



Prognostic AND Diagnostic Assessment of Shoulder Pain (PANDA-S)

Participant Information Leaflet : Research Assessment Clinic

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An invitation to take part in the PANDA-S research assessment clinic

Thank you for completing the recent questionnaire that we sent you. You are now being invited to attend a research clinic for an assessment of your shoulder.

This assessment is for research purposes only, and is an optional part of the PANDA-S study. If you choose only to complete the questionnaires, you will still be making a valuable contribution to the study.

Before you decide whether you would like to attend for a research assessment, it is important to understand why this research is being done and what it will involve. Please take time to read this leaflet carefully and discuss it with friends, relatives and your GP if you wish. Please contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the study about?

Shoulder pain is a common condition affecting 1.5 million people every year. Most people recover quickly from shoulder pain, but in some people shoulder pain lasts longer than 6 months and affects sleep, work and everyday life.

Clinicians, including doctors and physiotherapists often make their diagnosis and decide what should be done on the basis of clinical assessment – that is, what the patient tells them (for example, how the problem started and what symptoms they have) and what they find on examining the shoulder. Occasionally they may also ask for an ultrasound assessment of the shoulder if they are looking for something specific.

However, we still do not know what information from this clinical and ultrasound assessment is most important when making the diagnosis, what is likely to happen to shoulder problems over time, and how best to manage them. This study is designed to answer these questions and provide doctors with this information so that the care of such problems in the future can be improved.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form when you attend for your assessment. You are still free to withdraw at any time and without giving a reason. A decision either way will not affect the care you receive from your doctor or any other health care professional now or in the future.

What does the research clinic involve?

Consent (approximately 15 minutes)

When you arrive at the clinic, one of the research staff will explain the assessment to you and ask if you have any questions. Please do not hesitate to ask about anything that is not clear. We need to know that you fully understand what taking part in the research clinic means for you. You will be asked to consent to being examined by a research physiotherapist and having an ultrasound assessment of your shoulder, which will be performed by an ultrasonographer - a technician experienced in the use of ultrasound. If you agree to have the assessments you will be asked to sign a detailed consent form. If you have previously given us your consent for authorised members of the PANDA-S research team to extract and review an electronic copy of your de-personalised medical record, we will ask for your consent to link information collected during the assessment to information relevant to the PANDA-S study in the electronic copy of your depersonalised medical record. This will be done using codes which will not identify you personally. We suggest that you bring reading glasses with you if you need them.

Clinical Assessment (approximately 45 minutes)

If you agree, the research physiotherapist will ask you some questions about your shoulder pain and how it affects you. During the physical examination the physiotherapist will assess how well you can move and use your arm using a variety of different tests. To give us an idea of your general function, your hand grip strength will also be measured and you will receive a brief and simple assessment of your leg strength and balance. In some situations, through the questions asked and the tests undertaken, the research physiotherapist might identify that you are not eligible to participate further in the study. If this does happen the reasons will be explained along with the next steps for you.

Ultrasound assessment (approximately 20 minutes)

If you agree, an ultrasound assessment will be carried out on both of your shoulders so that we can compare the results. It is an examination that involves taking pictures of the shoulder using high frequency sound waves in exactly the same way as during pregnancy. Sound waves from a small sensor are sent through the skin into the shoulder, they then echo (bounce back) from the soft tissue structures of the shoulder, creating an image. In this study, the ultrasonographer will take images of particular structures such as tendons so that they can be assessed and measured later. This information will be used to help us learn more about what we can see in patients who have shoulder pain.

What should I wear?

In order for your shoulders to be examined and the ultrasound assessment performed, you will need to uncover your shoulders and upper arms. The ultrasonographer will use a water-based gel on your shoulders during the assessment. You may find it more comfortable to wear a vest or sleeveless T shirt although the gel does not stain your clothes.

How long will it take?

We anticipate that the assessment and ultrasound will take approximately 1½ hours.

Will I be paid for attending the clinic?

You will be given a £10.00 gift voucher as a gesture towards your travel and out-of-pocket expenses.

What are the benefits and risks of taking part?

Benefits: Although any direct benefit to you is unlikely, what we learn from this research will help people with shoulder pain in the future. You will not receive any treatment in this research clinic. It involves questions, clinical and ultrasound assessments for research purposes only – these are extra assessments that may not normally be used at this stage of your care. We will not give any results of these assessments to you or your doctor. In the very unlikely event that the assessment revealed a serious underlying problem, appropriate action would be taken and your GP would be informed. Your doctor will continue to give advice about your shoulder pain and treatment where appropriate as normal. In the future, your doctor may wish to send you on to specialists for imaging or treatment for your shoulder pain – this will not be affected by the assessment you have in the research clinics.

Risks: All the questions and examinations in this study are already currently used to assess shoulder pain. People with shoulder pain do occasionally find that a physical examination can cause some discomfort, although this is usually short-lasting and does not indicate any underlying change in their condition. The research physiotherapist and ultrasonographer will explain what they are going to do. If there is anything that you do not want to do, then please let them know.

There are no known risks from the sound waves used in an ultrasound assessment. Unlike some other assessments, such as x-rays, ultrasound assessments don't involve exposure to radiation, they don't have any side effects and are generally painless.

What will happen to the information you collect about me?

The information (data) collected about you will be treated in strict confidence and in accordance with the general data protection regulations (Data Protection Act 2018), details of which were provided in the original Participant Information Leaflet. You can find out more about how we use your information at:

<https://www.keele.ac.uk/informationgovernance/informationgovernanceforthepublic/>

Further Information

What if I have any questions?

If you have any questions or would like more information, please contact Keele Clinical Trials Unit during office hours on 01782 732950 or email sch-tr.pandasstudy@nhs.net. If you have a concern about any aspect of the study, it is often worthwhile discussing your concerns with the study team, as they may be able to sort the issue out. If you have questions about research studies in general you can contact NHS England on Tel: 03003112233, email: england.contactus@nhs.net. If you have any concerns or complaints about this study, please

contact Dr Clark Crawford, Head of Research Integrity at Keele University via research.governance@keele.ac.uk or 01782 733371.

Who is funding and organising the research?

PANDA-S is funded by the National Institute for Health Research (NIHR) Programme Grants for Applied Research programme (RP-PG-0615-20002) and Arthritis Research UK. The Research Institute for Primary Care and Health Sciences at Keele University is organising this study, together with Keele Clinical Trials Unit (CTU). The research team at Keele is working in collaboration with a research team at the University of Oxford.

How do I make an appointment?

If you would like to make an appointment for the research clinic, please telephone Keele Clinical Trials Unit on **01782 732950**

You will be booked in for your assessment at the first available appointment that is convenient for you. This will need to be within 6 weeks of your questionnaire being returned to us

If you have any questions or are unclear about any aspect of the study, the administrator will arrange for one of the research team to telephone you back

If you have previously provided your telephone number, and we haven't heard from you within 2 weeks, we will ring you to check whether you would like to attend the research clinic

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