Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Westmead hospital

Title	Tobacco, Exercise, and Diet Messages for primary prevention of cardiovascular disease
Short Title	TEXTME-2
Protocol Number	Version 3.0
Project Sponsor	Westmead hospital
Coordinating Principal Investigator/ Principal Investigator	Prof Clara K Chow
Associate Investigator(s)	Dr Harry Klimis; Dr Aravinda Thiagalingam; Dr Mikhail Altman; Dylan Wynne; Mrs Monique Bartlett
Location	Westmead Hospital

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are at high risk of developing cardiovascular disease in the future. The research project is testing a new treatment to reduce the risk of future heart attacks or cardiovascular events in people at high risk. The new treatment is called TEXTME2 and involves sending text messages with healthy advice on lifestyle and treatments via mobile phones.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments 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.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

This study will be conducted over 2 years and individual participation is for 6 months.

2 What is the purpose of this research?

The purpose is to investigate whether sending advice about healthy living and preventing heart disease via mobile phone text messages to patients who have a high risk of cardiovascular events (such as heart attack and stroke) will improve their risk factors after 6 months. What we hope is that this simple and affordable method of education and support reduces the risk of future heart attacks or cardiovascular events for the people in the study.

TEXTME2 is an experimental treatment. This means that it is not an approved treatment to prevent cardiovascular disease in Australia.

The results of this research will be used by the study doctor Dr Harry Klimis to obtain a Doctor of Philosophy (PhD) degree.

This research has been initiated by the study doctors, Prof Clara Chow and Dr Harry Klimis

3 What does participation in this research involve?

You are invited to participate in this study because you are over 18 years of age, you have presented to the Rapid Access Cardiology Clinic because of chest pain, are at high risk of cardiovascular disease (but don't have disease at present), and you have an active mobile telephone.

Registration visit: (the first visit)
At this visit the study will be explained to you and any questions you may have will be answered. If you agree to participate you will be asked to sign the Participant Consent Form. It is important that you fully understand what the research is about and that you agree, by signing, to all statements on the Consent Form in order to take part.

The Research Coordinator will check that you are eligible for the study.

If you decide to take part in the study, you will have one further study visit (at the outpatients clinic). The follow-up period will be 6 months. Before the final study visit you may be contacted by phone and/or text message to remind you that you have a study visit appointment.

Also at this visit we will ask you questions related to your health and risk of heart disease such as your smoking, exercise and dietary habits. Your blood pressure and heart rate, weight, height, hip and waist circumference measurements will also be taken. You will also be asked to complete more detailed questionnaires about diet, mood (anxiety), quality of life and exercise. A blood test to check for fasting cholesterol levels will also be taken if this was not already taken as part of your assessment at the Rapid Access Cardiology Clinic. The first visit should take less than 30 minutes.

Randomisation (random allocation):
Randomisation will occur within 5 days. What this means is that you will be randomly allocated to receive either text messages (intervention group) or you will continue with standard care. Your chances of being assigned to either group are the same, 50:50. This allocation is random (like "tossing a coin") so if you participate in the study there is an equal chance that you will receive the text messages or your standard care. Neither the doctor nor the study participant

can decide which treatment the participant receives. The doctors and health professionals involved in your care will not be told which group you have been allocated.

You will be notified by text message about which group you have been assigned.

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

Participants who are randomised to the intervention group of the study will receive text messages about smoking (if applicable), diet, exercise, and medication up to 4 times a week, on different days and at different times. You do not need to respond to any of these messages.

Participants who are randomised to the usual care arm of the study will receive standard care including medication and lifestyle counselling as determined by their usual doctors.

6 months End of Study Visit:
You will be asked to attend the outpatient's clinic at the hospital where you were recruited. Before this visit you will be asked not to eat or drink (except for water) after 9pm the day before this visit, so a fasting blood test can be taken to check your cholesterol levels. The amount of blood taken will be equivalent to 5 millilitres (or 1 teaspoon).

Also at this visit your blood pressure, weight, hip and waist circumference measurements will be taken. There are six questionnaires to be completed, about exercise, diet, mood (anxiety and depression), quality of life, medication use, and about health understanding. The final visit should take less than 30 minutes.

In all, the procedures at the two visits should take less than 1 hour. In addition, the researchers would like to have access to your medical record to obtain information relevant to the study, such as medication, treatment and use of hospital services including emergency department information.

At the end of the study visit some participants who received the intervention will be invited to complete a written questionnaire about their experiences of being sent health text messages. It will take approximately 15 minutes to complete.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

You may be reimbursed for any reasonable travel, and parking expenses associated with the research project visit.

4 What do I have to do?

Apart from attending the appointments and filling out the questionnaires above, there are no other requirements for you to do. There are no healthcare or lifestyle restrictions from your enrolment in this study. If during your involvement in the study you are hospitalised due to a cardiovascular condition or heart attack, you will need to contact the research coordinator (the contact details are attached to this form).

5 Other relevant information about the research project

We plan to enrol 246 patients during this study. Westmead Hospital is the only site involved. TEXTME2 is a follow-on study of TEXTME, which has demonstrated that lifestyle-focused text messages delivered participants who have had a heart attack, compared to usual care, reduced bad cholesterol, blood pressure, weight, smoking, and increases physical activity. We want to see if the success of TEXTME can be extended to participants who have not had a heart attack, but are at high risk of having one.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Westmead Hospital.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include non-texting related lifestyle modification programs. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include reducing your risk factors for future cardiovascular events.

9 What are the possible risks and disadvantages of taking part?

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are the risks associated with taking blood:

- minor discomfort and bruising (5%)
- minor bleeding (5%)
- local infection at the site of needle insertion (less than 0.1%).

There may also be risks associated with this trial that are presently unknown or unforeseeable.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to my test samples?

As part of this study, fasting blood samples will be collected for cholesterol levels during the registration (initial) visit if not already performed as part of your routine care during your outpatient clinic appointment, and at 6 months during the final visit. The results of the blood test

will be available on your hospital medical record, and may be made available to your general practitioner if requested as part of routine care.

You will be asked to provide additional consent for the collection of your blood during the research project.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may be able to take all of the medications or treatments you have been taking for your condition or for other reasons. However, it is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the researcher up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14 Could this research project be stopped unexpectedly?

This research project unlikely to be stopped unexpectedly.

15 What happens when the research project ends?

The text message service will not be available after the study finishes.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential, and only accessible to TEXTME2 research staff. Your data (demographics and all responses to questionnaires) is entered directly into a secure online database called RedCap (Research Electronic Data Capture). RedCap is a secure web application for building and managing online surveys and databases. It is currently being used for secure data collection by various projects in The University of Sydney and Western Sydney Local Health District. Access requires a password and username entered in the institutions log-in portal. Identifying information must be entered into this database to allow the text message program to be deliver customised information to you. However, identifying information will be removed/coded prior to any analyses and not used in publications. No patient unit data from your medical record (i.e. your medical record number) will be included in RedCap. 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. The information will not be stored for longer than 5 years, and then permanently electronically deleted. After deletion it will not be possible to access the data.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained, relevant to the study during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, Westmead Hospital, the institution relevant to this Participant Information Sheet, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

In accordance with relevant Australian and New South Wales 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.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This research project is being conducted by Dr Harry Klimis.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Westmead Hospital.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project, you can contact the principal study doctor on (02) 8890 3125 or any of the following people:

Clinical contact person

Name	Harry Klimis
Position	Principal investigator
Telephone	(02) 8890 3125
Email	warc.textme2@sydney.edu.au

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

Complaints contact person

Name	Westmead Hospital Patient Advice and Liaison Service
Telephone	02 8890 7014
Email	*wslhd-pals-mail@health.nsw.gov.au*

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	WSLHD Human Research Office
HREC Executive Officer	Kellie Hansen
Telephone	8890 9634
Email	wslhd-researchoffice@health.nsw.gov.au

Local HREC Office contact (Single Site -Research Governance Officer)

Name	Margaret Piper
Position	Research Governance Officer
Telephone□8890lephone 8890lephone	8890 9634
Email	wslhd-rgo@health.nsw.gov.au

Consent Form - *Adult providing own consent*

Title	Tobacco, Exercise, and Diet Messages for primary prevention of cardiovascular disease
Short Title	TEXTME-2
Protocol Number	Version 3
Project sponsor	Westmead Hospital
Coordinating Principal Investigator/ Principal Investigator	Prof Clara K Chow
Associate Investigator(s)	Dr Harry Klimis; Dr Aravinda Thiagalingam; Dr Mikhail Altman; Dr Dylan Wynne; Mrs Monique Bartlett
Location	Westmead Hospital

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Westmead hospital and The George Institute for Global Health concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I acknowledge that any regulatory authorities may have access to my medical records **specifically related** to this project to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

I consent to the storage and use of blood and tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for this specific research project.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to
Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

Title	Tobacco, Exercise, and Diet Messages for primary prevention of cardiovascular disease
Short Title	TEXTME-2
Protocol Number	Version 3.0
Project Sponsor	Westmead Hospital
Coordinating Principal Investigator/ Principal Investigator	Prof Clara Chow
Associate Investigator(s)	Dr Harry Klimis; Dr Aravinda Thiagalingam; Dr Mikhail Altman; Dylan Wynne; Mrs Monique Bartlett
Location)	Westmead Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Westmead Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.