



Participant Information Sheet

Department of Medicine

Faculty of Medical and Health Sciences, University of Auckland

85 Park Rd, Grafton, Auckland 1023, New Zealand

Study Title: Patient perceptions of remission in gout

Principal Investigator: Professor Nicola Dalbeth

PhD student: Dansoa Tabi-Ampsonah

INTRODUCTION

Thank you for showing interest in this study. Please read this information sheet carefully before deciding whether you want to participate. If you decide to participate, we thank you. If you decide not to participate, we thank you for taking the time to consider our request.

This Participant Information Sheet is a document which sets out to explain why we are doing the study, what your participation would involve, what would happen after the study ends and who to contact if you want further information. It will help you decide if you'd like to take part in this study. You may also want to talk about the study with your healthcare provider or family, whānau and friends before deciding. Feel free to do this and show them the document, you do not have to make an immediate decision on whether you will participate in this study.

WHY ARE WE DOING THIS STUDY?

Gout is the most common form of inflammatory arthritis in Aotearoa/New Zealand. This agonizing disease is characterized by severe attacks of pain and swelling. It has a very negative impact on quality of life, as such remission is an important goal. Remission is a state where your gout symptoms have gone away, and your gout is well controlled on medication. We are conducting this study to gain a better understanding of how people with gout perceive remission. The findings from this study will help doctors and researchers to assess whether the preliminary remission criteria that has been developed reflect outcomes of remission that are important for people with gout.

WHO ARE WE SEEKING TO PARTICIPATE IN THIS STUDY?

You have been invited to take part in this study which aims to understand patient perceptions of remission in gout. We seek individuals who have had no gout flares in the last 6 months or longer.

The decision to take part in this study is yours to make. If you don't want to take part, you don't have to give a reason, this won't affect the medical care you receive.

WHAT DOES YOUR PARTICIPATION INVOLVE?

If you agree to take part in this study, you will be asked to sign a Consent Form, or if you agree to do the study remotely through Zoom, you will be asked to give verbal consent. You will be given a copy of both the Participant Information Sheet and Consent Form to keep. Even after agreeing to take part, you can pull out of the study at any time.

You will be invited to attend a single research interview either through Zoom or at the University of Auckland Clinical Research Center. Parking is provided. Please take your normal medications on this day.

Each interview will take up to one hour in a private setting. During the interview, you will be asked questions about your experience with gout and the impacts and factors of remission that you view as important. You will be given plenty of time to provide your responses, along with prompts to help elaborate your answers.

You will also be asked for information regarding your name, age, ethnicity, and gout history. We will also have a questionnaire in which you will be asked to mark your pain due to gout in the last month or longer and how your gout has affected you in the last week, on a scale of 0-10.

We will need to look at your gout related medical records and record your recent serum urate levels. We will only access your medical records if you give us permission to do so. If this information is not available, we will perform a finger-prick test to measure your serum urate. During a finger-prick test, the skin is pierced with a sterile lancet to produce a blood droplet which is captured in a capillary tube. The blood urate is then screened using a blood meter. If you choose to do the study remotely through Zoom, and have not had a recent blood test, we will ask you to get one so we can determine your serum urate levels; there will be no costs associated with this. Please note that you can refuse to have a blood sample taken and still participate in the study.

For your participation in the study, you will receive a \$50 fuel voucher. This will be made available to you even if you withdraw before completing the study visit.

THE RISKS OF DISCOMFORT OR HARM FROM PARTICIPATING

It is possible that you will be emotionally affected when recalling your past experiences. If this were to happen, you will be given additional time, and the option of discontinuing the interview. With your consent, a family member or support person can also be present at the interview. The following are also free support services that you can go to if needed:

- Need to Talk? Free call or Text 1737 anytime for support or help from a trained counsellor
- The Depression Helpline – 0800 111 757 or free text 4202 (to talk to a trained counsellor about how you are feeling or to ask any questions)
- Alcohol Drug Helpline (0800 787 797)
- Anxiety New Zealand Trust (0800 269 4389)

THE RIGHT TO WITHDRAW FROM PARTICIPATION

- Participation in this study is your choice.
- You are free to decline to participate or withdraw from the research.

- You do not need to give a reason to withdraw from the study.

Please note: If you decide after the interview to withdraw from the study, you have the right to withdraw your collected information as long as you let us know within 2 weeks. After 2 weeks, the information collected may continue to be processed as part of the study.

THE COLLECTION OF DATA AND INFORMATION

As part of the interview, we will be collecting personal and health information from you. This may include information about your medicines and latest blood test results from your medical records. Information from your health records will only be accessed if you give us permission to do so. Only information relevant to gout will be accessed. You have the right to access the information collected about you as part of the study.

The interview will be audio-recorded and transcribed word for word by Dansoa Tabi-Amponsah (PhD student). You will be offered an opportunity to review and edit the audio recording transcripts of your interview. These transcripts can be kept for two weeks before any changes have to be returned. You will also be given the option to either discuss these over the phone with the researcher or discuss these in person with the researcher. If you do wish to review your transcripts, please indicate so on the relevant section of the Consent Form.

Please note: If you choose to view your audio recording transcripts, you will also be given the option of withdrawing up to 2 weeks from the date of viewing your transcripts.

WHAT HAPPENS AT THE END OF THIS STUDY?

Your participation will be kept confidential, and all data will be stored securely for 6 years. All physical data will be stored securally at the Department of Medicine, at the University of Auckland and all electronic data will be stored on a password protected data server. After 6 years all paper forms will be shredded, and all electronic data will be erased.

We will send you a letter with results of the study following its completion. We plan to publish results from this study in scientific journals so that the information is available to other doctors, researchers, and the public. The results generated from the study may be made available for use in future research in gout. As a participant, you will not be identified in any report or publication and all information about your identity will be kept strictly confidential.

ANONYMITY AND CONFIDENTIALITY

- Your participation in this study will remain confidential.
- We will ensure that the transcript of your interview and your personal details are protected, by assigning all data we collect from you with a study number.
- No information collected, which could identify you personally, will be used in any reports on this study.
- Your information will be stored securely in electronic and paper form.
- Apart from the study researchers, no one else will have access to your information.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any concerns or complaints about the study at any stage, you can contact:

Professor Nicola Dalbeth (Principal Investigator)
Telephone 09 923 2568
Email: n.dalbeth@auckland.ac.nz

Dansoa Tabi-Amponsah (PhD student)
Mobile number: 021 134 4303
Email: dansoa.tabi-amponsah@auckland.ac.nz

If you require Māori cultural support, please talk to your whānau in the first instance. You may also contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 or contact the Auckland and Waitematā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 4868920 ext 3204 to discuss any questions or complaints about the study.

For any concerns regarding ethical issues you may contact the Chair of The University of Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 x 83711, or at Auckland Health Research Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

Approved by the Auckland Health Research Ethics Committee on 27/06/2022 for three years. Reference number AH24277.