

Online Participant Information Sheet

The Genetics of Non-Identical Twinning (NZ)



Short title: TWINGENE

Sponsors: University of Otago

Queensland Institute of Medical Research – Berghofer,
Brisbane, Australia

Lead Investigator:

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+64 (03) 364 0590

Ethics committee ref: 2022 EXP 12825.

You are invited to participate in a research study investigating the genetic factors that influence the development of non-identical, or dizygotic, twins. Specifically, our study is trying to find genes for non-identical twinning to understand better the genetic components involved in having twins and learn more about female fertility and infertility.

If you choose to participate, we will ask you to fill in a short questionnaire (online or via mail) and may ask you to supply us with a saliva sample, which will be used to extract your DNA. A caregiver or support person may help you complete the questionnaire if you feel you are not able. Your survey information and saliva sample will be sent and analysed overseas. We will not be able to return your saliva sample to New Zealand at the end of the storage period – any leftover sample will be destroyed once the analysis is complete.

If you are interested in learning more about this study, please continue reading below.

This Participant Information Sheet for the Genetics of Non-Identical Twinning (TWINGENE) study 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. It is important that you understand this information so that you can make an informed choice about being in this study. You do not have to decide today whether or not you will participate in this study. Feel free to talk about the study with other people, such as family, whānau, friends, or healthcare providers, or contact us if you have any questions. You may choose not to participate or withdraw your consent to be in the study for any reason.

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

If you agree to take part in this study, click at the end of this section to indicate your consent to participate in the survey. You can save a copy of the Participant Information Sheet and the Consent Form.

WHAT IS THE PURPOSE OF THE STUDY?

Genes are made of DNA – the chemical structure carrying your genetic information that determines many human characteristics, such as the colour of your eyes or hair. Researchers have discovered a genetic component to having non-identical twins; in other words, having non-identical twins runs in families.

We want to study these genes further in order to try and understand why some people have non-identical twins and others do not. We also want to try and identify other genes that may contribute to non-identical twinning.

Some of the genes already found related to non-identical twinning also control female fertility. Therefore, finding the genes responsible for non-identical twinning may also reveal important information about female fertility and infertility.

WHO CAN TAKE PART IN THE STUDY?

We are seeking women 18 years of age and over who have given birth to one or more sets of non-identical twins.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

In order to participate in this study, you will be asked to complete an online consent form. We will then ask you for your contact details so we can contact you about the study;

After giving your consent, you will be asked to complete a short online questionnaire about your twins and other related information. Completing the online questionnaire will take approximately 5 to 10 minutes.

Depending on your responses to the online questionnaire, you may be asked to donate a saliva sample, from which we will extract your DNA from your sample to investigate genetic factors for non-identical twinning. To collect your sample, we will send you a specialised collection container. The collection kit is easy to use, and the sample can be collected in

your own home at your convenience. You will be asked to return this sample via pre-paid New Zealand Post bag to our laboratory at no cost to you.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Possible benefits:

This study is unlikely to be of any immediate and specific benefit to you. Extensive research is required to find answers to the questions we are studying. However, future medical or scientific discoveries may come from the research in which you participate. These may help improve our understanding of genetic factors, including female fertility, that are important for conceiving and carrying non-identical twins.

Possible risks:

You may find some items in the questionnaire stressful or upsetting. No survey items are compulsory, so if you do not wish to answer a question during the questionnaire, you may skip it and go to the next question or stop immediately if you do not wish to continue.

If you find you are distressed by completing the questionnaire, mental health support services are available to you to contact 24 hours a day, 7 days a week. We have included details for mental health services below, should you require any further assistance for any distress.

- Text 1737 24 hours
- Lifeline 24 hours ph. 0800 543 354
- Your general practitioner, who also has access to referral pathways if you need more ongoing support.
- Crisis team contact numbers for each DHB area:
<https://www.health.govt.nz/your-health/services-and-support/health-care-services/mental-health-services/crisis-assessment-teams>

Cultural issues statement:

For Māori participants, there may be cultural issues associated with the collection and storing of your samples/specimens. These issues should be discussed with your family/whānau as appropriate, citing the protection of whakapapa. Controlling access to your samples/specimens and data and limiting unauthorised use of those are important questions that you may need to think about before consenting to research. It is also acknowledged that individuals have the right to choose whether they participate or not in a research study. We encourage you to consider the benefits and risks that this research may have for yourself, your whānau and for Māori as a people. Participants may wish to consult with their whānau prior to consenting to participate in a research study.

ACC statement:

If you were injured in this study, 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.

In the very unlikely event that ACC determines that their cover did not apply to your injury, then the University of Otago's clinical trial insurance would apply. This cover would provide you with compensation equivalent to that you would otherwise have been entitled to under the Accident Compensation Act 2001. By signing the Consent Form for this study, should ACC decline cover, you are explicitly agreeing that compensation for any injury will be as per the terms of University's then current clinical trials insurance cover, the full terms and conditions of which are freely available on request.

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.

WHO IS FUNDING THE STUDY?

This study is to be conducted by research staff from the University of Otago, Christchurch, and colleagues at Queensland Institute of Medical Research Berghofer (Brisbane, Australia). It is funded by a National Health and Medical Research Council Australia (NHMRI) Investigator grant to Professor Nick Martin, QIMR Berghofer.

WILL ANY COSTS BE REIMBURSED?

There are no direct costs associated with participating in this research project, nor will you receive any payment for participating

WHAT HAPPENS TO MY SURVEY DATA AND SALIVA SAMPLE?

During this study, the research staff will record information about you and your study participation. This includes the results of any surveys. You cannot take part in this study if you do not consent to the collection of this information.

Your personal details and questionnaire data will not be linked with your genetic data, and will be stored only under a participant identification number and not your name. The only link between your personal details and your other data is your participant identification number, which will be assigned after you have completed the questionnaire. Linking your personal details and other data using this number is restricted to authorised members of the New Zealand research team. All information about you will be stored securely, with access restricted to authorised members of the research team.

Results of this research project may be presented in scientific papers in medical literature, or in public talks, but your identity will not be revealed. The data collected as part of this study will be combined at analysis with the data from many other people, and as such there will be no way of identifying you as a participant.

Survey data:

All survey information will be stored on password-protected files on a secure University of Otago computer system. Access to this data will be restricted to authorized members of the New Zealand research team, although de-identified survey information and genetic data will also be shared with our Australian collaborators at QIMR Berghofer Medical Research Institute (Brisbane, Australia). In addition, representatives of the NZ Health and Disability Ethics Committee (HDEC) will also have access to identifiable and coded data for auditing purposes.

Saliva sample:

We will post a barcoded saliva sample kit with instructions for sample collection to the address you provide. We ask you to send the sample back in a pre-labelled, pre-paid courier bag to our laboratory at University of Otago, Christchurch. Your saliva sample will provide DNA for the genetic analysis.

Each saliva sample will be registered electronically, and stored at room temperature in a secure location at the University of Otago, Christchurch. They will be re-identifiable, which means that they will be stored with a barcode label, and can be identified as yours even though your personal details are stored separately. Linking your personal details with your biological sample or DNA using the barcode is restricted to members of the New Zealand research team.

Batches of saliva samples will be sent to our colleagues at QIMR Berghofer Medical Research Institute (Brisbane, Australia) for DNA extraction. After DNA is extracted, part of your DNA will be sent to another laboratory (which may be within Australia, or elsewhere overseas) for genetic processing and analysis. This is called genotyping. No personal information about you will be sent to or accessible to the laboratory that carries out the genotyping. Any sample remaining after genetic processing or analysis by another laboratory will be destroyed, and there is no option for the disposal of samples with a karakia (blessing).

QIMR Berghofer will store the remainder of your DNA sample until 10 years after the completion of the study.

WHAT ARE MY RIGHTS?

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason with no disadvantage to you. If you withdraw consent, we will remove your data and sample from the study from that point forth. However, if the data has already been processed into group summary form or has been published, we are unable to retract that information.

Please contact twingene@otago.ac.nz if you wish to withdraw from the study. If you consent to participate, you will be donating your survey and genetic data for these purposes and waive any claim to commercial or intellectual property rights arising from this work.

Can I access my data?

We are not able to provide individualised interpretation of survey questions. Similarly, it will not be possible to return individual genetic data or provide meaningful interpretations of genetic information on an individual basis. These data are not of clinical grade, and we do not have sufficient resources to provide interpretation of such data.

You have the right to receive the general results of the study for participants as a group, and we will provide periodic updates by email to the address you provide. It will take some time, however, before the main findings will be available.

How will we protect your confidentiality?

The only information collected about your health is provided by you in the survey. Your personal details are securely stored in a password protected secure file by the University of Otago, Christchurch. Your survey and genetic data will be given a unique identifying code to ensure your confidentiality. Only the New Zealand research team will hold the linking code that links your de-identified survey data to your de-identified saliva sample and DNA. No identifying information about you will be sent overseas, or will be used in any publication related to this project.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Central Health and Disability Ethics Committee have approved this study - Ethics reference: 2022 EXP 12825.

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 Martin Kennedy – Lead investigator
+64 (3) 364 0590
Martin.Kennedy@otago.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@advocacy.org.nz
Website: <https://www.advocacy.org.nz/>

For Maori health support please contact:

Kaitohutohu Rangahau Hauora Maori – Maori Health Research Advisor
University of Otago, Christchurch
maoriresearchconsult.uoc@otago.ac.nz

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

Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz

Online Consent Form

The Genetics of Non-Identical Twinning (NZ)



Please check the optional consent boxes below and then click on the link to indicate your consent to the following in relation to the Genetics of Non-Identical Twinning study.

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- I have read and understand the Participant Information document on this webpage
- 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, as appropriate
- I know who to contact if I have any questions about the study in general
- I understand that taking part in this study is voluntary (my choice)
- I understand that I may withdraw from the study at any time
- I know who to contact if I wish to withdraw from the study
- I consent to giving information about my health in this survey
- 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 am aware that my de-identified survey and sample will be sent and analysed overseas in approved facilities
- I am aware that my survey and genetic data will be stored indefinitely
- I am aware that any saliva sample remaining after genetic processing or analysis will be destroyed using standard disposal methods, and that there is no option for the disposal of samples with a karakia (blessing).

I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant survey for the sole purpose of checking the accuracy of the information recorded for the study

I consent to being contacted in the future to ask about participating in related studies Yes No

I wish to receive a summary of the results from the study. Yes No

I consent to take part in the Genetics of Non-Identical Twinning (NZ) study Yes No