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RaCeR 2- Comparing different approaches to physiotherapy following surgery to repair the rotator cuff of the shoulder

Submission date
13/03/2023

Recruitment status
Recruiting

Registration date
23/03/2023

Overall study status
Ongoing

Last Edited
30/06/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Tears of the tendons of the shoulder (rotator cuff) are a significant cause of shoulder pain. In 2018/2019, almost 9,000 surgical repairs were undertaken in the NHS costing up to £56.7 million in direct NHS treatment costs alone. Despite the high number of operations and surgical advancements, rehabilitation after rotator cuff repair has not advanced for over 20 years. The traditional cautious approach, where patients use a shoulder sling for about 1 month, might be contributing to sub-optimal outcomes. It is remiss that we still do not have a better understanding of the optimal approach that maximises outcomes, including early and safe return to usual activities. The study aims to investigate the effect of standard rehabilitation (4 weeks in a sling) or patient-directed rehabilitation (patients can choose to remove the sling when they feel able to).

Who can participate?
Adults over 18 years, due to have arthroscopic rotator cuff surgery.

What does the study involve?
Following surgery, participants will be randomised to standard rehabilitation (4 weeks in a sling) or patient-directed rehabilitation (patients can choose to remove the sling when they feel able to). Patients will be followed up remotely via completion of questionnaires (choosing to complete these by post or online) at 12 weeks, 6 months and 12 months post randomisation. They will also document their sling use by completing a diary for 4 weeks following surgery. At 12 months, we will invite patients to attend for an ultrasound of their rotator cuff to assess for re-tear. The study also includes the "Quintet Recruitment Intervention" (QRI) which is a well-established study that is often embedded within large trials to monitor recruitment. This involves recording discussions about the study and offering advice and training to recruiters at site.
The study will be a host trial for a SWAT (Study Within a Trial) to explore participant characteristics and their choice of paper vs online questionnaire completion.

What are the possible benefits and risks of participating?
The study will help us improve our approach to physiotherapy treatment after surgery to repair the rotator cuff of the shoulder. There are no anticipated risks of participating; taking part in this study requires time to complete the questionnaires and to attend the hospital for the ultrasound scan at twelve months.

Where is the study run from?
University Hospitals of Derby and Burton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2022 to April 2027

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

Who is the main contact?
Uhdb.racer2@nhs.net

Study website
https://www.racer2study.co.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
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Salford
United Kingdom
M6 6PU
-
Uhdb.racer2@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
318438

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

CPMS55415, NIHR133874, IRAS 318438

Study information

Scientific Title
Clinical and cost-effectiveness of individualised (early) patient-directed rehabilitation versus standard rehabilitation after surgical repair of the rotator cuff of the shoulder: a multi-centre, randomised controlled trial with integrated Quintet Recruitment Intervention

Acronym
RaCeR 2

Study objectives
Individualised (early) patient-directed rehabilitation (EPDR) will be superior in terms of shoulder pain and disability compared to standard (delayed) rehabilitation after surgical repair of the rotator cuff of the shoulder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/04/2023, London - Stanmore Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 2071048387; stanmore.rec@hra.nhs.uk), ref: 23/LO/0195

Study design
Interventional randomized controlled trial with embedded qualitative study within a trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Telephone

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Rehabilitation after surgical repair of the rotator cuff of the shoulder

Interventions
Current interventions as of 22/08/2024:

The study is an open-label randomised controlled trial comparing standard rehabilitation following rotator cuff repair surgery to individualised (early) patient directed rehabilitation. In standard rehabilitation, patients are required to keep their arm in a sling for 4 weeks, whereas for patient-directed rehabilitation, they may remove their sling and move their arm as they feel able, usually before 4 weeks.

Patients undergoing arthroscopic repair for a full-thickness rotator cuff tear, will be approached to take part in the study before their surgery. They will be asked to complete a baseline questionnaire pre-surgery and will be randomised once arthroscopic surgery has been completed. For the first 4 weeks following surgery, they will be asked to complete a diary documenting their sling use (i.e. time out of sling). At 12 weeks, 6 months and 12 months, they will complete follow-up questionnaires to inform the study outcomes which will be inputted onto Dacima, the electronic data capture system. Participants will have a choice to complete these electronically via an email/text link, or postally via paper questionnaires. This will be coordinated centrally by Derby Clinical Trial Support Unit (DCTSU). At 12 months, participants will return for an ultrasound scan of their shoulder to assess repair integrity.

We have chosen the validated, self-reported SPADI measure for shoulder pain and disability as we found this to be more responsive than the Oxford Shoulder Score (OSS) in our RaCeR pilot trial. The EQ-5D-5L is a widely used, validated measure of health-related quality of life.

The study will take place across 24 sites (with scope to increase this if necessary) across the UK to recruit (and randomise) 638 patients in 24 months. Each patient will participate in the study for 12 months following randomisation.

An internal pilot phase encompasses the first 6 months of recruitment and will monitor the rate of recruitment, overall and per-site, as well as the number of sites open. At the end of this pilot phase, we will assess study progress according to these criteria and act accordingly.

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Previous interventions:

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Intervention Type
Other

Primary outcome measure
Shoulder pain and disability will be measured at 12 weeks post-randomisation using the Shoulder Pain and Disability Index (SPADI) validated questionnaire

Secondary outcome measures
1. Shoulder pain and disability at 6- and 12-months post-randomisation will be measured using the total SPADI score
2. Health-related quality of life at 12-weeks, 6- and 12-months post-randomisation will be measured using the EQ-5D-5L
3. Time to return to usual activities, including work and driving, will be measured via self-report questionnaire at 12-weeks, 6- and 12-months
4. Healthcare resource use at 12-weeks, 6- and 12-months will be measured via self-report questionnaire.
5. Rotator cuff repair integrity (evidence of full-thickness re-tear; yes/ no) at 12-months will be assessed via diagnostic ultrasound scan
6. Number and nature of adverse events at 12-weeks, 6- and 12-months will be measured via self-report questionnaire and clinician report.
7. Self-report time out of sling, measured in hours, over 4 weeks post-surgery via self-report diary.

Overall study start date
01/09/2022

Completion date
30/04/2027

Eligibility

Key inclusion criteria
1. Adults awaiting arthroscopic surgical repair of a full thickness tear of their shoulder rotator cuff, of any size
2. Able to return (remote or in-person consultation) to the recruiting centre or affiliated site for rehabilitation supported by a physiotherapist trained to deliver the study interventions

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 638; UK Sample Size: 638

Key exclusion criteria
1. No full thickness tear at surgery and/or arthroscopic repair not undertaken
2. Unable to provide informed consent
3. Patients taking part in another research study that mandates the post-operative rehabilitation pathway.

Date of first enrolment
01/06/2023

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Derby and Burton NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Royal Orthopaedic Hospital
The Woodlands
Bristol Road South
Northfield
Birmingham
United Kingdom
B31 2AP

Study participating centre
Airedale General Hospital
Skipton Road
Steeton
Keighley
United Kingdom
BD20 6TD

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

Study participating centre
Calderdale and Huddersfield NHS Foundation Trust
Trust Headquarters
Acre Street
Lindley
Huddersfield
United Kingdom
HD3 3EA

Study participating centre
North Cumbria Integrated Care NHS Foundation Trust
Pillars Building
Cumberland Infirmary
Infirmary Street
Carlisle
United Kingdom
CA2 7HY

Study participating centre
East Suffolk and North Essex NHS Foundation Trust
Ipswich Hospital
Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
Kings Mill Hospital
Mansfield Road
Sutton-in-ashfield
United Kingdom
NG17 4JL

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Kent & Canterbury Hospital
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre
Kingston Hospital
Galsworthy Road
Kingston upon Thames
United Kingdom
KT2 7QB

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
Chesterfield Road
Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre

Warrington and Halton Teaching Hospitals NHS Foundation Trust
Warrington Hospital
Lovely Lane
Warrington
United Kingdom
WA5 1QG

Study participating centre
James Paget University Hospital
Lowestoft Road
Gorleston
Great Yarmouth
United Kingdom
NR31 6LA

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Harrogate & District NHS Foundation Trust
Strayside Wing
Harrogate District Hospital
Lancaster Park Road
Harrogate
United Kingdom
HG2 7SX

Study participating centre
Homerton Healthcare NHS Foundation Trust
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre

Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

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
Gloucestershire Hospitals NHS Foundation Trust
Cheltenham General Hospital
Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre

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

Study participating centre
St George's University Hospitals NHS Foundation Trust
St. Georges Hospital
Cranmer Terrace
London
United Kingdom
SW17 0RE

Study participating centre
Mid Yorkshire Teaching NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Aneurin Bevan U Hb Cds
Grange House
Llanfrechfa Grange
Cwmbran
United Kingdom
NP44 8YN

Study participating centre
The Rotherham NHS Foundation Trust
Moorgate Road
Rotherham
United Kingdom
S60 2UD

Study participating centre
East and North Hertfordshire NHS Trust
Lister Hospital

Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
Hywel Dda Health Board
Unit 5
Heol Cropin
Dafen Industrial Estate, Dafen
Llanelli
United Kingdom
SA14 8QW

Sponsor information

Organisation
University Hospitals of Derby and Burton NHS Foundation Trust

Sponsor details
Royal Derby Hospital
Uttoxeter Road
Derby
England
United Kingdom
DE22 3NE
+44 1332 724710
uhdb.sponsor@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.uhdb.nhs.uk/research

ROR
https://ror.org/04w8sxm43

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 high impact, peer-reviewed journal, presentation at relevant clinical conferences and publication of materials in multimedia formats for the wider public.

Intention to publish date
01/04/2028

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.2	14/04/2023	31/07/2023	No	No
HRA research summary			20/09/2023	No	No
Protocol file	version 2.4	09/05/2024	22/08/2024	No	No
Protocol file	version 3.0	05/03/2025	03/04/2025	No	No
Protocol article	Protocol for the economic evaluation	20/06/2025	24/06/2025	Yes	No
Protocol article	Protocol for the Quintet Recruitment Intervention	05/04/2024	30/06/2025	Yes	No