



PARTICIPANT INFORMATION STATEMENT

Quit by Phone Study

Principal Investigator: Dr Ryan Courtney

1. What is the research study about?

You are invited to take part in the Quit by Phone Study, a study conducted as a research trial. This study aims to compare the effectiveness and cost-effectiveness of a Tailored Text Message (TTM) quit support program to the New South Wales (NSW) Quitline telephone quit support service, in helping people quit tobacco smoking.

You have received this information statement because you have: expressed an interest in participating in this study; consulted the Quit by Phone Study webpage to view this information statement or discussed the study over the phone with one of our research team members.

Please read all the information in this document. If you have any questions about the study, you can contact a member of the research team listed at the end of this document.

2. Who is conducting this research?

Research Funder: This study is funded by the National Health and Medical Research Council (NHMRC). The study is being conducted by Dr Ryan Courtney from the National Drug and Alcohol Research Centre (NDARC), at the University of New South Wales (UNSW). Contact details for the research team can be found at the end of this document.

3. Inclusion/Exclusion Criteria

To take part in this research you must meet the following criteria:

- You are 18 years of age or over;
- You are receiving a government pension or allowance;
- You are a current daily smoker* wanting to quit tobacco smoking;
- You can understand and speak English;
- You are willing and interested to make a quit attempt in the next week;
- You have a mobile phone that can receive and send text messages;
- You agree to use the allocated behavioural quit support service (either the TTM or NSW Quitline telephone quit support program); and
- You are able to provide informed consent

* Tobacco smoker defined as person using any combustible tobacco-containing product

4. Do I have to take part in this research study?

Taking part in this research study is entirely voluntary. If you do not want to take part, you do not have to. If you decide to take part and change your mind later, you can withdraw from the study at any stage. Your decision will not affect your relationship with the UNSW or any other organisation. You can choose not to answer any question(s) or parts of questions during interviews.

5. What does participation in this research study require?

If you agree to participate, we will ask you to do the following tasks:

Complete screening and consenting

- The UNSW Quit by Phone Study research team will contact you to complete a screening questionnaire asking about your understanding of the study, and inclusion criteria; this will tell us if you are eligible to take part.
- The screening process will be done via an online survey or a telephone interview with the research team. You will be asked to provide your consent by signing an online electronic form or returning a hard copy form via post.
- This will take approximately 10-15 minutes.



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PARTICIPANT INFORMATION STATEMENT

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- If the screening questionnaire shows that you meet the criteria for inclusion, then you will be able to participate in the study.
- If the screening questionnaire shows that you are not eligible for the study, you will be unable to take part in the study. You can independently contact the NSW Quitline on 137 848, if you would like support to quit smoking.

Complete a baseline telephone interview

The UNSW Quit by Phone Study research team will ask you to do a telephone interview within a few days of joining the study.

- The Quit by Phone Study team will be using Computer Assisted Telephone Interviews (CATI) and will organise a time to do the interview with you.
- The interview will take approximately 20 minutes (depending on how much you have to say).
- You will receive \$50 as compensation for your time completing the interview.
- The interviewer will ask you questions about your smoking, lifestyle, financial and demographic factors.
- This interview should not cause any harm or discomfort, however, if you experience feelings of distress because of the questions, you can let the interviewer know and they will help you. A list of services is also included in the contact details below to help you if necessary.

Comply with random allocation

Once you have finished the first interview, you will be randomly assigned to one of two groups.

- One group will get free tailored text message quit support (TTM) for 52 weeks,
- The other group will get free telephone quit support from the NSW Quitline.

The type of quit support service you receive will be decided by chance, like tossing a coin. Neither you nor the interviewer can choose which group you go into.

Make a quit attempt and use the study quit support service to help you quit tobacco smoking

If you are allocated to the TTM quit support program, the UNSW Quit by Phone Study research team will need to give your first name and your mobile number to the contracted third-party text message service provider called Burst SMS located in Sydney, Australia, for quit support text messages to be sent to you. This third-party service provider is bound by the UNSW's privacy and security requirements and your details will only be used for providing the TTM quit support program.

- The TTM quit support program is a new quit support service developed by the UNSW research team.
- The program aims to provide mobile phone-based quit support to smokers who want to quit and stay quit from tobacco smoking, through an easy-to-use service tailored to individual needs and goals.
- The TTM quit support program will use a virtual Quit Buddy named *Lou*. It will give you on-demand "anytime" support in your quitting process via 'keywords' that you can text-in, as well as the option to opt-out of the service at any time.
- The full list of keywords and instructions for the program, will be given to you for free; the research team will send you the list of keywords via email and also provide you with a small wallet card that you can check at any time.
- The start of a quit attempt is the hardest, particularly in the first few days and weeks. The TTM quit support program will provide more support in the first few weeks of your quit attempt, then will reduce the number of texts sent to you.



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PARTICIPANT INFORMATION STATEMENT

Quit by Phone Study

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To give you the best chance of quitting, please try to use your allocated quit support service for the entire study. Whilst using the allocated quit support service, you can also use quit smoking medications.

If you are allocated to the NSW Quitline telephone quit support service, you will be referred to the NSW Quitline (**137 848**), free-of-charge, and will be given NSW Quitline support, which will help you in your quit attempt(s).

- The NSW Quitline telephone quit support service is a confidential information and advice service, managed by the Cancer Institute NSW.
- Advisors are qualified professionals with specialist training to help you quit tobacco smoking and remain quit.
- They will help you make a quit plan, discuss strategies for managing nicotine withdrawals and cravings, help with managing setbacks, give you advice on products to help you with quitting, and recommend local support services.
- The NSW Quitline also has a free call-back service and callers can schedule more telephone support with a NSW Quitline advisor, after their first telephone consultation.
- Callers can also ask for a Quit Kit (either by mail or e-mail), which has a guide and more resources to help quit tobacco smoking.

Receive a check-in call during the first month of the study

The UNSW Quit by Phone Study research team will call you to do a check-in support call between the 15th and 28th day after completing your baseline interview.

- The check-in call will check to see how you are going with your quit attempt, help you with using your allocated behavioural quit support service, and check for any problems.
- The call will take approximately 5-10 minutes to complete and will include questions about your current smoking status, your use of the quit support service, and any problems or difficulties with quitting.

Complete an online survey about the telephone-based quit support service

During the study, the UNSW Quit by Phone Study research team will collect your feedback on your allocated telephone-based quit support service.

- You will be sent a URL by text message or email, which will let you access an online survey. The survey will ask about the acceptability, helpfulness, and overall use of your allocated quit support service.
- This will be sent to you at the end of the third month of the study.
- This survey will take approximately 10 minutes and you will be reimbursed \$25 for completing this survey as compensation for your time.
- If preferred, the research team can complete this survey with you over the phone.

Complete a follow-up interview

The follow-up interview will take place approximately 12 months after the baseline interview and will be scheduled and completed by the UNSW Quit by Phone Study research team via aCATI.

- This interview will take about 20 minutes (depending on how much you have to say) and you will be given \$50 as compensation for your time doing the interview.

Assessing exposure to cigarette smoke

Finally, as part of the study we will be assessing some participants' exposure to cigarette smoke.



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Quit by Phone Study

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- You may be asked to complete a voluntary breath test (for carbon monoxide) after your follow-up interview to confirm your smoking status. This test is a non-invasive and easy way to test for cigarette smoke exposure.
- A trained professional will collect a breath test directly from you. This will be done either by you visiting the UNSW Trial Coordinating Centre or having a UNSW researcher attend your house to perform this test, or you performing the test yourself using a hand-held device that we send to you.
- If you want to do the test yourself, you will need a smartphone or tablet device to download the app; it is a very simple and quick test, and we will give you instructions and guide you through it.
- For the breath test you will have to blow into a machine, like a random alcohol breath test.
- If the breath test is required, you will be told in the follow-up interview.
- You will be reimbursed \$50 for completing this test as compensation for your time.

Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Schedule (MBS) linkage

If you consent, you will be asked to sign a separate form authorising the study to access your Services Australia information, see the separate Services Australia Participant Information Document and Participant Consent Form.

- Medicare collects information on your doctor visits and the costs, whilst the PBS collects information on the prescription medications you have filed at pharmacies.
- The consent form is sent securely to Services Australia who holds this information confidentially.
- This information is important because it will help us understand the costs related to quitting tobacco smoking and what treatments work best for quitting.
- This information will also help future generations quit tobacco smoking.
- All Services Australia data will only be used for this study and will be destroyed at the end of the study.
- Retuning this form is optional, and you can still participate in this study if you choose to decline.
- Your privacy will always be protected.

Services Australia is not involved in this research other than to provide the information that you have consented to the release of, should you decide to participate in this study. Services Australia has confirmed that this research and any associated documents have received approval from a Human Research Ethics Committee (HREC) that is registered with and operates within guidelines set out by the National Health and Medical Research Council (NHMRC).

6. What are the possible risks, side-effects and/or discomforts?

This study does not use any pharmaceutical products or medical devices. There is minimal risk in participating in this study.

- When quitting tobacco smoking, you may experience symptoms or discomforts related to nicotine withdrawal, such as agitation, anxiety, depression, and disturbed sleep.
- These symptoms happen because the body is adjusting to the lack of nicotine.
- Symptoms are usually stronger in the first 24 to 48 hours of quitting, and steadily ease over the first few weeks after you quit.
- The behavioural quit support services offered in this study, (TTM and NSW Quitline telephone quit support), are designed to help you quit and remain quit from tobacco smoking.
- Both quit support services will help you manage any nicotine withdrawal symptoms by giving you advice, guidance, and support on how to manage and reduce them.



PARTICIPANT INFORMATION STATEMENT

Quit by Phone Study

Principal Investigator: Dr Ryan Courtney

7. What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however,

- This study will give you free telephone-based behavioural quit support, either through the TTM or NSW Quitline quit support program, to help you quit tobacco smoking and stay quit.
- This study is important because it will help develop the most useful programs to assist smokers successfully quit tobacco smoking.

8. Can I take other treatments or medications while participating in this study?

You can take any medications as required whilst you are using the allocated behavioural quit support service in this study. You cannot use other behavioural quit smoking support services (as mentioned above) other than your allocated quit support service while you are in this study. You can get any required medications by visiting your doctor and pharmacist. We also encourage you to inform your doctor or pharmacist that you are participating in this quit smoking study.

9. What will happen to information about me?

Your information will help guide future quit programs and approaches to help people quit tobacco smoking. De-identified group data will be presented in scientific journals and at research conferences. De-identification protects the privacy of people taking part in this study by allowing data to be used without anyone being identified.

By signing the consent form, you consent to the research team collecting and using information about you for the research study.

The research team will store the data collected from you for this research project for:

- A minimum of 15 years after the publication of research results

The information about you will be stored in a:

- Re-identifiable format where any identifiers such as your name, address, date of birth will be replaced with a unique code.

You will be asked to provide your consent for the research team to share or use the information collected from you in future research that:

- Will be used in any future research.

Your information will only be shared in a format that will not identify you. Your contact details will be stored in a separate password-protected computer database at UNSW.

- Information collected from you in an electronic format stored on a UNSW password protected OneDrive only accessible to the approved research investigators.
- Information collected from you using paper-based measures will be stored in securely locked filing cabinets at the UNSW Randwick Campus and only the approved research investigators will have access to this information.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the [UNSW Privacy Management Plan](#).

10. How and when will I find out what the results of the research study are?



PARTICIPANT INFORMATION STATEMENT

Quit by Phone Study

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When the study is finished you will be mailed a summary of the study results. The research team plan to publish and report the results of this research in many ways. All information published will be done in a way that will not identify you. If you would like to receive a copy of the results you can let the UNSW research team know by sending an email to quitbyphone@unsw.edu.au, or call us on our toll-free study number 1800 833 717. The results will also be made available via the UNSW NDARC's website (<http://ndarc.med.unsw.edu.au/>).

11. What if I want to withdraw from the study?

If you consent to participate, you may withdraw from the study at any time.

- You can withdraw by filling out the 'Form for Withdrawal of Participation' (see page 8) and returning it to the UNSW Quit by Phone Study research team via the reply-paid envelope that will be attached to this document when we send it to you.
- Otherwise, you can call or email the UNSW Quit by Phone Study research team and tell them you no longer want to participate in the study (please see below for contact details).
- If you withdraw from the study, the UNSW Quit by Phone Study research team will not collect any more information from you.
- Your decision to no longer participate in this study will not affect your relationship with UNSW Australia or any other organisation.

12. What should I do if I have further questions about my involvement in this study?

If you want further information about the study or need to speak to a UNSW Quit by Phone Study research team member, please contact our toll-free number 1800 833 717 or email the UNSW Quit by Phone Study research team on quitbyphone@unsw.edu.au.

13. Study-related support and contacts

To report study-related discomforts or any other concerns to the UNSW Quit by Phone Study research team, please call 1800 833 717

The after-hours GP Helpline is 1800 022 222

The Principal Investigator can be contacted at the below address:

Dr Ryan Courtney
National Drug and Alcohol Research Centre
University of New South Wales
Sydney, NSW 2052
(02) 9065 7655
r.courtney@unsw.edu.au

14. What if I have a complaint or any concerns about the study and will I receive compensation if I suffer any injuries or have complications??

If you have any concerns or complaints about the study or the way it is being conducted, and would like to speak to someone independent of the study, please contact:

Complaints Contact

Position	Human Research Ethics Coordinator
Telephone	+ 61 2 9348 0759
Email	humanethics@unsw.edu.au



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Quit by Phone Study

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HC Reference Number	HC210410
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If you suffer any injuries or complications as a result of this research project, you should contact the UNSW Quit by Phone Study research 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.



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PARTICIPANT INFORMATION STATEMENT

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ONLY RETURN THIS FORM IF YOU DO NOT WANT TO BE IN THE TRIAL

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales or any other organisation. I have been provided information about the implications of my data once I withdraw from the study.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

Principal Investigator:	Dr Ryan Courtney
Email:	r.courtney@unsw.edu.au
Phone:	(02) 9065 7655
Postal Address:	University of New South Wales National Drug and Alcohol Research Centre Building R3 22-32 King Street Randwick NSW 2031