Effectiveness of supervised versus self-directed rehabilitation for adults aged 50 years and over with ankle fractures: protocol for the AFTER trial

From University of Oxford, Oxford, UK

Correspondence should be sent to D. J. Keene d.keene@exeter.ac.uk

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D. J. Keene,[1,2] J. Achten,[1] C. Forde,[1] M. E. Png,[3] R. Grant,[4] K. Draper,[1] D. Appelbe,[1] E. Tutton,[1] N. Peckham,[1] S. J. Dutton,[1] S. E. Lamb,[2] M. L. Costa[1]

[1]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK
[2]Exeter Medical School, University of Exeter, Exeter, UK
[3]Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK
[4]Patient and Public Involvement Member, Coventry, UK

Aims

Ankle fractures are common, mainly affecting adults aged 50 years and over. To aid recovery, some patients are referred to physiotherapy, but referral patterns vary, likely due to uncertainty about the effectiveness of this supervised rehabilitation approach. To inform clinical practice, this study will evaluate the effectiveness of supervised versus self-directed rehabilitation in improving ankle function for older adults with ankle fractures.

Methods

This will be a multicentre, parallel-group, individually randomized controlled superiority trial. We aim to recruit 344 participants aged 50 years and older with an ankle fracture treated surgically or non-surgically from at least 20 NHS hospitals. Participants will be randomized 1:1 using a web-based service to supervised rehabilitation (four to six one-to-one physiotherapy sessions of tailored advice and prescribed home exercise over three months), or self-directed rehabilitation (provision of advice and exercise materials that participants will use to manage their recovery independently). The primary outcome is participant-reported ankle-related symptoms and function six months after randomization, measured by the Olerud and Molander Ankle Score. Secondary outcomes at two, four, and six months measure health-related quality of life, pain, physical function, self-efficacy, exercise adherence, complications, and resource use. Due to the nature of the interventions, participants and intervention providers will be unblinded to treatment allocation.

Conclusion

This study will assess whether supervised rehabilitation is more effective than self-directed rehabilitation for adults aged 50 years and older after ankle fracture. The results will provide evidence to guide clinical practice. At the time of submission, the trial is currently completing recruitment, and follow-up will be completed in 2024.

Take home message

- The AFTER study is a multicentre, superiority randomized controlled trial comparing supervised versus self-directed rehabilitation for adults aged 50 years and over with ankle fractures.
- The results will inform updates to clinical guidelines and support clinical decision-making in ankle fracture management.

Introduction

Ankle fractures are very common, accounting for 9% of all fractures managed in secondary

care.[1] In the UK, incidence of these fractures is highest in adults aged 50 years and over, peaking at 16 per 10,000 person-years in females aged 60 to 70 years.[2] As the population ages, a three-fold increase in these fractures is projected over the next two decades.[3] The mechanism of injury for adults aged over 50 years is usually a fall from standing height; the fracture is then defined as a fragility fracture.[4]

Treatments for ankle fractures range from conservative plaster casts or boots to surgical fixation. Our recent National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA)-funded trial including adults aged 60 years and over found that, regardless of the initial fracture management, post-injury reduced ankle function and walking abnormalities remain at six months post-injury.[5,6] Participants reported an average 30% loss of pre-injury ankle function. Function is poor due to pain, reduced joint motion,[7] lower limb muscle strength deficits,[8] gait abnormalities,[9] and resultant mobility limitations.[7,10]

Weightbearing and ankle movement restrictions are usually lifted by the orthopaedic team six weeks after injury. At this stage, national guidance is that patients should be given advice on simple exercises and gradually resuming usual activities.[11] Advice is provided face-to-face in a fracture clinic and is sometimes supplemented with an information booklet.

Data from 24 UK hospitals indicated that, in addition to this advice, about two-thirds of patients were referred to see a physiotherapist in an outpatient clinic for supervised rehabilitation.[5] Referral patterns varied both within and between hospitals; at some centres, few patients were referred, while at others the majority receive four to six sessions of physiotherapy over several months.[5] The variation reflects that referrals are currently being made based on local practice or clinical opinion due to a lack of robust evidence to inform national guidance.

A James Lind Priority Setting Partnership on lower limb fragility fractures ranked, "What is the best physiotherapy and/or occupational therapy regime for adults during out-of-hospital recovery from a fragility fracture of the lower limb?" as second in the top ten priorities, highlighting the importance of this research to clinicians, patients and carers.[12] Ankle fractures have a substantial impact on people's lives, resulting in mobility problems and reduced independence, and the prognosis worsens with increasing age.[13] It is uncertain why people fare worse as they age, but lower physiological reserves, comorbidities, reduced muscle mass and power (sarcopenia), and balance impairments are likely to contribute.[14] The resultant disability after injury has a significant associated socioeconomic burden, impacting on an individual's capacity to work, care for others, and perform daily activities.[5]

Physiotherapy after ankle fracture aims to support patients during the recovery period and provide individualized progressive exercise to improve muscle strength, range of motion, gait, and balance. However, as physiotherapy is not without patient and health service burden and costs, it is important that the clinical and cost-effectiveness of physiotherapy-supervised rehabilitation is compared with good quality self-management advice. If superiority of physiotherapy is not demonstrated, this would support disinvestment in routine physiotherapy in this population, and support widespread implementation of a standardized self-directed rehabilitation intervention.

A Cochrane review in 2012 of ankle fracture rehabilitation concluded that there was insufficient evidence regarding physiotherapy after ankle fracture.[15] Our updated searches identified just one new study, the EXACT trial (n = 213),[16] which reported no differences in lower limb function between supervised exercise and one-off advice for adults with ankle fractures. While this trial certainly adds to the body of evidence in this area of research, the vast majority of patients (> 70%) were aged younger than 50 years, and in the group allocated to basic advice, about 36% sought additional out-of-trial physiotherapy. In the proposed study, we will focus on patients aged 50 years and over to allow clinical practice in this patient population to be informed by appropriate evidence. In adults aged 50 years and over, experience of losing confidence and fear of future injuries are common after ankle fracture.[5,6] There is also good evidence that progressive exercise reduces risk of falls in other clinical populations.[17] A tailored progressive exercise intervention supervised by a physiotherapist therefore has the potential to improve recovery in this older group, where rehabilitation needs are often more complex.

We have conducted a feasibility randomized controlled trial (RCT) that informed the design of this definitive trial.[18] We have conducted a programme of research with stakeholders from clinical practice, research, and patient and public involvement (PPI) representatives from the UK Musculoskeletal Trauma PPI group to optimize a physiotherapist-supervised rehabilitation intervention and self-directed rehabilitation intervention. Both of these interventions fit within the range of care pathways currently offered, but there is hospital-to-hospital variation. The intervention content has been refined and standardized during the feasibility RCT to enable evaluation and implementation across the NHS. This study will assess which of these approaches is most clinically and cost-effective for patients and the NHS. In the feasibility study, there were lower completion rates for secondary physical outcome measures compared to patient-reported outcomes (including the primary outcome of patient-reported ankle function). Given the greater extent of missing outcome data and the extra clinical and participant burden, and the context of trying to reduce hospital visits following the COVID-19 pandemic, use of remote follow-up with questionnaires is considered important for this definitive RCT.

Objectives

The aim of this pragmatic, parallel-group, randomized controlled superiority trial is to evaluate the clinical and cost-effectiveness of supervised versus self-directed rehabilitation in improving ankle function for adults aged 50 years and over with ankle fractures.

Primary objective

The primary objective is to quantify and draw inferences on differences in ankle function at six months post-randomization between the trial intervention groups (supervised vs self-directed rehabilitation).

Secondary objectives

The secondary objectives are to quantify and draw inferences on differences in: ankle function at two and four months; ankle

Table I. Assessments performed to enable delivery of objectives.

Outcome	Objective	Instrument	Timepoint
Primary	Ankle function	OMAS	6 months
Secondary	Ankle function	OMAS	Baseline, 2, and 4 months
	Health-related quality of life	EQ-5D-5L	Baseline, 2, 4, and 6 months
	Pain	Pain sub-scales of the EQ-5D-5L and OMAS	Baseline, 2, 4, and 6 months
	Physical function	PROMIS Physical Function	Baseline, 4, and 6 months
	Self-efficacy	Self-Efficacy Exercise Score	Baseline, 4, and 6 months
	Exercise adherence	Self-reported exercise frequency	2, 4, and 6 months
	Complications	Complications questionnaire and case report form	2, 4, and 6 months
	Cost effectiveness	Health economics questionnaire	2 and 6 months

EQ-5D-5L, EuroQol five-dimension five-level questionnaire; OMAS, Olerud and Molander Ankle Score; PROMIS, Patient-Reported Outcome Measurement Information System.

pain at two, four, and six months; health-related quality of life (HRQoL) at two, four, and six months; physical function at four and six months; self-efficacy to exercise at four and six months; exercise adherence at two, four, and six months; risk of related complications over the initial six months; and cost-effectiveness of the interventions at two and six months. Assessments to be performed are outline in Table I.

Outcome measures

Primary outcome

Patient-reported ankle-related symptoms and function at six months after randomization measured by completion of the Olerud and Molander Ankle Score (OMAS).[19] The OMAS is a nine-item questionnaire that is completed directly by the participant (0 to 100, with higher scores indicating better function). The OMAS has been validated as a measure of ankle function after ankle fracture,[20] and is the primary outcome for a number of other ankle fracture trials, including a NIHR HTA trial.[5]

Secondary outcomes

Health-related quality of life is assessed using the EuroQol five-dimension five-level (EQ-5D-5L) questionnaire.[21] The EQ-5D-5L is a validated, generalized, and standardized instrument comprising a visual analogue score (VAS) measuring self-rated health and a health status instrument, consisting of a five-level response for five domains related to daily activities: mobility, self-care, usual activities, pain and discomfort, and anxiety and depression. Responses to the health status classification system are converted into an overall score using a published utility algorithm for the UK population. The EQ-5D health status scale ranges from negative scores reflecting a patient's quality of life being worse than death, ranging from 0 (death) to 1 (perfect health). A respondent's EQ-VAS gives self-rated health on a scale where the endpoints are labelled 'best imaginable health state' (100) and 'worst imaginable health state' (0).

Pain is assessed using the sub-scales of the OMAS and EQ-5D-5L.

Physical function is assessed using Patient-Reported Outcome Measurement Information System (PROMIS) Physical Function.[22] PROMIS questionnaires are administered electronically, via a computer adaptive test (CAT), which are dynamic tests based on item response theory (IRT). A mathematical model adapts the sequential questions asked based on a participant's previous response. A tailored set of questions is therefore asked from a large item pool. Participants are typically asked four to six questions. PROMIS instruments are scored from 0 to 100, with 50 points representing the mean score for the USA general population. Higher scores indicate better function. Participants who have not completed the online questionnaire or who have no internet access will be able to complete a paper-based version of the PROMIS questionnaire with four items (PROMIS Physical Function short form 4a) via postal follow-up. If a participant needs to be contacted directly by phone to complete their follow-up, they will be asked the PROMIS Physical Function CAT questionnaire as the central site team can directly enter patient responses on their behalf.

Self-efficacy is assessed using the Self-Efficacy Exercise Score.[23] The score measures a participant's judgment of their confidence to carry out exercise. The questionnaire has nine items specifically about the ability to continue to exercise despite barriers. The participant scores their confidence level from 0 (not confident) to 10 (very confident), if they were to exercise three times per week for 20 minutes during each of the nine situations presented. The overall scores range 0 to 90, with higher scores indicating greater confidence to exercise. Meanwhile, exercise adherence is assessed using patient-reported exercise frequency.

For complications, fracture and treatment complications will be recorded, but particular note will be made of complications related to the interventions (see Safety Reporting section).

Patient-reported resource use and information on hospital treatments and appointments will be collected. This will include consultations with primary and secondary care, prescribed and over-the-counter pain medication use, additional physiotherapy and hospital admission, self-funded health and social care, out-of-pocket expenses, and work absence.

Study design

AFTER (Ankle Fracture Treatment: Enhancing Rehabilitation) is a multicentre, parallel-group, superiority individually RCT assessing the clinical effectiveness of supervised versus self-directed rehabilitation in improving ankle function for adults aged 50 years and over after an ankle fracture. The trial will be conducted at secondary care trauma departments in a minimum of 20 NHS hospitals and their related physiotherapy services. Participant flow through the study is presented in Figure 1.

Participant identification

Inclusion criteria

The inclusion criteria for the trial are if the patient is aged 50 years and over with an ankle fracture undergoing surgical fixation or non-surgical management; has been provided with a cast or orthotic boot (non-removable or removable for non-weightbearing ankle movement) for at least four weeks and no longer than ten weeks; and is able and willing to give informed consent for participation in the study within 14 days of removal of the cast/boot.

Exclusion criteria

The patient may not enter the study if any of the following apply: patient is deemed unable to adhere to trial procedures or complete questionnaires; is not ambulatory before the injury; and has contraindications to participation in an exercise programme.

Protocol procedures

Recruitment

Recruitment centres will be chosen from our existing network of over 100 research active sites, based on track records with regards to efficiency of governance approvals, communication with central research teams, predicted recruitment numbers, and representation of diverse geographical regions, hospital sizes, and sociodemographic characteristics. An invitation pack, which includes a site feasibility questionnaire (SFQ), will be provided to potential sites. The SFQ may be completed by an individual with adequate, authoritative knowledge of the site (where a site is known to the study office through previous research enterprises the SFQ may be part-completed in advance). The principal investigator (PI) or an appropriate deputy must confirm participation and the accuracy of any SFQ submitted to the central trial team in Oxford.

The central trial team will evaluate returned SFQs to ensure a site is equipped with appropriate resources to deliver the project and meet recruitment targets. Confirmation of collaboration will be provided in writing to the PI.

A conservative recruitment rate of 1.4 patients per centre per month has been based on screening and recruitment data collected during our feasibility trial, as well as experience from other trials in the area of orthopaedic trauma.

Screening and eligibility assessment

Potentially eligible patients will be identified by the clinical teams in the emergency department/minor injuries unit or via inpatient, virtual, or outpatient trauma and orthopaedic clinics. A participant information sheet (PIS) will be provided. The PIS will contain a link to the study website that will host a study explainer animation. The initial approach and provision of the PIS will be at any timepoint from initial presentation to hospital up to and including the clinic review when the cast/boot is no longer recommended when weightbearing. Experience from the AFTER feasibility study indicated that flexibility in when the first approach occurs to fit local clinical and research pathways is critical to successful recruitment. Patients that are happy to be consulted about participation in the study will be approached in the clinical setting. The local research team will approach the patient in person in a clinic or via telephone or video call to discuss the trial.

Eligibility will then need to be confirmed by a member of the clinical team at the clinical appointment where the cast/boot is being discontinued, prior to randomization. This is usually six weeks (and a minimum of four weeks) after initial surgical/non-surgical fracture management.

Screening logs will record patients' age, sex at birth, ethnicity, index of multiple deprivation, and initial fracture management (surgical or non-surgical), and if provided, the reasons for declining participation. This will determine the demographics and number of patients assessed for eligibility and reasons for exclusion and should demonstrate that the study is accessible to all. In addition, the number of patients eligible, approached, missed, and recruited, and the number of patients who decline consent or withdraw will be recorded.

Informed consent

As this is an intervention requiring active self-management, following advice and instructions, and use of written materials, all participants will be required to have capacity to consent to participation and sufficient cognitive function to manage a self-guided exercise programme.

A member of the responsible clinical team will briefly highlight the study to the patient and introduce a member of the local research team. They will approach the patient and explain the trial, as described above. The local research team will also be able to answer any additional questions that the patient might have. In order to standardize the information provided to the patients, online and written recruitment materials will be made available to local research teams, including a short video detailing the study.

After eligibility has been confirmed by the clinical team at the clinical appointment where the cast/boot is removed, interested patients will then have a discussion with a member of the local research team. It is anticipated that most patients will be approached about consenting to study participation at the fracture clinic appointment but, as per the eligibility criteria, consent and randomization can proceed if the patient has been informed by the orthopaedic team within the last 14 days that a cast/boot is no longer needed while weightbearing.

The informed consent discussion may either be in person or via telephone/video call, in accordance with the local recruitment centre policy. If happy to proceed, the patient will provide their consent using the latest approved version of the electronic informed consent form (ICF) prior to any study related procedures or data being collected. Alternatively, if face-to-face consent is not feasible, consent will be recorded by a member of the local team on an online verbal ICF during the informed consent video/telephone call. A copy of the completed online or verbal ICF will be given to participants.

Fig. 1
Participant flow through the study.

Patients will be given as much time as possible to consider the information and discuss it with relatives/carers. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal. The person who obtained the consent must be suitably qualified and experienced and have been delegated to do so by the PI and listed to take consent on the study delegation log. Permission from the participants will also be obtained to inform their general practitioner (GP) of their inclusion in the study. If the participant has an email address, an electronic version of the signed ICF will be automatically emailed to them. If the participant does not have access to an email address the local team will be able to print a copy of the signed ICF and provide this to the participant. The local research team will also store a further copy in the participants' medical notes.

Randomization

Randomization will occur after eligibility has been confirmed by the clinical team at the clinical appointment where the cast/boot is removed and when informed consent for trial participation has been provided. Participants will be randomized by the local research team using a web-based service. Participants will be randomized at the stage they have weightbearing and movement restrictions outside of a cast or boot lifted at approximately six weeks (and no earlier than four weeks) after injury/surgery, and eligibility has been confirmed, consent received, and baseline data completed.

The randomization will be on a 1:1 basis to supervised versus self-directed rehabilitation, using a validated computer randomization programme managed through a secure (encrypted) web-based service by the Oxford Clinical Trials Research Unit (OCTRU). Randomization will use a minimization algorithm to ensure balanced allocation across the two treatment groups, stratified by centre and initial fracture management (surgical vs non-surgical). The first few participants will be randomized by simple randomization to seed the minimisation algorithm and a probabilistic element introduced to the algorithm to ensure the unpredictability of intervention allocation.

On randomization of a participant, the central trial office, main site contact, and local study team will be notified. This will take place via an automated email as part of the randomization process.

Blinding and code-breaking

The patient-reported outcome data will be collected from participants remotely via self-reported questionnaires. It will not be possible to blind participants or those delivering the interventions. The local research team reviewing hospital records will also not be blind to the treatment allocation.

Description of study intervention, comparators, and study procedures (clinical)

After randomization, the trial interventions will be delivered from the timepoint when the participant's weightbearing and ankle movement restrictions outside of a cast or boot are lifted by the orthopaedic team, typically six weeks (and no earlier than four weeks) after injury/surgery, regardless of the initial treatment of the fracture (surgical or non-surgical).

Self-directed rehabilitation

Self-directed rehabilitation is the provision of standardized high-quality detailed advice on self-management and a set of exercises that can be progressed independently by the participant in the following months of recovery. The advice materials will be provided by a healthcare professional during the fracture clinic appointment. The advice will be accessible in paper format, as well as online with additional instruction videos. Commonly used simple methods to support exercise adherence will be used, including goal setting and provision of an exercise diary.[24]

Supervised rehabilitation

Participants randomized to supervised rehabilitation will also receive a study advice booklet, available in paper or online format from the fracture clinic. It will contain key information on early recovery after removal of the cast/boot and basic initial exercises that they can start ahead of seeing a physiotherapist. They will be referred to see a physiotherapist, which is the most common current standard of care. Participants will have four to six one-to-one sessions with a physiotherapist, spread over three months from the initial session. This period allows sufficient time for neuromuscular adaptation to exercise.[25] The first session will be as soon as possible after the referral, and no later than three weeks from randomization. The first session will be up to 60 minutes and follow-up sessions up to 30 minutes. This volume of physiotherapy can be delivered within NHS commissioning paradigms of four to six sessions in an outpatient physiotherapy department. We have previously used similar intensity of physiotherapy to enhance implementation into the NHS to good effect in other trials.[26,27] Sessions will be delivered via face-to-face or via telephone/videoconference, whichever mode of physiotherapy delivery would usually be provided for the patient.

Therapists will support participants with a progressive exercise programme focusing on recovery of movement, muscle strength, balance, and gait training, and ensure access to exercise programme supporting materials. The exercise programme, refined during our feasibility work, is highly structured, but permits tailoring to enable the physiotherapist to build a programme with the participant that targets their recovery goals and increases physical activity.[28] The programme uses contemporary evidence-based guidelines on exercise volume and load to optimize the physiological response.[29] Based on the participant's functional goals, exercises are progressed to make them task-specific; for example, walking on uneven surfaces or slopes, climbing stairs, or jogging. Exercise progression will be individualized by progressing and regressing the volume and load in line with each participant's capabilities and preferences. As adherence to physiotherapy advice and exercises can be poor,[30] the supervised rehabilitation intervention includes evidence-based exercise adherence strategies used successfully in previous rehabilitation trials.[26,27,31] These are integrated into exercise planning with the participant. Participants will be asked to identify their goals and, with the physiotherapist's help, write an action plan for where and when they will perform their home exercises and a contingency plan for managing difficulties. Participants receive a personal exercise guide and diary. Therapists will be trained to focus on helping participants identify barriers to exercise and becoming more physically active post-injury, and facilitating problem-solving. The therapists will offer education on how exercise and physical activity can help participants to achieve their goals, and will reassure participants about their capacity to exercise and increase their physical activity.[32] The intervention will give participants individualized feedback on their rehabilitation progress and reinforcement over the sessions, and will facilitate identification of barriers to doing the home exercise programme, which all have a strong evidence base to support their use.[28]

All physiotherapists will have online training (or face-to-face if COVID-19 restrictions allow) in the exercise protocols and equipment requirements. All physiotherapists delivering the supervised rehabilitation programme will be provided with a manual with full details of the exercise protocols and equipment requirements. Any materials (workbook, website access, exercise planner, and diary) required by the participants will be provided to the local physiotherapy teams by the central study team.

If hospital sites are unable to reach participants to book their supervised rehabilitation session, then the central trial team may send a letter, SMS text message, or email to request participants to either get in touch with their treating hospital or the central trial team to arrange this.

Concomitant care

Other aspects of health and social care will continue as normal. Records will be made of additional treatments related to their ankle fracture received by the participant. The manualized intervention delivered by physiotherapists will not be available outside of those allocated to the intervention in the trial, although usual physiotherapy care would be available for those requiring it. The use of out-of-trial physiotherapy will be captured in follow-up questionnaires and will be carefully monitored and reported. The participant's GP will be notified that they need to be aware their patient is taking part in the study, as they can also make physiotherapy referrals.

Intervention quality assurance and fidelity

All clinical staff delivering the interventions will be trained to enhance standardization of the study procedures. Sites will identify physiotherapists that will deliver the AFTER supervised rehabilitation intervention and receive the training. We will ask that the AFTER-trained physiotherapists are not involved in the rehabilitation of participants in the self-management group as far as it is practical to do so. Also, physiotherapists not trained in the AFTER supervised rehabilitation will be asked not to deliver the intervention. Although this has been feasible in other rehabilitation trials to limit potential contamination, we appreciate this can be challenging, so we will ask staff

to record where this occurs so issues can be identified and addressed during the trial.

A rigorous process of fidelity checks will be conducted to ensure fidelity of intervention delivery.[33] Treatment case report forms (CRFs) will be used to monitor intervention fidelity. Data will be collected with regard to the health professional delivering the intervention (profession, grade), the intervention content delivery, and the number of treatment sessions attended, to facilitate monitoring and reporting. If deemed necessary, site visits and/or audio recording of interventions will be conducted. Permission will be sought, and verbal consent recorded, from the trial participants to observe or record treatment sessions. The sites will regularly receive feedback from quality assurance activities to help maintain and improve fidelity. A full description of the AFTER interventions will be published at a later date.

Baseline assessments

Baseline sociodemographic, injury, mobility, height, weight, smoking status, diabetes diagnosis, and alcohol consumption data will be collected in the baseline CRF. Participants will also be asked to complete the validated questionnaires outlined in Table I.

Treatment logs

After the intervention sessions, the date, duration, session content, clinician profession and experience details, setting, mode of delivery, and the material and resources issued will be recorded on treatment logs. For the supervised rehabilitation arm, any advice given outside of the AFTER exercise programme and early discharge from the intervention will also be recorded here.

Remote follow-up

Participants will receive an electronic/paper invite (according to the participant's preference) to complete questionnaires. At two months post-randomization, this will include the OMAS, EQ-5D-5L, exercise adherence, complications, and resource use. At four months post-randomization, this will include OMAS, Self-Efficacy Exercise Score, exercise adherence, EQ-5D-5L, PROMIS Physical Function, and complications. At six months post-randomization, this will include OMAS, Self-Efficacy Exercise Score, exercise adherence, EQ-5D-5L, PROMIS Physical Function, complications, and resource use (Table I). Reminders will be sent by email, post, and/or text message. A secure online link will be included in the email or text message so that participants can complete the questionnaires online. Participants who do not complete the questionnaires within a specified timeframe will receive reminder emails and/or SMS messages, and if this does not elicit a response, an SMS message may be sent to inform participants that they will be contacted by phone by the trial team within a specified timeframe. Participants will then be followed-up with a telephone call from the central study office, and questionnaires completed verbally. A postal CRF will be sent to participants who do not respond to an electronic invite and if the central trial team are unable to reach participants by telephone. A schedule of email and SMS reminders, follow-up phone calls, and postal reminders for those participants failing to complete the questionnaires will be outlined in the trial data management plan and approved by the chief investigator (CI) and trial statistician. We will send up to three reminders in the form of a letter, email, or text message. If required, we will phone participants to provide support in completing the questionnaire. We may send a text message ahead of the call so that participant knows it is the study team contacting them.

Should data queries arise from participant-completed questionnaires, the central study office will attempt to contact the participant by telephone, email, or SMS message to resolve the query if it is not appropriate to be clarified with the clinical site team.

Further communication will be posted to participants as a letter, three weeks after joining the trial, in the form of a welcome pack. This pack will prepare them for future questionnaire invitations, explain the process of accessing the trial website, and will ensure those in the supervised rehabilitation arm have been booked into their initial intervention appointment by site. All participants will also be thanked for their participation. A small gift of a keyring will be sent to all participants alongside this information.

Embedded qualitative study

People with cognitive impairment to a level where self-directed rehabilitation would not be feasible are not eligible for inclusion in the AFTER trial. It is essential that participants in the trial engage with the self-management advice and independent home exercises. An embedded qualitative study will explore the support needs of family/friends (also called informal carers) of people with cognitive impairment who have an ankle fracture and are recovering at home. This will inform the design of future ankle fracture rehabilitation trials that include people with cognitive impairment.

Physiotherapy rehabilitation trials for people with lower limb fractures have not included people with cognitive impairment.[15] Informal carers of older people can find providing rehabilitation empowering,[34] but rehabilitation is challenging where the patient has cognitive impairment.[35] There is a lack of evidence about what interventions might be effective in supporting recovery from ankle fracture in patients with cognitive impairment. Furthermore, there is a paucity of evidence-based support packages for family/friends to help them with home-based rehabilitation interventions.

Managing cognitive impairment is a challenge for carers,[36] and they can feel abandoned after hospital discharge, with little idea of where to get help.[37] We will use qualitative interviews to gain family/friends' experience of helping their family member recover from ankle fracture, and explore what rehabilitation support is required to help people with cognitive impairments.

There are two research questions: 1) what are family/friends' experience of supporting their family member recover from ankle fracture?; and 2) what rehabilitation support, in their view, would facilitate recovery?

The study will draw on phenomenology to gain an understanding of how participants come to know and understand their experience, as used in other studies of injury.[38,39] In-depth interviews will allow the family/friend to express their experience and what is important to them. Interviews will focus on what their experience of caring for someone with an ankle fracture is like, and what support they feel helped or would help. The focus will be on enabling

participants to talk freely in a conversational style and to feel supported.

Interviews will take place at a time convenient for participants. PPI feedback identified that flexibility regarding timing of the interview is important. Interviews will continue until saturation of the data is achieved, i.e. no new themes or categories are evident. Interviews will be semi-structured and focus on the needs of ineligible patients and the experience of family/friends when caring for them and supporting them in their rehabilitation. Prompts will be used, such as: "what helped or hindered you?"; "how did you feel?"; and "what did you think?" The PPI group will help identify specific prompts relating to acceptability, feasibility, barriers, and facilitators. Interviews will be digitally recorded and transcribed verbatim. Telephone interviews will be digitally audio recorded on an encrypted recorder and downloaded to a secure password-protected computer as soon as possible.

The sample will be up to 20 family/friends who have experience of helping their family member/friend recover from ankle fracture. It will cover a range of sex and age of participants up to three months post-injury. This number has proven to provide sufficient data to ensure saturation of themes.[36,38] Participants may choose to talk on the telephone (digital audio) or via video conference call (digital audio/visual, Teams (Microsoft, USA), a software for conference calls).

Participants will be identified by the clinical team while screening for the main study. Patients with an ankle fracture who are not eligible for the AFTER study due to cognitive impairment will be identified. A family/friend who is actively planning to support or who is supporting the patient at home will be approached by clinical staff, provided with a PIS, and invited to take part in the study. If willing, they would sign a consent to be contacted form and be provided with the researcher's details. Participants will be given at least 24 hours to consider taking part. Informed verbal consent will be provided prior to interview. Interviews will be audio recorded and transcribed verbatim. A transcriber working for the University of Oxford will transcribe the interviews. Patients' personal details will be removed so that they cannot be identified, and all audio recordings of interviews will be routinely deleted when transcription is completed. A confidentiality agreement is in place with the transcriber. Audio recordings will be kept for 12 months after the study has finished, and then destroyed.

Analysis will be thematic, building up codes, categories, and themes or structures of experience.[40] Rigour will be assured through trustworthiness providing immersion in the data, an audit of decisions made, and description of sample and context.

An experienced qualitative researcher (ET) will lead the embedded study. She has held grants and published on the lived experience of people with injury, and carers of patients with cognitive impairment. The study will be supported by the CI and trial management structure. The senior PPI partner (RG), who has experience of injury and caring, will support this embedded study. He will take part in all stages of the embedded study research process.

Early discontinuation/withdrawal of participants

During the course of the trial a participant may choose to withdraw early from the study at any time, without giving reasons, and without prejudicing 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 (ITT) main analysis and analysis of safety. The options for withdrawal will be explained clearly in the PIS. The type of withdrawal and reason for withdrawal, if the participant is willing to provide one, will be recorded in the withdrawal CRF.

In addition, the investigator may discontinue a participant from the study treatment at any time if the investigator considers it necessary to safeguard the safety or wellbeing of the participant, including, but not limited to, ineligibility (either arising during the study or retrospectively having been overlooked at screening). Withdrawn participants will not be replaced.

Definition of end of study

The end of the study is defined as the last follow-up of the last participant and once all queries have been resolved.

Safety reporting

Safety reporting for each participant will begin from randomization, and will end when the participant has reached their final main follow-up timepoint, at six months post-randomization.

Definition of serious adverse events

A serious adverse event (SAE) is any untoward medical occurrence that results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; and consists of a congenital anomaly or birth defect.

Other 'important medical events' may also be considered a SAE when, based upon appropriate medical judgement, the event may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

Reporting procedures for SAEs

If a SAE arises in the period between randomization and the final follow-up visit, which is deemed related to the trial interventions, the site will complete a SAE form on the electronic SAE (eSAE) system on REDCap (Research Electronic Data Capture),[41,42] and record the description, date of onset, end date, severity, and assessment of relatedness to trial intervention. REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

For the purpose of safety recording for this trial, only unforeseeable SAEs potentially related to the intervention will

be reported immediately to the central trial team. When the local research team becomes aware of a SAE in a trial participant, the PI will review the SAE locally and make a decision about the causality (i.e. likelihood of the event to be related/attributed to the intervention). Further details on the grades of causality are available in the SAE reporting guidelines document in the investigator site file. Following the assessment of causality, the PI will assess any related events for expectedness. For any SAEs assessed as unexpected and potentially related, the details of the event will be entered on the eSAE system on REDCap, and the local research team will notify the central trial team via email or telephone within 24 hours of the PI becoming aware of the event. Once received, causality and expectedness will be confirmed by the 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. However, if no consensus decision is reached about expectedness after further discussion within one working day, and the SAE is judged to be unexpected by any one of either the PI, nominated person, or CI, the event will be classified as an unexpected event.

A SAE occurring in a participant should be reported to the research ethics committee (REC) that gave a favourable opinion of the study where, in the opinion of the CI, the event was 'related' (resulted from administration of any of the research procedures) and 'unexpected' in relation to those procedures. Reports of related and unexpected SAEs should be submitted within 15 working days of the CI becoming aware of the event, using the Health Research Authority (HRA) report of a SAE form.[43] All such events will also be reported to the trial management group (TMG) at their next meeting.

Adverse events (AEs) that are unrelated to the injury, intervention, or treatment will not be recorded locally or reported.

Reporting procedures for foreseeable SAEs and AEs not defined as serious

Foreseeable SAEs and AEs not defined as serious that are related to the interventions will be recorded by participants (through a bespoke participant-reported complications questionnaire) or recruitment centre staff (on a site complication CRF), but will not need to be reported immediately. These events will be verified with the participant and/or by the site investigators to ensure accurate recording and avoidance of duplicate reports over the follow-up timepoints.

Foreseeable AEs include pain increase after exercises that requires an increase in analgesia, or medical doctor consultation; treatment-related exacerbations of other medical conditions after exercise that require medical treatment, which also do not meet the definition of serious (for example, angina after exertion); and falls and injurious falls during performance of exercise that do not meet the definition of serious.

Fracture management complications will be collected from participants in the two-, four-, and six-month questionnaires, but will not be reported as AEs, including deep vein thrombosis/pulmonary embolism, wound infection treated with antibiotics, heel or ankle pressure sore (grade II or above), and surgery/further surgery to the injured ankle (unless an AE directly related to the exercise intervention, in which case this would be a SAE).

Statistics and analysis

Statistical analysis plan

The statistical aspects of the study are summarized here with full details of all analyses described in the separate statistical analysis plan (SAP) (Supplementary file 1). The SAP was drafted early in the trial and finalized prior to completion of follow-up and the primary outcome analysis. The SAP was reviewed by the trial oversight committee (TOC). Interim analyses of the efficacy outcomes are not planned, and will be performed only if requested by the TOC. It is anticipated that all analysis will be undertaken using the well-validated statistical package Stata (StataCorp, USA).

Sample size determination

Overall, 292 (146 per arm) participants providing primary outcome data at six months are required to detect a difference of eight points on the OMAS score, with an estimated standard deviation (SD) of 21 with 90% power and 5% (two-sided) significance. The minimum clinically important difference for the OMAS selected in surgical trials has usually been ten points, but for this trial of physiotherapy we have chosen a smaller difference of eight points, which is likely to be clinically important and was supported by our patient advisory group. The chosen SD of 21 is based on the AIM trial (SD 21.7),[6] and the feasibility study data (SD 20.5 based on 32 participants having reached the six-month timepoint (unpublished)). This equates to a standardized effect size of 0.38, a small to moderate effect. In the AFTER feasibility study, there was 11% loss to follow-up (those not providing the primary outcome data). In order to allow for potential loss to follow-up of participants in the definitive trial, we have inflated the sample size by 15% to 344 participants (172 per arm).

Analysis populations

Primary analysis population will be the ITT; participants will be analyzed in the group in which they were randomized, regardless of what treatment they received. The per-protocol population will exclude participants who did not start the allocated treatment and participants with any other major protocol deviations, which will be defined in the SAP.

Description of the statistical analysis

All available data from both treatment arms will be used in data analysis based on the ITT population. Reporting of the results will be in accordance with the CONSORT statement,[44] using the extensions for non-pharmacological treatment interventions and patient-reported outcomes. Standard descriptive statistics will be used to describe the demographics between the treatment groups reporting means and SDs or medians and interquartile ranges as appropriate for continuous variables and numbers and percentages for binary and categorical variables. Standard statistical summaries and graphical plots will be presented for the primary outcome measure and all secondary outcome measures.

The OMAS score at six months is the primary outcome in this study, and will be compared between treatment groups as the dependent variable in a mixed-effects linear regression model, including outcome information at intermediate timepoints. This model will adjust for stratification factors (recruitment centre and initial fracture management; surgical

or non-surgical) and baseline OMAS score. A random effect will be included to account for heterogeneity due to recruitment centres. The treatment effect will be based on adjusted mean differences at six months and will be reported together with their 95% confidence intervals.

We will also undertake a complier average causal effect (CACE) analysis which essentially compares the "compliers" in each group. Full compliance in the intervention group is defined as receiving a minimum of four physiotherapy sessions and partial compliance is receiving at least one physiotherapy session (i.e. starting the treatment). This will provide supporting evidence to any findings from the principal analysis. Subgroup analysis by surgical versus non-surgical treatment of the fracture, and by self-perceived self-efficacy at baseline will be undertaken using the same methodology incorporating a treatment by subgroup interaction term and presented using forest plots.

Similar methods to the primary outcome will be used to analyze continuous secondary clinical outcomes and patient-reported outcomes. Complications will be reported by type for each intervention group, and, if appropriate, compared between the two groups using logistic regression models.

The level of statistical significance

All outcomes will be assessed with 5% level of significance and will be presented with effect sizes and 95% confidence intervals, with p-values being reported with up to three decimal places.

Procedure for accounting for missing, unused, and spurious data

Missing data will be minimized by careful data management. Missing data will be described with reasons given where available; the number and percentage of individuals in the missing category will be presented by treatment arm. All data collected on data collection forms will be used, since only essential data items will be collected. No data will be considered spurious in the analysis since all data will be checked and cleaned before analysis. The nature and mechanism for missing variables and outcomes will be investigated, and if appropriate multiple imputation will be used. However, the analysis method proposed is reasonably robust to missing at random data. Sensitivity analyses will be undertaken to assess potential departures from the missing at random assumption. Any imputation techniques will be fully described in the SAP.

Procedures for reporting any deviation(s) from the original statistical plan

Any changes or deviations from the original SAP will be described and justified in the protocol, updated SAP, final report, and publications as applicable, depending on the timing of the changes.

Health economics analysis

A within-trial cost-effectiveness analysis will be conducted from an NHS and Personal Social Services perspective using the multiple imputed trial data over a period of six months for the base case (or primary) analysis. To view the health economic analysis plan, see Supplementary file 2. Trial data will consist of resource use extracted from the trial report forms and questionnaires. Unit costs for resource inputs will be drawn from a range of primary and secondary sources. Completion rates for values for each resource use and cost category will be calculated by trial arm at each timepoint. Use of resources will be summarized by trial arm and follow-up period and differences between arms will be analyzed using independent-samples *t*-tests for continuous variables and chi-squared test for categorical variables. Means and standard errors for values of each cost category will be estimated by treatment allocation and follow-up period. Differences in mean costs will be assessed using independent-samples *t*-tests and the bootstrap 95% confidence intervals will be calculated based on 10,000 replications. The cost-effectiveness analysis will adopt an ITT ("as randomized" with imputation of missing data) approach and an incremental cost-effectiveness ratio (ICER) will be calculated as the difference in mean costs divided by the difference in mean quality-adjusted life years (QALYs) between the trial comparators. The National Institute for Health and Care Excellence cost-effectiveness threshold of £20,000 to £30,000 per additional QALY will be used to determine the cost-effectiveness of supervised progressive exercise compared to best practice advice. Sensitivity analysis will be performed to explore the effects of: 1) extending the study perspective (i.e. societal perspective where the out-of-pocket expenses and productivity loss will be included); 2) assessing the impact of missing data (i.e. using complete case analysis) on the ICERs; and 3) including an additional £15,000 per QALY threshold to reflect recent trends in healthcare decision-making. Findings of this economic evaluation will be reported in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement.[45]

Data management

The data management aspects of the study are summarized here with full details described in the data management plan (DMP). At enrolment, participants will be asked to indicate their preference for the delivery and completion of follow-up questionnaires – electronic, postal, or telephone follow-up at two, four, and six months. Data collected in electronic format will be done by direct entry onto the trial database, including the collection of documentary evidence of consent. Electronic data collection has the major advantage of building "data logic" into forms, minimizing missing data, data input errors, and ensuring completeness. All data entered will be encrypted in transit between the participants/recruitment centre and server. All electronic patient-identifiable information will be held on a server located in an access-controlled server room at the University of Oxford. The data will be entered into a good clinical practice (GCP)-compliant data collection system and stored in a database on the secure server, accessible only to the research team based on their role within the study. The database and server are backed up to a secure location on a regular basis.

Identifiable data will be limited to contact details (including name, address, including postcode, telephone numbers, and email addresses), NHS/CHI/HCN number, sex at birth, and date of birth and will be accessed separately from the outcome data obtained from/about the participants and managed within the rules of the clinical database system.

Table II. Data retention policies.

Data/document	Type	Retention period	Retention location
Contact details		12 months after completion of the trial	University of Oxford
Consent forms: Main study and qualitative study	Investigator site file copy	12 months after completion of the trial	Recruitment centre
	Medical record copy	As per local hospital policy	Recruitment centre
	Central trial team copy	12 months after completion of the trial	University of Oxford
Research data	De-identified	Five years after publication of the primary results	University of Oxford
	Anonymized	Indefinitely	University of Oxford
Qualitative study: informed consent discussion transcriptions	De-identified	12 months after publication of the primary results	University of Oxford
Qualitative study: interview transcriptions	De-identified	12 months after publication of the primary results	University of Oxford

In all other data, participants will be identified by a trial ID only. Direct access to source data/documents will be required for trial-related monitoring and/or audit by the sponsor, NHS Trust, or regulatory authorities as required. Data retention policies are outlined in Table II.

Source data

Source documents are where data are first recorded, and from which participants' CRF data are obtained. These include, but are not limited to, hospital records (from which medical history and previous and concurrent medication may be summarized into the CRF), clinical and office charts, laboratory records, diaries, microfiches, radiographs, audio recordings, and patient-reported outcome measures that are submitted directly to the sponsor and correspondence.

CRF entries will be considered source data if the CRF is the site of the original recording (e.g. there is no other written or electronic record of data). All documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent and contact details form, the participant will be referred to by their study ID, not by name.

Access to data

Direct access will be granted to authorized representatives from the sponsor (University of Oxford's Research Governance, Ethics and Assurance (RGEA) team) and host institution for monitoring and/or audit of the study to ensure compliance with regulations. Site staff will have access to the centrally collected patient-reported outcome data for participants that they recruit at their site on REDCap, to ensure that they can download a complete dataset for their patients at the end of the trial.

Data recording and record keeping

Trial data will be collected and managed using REDCap electronic data capture tools hosted at OCTRU. Wherever possible, trial data will be entered directly into the trial database by site staff or participants. Data on paper forms or captured during phone calls to participants will be entered into the trial database by suitably trained central office staff. Full details will be recorded in the DMP. The participants will be identified by a unique trial specific number in any data extract. Identifiable data will only be accessible by members of the study team with a demonstrated need (managed via access controls within the application) and only used to communicate with the participant (e.g. sending follow-up reminders for online form completion or telephone follow-up).

Audio recordings of intervention sessions will be made digitally on password-protected devices. They will be stored on secure servers at the University of Oxford, identified by a trial ID and/or initials only, and will only be accessible to the CI and those members of the Oxford research team who have been authorized to do so by the CI. Any audio recordings will be retained for 12 months after intervention delivery checks and then deleted. It is necessary to retain the recordings for this period, as they are the source data and help us to interpret treatment delivery. Access to these is required in case they need to be referred back to during analysis and reporting.

Quality assurance procedures

This study will be coordinated by the UK Clinical Research Collaboration (UKCRC)-registered OCTRU at the University of Oxford. A rigorous programme of quality control will be implemented to ensure compliance with the current approved protocol, GCP, relevant regulations, and OCTRU standard operating procedures (SOPs). Quality assurance checks will be undertaken by the trial management team to ensure integrity of randomization, study entry procedures, and data collection. Inspections of the trial master file will be carried out by the OCTRU quality assurance team (at least once in the lifetime of the study, more if deemed necessary). Furthermore, the processes of consent taking, randomization, registration, provision of information, and provision of treatment will be monitored centrally.

Intervention delivery will be monitored periodically to ensure fidelity. Site visits and/or audio recording of interventions will be conducted. Permission will be sought from the trial participants to observe or record treatment sessions. Verbal consent will be provided and recorded on site visit checklists or on the audio recording as appropriate.

CRFs will also be used to monitor intervention fidelity. Data will be collected on intervention content delivery and number of treatment sessions attended to facilitate monitoring and reporting. The sites will regularly

receive feedback from quality activities to help maintain and improve fidelity.

Additionally, the study may be monitored, or audited by sponsor or host sites in accordance with the current approved protocol, GCP, relevant regulations, and SOPs.

Risk assessment

A risk assessment will be prepared before the study opens, and will be reviewed as necessary over the course of the study to reflect significant changes to the protocol or outcomes of monitoring activities.

Study monitoring

The monitoring activities will be based on the outcome of the risk assessment. Quality control procedures will be undertaken during the recruitment and data collection phases of the study to ensure research is conducted, generated, recorded, and reported in compliance with the protocol, GCP, and ethics committee recommendations. The CI and the trial manager will develop data management and monitoring plans.

Trial oversight

The trial will be conducted in accordance with the principles of GCP and guidelines, the Declaration of Helsinki,[46] OCTRU SOPs, relevant UK legislation, and this protocol. GCP-trained personnel will conduct the trial.

Trial management group

The day-to-day management of the trial will be the responsibility of the trial manager, supported by a senior trial manager. This will be overseen by the TMG, who will meet monthly to assess progress. A PPI representative will be an integral member of the TMG. It will also be the responsibility of the trial manager to undertake training of the research staff at each of the trial centres. The trial statistician, health economist, and information specialist will be closely involved in setting up data capture systems, design of databases, and clinical reporting forms.

Trial oversight committee

The TOC, which includes independent members, provides overall supervision of the trial on behalf of the funder. Its terms of reference will be drawn up in a TOC charter, which will outline its roles and responsibilities. Meetings of the TOC will take place at least once a year during the recruitment period. An outline of the remit of the TOC is to: monitor and supervise the progress of the trial towards its interim and overall objectives; review accruing data, completeness, and blinded summaries if required, and assess the screening algorithm against the eligibility criteria; consider emerging evidence from other related trials or research; review any safety issues; and inform the funding body on the progress of the trial.

The TOC will include at least one PPI representative as an independent member. Full details including names will be included in the TOC charter.

Protocol deviations

A study-related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention), or from GCP or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file, and all protocol deviations will be evaluated for whether they should be classified as important or non-important deviations.

Serious breaches

A "serious breach" is a breach of the protocol or of the conditions or principles of GCP which is likely to affect to a significant degree the safety or physical or mental integrity of the trial subjects, or the scientific value of the research.

In the event that a serious breach is suspected, the sponsor must be contacted within one working day. In collaboration with the CI, the serious breach will be reviewed by the sponsor and, if appropriate, the sponsor will report it to the approving REC committee and the relevant NHS host organization within seven calendar days.

Ethical and regulatory considerations

Declaration of Helsinki

The investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.[46]

Guidelines for good clinical practice

The investigator will ensure that this study is conducted in accordance with relevant regulations and in compliance with the principles of GCP.

Approvals

Following sponsor approval, the protocol, informed consent form, participant information sheet, and all patient facing study materials were submitted to a REC and HRA for written approval. REC approval was obtained from the National Research Ethics Service, North West - Liverpool Central Research Ethics Committee (reference 22/NW/0131). The CI will submit and obtain approval from the above parties for all substantial amendments to the original approved documents.

Reporting

The CI shall submit once a year throughout the study, or on request, an annual progress report to the REC committee, HRA (where required) host organization, sponsor, and funder (where required). In addition, an end of study notification and final report will be submitted to the same parties. The CI will submit progress reports to the funder according to their reporting requirements.

Transparency in research

Prior to recruitment of the first participant, this trial was registered on the ISRCTN registry (identifier: ISRCTN11830323). The trial team undertakes to keep trial data up to date and to make the results publicly available.

Participant confidentiality

The participants will be identified only by a trial ID number on all study documents and any electronic database, with the exception of the randomization CRF, where participant initials may be added. The authorization functionality within the data collection system will be used to ensure that identifiable data can only be accessed by appropriate members of the trial team. All documents will be stored securely and only be

accessible to study staff and authorized personnel. The study will comply with the UK General Data Protection Regulation and the UK Data Protection Act (2018),[47] which requires data to be de-identified as soon as it is practical to do so.

Expenses and benefits

Participants will not undergo any hospital visits in addition to normal care, therefore no expenses will be payable. Participants will have remote sessions via video/telephone call, or face-to-face sessions at their local hospital, in order to receive the exercise interventions. As this is part of delivering the intervention treatment, no expenses will be payable to them.

Publication policy

The core aim of our dissemination and communication strategies is to translate our research findings into clinical practice for the benefit of patients and the NHS. To achieve this impact, there is a requirement to report our study open-access and to a high standard in accordance with guidelines. The next stage is to ensure that these findings, and the intervention indicated for implementation, reach the patients and clinicians within the NHS.

The study protocol and results will be published in open access journals in accordance with CONSORT statement and related extensions,[44] and the template for intervention description and replication (TIDieR) complex intervention reporting guidance.[48] We will work with networks to disseminate findings, for example through newsletters and scientific conferences. The findings will also be shared with patients and the public more widely through local and national charity newsletters and other media channels.

The protocol date and version is 22 May 2023 version 2.0. Amendments between version 1.0 and 2.0 included updating employment information, updates to relevant addresses/emails/telephone numbers, update to TMG members and trial statistician, verbal consent witness role removed to reflect working process, addition of details and description of embedded qualitive study, further clarification of analysis populations, and insertion of a data retention policies table.

Social media

Follow Oxford Trauma on X @Oxford_Trauma
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Supplementary material

The health economic analysis plan and the statistical analysis plan.

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Author information

D. J. Keene, DPhil, Associate Professor in Trauma and Orthopaedics, Honorary Senior Researcher in Trauma Rehabilitation,
Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK;
Exeter Medical School, University of Exeter, Exeter, UK.

J. Achten, PhD, Research Manager
C. Forde, MRes, NIHR Doctoral Research Fellow
K. Draper, Trial Manager
D. Appelbe, PhD, Senior Research Information Specialist
E. Tutton, PhD, Senior Research Fellow in Patient Experience and Qualitative Methods
N. Peckham, MSc, OCTRU Senior Medical Statistician
S. J. Dutton, MSc, OCTRU Lead Statistician
M. L. Costa, PhD, Professor of Orthopaedic Trauma Surgery
Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK.

M. E. Png, PhD, Senior Researcher in Health Economics, Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK.

R. Grant, Patient and Public Involvement Representative, Patient and Public Involvement Member, Coventry, UK.

S. E. Lamb, DPhil, Mireille Gillings Professor of Health Innovation, Exeter Medical School, University of Exeter, Exeter, UK.

Author contributions

D. J. Keene: Conceptualization, Funding acquisition, Methodology, Writing – original draft, Writing – review and editing.
J. Achten: Funding acquisition, Methodology, Writing – original draft, Writing – review and editing.
C. Forde: Writing – original draft, Writing – review and editing.
M. E. Png: Methodology, Writing – original draft, Writing – review and editing.
R. Grant: Writing – review and editing.
K. Draper: Project administration, Writing – original draft, Writing – review and editing.
D. Appelbe: Methodology, Writing – review and editing.
E. Tutton: Methodology, Writing – review and editing.
N. Peckham: Methodology, Writing – review and editing.
S. J. Dutton: Methodology, Writing – review and editing.
S. E. Lamb: Conceptualization, Writing – review and editing.
M. L. Costa: Conceptualization, Funding acquisition, Methodology, Writing – review and editing.

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