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Ankle Fracture Treatment: Enhancing Rehabilitation – the AFTER study

Submission date
30/07/2018

Recruitment status
No longer recruiting

Registration date
31/07/2018

Overall study status
Completed

Last Edited
25/07/2023

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Broken ankles represent a high proportion of injuries treated in the National Health Service (NHS). The most severe injuries require surgery or casting to align the bones until healing has occurred. An increasing number of these injuries are in adults over 50 years old as the age of the population is rising. For older adults, an ankle injury can be the start of a decline in their ability to move around confidently as the limb can feel weak, walking is difficult, balance worsens and a fear of falling is common. On average, older adults lose around 30% of their ankle function at 6 months after breaking their ankle. In the NHS, physiotherapy provision after acute fracture treatment with a surgery or a cast varies from hospital to hospital. Some patients may not get any physiotherapy, although most do, and usual care is generally a session of advice with occasionally the option of a further one or two sessions follow-up. In clinical trials to date longer courses of supervised physiotherapy have not shown advantages for patients, compared with a single session of advice. However, these studies have not focussed specifically on the needs of older adults, who may have more complex needs. The aim of this study is to assess the feasibility of conducting a large trial to test whether a new approach to physiotherapy provision or best practice advice is the best and most affordable approach to treating ankle fractures in older adults in the NHS.

Who can participate?
Patients aged 50 and over with an ankle fracture

What does the study involve?
Participants are randomly allocated to one of two different types of physiotherapy regime. One type regime is best-practice advice, which includes guidance on self-management and a home-based exercise programme, and access to an information booklet. There are one or two optional extra contacts with the physiotherapist to reinforce advice for people who are struggling to manage. The second type of regime includes up to six sessions with a physiotherapist. The additional sessions involve functional progressive exercises to be practised and progressed under supervision. The physiotherapist facilitates self-management and independent exercise practice at home. The aims are to estimate rates of recruitment and follow-up and the adherence to the physiotherapy regimes. Ten participants are interviewed to better understand their experience of taking part in the study and the physiotherapy regimes.

What are the possible benefits and risks of participating?
Fully qualified, registered physiotherapists provide treatment. They use widely recognised treatments used in the NHS. It is hoped that the information from this study will be used to help treat people with broken ankles more effectively. Participants are unlikely to be harmed by this treatment. The physiotherapist assesses participants to make sure they are given exercises at the right level. Participants may experience soreness after completing some of the exercises. This is normal, and participants are given advice on how to manage this soreness.

Where is the study run from?
John Radcliffe Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2015 to March 2020 (updated 06/08/2019, previously: December 2019)

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

Who is the main contact?
Dr David Keene
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Study website
https://after.octru.ox.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38188

Study information

Scientific Title
Optimising mobility after ankle fracture in older adults: a multi-centre pilot randomised controlled trial

Acronym
AFTER

Study objectives
The aim of the AFTER (Ankle Fracture Treatment: Enhancing Rehabilitation) study is to assess the feasibility of conducting a large randomised controlled trial to test whether a new approach to physiotherapy provision or best practice advice is the best and most affordable approach to treating ankle fractures in older adults in the NHS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central – Hampshire B, 02/07/2018, ref: 18/SC/0281

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural, Complex Intervention, Physical, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions

This is a multicentre pilot randomised controlled trial with an embedded qualitative study. Participants will be allocated to best practice advice (one session of face-to-face advice delivered by a physiotherapist, with up to two additional sessions face-to-face or over the telephone) or progressive functional exercise (up to six sessions of individual face-to-face physiotherapy).

After consent participants will be randomised to either best practice advice or progressive exercise.

For those randomised to the best practice advice group - these individuals will have 1 session with a physiotherapist and be given lots of advice, with the option if required of having up to 2 follow up sessions - this will end their intervention.

For those randomised to the progressive exercise group - these individuals will have up to 6 sessions with a physiotherapist (depending upon their progress) of exercises and assessments - this will end their intervention.

Then for both groups at 3 and 6 months participants will be asked to complete questionnaires. At 3 months the questionnaire will be administered via the post/email, whereas at 6 months the questionnaire will be administered either via the post/email or at the follow-up visit participants are asked to attend - where they will have a few standard functional tests administered.

There will also be a sub-study within the trial where we hope to interview up to 10 of the participants on their views about the study. This would involve a one to one interview for patients - which would most commonly take place in their home.

Intervention Type
Other

Primary outcome measure
The feasibility of a definitive RCT, assessed using the following success criteria:
1. Study participation rate of at least 25% of those eligible. Below this threshold would indicate lack of acceptability and there would be issues with generalisability
2. 48 eligible participants agree to participation over 3 sites over a maximum of 18 months (equivalent to at least 1 participant per month per site)
3. At least 85% of participants complete the study intervention sessions
4. At least 80% attend study follow-up at 6 months

Secondary outcome measures
The viability of measuring the following outcomes at 3 and 6-month follow-up:
1. Ankle-related symptoms and function, measured using the Olerud and Molander Ankle Score
2. Lower limb function, measured using the Lower Extremity Functional Scale
3. Pain, measured using Visual Analogue Scale
4. Health-related quality of life, measured using the EQ-5D-5L score
5. Fear of falls, measured using the Falls Efficacy Scale – International [short]
6. Self-efficacy, measured using the self-efficacy exercise score
7. Return to desired activities, including work, social life and sport activities (patient-reported)
8. Walking aid use and distance
9. Use of medications (patient-reported)
10. Work disability, measured using days off sick
11. Healthcare resource use (patient-reported)

12. Out-of-pocket expenses (patient-reported)
13. Adverse events
14. Adherence to exercise (patient-reported)

6-month follow-up only:
1. Ankle joint range, measured using hand-held goniometry
2. Muscle strength, measured using hand held dynamometry
3. Short Physical Performance Battery (SPPB)

Embedded sub-study (optional participation):
1. The patients' experiences of being recruited to a randomised trial of physiotherapy rehabilitation
2. What helps or hinders patient participation in the trial interventions and how this fits into their daily lives

Overall study start date
01/01/2015

Completion date
24/04/2020

Eligibility

Key inclusion criteria
1. Adults aged 50 years or over with an ankle fracture
2. Undergoing surgical fixation, or conservative management involving ankle immobilisation for at least 4 weeks

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 48; UK Sample Size: 48

Total final enrolment
61

Key exclusion criteria
Patients who:
1. Are unable to understand spoken and written English
2. Do not have capacity to consent to study participation
3. Who were not ambulatory prior to the injury
4. Who are considered inappropriate for referral to physiotherapy (in the opinion of the clinician)
5. Who are unable to attend outpatient physiotherapy at a participating centre

6. With serious concomitant disease (such as terminal illness)
7. With avulsion fractures or other fractures not requiring surgery or immobilisation for definitive management
8. With bilateral lower limb fractures

Date of first enrolment
01/08/2018

Date of final enrolment
31/08/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
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Sponsor information

Organisation
University of Oxford

Sponsor details
Joint Research Office
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Trainees Co-ordinating Centre (TCC); Grant Codes: PDF-2016-09-056

Results and Publications

Publication and dissemination plan
Protocol, intervention and results papers in peer-reviewed journals and conferences.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/11/2019	27/10/2020	Yes	No
Results article	Primary outcomes	24/11/2022	25/11/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article	Results of embedded qualitative substudy	24/07/2023	25/07/2023	Yes	No