Digital Technologies for Stroke Prevention Trial

(DIGITS Trial)

Participant Information Sheet

You are invited to take part in a clinical trial titled "**Digi**tal **T**echnologies for **S**troke Prevention Trial (**DIGITS** Trial)". This study is coordinated by the National Institute for Stroke and Applied Neurosciences (NISAN), 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. 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.

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.

If you agree to take part in this study, you will be asked to sign the Consent Form electronically. You will receive a copy of the Participant Information Sheet, and we will email you a copy of the signed Consent Form for your records.

Study investigators and funder

The principal investigator for this study is Professor Rita Krishnamurthi, Deputy Director of NISAN, AUT.

The funder of this study is the Health Research Council of New Zealand.

Study background

Stroke carries an enormous emotional and socioeconomic impact on patients, families, whānau, and health services. There is an increased risk of further strokes in those who have previously experienced a stroke or transient ischaemic attack (TIA). Recurrent strokes account for one quarter of the stroke burden.

However, strokes, including second strokes, are preventable. There is evidence that the risk of having another stroke can be reduced. This can be done by being aware of, and controlling, certain lifestyle factors (e.g. diet and smoking) as well as following doctors' recommendations and taking medications as prescribed.

What is the purpose of this study?

This study is looking at two different ways (intervention or usual care) to provide stroke/ TIA patients with information about their risk of having another stroke. We will test whether the intervention method is better than the usual care method in helping patients change risk factors, which are things like medication adherence, diet, physical activity, and blood pressure. This type of study is called a randomised controlled trial, in which participants are randomised into the intervention (test) group or usual care group.

Who can participate in the study?

Everyone between the age of 35 and 85 who had a stroke/ TIA in the past three months and has access (personal or family member) to a smartphone or device (e.g. iPhone or Android, iPad or Tablet).

You may not be able to take part if you are very unwell; have problems with mood, memory, or thinking; or are already participating in another clinical trial.

How was I identified as a potential participant?

You were identified as a potential participant because - you have recently experienced a stroke or TIA. The research team has permission to contact you in regard to this study via verbal consent you provided through the hospital or GP.

What happens during this study?

We expect that around 360 people will take part in this study.

The main criteria to be eligible to participate (explained earlier) will be checked by hospital-based researcher through the hospital records where you were admitted for stroke or TIA. If you meet those criteria and agree to participate 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 electronically sign the Consent form.

Following this, a Baseline appointment will be made during which the clinical researcher or research nurse will ask you some questions about your health. The clinical researcher or research nurse will do a final check by asking you some questions about your memory, and mood, to check you meet all the criteria for the study. We will also be collecting all relevant medical and clinical information to the stroke, TIA (e.g. medications, risk factors, blood test results, and physical measurements). If you do not meet the study criteria, you will be informed at this stage.

If you are eligible, you will be allocated into one of two groups in a randomized manner using a computer programme. This will be either the intervention (test) group or the usual care group. The clinical researcher (research nurse) will 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 researchers which group you are in. The researchers collecting your information will be blinded to the group you are in. This type of trial is known as a single-blind trial. This is to avoid bias in the way researchers record your information. Your doctor (GP) will be notified about your participation in the study.

What will happen after randomisation

Usual care group

If you are randomised 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. If baseline physical measurements are required (such as blood pressure, blood glucose, height, and weight), a home visit by a study researcher will be arranged.

In most cases, 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 measure of your weight and blood pressure. Blood cholesterol and 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. The researcher will also ask you some questions about your health and wellbeing. The 6-month assessment may be completed by attending one of the

designated clinics (AUT South, North Shore, City, or a clinic based at Whangarei Hospital) 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.

Intervention (test) group

If you are randomised to the intervention (test) group, you will have the same assessments as the control group as described above at 3, 6, 9 and 12 months. If baseline physical measurements are required (such as blood pressure, blood glucose, height, and weight), a home visit by a study researcher will be arranged. You will also receive the intervention package (either during the time you are at the hospital or following discharge) on how you can manage your stroke risk factors. Your GP will also receive a copy of your assessment summary.

Apart from the researcher conducting the assessment, you will also be contacted by a member of the intervention support team to follow-up about the intervention package you received. This will occur about 1-2 weeks after the baseline assessment. This support person will be aware of which group you are in and will provide any additional support you may need.

During the study, if the researcher is concerned about your health, we may contact your GP to inform them of this. GP notification is a mandatory requirement of the study. You are unable to participate in the study if you do not agree to this. We will discuss this with you at the time of your assessment.

How much time will the study tasks take?

The trial will be for a duration of 12 months, which includes the screening, baseline, 3, 6, and 12-month follow-up activities. Face-to-face assessment at baseline will take approximately 30 minutes, and at the 6 months it will take 30-45 minutes.

The online/ telephone assessment at baseline, 3, 9 and 12 months will take approximately 30 minutes. We expect the total amount of time of your involvement over the 12 months to be around four hours.

What are the discomforts and risks?

There is a small risk of physical discomfort from the blood-test done at the 6 months 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 removedThere 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 you need it. 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.

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 the study?

At the 6 months 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. At the end of the study, you will receive a full profile of your risk factors for stroke. You will be reimbursed for your time and travel/parking costs.

Those in the intervention (test) group will learn more about how to manage your risk factors to reduce the risk of another stroke. Those in the usual care group will receive an information package including relevant information about the intervention at the end of the study with guidelines on managing the risk factors for another stroke.

How can I withdraw from the study?

Taking part in this study is completely voluntary. 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 using the contact details provided at the end of this information sheet.

If you withdraw from the study before your 12-month follow-up assessment, information collected up until your withdrawal from the study, analysed and/or included in a publication by the study, will not be able to be destroyed and will continue to be used and included in the study. This is to protect the quality of the study. No material that could personally identify you will be used in any analysis or publications.

If you withdraw, you will be asked if you are willing to complete follow-up phone calls and data collection without taking part in the intervention. If you agree, you will be contacted for follow-up as scheduled.

Your participation in this study will be stopped in the unlikely event that any harmful effects (for example experience of anxiety, or excessive stress due to any aspect of the study) appear or if you have a conversation with your doctor (GP) about the study and they feel 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.

What are the costs of participating?

Participation in the study will not cost you anything.

However, if you travel to a designated study clinic, you will be provided with a $20 food/fuel voucher to cover the cost of private or public transport for each session that you attend.

You will receive a $60 food/fuel voucher at the completion of the 6-month assessment as a token of appreciation.

What are my rights?

The study files and all other information that you provide will remain strictly confidential, unless information is revealed that indicates you 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.

What if something goes wrong?

If you were injured in this study, which is unlikely, you would be eligible 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 any questions about ACC, contact your nearest ACC office or the investigator.

You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.

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 (GP), 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.

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 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.

Data-linking Data linking will allow us to match your assessment information with your hospital/GP/clinic stroke records.

Future Research Using Your Information

If you agree, your coded (de-identified) information may be used for future research related to applied intervention in this study. This is optional in the consent form.

Māori Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We acknowledge and recognise the taonga of the data collected for this study. To help protect this taonga and to emphasise the importance of recognising and respecting the rights of Māori people and communities in New Zealand when it comes to their data we have consulted with Tui Barbarich-Tawera – Research Engagement Manager from Te Kāhui Poipoi Rangahau (AUT Research office) about the collection, ownership, and use of study data.

What happens after completion of the study?

At the end of the study, your information will be analyzed along with data from all other participants. A skilled and experienced researcher will conduct this analysis.

Upon completion of the study, your electronic records will be stored for 10 years. Any paper records will be securely stored by University personnel in a locked cabinet at AUT University in Auckland. All electronic information will be stored in password-protected files. Your identifying information will not be shared outside of the research team without your permission.

After 10 years, all electronic information will be deleted, and paper forms will be shredded and destroyed using university confidential waste procedures. Once we have analyzed all the data, we will provide you with a summary of the results if you would like to receive them.

How can you find out the results of the study?

If requested, a summary of the main findings of the study will be provided to you within 6 months of the study report being published.

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

You may wish to consult your doctor before participating in the study or if you are concerned about another stroke risk.

For general inquiries, you can reach us on our 0800 number: **0800947260**

If you would like some more information about the study, please feel free to contact **the DIGITS Trial Manager** Dr. Shabnam Jalili-Moghaddam on phone 09 921 9999 ext. 7528 or email shabnam.jalili@aut.ac.nz.

Alternatively, you can contact:

the **Lead investigator**, Professor Rita Krishnamurthi, Deputy Director, NISAN, AUT on 09 921 9999 ext. 7809 or email: rita.krishnamurthi@aut.ac.nz.

Or the **Co-lead investigator** Professor Valery Feigin, Director of National Institute for Stroke and Applied Neurosciences (NISAN), AUT on 09 921 9999 ext. 9166 or e-mail valery.feigin@aut.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:

Free phone: 0800 555 050
Email: advocacy@advocacy.org.nz
Free fax: 0800 2787 7678 (0800 2 SUPPORT)
Website: www.advocacy.org.nz

For Māori cultural support, please contact:

Name: Tui Barbarich-Tawera
Position: Research Engagement Manager – Māori, AUT Research Office - Te Kāhui Poipoi Rangahau
Telephone: +64 921 9999 ext 30463
Email: tui.barbarich-tawera@aut.ac.nz

This study has been approved checks independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Northern BHealth and Disability Ethics Committee has approved this study (2024 EXP 20178). It also has been reviewed and approved by Auckland University of Technology Ethics Committee (

24/202).

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

Please keep this brochure for your information.

Thank you for reading about this study.