**Prognostic AND Diagnostic Assessment of Shoulder Pain research study [PANDA-S]**

# PARTICIPANT INFORMATION LEAFLET

**Version 2.0, 20/Sep/2018 IRAS Project Ref: 242750**

- This information sheet explains in detail why the study is being carried out, what is involved and how you can take part. This information will help you decide whether or not you want to take part.
- If you choose to take part you are free to withdraw at any time. If you choose not to take part, this will not affect the current or future health care you receive.

## Key things to know

- You have been invited to take part in the PANDA-S research study because you have recently been to see your doctor or physiotherapist about your shoulder pain.
- **If you decide to take part in the PANDA-S research study it will involve:**
  - Completing 6 questionnaires over the next 3 years. Each questionnaire will ask about your shoulder pain and how it has affected you, and will take you approximately 20 minutes to complete.
- You will also be given the opportunity to take part in additional ***optional*** parts of the PANDA-S Study:
  - You will be invited to attend a research clinic for a detailed physical examination and an ultrasound scan of your shoulder. We anticipate the examination and scan will take approximately an hour and a half.
  - You will be invited to complete a weekly record of your shoulder pain either using an app for your smart phone / tablet ***or*** by using SMS text messaging. You will be asked to complete this weekly record for 12 weeks. We anticipate that this will take you approximately 10 minutes per week.
  - A small number of people will also be invited to take part in an interview with a researcher from the study team to discuss their shoulder pain and the care and treatment they have received.

If you choose only to complete the questionnaires, you will still be making a valuable contribution to the study.

**If you think you might be interested in taking part, please now read the rest of the information sheet carefully.**



Funded by NHS National Institute for Health Research

## 1. Why is this research study being carried out?

The results from this research study will help to support General Practitioners (GPs) and physiotherapists in the decisions they make about the best and most timely treatments for people with shoulder pain.

- In England, 1.5 million people visit their GP with shoulder pain every year
- Most people recover quickly from shoulder pain, but in 40% the shoulder pain lasts longer than 6 months and affects sleep, work, and everyday life
- The PANDA-S study is looking at a new way of helping GPs and physiotherapists decide which type of treatment is best to use for each patient

All treatment for your shoulder pain will continue to be delivered by your healthcare team.

Participation in the PANDA-S study does not mean you will receive any additional or alternative treatment for your shoulder pain.

The research team have worked with patients and members of the public to ensure that the research meets the needs of patients, and the information provided is easily understandable. Being involved in research can help to improve healthcare and patient choice.

## 2. Who is funding the research study?

This study has been funded by the National Institute for Health Research (NIHR) Programme Grants for Applied Research programme (RP-PG-0615-20002) and Arthritis Research UK.

## 3. Why have I been invited to take part in this study?

You have been invited to take part in the PANDA-S research study because you have recently been to see your doctor or physiotherapist about your shoulder pain and you indicated that you were happy to receive further information about the PANDA-S research study.

Most people with shoulder pain will recover within a few months, but in others the pain may last much longer. In order to understand why some people experience more long-lasting shoulder pain, it is important to follow a large number of people with shoulder pain over a period of several years.

## 4. What would taking part in this study involve?

Taking part in the PANDA-S research study will involve completing 6 questionnaires over the next 3 years. If you would like to take part in the study, you will need to complete and return the enclosed questionnaire and consent form. It is important for us to receive questionnaires from people within **two weeks**, so that we can follow any early improvement or worsening of your shoulder pain.

You will then receive a follow-up questionnaire after 3-months, 6-months, 1 year, 2 years and 3 years. These questionnaires will ask about your shoulder pain and how it affects you. Only by you completing and returning the questionnaires can we start to understand the short and long-term effects of shoulder pain. We would also like to know when your shoulder pain has gone away or if it comes back. It is therefore important to complete all the questionnaires even if your shoulder pain is better. There may be times during the study when we need to contact you by telephone, for example, to remind you about the questionnaire.

In addition to completing questionnaires, you will receive invitations to take part in additional, ***optional*** parts of the PANDA-S research study:

- You will be invited to attend a research clinic for a detailed physical examination and an ultrasound scan of your shoulder. We anticipate the examination and scan will take approximately an hour and a half. You will not receive treatment during this visit to the research clinic.
- You will be invited to complete a brief weekly record of your shoulder pain either by using an app for your smart phone / tablet ***or*** by using text messaging. This is being done to record any early changes in your shoulder condition, and will take no more than 10 minutes per week. You will be asked to complete this weekly record for 12 weeks.
- A small number of people will be invited to take part in an interview with a researcher from the study team to discuss their shoulder pain and the care and treatment they have received.
- On the consent form at the front of the questionnaire, we ask your permission to review your GP medical records. The medical record review is so we can look at healthcare use (for example consultations and prescriptions) by people with shoulder pain. The review of medical records will be done electronically, and your name will not be used, meaning that you cannot be identified personally

In order to help us better understand the short and long-term effects of shoulder pain we would like as many people as possible to take part in these optional parts of the PANDA-S research study. However, if you choose only to complete the questionnaires, you will still be making a very valuable contribution to the research study.

## 5. Do I have to take part?

**Will I be able to take part if I want to?**

The first section of the enclosed questionnaire will indicate whether or not the PANDA-S research study will be suitable for you. If the study is suitable for you, you can decide whether or not to take part. Your participation is **voluntary.** We can assure you that whatever you decide to do, your healthcare will not be affected in any way, now or in the future.

If you do decide to take part, you will still be free to **withdraw** from the study at any time, without giving a reason and again your healthcare will not be affected in any way, now or in the future.

**What shall I do if I do not want to take part?**

If you do not wish to take part in this study you can write on the front of the questionnaire that you do not want to take and return it to us in the envelope provided. We realise that people are busy, and do not always have the time to complete and return the questionnaire. For this reason, we will send you a reminder if we do not receive the questionnaire or have any contact from you after 2 weeks. If you have decided that you do not want to take part please ignore this reminder, or contact Keele Clinical Trials Unit to let us know that you do not wish to take part.

## 6. What are the possible benefits and risks of taking part?

The information we get from this study will help to support how doctors and physiotherapists treat people with shoulder pain, how patients can manage their own shoulder pain, and deciding when people with shoulder pain should be seen by other healthcare professionals, for example, a surgeon. There may not be any immediate benefits for you, although some people find it rewarding to take part in health research. Your participation in this study will help to:

- improve information for patients with shoulder pain about its possible cause
- help doctors and physiotherapists to better advise patients with shoulder pain which treatment is best for them
- improve treatment options and reduce unnecessary tests or treatments in those who don't need them
- reduce long-term pain, disability, and work loss due to shoulder pain

We are not anticipating any risks in taking part in the PANDA-S research study. The care you receive from your GP practice or physiotherapy service will not be affected.

## 7. What will happen to the information collected about me during the study?

If you do decide to take part in this study, the information collected about you will be treated in strict confidence and in accordance with the general data protection regulations (Data Protection Act 2018).

Keele University is the sponsor for this study. We will be using information from you in order to undertake this study and will act as data controller for this study. This means that we are responsible for looking after your information and using it properly. Keele University will keep identifiable information about you for 6-12 months after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by

organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Any personal information, such as your name and address, will only be used for the PANDA-S research study e.g. to allow questionnaires to be posted to you. To ensure data is stored securely, it will be held on networks approved by a government backed cyber security scheme.

When you return your completed questionnaire to Keele Clinical Trials Unit, this will be securely stored under a unique study number. Your questionnaire answers (data) will only be associated with this number, not your personal details. Anonymous data held on this basis may be used in other research studies. Your consent form, will also be stored securely at Keele Clinical Trials Unit but separately to your data. Your personal details will only be retained for the duration of the study, after which they will be confidentially destroyed. The anonymised paper questionnaires will be stored securely for a period of 10 years after the full research programme has completed. After this time the questionnaires will be destroyed.

Your medical records may be looked at by authorised individuals from the research team, Keele University (the study sponsor) or the regulatory authorities to check that the study is being carried out correctly. Authorised members of the PANDA-S research team would like to review information on your consultations, prescriptions and other information relevant to the PANDA-S study. To do this, your medical records will be extracted electronically and de-personalised at your GP surgery before being securely transferred to Keele Clinical Trials Unit. We ask your permission for this on the consent form.

If you decide to withdraw from the study, information you have provided up to that point must be kept for regulatory purposes.

To ensure continuing care, we will inform your GP of your participation of the study.

You can find out more about how we use your information at:
https://www.keele.ac.uk/informationgovernance/informationgovernanceforthepublic/

## 8. What will happen to the results of the study?

Study participants will be informed about the PANDA-S research study findings through newsletters, leaflets and posters in participating GP surgeries, participating self-referral physiotherapy clinics and via the Keele University website. Results may take 2 to 3 years to become available once we have finished the study. We plan to present results at medical meetings and conferences, and to publish results through medical journals. You will not be personally identifiable in these presentations or publications.

## 9. Who is organising the study?

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.

**What is Keele Clinical Trials Unit (CTU)?**
Keele CTU specialises in the development and delivery of high-quality research studies. Keele CTU is a UKCRC registered Clinical Trials Unit. Please go to https://www.keele.ac.uk/kctu/ to find out more about Keele CTU.

## 10. 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 given favourable opinion by [*inset Ethics committee HRA approval information*]. The study has also been reviewed by scientific experts on behalf of the National Institute of Health Research (NIHR), who assessed it before awarding funding.

## 11. Contact for further information

If you would like to know more about this study, or have any questions, please contact **Keele Clinical Trials Unit:**

**01782 732950**

**Office hours are Monday - Friday 9am - 5pm**

***Insert PANDA-S study NHS.net email address***

We also have information about the study on the Keele University website *[insert study web site address].*

**What if there is a problem?**

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. However, in some cases you may feel more comfortable discussing your concerns with someone outside of the study team. If you have questions about research studies in general you can discuss them with the person treating you or your GP Practice / physiotherapy service. Alternatively you can contact NHS England on 03003112233, or 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.

## Thank you for taking the time to consider taking part in this study

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