PERsonalised Knowledge to reduce the risk of Stroke (PERKS-International Trial)

PARTICIPANT INFORMATION SHEET

STOPSTROKE

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UNIVERSITY of TASMANIA MENZIES Institute for Medical Research · MONASH University · AUT · Government of South Australia SA Health

Invitation

You are invited to take part in a clinical trial titled “PERsonalised Knowledge to reduce the risk of Stroke (PERKS-International)”. Your participation in this study will be for a duration of 12 months. This study is coordinated by the University of Tasmania with collaboration from the Auckland University of Technology, Monash University and the Royal Adelaide Hospital (Central Adelaide Local Health Network).

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests involved. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

What is the purpose of this study?

Stroke is one of the biggest causes of death and disability in the world today. It carries an enormous emotional and socioeconomic impact on patients, families, and health services. However, many strokes are preventable, and you could reduce your risk of having a stroke simply by being aware of, and controlling, certain lifestyle factors.

Did you know that 1 in 4 people will have a stroke in their lifetime? Knowing your risk factors for stroke may help you to prevent stroke.

We are running a study to compare two different ways of showing people their risk factors for stroke. We will test whether one method is better than the other to helping people change their stroke risk factors, which are things like diet, exercise and blood pressure.

How is the study being funded?

This is an investigator initiated study that is funded as part of a 5-year grant from the National Health and Medical Research Council (NHMRC).

Why have I been invited to participate?

You are eligible to take part in this study if you are aged between 35 and 75; have at least two risk factors for stroke; have a smartphone (e.g. iPhone or Samsung Galaxy).

You may not be able to participate if you do not have a smartphone; have a terminal illness; have had a stroke or other cardiovascular event, like a heart attack; are already in another study to manage your stroke risk factors; have a family member participating in this study; or have problems with memory or thinking.

What will I be asked to do?

Firstly, to confirm eligibility for the study, you will be asked to complete a short health and physical activity online questionnaire. This will ask for information about you and your health including your diet, level of physical activity, blood pressure, your weight and height, and daily tobacco intake. If you are eligible to participate in the study, you will then be asked to complete a short quiz at your face-to-face appointment to test whether you have any problems with memory or thinking. If you are found to have problems with memory and thinking on this quiz you will not be eligible to participate. We expect the online health questionnaire to take no more than 30 minutes. Your results of both the health questionnaire and memory quiz will determine your eligibility to participate in the study.

To continue with the study, if you agree to participate, you will be sent a link via e-mail to book an appointment for a health assessment and to complete some more detailed online questionnaires about your health, medical conditions, diet, exercise, quality of life and psychological wellbeing. You can complete the questions online in your own time, which will

take about 30 minutes. All questions are voluntary, and you can choose whether to answer or not.

The face-to-face appointment will be in a central location and can be made at a time convenient to you. At the clinic, a research assistant will take measurements of your risk factors including height, weight, blood pressure, blood lipids and glucose level. We will also seek your permission to access your Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data from Services Australia. Medicare collects information on your doctor visits and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. Services Australia supplies the data with your consent. This data then undergoes a process which is called data linkage. is done by specially trained staff in secure facilities to protect your privacy. With your consent we provide your personal details securely that can then be linked to your use of health services including medications to help manage cardiovascular or metabolic diseases because these will help us to understand how the different ways of presenting the information about your risk factors may have changed health service use.

After the assessment you will be randomized to receive your risk factor information in one of two different ways. You cannot choose which group you are put into. You will be required to read the information we provide to you and follow links to information via your mobile phone. The minimum time required for each intervention is around 10 minutes for reading but you can choose how much time you spend reading the information. Depending on the group you are assigned to, you may receive some brief correspondence (e.g. 1 to 2 minutes reading time) from the study investigators about your risk factors over the next 6 months. You may receive also an additional short questionnaire online 1 week after the first assessment to follow-up about the summary you received. This will take less than 5 minutes to complete.

There will then be three follow-up appointments to complete over 12 months:

1. Online questionnaires at 3 months – 30 minutes
2. Face-to-face health assessment 6 months – 60 minutes
3. Online questionnaires at 12 months – 30 minutes

This will enable us to see if there has been any improvement over time.

You will also be asked to complete a brief satisfaction survey after the 6- and 12- month assessment. There is also the option to participate in a group or individual interview to further explore your experiences with the study.

We expect the total amount of time over the twelve-month period being around 3½ to 4 hours to participate in screening, baseline, 3, 6, and 12-month follow-up assessments.

Are there any possible benefits from participation in this study?

The main benefit for you is to learn more about your individual stroke risk factors. All the physical measurements will be done for free and you will receive a full profile of your risk

factors for stroke. You can also be reimbursed for your time and travel costs if needed to a total value of $50 ($25 at the start and $25 at the end of the study).

Overall, information gained from this research has the potential to improve primary prevention of stroke, heart attack, dementia, diabetes mellitus and some types of cancer.

Are there any possible risks from participation in this study?

There may be some minor discomfort from the blood-test done via a finger-prick to measure blood lipids and glucose. We will also ask questions about your physical health and psychological wellbeing, which may make you feel uncomfortable. You can choose to not answer questions if they make you too uncomfortable. We will provide links to high quality information to help you if needed. 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 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 or phone. The contact details are at the beginning of this document.

Your participation is voluntary

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way.

Your withdrawal from the study

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons and you do not need to provide a reason.

You can withdraw from the study at any time by completing and signing the “Participant Withdrawal of Consent Form”. This form is provided at the end of this document and is to be completed by you and supplied to the research team if you choose to withdraw at a later date.

If you withdraw from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you. You should only choose one of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about you.

What will happen to the information about me?

Your information will be stored, retained and destroyed in accordance with relevant Australian and/or South Australian, Tasmania or Victorian, privacy and other relevant laws’. All information collected for this study will be stored in a secure database on a University of

Tasmania server. This database is password-protected and only accessible to the researchers of this study. The study manager will control access and monitor database use. At the conclusion of the study all data will be non-identifiable. It will be stored on a University of Tasmania server for 15 years from the publication of results of this study. Data will be securely destroyed at the end of the 15 year period and done in such a way that the data cannot be recovered.

Any extension to these storage periods would only occur with ethical approval from the approving institution.

Any paper documents resulting from the study such as consent forms will be stored in accordance with the University of Tasmania's data storage policy. Paper study documents will be stored in a locked draw in a restricted research facility. Only members of the research team who require this information will be given access.

In accordance with relevant Australian and/or South Australia, Tasmania or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

What if I change my mind during or after the study?

You are free to withdraw without consequence before your 12-month follow-up assessment. There is a form to complete to withdraw from the study and you can choose to either keep your data in the study or have it destroyed. At up to 12 months after the start of the study it is easier for us to remove your data, after this time your data may have been included in the analysis and it will not be possible to remove it because it will have been de-identified and potentially included in publications.

How will the results of the study be published?

All published data from this study will be de-identified, without the possibility of re-identification of participant data at any stage. We will only use the information you provide to this study, including your MBS and PBS data, for the purpose of this study. The consent form allows you to choose if we can only use your data for this study or if we can also use it in other studies. This consent also relates to the data we collect from the Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS). If the data is used in other studies, these will be approved by an ethics committee and your data will be de-identified to protect your privacy. We will provide you with a summary of the study findings by e-mail when it has finished.

What if I have questions about this study?

If you have any queries, concerns or issues with this study, please feel free to contact us:

Tasmanian coordinating centre:
Ass/Pro Seana Gall
Phone: 03 6226 4653
E-mail: Seana.Gall@utas.edu.au

South Australian contact:
Prof Timothy Kleinig
Phone: 0421 832 272
Email: Timothy.kleinig@sa.gov.au

Victorian contact:
Prof Amanda Thrift
Phone: 03 8572 2656
E-mail Amanda.Thrift@monash.edu

This study has been approved by the Tasmania Health and Medical Human Research Ethics Committee, [names of other committees here].

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Tasmania
Executive Officer of the HREC (Tasmania) Network on (03) 6226 6254 or email human.ethics@utas.edu.au. The Executive Officer is the person nominated to receive complaints from research participants. You will need to quote H0023615.

South Australia
CALHN Research Office Manager, Ms Bernadette Swart, Ph (08) 7117 2209, e-mail: Health.CALHNResearchGovernance@sa.gov.au.

Victoria
Monash University Research and Ethics Office, Ph (03) 9902 0132, e-mail: managerresearchethics@monash.edu

How can I agree to be involved?

If you are interested in participating in this study, please complete the initial questionnaire at: https://redcap.utas.edu.au/surveys/?s=M7N8DHFE3J

To be involved further we will ensure your informed consent to the study. There two aspects to your consent, the first being participation in the study as described above, and the second being that you authorise the study to access your complete Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data as outlined in the consent form.

This part of the consent form is sent securely to Services Australia who holds the MBS and PBS data confidentially.

If you have a privacy complaint in relation to the use of your MBS/PBS data you should contact the Office of the Australia Information Commissioner. You will be able to lodge a complaint with them.

Website: www.oaic.gov.au
Telephone: 1300 363 992
Email: enquiries@oaic.gov.au
Mail: GPO Box 5218, Sydney NSW 2001

If you have a privacy complaint in relation to the use of general study data you should contact the Privacy Commissioner in your relevant state. You will be able to lodge a complaint with them.

New South Wales
Website: www.ipc.nsw.gov.au
Telephone: 1800 472 679
Email: ipcinfo@ipc.nsw.gov.au
Mail: GPO Box 7011, Sydney NSW 2001

Queensland
Website: www.oic.qld.gov.au
Telephone: (07) 3234 7373 or 1800 642 753
Email: enquiries@oic.qld.gov.au
Mail: PO Box 10143, Adelaide Street, Brisbane, Queensland 4000

Victoria
Website: www.ovic.vic.gov.au
Telephone: 1300 006 842
Email: enquiries@ovic.vic.gov.au
Mail: PO Box 24274, Melbourne VIC 3001

Thank you for your time

PARTICIPANT CONSENT FORM

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Research team

Associate Professor Seana Gall, Menzies Institute for Medical Research, University of Tasmania
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Royal Adelaide Hospital
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Professor Amanda Thrift
Monash University
Amanda.Thrift@monash.edu

Professor Dominique Cadilhac
Monash University
Dominique.Cadilhac@monash.edu

By signing below, I confirm that I have been provided with information and understood the information sheet and in particular:

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Government of South Australia SA Health

- I understand that my involvement in this research will include answering questions about my health, medical conditions, diet, lifestyle, and psychological wellbeing. These questions will be answered at the commencement of the study, then again at 3, 6 and 12 months.

- I understand my involvement in this research will include attending two face-to-face interviews where physical measurements will be taken, including a blood test. The face-to-face interview will be at the commencement of the study and again at 6 months.

- I understand that participation may risk some discomfort arising from the blood test and answering questions about my physical and emotional wellbeing. I understand that if I do feel uncomfortable, I am not obliged to answer all the questions and may withdraw from the study at any time.

- Details of procedures and any risks have been explained to my satisfaction.

- I have been given the opportunity to ask questions and any questions that I have asked have been answered to my satisfaction.

  I understand that all study data will be securely stored on the University of Tasmania premises for fifteen years from the publication of the study results, and will then be destroyed unless I give permission for it to be used to support other research in the future.

  Please select at least one of the following

  ☐ I agree that my study data can be used for this specific project

  ☐ I agree that my de-identified study data can be shared and used for future research projects in the same general area of this research

  ☐ I agree that my de-identified study data can be shared and used for any future research

- I understand that the results of the study will be published so that I cannot be identified as a participant.

- I understand that my participation in this research is voluntary.

- I understand that I am free to withdraw at any time, without explanation or penalty.

- If I wish, I may request that any data I have supplied be withdrawn from the research until 12 months from this day.

- I agree to participate in the study.

Name	
Signature	
Date	

Statement by Researcher

☐ I have explained the project and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

If the researcher has not had an opportunity to talk to participants prior to them participating, the following must be ticked.

☐ The participant has received the Information Sheet where my details have been provided so participants have had the opportunity to contact me prior to consenting to participate in this project.

Name	
Signature	
Date	