ISRCTN11830323 https://doi.org/10.1186/ISRCTN11830323

# AFTER – Ankle fracture treatment: enhancing rehabilitation trial

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 06/01/2022 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 03/05/2022 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 01/06/2026 | Musculoskeletal Diseases | [X] Record updated in last year |

## Plain English summary of protocol

Background and study aims
After a broken ankle, the lower leg is usually placed in a cast or boot for a number of weeks so the broken bone can heal. When the cast or boot is removed the ankle initially feels stiff and sore. At this time, patients are given advice by health professionals on how to gradually get back to their usual activities and are given exercises to do at home.
In some hospitals, patients are asked to attend physiotherapy sessions, whilst in other hospitals, patients will just receive advice. There is currently no scientific evidence showing that seeing a physiotherapist after an ankle fracture improves recovery. As physiotherapy appointments aren’ t always convenient for patients, and because it’s important to make the best use of NHS time and resources, we want to find out if attending physiotherapy after an ankle fracture really does help improve recovery. This study aims to find out the best way to provide rehabilitation for people aged 50 and over who have a broken ankle.

Who can participate?
People aged 50 and over who have a broken ankle.

What does the study involve?
If patients are happy to take part in this study, a researcher will help them to complete a short online questionnaire that asks about the patient's health and level of activity, and ankle. This questionnaire should take no more than 10 minutes to complete.
Researchers will then use a computer program to allocate patients to one of the treatment groups. Patients will be randomised to either self-directed or supervised rehabilitation.
Self-directed rehabilitation involves the doctor, physiotherapist or nurse at the hospital providing advice and exercises to be followed at home. Patients will be provided with a detailed advice workbook and/or access to a website. The workbook and website contain a set of exercises that can be progressed independently over the next few months.
If patients are randomised to supervised rehabilitation they will receive the same advice and a workbook/access to a website. In addition, they will also attend 4-6 sessions with a physiotherapist to receive advise on exercises and progression. Sessions may be face-to-face or remotely by telephone/video call. The physiotherapy sessions will take place over three months.
All patients will then be asked to complete a further questionnaire at two, four and six months post randomisation.

What are the possible benefits and risks of participating?
Fully qualified, registered health professionals will provide treatment. They will use widely recognised treatments in the NHS. We hope the information from this study will be used to help treat people with broken ankles more effectively.
Patients are unlikely to be harmed by this treatment. They may experience soreness after completing some of the exercises. This is normal, and patients will be given advice on how to manage this soreness. We are not able to pay travel expenses for attendance at physiotherapy sessions as this part of patients treatment.

Where is the study run from?
The University of Oxford (UK)

When is the study starting and how long is it expected to run for?
September 2021 to April 2025.

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr David Keene, after@ndorms.ox.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr David Keene

### ORCID ID
https://orcid.org/0000-0001-7249-6496

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# Additional identifiers

### Integrated Research Application System (IRAS)
308989

### Central Portfolio Management System (CPMS)
52704

# Study information

## Scientific Title
Effectiveness of supervised versus self-directed rehabilitation for people aged 50 years and over with ankle fractures: the AFTER trial

## Acronym
AFTER

## Study objectives
Our study will find out if referral for physiotherapy appointments after a person over 50 years has suffered a broken ankle helps them recover quicker and better when compared to good quality advice on self-management which includes booklets and videos.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 12/05/2022, North West - Liverpool Central Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048118, +44 (0) 2071048035, +44 (0)2071048016; liverpoolcentral.rec@hra.nhs.uk), ref: 22/NW/0131

## Primary study design
Interventional

## Study design
Multicentre randomized parallel-group superiority trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Ankle fracture

## Interventions
Randomisation procedure
Participants will be randomised by the local research team using a web-based service. Participants will be randomised at the stage they have weight bearing and movement restrictions outside of a cast or boot lifted at approximately 6 weeks (and no earlier than 4 weeks) after injury/surgery. The randomisation will be on a 1:1 basis to supervised versus self-directed rehabilitation.

Supervised rehabilitation arm
Participants randomised to supervised rehabilitation will receive an 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 4 to 6 one-to-one sessions with a physiotherapist, spread over 3 months from the initial session. The first session will be as soon as possible after the referral, and no later than three weeks from randomisation. Sessions will be delivered via

face-to-face or telephone/videoconference, whichever mode of physiotherapy delivery would usually be provided for the patient. Exercise progression will be individualised by progressing and regressing the volume and load in line with each participant's capabilities and preferences. 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.

Self-directed Rehabilitation arm
Participants randomised to Self-directed rehabilitation will receive an advice booklet available in paper or online format from the fracture clinic, it will contain standardised 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. Participants will access this booklet/ website facility when they wish.

Both arms
Participants will receive an electronic/paper invite (according to the participant's preference) to complete questionnaires. Reminders will be sent by email, post and/or text message. Any secure online link will be included in the email or text message so that participants can complete the questionnaires online.
These questionnaires will be sent at 2, 4 and 6 months post randomisation

## Intervention Type
Other

## Primary outcome(s)
Ankle function measured by Olerud and Molander Ankle Scale (OMAS) at 6 months post randomisation

## Key secondary outcome(s)
1. Ankle function measured by Olerud and Molander Ankle Scale (OMAS) at baseline and 2 and 4 months post randomisation.
2. Health-related quality of life measured by EQ-5D-5L at Baseline, 2, 4 and 6 months post-randomisation.
3. Pain, measured by pain sub-scales of the EQ-5D-5L and OMAS at Baseline, 2, 4 and 6 months post-randomisation.
4. Physical Function, measured by PROMIS Physical Function at Baseline, 4 and 6 months post-randomisation.
5. Self-efficacy measured by Self-Efficacy Exercise Score at Baseline, 4 and 6 months post-randomisation
6. Participant exercise adherence, measured with self-reported exercise frequency at 2, 4 and 6 months post-randomisation.
7. Participant complications, measured with complications questionnaire and Case Report Form at 2, 4 and 6 months post-randomisation.
8. Cost effectiveness of interventions measured with health economics questionnaire at 2 and 6 months post-randomisation

## Completion date
30/04/2025

# Eligibility

### Key inclusion criteria
1. Patient is aged 50 years and over with an ankle fracture undergoing surgical fixation or nonsurgical management
2. Patient is provided with a cast or orthotic boot (non-removable or removable for non-weight bearing ankle movement) for at least 4 weeks and no longer than 10 weeks
3. Patient has capacity to consent to trial participation within 14 days of removal of the cast/boot

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
50 Years

### Upper age limit
100 Years

### Sex
All

### Total final enrolment
377

### Key exclusion criteria
1. Patient is deemed unable to adhere to trial procedures or complete questionnaires
2. Patient was not ambulatory before the injury
3. Patient has contraindications to participation in an exercise programme

### Date of first enrolment
15/09/2022

### Date of final enrolment
15/11/2023

# Locations

### Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

**Study participating centre**
**Royal United Hospitals Bath NHS Foundation Trust**
Combe Park
Bath
England
BA1 3NG

**Study participating centre**
**Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust**
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
England
DN2 5LT

**Study participating centre**
**Oxford University Hospitals NHS Foundation Trust**
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

**Study participating centre**
**Pinderfields Hospitals NHS Trust**
Trust Hq, Rowan House
Pinderfields General Hospital
Aberford Road
Wakefield
England
WF1 4EE

**Study participating centre**
**Nottingham University Hospitals NHS Trust - City Campus**
Nottingham City Hospital
Hucknall Road

Nottingham
England
NG5 1PB

**Study participating centre**
**Somerset NHS Foundation Trust**
Trust Management
Lydeard House
Musgrove Park Hospital
Taunton
England
TA1 5DA

**Study participating centre**
**North Bristol NHS Trust**
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

**Study participating centre**
**Royal Devon University Healthcare NHS Foundation Trust**
Royal Devon University NHS Ft
Barrack Road
Exeter
England
EX2 5DW

**Study participating centre**
**The Princess Alexandra Hospital**
Hamstel Road
Harlow
England
CM20 1QX

**Study participating centre**
**King's College Hospital NHS Foundation Trust**
Denmark Hill
London

England
SE5 9RS

**Study participating centre**
**Airedale General Hospital**
Skipton Road
Steeton
Keighley
England
BD20 6TD

**Study participating centre**
**Betsi Cadwaladr University Lhb Anglesey Office**
17 High Street
Llangefni
Wales
LL77 7LT

**Study participating centre**
**Northern General Hospital**
Herries Road
Sheffield
England
S5 7AU

**Study participating centre**
**Surrey and Sussex Healthcare NHS Trust**
Trust Headquarters
East Surrey Hospital
Canada Avenue
Redhill
England
RH1 5RH

**Study participating centre**
**University Hospitals of Leicester NHS Trust**
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

**Study participating centre**
**Royal Cornwall Hospitals NHS Trust**
Royal Cornwall Hospital
Treliske
Truro
England
TR1 3LJ

**Study participating centre**
**Northumbria Healthcare NHS Foundation Trust (headquarters)**
Rake Lane
North Shields
England
NE29 8NH

**Study participating centre**
**Milton Keynes General Hospital**
Milton Keynes Hospital
Standing Way
Eaglestone
Milton Keynes
England
MK6 5LD

**Study participating centre**
**Eastbourne Hospitals NHS Trust**
Eastbourne District Gen Hospital
Kings Drive
Eastbourne
England
BN21 2UD

**Study participating centre**
**South Tyneside and Sunderland NHS Foundation Trust**
Sunderland Royal Hospital
Kayll Road
Sunderland
England
SR4 7TP

**Study participating centre**
**Luton and Dunstable University Hospital**
Lewsey Road
Luton
England
LU4 0DZ

**Study participating centre**
**William Harvey Hospital**
Kennington Road
Willesborough
Ashford
England
TN24 0LZ

**Study participating centre**
**North West Anglia NHS Foundation Trust**
Peterborough City Hospital
Bretton Gate
Bretton
Peterborough
England
PE3 9GZ

**Study participating centre**
**Victoria Hospital**
Hayfield Road
Kirkcaldy
Scotland
KY2 5AH

**Study participating centre**
**Royal Berkshire Hospital**
Royal Berkshire Hospital
London Road
Reading
England
RG1 5AN

**Study participating centre**

**Hampshire Hospitals NHS Foundation Trust**
Basingstoke and North Hampshire Hos
Aldermaston Road
Basingstoke
England
RG24 9NA

**Study participating centre**
**West Suffolk NHS Foundation Trust**
West Suffolk Hospital
Hardwick Lane
Bury St. Edmunds
England
IP33 2QZ

**Study participating centre**
**Wrightington, Wigan and Leigh NHS Foundation Trust**
Royal Albert Edward Infirmary
Wigan Lane
Wigan
England
WN1 2NN

# Sponsor information

**Organisation**
University of Oxford

**ROR**
https://ror.org/052gg0110

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the chief investigator, Dr David Keene, after@ndorms.ox.ac.uk, and will be assessed on a case-by-case basis

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 20/06/2024 | 01/06/2026 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Other publications | Design and delivery of the interventions | 24/03/2025 | 23/04/2025 | Yes | No |
| Participant information sheet | version 0.6 | 17/02/2022 | 21/02/2022 | No | Yes |
| Participant information sheet | version 3.0 | 12/05/2022 | 16/09/2022 | No | Yes |
| Protocol file | version 0.5 | 17/02/2022 | 21/02/2022 | No | No |
| Study website | | 11/11/2025 | 11/11/2025 | No | Yes |