

Understanding **PAIN** and its management in **PATients** with inflammatory ar**TH**ritis: the **PAIN PATH** studies

Participant Information Sheet

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This information sheet explains why the PAIN PATH studies are being done, what they involve, and how you can take part. This will help you decide if you want to take part in them.

If you decide to take part you are free to withdraw at any time. If you decide not to take part, this will not affect the health care you receive.

Why are the PAIN PATH studies being done?

The results from the PAIN PATH studies will **help us improve how pain is treated in people with inflammatory arthritis in the NHS.**

- Inflammatory arthritis refers to conditions causing joint pain and swelling.
- The most common conditions are “rheumatoid arthritis”, “psoriatic arthritis”, and “axial spondyloarthritis”.
- Inflammatory arthritis affects as many as 1 in 100 people in the UK.
- Despite the availability of powerful medicines that reduce joint inflammation, many people with inflammatory arthritis suffer from pain every day.
- This pain can be life changing. It can affect all parts of their lives, including how they sleep, feel, and move.
- Strong pain medicines like “opioids” and “gabapentinoids” are often prescribed for long periods of time to people with inflammatory arthritis.
- However, no studies have looked at if they help pain in people with inflammatory arthritis if used like this. They also often cause side-effects.
- Studies have shown that many non-drug treatments like exercise, footwear, and talking therapies can help pain in people with inflammatory arthritis.
- We do not know how often these non-drug treatments are used in people with inflammatory arthritis.

To improve NHS pain care in people with inflammatory arthritis, we first need to know how it is being treated. The PAIN PATH studies will do this in the following ways.

- “The PAIN PATH Survey” (*Study 1*): this involves people with inflammatory arthritis completing a short, one-off questionnaire about their pain and the pain care they have received for their arthritis.
- “The PAIN PATH Longitudinal Study” (*Study 2*): this involves people with inflammatory arthritis answering text-messages on their mobile phone twice a day for 14 days to understand how often and why they take pain medicines.

Together, these studies will answer many important questions including:

- *What is the pain experience of people with inflammatory arthritis?* - this will help us better understand the impact that pain has on their lives.
- *Does pain care in people with inflammatory arthritis follow expert recommendations?* – this will show areas of pain care that most need improving.
- *Do all people with inflammatory arthritis receive the same pain care?* – understanding this is important to making sure pain care is equal for everyone.
- *How often do people with inflammatory arthritis use pain medicines?* – knowing this will help us better understand the burden of pain and pain medicine use on their lives.
- *Why do people with inflammatory arthritis take pain medicines?* – people may use pain medicines for many reasons like helping them sleep. Knowing this will help us develop information for people about how to use their pain medicines safely.

Will taking part in the PAIN PATH studies affect my care?

Taking part in these studies **will not affect your care in any way**. All treatment for your inflammatory arthritis will continue to be delivered by your healthcare team.

Why have I been invited to take part in the PAIN PATH studies?

The PAIN PATH Survey

You have been invited to take part in the PAIN PATH Survey because you have been diagnosed with rheumatoid arthritis, psoriatic arthritis, or axial spondyloarthritis, are at least 18 years old, and have been told about the study by your rheumatology team.

This Participant Information Sheet and the questionnaire are provided in English. Keele Clinical Trials Unit (CTU) can help with language translation if needed. Their contact information can be found on the last page of this information sheet.

The PAIN PATH Longitudinal Study

Some people who complete the PAIN PATH Survey may also wish to take part in this study. The PAIN PATH Longitudinal Study will include people who currently use pain medicines at least once a week *and* use pain medicines that can be taken at least twice a day. To take part people also need to be able to read and reply to text messages written in English either by themselves or with help from someone else.

We are also asking people with inflammatory arthritis that see online advertisements from national patient organisations (the National RA Society, National Axial Spondyloarthritis Society, and Psoriasis Association) or an Arthritis Register (the Norfolk Arthritis Register) to take part in the PAIN PATH studies. If you are one of these people and have already taken part in the studies, please do not take part again.

What does taking part in the PAIN PATH studies involve?

The PAIN PATH Survey

- You will be asked to complete a **short questionnaire**. This takes about 20 minutes to complete. The questions will ask about your pain experience and pain care, your arthritis and how it is affecting you, how you are feeling, and about you (for example what your age is and what your job is).
- If you are told about this study at your “in-person” clinic appointment, you will be asked if you would like to complete the questionnaire online using a tablet in clinic.
- If you prefer to, or if you are told about this study at your “remote” hospital appointment (where you are not seen in person) you can instead complete the questionnaire later online at home. You will be asked to provide the research team with your email address. You will then receive an email with a link to the questionnaire and a password to access it.
- If you are unable to complete the questionnaire online, you can complete it on paper at home and send it back to the research team (using a freepost envelope that will be given to you).

PAIN PATH Longitudinal Study

- At the end of the online PAIN PATH Survey questionnaire, you will be able to answer a few questions to understand if you are eligible to take part in the PAIN PATH Longitudinal Study.
- If you are eligible and wish to take part, you will be asked to provide your consent. You will then be asked to enter your mobile telephone number into the online questionnaire and select a date to start receiving text messages.
- You will then be sent text messages from Keele University. Your responses to these will be used to collect information about your pain and pain medicine use.
- You will receive text messages twice a day (at 8am in the morning and 8pm in the evening) for 7 days. This will start the day after you agree to take part in the study, although this can be delayed if you prefer to start later.
- After 7 weeks this will be repeated.
- At 8am and 8pm you will receive up to three text messages. Each message will ask you a different question.

First Question

- This will ask if you have taken **any** pain medicines in the last 12 hours.
- The morning text will ask you about your pain medicine use between 8pm last night and 8am that morning.
- The evening text will ask you about your pain medicine use between 8am that morning and 8pm that evening.
- You will be asked to reply using the words “yes” (if you have taken a pain medicine) or “no” (if you have not taken a pain medicine).

Second Question

- This will only appear if you reply “yes” to question 1.
- It will ask you to select **the main reason** why you took your pain medicines in the last 12 hours.
- You will be able to choose from one of six options:
 - 1 is “help pain”: select this if you took them to help your pain.
 - 2 is “usual time”: select this if you take pain medicines regularly at around the same each day and this was the usual time you take them.
 - 3 is “help work/activities”: select this if you took them to help you do your work or certain activities like exercise or shopping.
 - 4 is “help sleep”: select this if you took them to help you sleep.
 - 5 is “help stiffness”: select this if you took them to help your joint stiffness.
 - 6 is “other”: select this if you used them for any other reason not covered by options 1 to 5.
- You will be asked to reply to this question by typing the reason number, for example replying “1” if you took them to help with your pain.

Third Question

- This will ask you how severe your worst pain level has been in the last 12 hours.
- You will be asked to think about the same time periods as you did when answering question 1.
- You will be asked to score your worst pain using a number from 0 (which is “no pain”) to 10 (which is “pain as bad as you can imagine”).
- You will be asked to reply to this question by typing your pain score, for example typing “10” if you have suffered from pain that is as bad as you can imagine.

We appreciate that life is busy, and you may not be able to respond to your text messages there and then. Please don't worry. Just reply when you are ready to. Please try your best to reply as soon as you can. We will only use your answers that you make within 6 hours of receiving a text message question from us.

If you have not responded to any text messages for 3 days back-to-back, we will text you to ask if you would like to stop receiving text messages.

Do I have to take part in these studies?

No, your participation is **voluntary**. Whatever you decide, your healthcare will not be affected in any way, now or in the future.

If you do decide to take part, you can withdraw from either study at any time, without giving a reason.

What are the possible benefits and risks of taking part in the studies?

The findings from the PAIN PATH studies will be used to improve the way pain is managed in people with inflammatory arthritis in the NHS.

There may not be any immediate benefits for you, although some people find it rewarding to take part in health research.

The research team have worked with patients and members of the public to ensure the studies address a problem of importance to people with inflammatory arthritis in a way that is acceptable to them. Being involved in research helps improve patient care.

We do not anticipate any risks to you from taking part in either the **PAIN PATH Survey** or **Longitudinal Study**.

What happens to information collected about me during the studies?

For the PAIN PATH Survey

- Your questionnaire answers will be securely stored under a unique study number.
- The anonymised paper questionnaires will be stored securely for 10 years after the study ends. After this they will be destroyed.

For the PAIN PATH Longitudinal Study

- A computer programme developed by Keele University will share your mobile phone number with a text messaging service. This will send you text messages. Your answers to these will be returned to the Keele University computer programme and securely stored under a unique study number.

For both studies

If you decide to take part in either study all information collected about you will be treated in **strict confidence** in accordance with general data protection regulations.

Your consent form, which can link you to your unique study number, will be stored separately to your research information (on Keele University's secure servers). Only the research team will be able to link you to your research information.

Unless you consent to be contacted in the future about related research studies, your personal details will only be retained for the duration of the study, after which they will be confidentially destroyed. If you consent to be contacted in the future about related research studies, we will securely save your name, postal address, telephone number and email address (if you have one) to be able to contact you.

You will be asked if you are happy for your depersonalised research data to potentially be shared with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoid duplication of research) and to understand the bigger picture in particular areas of research. Your depersonalised data may be used in other research studies, subject to appropriate approvals. Any requests for access to your depersonalised data from anyone outside of the study team will follow Keele University's procedures for data requests.

Keele University is the sponsor for this study. Your medical records may be looked at by authorised individuals from Keele University or the regulatory authorities, to make sure the study is being carried out correctly.

We will need to use information from you for this research project. This information will include your name, mobile telephone number and email address. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will

not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the studies.

What are your choices about how your information is used?

You can stop being part of either study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is being used?

You can find out more about how we use your information by:

- Visiting the webpages www.hra.nhs.uk/information-about-patients/ or <https://www.keele.ac.uk/legalgovernancecompliance/legalandinformationcompliance/informationgovernance/>.
- Asking one of the research team.
- Sending an email to ctu.painpathstudy@keele.ac.uk.
- Ringing us on 01782 732950.

What will happen to the results of the studies?

We will use the findings from the PAIN PATH studies, together with results from other related studies undertaken by our research team, to **understand how to better manage pain in people with inflammatory arthritis in the NHS.**

One way of doing this is to make recommendations about the best way to treat pain. These recommendations are called a "Quality Standard". We will then work with professional bodies, patient organisations, and guideline developers to get these recommendations used in the NHS, promoting the use of safe pain care that works.

We will also share the studies' findings through presenting them at medical meetings, press releases, websites, social media, and publishing them in scientific journals. You will not be identifiable in any of these presentations, publications, or media releases.

Who is organising the studies?

The PAIN PATH Studies have been funded by the National Institute for Health Research. They are part of a larger research project (the “PAIN PATH Project”), which seeks to improve the pain care that people with inflammatory arthritis receive. For more information on this project please see:

<https://dev.fundingawards.nihr.ac.uk/award/NIHR300826>.

Dr Ian Scott is leading the study team. He is a Consultant Rheumatologist and Researcher working at Keele University and Midlands Partnership NHS Foundation Trust.

Who has reviewed the studies?

All NHS research is looked at by an independent group of people called a “Research Ethics Committee”. They make sure that research is undertaken appropriately.

The PAIN PATH Studies have been reviewed and given a favourable opinion by North East - Newcastle & North Tyneside 2 Research Ethics Committee. They were also reviewed by scientific experts on behalf of the National Institute for Health Research.

Who can I contact for more information about the studies?

If you would like to know more about the PAIN PATH studies, or have any questions, please contact Keele University’s Clinical Trials Unit on the below phone number or email.

Phone Number

01782 732950

Office hours are Monday - Friday 9am - 5pm

Email Address

<mailto:ctu.painpathstudy@keele.ac.uk>

What do I do if I have any concerns about the studies?

If you have any concerns about any aspects of the studies, it is often worth discussing them first with the research team as they know the studies well and may be able to address them for you.

However, in some cases you may feel more comfortable discussing your concerns with someone outside of the research team. If this is the case you can contact NHS England on 03003112233, or email: england.contactus@nhs.net.

If you have any concerns or complaints about this study, please contact the Head of Research Integrity at Keele University via research.governance@keele.ac.uk or 01782 733371.

Thank you very much for taking the time to consider taking part in the PAIN PATH studies.

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