

# Can Shoulder Arthroscopy Work? (CSAW)

## Full Patient Information Sheet

We would like to invite you to take part in a research study called CSAW.

The study is looking at the treatment of shoulder pain.

Before you decide whether to take part or not, we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you and answer any questions you have, we anticipate that this will take about 30 minutes.

### PART 1: INFORMATION REGARDING THE PURPOSE OF THE STUDY

#### 1a. What is the purpose of the CSAW study?

- The aim of the CSAW study is to find out what the best way is to treat persistent shoulder pain.
- We will also examine ways to improve communication about treatments for people with shoulder complaints.

#### 1b. Why have I been invited to take part in CSAW?

You are being invited because you have a diagnosis of shoulder pain called sub-acromial pain.

#### 1c. Do I have to take part?

No, taking part in a research study is always optional. We will describe the study and go through this information sheet with you. You do not have to decide straightaway. Please feel free to take the information sheet home with you and discuss your participation with friends, family or your own GP. If you agree to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive.

**1d. What will happen to me if I take part in the study?**

To begin with you will have your shoulder assessed and be asked to complete some questionnaires relating to your pain. If you then decide to take part in CSAW you will undergo one of the following:

- **Active Monitoring with Specialist Reassessment**

This involves reviewing your shoulder at regular intervals to see if the pain gets better by itself. This is common practice at this time for shoulder pain, particularly if you have already undergone previous physiotherapy and/or injections. Some patients may find their shoulder pain improves without any surgical treatment. Patients allocated to this group may also have the option of alternative treatment after 6 months if their surgeon believes there is a need to try another treatment.

- **Shoulder Arthroscopy**

This is a key-hole operation performed under general anaesthetic. The inside of your shoulder is viewed using a special camera. The shoulder is assessed to see if there are any problems with your tendons or joint. Your shoulder joint will also be washed out.

- **Arthroscopic Sub-acromial Decompression**

This is also a key-hole operation performed under general anaesthetic. Apart from the shaving away of a small amount of bone that sits above the tendons, the operation is very similar to the shoulder arthroscopy (above).

You will be seen at regular intervals by members of your Consultant's clinical research team over a period of 12 months. We will ask you to complete some questionnaires at these clinic appointments to tell us how the shoulder pain is.

At the end of the study, we will compare outcomes in the three groups to see which treatment is the best for shoulder pain. If surgery proves to be the best option, we will look to determine which aspects of the surgery help with the pain.

**1e. Which of these groups will I be in?**

We don't know. We ask that allocation to these groups is random (like a lottery). We are advising this because it is the best way to allow a fair comparison to be made between the different groups. Dividing people into groups in this way is what is called a "randomised clinical trial" and it is the standard and only reliable way to see how good a treatment is. Whatever group you are in, you will still be under the care of your Consultant Surgeon and followed up regularly.

**1f. Will I know what group I am in?**

Not necessarily. CSAW is a “blinded” trial, so if you are in one of the surgery groups you will **NOT** know which type of surgery you have had. Both operations will be performed in the same way. They will both involve a general anaesthetic, with 2 small skin incisions and key-hole surgery.

The nurse or physiotherapist that performs your follow up assessments will not know which treatment group you are in. During the clinic appointments you will be asked to **NOT** reveal whether you have had surgery or not. We will ask you to keep your shoulders covered during the clinical assessments so as not to reveal any surgical scars. There will be an opportunity to see an ‘unblinded’ member of the team if you need to speak to someone about your treatment.

**1g. Would taking part in CSAW involve extra clinic visits?**

Yes, participating in CSAW will involve 2 or 3 extra clinic visits to assess your shoulder and answer questionnaires. All patients in the study will be asked to attend the following appointments:

- Appointment 1 – is called **a baseline assessment** and is undertaken when you first enter the study
- Appointment 2 – is called **a follow up assessment** and is undertaken 6 months after you enter the study
- Appointment 3 – is also called **a follow up assessment** and is undertaken 12 months after you enter the study

The baseline visit and the 12 month visit are extra appointments. Depending on your surgeon’s follow up schedule the 6 month follow-up visit may coincide with your routine clinic appointment.

If you are not having surgery you will be asked to attend an appointment 3 months after you enter the study. This is in addition to the 3 appointments listed above and would be a part of your clinical monitoring and reassessment.

If you are randomised to one of the surgical groups and you are on the waiting list for longer than 4 months, some of the baseline assessments may need to be repeated. If this is the case, a member of the research team will contact you to arrange this.

At each of these visits a member of your Consultant’s clinical research team will see you to assess your shoulder and ask you to complete some questionnaires.

## **1h. Audio-Recording and Interviews**

We know very little about how people with shoulder complaints decide on treatment options. To improve this knowledge, part of the CSAW study will explore the treatment information given to patients with shoulder pain and will also review the patients' willingness to participate in the CSAW study. To do this we may:

- Ask to audio-tape the conversations you have with the research team who are providing you with information about the CSAW study.
- Ask you to participate in interviews with members of the CSAW team. These interviews will involve discussions about the information you have received in relation to your shoulder pain and the CSAW study. The interviews will take place in a location of your choice – for example over the telephone, or face-to-face at your home or your hospital. The interviews will also be audio-recorded.

If you have any questions about this, the study team can provide you with more information.

## **1i. Expenses and Payments**

There is no payment to people taking part in the study but reasonable travel expenses to the hospital for your follow up appointments can be reimbursed. Ask the local research team for further details about this.

## **1j. What are the possible disadvantages and risks involved of taking part?**

There are no anticipated risks or disadvantages to participating in this study. Whichever type of treatment you are allocated to, your care will be coordinated by a competent and trained surgeon. If you are randomised to one of the surgical options there are the usual risks associated with surgery and anaesthetics. Steps are always taken to ensure that these risks are minimised. Your surgeon will be able to tell you about the risks and complication rates in your own local hospital.

## **1k. What are the possible benefits of taking part?**

We can't guarantee any benefit to patients who take part. Any one of the three treatments we are comparing would be a good option for you and, until we've completed the study, we can't be sure which one is best. The main benefit from you taking part will be the information we get from this study, which should help us to improve the future treatment of patients with shoulder pain. During the follow up visits you will have one-to-one sessions with an experienced clinical researcher who may be able to help with any problems you are having related to your shoulder.

## **PART 2: DETAILED INFORMATION ABOUT THE CONDUCT OF THE STUDY.**

### **2a. What happens when the research study stops?**

Any shoulder related care required beyond this time should be arranged in the usual way via your GP.

### **2b. What if there is a problem?**

Taking part in the study will not affect your legal rights. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, **you should contact your local principal investigator** (contact details can be found on the last page of this document)

**Or**

Naomi Cummings, trial co-ordinator at the central office in Oxford by e-mail at [CSAW@ndorms.ox.ac.uk](mailto:CSAW@ndorms.ox.ac.uk) or by telephone on (01865) 223404

**Or**

You may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or the head of CTRG by email at [heather.house@admin.ox.ac.uk](mailto:heather.house@admin.ox.ac.uk).

NHS indemnity operates in respect of the clinical treatment with which you are provided. In addition, in the unlikely event you were harmed by participation, the University of Oxford has appropriate insurance-related arrangements in place in respect of the University's role as Research Sponsor of this study.

### **2c. Will taking part be kept confidential?**

Yes. All patient information will be stored on password protected computer databases or in locked filing cabinets. You will be allocated a study number and staff not directly involved with your care will know you only by this number. When the results of the study are reported, individuals who have taken part will not be identified in any way. Responsible members of the University of Oxford or your NHS Trust may be given access to data for monitoring and/or audit of the study to ensure we are complying with research regulations.

### **2d. What if relevant new information becomes available?**

Any new information about the treatment for shoulder pain will be considered in relation to its effect on your care. If one of the study treatments is proved to be more effective or less harmful than the others that part of the study will be stopped. If this is relevant to your care, the research team will contact you to discuss the situation further.

**2e. What will happen if I don't want to carry on with the study?**

If you decide to withdraw from the study, your standard of care will not be affected. You will still be asked to attend the usual follow-up clinics required by your surgeon and hospital. These will not be part of the study. Any information you have already provided will still be considered as part of the final study outcome.

**2f. Will my GP be informed about my participation in the study?**

With your consent we will notify your GP about your participation in this study.

**2g. What will happen to the results of the research study?**

At the end of the study patients who participated will be offered a report detailing the study's findings. This will also be made available on the study website. We plan to publish the results in a medical journal so others can read about and learn from the results of the study.

**2h. If I am randomised to have an operation, when can I find out which procedure I had?**

You will be able to find out on the day after the last patient in the study completes their 12 month follow up assessment. This delay is necessary to prevent any unfairness within the study. If it is deemed clinically necessary to inform you before this, your surgeon will do so.

**2i. Who is organising and funding the study?**

The study is organised by a team of surgeons, nurses, physiotherapists, patient representatives, medical ethicists, health economists and statisticians working with Professor David Beard and Professor Andrew Carr. The team are based at the Nuffield Department of Orthopaedics, Rheumatology & Musculoskeletal Sciences (NDORMS) at the University of Oxford.

CSAW is funded by Arthritis Research UK, a registered charity specialising in research into treatments for patients with musculoskeletal problems. You can access information about them on their website [www.arthritisresearchuk.org.uk](http://www.arthritisresearchuk.org.uk).

**2j. Who has reviewed the study**

To protect your interests, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This study has been reviewed and approved by the Oxfordshire Research Ethics Committee B. (REC Reference 12/sc/0028)

The UK Comprehensive Research Network, each hospital's Research and Development Committee/Department and your local Orthopaedic Consultant have also reviewed and approved this study.

**2k. Further information**

If you have any questions please contact the clinical research team at your local hospital:



You may also contact the Oxford CSAW team via e-mail at [CSAW@ndorms.ox.ac.uk](mailto:CSAW@ndorms.ox.ac.uk) or on the telephone number provided in section 2b. Information about the study is also available on the NDORMS website; [www.ndorms.ox.ac.uk/csaw](http://www.ndorms.ox.ac.uk/csaw).