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# Randomised evaluation of rehabilitation after acute proximal humerus (shoulder) fracture: the REACH study

**Submission date**
09/09/2024

**Recruitment status**
Recruiting

**Registration date**
08/10/2024

**Overall study status**
Ongoing

**Last Edited**
01/07/2025

**Condition category**
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
A break (fracture) to the bone of the upper arm at the shoulder (proximal humerus) is a painful injury. It results in a sudden loss of use of the arm with recovery taking many months. Most injuries occur in people over 50 years of age after a fall, due to reduced bone strength, and are usually treated with a sling, although some fractures may need surgery.
At the moment, people are asked to see a physiotherapist a number of times to help with recovery after a proximal humerus fracture. Attending physiotherapy appointments can however be very difficult, especially for people who live alone or have poor social support networks. Driving is not possible and public transport is a struggle due to low confidence after a fall. A one-off advice session, with clear verbal and written instructions and videos of exercises patients can do at home, could be an alternative to attending a physiotherapy clinic for multiple sessions. Providing high-quality advice so people can manage their own recovery could be less of a burden for patients and their carers who might use fewer healthcare resources.
Before widely using an alternative advice approach, it is important to know that people receiving a one-off advice session would not be disadvantaged in their recovery compared with people having a series of physiotherapy appointments.
The REACH trial aims to find out the best way to support recovery and will compare the recovery of patients who receive a single advice session with a health professional and access to a workbook and videos to use at home, with the recovery of patients who are referred to see a physiotherapist

Who can participate?
People aged 16 years or above with a broken shoulder.

What does the study involve?
The two rehabilitation programmes in this study are referral for physiotherapist-supervised rehabilitation or self-directed rehabilitation. Participants allocated to self-directed rehabilitation will get detailed advice from a trained health professional in the hospital and will be provided

with a workbook and access to a website with exercises that can be completed at home. Participants will be asked to complete follow-up questionnaires 2, 4 and 6 months after joining the study.

What are the possible benefits and risks of participating?
People are unlikely to be harmed by the rehabilitation programmes. The NHS already uses these types of advice and exercises for people with broken bones. Patients may feel some soreness in their shoulder after exercises but will be given advice on how to manage it. Participants 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.

Where is the study run from?
The study is sponsored by the University of Exeter and run by the University of Oxford (UK)

When is the study starting and how long is it expected to run for?
October 2023 to August 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (UK)

Who is the main contact?
Kylea Draper, reach@ndorms.ox.ac.uk

# Contact information

### Type(s)
Scientific


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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
345581

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
CPMS 63906, IRAS 345581, NIHR153139

# Study information

### Scientific Title
Randomised evaluation of rehabilitation after acute proximal humerus fracture (REACH): a multi-centre, non-inferiority, randomised trial to compare the clinical and cost-effectiveness of a self-directed rehabilitation programme versus physiotherapist-supervised rehabilitation (usual care) for adults with a proximal humerus fracture

### Acronym
REACH

### Study objectives
The aim of the REACH trial is to compare the clinical and cost-effectiveness of a self-directed rehabilitation programme versus physiotherapist-supervised rehabilitation (usual care) for adults with non-surgically managed proximal humerus fractures.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 05/09/2024, London - Chelsea Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8156; chelsea.rec@hra.nhs.uk), ref: 24/LO/0605

### Study design
Interventional randomized controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Participant information can be found at: https://reach.octru.ox.ac.uk/patient-information-sheet

## Health condition(s) or problem(s) studied
Proximal humerus fracture

## Interventions
Participants will be randomised by the local research team using a web-based service. The randomisation will be on a 1:1 basis to one of the following groups:

Self-directed rehabilitation (provision of high-quality self-management advice):
Participants allocated to this group will receive detailed advice by a health professional and a workbook and website with a set of exercises that can be progressed independently.

Physiotherapist-supervised rehabilitation (usual care):
Participants allocated to this group will receive usual fracture clinic advice and a referral to physiotherapy.

Participants will be asked to complete follow-up questionnaires 2, 4 and 6 months after joining the study.

## Intervention Type
Behavioural

## Primary outcome measure
Patient-reported shoulder-related pain and function measured by the Oxford Shoulder Score (OSS) at 6 months post-randomisation

## Secondary outcome measures
1. Patient-reported shoulder-related pain and function measured by the Oxford Shoulder Score (OSS) at 2 and 4 months post-randomisation
2. Upper extremity physical function is measured using the Patient Reported Outcome Measurement Information System (PROMIS) Physical Function (Upper Extremity) at 2, 4 and 6 months post-randomisation
3. Health-related quality of life is measured using EuroQol 5 Dimensions EQ 5D-5L at 2, 4 and 6 months post-randomisation
4. Self-efficacy to exercise is measured using Self-Efficacy to Exercise Scale (SEE) at 2, 4 and 6 months post-randomisation
5. Resource use is measured by self-reported bespoke questionnaire at 2, 4 and 6 months post-

randomisation
6. Rates of complications are measured using a bespoke participant questionnaire and site-completed Case Report Forms up to 6 months

### Overall study start date
01/10/2023

### Completion date
31/08/2027

## Eligibility

### Key inclusion criteria
1. Aged 16 years or over
2. Diagnosis of a proximal humerus fracture which is to be managed non-surgically

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
16 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 1214; UK Sample Size: 1214

### Key exclusion criteria
1. Patient has a concurrent neurological injury leading to a significant deficit in the affected arm
2. More than 21 days have elapsed since the fracture
3. Patient has other upper limb injury which may reasonably be expected to impact shoulder rehabilitation and affect responses to patient-reported outcome measures
4. Patient is unable to adhere to the trial procedures.

### Date of first enrolment
12/12/2024

### Date of final enrolment
12/12/2026

## Locations

### Countries of recruitment
England

Scotland

United Kingdom

Wales

**Study participating centre**
**Nottingham University Hospitals NHS Trust**
Trust Headquarters
Queens Medical Centre
Derby Road
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United Kingdom
NG7 2UH

**Study participating centre**
**Barts Health NHS Trust**
The Royal London Hospital
80 Newark Street
London
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E1 2ES

**Study participating centre**
**Cambridge University Hospitals NHS Foundation Trust**
Cambridge Biomedical Campus
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CB2 0QQ

**Study participating centre**
**Airedale NHS Foundation Trust**
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**Study participating centre**
**University Hospitals of Leicester NHS Trust**
Leicester Royal Infirmary

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LE1 5WW

**Study participating centre**
**The Dudley Group NHS Foundation Trust**
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DY1 2HQ

**Study participating centre**
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**Study participating centre**
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Royal Berkshire Hospital
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RG1 5AN

**Study participating centre**
**South Tyneside and Sunderland NHS Foundation Trust**
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Kayll Road
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**Study participating centre**
**Surrey and Sussex Healthcare NHS Trust**
Trust Headquarters
East Surrey Hospital

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RH1 5RH

**Study participating centre**
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OX3 9DU

**Study participating centre**
**Imperial College Healthcare NHS Trust**
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St Marys Hospital

South Wharf Road
London
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W2 1BL

**Study participating centre**
**Royal United Hospitals Bath NHS Foundation Trust**
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BA1 3NG

**Study participating centre**
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BS10 5NB

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NN16 8UZ

**Study participating centre**
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**Study participating centre**
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**Study participating centre**
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CM20 1QX

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LL13 7TD

**Study participating centre**
**King's College Hospital**
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**Study participating centre**
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### Study participating centre
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### Study participating centre
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University of Exeter

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### Sponsor type
University/education

### Website
http://www.exeter.ac.uk/

### ROR
https://ror.org/03yghzc09

## Funder(s)

### Funder type
Government

**Funder Name**
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

# Results and Publications

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

**Intention to publish date**
30/08/2028

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

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