Ankle Fracture Treatment: Enhancing Rehabilitation – the AFTER study

Effectiveness of supervised versus self-directed rehabilitation for people aged 50 years and over with ankle fractures

Participant Information Leaflet

Invitation to join the AFTER study

We would like to invite you to take part in a research study. This study aims to find out the best way to provide rehabilitation for people aged 50 and over who have a broken ankle.

Please take time to read the following information and talk to others about the study. If anything is unclear, or if you would like more information, please ask a member of the study team who will be happy to answer any questions you have or visit our website for more information:

https://after-study.digitrial.com/
On the website is a short animation (video) explaining the study and what it involves that may answer some or all of your questions about the study.

What is the purpose of this study?

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. 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 improves recovery.

In the AFTER study, all participants will receive high quality information that will guide them with their recovery, with half of the participants also being asked to attend 4-6 physiotherapy sessions. Information on how quickly and how well participants are able to return to the majority of their usual activities will be used to make a comparison between the two treatments.

The AFTER study has been developed by patients and healthcare professionals, including physiotherapists and doctors. Their experience and knowledge have been used to plan this study which could provide an answer as to what type of rehabilitation is best.

Who is taking part and why have I been invited to join?

You have been invited to take part because you are aged 50 years or over and have been diagnosed with a broken ankle, which means you may be eligible for the study. We are hoping to recruit 344 men and women from hospitals across the UK.

Do I have to take part?

No. You decide whether or not to take part. Please keep this leaflet and use it to make your decision. If you decide to take part, you will be asked to sign a consent form.

If you choose not to join the study, you will get the standard treatment for your condition, according to the judgement of your healthcare professional in line with standard NHS practice. A note will be made of your age, sex at birth, ethnicity, what area of the country you live in, and whether or not you had an operation for your broken ankle, so that we can find out who decides not to take part in the study– you cannot be identified from this data. A researcher may ask you if you would be happy to give a reason for not wanting to take part in the study – this is entirely voluntary. Any responses you give would only be used to help the design of future studies.

What will happen if I take part?

Initial assessment: If you are happy to take part in this study, a researcher will ask you some simple questions and check your medical history to confirm that you are eligible. If you are eligible, we will ask you to sign and date a consent form on a computer. A researcher will then help you to complete a short online questionnaire that asks about you, your health and level of activity, and your ankle. This questionnaire should take no more than 10 minutes to complete.

Treatment allocation: Researchers will use a computer program developed by the study team to allocate you to one of the treatment groups. You will have equal chance of being allocated either treatment, rather like the toss of a coin. This is important because it means we can test the different treatments fairly. Your usual healthcare professional, the researcher, or physiotherapist will not be able to influence which treatment you get and you will not be able to choose. At this point you will be told which treatment you have been assigned to. The two types of treatments that are being used in this study are:

Self-directed Rehabilitation - this involves the doctor, physiotherapist or nurse at the hospital providing you with advice and exercises to be followed at home. You 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. You will also receive an exercise diary that can be completed in the workbook or on the website. There is information on how to gradually get back to your usual activities and how to manage common challenges during recovery. The website has extra videos on how to do the exercises in the workbook.

Supervised Rehabilitation – you will receive the same advice, a workbook, an exercise diary and access to a website. In addition, you will be provided with 4-6 sessions with a physiotherapist to receive advice on exercises and progression. The first session will last a maximum of an hour and follow-up sessions will be a maximum of 30 minutes. Sessions may

be face-to-face in an outpatient department or by telephone/video call. The sessions will be arranged by the physiotherapy team and will take place over three months.

A researcher from the central study team may visit your hospital to sit in on your physiotherapy session or listen to an audio recording of one of your physiotherapy sessions. They will check that the session is being delivered as we had intended them and to see if the physiotherapist needs any support. This type of check is normal in physiotherapy research. In case of an audio-recording being made, your consent for this part of the study will be captured on the recording. The recording will be deleted 12 months after it has been checked by the research team. If no audio-recording is made and a researcher attends your physiotherapy session in person, they will first ask you to confirm that you are happy for them to be present.

You will also receive a welcome pack in the post from our central study team.

What information will be collected from me?

We would ask you to complete questionnaires when you join the study and again two, four and six months later. Questionnaires will ask about you, your health and activity, and your ankle. We would also ask you about any healthcare appointments or treatments you have had for your ankle.

We will send you a link to an online questionnaire by email or text. If you are unable to complete the questionnaires online, we can send them to you in the post with a postage-paid addressed return envelope.

If you do not complete the initial questionnaire we will send you up to three reminders in the form of a letter, email or text message.

If required, we will phone you to provide support in completing the questionnaire – we might ask you the questions that are in the questionnaire over the phone. We may send you a text message to let you know we will be calling so that you know that it is the study team contacting you.

Questionnaires will take about 10 to 15 minutes to complete yourself, or about 20 to 25 minutes over the telephone. If you feel uncomfortable at any point, then you do not have to answer the questions.

Participants having supervised rehabilitation that have not had their first session of physiotherapy within three weeks of joining the study may also receive a text or letter from us. The study team will offer to help with booking this first appointment, over the telephone.

What are the benefits and risks of taking part in the study?

You may not get any benefit from taking part in the study, but the results will help to ensure those who break their ankle after the study is completed will have a clear pathway to the best recovery.

Fully qualified, registered health professionals will provide your treatment. They will use widely recognised treatments in the NHS. The treatment you receive may be different to the usual care provided at your hospital. You are unlikely to be harmed by this treatment. You may experience soreness after completing some of the exercises. This is normal, and you will be given advice on how to manage this soreness. The workbook provided to you by the study contains contact information for your local clinical team so that you can get in touch if you are having problems with your recovery. Your local clinical team will be able to advise you on what to do next, including whether they need to arrange further appointments or referrals. We are not able to pay travel expenses for you to attend your physiotherapy sessions

Who will know that I am taking part?

The only people who will know that you are taking part in this study are the members of the research team and the healthcare professionals involved in your care. Your local NHS Trust will pass your details to these people along with the information collected from you and your medical records. We will contact your GP (doctor) to tell them that you have agreed to take part in the AFTER study so they are aware of the care you are receiving for your injury. However, we will not share with them anything that you answer in your study questionnaires.

You can tell anyone that you are taking part. Paperwork completed by you or by the person treating you will be held by the study team running the AFTER study who are based at the University of Oxford. The hospital at which you were treated will also have access to copies of your completed questionnaires to ensure there is transparency in the data that the University collects. They will not contain your name.

Will my details be kept confidential?

The research team will keep all the information collected about and from you strictly confidential. Your research data will be de-identified, you will be allocated a number so that you cannot be identified

The de-identified study data is kept securely and might be shared with other researchers in the future so that they can understand more about people who have had a broken ankle. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care.

In line with what happens in the NHS, the only situation where confidentiality would need to be broken, would be if you told a health professional or research team member about something that could result in harm to yourself or others

What will happen to my personal data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest'. Any data from which you can be identified, such as your name, gender, date of birth, or data concerning your health, is known as personal data. The University of Oxford, as sponsor, is the data controller and is responsible for looking after your information and using it properly. We will be using information from you and your medical records, NHS Digital and other central NHS registries in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 12 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 3 years after the publication of the results of the study.

The local NHS Trust and University study teams will use your contact details to contact you about the research study and deliver the study treatment allocated to you. They will keep identifiable information about you from this study in accordance with their local policy.
Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.
If you would like further information about your rights with respect to your personal data please contact the Data Protection Officer via: https://compliance.web.ox.ac.uk/individual-rights where you will find contact details for the University of Oxford's Information Compliance Team.
You can find out more about how we use your information by contacting the study team on the details given at the end of this document.

What will happen if I don't want to carry on with the study?

You are free to withdraw from participation in the study at any time without giving a reason. If you take part now but you change your mind during the study, this will not change the standard of the care you get from the NHS. You would not be contacted about the study again or have any further data collected about you. If you withdraw from the study, we will use the study data collected up to your withdrawal.

What happens at the end of the study?

At the end of the study, summary results will be made available on the study website.
We will also publish the results and present them in research reports, at scientific conferences, and in scientific journals. De-identified data from the study will be stored securely. If the funders of this research ask us to make the study data available for other researchers in the future, it will only be the de-identified data so that the information cannot be recognised as yours.

How have patients and the public been involved in creating this study?

Patient partners have been key to the development of this research. Our patient partners helped researchers design this study, apply for funding and have helped to develop all documents that will be used by participants. Additionally, there is an oversight committee, that will regularly review the study progress, includes a patient partner who is a full member of the committee, taking part in decision-making throughout the study. If you would like to know

more about getting involved in research as a patient or member of the public, please see this link: https://www.nihr.ac.uk/patients-and-public/ or contact: oxfordtrauma@ndorms.ox.ac.uk

Who is organising and funding the research?

The University of Oxford is sponsoring this study. It is being conducted by a research team led by Dr David Keene, a University Research Lecturer in Trauma Rehabilitation and physiotherapist at the University of Oxford. A health professional from your local NHS Trust will be delivering the treatment.
The National Institute for Health Research is funding the study.

Who has approved this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by North West - Liverpool Central Research Ethics Committee.

What if I have concerns?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to discuss any aspect of the way in which you have been approached or treated during the course of this study, you should contact David Keene who is the overall lead of this study on after@ndorms.ox.ac.uk or 01865 223126; or you may contact the University of Oxford's Research Governance, Ethics & Assurance Team (RGEA) office on 01865 616480 or email ctrg@admin.ox.ac.uk .

The Patient Advice and Liaison Service (PALS) in England and Wales, Patient Advice and Support Service (PASS) in Scotland), or Patient and Client Council support service (PCC) in Northern Ireland, are confidential NHS services that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient.

PALS, PASS and PCC are unable to provide information about this research study.

If you wish to contact the PALS/PASS/PCC team please use contact details from:
https://after-study.digitrial.com/about-the-study/

If you have any questions about the study, please contact your local research team:
https://after-study.digitrial.com/about-the-study/

The AFTER Study Team:
Email: after@ndorms.ox.ac.uk Telephone: 01865 223126
Postal address: AFTER study, Kadoorie Centre, John Radcliffe Hospital, Oxford, OX3 9DU.

Thank you for reading this information leaflet and considering the study. If you would like to take part, please speak to your local AFTER research team