NDARC
National Drug & Alcohol Research Centre
The Difference is Research

UNSW AUSTRALIA

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM
Quit Smoking Study
1800 319 250
Chief Investigator: Professor Richard P Mattick

1. What is the research study about?

You are invited to take part in the Quit Smoking Study. This research study aims to compare the effectiveness of two nicotine delivery systems for quitting smoking, including: nicotine replacement therapy (NRT) such as nicotine gum or lozenges; and a vaporised nicotine product (VNP) sometimes known as an electronic cigarette or e-cigarette. This study will see if an 8-week course of VNP use is as effective as using an 8-week course of NRT to help smokers stop smoking.

You have received this information because you: expressed an interest in participating in this study; discussed the study over the phone with one of our research team members; completed the screening process; and provided verbal consent to participate in this study.

Please ensure that you read all the information provided in this document. If you have any questions about the study, 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 the following researchers: Professor Richard P Mattick, Dr Ryan Courtney, Dr Emily Stockings, Professor Michael Farrell, Professor Anthony Shakeshaft, Dr Veronica Boland, Ms Alexandra Aiken, Ms Rory Xinyue Chen and Ms Wing-See Yuen from UNSW. The project 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, Australia named the Social Research Centre (SRC) who is working with the UNSW research team on this study.

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 Quitline or the University of New South Wales (UNSW) or any other organisation. You can decline to answer any question/s or parts of questions during interviews.

4. 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 research team will ask you to complete a telephone interview with an interviewer from the Social Research Centre (SRC) within the next few days. The interview will take approximately 20-30 minutes (depending on how much you have to say) and the SRC will organise a time with you to complete the interview. 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. At the end of this interview you will receive $50 as compensation for your time.

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 replacement therapy (NRT) either gum or lozenges for 8 weeks. The other group will receive free vaporiser devices and 8 weeks supply of liquid nicotine. This will be done by chance, like tossing a coin. Neither you nor the researcher can choose which group you go in. The study products and instructions for correct use will be mailed to you for free.

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

The research team will contact you via phone to complete two check-in support calls in the first month of treatment. The support calls will check to see how you are going with your quit attempt and each call will take approximately 10 minutes to complete. The call will include some standard questions regarding any problem associated with your treatment, your progress with quitting, any health concerns, and the use of study products etc.

Complete a final follow-up interview

The second interview will take place approximately 7-months after the first (baseline) interview and be scheduled and completed by an interviewer at the SRC. This second interview will take about 20-30 minutes (depending on how much you have to say) and at the end of this interview you will receive $50 as compensation for your time.

We would also like to record the baseline and final follow-up interviews for quality assurance purposes and to maintain the integrity of the study. 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 researcher will instead make notes during the interview. 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) or a saliva test (for nicotine) after your final interview. These tests are a simple and easy way to test for cigarette smoke or nicotine exposure. This would involve a trained professional collecting a breath test directly from you. This will be done either by you visiting the trial coordinating centre or having a researcher attending your house to perform this test. The breath test involves blowing into a machine, a bit like doing a random alcohol test. The saliva test involves collecting a saliva sample into a dropper container and then applying the saliva to a test strip by using the dropper. Both tests will be performed in front of the participant and any remaining saliva sample will be destroyed by the participant. The test would be confidential and used only for assessing exposure to cigarette smoke and no other substances. If a test is required, we will ask in the final interview whether you would like to complete this test and you will be reimbursed $50 as compensation for your time.

Quitline support

If you talk to Quitline while you are participating in the study, we would like to ask them for information about the number and length of telephone calls you have with Quitline. This is voluntary, and you will still be able to participate in the study even if you don't want Quitline to provide this information to us.

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, while 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.

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

When you give up smoking you may experience symptoms associated with nicotine withdrawal, such as agitation, anxiety, depression and disturbed sleep. Taking NRT or using a VNP when you stop smoking may reduce these symptoms. However, both of these products may have some side effects. These are listed in the Consumer Medicine Information (CMI) leaflet and product information leaflet provided with the products in the pack. Follow the instructions if you experience side effects or contact your general practitioner or pharmacist, or one of the research team. Common side effects of NRT gum include hiccups, sore mouth or jaw, headache, indigestion and nausea, and for NRT lozenges include hiccups, indigestion, gas, nausea, diarrhoea, sore throat and mouth irritation. Most users rate these side effects as being mild. Common side effects of using a VNP include mouth and throat irritation, and these tend to subside over time. Both NRT and VNPs are much safer than smoking cigarettes.

If you experience any side effect from the study products during the treatment, please notify the research team on the toll-free number **1800 319 250** or inform the project co-ordinator's Dr Veronica Boland on **02 9385 0145** or Ms Alexandra Aiken on **02 9385 0111**.
If you have concerns about these potential side effects, please seek further information from the CMI or product information sheet located in the product pack or please speak to your regular doctor or pharmacist or call 1800 319 250 to speak to the research team for advice. 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.

Both study products should be stored safely out of reach of children and animals.

6. What are the possible benefits to participation?
This study will provide you with free nicotine replacement products 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 research study to benefit others who want help to quit smoking and stay quit.

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

You are free to take any non-smoking cessation medications as required. 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 if you visit them during the study period. You must not take any other smoking cessation medications or products other than those supplied to you during your participation in the study.

8. What will happen to information about me?

Information participants give will help guide future quit programs and approaches to help people quit. Non-identifiable group data will be presented in scientific journals and at research conferences. The data collected at 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. 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 will be sought during the screening and consent process. If you are interested in being contacted in the future about participating in other studies, your verbal consent will be obtained during the screening and consent call with the research team and 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.

9. 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 v.boland@unsw.edu.au or a.aiken@unsw.edu.au or request to the research team via our toll-free study number 1800 319 250. The results will also be made available via the school's website (http://ndarc.med.unsw.edu.au/).

10. 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**' and return to the research team via the reply-paid envelope attached at the end of this document. Alternatively, you can ring the research team and tell them you no longer want to participate, please refer to page 6 for contact details. If you decide to leave the research study, the researchers will not collect additional information from you. Your decision not to participate will not affect your relationship with UNSW Australia, Centrelink, Quitline, or the NHMRC.

11. 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.

12. Study related supports and contacts

Study toll-free number 1800 319 250
Reporting adverse events (side effects) 1800 319 250
Poison Information Centre 131126 (24 hours support)
After hours GP Helpline 1800 022 222
Quitline 137 848

The project coordinators can be contacted at the below address;

Dr Veronica Boland or Ms Alexandra Aiken

Dr Veronica Boland	**Ms Alexandra Aiken**
Project coordinator	**Project coordinator**
National Drug and Alcohol Research Centre	**National Drug and Alcohol Research Centre**
University of New South Wales	**University of New South Wales**
Sydney, NSW 2052	**Sydney, NSW 2052**
02 9385 0145	**02 9385 0111**
v.boland@unsw.edu.au	**a.aiken@unsw.edu.au**

13. 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 project, please contact:

Complaints Contact

Position	Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC17909