

AFTER – Ankle fracture treatment: enhancing rehabilitation trial

Submission date 06/01/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/05/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/04/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 advice 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>

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

308989

ClinicalTrials.gov (NCT)

Nil Known

Protocol serial number

IRAS 308989, 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

Study design

Multicentre randomized parallel-group superiority trial

Primary study design

Interventional

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

Senior

Lower age limit

50 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

United Kingdom

BA1 3NG

Study participating centre

Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust

Doncaster Royal Infirmary

Armthorpe Road

Doncaster

United Kingdom

DN2 5LT

Study participating centre

Oxford University Hospitals NHS Foundation Trust

John Radcliffe Hospital

Headley Way

Headington

Oxford

United Kingdom

OX3 9DU

Study participating centre

Pinderfields Hospitals NHS Trust

Trust Hq, Rowan House

Pinderfields General Hospital

Aberford Road

Wakefield

United Kingdom

WF1 4EE

Study participating centre

Nottingham University Hospitals NHS Trust - City Campus

Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre

Somerset NHS Foundation Trust

Trust Management
Lydeard House
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre

North Bristol NHS Trust

Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre

Royal Devon University Healthcare NHS Foundation Trust

Royal Devon University NHS Ft
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre

The Princess Alexandra Hospital

Hamstel Road
Harlow
United Kingdom
CM20 1QX

Study participating centre

King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD

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

Study participating centre
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

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

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square

Leicester
United Kingdom
LE1 5WW

Study participating centre
Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LJ

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

Study participating centre
Milton Keynes General Hospital
Milton Keynes Hospital
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Eastbourne Hospitals NHS Trust
Eastbourne District Gen Hospital
Kings Drive
Eastbourne
United Kingdom
BN21 2UD

Study participating centre
South Tyneside and Sunderland NHS Foundation Trust
Sunderland Royal Hospital
Kayll Road
Sunderland

United Kingdom
SR4 7TP

Study participating centre
Luton and Dunstable University Hospital
Lewsey Road
Luton
United Kingdom
LU4 0DZ

Study participating centre
William Harvey Hospital
Kennington Road
Willesborough
Ashford
United Kingdom
TN24 0LZ

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

Study participating centre
Victoria Hospital
Hayfield Road
Kirkcaldy
United Kingdom
KY2 5AH

Study participating centre
Royal Berkshire Hospital
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre**Hampshire Hospitals NHS Foundation Trust**

Basingstoke and North Hampshire Hos

Aldermaston Road

Basingstoke

United Kingdom

RG24 9NA

Study participating centre**West Suffolk NHS Foundation Trust**

West Suffolk Hospital

Hardwick Lane

Bury St. Edmunds

United Kingdom

IP33 2QZ

Study participating centre**Wrightington, Wigan and Leigh NHS Foundation Trust**

Royal Albert Edward Infirmary

Wigan Lane

Wigan

United Kingdom

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?
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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 0.5	17/02/2022	21/02/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes