

# 'Real world' pain outcomes and experiences of care for patients with musculoskeletal conditions in general practice (the MIDAS-GP study)

<b>Submission date</b> 13/05/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/06/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/08/2025	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Background and study aims:

Painful musculoskeletal conditions like back pain and osteoarthritis cause more disability in the general population than any other health conditions. Poorer communities and individuals appear to be the hardest hit. In order to have a suitably 'joined up' response to this challenge we need accurate and meaningful joined-up information on musculoskeletal health, risk, and care in local populations.

The study aims to provide new research evidence to find out how to improve treatment for different groups of people with painful musculoskeletal conditions and between different general practices.

Who can participate?

Adults patients who have recently consulted their general practice with a painful musculoskeletal condition.

What does the study involve?

Patients who have recently consulted their general practice with a musculoskeletal condition will be invited to complete an initial pen-and-paper questionnaire or online questionnaire. Those who agree to take part will be asked to complete a follow-up questionnaire (either pen-and-paper or online questionnaire) after 3 and 6 months and one follow-up question (either pen-and-paper questionnaire or by SMS text message) about pain intensity after 1, 2, 4, and 5 months. A number of measurements will be taken including Musculoskeletal Health Questionnaire, Pain intensity (0-10 Scale) and Work productivity and activity impairment (WPAI). Participants will be asked if they give permission for their questionnaire responses to be linked with information held in their medical records to enable the type of care people are receiving with the kind of problem they have and the outcome of their care to be pieced together.

What are the possible benefits and risks of participating?

Although there is no immediate direct benefit, some people find it rewarding to take part in health research. Participants in this study will help to support how doctors and physiotherapists treat people with musculoskeletal symptoms involving back, neck, joint or muscle pain and understand the local need for treatment and which groups of people are most under-served by the NHS at present.

There are no risks involved in participating in this study and the care participants receive from their general practice will not be affected whether they take part or not. There is a time burden of answering the questions which are estimated to take about 15-20 minutes for each questionnaire.

Where is the study run from?

Keele University (UK)

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

From October 2020 to March 2025.

Who is funding the study?

The Nuffield Foundation (UK) and Versus Arthritis (UK)

Who is the main contact?

Clare Thompson

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## Contact information

### Type(s)

Scientific

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

292109

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

RG-0327-21, IRAS 292109

## **Study information**

**Scientific Title**

'Real world' pain outcomes and experiences of care (MIDAS-GP)

**Acronym**

MIDAS-GP

## **Study objectives**

By linking patient questionnaires, electronic medical record data and publicly available data on neighbourhood health, assets and deprivation and on healthcare service characteristics, multi-level data sets will be created on patient cohorts that enable a better understanding of variations in, and determinants of, musculoskeletal outcomes in adults presenting to primary care with a common painful MSK condition. The intention is for this to impact on decisions about what information may be most useful and how it might be collected, linked, analysed, and disseminated within routine care.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 10/08/2021, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0) 207 972 2504; leedswest.rec@hra.nhs.uk), ref: 21/YH/0178

## **Study design**

Observational prospective cohort study

## **Primary study design**

Observational

## **Study type(s)**

Quality of life

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

Common musculoskeletal conditions that involve pain

## **Interventions**

Adults consulting their general practice with a painful musculoskeletal condition will be invited to answer some questions about their condition and their care either through an online questionnaire (with support over the telephone, if needed) or by pen-and-paper questionnaire. Those who agree to take part will be contacted again with short questionnaires at 3 and 6 months and a brief one-question update at 1, 2, 4, and 5 months, to show if they have got better. They will also be asked to provide permission to link their questionnaire responses with information held in their medical records so that this information can be pieced together to look at the type of care people are receiving with the kind of problem they have and the outcome of their care.

To get a proper overview, a second part of this study will look at the overall levels of prescribing painkillers, referrals to hospital specialists, and other measures of musculoskeletal care for each general practice.

## **Intervention Type**

Other

## **Primary outcome(s)**

1. Pain intensity measured using a 0-10 Number Rating Scale (NRS) at baseline, 1, 2, 3, 4, 5 and 6 months
2. Musculoskeletal pain measured using a Musculoskeletal Health Questionnaire (MSK-HQ) at baseline, 3, and 6 months

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

1. Pain Intensity measured using the Pain Intensity and Interference PEG (Pain, Enjoyment, General Activity) scale at baseline, 3, and 6 months
2. High impact chronic pain measured using a questionnaire at baseline, 3, and 6 months
3. Work status, absenteeism, and productivity loss measured using a questionnaire at baseline, 3, and 6 months
4. Global perceived change measured using a questionnaire at baseline, 3, and 6 months
5. Patient experience measured using a questionnaire at baseline
6. Healthcare use measured using a questionnaire at baseline, 3, and 6 months

### **Completion date**

31/03/2025

## **Eligibility**

### **Key inclusion criteria**

1. Aged  $\geq 18$  years
2. Registered with a participating general practice during the study period
3. Consulting any primary healthcare professional in the general practice for painful, non-inflammatory musculoskeletal disorder during the study period (according to predefined SNOMED code lists)
4. Able to read/understand English with or without assistance (patient-report survey component only)
5. Able to provide informed consent (patient-report survey component only)

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

2009

### **Key exclusion criteria**

1. Inflammatory musculoskeletal disease (according to predefined SNOMED code lists retrospectively examined over the previous 3 years)
2. Has indicated in the record that they do not consent to be approached about research studies

**Date of first enrolment**

01/09/2021

**Date of final enrolment**

31/08/2022

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Keele University**

Keele

Staffordshire

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## Sponsor information

**Organisation**

Keele University

**ROR**

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

## Funder(s)

**Funder type**

Charity

**Funder Name**

Nuffield Foundation

**Alternative Name(s)**

NuffieldFound

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

United Kingdom

## Funder Name

Versus Arthritis

## Alternative Name(s)

Arthritis UK

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Other non-profit organizations

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from [medicine.datasharing@keele.ac.uk](mailto:medicine.datasharing@keele.ac.uk). De-identified individual participant data will be available upon publication of main study findings or within 18 months of study completion (whichever is later) and with no end date. Data will be made available to bonafide researchers upon reasonable request for replication or new secondary analysis via our controlled access procedures and in accordance with Data Sharing Agreements. Consent for patient-reported outcomes/experiences data will be sought from patients; consent for EHR-only processes of care data will not be sought. Data will be anonymised.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		15/07/2025	16/07/2025	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No

<a href="#">Other unpublished results</a>	End of Research Summary Report to Research Ethics Committee version 1.0	13/01/2025	21/01/2025	No	No
<a href="#">Plain English results</a>	version 1.0	14/01/2025	27/01/2025	No	Yes
<a href="#">Protocol file</a>	version 1.0	05/07/2021	13/10/2021	No	No
<a href="#">Protocol file</a>	version 3.0	03/10/2023	09/11/2023	No	No
<a href="#">Protocol file</a>	version 9.1	16/04/2025	06/08/2025	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes