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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
02/12/2025

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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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
345581

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 63906, 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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

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
United Kingdom

England

Scotland

Wales

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

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

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Airedale NHS Foundation Trust
Airedale General Hospital
Skipton Road
Steeton
Keighley
England
BD20 6TD

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

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

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

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

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

Study participating centre
Surrey and Sussex Healthcare NHS Trust
Trust Headquarters
East Surrey Hospital
Canada Avenue
Redhill
England
RH1 5RH

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

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

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Manchester University NHS Foundation Trust
Cobbett House
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M13 9WL

Study participating centre
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John Radcliffe Hospital
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Oxford
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OX3 9DU

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
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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
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

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

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

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter
England
EX2 5DW

Study participating centre

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

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

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

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

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

Study participating centre
Torbay Hospital
Newton Road

Torquay
England
TQ2 7AA

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

Study participating centre
Lewisham and Greenwich NHS Trust
University Hospital Lewisham
Lewisham High Street
London
England
SE13 6LH

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Worthing Hospital
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Worthing
England
BN11 2DH

Study participating centre
Forth Valley Health Board
Carseview House, Castle Business Park
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FK9 4SW

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
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Exeter
England
EX2 5DW

Study participating centre
North West Anglia NHS Foundation Trust
Peterborough City Hospital
Bretton Gate
Bretton
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PE3 9GZ

Study participating centre
Hampshire Hospitals NHS Foundation Trust
Basingstoke and North Hampshire Hos
Aldermaston Road
Basingstoke
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RG24 9NA

Study participating centre
Fife Health Board
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Scotland
KY12 0SU

Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type

Government

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

Results and Publications

Individual participant data (IPD) sharing plan

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes