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| **Participant Information Sheet** |
| Study title: | Making information about gout and its treatment more understandable to patients with gout |
| Locality: | The University of Auckland | Ethics committee ref.: |  |
| Lead investigator: | Alina Krasnoryadtseva | Contact phone number: | 0210417277 |

You are invited to take part in a study looking at how information about gout and its treatment could be better communicated to patients. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

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. You do not have to decide today whether or not you will participate in this study. 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 on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

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

## What is the purpose of the study?

Some patients, especially with newly diagnosed gout, struggle to understand doctor’s advice and explanations of the condition. This may be due to the medical jargon doctors might use, short medical consultation times, or any other reasons.

The purpose of this study is to find out if there are better ways of how gout and its treatment could be explained to patients.

*This study has been approved by the Health and Disability Ethics Committee.*

*If you have any questions about the study, please contact Alina Krasnoryadtseva (see contact details below)*

## What will my participation in the study involve?

You have been chosen to participate as you have been diagnosed with gout and we would like to know more about your experience.

If you chose to participate in this study, you would be required to attend a single session at the University of Auckland Grafton Campus. Participation will include viewing a 12-minute presentation about gout and treatment for gout.

Also, you will be required to fill out two questionnaires – one before the presentation and another after it. The questionnaires ask a range of questions about your attitudes towards gout and its treatment, your demographic information and your feedback about the presentation. Overall, your participation will take approximately 30-40 minutes.

We would also like to gather some specific information concerning your diagnosis of gout from your medical records. For example if you had a computed tomography (CT) test of a joint done within a previous year.

## What are the possible benefits and risks of this study?

This study will give us information on how services for patients with gout could be improved.

Doctors can use this information to provide patients with simpler explanations of gout and its treatment.

## Who pays for the study?

It will not cost you anything to participate.

## What if something goes wrong?

If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

## What are my rights?

Participation in this study is completely voluntary. If you don’t want to take part, you don’t have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

You have the right to access information collected about you as a part of the study.

The data obtained from this study will be stored securely at the Department of Psychological Medicine at the University of Auckland. Participation in this study is confidential. No material that could identify participants will be used in any reports on this study. The questionnaires do not include any identity information only your personal digital code. An electronic file with the study data will be password protected. Only the lead investigator and two co-investigators will have access to the file. Hard copies will we stored in a locked cabinet. All data will be destroyed after a period of ten years.

## What happens after the study or if I change my mind?

All data will be kept private and stored securely for ten years. The lead investigator is responsible for data storage and will delete electronic materials and shred hard copies after the storage period expires.

We plan to publish the results of this study in scientific journals so that the information is freely available to doctors, researchers and the public. Participants will not be identified in any report or publication and all information about your identity will be kept strictly confidential.

If you would like to keep the materials you saw in the presentation, please indicate it on your consent form.

If you would like a summary of study results once they are available, please indicate it on your consent form too. We would expect to complete the study within the next 9 months.

All materials used in the presentation and a summary of the study results are available to you at no cost.

## 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:

Alina Krasnoryadtseva, Lead Researcher

Phone: 0210417277; Email: a.krasnoryadtseva@auckland.ac.nz

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

For any queries regarding ethical concerns you may have about this study, you can contact:

The Chair, The University of Auckland Human Participants Ethics Committee

The University of Auckland

Research Office

Private Bag 92019,

Auckland 1142

Phone:  09 373-7599 ext. 83711

Email: ro-ethics@auckland.ac.nz

If you require Māori cultural support please talk to your whānau in the first instance. Alternatively, you may contact He Kamaka Waiora (Māori Health Gains Team) by telephoning the team leader on phone 307 8968 or 021 924 032.

If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Maori Research Committee or Maori Research Advisor by phoning 09 4868920 ext 3204.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

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**Consent Form**

***Please read each statement carefully. Where appropriate tick to indicate whether you consent to a statement or not.***

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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 have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the 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 consent to the research staff collecting and processing my information, including information about my health including my computed tomography (CT) scans for gout | [ ]  |  |
| If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. | Yes [ ]  | No [ ]  |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. | [ ]  |  |
| I understand that my participation in this study is confidential and that **no** material, which could identify me personally, will be used in any reports on this study. | [ ]  |  |
| I understand the compensation provisions in case of injury during the study. | [ ]  |  |
| I know who to contact if I have any questions about the study in general. | [ ]  |  |
| I understand my responsibilities as a study participant. | [ ]  |  |
| I wish to receive a summary of the results from the study. | Yes [ ]  | No [ ]  |
| I wish to receive a copy of the materials used in the presentation I saw | Yes [ ]  | No [ ]  |

**Declaration by participant:**

I hereby consent to take part in this study.

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| 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.

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| Researcher’s name: |
| Signature: | Date: |