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**Participant Information Leaflet**

**Version 3.0, 03Nov2016**

**South Central – Berkshire B Research Ethics Committee, REC Ref: 16/SC/0508**

**Study title: Progressive exercise compared to best practice advice, with or without**

**corticosteroid injection, for the treatment of rotator cuff disorders**

**Invitation to join the GRASP study**

* We would like to invite you to consider taking part in a research study called GRASP. This study is looking at the best ways to treat shoulder pain in people with a rotator cuff disorder. Specifically, we are testing different types of physiotherapy treatment pathways that are routinely used to treat people with rotator cuff problems.

* The study is also investigating whether a routinely given pain relief injection also improves recovery in people with rotator cuff problems.
* Before you decide, it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. If anything is unclear, or if you would like more information, please ask a member of the local study team, or call the national GRASP study team on 01865 737432, or email them on [grasp@ndorms.ox.ac.uk](mailto:grasp@ndorms.ox.ac.uk).
* This leaflet explains why we are doing this research and what the study will involve and exactly what being in the study would mean for you, to help you decide whether you would like to take part.

**What is the purpose of this study?**

* This study is looking at how best to treat shoulder pain in people who have been diagnosed with a rotator cuff disorder. Most new cases are caused by problems with the muscles and tendons in the shoulder, called the rotator cuff.

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| * As may have been explained to you by your health care professional, the rotator cuff is a group of 4 muscles on your shoulder blade with tendons that attach to the “ball” of your humerus (upper arm bone). These muscles and tendons help you lift and rotate your arm. They also help hold the ball of your humerus firmly in your shoulder socket. As you will know problems with your rotator cuff can make moving your shoulder painful and simple daily tasks more difficult. | *Arm bone*  *3 of the 4 rotator cuff muscles attach from the back of the shoulder to the arm bone* |

* Health care professionals including doctors and physiotherapists usually treat shoulder pain with some combination of advice, rest, drugs (both tablets and sometimes an injection) and physiotherapy, but we don’t have much evidence for actually knowing which treatments work best. For example, we don’t know how much physiotherapy is the right amount for patients with a rotator cuff disorder, and also if having an injection of a drug called a steroid before any physiotherapy is of benefit to patients.
* The GRASP study will test whether people with a rotator cuff problem do better after a structured exercise programme supervised over 16 weeks by a physiotherapist or after one best-practice advice session with a physiotherapist and a self-managed exercise programme conducted at home.
* The trial will also test whether getting an injection in the shoulder joint before starting either regime helps to relieve pain, allows more comfortable exercise and improves a patients’ function any quicker.
* You should know that the treatment programmes and the injection (of a steroid) are all commonly used in the NHS to treat people with shoulder pain, this study aims to find out what is the best combination for patients with a rotator cuff problem.

**Who is taking part and why have I been invited to take part?**

* We are hoping to recruit 704 men and women from across the UK who have recently developed shoulder pain and where a health care professional has diagnosed that the pain is due to a rotator cuff problem.
* You have been invited to take part because you have been diagnosed with a rotator cuff problem and you may therefore be eligible for the study.
* We are recruiting patients who are early in their diagnosis and who have yet to have any physiotherapy for the latest episode of shoulder pain they are suffering from. Patients who have a rotator cuff problem that needs surgery are not eligible to take part in this study.

**Do I have to take part in this study?**



* No. You decide whether or not to take part in this study. Please keep this leaflet and use it to make your decision. If you decide to take part, you will be asked to sign a consent form. You are free to leave the study at any time without giving a reason.
* Please remember, it is your decision to take part, either now or if you change your mind during the study, this will not change the standard of the care you receive.
* Should you choose not to participate you will receive the standard treatment for your condition, as per the judgement of your healthcare professional and according to standard NHS practice.

**What will happen if I take part?**

* If you are happy to take part in this study, a researcher will carry out some simple assessments to confirm that you are eligible for the study. If you are eligible and still want to take part, you will be asked to sign and date a consent form and complete a short questionnaire that asks about you, your health and activity, and your shoulder pain. This questionnaire should take you no more than 10 minutes to complete.
* A researcher will then enter your details into a computer and a computer program will make a decision about which group you will be in while in the study. This allocation is made by chance, rather like the toss of a coin, this is important because it ensures that the different treatment pathways are tested fairly, no one can influence the group the computer puts you into.

**What treatment will I receive?**

* The treatment that you will receive would be 1 of the 4 treatment pathways below:

**TREATMENT 2** A best practice advice session

**TREATMENT 1** A structured exercise programme

**TREATMENT 4** A best practice advice session and an injection

**TREATMENT 3** A structured exercise programme and an injection

**OR**

**OR**

**OR**

* Remember, a computer will randomly select the treatment you will receive. Your usual healthcare professional, the researcher or physiotherapist will not be able to affect which treatment is selected and you will not be able to choose which treatment you will receive if you take part in the trial.

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| * You will be told which treatment you will receive at your clinic appointment. Your treatment will be provided by fully trained NHS physiotherapists at a centre in your local area. |  |

**Treatment 1**: You will receive up to 6 sessions with a physiotherapist over 16 weeks. The first session will last between 40 - 60 minutes, during which you will be given a simple set of exercises to do at home. You will then have up to 5 follow-up sessions of 20 to 30 minutes with the physiotherapist.

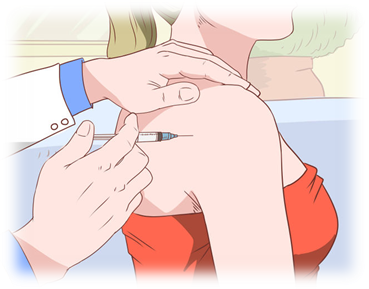
**Treatment 2:** You will receive 1 session with a physiotherapist lasting between 40 -60 minutes. You will be given advice on managing your shoulder pain and a simple set of exercises to do at home. You will also get an advice booklet and exercise DVD (or a link to a website with the exercise videos).

**Treatment 3:** You will first get an injection of a steroid and local anaesthetic into your shoulder. You will then receive the same programme of up to 6 sessions with a physiotherapist supervised over a 16 week period as in Treatment 1.

**Treatment 4:** You will first get the same injection of a steroid and local anaesthetic into your shoulder. You will then receive the same programme of 1 session with a physiotherapist and exercise materials as in Treatment 2.

* If you are assigned into Treatment 3 or 4 you will receive an injection of a drug called a steroid (also called a corticosteroid). A corticosteroid is medicine which can relieve swelling, stiffness and pain in a joint, tendon or surrounding tissue. The injection can give some short term pain relief and may help you return to your normal activities more quickly.
* Side effects from the injection are very uncommon, however, you may experience an increase in pain or flushing of the face but these generally resolve within 24 – 48 hours. Your local clinic will have more specific leaflets about the possible risks and benefits of steroid injections. Please ask for one of these injection specific leaflets.

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* The possible risks of the injection are:
  + A very small risk of infection in your shoulder joint after an injection (this happens in approximately 1 in 15,000 people).
  + You may feel pain after the injection once the local anaesthetic you are given before the injection wears off. This is usually about 4 hours after the injection and usually goes within 2 to 3 days. You can take painkillers such as paracetamol to help reduce this discomfort.
  + The fat layer below the skin where the injection is put into can become damaged so that a ‘dimpled’ appearance can be seen.
  + The skin at the site of the injection can become darker in appearance than the rest of your normal skin colour.
* If you have an injection, the person giving it to you will tell you what to do if you have any problems after having the injection, or if you have a problem after doing any exercises that the physiotherapist asks you to do at home.
* A researcher may visit while you are having your physiotherapy so that we can check how the treatments are being delivered. We will always check you are happy for this to happen. At the end of the study, we will report how well the treatments were delivered as it is important we fully understand this process. Please note no-one can ever be identified in any report about the study, data is always anonymised.

**What happens after I have attended for treatment?**

* If you take part in the study, we will ask you to complete 3 questionnaires that ask about you, your health and activity, and your shoulder problem. We will also ask you about any appointments you have had at the hospital or your GP practice. Also if you are put into one of the treatment groups where you have up to 6 physiotherapy sessions, you will be asked to sign an exercise plan that says that you understand it is important to commit to do the exercises you are given by the physiotherapist at home and you will be asked to complete a very short exercise diary.
* You will receive the first questionnaire in the post about 8 weeks after you join the study. You will receive the second questionnaire at 6 months and the final questionnaire at 12 months after joining the study.
* We ask that you complete each questionnaire and return it to the research team using the stamped addressed envelope provided. If we do not get your questionnaire back, we will send you at least one letter to remind you and we may call you to ask you the questions that are in the questionnaire.
* If you agree to take part in the study, we will ask you how you wish for the study team to send you your questionnaires. This could be by post or by email – this is your choice, and whichever method you choose, the questionnaires are the same.
* As part of this research, we may want to look at information held by the NHS and by sources maintained by NHS Digital and other central UK NHS bodies. We will only look at information that is relevant to this research. We will request your permission to access this information. If you give your permission, then only authorised individuals from the research team will access this information for up to 5 years after you entered into the study.
* All data collected as part of the study will be processed according to the Data Protection Act 1998, details of which can be found on the study website.

**What are the benefits and risks of taking part in the study?**

* Your rotator cuff problem will be treated by fully qualified, registered physiotherapists using widely recognised treatments in the NHS. We hope the information we obtain from this study will be used to help treat people with rotator cuff problems more effectively.
* You are unlikely to be harmed by this treatment. The physiotherapist will assess you to make sure you are given exercises at the right level for you. You may experience muscle soreness after completing some of the exercises or after receiving a shoulder injection. This is normal, and you will be given advice on how to manage this soreness.
* People sometimes feel uncomfortable answering certain questions about their health. If the researcher, physiotherapist, or follow-up questionnaire asks you questions that you are uncomfortable with, then you do not have to answer them.

**Expenses and payments**

* We are not able to pay travel expenses for you to attend your treatment sessions.

**Who will know that I am taking part?**

* The only people who will know that you are taking part in this study are the members of the research team and the healthcare professionals involved in your care. Representatives from the sponsor, << Insert local Trust >>, and Regulatory Authorities may also require access to monitor or audit the study.
* You can tell anyone you would like to that you are taking part.

**Will my details be kept confidential?**

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| * The research team will keep all of the information collected about and from you strictly confidential. However at the end of the study the data will be anonymised so that no-one could be identified from it. With your permission we would like to share this anonymised data so that more researchers can understand more about patients who have a rotator cuff problem. The data will be stored electronically on the University of Oxford central server, in accordance with the Data Protection Act (1998). It will be stored for a period of at least 5 years following completion of the study. |  |

**What happens at the end of the study?**

* If you would like, we will send you a summary of the trial results at the end of the study. If you decide to take part, you will be asked to sign a form (a consent form) which will ask if you would like to have a copy of the results, and how you would like to receive these (either by post or email). The results will be shared with healthcare researchers and professionals to improve future patient care. The results will also be published and presented in research reports, at scientific conferences, and in scientific journals.
* Any data that could identify you will not be included in the results. If the funders of this research request that the study data be made available for other researchers, we will first make your information anonymous so that you cannot be identified.

**Who is organising and funding the research?**

* The study is sponsored by the University of Oxford and conducted by a research team led by Professor Andrew Carr, a Consultant Shoulder Surgeon at the Centre for Research Rehabilitation in Oxford. Professor Carr for this study is the person known as the Chief Investigator.
* The study is funded by the National Institute of Health Research.

**Who has approved this study?**

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|  | * This study has been reviewed by a panel of independent researchers and patient representatives, who make sure that we conduct the study the right way. * The study has also been reviewed and approved by a Research Ethics Committee (REC Reference 16/SC/0508). |

**What if I have concerns?**

* The University of Oxford, as the study sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. If you have any concerns or complaints about any aspect of the study, please contact the GRASP research team using the details below. You can also contact the University of Oxford Clinical Trials and Research Governance office on 01865 572224 or by email on [ctrg@admin.ox.ac.uk](mailto:ctrg@admin.ox.ac.uk).
* If you would prefer to speak with someone who is not involved in the research, then please contact the Patient Advice and Liaison Service (PALS). PALS is a confidential NHS service that can provide you with support for any complaints or queries you have regarding the care you receive as an NHS patient. However, PALS cannot provide information about this research study.

PALS phone number: <Insert local PALS phone number>

PALS email: <insert local PALS email address>

* If you have any questions about the study, please contact the research team using the details below.

Email: [GRASP@ndorms.ox.ac.uk](mailto:GRASP@ndorms.ox.ac.uk) Website: <http://grasp.octru.ox.ac.uk/>

Telephone: 01865 737432 (available Monday to Friday, 9am to 5pm)

Postal address: GRASP research team, Botnar Research Centre, University of Oxford, Windmill Road, Headington, Oxford, OX3 7LD.

**THANK YOU FOR READING THIS INFORMATION LEAFLET AND CONSIDERING TAKING PART**