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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	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/04/2025	Musculoskeletal Diseases	[X] Record updated in last year

Plain English Summary

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

Study website
https://after-study.digitrial.com/

Contact information

Type(s)
Scientific

Contact name
Dr David Keene

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
308989

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
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 hypothesis
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See trial outputs table

Condition
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 measure
Ankle function measured by Olerud and Molander Ankle Scale (OMAS) at 6 months post randomisation

Secondary outcome measures

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

Overall study start date
01/09/2021

Overall study end date
30/04/2025

Eligibility

Participant 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

Age group
Senior

Lower age limit
50 Years

Sex
Both

Target number of participants
344

Total final enrolment
377

Participant 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

Recruitment start date
15/09/2022

Recruitment end date
15/11/2023

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

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

Sponsor details
Joint Research Office
1st floor, Boundary Brook House
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United Kingdom
OX3 7GB
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ctrg@admin.ox.ac.uk

Sponsor type
University/education

Website
https://www.ox.ac.uk

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/07/2025

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?
Participant information sheet	version 0.6	17/02/2022	21/02/2022	No	Yes
Protocol file	version 0.5	17/02/2022	21/02/2022	No	No
Participant information sheet	version 3.0	12/05/2022	16/09/2022	No	Yes
HRA research summary			28/06/2023	No	No
Other publications	design and delivery of the interventions	24/03/2025	23/04/2025	Yes	No