NDARC
National Drug & Alcohol Research Centre
The Difference is Research

UNSW AUSTRALIA

PARTICIPANT INFORMATION STATEMENT
Quit Smoking Study
Principal Investigator: Dr Ryan Courtney

1. What is the research study about?

You are invited to take part in the Quit Smoking Study, a study conducted as a clinical trial. This clinical trial aims to compare the effectiveness of an 8-week course of nicotine gum or lozenges compared to an 8-week course of nicotine vaporiser (also known as an e-cigarette) for quitting smoking.

You have received this information because you have: expressed an interest in participating in this trial; provided online consent to complete screening if expressing interest in this trial via the study webpage; discussed the trial over the phone with one of our research team members; completed the screening process; and provided consent.

Please ensure that you read all the information provided in this document. If you have any questions about the trial, you can contact a member of the research team using the contact details provided at the end of this document.

2. Who is conducting this research?

The study is being carried out by Dr Ryan Courtney from the National Drug and Alcohol Research Centre (NDARC), University of New South Wales (UNSW). The Study Coordinator's contact details are provided at the end of this document.

The study interviews will be conducted by an independent organisation located in Melbourne, named the Social Research Centre (SRC) who is working with the UNSW research team on this study. SRC will be using Computer Assisted Telephone Interviews (CATI).

Research Funder: This research is being funded by the National Health and Medical Research Council (NHMRC).

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

Participation in any research study is voluntary. If you do not want 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 study at any stage. Your decision will not affect your relationship with the UNSW or any other organisation. You can decline to answer any question/s or parts of questions during interviews.

4. Inclusion/Exclusion Criteria

In order to take part in this research you must have met the following criteria:

- You are willing to allow the research team and study doctor to access your data for quality assurance and to maintain the integrity of the trial;
- You are 18 years of age or older;
- You are receiving a government pension or allowance;
- You are a current daily smoker;
- You are interested in quitting smoking and using the study products;
- You are willing to make a quit attempt in the next two weeks;
- You have a mobile phone that can receive text messages;
- You are available for follow-up over a 7-month period;
- You agree to use the allocated study product and refrain from using another quit smoking medication whilst using the study products;

- You are willing to receive daily quit support text messages during the treatment period (with the option to opt out during the study);
- You speak English and can provide your consent;
- You are willing to and agree to allow the research team to share your contact details for the purpose(s) of (i) our study doctor contacting you if required, (ii) the Social Research Centre conducting two telephone interviews with you, and (iii) research staff from UNSW or Genesis Research Services mailing out your study products.
- You agree to allow the study doctor to call you if they need more information about your health status and to inform the UNSW research team of their decision;
- You are willing to complete two telephone check-in calls with the UNSW research team; and
- You are willing to complete baseline and follow-up interviews with the SRC.

You are unable to take part in this study if you meet any of the following conditions:

- You are enrolled in another quit smoking program or another quit smoking study;
- You are currently using quit smoking medications or products (i.e. NRT, bupropion [Zyban], varenicline [Champix], clonidine, nortriptyline, cytisine, vaporised nicotine products/electronic or e-nicotine cigarettes/inhalers, or other smoking cessation medication or product);
- You have had unstable angina (i.e. chest pain that occurs suddenly and becomes worse over time) in the last two weeks;
- You have been hospitalised for heart attack or stroke or another heart-related condition in the last two weeks;
- You are pregnant or breastfeeding or planning to become pregnant in the next 7 months. If you do become pregnant while participating in this study, you need to immediately cease using all study products and notify the UNSW research team. The UNSW research team is required to follow-up with you until your pregnancy has ended. You should also inform your treating doctor and don't use the study products until further advice from your doctor. Please inform the UNSW research team of your doctor's recommendation;
- You are deemed medically unfit by the study doctor.

5. What does participation in this research require?

If you decide to take part in the research study, we will ask you to complete the following tasks:

Complete a baseline telephone interview

The UNSW research team will ask you to complete a telephone interview with an interviewer from the SRC within a few days of joining the study. The SRC will be using Computer Assisted Telephone Interviews (CATI) and will organise a time with you to complete the interview. The interview will take approximately 20-30 minutes (depending on how much you have to say). The interviewer will ask you questions about your smoking, lifestyle, financial and demographic factors. We do not expect this interview to cause any harm or discomfort, however, if you experience feelings of distress because of the questions asked during the interview you can let the interviewer know and they will provide you with assistance. Alternatively, lists of services are provided in the contact details below to assist you if necessary.

Make a quit attempt and use the study products to help you quit smoking for up to 8 weeks

Once you have completed the first interview, you will be randomly allocated to one of two groups, one group will receive free nicotine gum or lozenges for 8 weeks. The other group will receive two free vaporisers, including 8 weeks supply of liquid nicotine.

The product you receive will be decided by chance, like tossing a coin. Neither you nor the interviewer can choose which group you go into. The study products will be stored and mailed to you from either UNSW or Genesis Research Services located in Newcastle. Instructions for correct use will also be included alongside the mailed study products for free. To give you the best chance of quitting, we ask that you try your study product as soon as you receive it for at least the first 4 weeks of the study. We will be supporting you through your quit attempt.

Whilst you are using the study products, we ask that you refrain from using other quit smoking medications.

Receive check-in support calls during the 8-week treatment period

The UNSW research team will contact you via telephone to complete two check-in support calls in the first month of treatment. The check-in calls will check to see how you are going with your quit attempt, provide assistance for using study products and to check for any problems. Each call will take approximately 5 to 10 minutes to complete. The call will include some questions about your current smoking status and your use of the study products, and any problems or difficulties associated with treatment and quitting.

Receive text message quit support during the treatment period

To give you the best chance of quitting, the research team in the first five weeks of study enrolment will provide additional text message quit support via a virtual Quit Buddy named Lou. Text message quit support has been shown to help smokers quit. It is quick and can be received when and where you need it, as you can view it when you like. The text message quit support program is voluntary and you can opt out at any time and you will still be able to continue participating in the study.

The start of a quit attempt is the hardest, particularly in the first few days and weeks. The text message quit support will provide more text messages in the first couple of weeks, to assist you in dealing with cravings and urges to smoke when they are the strongest. You will receive up to five texts per day initially, but this will taper off to only two texts per day by week five when the short text message program will end. These messages will include some advice around quitting smoking and how to effectively use your study products.

The UNSW research team has engaged a third-party service provider to provide the text messaging service. The UNSW research team will need to provide them with your first name and your mobile number to enable the text messages to be sent to you. The third-party service provider is bound by the UNSW's privacy and security requirements and your details will only be used for the purposes of providing the quit support text messages.

Complete a follow-up interview

The follow-up interview will take place approximately 7-months after the baseline interview and will be scheduled and completed by an interviewer from the SRC using Computer Assisted Telephone Interviews (CATI). This interview will take about 20 minutes (depending on how much you have to say) and at the end of this interview you will receive $40 as compensation for your time via bank transfer or a GiftPay gift card.

For quality assurance purposes and to maintain the integrity of the study, SRC and the UNSW research team would also like to record the baseline and follow-up interviews. This is entirely voluntary, and you can change your mind and stop the recording at any time. If you are not comfortable with being recorded, then no recording will be made, and the interviewer will instead continue with the survey. You are still eligible to participate in the study even if you don't want your interview to be recorded.

Assessing exposure to cigarette smoke

Finally, as part of the study we will be assessing some participants exposure to cigarette smoke. 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 simple and easy way to test for cigarette smoke exposure. Completing this breath test will involve a trained professional collecting 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 decide you'd like to proceed with completing the test yourself, you will need a smart phone or tablet device to download the app; it is a very simple and quick test, and we will provide you with any guidance and instructions as needed. The breath test involves blowing into a machine, a bit like a random alcohol breath test. If the breath test is required, you will be advised in the follow-up interview. You will be reimbursed $40 via bank transfer or a GiftPay gift card, for completing this test as compensation for your time.

Sending a letter to your regular GP (doctor) informing them of your participation in the study

We may inform your regular GP (doctor) that you are participating in this study, but this is optional. GP support is known to increase the likelihood of quitting. Our study clinician may contact your GP. Information will be only collected for purposes of confirming that this study is a good fit for you and as an opportunity for our study clinician to obtain further details on your health and wellbeing. We will send a letter to your GP outlining the study requirements, study products, and any medications that may need to be monitored. You are still eligible to participate in the study even if you do not want us to send this letter.

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

You will receive a Department of Human Services (DHS) consent form that seeks your permission to access your complete PBS and MBS claims history, as outlined on the back of the consent form. Medicare collects information on your doctor visits and the associated costs, whilst PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to the DHS who holds this information confidentially. This information is important because it will help to understand the costs associated with quitting and the most effective treatments for quitting. This information will help future generations quit. All DHS data will be destroyed at the end of the study period and will only be used for purposes of this study. The return of the form is optional, and you can still participate in this study if you choose to decline. If you decide to withdraw from the study, please advise the research team at the time of withdrawal about what you would like to do with your data up until that point. If you do not advise us, the data will continue to be used as described above. Your privacy will always be protected.

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

When you quit smoking, you may experience symptoms associated with nicotine withdrawal, such as agitation, anxiety, depression and disturbed sleep. Taking nicotine gum or lozenges or using a nicotine vaporiser when you stop smoking may reduce these symptoms.

All study products have some common sides effects and these symptoms are often categorised as mild (awareness of event but easily tolerated).

- For the **nicotine gum and lozenge**, common side effects and possible adverse events include hiccups, sore mouth or jaw, jaw pain, sore throat, mouth or throat irritation, oral discomfort, dry mouth, cough, pharyngitis (cold) cough, excess saliva, nausea, stomach upsets, gastrointestinal discomfort, vomiting, diarrhoea, flatulence, constipation, indigestion/heart burn, dyspepsia, upper abdominal pain, insomnia, irritability, dizziness and headache. Most users rate these side effects as being mild. These products are medicines and are safe to use by people who smoke. However, they should be kept out of reach of

children and pets. These products are registered on the Australian Register of Therapeutic Goods (ARTG) and available over the counter.

- For the **nicotine vaporiser**, common side effects and possible adverse events include dry cough, cough, throat irritation, mouth irritation, dry mouth, phlegm, shortness of breath, nausea, headache and dizziness, and these tend to subside over time. These products are not medicines and have not been around for long enough for us to establish safety of long-term use. We can say that they are less harmful than smoking tobacco/cigarettes, but not harmless. Vaporisers and liquid nicotine should not be used by non-smokers and should be kept out of reach of children and pets. We also recommend that you stop using the vaporiser as soon as you feel confident that you won't go back to smoking. These products are unapproved as a therapeutic good on the Australian Register of Therapeutic Goods (ARTG), available for use with a valid prescription.

If you experience any side effects from the study products during the treatment, please notify the UNSW research team on the toll-free number 1800 319 250 or inform the Study Coordinator, Ms Bridget Howard on 02 9065 0284.

You can also contact Poison Information Centre on 131126 (24 hours support) and the after-hours GP Helpline on 1800 022 222, if you require any urgent support.

7. What are the possible benefits to participation?

This study will provide you with free nicotine replacement products and text message quit support to help you quit smoking and stay quit. This study is important because it will help to develop the most effective programs for helping smokers to successfully quit smoking. We hope to use information we get from this study to benefit others who want help to quit smoking and stay quit.

8. Can I have other treatments during this research projects?

You are free to take any medications as required (except quit smoking medications, as outlined above, whilst you are using the study products). It is important to inform the research staff about any treatments or medicines you may be taking, including over the counter medications, vitamins or any other alternative treatments. It is also important to inform your doctor or pharmacist that you are participating in this study and taking these study products.

9. What will happen to information about me?

Information participants give will help guide future quit programs and approaches to help people quit. Deidentified group data will be presented in scientific journals and at research conferences. De-identification protects the privacy of individuals taking part in this study by allowing data to be used without the possibility of individuals being identified. The data collected by the SRC will be stored in an electronic database on password protected computers. The data will be transferred to the UNSW databases on a regular basis using a secured file exchange portal. Only mailing address details will be shared with Genesis Research Services for the purpose of sending your study products to you. The data will be stored at UNSW in a re-identifiable format for a period of 15 years.

Your interest in participating in future research studies was sought during the screening and consent process. If you were interested in being contacted in the future about participating in other studies or sharing your data anonymously with other UNSW researchers in future studies, your consent would have been obtained during the screening and consent call with the research team. Your contact details will be stored in a separate password protected computer database at UNSW.

All information you provide will be stored securely on electronic password protected files. Your contact details will be used for research purposes only i.e. contacting you about the study. Such information remains confidential and will not be given to any other persons. Information provided by participants will be used to guide future strategies aimed at reducing smoking in the community. Only de-identified group data will be presented in scientific journals and at international and national research conferences.

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

When the study is finished you will be mailed a brief summary of the study results. The research team intend to publish and report the results of this research in a variety of 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 research team know by sending an email to quitsmoking@unsw.edu.au or bridget.howard@unsw.edu.au or request via our toll-free study number 1800 319 250. 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 research study?

If you do consent to participate, you may withdraw at any time. You can do so by completing the '**Form for Withdrawal of Participation**' (see page 8) and return to the research team via the reply-paid envelope attached at the end of this document. Alternatively, you can call or email the UNSW research team and tell them you no longer want to participate, please see below for contact details. If you decide to leave the research study, the UNSW researchers will not collect additional information from you. Your decision not to participate 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 the research study?

If you require further information about the study or need to speak to a research team member, please contact our toll-free number 1800 319 250.

13. Study related supports and contacts

Reporting side effects, or any other concerns, you can call 1800 319 250
Poison Information Centre 131 126 (24 hours support)
After hours GP Helpline 1800 022 222

The Study Coordinator can be contacted at the below address:

Ms Bridget Howard
Study Coordinator
National Drug and Alcohol Research Centre
University of New South Wales
Sydney, NSW 2052
02 9065 0284
bridget.howard@unsw.edu.au

14. What if I have a complaint or any concerns about the research study?

If you have any concerns or complaints about the project 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 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC191025

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Quit Smoking Study
Principal Investigator: Dr Ryan Courtney

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:

Study Coordinator:	Ms Bridget Howard
Email:	bridget.howard@unsw.edu.au
Phone:	02 9065 0284
Postal Address:	University of New South Wales National Drug and Alcohol Research Centre Building R3 22-32 King Street Randwick NSW 2031