V3.0_21Jan2021_Clean.docx]	3.0	21 January 2021
Participant information sheet (PIS) [WAX_InterviewPIS_V3.0_21Jan2021_Tracked]	3.0	21 January 2021
Participant information sheet (PIS) [WAX_WorkshopsPIS_Non-EnglishSpeaking_V1.0_21Jan2021]	1.0	21 January 2021
Participant information sheet (PIS) [WAX_WorkshopsPIS_Staff_V1.0_21Jan2021]	1.0	21 January 2021
Participant information sheet (PIS) [WAX_WorkshopsPIS_V1.0_21Jan2021]	1.0	21 January 2021
Referee's report or other scientific critique report [22553BrethertonFeedback]	1.0	26 February 2020
Research protocol or project proposal [WAXSWAT_RAAFT_Protocol_V1.0_21Jan2021]	1.0	21 January 2021

Research protocol or project proposal [WAX_Protocol_V3.0_21Jan2021_Clean.docx]	3.0	21 January 2021
Research protocol or project proposal [WAX_Protocol_V3.0_21Jan2021_Tracked.docx]	3.0	21 January 2021

Membership of the Committee

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

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. 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 have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

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.

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 - 265559:	**Please quote this number on all correspondence**

Yours sincerely



P.P
Chair
Dr Hugh Davies

E-mail: oxforda.rec@hra.nhs.uk

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

Copy to: *Mr Christopher Bretherton, University of Oxford*

South Central - Oxford A Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 05 March 2021

Committee Members:

Name	*Profession*	*Present*	*Notes*
Ms Jane Cheeseman	Research Nurse	Yes	
Ms Christine Montague-Johnson	Paediatric Nurse	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Corcyra Burley	Approvals Administrator

G.2 Letters of access for qualitative study

Letters of access

Site	Letter of access	Site	Letter of access
Basingstoke and North Hampshire Hospital	No	Royal Derby Hospital	Yes
Cardiff and Vale University Health Board	Yes	Royal Preston Hospital	Yes
Conquest Hospital	No	Royal United Hospitals Bath	Yes
Craigavon Area Hospital	No	Royal Victoria Hospital Belfast	Not required
Dorset County Hospital	Yes	Salisbury District Hospital	No
East Surrey Hospital	Yes	Southampton General Hospital	Yes
Kings College Hospital Trust	No	The Princess Alexandra Hospital Harlow	Yes
Leicester Royal Infirmary	Yes	The Royal Cornwall Hospital	Yes
Maidstone and Tunbridge Wells Hospital	Yes	University Hospital Coventry	Yes
Queen Alexandra Hospital Portsmouth	Yes	University Hospital, Lewisham	Yes
Queens Medical Centre Nottingham	Not required	William Harvey Hospital	Not required
Royal Berkshire Hospital Reading	Not required		

An example letter of access is provided below:

Portsmouth Hospitals University
NHS Trust

Research & Innovation Department
1st Floor, Lancaster Building
Queen Alexandra Hospital
Cosham
Portsmouth
PO6 3LY

Tel: 023 9228 6236
Web: www.porthosp.nhs.uk

Chris Bretherton
Kadoorie Centre
Level
John Radcliffe Hospital
Oxford
OX3 9DU

23/06/2021

Dear Chris,

Letter of access for research

This letter should be presented to each participating organisation before you commence your research at that site. The participating organisation(s) is/are: **Portsmouth Hospitals University NHS Trust.**

In accepting this letter, each participating organisation confirms your right of access to conduct research through their organisation for the purpose and on the terms and conditions set out below. This right of access commences on **23/06/2021** and ends on **01/09/2022** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from **Portsmouth Hospitals University NHS Trust**. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving confirmation from the individual organisation(s) of their agreement to conduct the research.

The information supplied about your role in research at the organisation(s) has been reviewed and you do not require an honorary research contract with the organisation(s). We are satisfied that such pre-engagement checks as we consider necessary have been carried out. Evidence of checks should be available on request to the organisation(s).

You are considered to be a legal visitor to the organisations premises. You are not entitled to any form of payment or access to other benefits provided by the organisation(s) or this organisation to employees and this letter does not give rise to any other relationship between you and the organisation(s), in particular that of an employee.

While undertaking research through the organisation(s) you will remain accountable to your substantive employer but you are required to follow the reasonable instructions of the organisation(s) or those instructions given on their behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by the organisation(s) in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with the organisations policies and procedures, which are available to you upon request, and the UK Policy Framework for Health and Social Care Research.

You are required to co-operate with the organisation(s) in discharging its/their duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on the organisations premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and each organisation prior to commencing your research role at that organisation.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act 2018. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the organisations premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that the organisation(s) do not accept responsibility for damage to or loss of personal property.

This organisation may revoke this letter and any organisation(s) may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of the organisation(s) or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

No organisation will indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 2018. Any breach of the Data Protection Act 2018 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in **Portsmouth Hospitals University NHS Trust** and the **R&I office (02392 286000 ext 6236)** in this organisation.

Yours sincerely

Ian Gedge
Research Facilitator

G.3 Figure permissions

Figure permissions

Figure	Permissions
Figure 1.2: An ankle fracture with talar shift [6]	BJJ - License ID 1274865-1
Figure 1.3: A surgically fixed ankle fracture [7]	BJJ - License ID 1258005-1
Figure 1.4: Logic model for intervention development [249]	CC4
Figure 1.5: Different approaches to intervention development [249]	CC4
Figure 1.6: Behaviour change intervention design process [44]	CC2
Figure 1.7: The COM-B system - a framework for understanding behaviour [44]	CC2
Figure 1.8: Behaviour Change Wheel (BCW) [44, 49]	CC4
Figure 3.1: Flowchart: when should multiple imputation be used to handle missing data [104]	CC4
Figure 6.2: Matrix of links between COM-B and intervention functions [44]	CC2
Figure 6.3: Matrix of links between intervention functions and policy categories [44]	CC2
Figure 9.2: MRC Framework for developing and evaluating complex interventions [58]	CC4

CC2: Creative commons license 2

CC4: Creative commons license 4

BJJ: British Editorial Society of Bone & Joint Surgery via Copyright Clearance Centre. Inc

APPENDIX H

Published works

H.1 The WAX trial protocol

Bretherton et al. BMC Musculoskeletal Disorders (2021) 22:672
https://doi.org/10.1186/s12891-021-04560-7

BMC Musculoskeletal Disorders

STUDY PROTOCOL Open Access

Protocol for the Weight-bearing in Ankle Fractures (WAX) trial: a multicentre prospective non-inferiority trial of early versus delayed weight-bearing after operatively managed ankle fracture

C. P. Bretherton[1*], H. A. Claireaux[1], J. Achten[1], A. Athwal[1], S. J. Dutton[1], N. Peckham[1], S. Petrou[2], R. S. Kearney[3], D. Appelbe[1] and X. L. Griffin[4]

Abstract

Background: Unstable ankle fractures represent a substantial burden of disease, accounting for a mean hospital stay of nine days, a mean cost of £4,491 per patient and 20,000 operations per year. There is variation in UK practice around weight-bearing instructions after operatively managed ankle fracture. Early weight-bearing may reduce reliance on health services, time off work, and improve functional outcomes. However, concerns remain about the potential for complications such as implant failure. This is the protocol of a multicentre randomised non-inferiority clinical trial of weight-bearing following operatively treated ankle fracture.

Methods: Adults aged 18 years and over who have been managed operatively for ankle fracture will be assessed for eligibility. Baseline function (Olerud and Molander Ankle Score [OMAS]), health-related quality of life (EQ-5D-5L), and complications will be collected after informed consent has been obtained. A randomisation sequence has been prepared by a trial statistician to allow for 1:1 allocation to receive either instruction to weight-bear as pain allows from the point of randomisation, two weeks after the time of surgery (‘*early weight-bearing*’ group) or to not weight-bear for a further four weeks (‘*delayed weight -bearing’ group*). All other treatment will be as per the guidance of the treating clinician.
Participants will be asked about their weight-bearing status weekly until four weeks post-randomisation. At four weeks post-randomisation complications will be collected. At six weeks, four months, and 12 months post-randomisation, the OMAS, EQ-5D-5L, complications, physiotherapy input, and resource use will be collected. The primary outcome measure is ankle function (OMAS) at four months post-randomisation.
A minimum of 436 participants will be recruited to obtain 80% power to detect a non-inferiority margin of -6 points on the OMAS 4 months post-randomisation. A within-trial health economic evaluation will be conducted to estimate the cost-effectiveness of the treatment options.

* Correspondence: Christopher.Bretherton@ndorms.ox.ac.uk
[1]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK
Full list of author information is available at the end of the article

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Discussion: The results of this study will inform national guidance with regards to the most clinically and cost-effective strategy for weight-bearing after surgery for unstable ankle fractures.

Trial registration: ISRCTN12883981, Registered 02 December 2019.

Keywords: Ankle Fracture, Weight-bearing, Surgery, Rehabilitation, Randomised controlled trial

Background

One hundred seventy patients sustain an ankle fracture in the UK every day [1]. Ankle fractures are grouped into those in which the bones remain aligned (stable) and those in which they do not (unstable). Unstable fractures require surgery to stabilise the ankle bones whilst they heal [2]. 20,000 ankle operations are performed every year in the UK [3]. They represent a substantial burden of disease, with an average length of hospital stay of nine days and an associated mean cost of £4,491 per patient [4].

Post-operative mobilisation strategies are variable. Historically surgeons restricted patients' weight-bearing due to a fear that excessive loading of the bone and metal implants could lead to an early loss of alignment, soft tissue compromise, poor functional outcomes and a requirement for revision surgery [5]. This weight-bearing restriction has a major impact on patients and health services through enforced use of walking aids, increased dependency and/or longer hospital stays [6–8]. Patients also report significant time off work with the consequent personal and societal cost impact [6, 8, 9]. It is reasonable that if there were minimal risk of harm, many patients would prefer to walk without weight-bearing restrictions.

High-quality systematic reviews conducted by Cochrane and the National Institute for Health and Care Excellence (NICE) have found no credible evidence of harm associated with an early weight-bearing strategy [2, 10]. There is a pressing need to definitively test the appropriateness of this component of the surgical treatment of ankle fractures.

Methods

Aims

This study aims to establish whether early weight-bearing after an operatively managed ankle fracture is not inferior in terms of functional outcome compared to delayed weight-bearing.

The primary outcome is:

1. To quantify and draw inferences on observed differences in ankle function between early and delayed weight-bearing using the Olerud and Molander Ankle Score (OMAS) at four months after randomisation.

The secondary outcomes are:

1. To quantify and draw inferences on observed differences in ankle function between early and delayed weight-bearing using the Olerud and Molander Ankle Score (OMAS) at six weeks and 12 months after randomisation.
2. To quantify and draw inferences on observed differences in health-related quality of life using the EQ-5D-5L between the trial treatment groups at six weeks, four months, and 12 months after randomisation.
3. To investigate the difference in risk of complications between the trial treatment groups at four weeks, six weeks, four months, and 12 months after randomisation.
4. To investigate the resource use, costs and comparative cost-effectiveness of the treatment options using the Work Productivity and Activity Impairment: Specific Health Problem (WPAI), prospectively measured resource use, and health utility estimates at six weeks, four months, and 12 months.

Study design

This trial is a pragmatic, multicentre, randomised non-inferiority clinical trial with a parallel economic evaluation conducted in the United Kingdom. This protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines for reporting of clinical trial protocols (Additional file 1).

Trial registration

ISRCTN12883981, Registered 02 December 2019, https://www.isrctn.com/ISRCTN12883981

Protocol version

This publication is based on the WAX trial protocol version 3.0, approved by South Central- Oxford A- Health Research Authority on 29 March 2021.

Eligibility

Patients will be eligible for inclusion into the trial if:

- They are aged 18 years and older.
- They have undergone operative fixation for an unstable ankle fracture.
- Surgery was performed within 14 days of the injury.

- In the opinion of the treating surgeon, the patient might benefit from early weight-bearing.
- They are able and willing to give informed consent.

Patients will be excluded from this trial if any of the following apply:

- They have a lack of protective sensation (e.g. peripheral neuropathy).
- They are unable to adhere to trial procedures.
- They have bilateral operatively treated ankle fractures.
- They are already in a trial for ankle fracture.
- They received a hindfoot nail to treat index fracture.

Consenting

Patients will be approached by a member of the local recruitment centre team within two weeks of their surgery, to introduce them to the trial. Written and verbal versions of the Participant Information and Informed Consent documentation will be presented to the participants to explain the exact nature of the study.

Randomisation

Those patients who consent to take part in the trial will be randomly allocated to one of two intervention groups (1:1) using a secure (encrypted) remote computer randomisation service administered by the Oxford Clinical Trials Research Unit (OCTRU).

Randomisation allocation will be implemented using a minimisation algorithm stratified by age and centre; the sequence will be prepared by the trial statistician.

Stratification by age

There is a bimodal incidence in ankle fractures, with the older population typically suffering low energy fragility fracture, whilst in the younger population, the injuries are more often the result of sports-related injuries. To align with recently published and ongoing NIHR multicentre randomised controlled trials (RCTs) on ankle fracture management, we have chosen to separate patients younger and older than 60 years old as the stratification cut-off to ensure balance across the treatment arms and for subgroup analysis for this trial [11, 12].

Stratification by centre

Stratification by centre will help ensure that any effect related to the recruitment centre will be equally distributed in the trial arms. All hospitals throughout the NHS are familiar with giving rehabilitation advice that patients should weight-bear or avoid weight-bearing after various injuries.

Post-randomisation withdrawals

A participant may choose to withdraw from the study at any time, without giving reasons, and without affecting their clinical care. Participants will not have the option to withdraw the data collected up until the point of withdrawal, as the data will be required for the intention-to-treat and safety analysis. Withdrawn patients or patients deemed ineligible after consent will not be replaced.

Blinding

It will not be possible to blind participants or those delivering the intervention to the weight-bearing instruction. The primary outcome data will be collected from participants and entered directly onto the central trial database, without influence from the clinical or research team.

Trial treatments

A patient pathway is included in Fig. 1.

Pre-randomisation

All NHS hospitals are familiar with giving rehabilitation instructions for weight-bearing or non-weight-bearing. All patients will be non-weight-bearing for the first two weeks in the immediate post-operative period to allow swelling to settle and the wound to start healing. The type of ankle immobilisation will be decided as per usual care by the treating clinical team.

The timeframes and definitions of early and delayed weight-bearing are in line with NICE NG38 standards [10]. Clear instructions for patients to avoid weight-bearing if they experience pain or discomfort will act as an additional safety measure. The decisions for both groups of the trial about which form of immobilisation, such as a plaster, boot or other (if any) is used and how much unloaded ankle exercise is allowed will be at the treating clinician's discretion but will be made prior to randomisation and will reflect their routine practice. This is a pragmatic trial so these co-interventions will not be specified; details of any will, however, be recorded on the Case Report Forms (CRFs). At their routine two-week post-surgery clinic visit, participants will be randomised to either early or delayed weight-bearing.

Subsequent formal rehabilitation or adjunctive therapies will be left to the discretion of the treating clinician (e.g. referrals to physiotherapy). The type, frequency and duration of these will be recorded as part of the six weeks, four months and 12 months post-randomisation follow-ups.

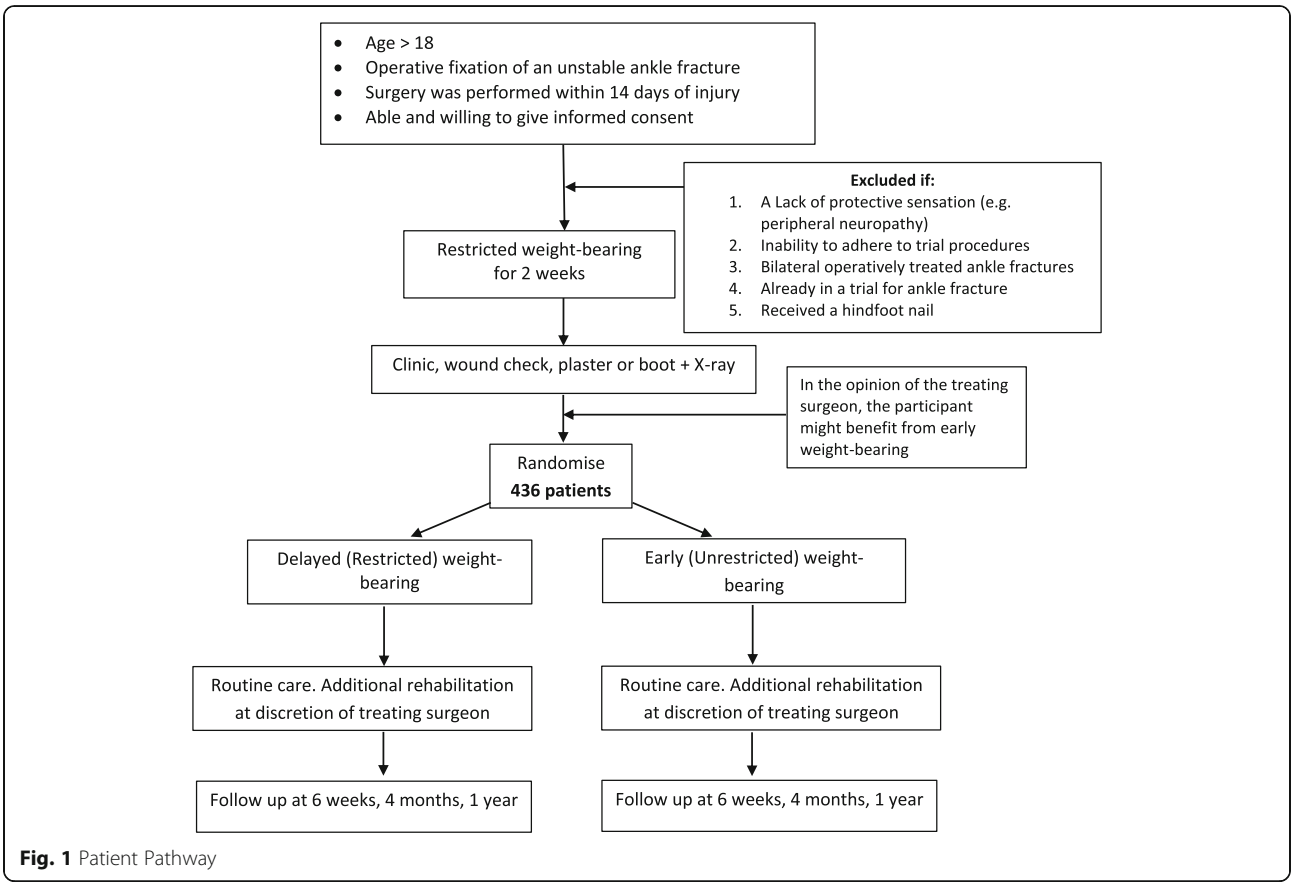


Fig. 1 Patient Pathway

Intervention: Early Weight-Bearing (unrestricted weight-bearing)

The local clinical and research teams will be trained in providing standardised weight-bearing instructions to participants; this will include a written training guide with key points to reinforce. Participants will receive the instructions for weight-bearing in verbal and written form. They will be instructed to put as much weight through their affected leg as they feel comfortable and without causing pain. They will be informed that while they are allowed to walk on their operated leg, it does not mean they have to, or that they will feel able to immediately. They can continue to use the walking aids provided to them during their inpatient hospital stay, or they can discard them if they feel confident to walk without them at any point during the following four weeks.

Comparator: Delayed Weight-Bearing (restricted weight-bearing)

A standardised verbal and written instruction to continue to delay weight-bearing for a further four weeks from the point of being randomised will be given to the patient. They will be instructed to avoid putting any weight through their operated leg. They will be asked to continue to use the walking aids provided to them during their inpatient hospital stay.

Rehabilitation adherence and fidelity

Training of rehabilitation providers will be undertaken at each site by the WAX research team. The rehabilitation materials will be delivered using standardised verbal, written and/or electronic/online instructions. Adhering to the Template for Intervention Description and Replication (TIDIeR) checklist for description and replication of rehabilitation interventions [13], the initial rehabilitation instructions will be recorded on a rehabilitation CRF. In addition, the interactions between the clinician and trial participant will be recorded (verbal consent will be sought) and evaluated for at least one participant during the recruitment and intervention delivery phase of the trial at each recruitment centre. These recordings will be used to assess the level of success of the clinician to introduce the aims/rationale of either intervention strategy.

Objective measurement of weight-bearing through direct pedal pressure monitoring or gait assessment was deemed infeasible. Adherence assessment within this study will be based upon participant self-report. Participants in both groups will receive weekly emails/SMS

messages (a total of 4) asking them to confirm if they have started weight-bearing.

Adverse events management

Safety reporting for each participant will begin at randomisation and will end when the participant has reached their final main follow up time point, at 12 months post-randomisation. When the local research team becomes aware of a Serious Adverse Event (SAE) in a trial participant, the Principal Investigator (PI) will review the SAE locally and make a decision about the causality. All expected and related events shall be reported as complications rather than SAEs. For any SAEs assessed as unexpected and potentially related, the details of the event will be entered on an SAE reporting form on the database, and the local research team will notify the central team via email or telephone within 24 hours of the PI becoming aware of the event. Once the SAE form is received, causality will be confirmed by the Chief Investigator (CI) or delegate (Nominated Person). In the event that consensus is not reached between the PI and Nominated Person about assessment of causality and expectedness, this will be escalated to the CI for further discussion. All such events will be reported to the Trial Steering Committee (TSC) and Data and Safety Monitoring Committee (DSMC) at their next meetings and to the Research Ethics Committee (REC) that issued favourable opinion within 15 working days. All participants experiencing SAEs will be followed up as per protocol until the end of the trial. As both groups are investigating procedures currently used in clinical practice, we will not be collecting unrelated SAEs.

Outcome measurements

The primary outcome measure is the Olerud and Molander Ankle Score (OMAS) [14]. It is a reliable and valid ankle-specific patient-reported outcome measure used in several other ankle fracture studies [2, 11, 12, 15]. It has three domains related to ankle symptoms, lower limb-related activities, and overall function. It has nine items that add to give a score of 0 (worst) to 100 (best). A difference of five points would represent someone who is able to walk upstairs without any difficulty compared to someone who could manage stairs, but with some difficulty.

The instrument will be collected at baseline (patients will be asked to recall their pre-injury ankle function), six weeks, four months and 12 months post-randomisation.

The secondary outcome measures are:

Health-related quality-of-life

The EuroQol 5 Dimensions 5L (EQ-5D-5L) [16] is a validated, generalised and standardised instrument comprising a visual analogue scale measuring self-rated health and a health status descriptive system. For analysis, responses to the descriptive system will be converted into EQ-5D-3L health utility scores using a published utility algorithm for the UK population, as recommended by NICE [17]. For the baseline measurement, patients will be asked to recall their pre-injury health state.

Return to work

The Work Productivity and Activity Impairment: Specific Health Problem (WPAI) is a validated instrument [18] that measures the impact of health and symptom severity on work productivity and non-work activities.

Complications

All potentially related complications will be recorded, including fracture displacement, non-union, malunion, infection, symptomatic deep vein thrombosis, pulmonary embolus, and unplanned return to theatre.

Resource use

NHS, social care, and personal out-of-pocket costs, including a comparison of return-to-work time between groups.

Radiological outcome

Routinely collected radiographs will be harvested. An independent adjudication committee will assess the radiographs for intra-operative mal-reduction and postoperative loss of reduction. Loss of reduction will be defined as a radiograph demonstrating any one or combination of showing talar subluxation > 2 mm (talar shift), excessive talar tilt (> 2°) or a diastasis (tibiofibular clear space ≥ 5 mm) [19].

A schedule of study procedures is included in Table 1.

We will use established techniques to ensure minimum loss to follow-up, including collecting multiple contact addresses, telephone numbers, and email addresses.

Sample size

The primary clinical outcome is OMAS at four months post-randomisation [14], as function has been shown to improve quickly in the first three months from surgery, improve little between three and six months and plateau thereafter [20]. Previous studies have demonstrated a minimally clinical important difference of 10 points for this instrument [11, 14] which is in accordance with expert opinion (for scales scoring 0-100) and statistical convention [21]. We have selected a standard deviation (SD) of 21.1 based on the largest published RCT reporting OMAS within six months for operatively treated ankle fractures [11]. Assuming a baseline SD (pre-injury) of 21.1 and a non-inferiority margin of -6 points on the OMAS, based upon data from the AIM trial, [11] 392

Table 1 Schedule of study procedures

	Screening -14 days	Enrolment Day 0	4 weeks (± 2 weeks)	6 weeks (+- 2 weeks)	4 months (±8 weeks)	12 months (±8 weeks)
Enrolment						
Eligibility assessment	X	X				
Informed consent		X				
Allocation		X				
Interventions						
Early weight bearing		X				
Delayed weight bearing		X				
Baseline characteristics						
Demographics		X				
Educational attainment		X				
Work status		X				
Tampa scale for Kinesphobia		X				
Self-efficacy report		X				
Modified Charlson Comorbidity Index		X				
Index of Multiple Deprivations		X				
Residential status		X				
Discharge destination		X				
Assessments						
OMAS / EQ-5D-5L		X		X	X	X
Complications		X	X	X	X	X
Weight-bearing diary			X			
Physiotherapy input				X	X	X
Resource use				X	X	X
Qualitative interviews				X		

participants providing data at four months (196 per arm) will provide 80% power and 2.5% (1-sided) significance. Allowing for 10% loss to follow-up (4.4% at six months in the AIM trial) [11] this yields an overall minimum target of 436 participants (218 per arm). If early weight-bearing is found to be non-inferior to delayed weight-bearing then superiority will also be tested at 2.5% (1-sided) significance.

Study within a trial

A Study Within a Trial (SWAT) will investigate the generalisability, acceptability and mechanism of action of the trial interventions using CRFs, enhanced screening Logs, and patient and staff interviews at six weeks post-randomisation. Recruitment for the semi-structured interviews and discussion workshops will occur alongside the initial WAX trial consent discussion. The SWAT will be published separately, and a protocol is available in the supplementary materials (Additional file 2).

Analysis

Statistical analysis

A separate Statistical Analysis Plan (SAP) complete with full details of the statistical analyses planned for this study will be drafted and finalised prior to the primary outcome analysis.

Non-inferiority trials assess whether an intervention is not clinically worse than a control, and therefore the interest is one-sided. The OMAS score at four months post-randomisation is the primary outcome in this study and we have defined a non-inferiority margin (ΔT) of -6 points, which is the maximum difference we are prepared to tolerate and still consider early weight-bearing not to be clinically inferior to delayed weight-bearing. The null hypothesis is therefore that a difference of greater than ΔT exists in favour of delayed weight-bearing ($H0: \Delta \leq -\Delta T$). This will be assessed by creating a 95% confidence interval (95% CI), which should be entirely above the non-inferiority margin for the intervention to be declared non-inferior. As well as assessing if

non-inferiority (and superiority) is demonstrated, sensitivity analyses will be undertaken to assess a range of potential biases that could have resulted from loss-to-follow-up, protocol deviations, withdrawal (including mortality).

The result of the analysis for the primary endpoint should be one of the following:

- The 95% CI lies entirely above the non-inferiority margin ($-\Delta_T$), so that non-inferiority may be concluded with only a small probability of error.
- The 95% CI includes points below the non-inferiority margin, then there is a possibility that the intervention is inferior to the control and non-inferiority cannot be safely concluded.
- The 95% CI is entirely above zero, indicative of a treatment effect, then superiority of the intervention can be concluded within a small probability of error.
- The 95% CI is entirely below the non-inferiority margin, indicative that the intervention is clinically inferior to the control.

All analyses will be carried out on the intention-to-treat (ITT) population and repeated for the per protocol population. Non-inferiority will be concluded only if both analyses show non-inferiority. This is due to the potential conservative nature of applying the ITT analysis only in a non-inferiority trial. A per-protocol analysis could introduce bias into the treatment comparison if there are differential numbers of protocol deviations in the different arms. Therefore, we will also undertake a Complier Average Causal Effect analysis which essentially compares the "compliers" in each group and is therefore randomisation preserving. This is therefore less prone to bias than a per-protocol analysis, although if the number of non-compliers is high this may affect the interpretation as the power is reduced for smaller subgroups (the compliers).

The OMAS score will be compared between treatment groups as the dependent variable in a mixed-effects linear regression model for the primary analysis with adjustments for stratification factors and baseline (pre-injury) OMAS score. A random effect will be included to account for any heterogeneity in the response due to recruitment centre. Fixed effects will be included to adjust for participant age and gender. The treatment difference will be based on the estimate of adjusted means and 95% confidence intervals.

Secondary clinical outcomes will be analysed using mixed effects regression, using logistic regression for binary data and linear regression for continuous data. Supplementary analyses to explore the recovery trajectory between the two treatments will be conducted for the OMAS score using the area under the curve summary statistics [14, 22].

Health economics evaluation

A prospective economic evaluation, conducted from an NHS and personal social services perspective, will be integrated into the trial design. The economic evaluation will estimate the difference in the cost of resource inputs used by participants in the two arms of the trial, allowing comparisons to be made between the two weight-bearing strategies following ankle fracture fixation and enabling costs and consequences to be compared. The economic assessment method will, as far as possible, adhere to the recommendations of the National Institute for Health and Care Excellence (NICE) Reference Case.

Primary research methods will be followed to estimate the costs of the treatment options, including supplementary interventions (e.g. revision surgery) and rehabilitation inputs. Broader resource utilisation will be captured through to principal sources: (1) routine health service data collection systems and (2) patient questionnaires administered at baseline, six weeks and four and 12 months post-randomisation. Unit costs for health and social care resources will largely be derived from local and national sources and estimated in line with best practice. Primary research using established accounting methods may also be required to estimate unit costs. Costs will be standardised to current prices where possible. Health-related quality of life will be measured at baseline preinjury, six weeks, four and 12 months post randomisation using the EuroQol EQ-5D-5L measure; responses will be used to generate quality-adjusted life-years (QALYs). Utility weights will be estimated using recommended algorithms until a national tariff set for the EQ-5D-5L is available. We will in the first instance use self-reports of the EQ-5D measure. Where these data are not available, we will estimate health utilities at each time point using mapping equations between the OMAS and EQ-5D health outcomes on the basis of existing datasets held by the trial team.

Multiple imputation methods will be used to impute missing data and avoid biases associated with complete case analysis. The results of the economic evaluation will be expressed in terms of incremental cost per QALY gained. We shall use non-parametric bootstrap estimation to derive 95% CIs for mean cost differences between the trial groups and to calculate 95% CIs for incremental cost-effectiveness ratios. A series of sensitivity analyses will be undertaken to explore the implications of uncertainty on the incremental cost-effectiveness ratios and to consider the broader issue of the generalisability of the study results. One such sensitivity analysis will involve adopting a societal perspective for the economic evaluation, which will incorporate direct costs to trial participants, informal care provided by family and friends and productivity losses. In the baseline analysis, and for each sensitivity analysis, cost-effectiveness acceptability curves

will be constructed using the net-benefits approach. Heterogeneity in the trial population will be explored by formulating net-benefit values for trial participants from the observed costs and effects and then constructing a regression model with an intervention variable and covariates such as age and sex. The magnitude and significance of the coefficients on the interactions between the covariates and the intervention variable will provide estimates of cost-effectiveness of the treatment options by participant subgroup.

Trial oversight

A Trial Steering Committee (TSC) and Data and Safety Monitoring Committee (DSMC) will be set up. The study DSMC will adopt a DAMOCLES charter which defines its terms of reference and operation in relation to oversight of the trial. They will not be asked to perform any formal interim analyses of effectiveness. They will, however, review accruing data, summaries of the data presented by treatment group, and will assess the screening algorithm against the eligibility criteria. They will also consider emerging evidence from other related trials or research and review related SAEs that have been reported.

This study will be conducted as part of the portfolio of trials in the registered UKCRC Oxford Clinical Trials Research Unit (OCTRU) at the University of Oxford. It will follow their Standard Operating Procedures ensuring compliance with the principles of Good Clinical Practice and the Declaration of Helsinki and any applicable regulatory requirements. The OCTRU Quality Assurance team will audit the trial at least once in the lifetime of the study, more if deemed necessary.

Dissemination

A manuscript will be submitted to a high impact peer-reviewed journal. Authorship will be determined in accordance with the International Committee of Medical Journal Editors guidelines [23] and other contributors will be acknowledged.

Discussion

The results of this study will inform national guidance with regards to the most clinically and cost-effective strategy for weight-bearing after surgery for unstable ankle fractures.

Sponsor

University of Oxford, Joint Research Office, 1st floor, Boundary Brook House Churchill Drive, Headington, OX3 7GB. ctrg@admin.ox.ac.uk. The Sponsor reviews the trial protocol and amendments before submission to REC but delegates the study design, management, analysis, interpretation of the data, report writing and decision to submit for publication to the CI and OCTRU.

Abbreviations

AE: Adverse Event; CI: Chief Investigator; CRF: Case Report Form; DSMC: Data and Safety Monitoring Committee; EQ-5D-5L: EuroQol 5 Dimensions 5L; NICE: National Institute for Health and Care Excellence; OCTRU: Oxford Clinical Trials Research Unit; OMAS: Olerud and Molander ankle score; PI: Principal Investigator; QALY: Quality Adjusted Life Year; RCT: Randomised Controlled Trial; SAE: Serious Adverse Event; SAP: Statistical Analysis Plan; SD: Standard Deviation; SWAT: Study Within a Trial; TIDiER: Template for Intervention Description and Replication; TSC: Trial Steering Committee; WAX: Weight-Bearing in Ankle Fractures; WPAI: The Work Productivity and Activity Impairment: Specific Health Problem

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12891-021-04560-7.

Additional file 1. The SPIRIT checklist with page numbers.

Additional file 2. The WAX SWAT study protocol.

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K Herbert; Trial Manager

Authors' contributions

CP Bretherton: Developed the research question, created the background section, wrote the first draft of study protocol. HA Claireaux: Wrote the first draft of study protocol and Manuscript. J Achten: Research methodology and management sections. A Athwal, Research management. SJ Dutton: Developed the research question, Research methodology and Statistical sections. N Peckham: Statistical analysis sections. S Petrou: Health economics evaluation sections. RS Kearney: Developed intervention, adherence and fidelity sections. D Appelbe: Data management sections. XL Griffin: Developed the research question, Research methodology sections. All authors read and approved the final manuscript.

Authors' information

C Bretherton, FRCS, Trauma and Orthopaedic Surgery Registrar, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK.
H Claireaux, MRCS, Honorary Research Assistant, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK.
J Achten, PhD, Research Manager, Oxford Trauma and Emergency Care, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK.
A Athwal, Senior Trial Manager, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK.
S Dutton, MSc, Senior Medical Statistician, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK.
N Peckham, MSc Medical Statistician, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK.
S Petrou, DPhil, Professor of Health Economics, Nuffield Department of Primary Care, University of Oxford, Oxford, UK.
R Kearney, PhD, Professor of Musculoskeletal Rehabilitation, University of Warwick, UK.
D Appelbe, PhD, Information Technology Specialist, Oxford Trauma and Emergency Care, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK.
X Griffin, PhD, Professor of Trauma and Orthopaedic Surgery, Division of Orthopaedics, Barts and The London School of Medicine and Dentistry, Queen Mary University of London, London, UK.

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Availability of data and materials
Not applicable.

Declarations

Ethics approval and consent to participate
National Research Ethics Committee: South Central- Oxford A- Health Research Authority approved this study on the 22 November 2019 reference number 19/SC/0566 (Current protocol version: 3.0 approved 29 March 2021). Amendments to the trial protocol will be submitted to the sponsor and REC for approval and disseminated to relevant parties. All participants will provide written electronic consent. Once completed, a PDF of the signed consent form will be automatically emailed to the participant and a copy available for download and placing in the participant's medical notes by the local research team.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

Author details
[1]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK. [2]Nuffield Department of Primary Care, University of Oxford, Oxford, UK. [3]Department of Musculoskeletal Rehabilitation, University of Warwick, Coventry, UK. [4]Trauma and Orthopaedic Surgery, Division of Orthopaedics, Barts and The London School of Medicine and Dentistry, Queen Mary University of London, London, UK.

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H.2 The WAX SWAT (RAAFT) protocol

WAX Study Within A Trial (SWAT) Protocol:

Rehabilitation After Ankle Fracture Treatment (RAAFT): Facilitating safe weight-bearing after ankle fracture surgery

CP Bretherton, H Sandhu, J Baird, XL Griffin

INTRODUCTION

The Weight-bearing in Ankle Fractures (WAX) trial is an NIHR Research for Patient Benefit (RfPB) study that will randomise patients to weight-bear early (at two-weeks postoperatively) or wait till six weeks postoperatively, which is the current standard of care.[1,2] It will also conduct health economic analysis to determine the cost-effectiveness of the two weight-bearing strategies.

Recent qualitative studies have highlighted the burden for patients having to endure a period of non-weight bearing.[3,4] While they often report difficulty with non-weight-bearing, it is not known how patients respond once permitted to weight-bear. Even if instructed to weight-bear, many patients are wary of pain, falls and reinjury and so avoid walking on their ankle for several weeks.[4]

We do not know how patients decide what is an acceptable level of discomfort when starting to weight-bear (whether this is undertaken early or late) or how they decide to stop using their post-operative splints or walking aids. There is little guidance for clinicians on advising patients and no rehabilitation package for patients themselves.

An intervention to encourage weight-bearing would be considered a "complex intervention".[5] This is because techniques to change weight-bearing behaviour would include several interacting components, which may be related to those delivering (healthcare professionals) and those receiving the intervention (patients).[5] Behaviour change theory has been used to design and evaluate similarly complex rehabilitation interventions in chronic musculoskeletal conditions.[6] This framework allows the linkage of determinants of behaviour (e.g. pain beliefs or resource availability) to behaviour change techniques, which can be used to develop an intervention.[7]

We therefore propose:

Co-production of a rehabilitation package to facilitate safe weight-bearing after ankle fracture surgery based on the behaviour change wheel.

STUDY DESIGN

This Study Within a Trial (SWAT) has three work packages:

1) An embedded exploratory study investigating the impact of adverse pain beliefs in patients with surgically managed ankle fracture.

2) Conduct an analysis of interviews of patients and healthcare professionals participating in the WAX trial. This analysis will investigate patients' experience of pain, recovery and commencing weight-bearing.

3) Co-design a rehabilitation package to facilitate weight-bearing after ankle fracture surgery, based on the behaviour change wheel. This will be through a series of workshops with healthcare professionals and patients.

METHODOLOGY

Study Participants

- Patients having undergone operative fixation of an unstable ankle fracture that have been approached to take part in the WAX trial

- Healthcare professionals that have been involved in the WAX trial.

Recruitment

Recruitment will be embedded in the WAX trial recruitment process.

Separate consent forms allow patients who decline participation in the WAX trial to be invited for interviews and workshops to ensure the qualitative study is maximally representative of an ankle fracture population

Additionally, patients, carers and healthcare professionals will be recruited through professional and charitable societies including Arbeitsgemeinschaft für Osteosynthesefragen (AO)UK, the Orthopaedic Trauma Society and through local Patient and Public Involvement (PPI) networks and those of existing patient representatives.

Consent

As part of the initial consent discussion for the WAX trial, patients will be asked whether they may be approached about participating in interviews and workshops. Prior to interview, participants will receive written and verbal information about participating in an interview. Participants who agree to be approached will have a separate informed consent discussion for the interviews with a member of the research team either in person, or by phone. NHS staff will initially be invited to interview by phone or email, and if they agree to be approached, an informed consent discussion will take place with a researcher from the WAX office by phone, videocall or in person.

SWAT PROCEDURES

The study will follow the Medical Research Council framework for developing and evaluating complex interventions[5]:

- Identify the evidence base (Completed pre-RAAFT)
- Identify/ develop theory (work package 1 and 2)
- Model process/ outcomes (work package 3)

Work package 1: An embedded exploratory study investigating the impact of adverse pain beliefs

<u>Baseline characteristics and variables for linear regression models:</u>

Additional patient characteristics are embedded into the baseline demographic data collection in the WAX trial. They include:

- Educational attainment
- The Charlson comorbidity index
- The Index of Multiple Deprivations (IMD)

Two short questionnaires will explore participants' pain beliefs:

Fear of movement: The Tampa Scale for Kinesiophobia -11 is a brief, reliable, and valid measure of fear of movement/(re)injury for patients with chronic painful conditions.[8]

Pain self-efficacy: The pain self-efficacy questionnaire-2 is a validated, abbreviated measure of an individual's confidence in their ability to accomplish tasks, overcome problems and live a normal life despite pain.[9]

The other predictor variables already collected as part of the WAX trial include age, gender, occupation (sedentary vs manual labour), injury mechanism and blinded weight-bearing allocation.

Outcome Measurements

The primary outcome measure for the exploratory analysis is the Olerud and Molander Ankle Score (OMAS) measured at 4 months post-randomisation. It is a reliable and valid ankle-specific patient-reported outcome measure used in several other ankle fracture studies. [10–12,13].

The secondary outcome measures are Health-related quality-of-life (EQ-5D-5L) and Adverse events (AEs).

Sample size/ available data:

The sample size for the WAX trial is 436 patients, with a predicted 10% loss to follow-up rate. With 10 predictor variables, 80% power and a significance level of 0.05, the regression model would be able to detect and account for 4% of the variability in OMAS at 4 months (F^2=0.042 = R^2=0.040; calculations performed using G*Power3.1.9.4). This R^2 is much lower than the expected adjusted R^2 based on previous studies.[14,15]

Work package 2: Qualitative interviews

Semi-structured interviews with patients

Participants' experiences of treatment and barriers and facilitators to commencing weight-bearing after ankle fracture surgery will be explored. Participants will be invited to take part in an interview at around 8 weeks after their surgery. Interviews will be up to 60 minutes and conducted by telephone or videocall. All interviews will be audio-recorded, anonymised and transcribed verbatim. Interviews will be semi-structured and use a brief, flexible topic guide.

Maximum variation sampling strategy to ensure the spread of patient characteristics by age (age over or under 60), and pain self-efficacy (scores higher or lower than eight based on mean results from previous studies[14,15]). Participant interviews will continue until data saturation is achieved. Based on a previous study, it is estimated data saturation will be achieved in around 25-30 interviews. [4]

Semi-structured Interviews with surgeons and healthcare professionals

25-30 Healthcare professionals, including surgeons, physiotherapists and research nurses will be sampled to reflect the multidisciplinary care team delivering care and research interventions to patients after ankle fracture. They will be invited to an interview to discuss their perceptions of how patients make sense of current weight-bearing instructions and any common difficulties they express.

Work package 3: Iterative co-design of a rehabilitation package to facilitate safe weight-bearing

Informed by work package 1 and 2, a rehabilitation strategy will be co-designed, using the three phases of the Behaviour Change Wheel (BCW). This technique is informed by extensive theory and has been used to design and implement rehabilitation interventions.[7] The three phases are:

1. ***Understand the behaviour*** by assessing participants' capability, opportunity and motivation (COM-B) to engage with the behaviour (weight-bearing). These will be derived from the qualitative interviews. These will then be mapped to the 9 intervention functions of the Behaviour Change Wheel.[7] A set of candidate behavioural change intervention bundles will then be generated.

2. ***Understand intervention options*** using the APEASE (affordability, practicability, effectiveness/ cost-effectiveness, acceptability, safety/ side effects and equity) criteria.[16]

Workshop 1. The formulated behaviour change intervention bundles (likely 3-5 options) will be presented to a workshop of 7-12 patients and carers. A maximum variation sample of patients from different demographic and socio-economic backgrounds will be recruited.

Workshop 2. The intervention bundles (likely 2-3 refined from workshop 1) will be presented to surgeons, physiotherapists and other healthcare professionals (7-12 in total).

Nominal Group Technique will be used to structure the discussions and prioritise the intervention bundles.

3. ***Understand the content and implementation options*** using the Template for Intervention Description and Replication (TiDieR) checklist.[17]

The 1-2 intervention bundles prioritised from workshops 1-2 will be explored. Candidate behavioural change techniques (BCTs) derived from the BCT Taxonomy v1 (BCTTv1)[18] will be selected and incorporated into the intervention bundles.

Workshop 3. All stakeholders from workshops 1 and 2 will be invited to a combined workshop to discuss the selected 1-2 intervention bundles. Using the TiDieR checklist, we will discuss the where, when, how and by whom the interventions could be delivered.

The techniques will be refined to formulate a coherent rehabilitation package. Stakeholders that consent to further contact will be invited to contribute and comment on this process.

Workshops will be conducted face-to-face, virtually via videoconference, or a combination of both. The workshop frequency, duration and format may be amended to cater for participants preferences and availability according to social distancing guidelines in place at the time.

Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw from the study at any time. All workshops will be audio-record, transcribed and anonymised. If a participant of the workshop meeting withdraws then it may not be possible to withdraw their data as well as it will constitute a part of the flow of workshops and removing it will leave subsequent elements of the discussion out of context.

ANALYSIS

Work package 1: Exploratory Analysis

Standard descriptive summaries for patient baseline characteristics and outcome values will be reported. Multiple imputation methods will be used to impute missing data using missing at random assumptions.[19] To test whether the candidate variables are predictors of outcome, univariate linear regression model analyses for continuous outcomes and logistic regression for binary outcomes will be used. Variables significantly associated with outcomes will be entered into multiple regression models. Three models will be generated with OMAS, EQ5D5L and adverse

events as the dependent variable and pre-injury values of the outcome measure and candidate predictors will be entered as independent variables.

Work package 2: Qualitative Interviews

Qualitative data will be managed using NVIVO 12. Framework analysis will be conducted, deductively coding interview responses into COM-B domains and then inductively generating summary themes from similar responses within domains.[20] A second researcher will double-code a sub-sample of transcripts to assess COM-B coding reliability. Themes will be discussed and verified during analysis with a multi-disciplinary healthcare group, with data saturation occurring when we agree that no new elements are arising from the data. Findings will be reported using the Consolidated Criteria for Reporting Qualitative Research (COREQ) guidelines.[21]

Work package 3: Iterative co-design of a rehabilitation package to facilitate safe weight-bearing

Themes from work-package 1 will be mapped onto the COM-B components of the Behaviour Change Wheel, which provides a structured, validated framework for describing behavioural interventions in healthcare.[7] Where further granularity is required, the 14 domains of the Theoretical Domains Framework will be used to map the themes onto the BCW.[20]

Mapping matrices will be used to identify target interventions functions and Behaviour Change Techniques (BCT's) that correspond to the behavioural barriers and facilitators to weight-bearing identified from work-package 1. Behavioural intervention bundles will be synthesised and prioritised based on the results of an on-going systematic review of BCT's in lower limb fracture rehabilitation. These will then be presented to stakeholders and refined at the workshops described in work-package 2, using the APEASE and TiDier criteria.

This will produce a novel, co-designed, flexible rehabilitation package to facilitate safe weight-bearing after ankle fracture surgery.

The content of the rehabilitation package will determine the next steps:

If the outcome is a combination of simple behavioural adjuncts to routine advice, these will be offered as part of the WAX trial dissemination plan. An example might be a short explanation video or a set of prompts to give to healthcare professionals delivering weight-bearing advice.

If the outcome selected is a new therapeutic intervention, further funding will be sought to test this. An example might be an online App or peer support forum.

QUALITY ASSURANCE PROCEDURES

This research project forms the body of the Lead Investigators DPhil project being undertaken at the University of Oxford. The project will be subject to regular supervision and management review by the named DPhil supervisors in this protocol. In addition, the study may be monitored, or audited in accordance with Good Clinical Practice, relevant regulations and standard operating procedures.

ETHICAL AND REGULATORY CONSIDERATIONS

National Research ethic Committee approved this study on the 23 March 2021 reference number 19/SC/0566.

PUBLICATION POLICY

The study report will be prepared and published separately to the WAX trial. Investigators will be involved in reviewing drafts of manuscripts, abstracts, press releases and any other publications arising from the study. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. No patient identifiable information will be contained in any form of dissemination of study results.

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