Prognostic AND Diagnostic Assessment of Shoulder Pain [PANDA-S II] Study

PARTICIPANT INFORMATION LEAFLET

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Can you help us improve consultations for shoulder pain?

Shoulder pain is common. In England, 1.5 million people visit their GP with shoulder pain every year. Most people recover quickly, but in 40% the shoulder pain lasts longer than 6 months and affects sleep, work, and everyday life. Patients have highlighted how important the first consultation is with their healthcare professional to discuss their shoulder pain, how it affects their everyday life and how it can be treated. PANDA-S II aims to study how the discussion between patients and physiotherapists during this first appointment can be best supported to ensure appropriate treatment, improvement in shoulder pain and everyday activity.

We are inviting you to take part in the PANDA-S II study because you have recently been referred to Physiotherapy for your shoulder pain.

What does taking part in the PANDA-S II study involve?

If you decide to take part in the PANDA-S II study, you will be asked to:

- Complete 4 questionnaires over the next 12 months (including the one enclosed with this pack). Each questionnaire will ask questions about your shoulder pain and how it affects you and will take you approximately 20 minutes to complete

You will be reimbursed for your time completing the questionnaires: a £10 shopping voucher will be included with each **follow-up** questionnaire.

Taking part in the PANDA-S II study is **voluntary**. If you choose to take part, you are free to withdraw at any time. If you choose not to take part, or you withdraw, this will not affect the current or future health care you receive.

If you wish to take part, please read all the information on the next pages, sign the consent form, and complete the Shoulder Pain questionnaire.

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Frequently asked questions and other information

Why is this research study being carried out?

The PANDA-S II study will help to support physiotherapists and patients with shoulder pain when making decisions about the best and most suitable treatments for them. The study is looking at the type of support and treatment offered by physiotherapists, and how this helps people to manage their shoulder pain problem over time. All treatment for your shoulder pain will continue to be delivered by your healthcare team.

What does taking part in this study involve?

If you would like to take part in the study, you will need to complete and return the enclosed consent form and questionnaire. You can take part in the study even if you haven't had your appointment (or date for your appointment) with the physiotherapist yet. 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.

A small number of people will be asked if they are willing to have their first consultation with the physiotherapist audio recorded. Some people will be invited to talk to a researcher from the study team to discuss their shoulder pain and their experience of their consultation with the physiotherapist. Information on these aspects of the study will be sent separately.

You will receive a follow-up questionnaire 6-weeks, 6-months, and 12-months after this first questionnaire. These questionnaires can be completed by post or online and will ask about your shoulder pain and how it is affecting you. The follow-up questionnaires will also ask about the consultation(s) you have had with the physiotherapist. 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. When going through your responses, if we find that you have left key questions unanswered, we *may* contact you by post, or by telephone if you have provided a telephone number, to request your completion of the missing information. There may be other times during the study when we need to contact you by post, telephone, or email, for example, to remind you about the questionnaire. If we have not received a completed questionnaire, we will send a reminder once a week for 4 weeks (if you have chosen to complete follow-up questionnaires online) or once a fortnight for 8 weeks (if you have chosen to complete follow-up questionnaires by post). Information about the study, including newsletters, invitations or reminders may be sent by post, even if you have expressed a preference to receive information online.

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

You can take part in the study if you have been referred or self-referred yourself to a physiotherapist about your shoulder pain. Taking part is **voluntary.**

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 your healthcare will not be affected in any way, now or in the future. To withdraw from the study please either contact the study team at Keele Clinical Trials Unit using the contact details in the 'Help and Support' section on the last page or send back the blank questionnaire with the word 'Withdraw' on the front page. Any information you have already provided up until this point will be anonymised and retained.

If you do not wish to take part, you don't need to do anything further.

What are the possible benefits and risks of taking part?

The information we get from this study will support physiotherapists to provide the best care for people with shoulder pain. There may not be any immediate benefits for you, although some people find it rewarding to take part in health research. We are not expecting any risks for you in taking part in the PANDA-S II study. The care you receive from your GP practice or physiotherapy service will not be affected.

What if there is a problem?

If you have a concern about any aspect of the study, for example completing the questionnaires or taking part in an interview, 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 the Head of Project Assurance at Keele University via research.governance@keele.ac.uk or 01782 733371. More detailed information can be found on the PANDA-S II Study Website (www.keele.ac.uk/panda-s) or you can contact the study team to request to receive this information by post. If you have any ongoing concerns about your shoulder pain, please contact your healthcare team.

How will we use information about you?

Keele University is the sponsor for this study. This means that we are responsible for looking after your information and using it properly. We will need to use information from you for this research study. This information will include your name, contact details and NHS number. People will use this information to do the research or to check your records to make sure that the research is being done properly.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. In future, research teams who may want to replicate our findings, or use the data to better understand shoulder pain and improve its management, can request data for further analysis. Keele University has a strict process in place to share data with other research teams and

will only share data that are anonymous and cannot identify you. You can read more about this on the PANDA-S II Study website (**www.keele.ac.uk/panda-s**) or you can contact the study team to request to receive this information by post.

What are your choices about how your information is used?

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

To ensure continuing care, if you have provided your GPs details and give your consent, we will inform your GP of your participation of the study.

Where can you find out more about how your information is used?

We are committed to protecting the privacy and security of the personal information of all participants in our research and adhere to appropriate regulations in the storage and management of data: for more information about how we manage your data please visit our website (**www.keele.ac.uk/panda-s**), contact Keele's Data Protection Office (**dpo@keele.ac.uk**), or contact the study team at Keele Clinical Trials Unit using the contact details in the 'Help and Support' section below.

Help and Support

This participant information leaflet and questionnaires in the study are provided in English. Keele Clinical Trials Unit can help with language translation if needed and can be contacted by telephone on 01782 732950, or email ctu.pandas2study@keele.ac.uk.

Where can I find more information about the PANDA-S study?

Further information can be found on the study website: **www.keele.ac.uk/panda-s**

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

Telephone: 01782 732950 Office hours are Monday to Friday 9am – 5pm

Email: ctu.pandas2study@keele.ac.uk

Thank you for taking the time to read this Participant Information Leaflet and for considering taking part in this study

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