REACH study
Participant Information Sheet

Invitation to join the REACH study

We are inviting you to take part in a research study called REACH. This study will explore the **best way to support adults with a proximal humerus fracture (broken shoulder) in their recovery**. The study has been designed by experts in surgery and rehabilitation alongside patient representatives.

Before you decide to participate, it is important for you to understand why we are doing this research and what it will involve.

Please take time to read this leaflet. If anything is unclear, or if you would like more information, please contact the study team using the details at the end of the leaflet. They will be happy to answer your questions.

Scan here or follow the link to see a short video explaining the study and what it involves: reach.octru.ox.ac.uk/

FUNDED BY
NIHR | National Institute for Health and Care Research

Study Summary

This study will compare two different ways to help people with their recovery from a broken shoulder. Patients with this injury are usually referred for physiotherapy appointments for advice on how to get their arm and shoulder working again. However, there is currently no scientific evidence that having these appointments improves recovery. Patients also often report that travelling to outpatient appointments can be difficult, and the sessions aren't always convenient. Therefore, we want to find out if starting a home-based rehabilitation plan immediately works just as well.

In this study, you will be asked to follow one of two rehabilitation programmes. You will either be offered:

1. Outpatient physiotherapy appointments to be shown what exercises to do.
2. Advice and information about a self-directed exercise programme that can be done at home. Advice will be given by a health professional in the hospital clinic, and you will also be given a high-quality workbook to help guide your recovery.

To measure your recovery progress, we will ask you to complete a set of questionnaires at the start of the study, and then again 2, 4 and 6 months later. These questionnaires will ask about your general health, activity levels, and how well your shoulder is working.

Why have I been invited to take part?

We have invited you to take part because you have broken your shoulder at the top of your upper arm bone. The medical term for this is a 'proximal humerus fracture'. We are hoping around 1200 people from all over the UK with a similar injury to yours will also take part.

Why is this study happening?

Health professionals and patients who have previously had a similar injury believe this study is important. It will help in making sure that future patients with a broken shoulder get the treatment that is best for them. It will also make sure the NHS uses its limited resources in the best way possible.

Do I have to take part in this study?

It is completely up to you if you want to join the study. If you decide to join, you will be asked to sign a consent form. If you choose not to join, a researcher might ask you why, but you don't have to give a reason. Any answers you give will help make future studies better. Not taking part will not change the care you get. You will still receive the normal NHS treatment.

For all patients with an upper arm bone injury, we make a note of their age, sex at birth, ethnicity, the area in the country they live in, and the date of their injury. This helps us to track and improve patient representation in the study. This information will be stored and analysed in a way that keeps patients anonymous.

What happens if I take part?

If you want to join the study, a researcher will ask you some simple questions about your injury and check your medical history to see if you can take part. If you can, they will ask you to sign a consent form on a computer. If you are not at the hospital, you can sign the form through a secure computer link.

You will then have some questions to answer about yourself, your health, your activity level, and your shoulder. This will take about 20 minutes.

To compare rehabilitation programmes, we will put people into groups. Each group will have a different rehabilitation programme. The results from the different groups are compared. To make a fair comparison we try to make sure the groups are the same to start with, so each patient is put into a group by chance (randomly). You have an equal chance of being placed into each rehabilitation programme. The people who care for you in hospital and researchers will not be able to influence which rehabilitation programme you get, and you will not be able to choose. Your General Practitioner (GP) will be informed of your involvement in the study.

What rehabilitation programme could I receive?

The two rehabilitation programmes in this study are:

1. **Referral for physiotherapist-supervised rehabilitation**

You will be referred to your local physiotherapy department for physiotherapy sessions.

2. **Self-directed rehabilitation**

You will get detailed advice from a trained health professional in the hospital. They will give you a workbook with exercises that you can do at home, so you don't have to attend outpatient appointments.

The health professional will assess you and explain what you need to do to get better. They will show you your recommended exercise plan.

You will get a workbook with pictures and advice on the exercises. You will be able to use a website with the same information if you prefer. Online exercise videos will also be available to you. The workbook and website will tell you what to expect and what to do if you have any problems.

What happens next?

As well as taking part in your rehabilitation programme we will ask you to complete **follow-up questionnaires** 2, 4 and 6 months after joining the study. There will be questions about your health, your activity, and your shoulder. We will also ask you about any appointments you have had at the hospital, community health services or your General Practitioner (GP).

Every time we need you to give us some information, we will send an electronic link to your questionnaire by email or text message. You can then give us your answers on the secure study website. Or, if you prefer, we can post the questionnaires to you as paper forms and post them back to us using the pre-paid addressed envelope we give you.

If we do not receive your questionnaire, we will send you at least one letter, email or text message as a reminder. We may also phone you to ask the questions that are in the questionnaires if you don't manage to return them, or to clarify any information that you gave us.

The questionnaires will take about 15 minutes to complete on your own, or about 20 minutes with a researcher over the phone.

If you have been placed in the physiotherapy-supervised group, we will also ask you some quick questions every 2 to 3 weeks about your physiotherapy appointments. To provide this information you will be sent an electronic link, or we will call you.

If you have been placed in the self-directed group, with your permission, the health professional might record the advice session (audio only) to send to the central study team. The recording will be used to check if information is delivered in the best way. This type of check is normal in injury research, but it is ok if you prefer not to take part in this part of the study. The recording will be anonymised before sending it to the central study team and will be deleted 12 months after the research team checks it.

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

You may not benefit just from taking part in the study, but the results will help people who break their shoulder have a clear best pathway to recovery. Doctors and physiotherapists will use the information from this study to help treat people with broken shoulders in the future.

You are unlikely to be harmed by the rehabilitation programmes. The NHS already uses these types of advice and exercises for people with broken bones. You may feel some soreness in your shoulder after exercises, but you will be

given advice on how to manage it. Unfortunately, we are not able to pay travel expenses for you to attend appointments as they are part of usual care.

How will we use information about you?

We will need to use information from you and from your medical records for this research project. This information will include your NHS number, name, contact details, age, sex at birth, ethnicity and demographic data. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason by contacting the REACH study team. We will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

In the unlikely event that you lose capacity, you will be withdrawn from the study, but we will keep information about you that we already have.

Where can you find out more about how your information is used?

- You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team

- by sending an email to reach@ndorms.ox.ac.uk or contacting the Exeter Data Protection Officer at informationgovernance@exeter.ac.uk, or
- by ringing us on 01865 223126 or 01392 726842 (Exeter Data Protection Officer)

What happens at the end of the study?

At the end of the study, we will put a summary of the results on the study website. We will share the results with healthcare researchers and professionals to improve future patient care.

We will also publish the results and present them in research reports, at scientific conferences, and in scientific journals.

If the funders of this research ask us to make the study data available for other researchers, we will first anonymise your information so that you cannot be identified.

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

Patient partners have been key to the development of this research as part of the study team. Additionally, the oversight committee, that will regularly review the study progress, includes a patient partner.

Who is organising and funding the research?

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-carers-and-the-public/ or contact: oxfordtrauma@ndorms.ox.ac.uk

The research team in Oxford

The University of Exeter is sponsoring this study. It is being conducted by a research team at Exeter and Oxford Universities, led by Dr David Keene, a Clinical Specialist Physiotherapist, and Prof Matthew Costa, an Orthopaedic Trauma Consultant.

The study is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme.

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 London - Chelsea Research Ethics Committee.

What if I have concerns or queries?

The University of Exeter, 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 talk to someone about 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 reach@ndorms.ox.ac.uk or 01865 223123; or you may contact the University of Exeter Research Ethics and Governance office on 01392 726621 or email res-sponsor@exeter.ac.uk.

For independent advice, your hospital has a Patient Advice Liaison Service (PALS) in England and Wales, the Patient Advice & Support service (PASS) in Scotland / Patient & Client Council (PCC) in Northern Ireland. These are a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. If you wish to contact the PALS/PASS/PCC team, please use contact details from:

PALS: https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/

PASS: https://pass-scotland.org.uk/

PCC: https://pcc-ni.net/

Please note PALS/PASS/The Patient & Client Council is unable to provide information about this research study.

If you have any questions or concerns about your clinical care, please contact your local Fracture Clinic on the telephone number provided.

If you have any questions about the study, please contact your local research team:

The REACH Study Team can be reached on:
Email: reach@ndorms.ox.ac.uk
Telephone: 01865 223126
Postal address: REACH study, Kadoorie Centre,
John Radcliffe Hospital, Oxford, OX3 9DU.

Thank you for considering taking part in the REACH study.