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

Participant Information Leaflet: Weekly Monitoring

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Thank you for completing the recent questionnaire that we sent you. You are now being invited to participate in an additional part of the PANDA-S study. We are asking you to record the progress of your shoulder pain and problems using your smartphone, tablet, or mobile phone. **This 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 participate, it is important to understand what it will involve and why. Please carefully read this leaflet and discuss it with friends, relatives or others if you wish. If anything is unclear, or if you would like more information, contact us on the telephone number given in the 'Further Information' section. Take your time, and decide whether or not you wish to take part.

Why are you collecting information by tablet, smartphone / mobile phone?

Shoulder pain is a common condition and we know that pain and symptoms often change week by week. We would like to measure change in pain and symptoms to see if these changes can be used in the future to predict shoulder pain in others. Pain and symptoms can be recorded on your tablet or smartphone (using an app) or sent via text from your mobile phone.

Why have I been chosen?

We are giving everyone who returned their questionnaire and provided consent to the PANDA-S study the opportunity to record their shoulder pain and symptoms weekly using their tablet, smartphone or by mobile phone text messaging.

Do I have to take part?

It is up to you to decide whether to take part. If you do take part, you will need to complete the enclosed reply slip and return it in the pre-paid envelope. If you do not wish to take part, you need do nothing further. Whatever you decide, your care now and in the future will not be affected.

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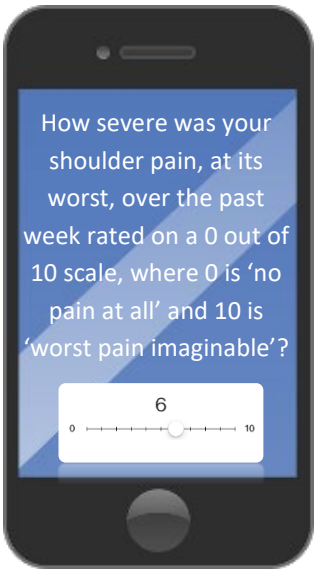
What does the pain recording involve?

If you have indicated on your reply slip that you would like to record your shoulder pain using a tablet or smartphone app, we will send you a username and password, along with instructions on how to download and use the app. The app will ask you 11 questions per week, including questions about your pain, your sleep and your mood. You will also have some space to note down anything you think might be important and related to your shoulder problem. The app is free to download and use, and will allow you to track your pain and symptoms over the 12 weeks that the information is being collected. Completing the app should not take much longer than if you choose to complete the SMS text messages (we anticipate no more than 10 minutes per week).



If you are using the App, you will be able to click 0-10 on a scale to respond to the questions.

If you choose to receive text messages, you will receive two text messages each Sunday at 2pm that will ask you about your pain and activity. You will need to respond to each text message using the response options given in the text message. If you choose this option, we will send you a FAQ sheet with more detailed instructions for responding.

If you are using text messaging you will be prompted to text 0-10 on your keypad to respond to the questions. We anticipate that this will take you no more than 5 minutes per week.

What are the costs?

If you choose to take part in this optional part of the PANDA-S study there are no costs associated with completing the app. If you choose to take part in the text messaging we will ask you to send two text messages back to the research team: each message will be charged at your standard network rate.

What might be the benefits of taking part?

The information we get from this study may help to improve future decisions to help patients treat their own pain and help decide when patients should be sent to hospital for further treatment. Some people find it rewarding to take part in medical research. However, there may not be any immediate benefit for you.

How will my data be stored?

The information 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. Further details about how the information you provide is managed can be found on Keele University's website:

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

Any information you provide by responding to either the app or text messages will not contain any information that could be used to identify you personally. For the app, you will be sent a unique username and password to enter when you first download the app, which will allow us to attribute all your data to that particular username, rather than using personal information. When you send us the data, this will be sent using a secure link (https) and stored on a secure Google Server where the information can only be accessed by authorised members of the study team. All information you send to us, whether through the app or text messages, will be treated in strict confidence and in accordance with the general data protection regulations.

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 [*insert PANDA-S study nhs email address*]. Alternatively, for independent advice, feedback or complaints you can contact NHS England on 0300 3112233 (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 Arthritis Research UK Primary Care Centre, Keele University is organising the research in collaboration with the University of Oxford.

If you would like to take part, please complete and return the enclosed reply slip.

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