Report Supplementary Material 9 Trial Participant Information Sheet

Patient Information Sheet for UK FROST - a United Kingdom multi-centre study of three commonly used active treatments for a 'Frozen Shoulder'. Can you help?

- We would like to invite you to take part in a study about three different treatments for a frozen shoulder. These are all currently used to treat a frozen shoulder in the National Health Service (NHS).
- Before you decide whether to take part, you need to understand why we are doing this and what it involves.
- Please take your time to read the following information carefully. Discuss it with others if you wish before deciding whether you would like to take part.
- Ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information.

1. What is a frozen shoulder?

A frozen shoulder is when the tissues around your shoulder have become inflamed, painful and feel tight. A frozen shoulder tends to improve with time, sometimes taking up to three years. Most people are treated by their family doctor, and some may have physiotherapy. 1 in 10 patients with a frozen shoulder do not improve, and are referred to hospital for further, specialist, treatment. This may involve a structured programme of physiotherapy or surgery as described below.

2. Why are we doing this study?

The purpose of this study is to compare three treatments that are commonly provided in NHS hospitals to treat a frozen shoulder. These treatments may vary in how they are applied in different hospitals. Therefore, for this study, we are making the treatments standard, as agreed with experts, who think that these are the three important treatments to be compared. The aim of each treatment is to reduce your pain and to improve movement and function but we do not know which works best. To find this out we need evidence from this UK wide study.

The three treatments that we are comparing are:

(a) **Early structured physiotherapy.** This will be a structured programme based on national guidelines and accepted good practice in agreement with experts who were consulted especially for this study. A steroid injection will be offered to reduce pain and inflammation.

There are also two different types of surgery:

(b) **Manipulation under anaesthetic.** Under a general anaesthetic, the shoulder will be stretched in a controlled way to tear tight structures around the joint. This will include a steroid injection;

(c) **Keyhole surgery (arthroscopic capsular release).** Under a general anaesthetic, the tight structures around the shoulder will be released using keyhole surgery. While the anaesthetic is still working the shoulder will be stretched in a controlled way (manipulation under anaesthetic).

The aim of the study is to help your treating clinician understand what treatment works best. To do this we are comparing patients who receive (a) early structured physiotherapy with those patients who are put on a waiting list for either of the two different types of surgery, that is (b) or (c). Both types of surgery are also followed by routine physiotherapy which aims to reduce pain and to maintain or regain the movement in your shoulder. Therefore all patients will receive some form of physiotherapy. The content of the physiotherapy will depend on whether you receive it as part of the early structured physiotherapy programme or routinely after surgery.

3. Why am I being asked to take part?

You have been invited to take part in this study because you have a frozen shoulder. Your treating clinician has recommended that you have further treatment and agrees that there is a need for this study to find out which treatments works best.

4. Do I have to take part?

No. You do not have to take part in this study if you do not want to. Even if you decide to take part now, you can change your mind and tell us that you no longer want to take part at any time. If you decide not to take part, nobody will be upset with you and it will not affect the standard of care that you receive.

5. What will happen if you don't take part?

If you choose not to take part in this study, it will not affect your usual treatment in any way. Your treating clinician will discuss your treatment options in the usual way. It is likely that your treating clinician will advise you to have one of the three treatment options offered in this study.

6. What will I be asked to do if I take part?

When you have read and, should you wish, discussed the content of this leaflet, you will be asked to sign a consent form. Once you sign the consent form, you will be asked to complete a brief questionnaire and we will then use a computer to **randomly choose one of the three treatments** for you. This is like throwing a dice to see which treatment you get. We do this because your treating clinician does not know which treatment is best for you. Therefore we leave you to get one of the three treatments by chance which your treating clinician agrees is the fairest way to find out which treatment works the best for patients. For this study the advice from experts is that for each person chosen to have (a) early structured physiotherapy, two people will be chosen to have either (b) manipulation under anaesthetic or (c) keyhole surgery.

Treatment: If you are chosen to have (a) early structured physiotherapy, you will receive a 12 week structured programme designed for this study. This programme is based on national guidelines for physiotherapy management of frozen shoulder, accepted good practice and agreement between experts who were consulted especially for this study. We call this 'early structured physiotherapy' because it will be started with the least possible delay. You will receive an information leaflet with advice about your frozen shoulder. You will be offered a steroid injection to relieve your pain and help you perform your shoulder exercises more easily. The physiotherapist will monitor your progress and discuss the exercises with you that meet your individual needs. Your shoulder function will be assessed at each visit by your physiotherapist. You will also be reassessed by your treating clinician at 12 weeks. If necessary, at that stage, your treating clinician will discuss further treatment options with you.

If you are chosen to have surgery, it will be either to (b) manipulation under anaesthetic; or (c) keyhole surgery that includes manipulation under anaesthetic. Your surgery will take place within the normal NHS waiting list at your hospital. The surgery will be performed under a general anaesthetic and / or a regional block (where the nerves to your shoulder are numbed with local anaesthetic) and will usually be done as a day case. Your treating clinician may also choose to do some additional surgical procedures and/or provide steroid injections for pain relief as needed. Both of the operations are followed by routine physiotherapy treatment to maintain or regain shoulder mobility. The physiotherapy will usually start within 24 hours of your surgery. You will be given information about when and how to do the shoulder exercises. If you continue to have problems with your shoulder then further treatment can be discussed with a member of the shoulder team.

Follow-up appointments:

(a) Early structured physiotherapy. You will attend weekly physiotherapy sessions in hospital for up to 12 weeks. A follow-up clinic appointment with your treating clinician 12 weeks after the start of treatment will be organised to reassess your shoulder.

(b) Manipulation under anaesthetic. You will attend:

- Routine physiotherapy sessions following surgery to maintain or regain shoulder movement. Your physiotherapist will assess how often you need to attend. This may be regularly in the first couple of weeks but decrease when you can maintain shoulder movement between sessions.
- A routine follow-up clinic appointment after 6 weeks of surgery to reassess your shoulder.

(c) Keyhole surgery. You will attend the same follow-up as for (b) manipulation under anaesthetic.

Study Questionnaires and Hospital Records: Whichever treatment you receive, we will ask you to complete a short questionnaire (five minutes of your time) when you start your treatment and 6 months later. There are also more detailed questionnaires to complete at 3, 6, and 12 months after agreeing to take part which should take around fifteen minutes of your time. These questionnaires are very important to allow us to assess any changes in your shoulder condition and general health and your access to health care. We will also collect details of treatments you received in hospital and any complications to your treatment.

The Table below shows the timeline for the study for each of the three treatments:

	Pre-treatment questionnaire	Study treatment	12 week review	Routine physio-therapy	Postal questionnaire to the patient			
					Three month	Six month	Twelve month	Post-study treatment
(a) Early structured physiotherapy	X	X	X		X	X	X	X
(b) Manipulation under anaesthetic	X	X		X	X	X	X	X
(c) Keyhole surgery	X	X		X	X	X	X	X

Patient interviews: We would also like to talk with some of you about your experience of a frozen shoulder and your treatment. These interviews will take place 12 months after the start of the study and will ideally be done face-to-face, but it may be more practical to do this over the telephone or on-line. Your views and opinions will help us to make useful improvements to how we treat patients with a frozen shoulder in the future. For those of you who are interested in an interview we will send to you a leaflet and consent form nearer to the time to help you decide whether you would like to take part.

7. What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time. You do not have to give a reason for this. It will not affect your hospital care or rights in any way. If you decide to withdraw please tell us whether you would also prefer that we didn't contact the hospital for any further information about you. All the other information collected about you up to the time of your withdrawal from the study will be kept.

8. What are the possible benefits of taking part?

All three treatments being compared in this study are routinely used in the NHS to treat frozen shoulder, but we do not know which treatment works best. With your help, the information we get will inform the best treatment in the future for people with this painful and disabling condition.

9. What are the possible risks of these routine treatments?

While your treatment is left to chance, you will receive the same standard of NHS care as normal. Your surgeon and physiotherapist are experienced in the treatments provided and will do all they can to reduce risk. There are no new treatments being tested in this study. All surgery involves risks, such as from general anaesthesia, bleeding, risk of deep vein thrombosis, damage to nerves and blood vessels in the surgical area and infection. You need to consider this when deciding whether you would be prepared to have surgery. If you receive early structured physiotherapy, you will be offered a steroid injection (unless there is a medical reason not to do so), as this usually helps control pain. The steroid injection carries with it a very small risk of introducing infection into the shoulder, but the clinicians treating you will take every opportunity to reduce any risk. If something went wrong, they would offer the best possible solution to resolve it. Manipulation under anaesthetic is also supplemented with a steroid injection.

10. What happens if something goes wrong?

If you are concerned with any aspect of this study, you should speak to your treating clinician or one of the researchers who will do their best to answer your questions (see contact details at the end of this information sheet). If you are harmed due to someone's negligence, then you may have grounds for legal action but may have to pay for it. If you wish to make a complaint you can do this through the usual NHS procedures by contacting a Patient Advice and Liaison Services (PALS) officer.

11. How will I be contacted?

Post: With your permission we will use your contact details to send you the study questionnaires.
Mobile: With your permission we will text you via your mobile number about when to expect a study questionnaire. We will also call you when a questionnaire isn't returned.
Email: With your permission we will use your email to update you about the study with a newsletter.

12. Who will meet my expenses for taking part in the study?

We will cover your travel costs for attending the 'early structured physiotherapy programme' and your clinic review at 12 weeks, if you take part in the study and are chosen to be in that group. This is because of the need to attend weekly physiotherapy sessions. In recognition of your help with this study, which applies to all treatment groups, you will receive five pounds when asked to complete the final questionnaire at 12 months.

13. Will my taking part in this study be kept confidential?

Yes. All information that is collected about you during the study will be kept strictly confidential at your hospital, at the co-ordinating centre in York Trials Unit or at an alternative secure facility. Research information about you may be checked by authorised persons to make sure that the study is being carried out properly. All of the research information will be held for at least 20 years. Then we will destroy any papers containing research information about you. We will also keep research information electronically, but there will be nothing in this information that could identify you. You will be allocated a study number so that when any research information about you leaves York Trials Unit you cannot be recognised from it. With your consent, we will inform your GP about your participation in the study and, if necessary, ask your GP for your latest contact details.

14. What will happen to the the results of the study?

The study should finish in June 2019. Once the study has ended and the results have been analysed, reports will be published in medical journals and presented at conferences. You will not be identified in any study reports or presentations. You will be asked at the start of the study whether you would like a summary of our findings.

15. Who has reviewed this study?

Before the study has begun it has been looked at by an independent group of people, called a Research Ethics Committee (REC). This is to protect your interests. This study was reviewed and approved by NRES Committee North East (14/NE/1176). In addition, patient representatives, who have had a frozen shoulder or have an understanding of it, have provided feedback about this leaflet and other aspects of the study.

16. Who is organising and funding this research?

This study is funded by the 'National Institute for Health Research' Health Technology Assessment programme. The Sponsor is the James Cook University Hospital of South Tees NHS Foundation Trust, Middlesbrough. Study management is by University of York Trials Unit. The interviews are being undertaken by University of Oxford. This study has been endorsed by the British Elbow and Shoulder Society (BESS) and the National Injuries and Emergencies Speciality Group. Your treating clinician will not receive payments for their involvement in the study. The hospitals receive payments for when a patient agrees to take part and for collecting follow-up data. This only covers the cost to the hospital for helping with the study.

17. Who can I contact for more information?

You can find independent information on research in general by contacting INVOLVE, the national advisory group of the National Institute for Health Research (Phone: 02380 651088, Email: admin@invo.org.uk, website: www.invo.org.uk). If you would like specific information about this study you may contact Dr Stephen Brealey, the Trial manager on 01904 321357 or stephen.brealey@york.ac.uk. Alternatively, you can contact Professor Amar Rangan who is the overall lead for this study on 01642 854380.

Your local hospital contact for the UK FROST study is:

Principal Investigator	Research Nurse
Name: [INSERT NAME]	Name: [INSERT NAME]
Tel: [INSERT NUMBER]	Tel: [INSERT NUMBER]

Thank you for reading this information sheet and for considering whether to take part.

This project was funded by the National Institute for Health Research [NIHR Health Technology Assessment] (project number 13/26/01).