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Can we offer better, more personalised care for people with shoulder pain?

Submission date
12/05/2023

Recruitment status
No longer recruiting

Registration date
15/06/2023

Overall study status
Ongoing

Last Edited
07/05/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
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.

Who can participate?
Patients with shoulder pain, aged 18 years and over referred / self-referred to participating NHS Physiotherapy services

What does the study involve?
Completing four questionnaires over a 12-month period; a small number of people will be invited to talk to a researcher about their experience of shoulder pain

What are the possible benefits and risks of participating?
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 participants, although some people find it rewarding to take part in health research. We are not expecting any risks to people taking part in the PANDA-S II study.

Where is the study run from?
Keele Clinical Trials Unit based at Keele University, Staffordshire (UK)

When is the study starting and how long is it expected to run for?
October 2015 to December 2025

Who is funding the study?
1. National Institute for Health and Care Research (NIHR) (UK)
2. Versus Arthritis (UK)

Who is the main contact?
Keele Clinical Trials Unit, ctu.pandas2study@keele.ac.uk

Study website
https://www.keele.ac.uk/panda-s/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
315321

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55765, RP-PG-0615-20002, IRAS 315321

Study information

Scientific Title
Maximising outcome for patients with shoulder pain: using optimal diagnostic and prognostic information to target treatment

Acronym
PANDA-S

Study objectives
A more holistic approach to the management of shoulder pain, including an assessment of concerns and healthcare needs, shoulder pain characteristics and prognosis, can inform personalised care and support for self-management, leading to improved patient reported outcomes including shoulder pain and disability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/04/2023, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 2071048091; southyorks.rec@hra.nhs.uk), ref: 23/YH/0070

Study design
Interventional cluster randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Shoulder pain

Interventions
The design of the trial is a cluster-randomised controlled trial. The physiotherapy services are the unit of randomisation and will be randomised to either deliver the guided consultation of shoulder pain (intervention) or to continue with care as usual (control).

All eligible patients, irrespective of whether the site is allocated to the intervention or control arm, will be invited to take part in the trial (shortly after referral or self-referral to the physiotherapy services). Consenting participants will complete a baseline questionnaire and be followed up over a period of 12 months with questionnaires mailed at 6 weeks, 6 and 12 months. Participants will be offered a shopping voucher with each follow-up questionnaire in recognition of the time they are contributing to the trial.

After the return of the baseline questionnaire and consent form, participants who come under the care of a Physiotherapy service randomised to the intervention may be invited to the optional aspects of the trial:
1. Audio recording of their physiotherapy consultation: Some participants will be contacted to

ask whether they would consent to have their consultation with the physiotherapist audio recorded. Should participants choose to take part in this aspect of the trial, the trial team will confirm the date of their physiotherapy appointment and inform the physiotherapist that the participant has given informed consent. The physiotherapist will reconfirm consent prior to recording. All audio recordings will be securely transferred to Keele CTU and the physiotherapist will wipe the recording from their equipment.
2. Interview: Some 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, online, or via the phone). In addition to up to 20 study participants, we will also interview up to 10 clinicians (physiotherapists) about their experience of delivering the guided consultation to people with shoulder pain, and how this can be further improved and implemented in their clinical practice.

Participants in the intervention arm will receive the guided consultation when they attend their Physiotherapy appointment. Participants in the control arm will receive the usual consultation offered by their Physiotherapy service.

Intervention Type
Behavioural

Primary outcome measure
Shoulder pain and disability are measured using the Shoulder Pain and Disability Index (SPADI) at baseline, 6 weeks, 6 months and 12 months

Secondary outcome measures
1. Perceived change in shoulder pain symptoms will be measured using the Global Perceived Change single-item question at 6 weeks, 6 months, and 12 months
2. Sleep difficulties will be measured using the Jenkins Sleep Questionnaire at baseline, 6 weeks, 6 months and 12 months
3. Work absence will be measured by asking how many days off a participant has had in the past days/weeks at baseline, 6 months and 12 months
4. Work performance will be measured using the single-item work performance VAS scale at baseline, 6 months and 12 months
5. Healthcare utilisation will be measured using standardised items at 6 months and 12 months
6. Health-related quality of life will be measured using the EQ-5D-5L at baseline, 6 weeks, 6 months and 12 months

Overall study start date
02/10/2015

Completion date
03/12/2025

Eligibility

Key inclusion criteria
1. Patients referred or self-referred to participating physiotherapy services
2. Aged 18 years or over
3. Presenting with shoulder pain

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 832; UK Sample Size: 832

Key exclusion criteria
1. Present to the physiotherapy service with symptoms or signs indicative of serious pathology (e.g. fractures, infection, inflammation, malignancy or referred pain from other sites (e.g. cardiac, hepatobiliary))
2. Have shoulder pain caused by stroke-related subluxation
3. Been referred for rehab post-surgery
4. Have a diagnosis of inflammatory arthritis, including rheumatoid arthritis, and polymyalgia rheumatica
5. Have shoulder pain caused by cervical pathology or predominantly neck pain
6. Are considered by the staff triaging to be vulnerable (e.g. severe physical and/or mental health problems, dementia)

Date of first enrolment
30/06/2023

Date of final enrolment
03/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Midlands Partnership NHS Foundation Trust
Trust Headquarters
St Georges Hospital
Corporation Street
Stafford
United Kingdom
ST16 3SR

Study participating centre
Birmingham Community Healthcare NHS Foundation Trust
3 Priestley Wharf
Holt Street
Birmingham Science Park, Aston
Birmingham
United Kingdom
B7 4BN

Study participating centre
Gloucestershire Hospitals NHS Foundation Trust
Cheltenham General Hospital
Sandford Road
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GL53 7AN

Sponsor information

Organisation
Keele University

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Sponsor type
University/education

Website
http://www.keele.ac.uk/

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Funder Name
Versus Arthritis

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

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 medicine.datasharing@keele.ac.uk. Data will become available once the main findings from the trial has been published.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	21/04/2023	25/05/2023	No	Yes
HRA research summary			20/09/2023	No	No
Protocol article		06/05/2025	07/05/2025	Yes	No