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	[X] Prospectively registered[X] Protocol
Registration date 23/03/2023	Overall study status Ongoing	 Statistical analysis plan Results
Last Edited	Condition category	 Individual participant data
30/06/2025	Musculoskeletal Diseases	[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 Prof Chris Littlewood

Contact details PO34 Blatchford Building University of Salford 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

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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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 ORE

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?
<u>Protocol file</u>	version 2.2	14/04/2023	31/07 /2023	No	No
<u>HRA research</u> summary			20/09 /2023	Νο	No
<u>Protocol file</u>	version 2.4	09/05/2024	22/08 /2024	Νο	No
<u>Protocol file</u>	version 3.0	05/03/2025	03/04 /2025	No	No
<u>Protocol article</u>	Protocol for the economic evaluation	20/06/2025	24/06 /2025	Yes	No
<u>Protocol article</u>	Protocol for the Quintet Recruitment Intervention	05/04/2024	30/06 /2025	Yes	No