Physiotherapy Manual

Disclaimer

The views expressed in this publication are those of the author(s) and not necessarily those of the MRC, NHS, NIHR or the Department of Health and Social Care.

*The EME Programme is funded by the MRC and NIHR, with contributions from the CSO in Scotland and Health and Care Research Wales and the HSC R&D Division, Public Health Agency in Northern Ireland.

Disclaimer: The START:REACTS Study is being conducted in compliance with current regulations, guidelines, and legislation which serve to ensure the well-being of its participants and integrity of the data. To ascertain compliance from the research sites involved in this research we request readers of this manual to have awareness of the GCP principles listed below:

Good Clinical Practice (GCP) - 13 Principles

GCP is an internationally agreed **ethical and scientific quality standard** for designing, conducting, recording and reporting trials that involve the participation of **human subjects**.

Working to GCP principles provides assurance that the **rights, safety and well-being** of trial subjects are protected, we are working ethically and in accordance with the principles that have their origin in the **Declaration of Helsinki**, and that the clinical trial **data is credible.**

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).
2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
3. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.
4. The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.
7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.
10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
12. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.
13. Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Contents Page

Getting Started:

The patient that has been referred to you is taking part in a clinical study.

This manual contains the relevant background information about trial processes and procedures. The trial is being led by Andrew Metcalfe through Warwick Clinical Trials Unit based at the University of Warwick and is funded by the National Institute for Health Research (NIHR) under the Efficacy and Mechanism Evaluation (EME) funding stream.

The purpose of the RCT is to assess the clinical effectiveness and safety of a sub-acromial spacer balloon (the InSpace balloon) for patients with symptomatic irreparable tears of the rotator cuff. This manual has been written to ensure the post-operative physiotherapy is consistent across the trial population.

The study is **blinded**. It is intended that neither yourself nor the patient know which treatment group they are in. **Please do not try and find out which group they are in** unless there is a sound clinical reason for doing so. This manual is designed to be appropriate for the treatment of both arms in the study.

The aims of this Physiotherapist Manual are:

- To explain the trial design
- To describe procedures for the assessment and treatment of study participants
- To describe reporting procedures

This manual is based on the latest published evidence, orthospace guidelines (sub-acromial spacer balloon supplier) and clinical expertise and has been written and reviewed by the research team detailed on the next page in addition to the research ethics committee and other regulatory approvals required for the conduct of this study. Thank you again for taking the time to review this information and please contact the trial team start@warwick.ac.uk if you have any questions.

Research Team:

Mr Andrew Metcalfe

Chief Investigator

Dr Rebecca Kearney

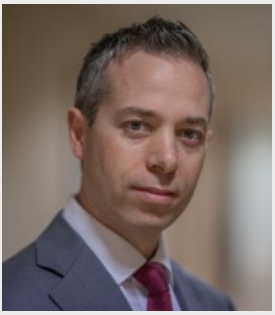
Physiotherapy Expert

Mrs Elke Gemperle Mannion

Clinical Trial Manager

Stephen Drew

Co-investigator



Thomas Lawrence

Co-investigator

Howard Bush

Shoulder Physiotherapy Specialist

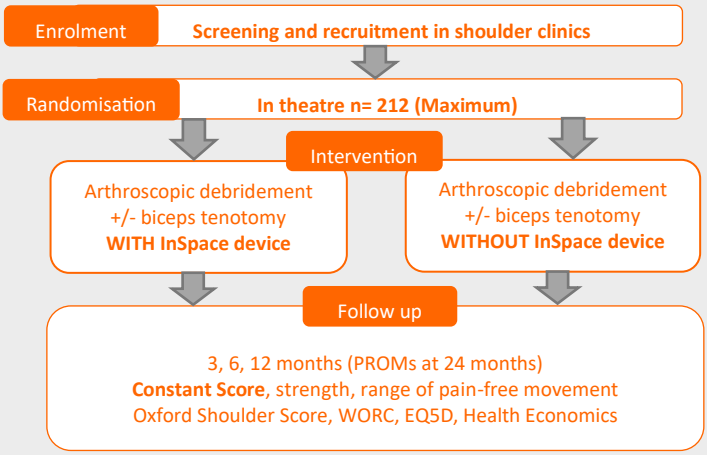
Study Summary	START is a participant and assessor blinded, multi-centre RCT comparing arthroscopic debridement with the InSpace balloon to arthroscopic debridement alone for people with an irreparable rotator cuff tear. This pivotal new trial will be an adaptive design, its sample size will vary according to the outcomes of an interim analysis. This is proposed to be the first trial in a new programme of research aimed at improving the assessment of new surgical procedures. The participant and all staff outside of theatre will be blinded to the allocation. The primary outcome will be the Constant score, which will be recorded at baseline, 3, 6 and 12 months. A per-patient payment will be made for the follow-up appointments and we will provide necessary equipment for the measurements.
Eligibility Criteria	**Inclusion criteria:** • Irreparable rotator cuff tear • Intrusive symptoms that warrant surgery • Non-operative management has been unsuccessful **Exclusion criteria:** • Advanced gleno-humeral osteoarthritis on pre-operative imaging (in the opinion of the treating clinician). • Subscapularis deficiency*, defined as a tear involving more than the superior 1cm (approximately) of the subscapularis if repaired, or any tear that is not repaired. • The treating clinician determines that interposition grafting or tendon transfers are indicated. • Pseudoparalysis (an inability to actively abduct or forward flex up to 20°), as determined by the treating clinician. • Unrelated, symptomatic ipsilateral shoulder disorder that would interfere with strength measurement or ability to perform rehabilitation

Eligibility criteria continued

Exclusion Criteria continued…..

- Other neurological or muscular condition that would interfere with strength measurement or ability to perform rehabilitation, in the opinion of the treating clinician.
- Previous proximal humerus fracture that could influence shoulder function, as determined by the treating clinician.
- Previous entry into the present trial (i.e. other shoulder).
- Unable to complete trial procedures.
- Age under 18
- Unable to consent to the trial.
- Unfit for surgery as defined by the treating clinician.

Study Summary



Overview of surgical procedures:

Group 1 – Standard Arthroscopic debridement (control): The control intervention will be an arthroscopic debridement of the subacromial space with removal of inflamed tissue (bursectomy) and unstable remnants of the torn tendon, limited bone resection of the acromion, retention of the coraco-acromial (CA) ligament and biceps tenotomy (if not already torn). Within the confines described in a trial specific surgical guideline described in the START surgery operative technique manual, surgeons may use their normal surgical technique.

Group 2 – Standard Arthroscopic debridement plus insertion of InSpace balloon (Intervention): Arthroscopic debridement, as above, with insertion of the InSpace Balloon performed by sub-speciality trained shoulder surgeons. The same arthroscopic debridement will be performed as described in group 1 and the allocation will be confirmed intra-operatively. The balloon procedure is also described in the START surgery operative technique manual This is a short procedure that does not add greatly to the surgical time.

The balloon is believed to work by allowing rehabilitation of the remaining rotator cuff and deltoid. However the standard operation may also help with this. So whichever group that patient is in, it is likely that they will benefit from rehabilitation.

The participant and trial team will be blinded to the allocated intervention. The operating clinician will be the only individual with knowledge of the allocation.

The clinician has recorded the allocation on the participants operation note which is held at Warwick CTU and can be accessed in cases where there is a clinical need to know the allocation. If this action is required please go to XXXX website where you can find online instructions on how to access the record. Please only do so if there is an urgent clinical need to know the allocation. Otherwise, if you believe there may be a surgical complication requiring treatment please discuss the patient with the surgical team and maintain blinding where possible.

If you find out which group the patient was in (for any reason) please do not communicate this to the patient unless it is strictly necessary.

Pain Relief and Complications:

Pain is to be expected after any surgery - pain occurs because of tissue injury and inflammation but this should gradually settle within a few days or weeks after surgery. It is important that painkillers are taken in the immediate postoperative period to ensure that participants can mobilise without too much discomfort. Anti-inflammatory painkillers can also reduce wound inflammation. Please discuss with the participant pain control and discuss with the referring clinician and/or the participants GP if pain is not controlled and requires medical review

Pain can occur, or be exacerbated, between 6 weeks and 3 months when the balloon deflates. This usually settles after approximately 2 weeks and can be managed symptomatically during that time.

Participants have been advised that there is a small risk that they may develop an infection, stiffness, frozen shoulder, worsened pain, blood clots or wound healing problems. Specific to the InSpace balloon there is also a small risk this can be put in the wrong place, move after the operation, or can cause inflammation in the shoulder.

If any complications occur please contact the trial team start@warwick.ac.uk and referring clinician. If you cannot contact a member of the trial team or referring clinical team participants can access their GP and A&E department in the usual way.

Rehabilitation overview:

All participants will have received a booklet providing information regarding the surgical procedure they have had, why physiotherapy is required, how long it will be needed, expected recovery times and a basic set of exercises that will be performed at each recovery stage. The basic set of exercises incorporate the principles of rehabilitating the deltoid muscle to compensate for the deficient rotator cuff.

In the first two weeks after surgery, all trial participants are advised to remain in a sling. However to avoid complications associated with immobilisation, participants are advised to remove the sling for short periods to complete active/active-assisted movements of the elbow, wrist and hand. They are also advised to slowly move the shoulder into flexion and abduction, but not past 60^0.

Following the initial two week period the sling can be removed and unrestricted range of movement exercises and slow steady stretching can commence.

From twelve weeks strength exercises can be introduced. It is recommended that patients are seen at least once during each of these three phases of recovery.

In keeping with these phases of recovery participants have been advised the following in regards to returning to common activities and sports:

- Driving: Not recommended until you can safely hold a steering wheel with both hands, you may want to discuss this with your physiotherapist.
- Lifting: Not recommended to lift anything heavier than a drink for three months.
- Sports involving overhead movements (e.g. tennis): After 12 weeks , and with advice from their physiotherapist

To aid adherence and compliance, participants have been supplied with pages within their booklet to record their exercises and have been encouraged to discuss agreed joint goals with their therapist. You should review these materials during follow-up appointments to encourage compliance.

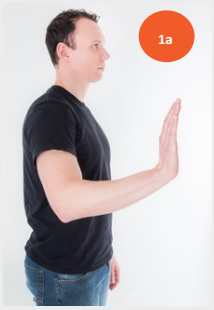
Phase One (0-2 weeks):

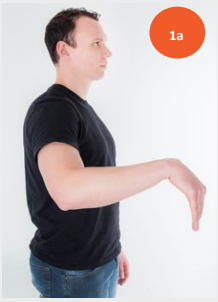
At the first appointment it is important to establish a good relationship. This will be the first of at least three face-to-face physiotherapy sessions. The aims during phase one are:

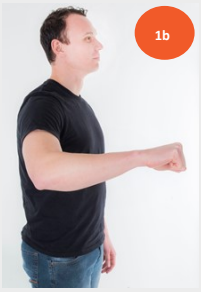
- Establish and expand on the participants understanding of the procedure they have had (in a blinded way)
- Emphasise the benefits of physiotherapy in relation to the procedure outcome
- Discuss possible complications, how to recognise them and what to do if they occur
- Assess pain and discuss pain control
- Assess the surgical wounds
- Discuss expectations and set agreed goals
- Prevent complications associated with immobilisation through early restricted movements (see below)

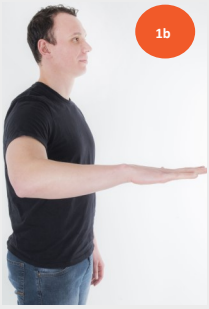
To allow the tissues to heal it is important that the sling is worn for two weeks. However, to avoid the complications associated with immobilisation it is important to remove the sling for short periods in the home and slowly move the neck, shoulder, elbow and hand. The participants have been provided with the exercises below to be completed a minimum of three times daily and to complete up to three sets of ten repetitions or as pain allows:

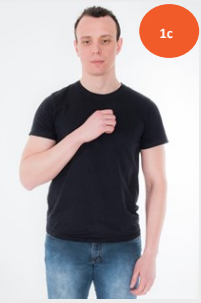
Exercise One: In a sitting position remove your sling and move your elbow wrist and hand as pain allows (Picture of moving elbow and hand)







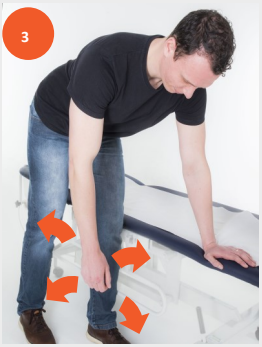




Exercise Two: In a standing position remove your sling and let your arm straighten next to your body. Slowly move your arm forwards in front of you and back down next to your body and then move your arm out to the side and back down next to your body. Ensure you only move as pain allows and no more than around 60^0 in each direction.

Exercise Three: In a standing position remove your sling and lean forwards to let your arm hang relaxed straight down, then begin to gently swing your arm forwards and backwords and side to side.

This is a guideline only and other physiotherapy advice and exercise prescription can be incorporated within the restrictions of no shoulder flexion and abduction beyond 60^0; slow controlled unrestricted movements of neck, elbow, hand and wrist and no strengthening/resistance exercises during this phase.



Phase Two (2-12 weeks)

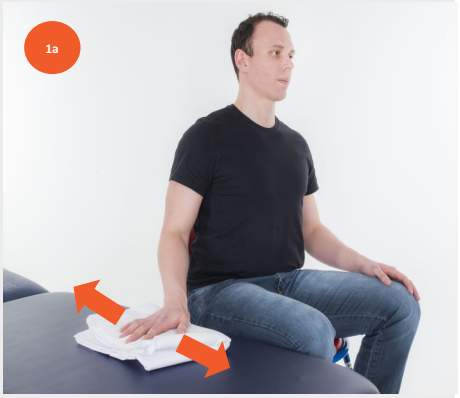
Following the initial two weeks, the aims during phase two are:

Consolidate the participants understanding of the benefits of physiotherapy
Reiterate possible complications, how to recognise them and what to do if they occur
Continue to assess and review pain control
Review agreed goals and re-evaluate as treatment progresses
Regain participants pre-operate range of movement
Re-educate the deltoid muscle

The exercises below have been provided to participants. They are designed to stretch, regain movement and re-educate the deltoid muscle. The deltoid's function in this setting is to stabilise the humeral head and compress it against the glenoid, even in the presence of a large cuff tear.

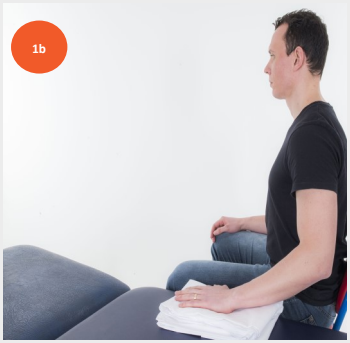
Exercise One: In a sitting position at a table place your operated arm on a towel and move the towel:

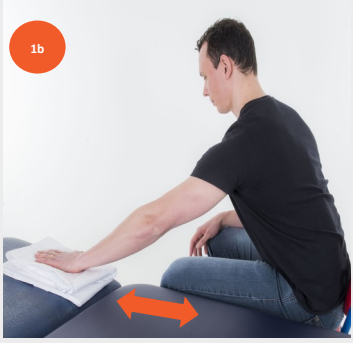
- Side to side with your arm straight
- Side to side with your elbow bent



Exercise 1 continued …….

- Forwards and backwards





- Round in a circle

Exercise Two: Once exercise one becomes easy move to a standing position, and with your operated arm on a towel move the towel in the same directions as exercise one.

- Side to side with your arm straight
- Up and down with your arm straight

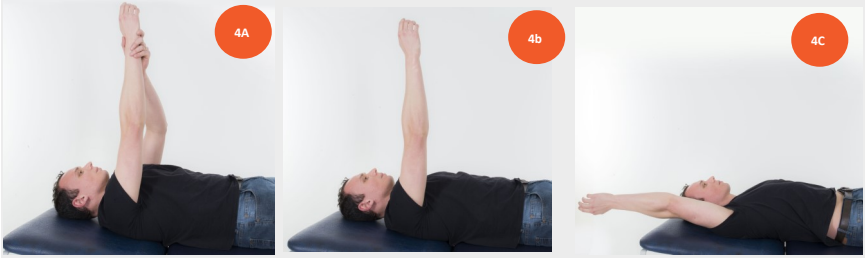
- Round in a circle

Exercise Three: Lie flat on the bed and lift your operated arm to a vertical position with the help of your un-operated arm and then hold the operated arm in place unsupported for ten seconds before lowering back down. Once you can do this without the help of your un-operated arm you can begin the same movement but this time move the arm all the way above your head and back again and continue for up to five minutes.

Note: **3a** can be performed with arm

These three exercises are the recommended 'baseline' for participants to complete. Additional exercises within the context of regaining pre-operative range of movement and re-educating deltoid muscle are permitted. However prescribed exercises should not include any resisted strengthening, fast movements or power activities.

Exercise Four: Once you can do exercise 3 you can do the same exercise with your arm straight.



Note: **4a** can be performed with arm

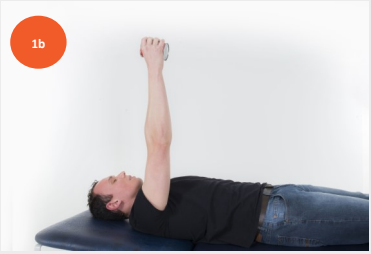
Phase Three (12 weeks onwards)

Following the first 12 week period, the aims during phase three are:

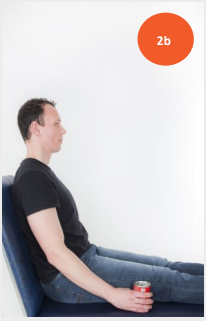
- Re-evaluate and complete agreed goals
- Re-educate and strengthen the deltoid muscle
- Set sport/activity specific exercises as appropriate

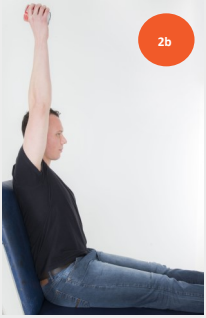
The exercises below have been provided to participants. They are designed to re-educate and strengthen the deltoid muscle. They build on the phase two exercises and therefore participants should only progress to phase three exercises once they can complete phase two exercises in a pain-free and controlled manner.

Exercise One: Once you are able to lie on your back and slowly move your arm from the side of your body to the bed above your head for at least five minutes you can progress to doing the same exercise whilst holding a small weight, such as a tin of beans.



Exercise Two: Once you can complete exercise one easily you can begin doing the same movement in a reclined, sitting and then standing position, each time beginning without a weight and then progressing to using a weight.





The above exercises are recommended as the minimum that should be completed. Participants will have differing expectations post operatively regarding the level of activity they wish to return to. To enable a safe return to a range of activities, the above exercises can be in addition to other more activity specific strengthening exercises prescribed by the physiotherapist.

From this phase onwards there are no restrictions, however it is expected that progressions will be made sequentially once pain free movement and control has been achieved and resistance/strengthening exercises will be introduced in a phased manner.

Between 8-12 weeks, patients may experience some discomfort in their shoulder however this usually settles within 2 weeks.