

Participant Information Sheet

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The relationship between physical activity and gout flares

Kia ora

Kia ora, Ko Kōtirana te whakapaparanga mai, engari, Ko Tāmaki Makaurau te whenua tupu. Ko Te Motu Waiheke te kāinga. He Kaiwhakaako au i Te Wānanga Aronui o Tāmaki Makau Rau. Ko Sarah Stewart taku ingoa.

My name is Sarah Stewart. I am a researcher at the Auckland University of Technology (AUT). I am working with Professor Tania Ka'ai (Ngāti Porou, Ngāi Tahu, AUT), Dr Irene Zeng (AUT), Professor Nicola Dalbeth (University of Auckland), Karl Rudolph (Ngā Puhī, Tai Poutini, patient research partner), Associate Professor David Rice (AUT), Professor Nicola Kayes (AUT), Dr Julie Collis (Swinburne University, Australia) and research officer, Mia Clarke (AUT). We are interested in exploring the relationship between physical activity and gout attacks and would like to invite you to participate in a research study.

What is the purpose of this research?

Gout (mate waikawa kai kōiwi) is a common form of arthritis. Gout can cause sudden attacks (flare-ups) of pain and swelling. Research has shown that some people with gout have lower levels of physical activity compared to people without gout. This could be due to a number of reasons. Some people with gout have identified excessive physical activity as being a trigger for their gout attacks and avoid being physically active for fear of triggering an attack. The pain of a gout attack also prevents people with gout from being physically active. This poses an important problem, because 'regular exercise' is recommended for people with gout to improve overall health. As part of this research, we will be measuring people with gout over a 6-month period. Participants will be given a wristwatch to measure their physical activity and sleep over the 6 months. Participants will also be asked to complete a daily gout attack diary on their phone over the 6 months.

The findings of this research may be used for academic publications and presentations and will be used to develop physical activity guidelines for people with gout. The data collected in this study may also be used for future analyses exploring gout, physical activity, and sleep. If this were to happen, your personal information will not be disclosed and you will not be identified in any report.

How was I identified and why am I being invited to participate in this research?

You have been invited to participate in this research because you have responded to an advertisement you have seen. To be eligible to participate, you must be living in Aotearoa New Zealand, have a diagnosis of gout, have had at least two gout attacks in the past 6 months, have your own smartphone, and be able to wear the study wristwatch to track your activity and sleep over the next 6 months. Unfortunately, we will not be able to include you in this study if you have other types of inflammatory arthritis (e.g., rheumatoid arthritis, lupus, psoriatic arthritis), are in a wheelchair, or have other musculoskeletal or neurological conditions that affect function or cognitive impairment. If you are unsure whether you are eligible for this study, please check with our research officer, Mia, whose contact details you will find at the end of this Participant Information Sheet.

How do I agree to participate in this research?

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. If you choose to participate, you will need to complete a Written Consent Form when you first arrive at your study visit. You are able to withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

What will happen in this research?

1. **Attend a single study visit.** You will be invited to attend a single study visit with our research officer, Mia, at either our AUT North Campus (located in Northcote, Auckland) or AUT South Campus (located in Manukau, Auckland). At the start of this visit Mia will answer any questions you have and ask you to complete a Consent Form. Mia will then ask you some general questions about yourself and your gout. Your height and weight will be measured. You will be asked to complete some questionnaires related to your quality of life, activity limitation, pain, and physical activity. You will also be asked to provide a finger-prick blood sample so Mia can measure the uric acid levels in your blood. With your consent, we will also be collecting information from your medical records, including the results from any previous uric acid blood test you may have had. Only information relevant to your gout will be accessed.

2. **Wear a study watch for 6-months to measure physical activity and sleep.** At the study visit, Mia will fit you with a study watch (Garmin Vivofit 4) which you will be asked to wear over the next 6 months. The study watch is small, lightweight, and waterproof, so you can wear it while swimming or showering, and while sleeping. You can wear the watch on either wrist. If you need to remove the watch during the next 6 months for cultural reasons (i.e., attendance at tangihanga), you may do so. It has a battery life of 1-year, so you will not need to charge it. Mia will help you to download the study watch app (Garmin Connect™) on to your phone. Every time you sync your physical activity and sleep data from your study watch to the Garmin Connect™ app, it will automatically be sent to Fitabase – a secure system that will store your activity and sleep data for the researchers to access and use.

3. **Record your gout attacks on an app on your phone for 6-months.** Mia will also help you download the gout attack daily diary app (MyCap™) on to your phone. Mia will show you how to use the app. The app will send you notifications once each day over the next 6 months to ask you whether you are experiencing a gout attack. For each day that you are experiencing a gout attack, you will be prompted to answer some additional questions relating to how painful your attack is that day, whether there is any swelling or warmth, which joints are affected, and whether you have taken any medications to help you with the pain.

You will not need to attend any additional study visits during the 6-month period unless you lose your watch or are having problems with the watch or phone app. At the end of the 6 months, you will get to keep your study watch – you will not need to return it.

You are welcome to bring a support person, family member/whānau with you to the study visit.

What are my rights around return and disposal of my blood samples?

At the study visit you will be asked to provide a finger-prick blood sample. This will involve the research officer pricking the end of your finger. The first drop of blood will be wiped away with a cotton bud and the second drop will be applied to a test strip and inserted into a small device which will tell us your uric acid level. No blood samples will be stored as part of this study. You may hold cultural beliefs about a sacred and shared value of any blood samples and you will be given the choice between having any cotton buds or used test strips containing your blood returned to you or allowing us to dispose of them. If you would like them returned to you, please indicate so on the relevant section of the Consent Form. If you would like a karakia said when we dispose of any cotton buds or used test strips containing your blood, please indicate so on the relevant section of the Consent Form.

What are the discomforts and risks and how will they be alleviated?

This study involves minimal to no risk.

The study watch (Garmin Vivofit 4) is a small device that should not get in the way of your day-to-day activities. If you are not used to wearing a watch, it may take a few days to get used to it. If your watch becomes uncomfortable or you develop a rash, feel free to wear it higher up on your arm, swap it to the other wrist, or wear it over the top of a sleeve. If you experience a gout attack on the wrist that you are wearing the watch on, please feel free to loosen the strap, wear it higher up on your arm, or swap it to the other wrist. If you have followed these actions and are still unable to wear the watch, please contact the research officer, Mia, for advice.

You may feel some very minimal discomfort with the finger-prick blood test. Finger-prick blood testing is a safe and routinely used procedure. Our research officer, Mia, is trained in this procedure and will be available during the study visits to talk you through the test.

AUT Student Counselling and Mental Health is able to offer three free sessions of confidential counselling support for adult participants in an AUT research project. These sessions are only available for issues that have arisen directly as a result of participation in the research and are not for other general counselling needs. To access these services, you will need to:

- drop into our centre at WB203 City Campus, email counselling@aut.ac.nz or call 921 9292.
- let the receptionist know that you are a research participant and provide the title of my research and my name and contact details as given in this Information Sheet.

You can find out more information about AUT counsellors and counselling on <https://www.aut.ac.nz/student-life/student-support/counselling-and-mental-health>

What are the benefits?

The information from this study will help patients and doctors to better support people with gout in maintaining regular physical activity. This information may be used to guide the development of gout-specific physical activity guidelines with the overall goal of reducing gout attacks, while also achieving physical fitness and managing overall health.

How will my privacy be protected?

Your privacy and confidentiality are very important to us. All data we gather from you, including from your study watch and study phone apps, will be de-identified. This means we will assign it with a unique code and not your name. This will ensure your personal information is kept confidential and any information that identifies you will not be included in any report. Any future analyses involving your de-identified data will be conducted by the research team. Your data will not be shared with any other parties. All your data will be stored safely without your personal contact details on AUT secure network servers for 10 years. After 10 years, all your data will be deleted.

The study watch only measures your movement. It does not measure heart rate and does not have a GPS tracker, so will not be able to identify where you are. The only information from your watch that the study researchers will see will be how much you move each day, including the number of steps you do each day and the time (in minutes) you spend in light and deep sleep each night.

Information from your health records will only be accessed if you give us consent to do this. Only information relevant to your gout will be accessed. You may hold beliefs about sacred and shared values of any health related data. The cultural issues associated with storing your data should be discussed with your whānau as appropriate.

What are the costs of participating in this research?

The study visit will take 45-60 minutes of your time. You will be reimbursed for your time with a \$50 supermarket voucher at the end of the study visit. At the end of the 6-month study, you will also be posted an additional \$50 supermarket voucher. You will also be given the study watch (Garmin Vivofit4, RRP\$149.99) to keep at the conclusion of the study.

What opportunity do I have to consider this invitation?

You will have four weeks to consider this invitation.

Will I receive feedback on the results of this research?

If you would like to receive a copy of your individual research results and/or a summary of the overall results from this research, please let us know by indicating so on the relevant sections of the Consent Form.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Primary Researcher, *Sarah Stewart*, sarah.stewart@aut.ac.nz, (09) 921 9999 ext 6038.

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEK, ethics@aut.ac.nz, (09) 921 9999 ext 6038.

Whom do I contact for further information about this research?

If you would like to participate in this study or have any questions about the study, please contact our research officer **Mia Clarke** using the contact details below:

Email: gout.research@aut.ac.nz

Mobile: 022 409 9343