

# United Kingdom Frozen Shoulder Trial (UK FroST)

<b>Submission date</b> 18/07/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/07/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/06/2025	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Frozen shoulder is a painful and debilitating condition causing stiffness and disability in the affected shoulder and arm. It happens when the flexible tissue surrounding the shoulder joint (capsule) becomes inflamed and thickened, resulting in contraction (tightening) of the tissue and scarring. The shoulder becomes very tight, painful and stiff. It affects around 1 in 12 men and 1 in 10 women of working age, interfering with their work, home and leisure activities. Most people eventually get better, even without treatment, and it does tend to improve and settle with time (typically taking 1 to 3 years). However, for some people it causes severe symptoms and these cases need more active treatment. Around 1 in 10 patients are referred to hospital. Hospital treatment could involve something called early structured physiotherapy (ESP), which includes education, general reassurance and advice and exercises to mobilise and stretch the tightened shoulder capsule. A steroid injection into the joint (intra-articular) can be used for pain relief. An alternative is manipulation under anaesthesia (MUA) where the shoulder is manipulated to stretch and tear the tight capsule under a general anaesthetic and therefore restoring a more normal range of movement to the shoulder. A steroid injection is again given for pain relief. Lastly, the patient can undergo keyhole surgery, again carried out under general anaesthetic, in a procedure called arthroscopic capsular release (ACR) where the tight capsule is opened up though cutting out the thickened parts using high-frequency radio waves. Steroid injections are usually avoided after this surgery to reduce the risk of infection, and alternative methods of pain relief are offered. All three of these treatments are regularly offered on the NHS, but it is not actually known which works best and at what cost. The aim of this study is to compare these three treatments for both clinical and cost effectiveness.

### Who can participate?

Patients who are at least 18 years old, diagnosed with frozen shoulder and for whom secondary causes for their condition have been ruled out.

### What does the study involve?

Participants are randomly allocated into one of three groups. Those in group 1 undergo ESP for 12 weeks. Those in group 2 undergo MUA. Those in group 3 undergo MUA with ACR. Participants in group 2 or 3 are then given a 12 week programme of physiotherapy, usually within 24 hours of the surgery, to reduce pain and to regain and maintain range of movement in the shoulder.

Improvements in pain, function and general wellbeing for all three groups of participants are then assessed at 3, 6 and 12 months after treatment.

What are the possible benefits and risks of participating?

There are no new treatments being tested in this study and, therefore, no new risks beyond those that are already associated with the treatments used are anticipated. All surgery involves risks, such as from general anaesthesia, bleeding, risk of deep vein thrombosis (blood clot in a major vein), damage to nerves and blood vessels in the surgical area and infection.

Where is the study run from?

James Cook University Hospital (UK)

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

October 2014 to June 2019

Who is funding the study?

National Institute for Health Research (NIHR), Health Technology Assessment (HTA) (UK)

Who is the main contact?

Professor Amar Rangan

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## Contact information

### Type(s)

Scientific

### Contact name

Prof Amar Rangan

### ORCID ID

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## Additional identifiers

### Protocol serial number

HTA 13/26/01; Protocol Number V4.0\_151116

## Study information

## Scientific Title

Multi-centre randomised controlled trial with economic evaluation and nested qualitative study comparing early structured physiotherapy versus manipulation under anaesthesia versus arthroscopic capsular release for patients referred to secondary care with a primary frozen shoulder (Adhesive Capsulitis)

## Acronym

UK FroST

## Study objectives

To assess the clinical and cost effectiveness of the three treatments that are most often provided in NHS hospitals to treat primary frozen Shoulder (Early Structured Physiotherapy (ESP) versus Manipulation under Anaesthesia (MUA) versus Arthroscopic capsular release (ACR) with MUA) .

Further details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/132601>

Protocol can be found at: [http://www.nets.nihr.ac.uk/\\_data/assets/pdf\\_file/0012/130701/PRO-13-26-01.pdf](http://www.nets.nihr.ac.uk/_data/assets/pdf_file/0012/130701/PRO-13-26-01.pdf)

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. North East (Newcastle & North Tyneside 2) Ethics Committee, 18/11/2014, REC Ref: 14/NE/1176
2. Substantial Amendment 1 – REC Favourable Opinion 02/02/2015
3. Substantial Amendment 2 – REC Favourable Opinion 24/05/2016
4. Substantial Amendment 3 – REC Favourable Opinion 21/12/2016

## Study design

Pragmatic multi-centre randomised controlled trial with economic evaluation and nested qualitative study, with an internal pilot to check assumptions on trial recruitment and feasibility

## Primary study design

Interventional

## Study type(s)

Treatment

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

Frozen shoulder (adhesive capsulitis)

## Interventions

Participants will be randomly allocated into one of three groups:

1. Evidence based, early structured physiotherapy (ESP) for 12 weeks (' active control') based on national clinical guidelines for management of frozen shoulder. Core elements of this are education, reassurance and advice; instruction on exercises from gentle active, gentle pendular movements in comfortable range to stretches of the tightened capsule augmented by hands-on mobilisation techniques, applied by the physiotherapist and intra-articular (into the joint) steroid injection is a core option for pain relief.

2. Manipulation under anaesthesia (MUA) without arthroscopic capsular release (ACR) within 18 weeks from randomisation. This is a day case procedure which involves controlled manipulation of the affected shoulder whilst the patient is under general anaesthesia. The manipulation stretches and tears the tight capsule restoring range of motion to the shoulder. This is not preceded by any formal surgical release of the tight structures. Steroid injection into the joint is provided for pain relief.

3. Manipulation under anaesthesia (MUA) with arthroscopic capsular release (ACR) within 18 weeks from randomisation. This typically is done as a day case procedure, where the contracted and tight shoulder capsule is released using arthroscopic (keyhole) techniques, followed by manipulation to confirm restoration of range of motion in the shoulder. Steroid injection is generally avoided following key hole surgery, as the risk of infection is increased in the presence of steroid. Alternative methods of pain relief, which are part of usual care following ACR, will be provided.

Additional procedures like posterior capsular release, subacromial decompression and supplementary steroid injections for pain control occur in a minority of patients and will be left pragmatic as a needs based intervention. Following MUA or ACR, patients will undergo a further 12-week programme of physiotherapy, normally commencing within 24 hours, with the aim of reducing pain and regaining/maintaining the mobility achieved at operation. It is expected that a steroid injection will be avoided during post procedural physiotherapy.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Oxford Shoulder Score (OSS) (12-item condition-specific questionnaire providing a total score based on the person's subjective assessment of pain and activities of daily living impairment) assessed at 3, 6 and 12 months post randomisation. Primary time point is 12 months after randomisation. OSS will also be collected at pre-treatment, as well as 6 months post-treatment

## **Key secondary outcome(s)**

1. Disabilities of Arm Shoulder and Hand (DASH) - The QuickDASH will be measured at baseline, 3, 6 and 12 months.
2. Medical Outcomes Study Short Form 36-item questionnaire (MOS SF-36) to assess health related quality of life - will be collected at baseline, 3, 6 and 12 months.
3. The EQ5D-5L, generic and health economic self-complete patient-reported outcome measure - will be collected at baseline, 3, 6 and 12 months.
4. Pain measured using the Numeric Rating Scale for pain - will be collected at baseline, 3, 6 and 12 months.
5. Time to resolution- a simple subjective global question to be administered at baseline, 3, 6 and 12 months
6. Complications - All complications will be recorded at 12 months
7. Adverse events- will be collected over 12 months
8. The economic evaluation to determine the relative cost-effectiveness of three interventions for the treatment of frozen shoulder- at baseline, 3, 6 and 12 months
9. Qualitative study (Up to 45 patients and 10 to 15 health care professionals) - at 12 months

## **Completion date**

30/06/2019

## Eligibility

### Key inclusion criteria

1. Patients with frozen shoulder, including diabetics,  $\geq 18$  years old
2. Passive external rotation in the affected shoulder that is  $< 50\%$  of the contralateral shoulder
3. Radiographs to exclude secondary causes e.g. glenohumeral arthritis

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

All

### Total final enrolment

503

### Key exclusion criteria

1. Bilateral concurrent frozen shoulders
2. Secondary to trauma or other causes
3. Trial treatments contraindicated
4. Unfit for general anaesthesia
5. Not resident to trauma catchment area of a participating trial site
6. Lack mental capacity to comply with treatment or data collection

### Date of first enrolment

01/01/2015

### Date of final enrolment

31/12/2017

## Locations

### Countries of recruitment

United Kingdom

England

**Study participating centre**  
The James Cook University Hospital  
Middlesbrough  
United Kingdom  
TS4 3RT

**Study participating centre**  
**30 sites**  
United Kingdom  
-

## Sponsor information

**Organisation**  
South Tees NHS Foundation Trust (UK)

**ROR**  
<https://ror.org/02js17r36>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Health Technology Assessment Programme

**Alternative Name(s)**  
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## 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 Ms Ada Keding, trail statistician (Ada.Keding@york.ac.uk). Ms Keding will be the point of contact for data queries.

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	03/10/2020	07/10/2020	Yes	No
<a href="#">Results article</a>	results	01/12/2020	10/12/2020	Yes	No
<a href="#">Results article</a>	qualitative results	11/06/2021	14/06/2021	Yes	No
<a href="#">Results article</a>	Implementing evidence into practice for the management of frozen shoulder: engaging with key stakeholders and evaluating barriers and facilitators using the Consolidated Framework for Implementation Research	30/05/2025	04/06/2025	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes