

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

Submission date 09/09/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/10/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/07/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

Dr David Keene

ORCID ID

<https://orcid.org/0000-0001-7249-6496>

Contact details

University of Oxford - NDORMS, Kadoorie Centre, Level 3, John Radcliffe Hospital
Oxford

United Kingdom

OX3 9DU

+44 (0)1865 223126

david.keene@ndorms.ox.ac.uk

Type(s)

Public

Contact name

Mrs Kylea Draper

Contact details

University of Oxford - NDORMS
Kadoorie Centre,
Level 3, John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 223126
reach@ndorms.ox.ac.uk

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

Nottingham

United Kingdom

NG7 2UH

Study participating centre

Barts Health NHS Trust

The Royal London Hospital

80 Newark Street

London

United Kingdom

E1 2ES

Study participating centre

Cambridge University Hospitals NHS Foundation Trust

Cambridge Biomedical Campus

Hills Road

Cambridge

United Kingdom

CB2 0QQ

Study participating centre

Airedale NHS Foundation Trust

Airedale General Hospital

Skipton Road

Steeton

Keighley

United Kingdom

BD20 6TD

Study participating centre

University Hospitals of Leicester NHS Trust

Leicester Royal Infirmary

Infirmery Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
The Dudley Group NHS Foundation Trust
Russells Hall Hospital
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

Study participating centre
Milton Keynes University Hospital NHS Foundation Trust
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
South Tyneside and Sunderland NHS Foundation Trust
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Surrey and Sussex Healthcare NHS Trust
Trust Headquarters
East Surrey Hospital

Canada Avenue
Redhill
United Kingdom
RH1 5RH

Study participating centre
West Suffolk NHS Foundation Trust
West Suffolk Hospital
Hardwick Lane
Bury St. Edmunds
United Kingdom
IP33 2QZ

Study participating centre
NHS Forth Valley
33 Spittal Street
Stirling
United Kingdom
FK8 1DX

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital

South Wharf Road
London
United Kingdom
W2 1BL

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Kettering General Hospital NHS Foundation Trust
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

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
North Tees and Hartlepool NHS Foundation Trust
University Hospital of Hartlepool
Holdforth Road
Hartlepool
United Kingdom
TS24 9AH

Study participating centre
Princess Alexandra Hospital
Hamstel Road
Harlow
United Kingdom
CM20 1QX

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham Technology Park
Wrexham
United Kingdom
LL13 7TD

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Royal Albert Edward Infirmary
Wigan Lane
Wigan
United Kingdom
WN1 2NN

Study participating centre
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
The Royal Bolton Hospital
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Sponsor information

Organisation
University of Exeter

Sponsor details
Stocker Road
Exeter
England
United Kingdom
EX4 4PY
+44 (0)1392 726621
res-sponsor@exeter.ac.uk

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