

**Participant Information Sheet**

|  |  |  |
| --- | --- | --- |
| Study title: | **T**rial of an **I**ndividualised **I**ntervention for the Prevention of **S**troke | |
| Locality: Auckland  Ethics committee: Central Health and Disability Ethics Committee | |

An invitation to participate

This information is about a clinical trial titled “Trial of an Individualised Intervention for the Prevention of Stroke” (TIIPS). The study is coordinated by the National Institute for Stroke and Applied Neurosciences, at the Auckland University of Technology (AUT).

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 10 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Study background

Stroke is one of the most common causes of death and disability in the world today. It carries an enormous emotional and socioeconomic impact on patients, families, and health services. People who have experienced a minor stroke or a transient ischaemic attack (TIA) (similar to stroke but symptoms resolve in less than 24 hours) are at an increased risk of having a major stroke. However, strokes, including second strokes, are preventable, and you could reduce your risk of having a stroke by being aware of, and controlling, certain lifestyle factors. This study is looking at whether controlling these risk factors in people who have already experienced a minor stroke or TIA, can be further improved with the help of a health coach, compared to usual care (the health services you would normally receive). This type of study is called a randomized controlled trial, in which participants are randomised to into the test group or usual care group.

You are invited to take part in this clinical trial because you have had a TIA or a minor stroke in the past few weeks.

Study investigators and sponsor?

The lead investigators in the study are Professor Valery Feigin, Director, and Associate Professor Rita Krishnamurthi, Deputy Director, of the National Institute for Stroke and Applied Neurosciences (NISAN), Auckland University of Technology, Auckland, New Zealand.

The sponsor for this study is the Health Research Council of NZ.

Who can take part in this study?

Everyone between the ages of 18 and 75 who has had a minor stroke (meaning a person who has had a stroke but is independent in their daily affairs) or TIA in the past six weeks.

You may not be eligible to take part in this study if you are very unwell; have already had a major stroke or heart attack; are already in another clinical trial to manage your stroke risk factors; or have problems with mood, memory or thinking.

How was I identified for this study?

You were identified as a potential participant because we have permission through the hospital where you were admitted for stroke or TIA or by your doctor (GP) to be contacted by our research team in regard to this study.

What is involved in this study?

We expect that around 360 people will take part in this study. The study will take place in the Auckland region. Your involvement, if you are eligible, will be for 12 months.

You will be asked a few questions over the phone to check if you may be eligible to take part in this study. The main criteria to be eligible to participate in this study are - aged 18-75 years; living within the Auckland region; had a minor (non-disabling) stroke or TIA in the past 6 weeks. You are not eligible if you have had a previous stroke which resulted in significant disability. If you are eligible, you will be provided with the Participant Information Sheet and Consent form. You may take as much time as you need to read this information. If you decide to take part, you will be asked to sign the Consent form and make a booking for your first appointment. This appointment will be in-person either at a designated study clinic or in your home, depending on your preference. The appointment will take 30 to 45 minutes.

At this appointment (called the Baseline appointment), the researcher will ask you some questions about your health. The researcher will do a final check by asking you some questions about your blood pressure, memory, and mood, to check you meet all the criteria for the study. If you do not meet the study criteria, you will be informed at this stage, and a $30 koha will be provided to thank you for your time.

If you do meet the criteria for the study, the Baseline assessment will continue. The researcher will take measurements of your risk factors including height, weight, blood pressure, blood cholesterol and glucose levels. Blood cholesterol and blood glucose levels will be tested using a finger prick test where a small amount of blood will be collected and tested using a blood test machine. You will be provided with a summary of your results by e-mail. You will be provided with a $30 koha to thank you for your time.

After this, you will be allocated into one of two groups in a randomized manner using a computer programme. This will be either the test group, which is the health coaching group, or the usual care group. You will be contacted by a separate member of the team to inform you of which group you are in. You will also be informed of what is involved as part of the group you are in. It is important that in all future appointments, you do not reveal to the researcher which group you are in. The researcher collecting your information will be blinded to the group you are in. This type of trial is known as a single-blinded trial. This is to avoid bias in the way researchers record your information.

What happens after randomisation?

Usual care group: If you are randomized to the usual care group, you will have four further assessments over the next 12 months. These will be 3, 6, 9 and 12 months after your Baseline assessment. All the assessments except the 6-month assessment will be done over the telephone, at a time that is convenient to you. The 6-month assessment will take place in-person, as the researcher will do a repeat measure of your weight, blood pressure, blood cholesterol and glucose levels (similar to the Baseline assessment), in addition to asking questions about your health and wellbeing. The 6-month assessment may be completed by attending one of the designated clinics or by a home visit depending on your preference.

It is important that you complete all assessments as the usual care group provides crucial data for the trial. Without the usual care group, the trial cannot be completed. At the end of your last assessment (at 12 months), a researcher will offer you an information package if you wish to receive one. This package will include educational materials and guidelines on ways to reduce the risk of stroke.

Health Coaching group: If you are randomised to the health coaching group, you will have the same assessments as the control group as described above at 3, 6, 9 and 12 months, but you will also receive health coaching. There will be 12 coaching sessions in total over 6 months, with the first session taking place in-person, at your home or a location of your preference at a convenient time. The remaining sessions will be by telephone, weekly, then once every 2 weeks, then once every month. This will involve 30 to 60-minute sessions with a health coach who will talk to you about your health, risk factors and support you to make lifestyle changes. The sessions will be audio-recorded for the health coach to be able to review the sessions and prepare for future sessions. This is a standard practice for quality control purposes as well. The recordings and the contents of the sessions will be confidential between you and the health coaching team. The health coaches will be trained by a certified health coach trainer and will receive ongoing supervision by the trainer throughout the study.

Between the last coaching session at 6 months and the 12-month assessment, you will also receive a short (5- 10 minutes) monthly phone call from the health coach to check in with you and answer any questions.

During the study, if the researcher is concerned about your health and/or wellbeing, we may contact your GP to inform them of this. We will discuss this with you at the time of your assessment.

what are the discomforts and risks?

There is a small risk of physical discomfort from the blood-test done at the face-to-face appointment. This test will measure the amount of sugar (glucose) and fats (lipids) in your blood. We only need a very small amount of blood which we can get using a finger-prick. No blood is stored, and we will dispose of the testing sample using current guidelines for biohazard waste.

You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with sending your samples overseas and/or storing your tissue should be discussed with your family/whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose. To respect Māori cultural views regarding handling and disposal of human samples collected for clinical testing (in the case of this study this is point of care testing), Māori participants are given the option to have a karakia performed before their blood sample is disposed. Participants are also given the opportunity to conduct the karakia themselves if they wish to, before the sample is taken by the collector.

• If karakia pathway is chosen, then once the sample has been taken and been tested, it will be labelled accordingly, and then kept separate from the non-karakia pathway samples.

• After the research assistant visit, the samples will be taken to our Māori cultural support where a karakia will be performed.

• Once this process is completed then samples will be moved on to be disposed of using established guidelines for discarding biohazard waste.

• For those participants that choose to perform the karakia themselves, the sample will be disposed of using established guidelines for discarding biohazard waste after the karakia.

We ask personal questions about your physical health and psychological wellbeing that you may find somewhat uncomfortable. You do not have to answer any question that you feel uncomfortable with. We will provide links to high quality information to help you if need. Our data collectors are well-trained, and they will provide you with the ability to opt out of any questions or assessment and to withdraw from the study at any time without the need to explain why. You may find answering the research questions tiring, but you can take a break if you need to.

If you are in the coaching group, you may find some discussions with the coach uncomfortable or upsetting. The coaches will be trained to provide you with support and links to additional resources to help you if you need.

If you require further information about the study or the questions, you will be able to contact the researcher by email. The contact details are provided at the end of this form.

What are the possible benefits of this study?

At the Baseline assessment you will receive a summary of your risk factors for stroke regardless of which group you are randomised to. All blood tests and other physical measurements will be done for free. The main benefit for will be the ability to learn more about your individual stroke risk factors.

Those in the health coaching group will learn more about how to manage your risk factors to reduce the risk of a future stroke. These lifestyle changes may also help reduce the risk of heart disease, diabetes and cancer as many of the risk factors for these diseases are the same as for stroke. Those in the usual care group will receive an information package at the end of the study with guidelines on managing the risk factors for stroke.

Voluntary Participation and Withdrawal from this study

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 without any explanation or disadvantage to you. You can withdraw from the study by advising anyone on the study team.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

If you chose to withdraw from the study, your usual medical care will not be affected in any way by participating in the study, or by declining to participate or withdrawing from the study at any stage. Your participation in this study will be stopped in the unlikely event that any harmful effects appear or if the doctor feels it is not in your best interests to continue. Similarly, your doctor may at any time provide you with any other treatment he/she considers necessary.

Will any costs be reimbursed?

If your assessment is conducted at a designated study clinic, you will be provided with a $20 food/fuel voucher to use private or public transport for each session that you attend.

You will also receive a $30 food/fuel voucher at the completion of the Baseline and another a $30 food/fuel voucher at the completion of the 6-month assessments as a token of appreciation.

What are my rights?

Rights to Access Your Information.

The study files and all other information that you provide will remain strictly confidential, unless information is revealed that indicates you or someone else is at risk. No material that could personally identify you will be used in any reports or discussions about this study.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected. If any information that may be of benefit to you emerges during the study, we will contact you to let you know.

The section below outlines you rights to access and withdraw your information.

What will happen to my information?

During this study, the research team will record information about your study participation. This includes the answers you provide to our questions. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g., your name, date of birth, or address). The following groups may have access to your identifiable information:

• Research staff (to contact you about the study).

• University study monitors, to make sure the study is being run properly and that the data collected is accurate.

• The ethics committees or government agencies from New Zealand if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.

• Your usual doctor, if any questionnaire responses provide any unexpected result that could be important for your health. This allows appropriate follow-up to be arranged.

Rarely, it may also be necessary for the study researcher to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person OR if the information is required in certain legal situations.

De-identified (Coded) Information

To make sure that your personal information is kept confidential, information that identifies you will not be included in any report generated by the research team. Instead, you will be identified by a study registration number (code). The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed. The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Security and Storage of Your Information

Your identifiable information will be held at the Auckland University of Technology (AUT University) during the study. Your coded information will be entered directly into electronic case record forms and stored on a secure database that is maintained by the University. All electronic information will be stored in password protected files. All storage will comply with local and/or international data security guidelines.

Risks

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g., making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected. Please ask if you would like to access any of your information, including any screening information, during the study. If you have any questions about the collection and use of information about you, you should ask the Co-Lead Investigator, A/Prof Rita Krishnamurthi, by emailing rita.krishnamurthi@aut.ac.nz or by telephoning 09 921 9999 extension 7809.

Rights to Withdraw Your Information

You may withdraw your consent for the collection of your information at any time, by informing anyone from the research team.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

What happens to my INFORMATION AFTER the study?

At the end of the study, your information will be examined along with information from all other people taking part in the study. This information will be examined by a researcher who has with the skills and experience to do so.

Upon completion of the study your electronic records will be stored for 10 years. Paper records (if any) will be stored by University personnel in a locked cabinet at AUT University in Auckland. All electronic information will be stored in password protected files. Any identifying information will not be shared outside of the research team without seeking your permission.

After 10 years all your electronic information will be deleted, and paper forms will be shredded and destroyed with the university confidential waste. After we have looked at all data, we will send you a summary of results if you would like to receive them.

Can I find out the results of the study?

After we have looked at all data, we will send you a plain English summary of study results, if requested.

Who is funding the study?

This study is being funded by Health Research Council, New Zealand.

Who has approved this 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.

Who do I contact for more information or if I have concerns?

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

The **TIIPS Study Manager** Dr Devaki DeSilva on 0800 844 770 (0800 TIIPS0)

OR

**Co-lead investigator:** A/Prof Rita Krishnamurthi by emailing [rita.krishnamurthi@aut.ac.nz](mailto:rita.krishnamurthi@aut.ac.nz) or by telephoning 09 921 9999 extension 7809

OR

the **Lead investigator:** Prof. Valery Feigin by e-mailing [valery.feigin@aut.ac.nz](mailto:valery.feigin@aut.ac.nz) or telephoning 09 921 9166

**Health and disability advocate**

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

**Cultural support**

If you require Māori cultural support talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team Auckland and Waitematā District Health Boards Māori Research Committee) by telephoning 09 486 8324 extension 2324

If you have any questions or complaints about the study, you may contact the Māori Research Advisor by telephoning 09 486 8920 extension 3204

**Health and Disability Ethics Committee**

You can also contact the Health and Disability Ethics Committee that approved this study:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

***Please keep this for your information.***

|  |  |
| --- | --- |
| **Consent Form**  **[Individualised Intervention for Stroke Prevention, TIIPS]** | Text  Description automatically generated |

**Please tick to indicate you consent to the following**

|  |  |  |
| --- | --- | --- |
| I have read, or have had read to me, and I understand the Participant Information Sheet. | o |  |
| I have been given sufficient time to consider whether or not to participate in this study. | o |  |
| 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. | o |  |
| 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. | o |  |
| 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. | o |  |
| I consent to the research staff collecting and processing my information, including information about my health. | o |  |
| 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 o | No o |
| I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study. | Yes o | No o |
| I am aware that my blood samples will be disposed of using established guidelines for discarding biohazard waste, (with provisions for a karakia if relevant). | o |  |
| 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 medical records for the sole purpose of checking the accuracy of the information recorded for the study. | o |  |
| 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. | o |  |
| I understand the compensation provisions in case of injury during the study. | o |  |
| I know who to contact if I have any questions about the study in general. | o |  |
| I understand my responsibilities as a study participant. | o |  |
| I wish to receive a summary of the results from the study. | Yes o | No o |

**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: |

***Thank you for interest in this study.***