

# PANDA-S: Prognostic AND Diagnostic Assessment of Shoulder pain

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| <b>Submission date</b><br>29/10/2018   | <b>Recruitment status</b><br>No longer recruiting     | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>30/11/2018 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>19/07/2024       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Shoulder problems affect about one in five of adults and are often very painful, affecting sleep, work, and everyday life. In England, about 1.5 million people visit their GP for shoulder pain annually, of whom two in five experience on-going pain. Most patients receive treatment from GPs or physiotherapists, but 7 times more patients are having surgery compared with 10 years ago, but there is no evidence that surgery provides better results than other treatments. This study aims to develop and evaluate a better approach ('stratified care') to assessing the likely cause (diagnosis) and future outcome (prognosis) of shoulder problems, so that GPs and physiotherapists can ensure that patients are matched to the treatment most likely to improve their shoulder pain.

### Who can participate?

All patients registered at participating general practices or attending self-referral physiotherapy services, aged 18 years or over, presenting with a new episode of shoulder-related pain will be invited to take part. A new episode will be defined as no shoulder-related consultation, no injection, surgery, or physiotherapy-led exercise for shoulder pain, in the last 6 months.

### What does the study involve?

We will recruit 1000 patients consulting a GP or self-referral physiotherapy service with shoulder pain, and offer them a comprehensive clinical assessment and ultrasound scan. GPs and physiotherapists will continue to treat their patients in the way they feel is best. We will collect information on pain, disability and quality of life using questionnaires over 3 years. We will also collect information on pain and disability using an app developed in collaboration with our Research Users Group, over 3 months. We will investigate which information from the clinical assessment helps us tell which patients will recover quickly, and which patients develop long-term problems. We will also interview patients and healthcare professionals in order to investigate how they interpret diagnostic and prognostic information, and how they use this information to make decisions regarding further treatment and referral.

### What are the possible benefits and risks of participating?

All participants will receive the same treatment that they would have received if they had not participated in the study, so there are no additional risks or benefits to taking part. This research

aims to benefit patients and the NHS by:

- Improving information and advice for patients about the possible causes and best ways to assess and treat shoulder pain
- Supporting healthcare professionals to better advise patients which treatment is best for them
- Improving targeting of treatment options, and reducing unnecessary investigations and treatments in those who don't need them
- Reducing long-term pain, disability, and work loss due to shoulder pain

Where is the study run from?

The study will be run from, and led by, the Arthritis Research UK Primary Care Centre and Keele Clinical Trials Unit based at Keele University with an additional centre run from The Nuffield Centre for Primary Care and Health Sciences at Oxford University.

When is the study starting and how long is it expected to run for?

January 2018 to December 2024

Who is funding the study?

The study is funded by the National Institute for Health Research (NIHR) and Arthritis Research UK under grant RP-PG-0615-20002.

Who is the main contact?

Professor Danielle van der Windt (d.v.d.windt@keele.ac.uk)

## Contact information

### Type(s)

Public

### Contact name

Dr Danielle van der Windt

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## Additional identifiers

### Protocol serial number

CPMS 38630

## Study information

**Scientific Title**

Maximising outcome for patients with shoulder pain: using optimal diagnostic and prognostic information to target treatment (PANDA-S)

**Acronym**

PANDA-S

**Study objectives**

If treatment for shoulder pain is targeted earlier and more effectively to those patients who are likely to benefit most, efficiency of care and patient outcomes can be improved.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Yorkshire & The Humber - Sheffield Research Ethics Committee, 16/10/2018, ref: 18/YH/0346

**Study design**

Observational cohort study

**Primary study design**

Observational

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Shoulder pain

**Interventions**

Participants will be invited to take part in the cohort study and be followed-up over a period of three years with questionnaires mailed at baseline (shortly after consulting their GP or physiotherapist with shoulder pain) and at 3, 6, 12, 24 and 36 months. After the return of their baseline questionnaire participants will also be invited to the optional aspects of the study. Participants will be mailed an invitation and information leaflet about the research clinic once they have returned their baseline questionnaire and only if they have consented to be in the study. Should participants choose to take part in the research clinic it will take place up to approximately six weeks after the return of the participants' baseline questionnaire. Participants will be mailed an invitation and information leaflet about the app and SMS text messaging once they have returned their baseline questionnaire and consented to be in the study. Should the participants choose to take part in the app or SMS text messaging data collection they will be asked to complete eleven questions on the app once per week or to complete two questions via SMS text messaging also once a week for a total of twelve weeks. Selected participants will be mailed an invitation and information leaflet about the interview once they have returned their baseline questionnaire and consented to be in the study. Should participants choose to take part in the interview an appointment will be made at a time that is convenient to the participant to undertake the interview face to face or via the phone. The term participant here refers to those patients who consulted their clinician with shoulder pain and consented to be in the study and also the GPs or physiotherapists whom these patients consulted.

## **Intervention Type**

Other

## **Primary outcome(s)**

Pain and disability, assessed using the Shoulder Pain and Disability Questionnaire (SPADI) at baseline and 6 months

## **Key secondary outcome(s)**

The following are assessed at the baseline and after 3, 6, 12, 24, 36 months:

1. Pain (worst pain in the past week), assessed using a numerical rating scale (0-10)
2. Sleep, assessed using the Jenkins Sleep Evaluation Questionnaire (JSEQ)
3. Global perceived change in shoulder pain since baseline assessed using a single question "Compared to when you completed your last questionnaire X months ago how would you say your shoulder pain is now?". The answer is selected from "Completely recovered, much improved, somewhat improved, same, somewhat worse, much worse".
4. Work absence, assessed by:
  - 4.1. Participant report of current absence (days/weeks/months)
  - 4.2. Analysis of medical records (where there is consent to access)
5. Work performance, assessed using:
  - 5.1. Response to question "question "If your work has been affected, on average, to what extent has shoulder pain affected your performance at work in the past 1 month?" using numerical rating scale (0-10, where 0 is not at all to 10 is the pain is so bad I have been unable to do my job)
  - 5.2. Number of days work performance affected by pain assessed using question "Not including absence from work, on how many days in the last month has your work been affected by your shoulder pain?"
6. Health status, assessed using the EQ-5D-5L

## **Completion date**

31/12/2024

## **Eligibility**

### **Key inclusion criteria**

1. Registered at participating general practices or attending participating self-referral physiotherapy services
2. Aged 18 years or over
3. Presenting with a new episode of shoulder-related pain (defined as no shoulder-related consultation, no injection, surgery, or physiotherapy-led exercise for shoulder pain, in the last 6 months)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

491

**Key exclusion criteria**

1. Present to the GP or physiotherapist with symptoms or signs indicative of serious pathology (e.g. fractures, infection), have shoulder pain caused by stroke-related subluxation
2. Diagnosis of inflammatory arthritis, including rheumatoid arthritis, and polymyalgia rheumatica
3. Shoulder pain caused by cervical pathology
4. Considered by the GP or physiotherapist to be vulnerable (severe physical and/or mental health problems, dementia)
5. Unable to complete written questionnaires in English

**Date of first enrolment**

15/02/2019

**Date of final enrolment**

30/06/2021

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Arthritis Research UK Primary Care Centre (lead centre)**

Research Institute for Primary Care and Health Sciences

Keele University

Keele

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**Study participating centre**

**Primary Care Clinical Trials Unit, Nuffield Department of Primary Health Care Sciences**

University of Oxford

Radcliffe Observatory Quarter

Woodstock Road

Oxford

United Kingdom

OX2 6GG

# Sponsor information

## Organisation

University of Keele

## ROR

<https://ror.org/00340yn33>

# Funder(s)

## Funder type

Government

## Funder Name

ARTHRITIS RESEARCH UK; Grant Codes: ..,NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0615-20002

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from the Research Institute for Primary Care and Health Sciences. Researchers wanting to apply for access to individual patient data from archived studies hosted by the Keele Research Institute for Primary Care and Health Sciences should first email [primarycare.datasharing@keele.ac.uk](mailto:primarycare.datasharing@keele.ac.uk).

## IPD sharing plan summary

Available on request

## Study outputs

| Output type                          | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a>     |         | 17/09/2021   | 21/09/2021 | Yes            | No              |
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |