

# Tailored postoperative care for rotator cuff pathologies

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|----------------------------------------|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>09/08/2023   | <b>Recruitment status</b><br>Recruiting               | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>03/10/2023 | <b>Overall study status</b><br>Ongoing                | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>03/10/2023       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

It's hard to make sure patients follow and stick to their post-surgery recovery program, and this can affect the final results. In a past research study, we used a wearable system with special sensors to keep track of how patients were doing their recovery exercises after shoulder surgery (rotator cuff repair). Even though doctors told them how to do their exercises, people did them in a lot of different ways. The results of this study helped us find a new plan for physical therapy that gave better results for patients' health and recovery. But we haven't yet tested how well this new plan works in a big study. So, in this new study, we want to compare the new recovery plan to the usual care that patients get after shoulder surgery, and see which one works better.

### Who can participate?

Patients aged 45 - 70 years undergoing surgical rotator cuff repair

### What does the study involve?

Once we have all the patients who meet the criteria and they agree to be in the study, we will do some tests like MRI scans, movement analysis, and clinical evaluations using scores before their surgery. A skilled orthopedic surgeon will perform the needed surgery on all patients, fixing their shoulder using arthroscopic methods.

After the surgery, a certified researcher will tell the patients which group they are in: Group 1 gets the usual care, while Group 2 tries the new approach. The patients will come back for check-ups at 6 weeks and 3 months after surgery. We will use scores to evaluate their progress (CMS, ASES, SF-36, VAS).

Later, at 6 months and 12 months after the surgery, we will do more check-ups using scores (CMS, ASES, SF-36, VAS), do more tests like MRI scans and movement analysis, to see how well they are recovering.

### What are the possible benefits and risks of participating?

The expected results of this study could offer the prospect of providing high value care and reducing costs to the National Health System associated with ineffective aftercare, with immediate benefits for patients. There are no direct risks for the patients recruited in the study.

Where is the study run from?

Fondazione Policlinico Universitario Campus Bio-Medico (Italy)

When is the study starting and how long is it expected to run for?

January 2023 to January 2026

Who is funding the study?

Fondazione Policlinico Universitario Campus Bio-Medico (Italy)

Ministero della Salute (Italy)

Who is the main contact?

Prof. Umile Giuseppe Longo, g.longo@policlinicocampus.it

## Contact information

### Type(s)

Principal Investigator

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

0035/23 PAR ComEt CBM, Ricerca Finalizzata RF-2021-12372810

## Study information

### Scientific Title

Tailored postoperative care for rotator cuff pathologies: a randomized controlled trial

**Acronym**

CARE-RC

**Study objectives**

Adherence to an optimized rehabilitation protocol will reduce the number of rotator cuff re-tears and will improve clinical outcomes.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 30/01/2023, Università Campus Bio-Medico di Roma (Via alvaro del portillo, 200, Roma, 00128, Italy; +39 6225418718; comitato.etico@policlinicocampus.it), ref: 0035/23 PAR ComEt CBM

**Study design**

Two-arm monocentric randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life, Efficacy

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Rotator cuff tears

**Interventions**

After the enrollment of all the patients satisfying the inclusion criteria and after obtaining consent for the study participation, patients will undergo structural evaluation (MRI), kinematic analysis, and clinical assessment (clinical scores) before surgery. An experienced orthopedic surgeon will perform surgical procedures in all the patients. The arthroscopic RC repair will be performed.

After surgery, an authorized researcher will inform the enrolled patients of the treatment allocation (Group 1 - standard of care, Group 2 - experimental group). Patients will undergo clinical and functional assessments during follow-up visits at 6-weeks and 3-months after surgery using clinical scores (CMS, ASES, SF-36, VAS). At 6-months and 12-months after surgery, patients will undergo clinical and functional assessments using clinical scores (CMS, ASES, SF-36, VAS), structural evaluation (MRI), and kinematic analysis.

Patients will be assigned to each group using a computer-generated list of random numbers. An independent researcher responsible for data management will organize the treatment allocation and will provide sealed and numbered envelopes to the head nurse before surgery. The envelope will be opened only at the end of the surgical procedure. Therefore, the orthopedic surgeon will be blinded to the randomization assignment. The same independent researcher will inform the enrolled patients of the treatment allocation.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome measure**

Before surgery and at 6-months and 12-months after surgery:

1. Structural data are measured by structural evaluation (MRI)
2. Kinematic variables (such as range of motion, angular velocity) are measured by kinematic analysis

### **Secondary outcome measures**

Clinical data evaluated before surgery and at 6-weeks, 3-months, 6-months, and 12-months after surgery:

1. Physical and subjective measures of the affected shoulder in terms of pain, activities of daily living (ADL), range of motion (ROM), and strength are measured by CMS.
2. Patient self-reported and clinician scores about pain, ADL, ROM, signs, strength, and instability are measured by ASES.
3. The quality of life and mental health (such as physical and social functioning, general health perception limitations due to emotional aspects, vitality) are measured by SF-36.
4. The level of pain perceived by patients are measured by VAS.

### **Overall study start date**

30/01/2023

### **Completion date**

30/01/2026

## **Eligibility**

### **Key inclusion criteria**

1. Age 45-70 years.
2. Atraumatic, symptomatic, isolated full-thickness supraspinatus tendon tear documented with MRI.
3. No surgical treatment to the affected shoulder before.
4. No episodes of shoulder instability.
5. No radiographic signs of fracture of the glenoid fossa or the greater or lesser tuberosity.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

45 Years

**Upper age limit**

70 Years

**Sex**

Both

**Target number of participants**

The clinicians and the experimenters will randomize and allocate 100 patients (50 to each of the two groups. The Group 1 is the group of standard of care and the Group 2 is the experimental group)

**Key exclusion criteria**

1. Frozen shoulder.
2. Radiological osteoarthritis of the glenohumeral joint.
3. Neurological disease or language barriers.
4. Acute-on-chronic tears (after a traumatic event in a shoulder with preceding episodes of symptoms).
5. Impossibility to undergo MRI scan for any reason.
6. Tear involving the whole supraspinatus tendon combined with a tear of two or three tendons.
7. Muscle fatty degeneration > of stage 2 according to Goutallier classification
8. Muscle atrophy evaluated with Tangent sign, exceeding stage 2.

**Date of first enrolment**

21/12/2023

**Date of final enrolment**

21/12/2025

## **Locations**

**Countries of recruitment**

Italy

**Study participating centre**

**Fondazione Policlinico Universitario Campus Bio-Medico**

Via Alvaro del Portillo, 200

Roma

Italy

00128

## **Sponsor information**

**Organisation**

Fondazione Policlinico Universitario Campus Bio-Medico

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.policlinicocampusbiomedico.it/>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Ministero della Salute

**Alternative Name(s)**

Italian Ministry of Health, Italy Ministry of Health, Ministry of Health of Italy, Ministry of Health - Italy, Ministry of Health, Italy

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Italy

**Funder Name**

Fondazione Policlinico Universitario Campus Bio-Medico

## **Results and Publications**

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

21/12/2027

**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