Participant Information Sheet and Consent Form

Blacktown/Mount Druitt Hospital

Title	SMS SOS: Effectiveness of SMS text messages in improving survival and rehabilitation rates of deliberate self harm patients and reducing representation of DSH patients to hospital.
Short Title	Use of SMS text messages to prevent self-harm.
Protocol Number	AU/1/D928213
Project Sponsor	NSW Health
Coordinating Principal Investigator/ Principal Investigator	Associate Professor Naren Gunja
Location	Blacktown/Mount Druitt Hospital

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have recently experienced self-harming behaviour. The research project is testing a new support strategy for self-harming behaviour that involves SMS support messaging.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the process that's involved. Knowing what's 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 friend or relative.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will still 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 at the end of this form. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- 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?

SMS support messaging is approved in Australia to assist people with conditions such as diabetes and heart disease. However it is not approved to assist self-harming behaviour. As such, it remains an experimental approach to supporting those who have experienced self-harming behaviour and it must be tested to see if it is an effective way to provide such support.

This research has been initiated by the study doctor, Associate Professor Naren Gunja.

It is being conducted by the Western Sydney Local Health District (WSLHD) and has been funded by a grant from the NSW Ministry of Health.

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which approach is best for treating a particular condition. To find out, we need to compare different treatments or approaches. 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).

In this study, there's a 50% chance you will be in a group who receive an SMS support message 1-2 months apart over 12 months.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

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

We may contact you after the study to invite you to an interview to ask your views about the text message program. The interview will be either by telephone or face-to-face. It will take approximately one hour and will be recorded and analysed for research purposes. These comments will be used to inform the program.

4 What do I have to do?

If you are in the group receiving the SMS support messages, you simply need to be aware that you will receive a SMS message every 1-2 months over the next 12 months.

The content of the message is quite general – it will only be understood by you. It does not mention anything about the nature of your contact with the hospital or myself (your treating doctor/treating health professional).

5 Other relevant information about the research project

Half of those taking part will receive the SMS text messages plus normal follow-up care and the other half will receive normal follow-up care only.

This is a follow-up to a previous study where these messages were sent as mail-out 'postcards' rather than as SMS text messages.

About 1200 people will take part in the study, which is also being conducted at Westmead and Nepean Hospitals.

The study is being conducted by the Western Sydney Local Health District (WSLHD), Lifeline Australia and several universities.

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 Blacktown/Mount Druitt 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 follow-up contact with our community mental health team. 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 the sense of support you may have when receiving our contacts over this period, and perhaps having an easier way to get in touch with us if you need to.

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

One possible risk of receiving SMS messages may be that they remind you of a difficult or distressing time in your life.

We believe that keeping in touch with you through these messages, and providing help early if it's needed, probably outweigh any risks like this.

10 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.

11 What if I withdraw from this research project?

If you decide to withdraw from the project, that can be arranged by contacting the research supervisor, Richard Baldacchino, contact no. 0429 128 096. The research supervisor can discuss with you any special requirements linked to withdrawing. They will then organise to stop any remaining SMS support messages from being sent to you.

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 sponsor 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.

12 Could this research project be stopped unexpectedly?

All research projects have the potential to be stopped unexpectedly for various reasons. It is possible, though unlikely, that this project could be stopped due to some unacceptable effects related to the SMS messaging program.

13 What happens when the research project ends?

After 12 months you will receive no further regular messages from the study team. However, any further support you may need will continue to be available at this hospital and the local community health centre.

At the end of the full project you will receive one final text mentioning an “interesting study”, which will simply provide a link to a summary of the key findings of the study in which you participated.

Part 2 How is the research project being conducted?

14 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. Any personally identifiable information about you is kept on password protected computers operated only by researchers on the project. This information is turned into group averages and no personally identifying information about individuals is ever released as part of the study findings. 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 permission.

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.

Information about your participation in this research project may be recorded in your health records.

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 and for the future research described in Section 14 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.

15 Complaints and compensation

If you suffer any adverse effects 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 follow-up care. In the event of specific loss or injury, the parties involved in this research project have agreed to a schedule of appropriate compensation arrangements.

16 Who is organising and funding the research?

This research project is being conducted at the Blacktown/Mount Druitt site by Associate Professor Naren Gunja, Western Sydney Local Health District, and is being funded by NSW Health.

17 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.

18 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 issues which may be related to your involvement in the project, you can contact the principal study doctor, Dr Naren Gunja, on 9845 6688, or any of the following people:

Study Co-ordinator

Clinical contact person

Name	Richard Baldacchino
Position	Clinical Nurse Consultant
Telephone	0429 128 096 (Work)
Email	Richard.Baldacchino@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	Amanda Lloyd
Position	Office of the General Manager
Telephone	9851 6066
Email	wslhd-bmdhexec@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	Western Sydney Local Health District Human Research Ethics Committee
HREC Executive Officer	Kellie Hansen, Research Office Manager
Telephone	8890 8183
Email	Kellie.Hansen@health.nsw.gov.au

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

Name	Margaret Piper
Position	Governance Officer
Telephone	8890 9634
Email	margaret.piper@health.nsw.gov.au

Consent Form

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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 concerning my presenting condition 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

Declaration by Doctor/Mental Health Clinician†

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 Doctor/
Mental Health Clinician† (please print)

Signature Date

† Doctor/Mental Health Clinician must provide the explanation of, and information concerning, the research project.

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

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Form for Withdrawal of Participation

Title	SMS SOS: Effectiveness of SMS text messages in improving survival and rehabilitation rates of deliberate self harm patients and reducing representation of DSH patients to hospital.
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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 treatment, my relationship with those treating me or my relationship with Blacktown/Mount Druitt Hospital.

Name of Participant (please print)

Signature Date

Declaration by Doctor/Mental Health Clinician†

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 Doctor/
Mental Health Clinician† (please print)

Signature Date

† Doctor/Mental Health Clinician 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.