Participant Information Sheet

Patient Expectations and Experiences of Current and Novel (PECAN) Management of Gout: A Qualitative Study

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The global prevalence of gout is currently on the rise, and despite widely available treatments for gout, people with gout may not always be prescribed these medications. We understand there are several barriers preventing optimal management of gout, and new self-management strategies are being explored to improve gout care. We want to further explore patient views on gout, gout management, and these new strategies, to see if they are acceptable to patients. Furthermore, patient views on the gout flare itself and what gout remission means to patients with gout are understudied and we want to add to this body of research. You will be invited to fill out a questionnaire, as well as take part in a recorded interview. We aim to recruit 20-30 people for this study.

Why have I been invited to take part?

You have been invited to take part in this study because you have gout.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

We will provide you with this information sheet as either a paper copy or online, and you will have the chance to read and consider participation. You will then be asked a number of screening questions prior to formally entering the study to check your eligibility. If you are eligible to take part in the study, you will then be asked to sign a consent form indicating that you agree to take part in the study.

Baseline questionnaire:
After consent has been obtained, you will be contacted to fill in a baseline questionnaire. This can be done at your own pace. All participants will be asked for details about their gout and any gout medication. Further questions include what other medical conditions you have and details about your overall quality of life. We ask these questions to give context to what you may say in the interview.
The directions in the questionnaire should help guide you through how to answer each question, and which questions to answer, however, if you need help then there will be someone to help you fill out the questionnaire, or a contact email if you are filling out the questionnaire online.
Once you fill out the baseline questionnaire, we will invite you to take part in a recorded interview exploring your understanding of gout, its management, and remission. This interview is voluntary, and you can let us know at any stage if you would rather not take part in these discussions. We expect the baseline questionnaire will take no longer than **20 minutes** of your time.

Interview:
If you accept the invite to take part in a recorded interview, we will arrange with you a time that is most suitable for you. If you decide to take part in the interview in-person, we will bring you to a private room at the research site and talk over how the interview will work. We will ask you to give consent again before starting the recording of the interview. Only audio will be recorded. If you decide to take part in the interview online, you will be sent a Microsoft Teams link via email.

Travel expenses and any carer costs will be reimbursed to you if you take part in this research study.

Is there anything I need to do or avoid?

There are no direct benefits to you taking part in the study. However, we hope that the knowledge gained from the study will be beneficial to other patients with gout in the longer term. Your travel expenses to the study location will be reimbursed if you choose to come to the study site.

What are the possible benefits of taking part?

There are no direct benefits to you taking part in the study. However, we hope that the knowledge gained from the study will be beneficial to other patients with gout in the future. Your travel expenses to the study location will be reimbursed if you choose to come to the study site.

What are the possible disadvantages of taking part?

There are no direct disadvantages to you taking part in the study. Taking part in the study will not affect the healthcare you receive. Filling out the baseline questionnaire and taking part in an interview will take up some of your time.

What if there are any problems?

If you have a concern about any aspect of this study please contact our research team Monday to Friday between the hours of 8.00am and 4.00pm on the NHS Lothian switchboard on 0131-537-1000 stating your participation in the PECAN gout study and you will be put in contact with Dr Philip Riches who will do his best to answer your questions. In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time. If you decide to withdraw you do not have to give us a reason why. Your decision to withdraw will not affect the standard of any future care that you might require. You will not take part in the interview if it has not yet happened. If you decide to withdraw after filling in the baseline questionnaire, you will be given the option to withdraw from all aspects of the study, however, we will retain and use the data that you have given up to that point. Your personal data which may identify you (name, contact details) will be deleted immediately at the point of withdrawal.
In the unexpected event that you can no longer communicate your wishes, due to unforeseen circumstances for example a severe stroke, then you will be withdrawn from the study automatically, however we will retain and use the data that you have contributed up until this time point.

What happens when the study is finished?

It is our intention to let all participants know about the results of the study when the analysis is complete and this will most probably be done within 6-12 months of the study finishing. We hope the results of this study will guide future gout treatment within the NHS.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you for this research project. Personal information will include your name, demographic details, and contact details, and other information will include answers gathered during the questionnaire and interview. The research team will use this information to do the research and regulatory authorities may check your records to make sure that the research is being done properly. Information gathered will be stored securely on computers within the NHS and The University of Edinburgh. 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 assigned instead.

ACCORD is the Sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Encrypting your information using an approved encryption standard at all stages of research.
- Limiting access to your data to only those involved in the research study
- Storing electronic data in password-protected folders and secure servers
- Storing any physical data in a locked room not accessible to the general public

With your consent, we may share anonymised data about you for future ethically approved studies research related purposes to:

- Allow other researchers to combine their own research with ours for a larger analysis.
- Allow other researchers a more in-depth exploration at our research, beyond what is published publically.

If this happens, we will only share the data that is needed. We will also make sure you cannot be identified from the data that is shared. If your data is shared outside the UK, it will be with the following types of organisations:

- Universities
- Independent Research Institutes
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We will make sure your data is protected. Anyone who accesses your data outside the UK must follow our instructions so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website.
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the ICO website.

Once we have finished the study, we will keep some of the data so we can check the results. We will keep your study data for the minimum period of 10 years, and study documentation will not be disposed of without permission from the research sponsor. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

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

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

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- Our leaflet available from www.hra.nhs.uk/patientdataandresearch
- By asking a member of the research team
- By sending an email to dpo@ed.ac.uk or enquiries@accord.scot
- By ringing us on 0131 651 4114

What will happen to the results of the study?

The results of this research will be presented at scientific meetings in the UK and overseas and published in medical journals. We will write our reports in a way that no-one can work out that you took part in the study. We hope that this study will lead to a better understanding of what patients with gout feel is most important to them and therefore be able to provide better care in the future. You will not be entitled to receive any financial benefit from this work, but we will contact all the participants via email after close of study to let them know the outcome of the study.

Who is organising and funding the research?

The study has been organised by Miss Rowan Hart, a PhD Student at the Institute of Genetics and Cancer at the University of Edinburgh, and is being co-sponsored by NHS Lothian and the University of Edinburgh at ACCORD.

Who has reviewed the study?

The study proposal has been reviewed by xxxx.

The research team has met with two people with lived experience of gout, as well as a representative of the charity Versus Arthritis to speak about their experiences to help develop the interview topic guide for the study. They gave feedback on a draft interview guide, looking at the relevance of the questions and how easy they are to understand. We have since adapted the interview guide, reflecting the feedback given in the meeting.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from ***REC name*.** NHS Management Approval has also been given.

Researcher Contact Details

If you have any further questions about the study please contact:

Miss Rowan Hart

Institute of Genetics and Cancer
The University of Edinburgh, Western General Hospital,
Crewe Road, Edinburgh EH4 2XU
Email: R.E.Hart@sms.ed.ac.uk

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact:

George Nuki
Email: g.nuki@ed.ac.uk
Telephone: 07790549446

Complaints

If you wish to make a complaint about the study please contact:

Patient Experience Team – NHS Lothian
Mainpoint
102 Westport
Edinburgh
EH3 9DN

By telephone
0131 536 3370 (open Mon-Fri, 9am to 2pm)

By email
LOTH.Feedback@nhs.scot

Participant ID:

CONSENT FORM

Patient Expectations and Experiences of Current and Novel (PECAN) Management of Gout: A Qualitative Study

Please **initial** box

1. I confirm that I have read and understand the information sheet for the above study. ☐

Date (DD MMM YYYY)	Version Number

2. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected. ☐
4. I understand that relevant sections of my data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data. ☐
5. I give permission for my personal information (including initials, name, date of birth, ethnicity, telephone number, email address, and consent form) to be passed to the University of Edinburgh for administration of the study. ☐
6. I understand that data collected about me during the study may be converted to anonymised data. ☐
7. I agree to my anonymised data being used for future ethically approved studies. Yes ☐ No ☐
8. I agree to my interview being audio recorded and the use of anonymised quotes in research reports and publications. Yes ☐ No ☐
9. I agree to take part in the above study. ☐

Name of Person Giving Consent	Date	Signature
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1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record