Understanding PAIN and its management in PAtients with inflammatory arTHritis: the PAIN PATH studies

Participant Information Sheet

Version 3.2, 15th May 2024

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 questions using an online "Patient Portal" every week for 3 months 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.

Who can take part in the PAIN PATH studies?

The PAIN PATH Survey

You can take part in the PAIN PATH Survey if you have been diagnosed with rheumatoid arthritis, psoriatic arthritis, or axial spondyloarthritis, are at least 18 years old, receive care in one of the UK National Health Services, and are able to complete an online questionnaire.

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 have used any pain medicines in the last month, have an email address (which is needed to register with the "Patient Portal"), and can read and answer questions written in English either by themselves or with help from someone else.

We are also asking people with inflammatory arthritis that are attending rheumatology clinics across the Midlands to take part in the PAIN PATH studies. They are being told about these studies at their clinic appointments. 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, secure, online questionnaire**. This takes around 20 minutes. The questions will ask about your pain experience, your pain care, your arthritis and how it is affecting you, how you are feeling, and questions about you like your age and your employment. Please try to complete the questionnaire in one sitting. If you are unable to complete the questionnaire in one sitting, any responses you have already given will not be saved and you will have to begin the questionnaire again the next time.

The PAIN PATH Longitudinal Study

- You will be asked to **enter information into a secure online NHS system** called the "PAIN PATH Portal".

- The PAIN PATH Portal has been developed by the study research team and NHS staff to collect research information for this study. The information you enter is stored on a secure NHS server at the Midlands Partnership University NHS Foundation Trust.
- Once a week for 3 months you will be asked to answer questions on the Portal.
    - **Every week** you will be asked to answer questions about how bad your pain has been, which pain medicines you have used, and why you have used them. These take around 5 minutes to answer.
    - **Every two weeks** you will also be asked to answer questions about how active your arthritis has been, how you are functioning, how you are sleeping, and how you are feeling. These take around 10 to 15 minutes to answer.
- You will be asked to select a day of the week that is best for you to enter information into the Portal (for example a Sunday). Please try and enter information on this day if you can. However, we realise life is busy, and this may not be possible. If this day no longer works best for you then you can choose another day of the week instead.
- We will send you an email reminder to fill out a Portal entry at 8am on your selected day of the week for 3 months. You can also enter information into the Portal whenever you would like, if you would find it helpful to do so (for example, to keep track of your pain levels over time).

How can I take part in the PAIN PATH survey?

- You can access the study questionnaire at the following webpage: https://redcap.link/keele-pain-path-national. Before you can start the questionnaire, you will be asked to sign a consent form. Signing it means you are giving your consent to take part in the study.
- You can access and complete the questionnaire on a computer, smartphone, or tablet. Just use whatever is easiest for you.

How can I take part in the PAIN PATH longitudinal study?

- At the end of the PAIN PATH survey questionnaire, if you report taking a pain medicine in the past month and are eligible to take part in the PAIN PATH longitudinal study, you will be asked if you wish to take part.

- If you are interested, you will be asked to sign a consent form. This means that you are giving your consent to take part in the study.
- After completing the consent form, you will be provided with a website link to click on. This will then take you to the Portal, where you can register to use it. You need to register there and then. For security reasons, if you move away from this link, you will not be able to register to use the Portal.
- You can access and complete the Portal on a computer, smartphone, or tablet. Please use whatever is easiest for you.

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.

If you take part in the **PAIN PATH Longitudinal Study, you will be able to download an anonymised copy of your question answers.** You may find it helpful to see how your pain levels, pain medicine use, arthritis activity, function, sleep, and emotional wellbeing have been over the study period. After 3 months you will be able to continue to use the Portal to answer these questions, and you will be able to answer them as often as you wish. You may find doing this helpful as it can help you keep track of your health. At the end of the study the Portal will be closed.

The research team have worked with patients and members of the public to ensure that 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 on a Keele University managed secure server.

For the PAIN PATH Longitudinal Study

- Your email address and research question answers will be held on a secure NHS computer server at the Midlands Partnership University NHS Foundation Trust.
- Your anonymised research information will be securely transferred to a Keele University server for the research team to analyse. This will be securely stored under a unique study number.
- At the end of the study (or if you decide to withdraw from the study), your email address will be deleted from the NHS server at the Midlands Partnership University NHS Foundation Trust.

Both studies

If you decide to take part in either of these studies, the information collected about you will be treated in **strict confidence** and in accordance with general data protection regulations.

Your consent forms, which can be used to link you to your unique study number, will be stored separately to your research information on Keele University managed 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 each 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 any contact details you entered (for example your name and telephone number) 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. We will need to use information from you for this research project. This information will include your name and potentially 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 and Care 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 at Keele University and the Midlands Partnership University 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 and Care Research.

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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 by phone or email (see below).

Phone Number

01782 732950

Office hours are Monday - Friday 9am - 5pm

Email Address

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 your concerns.

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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