

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

<b>Submission date</b> 13/03/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/03/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/06/2025	<b>Condition category</b> 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

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

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