Participant Information Sheet/Consent Form

Health/Social Science Research - *Adult providing own consent*

Westmead Hospital

Title	Use of text messaging support to aid smoking cessation in patients presenting for surgery – a single site randomised control trial. TextPOP
Short Title	TextPOP - Text Support for the Peri-Operative Patient
Protocol Number	Version 1
Project Sponsor	The University of Sydney
Coordinating Principal Investigator/ Principal Investigator	Dr Aravinda Thiagalingam
Associate Investigator(s)	Professor Clara Chow Dr Farheen Ali Dr Sophie Liang Dr Katherine Phillips Dr Kelly O'Shea Dr Ross Hayhurst Dr Sanaa Mathur Dr Maryanne Selim
Location	Westmead Public Hospital

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, which is called TextPOP - Text Support for the Peri-Operative Patient. You have been invited because you have been booked for surgery and you have identified yourself as a current smoker. Your contact details were obtained from your surgical booking form and the health questionnaire you filled out at the time of booking.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. 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 local health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

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 been read
• Consent to take part in the research project
• Consent to be involved in the research 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.

2 What is the purpose of this research?

This project has been designed to trial a program for people who are due to undergo surgery, to assist them to quit smoking. Smoking is associated with an increased risk of complications related to surgery. These risks can be reduced if the patient quits before surgery.

The project uses a text message based program, based on the successful TEXT ME program that has been rolled out at Westmead Hospital to assist people to make healthy lifestyle choices and improve their overall health.

3 What does participation in this research involve?

If you decide to take part in the research project, you will first be asked some questions to determine if you are eligible to take part, with your consent. These questions are:
1) do you own a mobile phone?
2) is English your primary language?
If the screening questions show that you meet the requirements, then you will be able to start the research project

Individuals who consent to participate in this trial and meet the inclusion criteria will be allocated to the usual care group or to the text message program group. All participants will be contacted at the end of the 12 week trial period. Questionnaires will be completed at the beginning of the 12 week period and at it's conclusion, with questions iincluding success of smoking cessation or current amount of cigarettes smoked. Participants will be asked to not inform researchers which group they were assigned to when they are contacted at the end of the trial period.

The text messaging support will consist of 4 messages a week for 12 weeks and will include:
1) text messages supporting healthy lifestyle changes such as diet and exercise and
2) practical orientation information for patients attending the hospital pre-admission clinic as well as the smoking cessation support messages.
Our aim with this project is to see if the text message program can help patients to quit smoking prior to their surgery and thereby improve outcomes after surgery.

Study week	Activity	Time commitment
1	Initial questionnaire completion – over the phone	30 minutes
2	Text message program 4 per week	0 minutes
3	Text message program 4 per week	0 minutes
4	Text message program 4 per week	0 minutes
5	Text message program 4 per week	0 minutes
6	Text message program 4 per week	0 minutes
7	Text message program 4 per week	0 minutes
8	Text message program 4 per week	0 minutes
9	Text message program 4 per week	0 minutes
10	Text message program 4 per week	0 minutes
11	Text message program 4 per week	0 minutes
12	Text message program 4 per week	0 minutes
13	Text message program 4 per week	0 minutes
14+	Pre-admission clinic visit – fill out follow-up questionnaire regarding smoking after text message program	30 minutes

The only personal health records that will be accessed for this trial are your surgical booking form and health questionnaire to determine if you are a current smoker.

Follow up procedures will occur over the phone, no recordings will be taken of these interactions.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid.

4 Other relevant information about the research project

This study is based on the landmark TEXT ME study which found improvement in patients' heart and lung disease with regular text messages motivating and encouraging them to make good lifestyle choices. We would like to investigate if this program will be successful in improving smoking rates prior to surgery. This trial will be conducted at Westmead Hospital in conjunction with the Westmead Applied Research Centre.

There will be an intervention group (who will receive the text message program) and a control group who will receive usual care. We aim to recruit 276 participants, with 138 people in each group.

5 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 contacted over the phone to complete this form 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 care, your relationship with professional staff or your relationship with Westmead Hospital.

6 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 increased success with quitting smoking or strategies to help you to quit smoking in the future.

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

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team 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 team. This counselling will be provided free of charge.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. You can reply to any of the text messages you receive with 'stop'. This will be confirmed with a follow-up phone call from the

research staff, after which and you will receive no further text messages and will not be contacted for follow up at the end of the trial period.
If you decide to leave the research project, the researchers 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 up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

Part 2 How is the research project being conducted?

9 What will happen to information about me?

By signing the consent form you consent to the research team 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. The information we collect from you and from your questionnaire will be stored in a secure file on a password protected computer in the research department. A code will be applied to your information to ensure your details are not identifiable. 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.
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 express permission. All information collected for this project will be coded and made non-identifiable.

In accordance with relevant Australian and NSW privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research 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 and for the future research described 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.

10 Complaints

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

11 Who is organising the research?

This research project is being conducted by members of the Westmead Anaesthetics department and the Westmead Cardiology department.

12 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 Western Sydney Local Health District.
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.

13 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 problems which may be related to your involvement in the project, you can contact the researcher on 88905555 or any of the following people:

Research contact person

Name	Dr Aravinda Thiagalingam
Position	Lead investigator
Telephone	Via switch (02 88905555)
Email	Aravinda.thiagalingam@health.nsw.gov.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	Patient Advice and Liaison Service (PALS)
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 HREC
HREC Executive Officer	Kellie Hansen
Telephone	02 88909007
Email	researchoffice@health.nsw.gov.au

Local HREC Office contact

Name	Lani Attwood
Position	Research Governance Manager
Telephone	02 88909007
Email	wslhd-rgo@health.nsw.gov.au

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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 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 project without affecting my future care.

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

Name of Participant (please print) _____

Phone consented _____ Date _____

Declaration by 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 Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified 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*

It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary.

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Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or Westmead Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by 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 Researcher (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

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