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PANDA-S: Prognostic AND Diagnostic Assessment of Shoulder pain

Submission date
29/10/2018

Recruitment status
No longer recruiting

Registration date
30/11/2018

Overall study status
Completed

Last Edited
19/07/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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)

Study website
Currently under construction

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/01/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 471; UK Sample Size: 471

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
England

United Kingdom

Study participating centre
Arthritis Research UK Primary Care Centre (lead centre)
Research Institute for Primary Care and Health Sciences
Keele University
Keele
United Kingdom
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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
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Sponsor information

Organisation
University of Keele

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Sponsor type
University/education

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

Publication and dissemination plan
Planned publications in high impact peer reviewed journals, conference presentations, through Institutes website, and dissemination event.

Intention to publish date
30/06/2026

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.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		17/09/2021	21/09/2021	Yes	No
HRA research summary			28/06/2023	No	No