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Development and delivery of the rehabilitation interventions for older adults with an ankle fracture in the AFTER (Ankle Fracture Treatment Enhancing Rehabilitation) trial

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Abstract

Objectives Describe the development and delivery of the interventions in the Ankle Fracture Treatment Enhancing Rehabilitation (AFTER) trial, a randomised controlled trial comparing the effectiveness of supervised versus self-directed rehabilitation for adults aged ≥50 years with an ankle fracture.

Design Intervention development.

Setting UK National Health Service (NHS) hospitals.

Method We developed the interventions in stages. First, we reviewed two UK clinical guidelines and the existing research evidence. We then conducted a clinical practice survey (n = 59 physiotherapists) to inform a stakeholder meeting which identified key intervention components. Subsequently, we designed the interventions, tested them in a pilot trial (n = 61 participants), then refined them for the definitive AFTER trial.

Results/findings The definitive AFTER trial interventions start after randomisation, which occurs when the participant's cast/boot is removed and weightbearing and ankle movement restrictions are lifted. Participants allocated to self-directed rehabilitation receive a high-quality advice workbook, a progressively challenging self-directed exercise programme that they follow to self-manage their recovery, and strategies to encourage exercise adherence. Supervised rehabilitation participants receive a high-quality workbook, then 4 to 6 one-to-one face-to-face/remote sessions with a physiotherapist. The physiotherapist provides specific advice, home exercises, and uses strategies to facilitate adherence to prescribed exercises. The supervised rehabilitation intervention is tailored to individual participants during review sessions.

Conclusions The definitive AFTER trial will provide high-quality evidence to guide rehabilitation provision for older adults with an ankle fracture. Results are anticipated in 2025.

Trial Registration Number ISRCTN registry (identifier: ISRCTN11830323).

Contribution of the Paper

- Although ankle fractures commonly affect older adults and their recovery is usually incomplete, the most effective rehabilitation for these patients remains unknown.
- The Ankle Fracture Treatment Enhancing Rehabilitation (AFTER) trial is a large multicentre randomised controlled trial comparing supervised versus self-directed rehabilitation for older adults.

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- In accordance with current complex intervention development guidance, this paper describes how we developed the AFTER trial interventions and how they are delivered.
- This transparent reporting will enable readers to understand the evidence and theory underpinning the AFTER interventions and aid future implementation of the intervention shown to be most effective.

Keywords: Exercise; Physical therapy; Physiotherapy; Intervention development; Ankle fracture

Introduction

Ankle fractures represent 9% of all fractures presenting to UK secondary care hospitals [1] and mainly affect women aged ≥50 years [2]. Initial treatment is either surgical fixation or non-surgical with a cast or boot. Most patients then have ankle movement and/or weight bearing restrictions that last for about six weeks. Regardless of the initial treatment approach, older adults with an ankle fracture normally do not regain pre-injury ankle function [3]. Common post-injury impairments include muscle atrophy [4], joint stiffness [5], and difficulty walking [6]. The aim of rehabilitation, once restrictions outside the cast/boot are lifted, is to reduce pain and restore function by targeting these and other modifiable impairments.

In our trial of surgery versus close contact casting for older adults with ankle fractures in the UK National Health Service (NHS), roughly two thirds of participants were referred to physiotherapy as part of their usual care [7]. However, physiotherapy referral patterns and the number of physiotherapy sessions provided varied within and between hospitals [7]. This variability likely reflects the limited high-quality evidence to guide rehabilitation provision for older adults with an ankle fracture after the initial immobilisation period [8].

Previously, we conducted an external pilot randomised controlled trial (RCT) which showed a definitive RCT comparing rehabilitation approaches for older adults after ankle fracture was feasible [9]. Findings from that pilot have informed the definitive Ankle Fracture Treatment Enhancing Rehabilitation (AFTER) trial: a parallel, two-group, superiority RCT evaluating the clinical and cost-effectiveness of supervised (4 to 6 physiotherapy sessions) versus self-directed rehabilitation (provision of self-management materials) in improving ankle function for people aged ≥50 years. Full details are in the published protocol [10]. Following current complex intervention development guidance [11], this paper aims to describe how the definitive AFTER trial interventions were developed and how they are delivered.

Methods

We briefly described the design and delivery of the interventions for the AFTER pilot RCT in the published protocol and results for that study [9,12]. Here, we fully describe how we developed the finalised interventions for the definitive AFTER trial and how these interventions are delivered.

In line with the Medical Research Council's guidance for developing and evaluating complex interventions [13], we developed the supervised and self-directed rehabilitation interventions in stages. First, we reviewed clinical guidelines and the existing research evidence. We then conducted a clinical practice survey to inform a stakeholder meeting which identified key intervention components. Subsequently, we designed the interventions and tested them in a pilot RCT. Finally, we refined the interventions for the definitive trial based on findings from the pilot RCT and an embedded qualitative study. Throughout, we aimed to ensure interventions were reproducible, scalable, and deliverable in the context of the UK NHS.

The intervention development process is described below. An overview is depicted in Fig. 1.

Intervention development

Phase 1a: clinical guidelines

To our knowledge, only two UK ankle fracture management guidelines existed at the time of intervention development [14,15]. In these, the only recommendations about rehabilitation after the acute injury period are that patients should be advised about their expected recovery and be able to re-access fracture services if they have problems [14,15].

Phase 1b: research evidence

Ankle fracture rehabilitation. The 2012 Cochrane review of adult ankle fracture rehabilitation found no evidence for stretching, exercise or manual therapy after the removal of immobilisation [8]. Only one RCT included in that review [16] compared different volumes of physiotherapy, finding no difference between a comprehensive 12 week exercise programme and usual care. However, usual care participants received on average 7 physiotherapy sessions (physiotherapy group received an average of 17 sessions). There were also potential biases related to allocation concealment and incomplete outcome data [8], limiting inferences about the comparative effectiveness of the interventions.

Our 2020 systematic review of exercise interventions for lower limb or pelvic fragility fractures [17] identified one

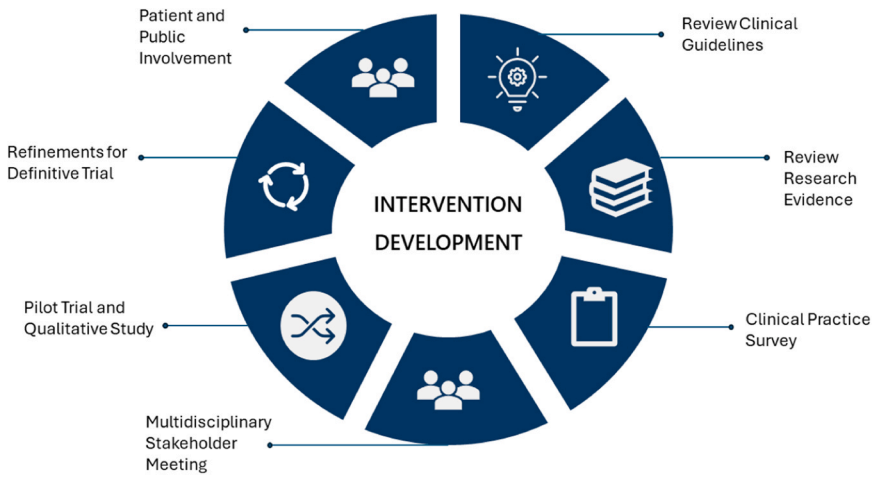

Fig. 1. Overview of the intervention development process.

new ankle fracture RCT, the EXACT trial [18]. This trial found that an intervention comprised of multiple physiotherapy sessions of advice and prescribed home exercise was not more effective than one session of advice in improving activity limitations or quality of life. However, 36% of participants in the advice only group accessed out-of-trial physiotherapy. Most participants were also aged under 50 years, so findings may not be generalisable to older adults with an ankle fracture who typically have a worse outcome [19]. In the EXACT trial, the higher dose intervention may also have been suboptimal. There were no high-level impact exercises, like running, and physiotherapists could not prescribe any exercises outside the standardised intervention, even if indicated. This may have affected functional restoration for some participants. Furthermore, behaviour change strategies to support exercise adherence, like goal setting and providing an exercise diary, were not used, potentially explaining why no between group difference in exercise adherence was observed.

AFTER intervention targets. Ankle fractures can result in various physical (described previously) and psychological impairments. In older adults, physical impairments may have a more pronounced impact due to reduced physiological reserve [20], with associated impacts on function and falls risk. After this injury, these patients have also reported experiencing loss of confidence, fear of falling, and fear of re-injury [21]. When designing the AFTER interventions, we considered the range of impairments that occur after ankle fracture and orthopaedic injury. Those targeted are described below.

Phase 2a: clinical practice survey

Given the limited evidence to guide rehabilitation for older adults with ankle fractures, capturing UK physiotherapists' rehabilitation practice was important to inform the intervention development process. Originally, we planned to evaluate rehabilitation in patients after ankle fracture fixation surgery only. So, in 2016, we circulated an online survey of UK physiotherapists' management of this patient group via social media, special clinical interest groups, and at academic conferences. Fifty-nine physiotherapists responded (respondents (*n*) working in England = 54, Wales = 3, Scotland = 2, and Northern Ireland = 0). Respondents mostly worked in NHS primary (26/59, 44%) or secondary care (27/59, 46%), and 61% (36/59) worked at NHS Agenda for Change band 7 or higher. The survey findings, along with physiotherapists' reported reasons for this variation, were taken through to the stakeholder intervention development meeting. For example, 51% of physiotherapists reported they saw younger and older adults for a different number of sessions with some treating younger patients more often than older patients and others the opposite. The characteristics of survey respondents and key survey findings are presented in Supplementary file 1.

Phase 2b: stakeholder meeting

To increase the chances that the interventions would be acceptable to patients and clinicians and deliverable in the NHS, input from a range of stakeholders was important. On the 24th of November 2017, we held an intervention development meeting for our pilot trial, attended by physiotherapists, surgeons, nurses, occupational therapists, and patient and public representatives. Invited healthcare professionals were identified from relevant clinical specialist interest groups and the authors' personal contacts. Patient and public involvement (PPI) representatives were invited from the UK Musculoskeletal Trauma PPI group.

Before the meeting, delegates completed a questionnaire asking them to identify important aspects of ankle fracture rehabilitation. At the meeting, questionnaire results, clinical practice survey findings, and the rationale for comparing two rehabilitation interventions with different volumes of physiotherapy in a pilot trial were presented. In small groups, meeting delegates then ranked, in order of importance, options for the volume of physiotherapy and components for an intervention called 'best-practice

advice'. Groups then discussed their choices with all delegates in order to achieve consensus. We also sought delegates' feedback on an intervention involving multiple physiotherapy session of progressively challenging and tailored home exercise called 'progressive exercise' e.g., practical challenges for patients and clinicians, what advice to include, and other possible intervention components that should be added.

Following this meeting, two physiotherapists on the research team (DJK and CPF) with experience of treating older adults with ankle fractures in the NHS discussed the consensus findings. The senior author (DJK) made the final decision about intervention content and designed the intervention materials.

The 'best-practice advice' intervention involved one session with a physiotherapist (with ≤2 optional extra sessions) who introduced a high-quality paper workbook of self-management advice and a self-directed exercise programme of progressively challenging ankle movement, calf muscle strengthening, and static balance exercises which participants followed to self-manage their recovery. For the 'progressive exercise' intervention, participants received a paper workbook of self-management advice and ≤6 sessions with a physiotherapist who supervised their recovery and prescribed home balance, gait, and intense lower limb resistance exercises. Behavioural strategies to promote exercise adherence were used as well. Further details are in the published report [9].

Phase 3a: pilot RCT and qualitative study

To assess if a definitive trial was feasible, we compared 'best-practice advice' with 'progressive exercise' in an external pilot RCT, recruiting 61 patients aged ≥50 years with an ankle fracture from five NHS hospitals [9]. An embedded qualitative study investigated the experiences of physiotherapist intervention providers and participants [22]. Findings indicated the definitive trial was feasible but minor intervention modifications were required. These are discussed below.

Phase 3b: refinements for the definitive trial

In the pilot trial, interventions started at the participants' first physiotherapy session. However, in some cases, this first session was several weeks after restrictions outside the cast/boot were lifted, potentially delaying recovery. Consequently, in the definitive trial, interventions start after randomisation which occurs when these restrictions are removed. An additional problem in the pilot trial was the similar number of physiotherapy sessions received by participants in both interventions. To address this, we modified the interventions to test different treatment pathways and ensure a clearer difference between treatment groups. 'Best-practice advice' participants no longer attend physiotherapy, instead they receive materials which they use to independently manage their recovery, and 'progressive exercise' participants now attend 4–6 physiotherapy sessions. The interventions were also renamed 'self-directed' and 'supervised rehabilitation' respectively, to better reflect their key distinguishing feature.

The intervention materials provided to the participants were also refined. For example, we added advice about expected recovery trajectories because concern about progress was the main clinical reason 'best-practice advice' participants attended additional physiotherapy sessions in the pilot trial. 'Supervised rehabilitation' physiotherapy sessions can also be provided by phone/video to address the main reason eligible participants declined participation in the pilot i.e., unable to attend physiotherapy at the participating site. The 'supervised rehabilitation' intervention was also streamlined (e.g., removing an assessment of participant's confidence to adhere to exercise) because some physiotherapists who provided the 'progressive exercise' intervention in the pilot felt it was too time consuming to implement clinically [22].

Phase 3c: patient and public involvement

The UK Musculoskeletal Trauma PPI Group provided input into the definitive trial's development and design. Building on PPI support in developing the pilot trial intervention materials, three members of the public reviewed the exercises in rehabilitation workbooks (described below) and one reviewed the online version of the workbook, providing feedback on content and formatting. PPI partners were representative of the trial's target population i.e., aged ≥ 50 years.

AFTER interventions

Intervention reporting follows the template for intervention description and replication (TIDieR) [23] and the Consensus on Exercise Reporting Template (CERT) [24]. Table 1 provides an overview of the interventions.

Reflecting this trial's pragmatic design, physiotherapists who provide the supervised rehabilitation intervention do not require specific experience in managing ankle fracture patients, but their year of qualification and average number of ankle fractures treated per week are recorded for study reporting.

Before providing the interventions, physiotherapists undergo training that lasts about two hours and covers the trial's background, an overview of the interventions, delivery of the supervised rehabilitation intervention, and study documentation. Initially, a physiotherapist on the research team (CPF) provided training to sites online, except one site where training was face-to-face. Once these initial training sessions were completed, training materials were refined and training provided to the remaining sites via pre-recorded videos on the study website. This allows physiotherapists to complete training at their own time and speed and to revisit training videos in future. All trained physiotherapists are sent an intervention delivery manual and encouraged to contact the trial team with any intervention queries.

Table 1
Overview of the AFTER interventions according to the TIDieR criteria.

TIDieR item	Supervised rehabilitation	Self-directed rehabilitation
Why	Follow-up appointments enable physiotherapists to review participants and provide individually tailored advice and exercise which could improve outcomes.	Independent management of recovery by patients, guided by high quality materials, avoids the burden of attending physiotherapy appointments and could reduce costs.
What		
Materials: participants	Paper workbook divided into 2 sections. Section 1 contains advice and basic initial exercises. Section 2 contains materials physiotherapists use to deliver the intervention: a goal setting section, an action planner, an exercise diary, and a menu of exercises that physiotherapist prescribe exercises from. Exercises have pictures and written instructions. The workbook is also available in an online version.	Workbook (a paper and online version including exercise videos is available) of self-management advice, a progressively challenging exercise programme, a goal setting section, and an exercise diary.
Materials: physiotherapists	All physiotherapists receive a manual concisely describing intervention delivery. Physiotherapists whose training is via pre-recorded videos can also revisit these videos whenever they want to.	N/A
Procedures	After randomisation, a healthcare professional introduces the paper workbook and refers the participant to physiotherapy. The participant starts their recovery by following the advice (see Table 2) and initial exercises in the workbook (see Supplementary file 2).	Same as supervised rehabilitation except participants are not referred to physiotherapy and manage their recovery independently by following the workbook advice (Table 2) and a progressively challenging exercise programme (Table 4).
Who provided	A healthcare professional/researcher usually a surgeon, physiotherapist or nurse, introduced the workbook. Fully qualified physiotherapists working in participating sites' musculoskeletal outpatient physiotherapy services provide supervised rehabilitation. No specific expertise is required but all treating physiotherapists were provided with trial-specific training in the intervention.	Workbooks are introduced by the same people as supervised rehabilitation.
How	Workbooks are provided face-to-face or posted if participants are consented remotely. Physiotherapy sessions are one-to-one and either face-to-face or by video or telephone call.	Workbooks provided as per supervised rehabilitation.
Where	Intervention workbooks are provided after randomisation, normally occurring in outpatient fracture clinics. Face-to-face sessions occur at participating sites' physiotherapy departments. Participants decide where to perform prescribed exercise.	Same as supervised rehabilitation for the workbooks.
When and how much	First session is ≤21 days of randomisation depending on local appointment availability. 4 to 6 physiotherapy sessions are provided over 3 months from the first session. Session frequency is at the discretion of the physiotherapist.	N/A
Tailoring	Advice: physiotherapists can re-emphasise any workbook advice or provide any individual advice judged relevant. Exercise: physiotherapists can prescribe up to 5 exercises per session. 1 must be a strengthening exercise and no more than 1 can be a "bespoke" exercise. Physiotherapists may provide other treatments as long as the core intervention components are delivered	Exercise: only certain participants progress to the impact exercise category and to different exercise levels within exercise categories (see text).
Modifications	In June 2023, we sent an infographic to physiotherapists summarising key intervention components for quick reference in clinic.	N/A
How well		
Planned: physiotherapists	A treatment delivery form records if participants received the correct workbook. See quality assurance section in text for monitoring of physiotherapists' fidelity to supervised rehabilitation.	As per supervised rehabilitation for receipt of correct workbook.
Planned: participants	Participant-reported exercise frequency is measured 2, 4 and 6 months after randomisation in follow-up questionnaires.	
Actual: physiotherapists and participants	Intervention fidelity results will be reported in the main results paper.	

N/A: not applicable; NHS: National Health Service.

Table 2
Advice in the AFTER intervention workbooks.

Section	Contents
Introduction	Explains the content and purpose of the workbook
About your ankle	Explains basic bony anatomy of the ankle
What is an ankle fracture?	Explains what an ankle fracture is and initial treatment i.e., surgical or non-surgical
What can I expect after an ankle fracture?	Explains: • Common symptoms after ankle fracture • Normal fracture healing and recovery timeframes
What can I do to help my ankle get better?	Consisting of: • Pain management strategies which covers medication, using cold, and flare-up management • Managing dry skin • Managing scars where relevant • Managing swelling • Walking advice which covers usual timeframes for restoration of normal gait, weight bearing, how to use crutches and sticks, and the importance of progressively increasing walking time along with guidance • How to ascend/descend stairs using crutches • Weaning from ankle support/splints
Returning to normal activities	Explains the negative consequences of fear avoidance behaviours and positive consequences of gradually increasing activity levels
Work	Signposts participants who are concerned about returning to work to sources of support
Driving	Return to driving guidance with links to further information from the DVLA and the Highway Code
Exercise[a]	Covers: • How exercise will help • How long exercises should be done for • Guidance about acceptable levels of pain during and after exercise • How to do exercises • How often to do exercises
What to do if you have problems	Explains normal duration and trajectories of recovery and who to contact if there are concerns
Physiotherapy[b]	Explains what physiotherapy entails, the importance of attendance, and reminds participants to bring their workbook to sessions

DVLA: Driver and Vehicle Licensing Authority.
[a] Details specific to the supervised and self-directed rehabilitation interventions.
[b] Only in supervised rehabilitation intervention workbook.

Supervised rehabilitation

The intervention starts after randomisation when participants' have their cast/boot removed and weight-bearing and ankle movement restrictions discontinued. This usually occurs in fracture clinic six weeks after injury/surgery (as per study eligibility criteria, this must be 4 to 10 weeks after injury/surgery). A healthcare professional or researcher, typically whoever obtained informed consent, introduces the supervised rehabilitation workbook, briefly explains it, and encourages the participant to implement the advice and basic initial exercises (see Supplementary file 2) within. The advice in both intervention workbooks (see Table 2) is the same apart from some intervention specific details about the exercises and physiotherapy.

Participants are told to bring their workbook to physiotherapy sessions as it also contains the materials to support exercise adherence (described below) and the menu of exercises that physiotherapists need to deliver the intervention during treatment sessions. Participants are given a paper workbook because delivering an intervention using an exclusively online workbook is not yet feasible across all physiotherapy departments. However, an online workbook is available for participants who wish to use this with their paper version, the main difference being the availability of exercise videos on the online version.

Participants are then referred to physiotherapy. The first session is as soon as possible and ideally within 21 days of randomisation.

Structure. Participants receive 4-6 one-to-one physiotherapy sessions over three months from the initial session. Follow-up sessions enable physiotherapists to re-assess participants, provide advice/reassurance, progress exercises, and revisit behaviour change strategies to help exercise adherence if required. Session frequency and mode (i.e., face-to-face or by telephone/video call) are whatever would normally be used for that participant. Initial sessions are ≤60 minutes and follow-up sessions ≤30 minutes.

Assessment and advice. In addition to their normal assessment, physiotherapists review participants' gait, mobility aids, and stair climbing where relevant due to the significant

Table 3
Behaviour change techniques in the AFTER interventions.

Behaviour change technique	Supervised rehabilitation	Self-directed rehabilitation
Graded tasks	Gradually return to normal activities, including walking, according to workbook advice. The participant starts initial basic exercises at level 1 in each exercise category, progressing to higher exercise levels according to workbook advice.	Return to normal activities as outlined for supervised rehabilitation. The participant starts the self-directed exercise programme at level 1, progressing to higher levels according to workbook advice.
Reduce negative emotions	Simple reassurance is provided in the workbook about the capacity to move and exercise and the benefits of this. Sources of support if there is anxiety about returning to work are also provided.	As for supervised rehabilitation
Behavioural practice	Participant performs each prescribed exercise and their physiotherapist provides feedback.	N/A
Self-monitoring of behaviour	Participant records if they performed exercise prescribed by their physiotherapist in an exercise diary each day.	Participant records if they performed the self-directed programme in an exercise diary each day.
Goal setting (behaviour or outcome)	Participant writes down their activity-based short- and long-term goals at session 1 following SMART principles. These are reviewed at follow-up sessions and amended if needed. The physiotherapist provides support as required.	Participant writes down activity-based short- and long-term goals following SMART principles.
Review goals (behaviour or outcome)	Physiotherapist reviews the participant's goals with them at follow-up sessions. Goals are amended if the previous goal was achieved or the participant wants to set a new goal.	N/A
Action planning	Participant writes in the 'exercise planner' in their workbook where and when they will perform prescribed exercises and a contingency if they cannot do them at the planned time.	N/A
Behavioural contract	Participant signs the 'exercise planner' underneath text 'I will do my exercises as planned'.	N/A
Problem solving	At review sessions, If adherence to prescribed exercise is low, the physiotherapist helps the participant to complete the 'exercise planner' again, helping to identify barriers to exercise adherence and how these can be overcome if needed.	N/A

N/A: not applicable; SMART: specific, measurable, achievable relevant, timely

impact impaired mobility can have after ankle fracture [21]. At the first session, physiotherapists reinforce the workbook advice about managing pain, progressively increasing walking, and restoring normal activities gradually. At follow-up sessions, advice focusses on ensuring participants are resuming normal activities—a key aim of the intervention. Throughout, physiotherapists can highlight any other advice from the workbook or provide any additional tailored advice deemed relevant.

Exercise prescription. Physiotherapists prescribe exercises from a menu of stretching, balance, strengthening and impact exercises in the participants' workbook (see Supplementary file 2). Exercise options aim to cater for variability in participants' physical capabilities, activity goals, and stages of recovery. In keeping with our focus on deliverability, exercises require no or minimal equipment. Physiotherapists are encouraged to select exercises using their clinical judgement and considering individual participants' preferences and activity goals as this is a key distinguishing feature from self-directed rehabilitation.

Physiotherapists can prescribe up to five exercises per session, limited in number to support adherence [25]. At least one exercise must be from the strengthening category and prescribed following guidelines to increase muscle strength (i.e., 1 to 3 sets, 8 to 12 repetitions, ≥3 times per week not all on consecutive days) [26]. To ensure strengthening exercises are sufficiently intense to stimulate improvements i.e., the "overload" exercise principle [26], participants perform 2 to 3 repetitions of prescribed strengthening exercises and rate their effort on a modified version of Borg's 11-point scale of perceived exertion [27] (see Supplementary file 3), validated for measuring resistance exercise intensity [28]. The effort should be 5 to 7 and the exercise is modified or an alternative selected if necessary until this is achieved. For time efficiency, the scale is not used after session 1 if the physiotherapist is confident the participant knows how intense strengthening exercises should be and the participant no longer wishes to use it.

One "bespoke" exercise not on the exercise menu may be prescribed per session if judged necessary to help the participant achieve their activity goal(s). This aims to account for anticipated variability in activity goals and to keep the exercise menu concise enough that it is easy to use.

For each prescribed exercise, physiotherapists write in prescription parameters (repetitions, sets/time, times per day, times per week) which are at their discretion (except for strengthening exercises) on the corresponding exercise sheet along with optional "make harder by" instructions and

"other tips/advice". An example exercise sheet is presented in Supplementary file 4. Physiotherapists place the exercise sheets of prescribed exercises in a plastic pocket labelled "current exercises" in participants' workbook for easy access and change these at each session as needed. Participants are told videos of prescribed exercises are available on the study website.

Strategies to promote exercise adherence. To complete a sufficient exercise dose to stimulate physiological adaptation, participant adherence to prescribed exercise is important. Yet, adherence to physiotherapist prescribed exercise can be poor [29]. Therefore, supervised rehabilitation uses strategies based on those in the NHS Health Trainer Handbook [30] and those that have been associated with increased adherence in another rehabilitation trial [31]. At session 1, physiotherapists ask participants to write down their short- and long-term activity-based goals ensuring they are meaningful and follow SMART principles (Specific, Measurable, Achievable, Relevant, Timely). Participants then write in an exercise planner where and when they will perform prescribed exercise along with a contingency and sign this. Finally, physiotherapists introduce and explain how to use a diary where participants record performance of prescribed exercise. At follow-up sessions, physiotherapists review the exercise diary to assess adherence and review goals to see if these have been achieved/need amending. For time efficiency, the participant only completes the exercise planner again if exercise adherence is low. Similarly, goals are only amended if previous goals were achieved or the participant wants to set a new goal. Throughout, the physiotherapist provides any assistance required. Table 3 summarises the behaviour change techniques [32] used in the AFTER interventions. Behaviour change materials are in the participants folder and presented in Supplementary file 5.

Other treatment(s). Physiotherapists may provide other treatment(s) (e.g., joint mobilisations) if the core intervention components described above are delivered. Any additional treatments are recorded for study reporting.

Self-directed rehabilitation

After randomisation, a healthcare professional/researcher introduces the intervention workbook, briefly explains it, and encourages the participant to implement the advice (Table 2) and self-directed exercise programme (Table 4) immediately. Because this intervention does not require physiotherapy attendance, participants can choose to use either an exclusively paper or online workbook, or both.

Exercise programme. The exercise programme is comprised of stretching, balance and strengthening exercise categories with stretching and strengthening further divided into subcategories. Each category contains exercises of progressive levels of difficulty. Participants start at level 1, the easiest level, in each category i.e., performing six exercises in total. To try and ensure exercises are sufficiently challenging, each exercise category is preceded by guidance on symptoms participants should experience during exercises, how to make exercises harder, and when to progress to the next exercise level. Recognising that older adults with ankle fractures have variable physical characteristics and recovery trajectories, participants are advised only to progress to the next exercise level if they are confident they could do this pre-injury and it is something they can manage. For participants who want to return to impact activities, there is an additional impact exercise category which they can start once they can perform the level 3 calf strengthening exercise (standing single leg heel raise).

Participants are advised to perform exercises at least three times per week for at least three months but to exercise more frequently and for longer if they find it beneficial. This follows guidance on training frequency to increase muscular strength [26] and typical durations required for neuromuscular adaptations to resistance exercise [33]. Participants are encouraged to compare exercise performance between legs, and if their affected leg performs worse, to continue their programme until performance is symmetrical. Exercise prescription parameters were informed by current exercise prescription guidelines [26,34], clinical experience, and what was considered practical and feasible.

Strategies to promote exercise adherence. The workbook contains a section for setting short- and long-term goals and recording exercise performance in a diary, as described for the supervised rehabilitation, along with instructions on how to complete these (see Table 3 and Supplementary file 5).

Concomitant care

Other aspects of participants' health and social care can continue as normal, but additional ankle-related treatments participants receive are recorded. Usual physiotherapy care is available for participants who need it but we anticipate this to be rare. Participants' use of out-of-trial physiotherapy is recorded in follow-up questionnaires. General practitioners (GPs) are notified of their patient's participation because GPs can refer to physiotherapy.

Quality assurance

To monitor supervised rehabilitation intervention fidelity, we review physiotherapist-completed treatment case report forms that record if the participant attended, the session number, session content, and the treating physiotherapist's name. We are also observing or audio recording supervised rehabilitation treatment sessions at sites. We provide feedback to individual physiotherapists and/or sites from quality assurance checks to maintain and improve fidelity. Full details of intervention quality assurance activities are in the published protocol [10].

Table 4
Exercise programme in the 'self-directed rehabilitation' intervention.

Category	Level	Description	Parameters	Progression
Stretching				
Bending ankle up	1	AROM ankle dorsiflexion in long sitting	3 ×10 reps	Bend ankle up further
	2	Step 1: Gastrocnemius stretch Step 2: Soleus stretch	3 × 30 seconds	Move the affected ankle further back
Bending ankle down	1	AROM ankle plantarflexion in long sitting	3 × 10 reps	Point ankle down further
	2	PROM ankle plantarflexion using hands with legs crossed in sitting	3 × 30 seconds	Push ankle down further
	3	PROM ankle plantarflexion in kneeling bringing bum to heels	3 × 30 seconds	Lower bum towards heels further
Turning ankle in and out	1	AROM ankle inversion and eversion in long sitting	3 × 10 reps	Turn ankle further inwards and outwards
	2	Option 1: PROM ankle inversion and eversion using towel in long sitting Option 2: PROM ankle inversion and eversion using hands with legs crossed in sitting	3 × 30 seconds	Turn ankle further inwards and outwards using the towel/your hands
Balance	1	Weight shifting onto injured leg in standing	3 × 10 reps for 5 seconds	Put more weight through affected leg, increase time up to 20 seconds
	2	Single leg stand with bilateral upper limb support	3 × 10 reps for 5 seconds	Increase duration up to 20 seconds
	3	Single leg stand	3 × 10 reps for 5 seconds	Increase duration up to 20 seconds
	4	Single leg squat	3 × 10 reps	Squat lower
Strengthening				
Calf strengthening	1	Seated single leg calf raise	3 × 10 reps, rest ≥1 minute	Push floor away harder, lift heel higher
	2	Standing double leg calf raise	3 × 10 reps, rest ≥1 minute	Put more weight on affected leg, lift heels higher
	3	Standing single leg calf raise	3 × max reps, rest ≥1 minute	Lift heel higher
Leg strengthening	1	Sit-to-stand	3 × 10 reps, rest ≥1 minute	Use a lower chair
	2	Sit-to-stand with staggered stance (affected leg behind)	3 × 10 reps, rest ≥1 minute	Place unaffected leg further in front and keep heel of this leg off the ground (i.e., rest on forefoot)
	3	Single leg squat with bilateral upper limb support	3 × 10 reps, rest ≥1 minute	Squat lower
Impact	1	Double leg hopping on the spot	10 seconds	Increase reps and time
	2	Single leg hopping on the spot	10 seconds	Increase reps and time
	3	Walking and running intervals[a]	Run 60 seconds, walk 90 seconds	Increase running time and speed, reduce walking time, and progress to uneven surface (if a goal)

[a] Included a link to the "couch to 5k" website as a guide on returning to running; AROM: active range of movement; Max: maximum; Min: minute; PROM: passive range of movement; reps: repetitions

Discussion

Despite the high incidence of ankle fractures amongst older adults and their typically incomplete recovery, the most effective rehabilitation for these patients remains unknown. The AFTER trial is comparing the effectiveness of supervised versus self-directed rehabilitation for older adults with an ankle fracture. The results, anticipated in 2025, will provide high-quality evidence to guide rehabilitation provision for these patients. In line with current complex intervention development guidance [11], this paper describes how the AFTER trial interventions were developed and are delivered. After publication of the trial results, we will support implementation by developing training resources for health professionals and preparing the materials for wider use.

Ethical approval

Ethical approval for the definitive AFTER trial was obtained from the National Research Ethics Service, North West - Liverpool Central Research Ethics Committee (reference 22/NW/0131). The University of Oxford's Medical Sciences Inter-Divisional Research Ethics Committee provided ethical approval for the clinical practice survey (reference R46784/RE002)

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Conflict of interest

None to declare.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.physio.2025.101789.

References

[1] Court-Brown CM, Caesar B. Epidemiology of adult fractures: a review. Injury 2006;37:691–7. https://doi.org/10.1016/j.injury.2006.04.130

[2] Curtis EM, van der Velde R, Moon RJ, van den Bergh JPW, Geusens P, de Vries F, *et al.* Epidemiology of fractures in the United Kingdom 1988 to 2012: variation with age, sex, geography, ethnicity and socioeconomic status. Bone 2016;87:19–26. https://doi.org/10.1016/j.bone.2016.03.006

[3] Keene DJ, Lamb SE, Mistry D, Tutton E, Lall R, Handley R, *et al.* Three-year follow-up of a trial of close contact casting vs surgery for initial treatment of unstable ankle fractures in older adults. JAMA 2018;319:1274–6.

[4] Psatha M, Wu Z, Gammie FM, Ratkevicius A, Wackerhage H, Lee JH, *et al.* A longitudinal MRI study of muscle atrophy during lower leg immobilization following ankle fracture. J Magn Reson Imaging 2012;35:686–95. https://doi.org/10.1002/jmri.22864

[5] Lin C-WC, Moseley AM, Herbert RD, Refshauge KM. Pain and dorsiflexion range of motion predict short-and medium-term activity limitation in people receiving physiotherapy intervention after ankle fracture: an observational study. Aust J Physiother 2009;55:31–7. https://doi.org/10.1016/s0004-9514(09)70058-3

[6] Wolf S, Lessl E, Müller S, Schmidmaier G, Dreher T. Persistent diminished joint function following ankle fracture – a risk factor for posttraumatic osteoarthritis? Gait Posture 2013;38:S101–2.

[7] Willett K, Keene DJ, Mistry D, Nam J, Tutton E, Handley R, *et al.* Close contact casting vs surgery for initial treatment of unstable ankle fractures in older adults a randomized clinical trial. JAMA 2016;316:1455–63. https://doi.org/10.1001/jama.2016.14719

[8] Lin C-WC, Donkers NA, Refshauge KM, Beckenkamp PR, Khera K, Moseley AM. Rehabilitation for ankle fractures in adults. Cochrane Database Syst Rev 2012. https://doi.org/10.1002/14651858.cd005595.pub3

[9] Keene DJ, Costa ML, Peckham N, Tutton E, Barber VS, Dutton SJ, *et al.* Progressive exercise versus best practice advice for adults aged 50 years or over after ankle fracture: the AFTER pilot randomised controlled trial. BMJ Open 2022;12. https://doi.org/10.1136/bmjopen-2021-059235

[10] Keene DJ, Achten J, Forde C, Png ME, Grant R, Draper K, *et al.* Effectiveness of supervised versus self-directed rehabilitation for adults aged 50 years and over with ankle fractures: protocol for the AFTER trial. Bone Jt Open 2024;5:499–513. https://doi.org/10.1302/2633-1462

[11] O'Cathain A, Croot L, Duncan E, Rousseau N, Sworn K, Turner KM, *et al.* Guidance on how to develop complex interventions to improve health and healthcare. BMJ Open 2019;9:1–9. https://doi.org/10.1136/bmjopen-2019-029954

[12] Keene DJ, Costa ML, Tutton E, Hopewell S, Barber VS, Dutton SJ, *et al.* Progressive functional exercise versus best practice advice for adults aged 50 years or over after ankle fracture: protocol for a pilot randomised controlled trial in the UK – the ankle fracture treatment: enhancing rehabilitation (AFTER) study. BMJ Open 2019;9:1–10. https://doi.org/10.1136/bmjopen-2019-030877

[13] Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;337:979–83. https://doi.org/10.1136/bmj.a1655

[14] British Orthopaedic Association Audit Standards for Trauma. BOAST 12: the management of ankle fractures; 2016.

[15] National Institute for Health and Care Excellence. Fractures (non-complex): assessment and management; 2016. ⟨https://www.nice.org.uk/guidance/ng38⟩. [Accessed 26 March 2024].

[16] Nilsson GM, Jonsson K, Ekdahl CS, Eneroth M. Effects of a training program after surgically treated ankle fracture: a prospective randomised controlled trial. BMC Musculoskelet Disord 2009;10. https://doi.org/10.1186/1471-2474-10-118

[17] Keene DJ, Forde C, Sugavanam T, Williams MA, Lamb SE. Exercise for people with a fragility fracture of the pelvis or lower limb: a systematic review of interventions evaluated in clinical trials and reporting quality. BMC Musculoskelet Disord 2020;21:1–13. https://doi.org/10.1186/s12891-020-03361-8

[18] Moseley AM, Beckenkamp PR, Haas M, Herbert RD, Lin CWC, Evans P, *et al.* Rehabilitation after immobilization for ankle fracture: the EXACT randomized clinical trial. JAMA 2015;314:1376–85. https://doi.org/10.1001/jama.2015.12180

[19] Beckenkamp PR, Lin CWC, Chagpar S, Herbert RD, Van Der Ploeg HP, Moseley AM. Prognosis of physical function following ankle fracture: a systematic review with meta-analysis. J Orthop Sports Phys Ther 2014;44:841–51. https://doi.org/10.2519/jospt.2014.5199

[20] Clegg A, Young J, Iliffe S, Rikkert MO, Rockwood K. Frailty in elderly people. The Lancet 381. 2013:752–62. https://doi.org/10.1016/S0140-6736(12)62167-9

[21] Tutton E, Gould J, Lamb SE, Costa ML, Keene DJ. 'It makes me feel old': understanding the experience of recovery from ankle fracture at 6 months in people aged 50 years and over. Qual Health Res 2023;33:308–20. https://doi.org/10.1177/10497323231153605

[22] Tutton E, Gould J, Lamb SE, Costa ML, Keene DJ. Experience of patients and physiotherapists within the after pilot randomised trial of two rehabilitation interventions for people aged 50 years and over post ankle fracture: a qualitative study. BMJ Open 2023;13. https://doi.org/10.1136/bmjopen-2023-071678

[23] Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, *et al.* Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014;348:1–12. https://doi.org/10.1136/bmj.g1687

[24] Slade SC, Dionne CE, Underwood M, Buchbinder R. Consensus on exercise reporting template (CERT): explanation and elaboration statement. Br J Sports Med 2016;50:1428–37. https://doi.org/10.1136/bjsports-2016-096651

[25] Medina-Mirapeix F, Escolar-Reina P, Gascán-Cnovas JJ, Montilla-Herrador J, Jimeno-Serrano FJ, Collins SM. Predictive factors of adherence to frequency and duration components in home exercise programs for neck and low back pain: an observational study. BMC Musculoskelet Disord 2009;10:1–9. https://doi.org/10.1186/1471-2474-10-155

[26] Ratamess NA, Alvar BA, Evetoch TK, Housh TJ, Kibler B, Kraemer WJ, *et al.* Progression models in resistance training for healthy adults. Med Sci Sports Exerc 2009;41:687–708. https://doi.org/10.1249/MSS.0b013e3181915670

[27] Borg GAV. Psychophysical bases of perceived exertion. Med Sci Sports Exerc 1982;14:377–81.

[28] Lea JWD, O'Driscoll JM, Hulbert S, Scales J, Wiles JD. Convergent validity of ratings of perceived exertion during resistance exercise in healthy participants: a systematic review and meta-analysis. Sports Med Open 2022;8. https://doi.org/10.1186/s40798-021-00386-8

[29] Peek K, Sanson-Fisher R, Mackenzie L, Carey M. Interventions to aid patient adherence to physiotherapist prescribed self-management strategies: a systematic review. Physiotherapy 2016;102:127–35. https://doi.org/10.1016/j.physio.2015.10.003

[30] Michie S, Rumsey N, Fussell A, Hardeman W, Johnston M, Newman S, *et al.* Improving health: changing behaviour. NHS health trainer handbook. Department of Health; 2008. p. 1–79.

[31] Lamb SE, Williamson EM, Heine PJ, Adams J, Dosanjh S, Dritsaki M, *et al.* Exercises to improve function of the rheumatoid hand (SARAH): a randomised controlled trial. Lancet 2015;385:421–9. https://doi.org/10.1016/S0140-6736(14)60998-3

[32] Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, *et al.* The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med 2013;46:81–95. https://doi.org/10.1007/s12160-013-9486-6

[33] Folland JP, Williams AG. The adaptations to strength training: morphological and neurological contributions to increased strength. Sports Med 2007;37:145–68. https://doi.org/10.2165/00007256-200737020-00004

[34] Garber CE, Blissmer B, Deschenes MR, Franklin BA, Lamonte MJ, Lee IM, *et al.* Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. Med Sci Sports Exerc 2011;43:1334–59. https://doi.org/10.1249/MSS.0b013e318213fefb