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# Pain and its management in patients with inflammatory arthritis

**Submission date**
13/02/2023

**Recruitment status**
No longer recruiting

**Registration date**
25/04/2023

**Overall study status**
Completed

**Last Edited**
20/08/2024

**Condition category**
Musculoskeletal Diseases

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

## Plain English summary of protocol

Background and study aims
Inflammatory arthritis refers to conditions causing joint pain and swelling. The commonest conditions are rheumatoid arthritis (RA), psoriatic arthritis (PsA), and axial spondyloarthritis (axial SpA).
Despite the availability of powerful medicines that treat joint inflammation, many people with inflammatory arthritis suffer from daily pain. This can be life-changing for them.
Strong pain medicines like “opioids” are often prescribed to people with inflammatory arthritis, despite limited evidence that they help arthritis pain, and many potential side effects.
Studies have shown that non-drug treatments like exercise can help inflammatory arthritis pain. Little is known about how often they are used, although one survey of people with rheumatoid arthritis reported that half of people could not access all the non-drug treatments they required.
There is an urgent need to improve NHS pain care for people with inflammatory arthritis. The first step to achieving this is to understand how pain is currently treated. The PAIN PATH Studies will do this by answering several questions, including:
1. What pain care do people with inflammatory arthritis receive?
2. Do all people with inflammatory arthritis receive the same pain care?
3. How often do people with inflammatory arthritis use pain medicines?

Who can participate?
Aged 18 years or older, with a diagnosis of RA, PsA or axial SpA.

What does the study involve?
Two studies will be undertaken. Study 1 (“PAIN PATH Survey”) involves people with inflammatory arthritis completing a questionnaire assessing their pain care. Study 2 (“PAIN PATH Longitudinal Study”) involves people with inflammatory arthritis answering mobile phone text messages (twice a day for 14 days) or entering information into an online NHS system (once a week for 3 months) to understand how they use their pain medicines.

What are the possible benefits and risks of participating?
We will provide participants using the PAIN PATH Portal for data entry with anonymised summaries of their research data, which they may find helpful for monitoring their health over time. We intend to use the research findings to improve pain care in patients with inflammatory

arthritis in the NHS, which would potentially benefit participants in the studies in the longer term.

Where is the study run from?
Keele University (UK)

When is the study starting and how long is it expected to run for?
March 2021 to March 2025

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

Who is the main contact?
Dr Ian Scott, i.scott@keele.ac.uk

# Contact information

### Type(s)
Principal investigator

### Contact name
Dr Ian Scott

### ORCID ID
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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
311575

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
CPMS 52587, NIHR300826, IRAS 311575

# Study information

## Scientific Title
PAIN and its management in PAtients with inflammatory arTHritis: the PAIN PATH Survey and Longitudinal Study.

## Acronym
PAIN PATH

## Study objectives
Survey:
1. Define the current pain experience of patients with inflammatory arthritis (IA) and examine whether this associates with patients' IA subtype, age, gender, ethnicity, socioeconomic status, comorbidity, and geographical region.
2. Describe the delivery of pain care in patients with IA against EULAR guidance and assess potential inequities in this by testing associations between the receipt of core recommended pain care and IA subtypes, age, gender, ethnicity, socioeconomic status, comorbidity, and geographical region.
3. Evaluate analgesic use in patients with IA and examine its relationship with patients' beliefs about the necessity and harms of their pain medicines.

Longitudinal Study:
1. Describe the frequency and patterns of analgesic use in patients with IA and examine how the frequency varies by (a) patient characteristics (age, sex, ethnicity), (b) the presence of fibromyalgia, depression, and anxiety, (c) patients' beliefs about the necessity and harms of medicines, and (d) IA subtypes.
2. Examine potential drivers of analgesic use in patients with IA, by (a) describing the frequency of self-reported triggers, and (b) evaluating the relationship between analgesic use and pain intensity and disease activity.
3. Compare the frequency of analgesic use and pain intensity levels in patients with IA that self-report using analgesics on a time-scheduled vs. pain-contingent basis.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 04/05/202, North East - Newcastle & North Tyneside 2 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 207 1048091; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 22/NE/0071

## Study design
Observational cross-sectional

## Primary study design
Observational

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Inflammatory arthritis

## Interventions

The PAIN PATH survey involves patients with inflammatory arthritis completing a one-off questionnaire online (or alternatively on paper for those taking part at their local hospital).

The PAIN PATH Longitudinal Study involves patients with inflammatory arthritis reporting information on their pain and pain medicine use over time using short-messaging service (SMS) text messages or an online patient portal.

Both studies will include patients that learn about the studies when they see their rheumatology team ("regional recruitment") or if they see online advertisements ("national recruitment").

Patients will be able to take part in the studies over a 2-year period. It is anticipated that at least 1,800 patients regionally and 1,000 patients nationally will take part in the PAIN PATH Survey, and at least 173 patients regionally and 210 patients nationally will take part in the PAIN PATH Longitudinal Study.

Longitudinal study for patients learning about the study from rheumatology team at six West Midlands NHS Trusts (regional recruitment):
After completing the questionnaire, if patients indicate they are interested in taking part in the PAIN PATH Longitudinal Study will receive text messages twice a day at 8am and 8pm for 7 days. Seven weeks later this will be repeated. The messages will ask them questions on whether they used pain medicines in the previous 12 hours, the reason they used them, and their worst pain level in the previous 12 hours.

Longitudinal study for patients learning about the study online (national recruitment):
Patients will be asked to enter research information into the Portal once a week for 3 months, starting in the week after Portal registration.

## Intervention Type

Other

## Primary outcome(s)

PAIN PATH survey questionnaire completed at a single time point:
1. Pain severity – evaluated using the simplified Graded Chronic Pain Scale Revised (GCPS-R), measured in the regional/national survey at NHS sites or on paper/online by the participant.
2. Fibromyalgia – its presence or absence will be established using the Widespread Pain Index and Symptom Severity Score, allowing diagnostic criteria to be applied measured in the regional /national survey at NHS sites or on paper/online by the participant.
3. Pain trajectories – the Visual Trajectories Questionnaire-Pain (VTQ-P) will ask patients to classify their pain experience into one of a number of trajectories using visual and word descriptions. measured in the regional/national survey at NHS sites or on paper/online by the participant.
4. Pain Assessments-n As EULAR guidelines recommend a broad range of pain assessment components it is unfeasible to assess all of these within the questionnaire. We therefore prioritized the following for evaluation, which represent core aspects of pain assessments:
5.1. assessment of pain severity.
5.2. invitation for patients to disclose the impact of pain on their daily functioning.
5.3. assessment of patients' ideas and concerns regarding the cause of their pain.
5.4. consideration of patients' expectations for treatment.
5.5. consideration of patients' preferences for treatment.
5.6. assessment of previous pain treatments and their effects.

5.7. assessment of pain-related factors that may need attention (questions 2H, considering mood, and 2I, considering sleep).
5. Pain Management - A further series of bespoke questions developed for this survey will assess pain management against EULAR guidelines measured in the regional/national survey at NHS sites or on paper/online by the participant.
6. The Beliefs About Medicines Questionnaire (BMQ) will evaluate patients' beliefs about their pain medicines measured in the regional/national survey at NHS sites or on paper/online by the participant.
7. Patient global assessment of arthritis activity measured in the regional/national survey at NHS sites or on paper/online by the participant.
8. Patients with an axial spondyloarthritis will also be asked to complete questions from the BASDAI measured in the regional/national survey at NHS sites or on paper/online by the participant.
9. Patients will be asked to complete the functional questions from the multidimensional Health Assessment Questionnaire (mdHAQ) measured in the regional/national survey at NHS sites or on paper/online by the participant.
10. Generalised Anxiety Disorder 2-Item (GAD-2) measured in the regional/national survey at NHS sites or on paper/online by the participant.
11. Patient Health Questionnaire 2-Item (PHQ-2) measured in the regional/national survey at NHS sites or on paper/online by the participant.
12. The single-item physical activity measure will evaluate physical activity levels in the last week measured in the regional/national survey at NHS sites or on paper/online by the participant.
13. Patients will be asked whether they have any of the comorbidities included in the Rheumatic Disease Comorbidity Index measured in the regional/national survey at NHS sites or on paper /online by the participant.
14. Patients will be asked their year of IA diagnosis, which DMARDs they are currently receiving, and if they have received intramuscular steroids in the last month measured in the regional /national survey at NHS sites or on paper/online by the participant.
15. Patients will be asked to record their ethnicity (using groupings advocated by the Office for National Statistics), date of birth, sex at birth, height, weight, postcode, and employment status measured in the regional/national survey at NHS sites or on paper/online by the participant.

Pain Path Longitudinal study: Regional Recruitment
The day after completing the PAIN PATH survey and consenting to take part, patients will receive SMS messages twice daily at 8am and 8pm for 7 days. Seven weeks later the process will be repeated. They allow analgesic use and pain intensity to be captured from two time-periods: (a) Daytime (8am to 8pm; Figure 5); (b) Night-time (8pm to 8am)

Pain Path Longitudinal study: National Recruitment
The following data will be captured each week on an NHS online portal developed by Midlands Partnership NHS trust, patients will be asked to make a research data entry once a week for 3 months:
1. Average pain intensity score in the last week on an 11-point numeric rating scale with the anchors "no pain" and "pain as bad as you can imagine".
2. Which analgesic(s) they used in the last week (from a pre-specified list)
3. Frequency of analgesic use in the last week for tablets/capsules, topical NSAIDs, and pain patches.
4. Reason(s) they used analgesics (unless no analgesics used): they can choose multiple pre-specified options (with the reasons as per those for the SMS messages) and enter a free-text reason.
The following additional data will be captured every 2 weeks:
5. Disease activity

5.1. all patients will be asked to complete a patient global assessment of arthritis activity on an 11-point NRS.
5.2. Patients with RA and peripheral PsA will be asked to perform self-reported swollen and tender joint counts.
5.3. Patients with an axial SpA will be asked to complete a BASDAI.
6. Function – all patients will complete the functional scale from the mdHAQ.
7. Sleep – all patients will complete the sleep item from the mdHAQ.
8. Mental health – all patients will complete the PHQ-2 and GAD-2.

### Key secondary outcome(s))
There are no secondary outcome measures

### Completion date
18/03/2025

## Eligibility

### Key inclusion criteria
REGIONAL RECRUITMENT
For both studies, patients will be included that are:
1. Aged >= 18 years
2. Have a clinical diagnosis of RA, PsA or axial SpA
3. Provide consent.

Additionally, for the longitudinal study patients will be included that:
1. Have completed the PAIN PATH Survey
2. Have mobile-phone access
3. Currently use an analgesic that can be taken at least twice a day (as per their understanding of their prescription)
4. Report currently using analgesics at least once a week (to allow drivers of analgesic use to be examined).

NATIONAL RECRUITMENT
For both studies, patients will be included that are:
1. Aged >= 18 years
2. Have a self-reported diagnosis of RA, PsA or axial SpA
3. Provide consent
4. Have internet access and an email address, and (e) receive care in one of the UK National Health Services.

Additionally, for the longitudinal study patients will be included that:
1. Have completed the PAIN PATH Survey
2. Report using analgesics in the last month

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group

Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. For both studies those patients who enroll via the national recruitment pathway will not also be able to participate in the regional study (and vice versa) to avoid people taking part in the study on more than one occasion.
2. For the longitudinal study the SMS-messages and Portal have questions that are written in English, which are answered remotely on multiple occasions. Consequently, patients who cannot respond to written English themselves, and are unable to access translation support from a relative, friend or carer, will not be able to participate.

### Date of first enrolment
18/07/2022

### Date of final enrolment
10/09/2024

## Locations

### Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

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

### Study participating centre

**University Hospitals Coventry and Warwickshire NHS Trust**
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

**Study participating centre**
**The Royal Wolverhampton NHS Trust**
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
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WV10 0QP

**Study participating centre**
**Sandwell and West Birmingham Hospitals NHS Trust**
City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH

**Study participating centre**
**The Dudley Group NHS Foundation Trust**
Russells Hall Hospital
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

**Study participating centre**
**The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust**
Gobowen
Oswestry
United Kingdom
SY10 7AG

# Sponsor information

**Organisation**
Keele University

**ROR**
https://ror.org/00340yn33

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR Academy

# Results and Publications

**Individual participant data (IPD) sharing plan**
The current data sharing plans for this study are unknown and will be available at a later date

**IPD sharing plan summary**
Data sharing statement to be made available at a later date

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | National PIS version 1.0 | 17/03/2022 | 02/03/2023 | No | Yes |
| Participant information sheet | Regional PIS version 1.0 | 17/03/2022 | 02/03/2023 | No | Yes |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |