

45 and Up Study Participant Information Sheet

The 45 and Up Mobile Health Study

June 2023

This research project is in addition to the main 45 and Up Study. Participation is voluntary. Participation in this project does not change your involvement in the main 45 and Up Study. Information collected by this research project will become part of the 45 and Up Study in future.

What is this research project about?

Heart disease is the leading cause of death in Australia and around the world. The *45 and Up Mobile Health Study* aims to see whether sending lifestyle-related text messages about heart health can engage and empower individuals to make heart healthy changes in their lifestyle, such as improving their diet, increasing their exercise levels and quitting smoking. This research project will find out if text messages about a heart healthy lifestyle, sent over 3 months, can prevent future heart attacks, stroke and heart disease. Selected 45 and Up Study participants who have provided permission to be contacted will be invited to join this research project.

Taking part in this research project is completely voluntary.

Please read this information carefully and feel free to ask questions about anything that you don't understand or want to know more about by contacting the 45 and Up Study team.

Who is running the research project?

The *45 and Up Mobile Health Study* is being carried out by researchers at the University of Sydney, including:

- Associate Professor Sarah Zaman, Academic Interventional Cardiologist at the Westmead Applied Research Centre, Faculty of Medicine and Health, The University of Sydney
- Professor Clara Chow, Professor of Medicine and Academic Director at the Westmead Applied Research Centre, Faculty of Medicine and Health, The University of Sydney

- Simone Marschner, Senior Biostatistician at the Westmead Applied Research Centre, Faculty of Medicine and Health, The University of Sydney
- Anushriya Pant, Doctor of Philosophy Student at The University of Sydney.

This research project is being funded by a National Health and Medical Research Council grant.

Who can take part in the research project?

You are invited to take part in this research project because you may have identified in a previous 45 and Up Study survey that you have heart disease, or are at risk for heart disease, based on a history of high blood pressure, high cholesterol or diabetes.

In order to take part in this research project you need to have at least one of the following conditions diagnosed by a doctor:

- Heart disease – this can include a previous heart attack, having had coronary artery bypass surgery or a coronary heart stent, heart failure or atrial fibrillation
- Stroke and/or transient ischemic attacks (TIAs), also known as a 'mini-stroke'
- Diabetes
- High blood pressure (or taking medications for high blood pressure)
- High cholesterol (or taking medications for high cholesterol).

If you are not eligible, you do not need to do anything further, but if you wish to you can inform the 45 and Up Study team that you are not eligible to participate by emailing 45andUp@saxinstitute.org.au or calling the Infoline 1300 45 11 45.

Your contact details will not be shared unless consent is given to participate in this research project.

If you are eligible and agree to participate in the research project, you will be asked to complete the Eligibility information and Consent Form that follows this information.

What will the research project involve for me?

To determine if you are eligible for this research project, you will be asked to answer some short questions about use of a mobile phone and text messages, your health, lifestyle and diet.

If you decide you want to take part in the research project, you will then be asked to complete the consent section. By completing this form you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to receive the two surveys and text messages that are described below
- Consent to the use of your personal and health information as described
- Consent to the Sax Institute providing your name, mobile phone number, and email address to the research team
- Consent to be contacted by the 45 and Up Mobile Health Study team via texts, calls and emails.

Your participation in the research project will last for 3 months from the time of receiving your first survey.

You will be participating in a randomised controlled trial. In this trial, participants will be randomly allocated (like tossing a coin) to one of two groups. Both groups will complete two surveys, one at the start of the project and one at the end. One group (intervention) will also receive text messages during the project. The other group (control) will not. You will be notified by text message at the start of the project which group you have been allocated to.

In the Intervention Group you will receive a welcome text message stating you are in the intervention group with a link to complete an initial survey.

Over the following 3 months, you will receive 4 text messages per week on different days, and at different times, all during working hours. The text messages will be customised to the information that you provide on your smoking, diet, diabetes,

and exercise status. At the end of the 3 months, you will receive a text message asking you to complete the final project survey.

In the Control Group, you will receive a welcome text message stating you are in the control group with a link to complete the initial survey. At the end of the 3 months, you will receive a text message asking you to complete the final project survey.

Survey information. We anticipate each survey will take less than 10 minutes to complete.

- The survey that you are asked to complete at the start of the trial will include brief questions about whether you smoke, alcohol consumption, your current exercise levels and diet.
- The survey that you are asked to complete at the end of the study project will include brief questions about any new medical history, your smoking status, your alcohol consumption, your current exercise levels and diet, as well as questions that help us assess your quality of life.
- If you are allocated to the Intervention Group, there will also be questions in the second survey about your experiences of being sent text messages and how useful you found them to improve your heart health. This is anticipated to take less than 5 more minutes of your time to complete.

You will be contacted by email and/or text message to complete the surveys. The research team may send up to 3 reminders and if you don't respond to the survey within 2 weeks, they may call you to follow up on the survey.

You will not be required to come for any face-to-face visits, pathology tests, or examinations as part of this research project. All aspects of this project are conducted online via email or via text messages to your mobile phone.

At the end of the 3 months, your participation in the trial will be complete and no further information will be asked from you.

By signing the consent form, you consent to the research project investigators collecting and using personal/health information about you. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Any information obtained that can identify you (such as your name, mobile phone number, and email address) will be stored at the Westmead Applied Research Centre, the University of Sydney, and

kept completely confidential on a secure password-protected computer. Any identifiable information will not be shared with anyone outside of the research project site without your permission and we will make sure to keep this information separate to your health information.

Your data will be entered onto two secure password-protected platforms: one is a secure database and the second is a platform to send the text messages at the research site. Identifiable information such as your first name and email address will be entered into the database in order to perform the survey and follow-ups. Your first name and mobile phone number will be required to send the text messages. Your identifiable information will only be visible to the research project site and delegated research staff at the Westmead Applied Research Centre, the University of Sydney, and will be login and password-protected.

The information you provided from the surveys will be entered and stored on the secure database. This information will be identified by a unique study number and your identifying details will then be removed from the information you give to research study investigators at the completion of the trial.

As part of this research project, the information collected will be linked to health information that you have already provided the 45 and Up Study. At 1 year after you have completed the 3 months program, it will also be linked to information from New South Wales hospital records, Medicare, and the Pharmaceutical Benefits Scheme that you have previously agreed the 45 and Up Study can access. All information and details will be provided to the research project investigators attached to your project number only. None of this information provided will have any personal details attached.

Can I withdraw once I've started?

Being in this research project is completely voluntary and you do not have to take part.

If you wish to withdraw, you can do so at any time without having to give a reason. Your decision will not affect your current or future relationship with the researchers or anyone else at the University of Sydney, your involvement in the main 45 and Up Study, or the Sax Institute. You can withdraw from the research project and still remain in the 45 and Up Study.

If you decide to withdraw consent for participation in this research project or if you decide to take part in the project and then change your mind and want

to withdraw, please contact 45 and Up on the Infoline 1300 45 11 45 or by email 45andUp@saxinstitute.org.au The 45 and Up Study team will advise the research project team about the withdrawal.

If you choose to withdraw, we will not collect any more information from you. If participants choose to withdraw, personal information will be deleted and removed. Information already collected will be kept in our records and may be included in the project results in a de-identified manner, where any identifying details will be removed.

Are there any risks or costs?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this research project nor will you be paid. Taking part in this project is considered to be of a low risk. If you become upset or distressed during, or as a result of your participation in the research, please contact the 45 and Up Study team on the Infoline 1300 45 11 45 or by email 45andUp@saxinstitute.org.au and they will be able to advise referral options. The research investigators will make sure that all of the information you have provided will be collected and kept securely at the research project site.

Are there any benefits?

The research project investigators cannot guarantee or promise that you will receive any benefits from this research. This project aims to further medical knowledge and may improve future management of heart disease. It may or may not directly benefit you. It is possible that participation in this project may reduce your risk factors for future heart disease and increase your awareness of healthy living for your heart health.

What will happen to information that is collected?

All information will be collected and used for health research only. This will be conducted completely confidentially.

By agreeing to be part of this research project, you agree to the Sax Institute providing the investigators with:

- Information relevant to this research project that you previously provided to the 45 and Up Study including information from questionnaires from health datasets
- Data and/or information that you provide as part of this research project

- Information relevant to this research project that is collected via data linkage as part of the 45 and Up Study.

Online survey answers and all the relevant information that you have consented to the Sax Institute giving to the 45 and Up Mobile Health Study team will be collected and stored in a password-protected computer at the research project site (Westmead Applied Research Centre, the University of Sydney). This will be kept safe and only be accessible to authorised research staff. We are committed to maintaining the security and privacy of all information collected throughout this project.

After a period of 15 years, any information related to this project within the research project site will be permanently deleted from the computer system and any hard copies will be destroyed.

The information will also become part of the 45 and Up Study resource. It will be stored by the Sax Institute for the life of the 45 and Up Study plus 7 years and combined with other information from the 45 and Up Study. All future research projects using this information will require approval from a relevant human ethics committee and the Sax Institute.

By providing your consent, you are agreeing to us collecting information about you for the purposes of this research project and any future approved 45 and Up Study research. Any information you provide to us will be stored securely and we will only disclose it with your permission unless we are required by law to release information. There will be no identifiable information published from the research project or any other research.

It is anticipated that the results of any research will be published and/or presented in a variety of forums. If you give us your permission by signing the consent document, we plan to discuss/publish the overall group results in peer-reviewed journals, at scientific meetings, and in the media. All results will be published and/or presented in summarised formats and will be provided in such a way that you will not be individually identifiable in these publications and/or presentations.

The conduct of the 45 and Up Study is overseen by the University of NSW Human Research Ethics and Committee and the conduct of the 45 and Up Mobile Health Study is overseen by the University of Sydney Human Research Ethics Committee.

Will I be told the results of the research project?

All participants can indicate if they are interested in receiving feedback about the overall results of this research project. Participants who respond that they wish to be provided with results will be sent a newsletter with the results in layperson terms via email, once the results are in a published form. As it is not currently known how any future 45 and Up Study approved research project may use the information collected, it will not be possible to provide feedback for any other projects.

What happens when the research project ends?

After the project is completed, the text message service will not be available. A summary of the results may be published at conferences or in journals. If the results of the project are presented to the public, you will not be named. Any data shared will not identify you.

What if I would like further information?

For any questions or comments about this research project, or if you wish to withdraw consent for participation, please contact the 45 and Up Study at the Sax Institute by email 45andUp@saxinstitute.org.au or call the Infoline 1300 45 11 45.

What if I have a complaint or any concerns?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney (2022/036) according to the National Statement on Ethical Conduct in Human Research (2007).

If you are concerned about the way this project is being conducted or you wish to make a complaint to someone independent from the project, please contact the University:

Human Ethics Manager
human.ethics@sydney.edu.au
 +61 2 8627 8176

About the 45 and Up Study

The 45 and Up Study is the largest general population program of health-related research ever conducted in Australia. More than 267,000 people aged 45 and over are participating in the Study, and they are being followed over time through routine follow-up questionnaires and linkage to health and other records.

The 45 and Up Study has been approved by the University of New South Wales Research Ethics Committee. Study participants have also given permission to be invited to participate in further research projects. Each of these research projects has been through a stringent review process prior to approval. Participation in these research projects is optional.

Study governance

The 45 and Up Study is owned and managed by the Sax Institute in collaboration with major partner Cancer Council NSW; and partners: the Heart Foundation; NSW Ministry of Health; NSW Department of Communities and Justice; and Australian Red Cross Lifeblood.

About the Sax Institute

The Sax Institute is an independent, not-for-profit organisation that improves health and wellbeing by driving better use of evidence in policies, programs and services.

The Institute is a registered charity that works with governments, health organisations, research organisations and a network of experts nationwide to analyse policy problems and find the best evidence-based solutions.

Contact the Sax Institute about the 45 and Up Study

For any questions, comments, or complaints about the 45 and Up Study or this research project, to withdraw consent for participation or for further communication, please contact us:

Telephone: 1300 45 11 45 (toll-free Study Infoline)

Email: 45andUp@saxinstitute.org.au

In writing to:

Dr Martin McNamara, Chief Investigator, 45 and Up Study, GPO Box 5289, Sydney NSW 2001

Confidentiality

The 45 and Up Study, and any research projects associated with it, are bound by Commonwealth and State privacy legislation and guidelines: the Privacy Act 1988 (Cth), Health Records and Information Privacy Act 2002 (NSW); and the NSW Health Privacy Manual for Health Information. The 45 and Up Study has strict procedures and systems in place to safeguard participant confidentiality. The Study is also bound by strict scientific ethical accountability to the University of New South Wales.

Ethics Secretariat

University of New South Wales
Sydney NSW 2052

Telephone: (02) 9385 6222

Email: humanethics@unsw.edu.au

Thank you. We could not conduct the 45 and Up Study without the generosity of our participants. We are immensely grateful to all of you. **This information sheet is for you to keep.**