

# Participant Information Sheet



**MEDICAL AND  
HEALTH SCIENCES**  
SCHOOL OF MEDICINE

Study title: Can smartphone notifications help with gout management?

Locality: **Auckland Health  
Research Ethics  
Committee** Reference number:  
**AH23037**

Lead investigator: **Professor Keith  
Petrie** Contact phone  
number: **(09) 923  
6564**

Thank you for showing an interest in this project. Please read this information sheet carefully before deciding whether to participate. If you decide to participate, we thank you. If you decide not to take part, there will be no disadvantage to you, and we thank you for considering our request. If you do want to take part now, but change your mind later, you can pull out of the study.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form. You will be given a copy of the Participant Information Sheet to keep.

This document is 7 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

## WHAT IS THE PURPOSE OF THE STUDY?

You are invited to take part in a study exploring how smartphone notifications can help with gout management.

This research is part of a PhD in Health Psychology thesis at the Department of Psychological Medicine at The University of Auckland. Professor Keith Petrie, Professor Nicola Dalbeth (contact details above) or Yasaman Emad (y.emad@auckland.ac.nz) can be contacted to answer any questions. This study is funded by the University of Auckland postgraduate research grant.

## **WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?**

You have been invited to participate because you are 18 or above, have gout and have been prescribed allopurinol. To take part in this study you also need to own a smartphone.

This is a study designed to understand your thoughts about smartphone notifications and will not influence your treatment.

Taking part in this study will involve receiving smartphone notifications for a 12-week period. There will be a study visit (either at Greenlane Clinical Centre or the University of Auckland) to obtain informed consent and to receive brief training on how to download the study application, how to read a notification and how to delete or save them. The application works offline, and you don't need to use cellular data/Wi-Fi to receive the notifications. The study visit will take 45-60 minutes. Considering that your health is our priority, the study visit and the interview will be held in person only in the **orange** traffic light settings (COVID-19 Protection Framework), and this study will adhere the University of Auckland's COVID-19 policies.

This study involves completing a few questionnaires using the study app. The app can be downloaded through App Store or Google Play. No personal information will be required to use the app or answer the study questionnaire through the app. Once you complete the study questionnaires, you will receive 130 notifications in total during a 3-month course. You can withdraw from the study and stop receiving the notification at any stage. Also, you can easily delete the app from your smartphone. Once deleted, none of your data will be retained in the app. Researchers will use some information recorded in your medical file, including the levels of serum urate and dispensing data for data analysis. There will be also a follow-up three months after receiving the intervention. You will be asked to complete some brief questionnaires to help the researchers to investigate the effects of the intervention over time. At the end of the program, you will be invited to take part in an interview and will be asked about the effectiveness of the program and readability as well as understandability of the notifications. The interview will be held either in person in the **orange** traffic light settings (COVID-19 Protection Framework), or online over Zoom.

You can always ask the researchers to attend the study visit and the interview online over Zoom.

Please note that your responses will not be shared with your rheumatologist or other members of your health care system.

Through your involvement in the study you will contribute to our understanding on how we can optimally deliver an effective intervention to improve treatment adherence in the future.

## **WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?**

This intervention is considered low risk, so researchers do not expect you to experience any kind of risk.

This study will not change your current medication. However, if you are worried your treatment you can talk to your doctor or another member of the rheumatology team.

### **WHO PAYS FOR THE STUDY?**

You will not incur any financial costs due to participation in this study.

As a thank you for your time involved you will receive a \$50 shopping voucher.

### **WHAT ARE MY RIGHTS?**

Participation in this study is completely voluntary. You are free to decline to participate.

If you choose to take part, you can leave the study at any time (you can also keep the gift-voucher) without giving a reason. Whether or not you participate in this study will not affect your relationship with your healthcare provider or your future health care.

You will be given a copy of this document to keep.

Your data will not affect the decision made in your future healthcare.

The data you provide will not be recorded in or linked to your clinical record.

You can ask questions about the study and can contact the student researcher (Yasaman Emad) or co-researchers of this project through their details at the bottom of this sheet.

All private information will remain strictly confidential and no material that could identify you will be used in any report on this study. Your name will only appear on the consent form, which will be coded with a participant identification number so that your identity is kept private.

Only the researcher and supervisors will access the data. Your answers will not be shared with your rheumatologist, other members of your health care system or anyone else. Publications and presentations on the study will not contain any information that could identify you. Please note that the researcher and supervisors will have access to some information recorded in your medical file, such as the medicines you have received from the pharmacist and your blood results. All the information will remain confidential.

### **WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?**

You can also request that the data you have provided is withdrawn until two weeks after taking part in the study. To withdraw your data, please contact the student researcher (Yasaman Emad).

A summary of the results of this study will be sent to you if you want. As it takes time to analyse the data, it can take more than a year after participation that the summary of the results will be sent to you.

Questionnaires and consent forms will be kept in a locked filing cabinet in the researcher's office at the University.

When the study is finished, all private data (including computer files) will be kept for 10 years, after this time it will be disposed of.

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

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

*Professor Keith Petrie, Supervisor/Principal Investigator, Department of Psychological Medicine*

*(09) 923-6564*

*[kj.petrie@auckland.ac.nz](mailto:kj.petrie@auckland.ac.nz)*

*Professor Nicola Dalbeth, Rheumatologist, Department of Medicine*

*(09) 923-2568*

*[n.dalbeth@auckland.ac.nz](mailto:n.dalbeth@auckland.ac.nz)*

*Yasaman Emad, PhDHealthPsyc candidate in the Department of Psychological Medicine*

*(09) 923-4687*

*[y.emad@auckland.ac.nz](mailto:y.emad@auckland.ac.nz)*

*For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at [ahrec@auckland.ac.nz](mailto:ahrec@auckland.ac.nz) or at 373 7599 x 83711, or at Auckland Health Research Ethics Committees, The University of Auckland, Private Bag 92019, Auckland 1142.*

**Approved by the Auckland Health Research Ethics Committee on [23/11/2021] for three years. Reference number [AH23037].**

# Consent Form



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- I have read and I understand the Participant Information Sheet.
- I have been given sufficient time to consider whether or not to participate in this study.
- I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
- I understand that my choice to/not to take part in this study will not affect my relationship with the researcher or with my healthcare provider.
- I understand that I can withdraw my data until two weeks after I have provided it without giving a reason.
- I understand that the study will take 12 weeks and there is a follow-up questionnaire after 3 months which can be done online.
- I understand that I will receive a number of notifications during a 12-week period.
- I consent to a member of the research team accessing some study-related information recorded in the medical file, such the levels of blood tests and medication information.
- I understand that all my information will be kept private and no material that could identify me will be used in any report on this study.
- I understand that the results of the study may be published/presented but will not include information that could identify me.
- I understand that the data will be stored for 10 years after which it will be disposed of.

- I understand that only the researcher and supervisors will access the data.
- I am aware that I will receive a \$50 shopping voucher at the end of the study. Also, I understand that the \$50 voucher will be given even if I withdraw from the study.
- I know who I can contact if I have any questions about the study.
- I understand that this form will be kept for a period of 10 years.
- I wish to receive a summary of the results from the study: **please circle yes/no**

My email is: \_\_\_\_\_

My phone/mobile number is: \_\_\_\_\_

My address is: \_\_\_\_\_

My NHI number is (if known): \_\_\_\_\_

**Declaration by participant:**

I hereby consent to take part in this study.

Participant's name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

The research team including Professor Keith Petrie ([kj.petrie@auckland.ac.nz](mailto:kj.petrie@auckland.ac.nz)), Professor Nicola Dalbeth ([n.dalbeth@auckland.ac.nz](mailto:n.dalbeth@auckland.ac.nz)) or Yasaman Emad ([y.emad@auckland.ac.nz](mailto:y.emad@auckland.ac.nz)) can be contacted to answer any questions.

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