ISRCTN18357968 https://doi.org/10.1186/ISRCTN18357968

The RaCeR study: rehabilitation following rotator cuff repair

Submission date
06/08/2018

Recruitment status
No longer recruiting

Registration date
10/08/2018

Overall study status
Completed

Last Edited
05/08/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Disorders of the muscles and tendons of the shoulder, the rotator cuff (RC), are the most common cause of shoulder pain. Injury to the RC, e.g. a tear, can result in significant pain and disability. The number of operations to repair the torn RC has increased significantly over recent years. Surgical techniques have advanced over time but the rehabilitation after surgery has not. This is problematic because rehabilitation is key to good outcomes. It is not known when rehabilitation after surgery should begin. Currently most patients are advised to rest their arm in a sling for four to six weeks after the operation, but evidence suggests that starting rehabilitation early (as soon as possible after surgery) might help people return to their usual activities more quickly, which is important to patients. The aim of this small study is to assess the feasibility of conducting a larger trial which will test whether early rehabilitation is more clinically and cost-effective than the usual practice of delayed rehabilitation.

Who can participate?
Patients aged 18 or over diagnosed with a non-traumatic symptomatic tear of the RC and listed for surgical repair

What does the study involve?
Participants are randomly allocated to receive one of two rehabilitation programmes: either early patient-directed mobilisation (movement) using pain as a guide, or immobilisation of the arm in a sling for four weeks. After four weeks both groups of patients undertake further rehabilitation led by a physiotherapist as per standard practice. The key difference is that those in the early mobilisation group begin moving their shoulder more quickly after the operation. Patients report their levels of pain and disability after surgery through questionnaires and responding to text messages to rate recovery. A shoulder ultrasound scan at 12 weeks checks how the RC is healing. A sub-sample of patient participants (up to 20) and clinician participants (up to 12) are also invited for interviews to discuss their study experiences.

What are the possible benefits and risks of participating?
Whilst there may not be any direct benefit to participants, this study will directly inform a larger study and it is hoped that the insight gained will help to inform how best to approach rehabilitation following RC repair. The results will be published to inform further research into

the effectiveness of rehabilitation following surgical repair of the RC. No additional risks to participants in either treatment group are anticipated. There will be some burden with regards to time for participants with an initial phone call to discuss the study (about 10 minutes), providing informed consent and completing a questionnaire at their pre-operative assessment appointment (about 30 minutes), daily completion of a Personal Exercise Diary for 4 weeks (about 5 minutes per day), responding to two text messages per week for 12 weeks (up to 5 minutes per week), completion of two further questionnaires (about 20 minutes each with postage costs covered where relevant), an ultrasound scan after 12 weeks (about 30 minutes, travel expenses available) and a small number of consenting participants will be invited to take part in an informal interview (about 45 minutes) to explore their views and experiences of post-operative treatment (travel expenses available, where relevant).

Where is the study run from?
The study is run from Keele Clinical Trials Unit, Keele University, UK. Up to five centres will recruit to the study including Derby Hospitals NHS Foundation Trust, Wrightington, Wigan & Leigh NHS Foundation Trust and the Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2018 to July 2020

Who is funding the study?
National Institute for Health Research: Research for Patient Benefit programme (UK)

Who is the main contact?
Ms Stephanie Butler-Walley, s.butler1@keele.ac.uk

Contact information

Type(s)
Public

Contact name
Ms Stephanie Butler-Walley

Contact details
Keele Clinical Trials Unit (CTU)
Room 1.60
David Weatherall Building
Keele University
Keele
United Kingdom
ST5 5BG
+44 (0)1782 732951
s.butler1@keele.ac.uk

Type(s)
Scientific

Contact name
Prof Nadine Foster

Contact details
Keele University
Keele
United Kingdom
ST5 5BG
+44 (0) 1782 734705
n.foster@keele.ac.uk

Additional identifiers

Protocol serial number
38705

Study information

Scientific Title
Rehabilitation following rotator Cuff repaiR: a multi-centre pilot & feasibility randomised controlled trial with nested qualitative study (the RaCeR study)

Acronym
RaCeR

Study objectives
In patients undergoing surgical repair of the RC, is it feasible to conduct a future, substantive, multi-centred randomised controlled trial to test the hypothesis that, compared to usual practice of delayed rehabilitation, early patient-directed rehabilitation is more clinically and cost-effective?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 5, 31/07/2018, ref: 18/WA/0242

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment, Rehabilitation

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rehabilitation following rotator cuff repair

Interventions
Control (reflective of current UK practice): participants will receive one treatment session with a physiotherapist after surgery where they will be advised to immobilise their arm in a sling for

four weeks. This will include advice to maintain sling in situ at all times including at night and only to be removed to perform specific daily exercise, and eating, washing and dressing. No further active movement will be encouraged. This initial discussion will be followed-up approximately two weeks later at an out-patient physiotherapy appointment to re-confirm these messages. Participants will be asked to record their adherence to the programme, i.e. the time out of their sling, at regular periods throughout the day using a Personal Exercise Diary.

Intervention (early patient-directed rehabilitation): participants will receive one session with a physiotherapist after surgery where they will be advised to remove the post-operative sling, as pain allows, as soon as possible and gradually begin actively using the arm as able. This will be progressed by the individual patient over time and to agreed goals within the context of their own pain experience and tolerance. Participants will also be advised to perform specific daily exercise. This initial discussion will be followed-up approximately two weeks later at an out-patient physiotherapy appointment to discuss progress, address barriers and to facilitate adherence with the early rehabilitation. Participants will be asked to record their adherence to the programme, i.e. the time out of their sling, at regular periods throughout the day using a Personal Exercise Diary.

Both groups will be provided with the same sling and advised to take pain medication as prescribed and use will be recorded and analysed. All participants will be asked to complete three questionnaires over 12 weeks, respond to two text messages per week measuring pain and function and invited to attend for an ultrasound scan 12 weeks' post-surgery to assess healing.

Consented patient participants and health care practitioners may be invited to an informal interview to share their perceptions and experiences of post-operative treatment and study processes.

Intervention Type
Other

Primary outcome(s)
The feasibility of recruitment, retention and acceptability of the RaCeR intervention assessed using the following outcomes:
1. Numbers of: potentially eligible and eligible patients, invited, seen in pre-operative assessment clinic, consent rates collected via screening and randomisation logs at screening and baseline timepoints
2. Number of eligible patients found subsequently not to have a RC tear at surgery (indicating false positive scan) collected via a Post-operative Case Report Form at 0 weeks
3. Feasibility of recruiting participating centres and numbers of additional centres who are interested in participating in the main trial collected via expressions of interest (ongoing)
4. Rate of retention in the trial, including response rates to questionnaires and individual measures (including resource use) and SMS text messages collected via SMS weekly from 0-12 weeks from surgery and self-report questionnaires at 6 and 12 weeks
5. Intervention fidelity and adherence, using physiotherapist-completed case report forms at 0, 2, 4, 6, 8 and 12 weeks and patient-completed personal exercise diaries at 4 weeks
6. Determining the primary outcome measure for the main trial by assessing and comparing sensitivity to change of the measures and other statistical properties to support sample size derivation, comparing follow-up rates of different methods of data capture (questionnaire at 6 and 12 weeks/SMS text weekly between 0-12 weeks) and of individual measures, and evaluating which outcome measures best reflect the patients' rehabilitation goals, identified from the

qualitative interviews between 0-4 weeks
7. Participant satisfaction with the interventions on a five-point ordinal scale: Very Satisfied /Satisfied/Neutral/Dissatisfied/Very Dissatisfied via self-report questionnaires at 6 and 12 weeks
8. Patient and clinician views about the acceptability of the interventions (qualitative data) via interviews between 0-12 weeks

Key secondary outcome(s)
Clinical outcomes will be measured as follows:
1. Pain and disability assessed using the Oxford Shoulder Score (OSS) and Shoulder Pain & Disability Index (SPADI) at baseline, 6 weeks' post-surgery by post and 12 weeks' post-surgery in person, during a follow-up clinic visit or postal questionnaire with telephone call for minimum data collection if no response to postal questionnaire
2. Health related quality of life assessed using the EQ-5D-5L at baseline, six weeks' post-surgery by post and 12 weeks' post-surgery in person, during a follow-up clinic visit or postal questionnaire
3. Global change question at 6 weeks' post-surgery by post and 12 weeks' post-surgery in person, during a follow-up clinic visit or postal questionnaire with telephone call for minimum data collection if no response to postal questionnaire
4. Pain in the last week (derived from the OSS) using weekly SMS text messages for 12 weeks (post-surgery) based on a 0-4 numerical rating scale (NRS) with anchors of 'No pain' (0) to 'Unbearable pain' (4)
5. Disability relating to work or activity interference due to the shoulder problem in the last week (derived from the OSS) using weekly SMS text messages for 12 weeks (post-surgery) based on a 0-4 NRS with anchors of 'Not at all' (0) to 'Totally' (4)
6. Days lost from work due to the shoulder problem at 6 weeks' post-surgery via postal questionnaire and 12 weeks' post-surgery via questionnaire completed during a follow-up clinic visit
7. Time taken to return to driving, if applicable, via questionnaire at 6 and 12-week follow-up
8. Number and type of adverse events; e.g. post-procedural exacerbation of pain, for up to 12 weeks' post-randomisation via patient self-report questionnaire at six and 12 weeks' post-surgery and via surgeon, physiotherapist or GP report
9. Integrity of surgical repair assessed using a diagnostic ultrasound scan performed by a sonographer independent to the study at 12 weeks' post-surgery only

Completion date
30/07/2020

Eligibility

Key inclusion criteria
1. Patients diagnosed with a non-traumatic symptomatic tear of the RC and listed for surgical repair
2. RC tear confirmed by ultrasound or MRI
3. Aged ≥ 18 years
4. Patients screened by the surgeon as suitable to participate (an opt-out scheme will be implemented whereby all patients under the care of a surgeon who is participating in the trial will be eligible unless the surgeon states otherwise in the medical notes at the time of listing for surgery)
5. Able to return to the recruiting centre or affiliated site for the initial outpatient follow-up

physiotherapy appointment
6. Access to a mobile phone and willing and able to receive and respond to SMS text messages
7. Able to understand English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
73

Key exclusion criteria
1. Traumatic RC tears (e.g. sudden onset of shoulder pain and weakness following a fall), given the different care pathways for such patients (these patients are typically fast-tracked to surgery)
2. Patients who are unable to give full informed consent

Date of first enrolment
01/11/2018

Date of final enrolment
20/11/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Derby Teaching Hospitals NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
Gobowen
Oswestry
Shropshire
United Kingdom
SY10 7AG

Study participating centre
Wrightington, Wigan and Leigh NHS Foundation Trust
Wrightington Hospital
Hall Lane
Appley Bridge
Wigan
United Kingdom
WN6 9EP

Sponsor information

Organisation
University of Keele

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0816-20009

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from primarycare.datasharing@keele.ac.uk. Core data will be available

immediately after main publication. A data request form is required to be completed and must outline the type of data to be obtained, the reason for obtaining this data (research question /objective), the timing for when the data is required to be available (start date/end date). Checks will be performed by a Data Custodian and Academic Proposals (DCAP) committee at Keele to ensure that the data set requested is appropriately suited to answer the research question /objective and that the request fits with the original ethical approval and participant consent and adheres to funder and legal restrictions. Only de-identified data are available for request in aggregated format or at the level of the individual participant.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	nested qualitative study	27/12/2020	05/08/2021	Yes	No
Results article	results	11/12/2020	05/08/2021	Yes	No
Protocol article	protocol	06/06/2019	10/06/2019	Yes	No
HRA research summary			28/06/2023	No	No