

# A randomized placebo controlled clinical trial of a rehabilitation programme for patients with a diagnosis of massive, irreparable rotator cuff tears of the shoulder

<b>Submission date</b> 29/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/03/2012	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Roberta Ainsworth

### Contact details

Consultant Physiotherapist  
Physiotherapy Department  
Torbay Hospital  
Torquay  
United Kingdom  
TQ2 7AA  
+44 01803 655340  
roberta.ainsworth@nhs.net

## Additional identifiers

### Protocol serial number

N0620168697

## Study information

## Scientific Title

### Study objectives

To investigate the effect of a specific rehabilitation programme for patients with massive tears of the rotator cuff tendons in their shoulder.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

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

Musculoskeletal Diseases: Shoulder disorders

### Interventions

Patients will be randomized to receive ultrasound or to receive ultrasound and a rehabilitation program. Patients randomized into the rehabilitation arm of the study will be following the rehabilitation program developed at Torbay hospital.

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome(s)

To use the information collected to improve the rehabilitation programme and to increase awareness of which patient will do well with the programme.

Primary outcome measure: Oxford Shoulder Score.

### Key secondary outcome(s)

Not provided at time of registration

### Completion date

31/08/2008

## Eligibility

### Key inclusion criteria

60 patients with a diagnosis of irreparable rotator cuff tears will be recruited from patients referred into the South Devon Physiotherapy Service by GPs, consultants or by self referral, 30 for the exercise group and 30 for the control group.

Inclusion criteria:

1. 18 years or over (no upper age limit)
2. Male or female
3. Clinical and ultrasonographic diagnosis of massive rotator cuff tear (full thickness tear of more than 5cm)
4. Diagnosis of massive, irreparable rotator cuff tear following shoulder surgery to try to repair the rotator cuff
5. Patient able to understand and co-operate with research and able to give informed consent
6. Fluent in written and spoken English

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Diagnosed neurological abnormality affecting the shoulder joint complex
2. Patients involved in an industrial claim or litigation
3. Patients whose rotator cuff tear is considered to be operable

### **Date of first enrolment**

05/09/2005

### **Date of final enrolment**

31/08/2008

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

Consultant Physiotherapist

Torquay

United Kingdom  
TQ2 7AA

## Sponsor information

### Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

## Funder(s)

### Funder type

Government

### Funder Name

Exeter Primary Care Trust (UK)

### Funder Name

NHS R&D Support Funding (UK)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2006		Yes	No