PARTICIPANT INFORMATION STATEMENT

Break the Habit Study

Effect of nicotine vaping products vs varenicline on smoking cessation among people experiencing social disadvantage: A randomised controlled trial

Principal Investigator: Associate Professor Ryan Courtney

1. **What is the clinical trial about?**

   You are invited to take part in the Break the Habit Study; a study conducted as a clinical trial. This clinical trial aims to compare the effectiveness of varenicline and nicotine vaping products (also known as vapes or e-cigarettes) for quitting smoking. Text message quit support will be provided alongside treatment to all participants.

   You have received this information because you have expressed an interest in participating 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 conducted by Associate Professor Ryan Courtney from the National Drug and Alcohol Research Centre (NDARC), University of New South Wales (UNSW), Sydney. This research is funded by the National Health and Medical Research Council (NHMRC).

3. **Do I have to take part in this clinical trial?**

   Participation in any clinical trial 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

Inclusion Criteria

You can take part in this study if you meet all the following criteria:

1. Aged 18 years or older.
2. Receive a government pension, support, or allowance.
3. Current daily tobacco cigarette smoker and wanting to quit.
4. Willing to use varenicline or nicotine vaping products in your next quit attempt.
5. Willing to make a quit attempt on a designated quit day (8-14 days after first/baseline interview).
6. Own a mobile phone that can receive and send text messages.
7. Willing to receive text message quit support.
8. Willing to complete telephone interviews for baseline, two check-in calls, and a 12-month follow-up, as well as a 4-month online survey.
9. Available for follow-up over a 12-month period.
10. Willing to allow the research team to share your contact details for the purpose of:
    - Passing on your contact details to the study doctor (they may call you if they require information about your health status).
    - Staff from central pharmacy mailing out the study products.
11. Can understand and communicate in English.
12. Can provide informed consent.

Exclusion Criteria

You cannot take part in this study if you meet any of the following criteria:

1. Are pregnant, breastfeeding or planning to become pregnant in the next 12 months*
2. Are currently participating in another quit smoking program, or previously enrolled in this study.
3. Are currently using quit smoking medications or products (i.e., nicotine replacement therapy (patches, lozenges, gum, spray), bupropion (Zyban), varenicline (Varenapix), cytisine, vaporisers containing nicotine (also known as vapes, electronic cigarettes, e-cigarettes, e-nicotine inhalers) or any other quit smoking medications or products.
4. Have allergies to varenicline or nicotine vaping products.
5. Have end stage or severe renal disease.
6. You are deemed medically unfit, by the study doctor, to participate at the time of screening.

*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.

5. What does participation in this research require?

If you decide to take part in the clinical trial, you will first need to complete a screening survey that will assess whether you are suitable for this trial or not. If eligible, we will ask you to complete the below tasks. Aboriginal or Torres Strait Islander participants will have the option for interviews to be conducted with an Aboriginal research staff member.

Complete a baseline telephone interview

All consented participants will be contacted by the research team within a few days of joining the study for their telephone baseline interview which will take approximately 20 - 30 minutes to complete, depending on how much you have to say. The interviewer will ask you questions about your smoking, lifestyle, wellbeing, 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 support services are provided in the contact details below to assist you if necessary. You will receive $50 reimbursement for completing your baseline interview.

Make a quit attempt and use the study products to help you quit smoking

After you complete the first interview, you will be randomly allocated to one of two study groups. The group you are in will determine which study product you receive, and this will be decided by chance, like tossing a coin. Neither you nor the interviewer can choose which group you go into, and your group cannot be changed.

One group will receive varenicline, the other group will receive two vaping devices and a supply of liquid nicotine. Both types of study products will be provided free of charge for up to three months (treatment period). The study products and instructions will be mailed to you in two packs, the initiation and the continuation pack. The initiation pack will be sent to you shortly after your baseline interview and you can receive the continuation pack after your first check-in call. To give you the best chance of quitting, use your study product as directed. Remember that these products are not a magic cure, but they will help make quitting a little easier.

For both treatment groups you will be asked to set a quit date within 8-14 days after your first interview and we will be supporting you through your quit attempt. You will be provided with additional text message quit support throughout the time you are taking the study products. If you would like to continue using your study product past the free supply period, the research team will provide you with instructions on how to obtain them through pharmacies.

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

Varenicline

This is a quit smoking medicine, known by its brand names Champix or Pharmacor, used to help with the symptoms commonly experienced when people quit smoking and to reduce cravings. The initiation pack consists of a white coloured (0.5mg) and blue coloured (1mg) pill that is taken orally with water and after eating. Initially the white coloured (0.5mg) pill is taken once a day, and then twice a day for a total duration of one week. Then, the dosing will change to the blue coloured (1mg) pill twice per day until the end of the treatment period. The continuation pack will consist of the blue pills only.

Nicotine Vaping Products

These are commonly known as "vapes" and are used to help people quit smoking. They can be pre-filled or refillable devices and are used when you have an urge to smoke. The initiation pack will include a pre-filled (alt. brand) and refillable (VAPO Rift Pro brand) device, e-liquid in tobacco and mint flavours, charging cables, and wall adapters. Replacement pods specifically for the VAPO Rift Pro device will also be provided. For the continuation pack, you will have the choice of which e-liquid and flavour(s) you would like and will also receive a spare device for your chosen e-liquid. You may choose to get e-liquids for both devices but will only receive one spare device.

Receive check-in support calls during the treatment period

The UNSW research team will contact you via telephone to complete two check-in calls during the period you are receiving treatment. The check-in calls will check to see how you are going with your quit attempt, provide assistance in using study products, and to check for any concerns. Each call will take approximately 10 minutes to complete. The call will include some questions about your current smoking status and your use of the study products, and any concerns or difficulties associated with treatment and quitting. The first check-in call will occur within 2 to 4 weeks after the baseline interview and the second check-in call will occur 8 to 10 weeks after the baseline interview.

Receive text message quit support during the treatment period

To give you the best chance of quitting, the research team, in the first 12 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, and 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. The text message program is a 12-week program. For the first three weeks you will receive 3 texts per day, and this gradually tapers down to 4 texts per week by the end of the program. These messages will include some advice around quitting smoking and how to effectively use your study products. Furthermore, the text message quit support provides an option for immediate support and advice via 'keywords' that you can text-in. The list of keywords will be on a fridge magnet that will be given to you along with 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 UNSW's privacy and security requirements and your details will only be used for the purposes of providing the quit support text messages.

Complete follow-ups

The first follow-up survey will be available online at 4 months and will take approximately 20-30 minutes to complete. A link to access this survey will be sent to you via text message and email. Alternatively, the research team can also call you and complete this survey over the phone with you. This survey will check on your use of the study products provided, and additional text message quit support. You will be asked to rate the acceptability and helpfulness of study treatments and report on your use of any other smoking cessation aids. You will receive $50 reimbursement for completing this online survey.

The final follow-up interview will take place 12 months after the baseline interview via telephone. This interview will take about 20-30 minutes depending on how much you have to say. You will receive $50 reimbursement for completing this telephone interview.

Assessing exposure to cigarette smoke

Finally, as part of the study we will be assessing some participants exposure to cigarette smoke. Participants who report long term smoking abstinence may be asked to do a voluntary breath test (for carbon monoxide) to confirm their smoking status. This test is a simple and easy way to test for cigarette smoke exposure. The breath test involves blowing into a small device, a bit like a random alcohol breath test. You will have the option to receive the device and instructions through the mail and conduct the test with a trained researcher providing instructions and supervision remotely via a video call. Alternatively, you can visit UNSW (Trial Coordinating Centre) or have a researcher attend your house to perform this test. The test will take approximately 10-15 minutes. If the breath test is required, you will be advised in the 12-month follow-up interview. You will receive $50 reimbursement for completing this test.

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

We would like to 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 Doctor may contact your GP, if required. We will ask for your approval before we send a letter to your GP outlining the study requirements, study products, and any medications that may need to be monitored. If you don't provide the research team with your GPs contact details, then we will provide you a copy of the information to provide to your GP yourself.

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

You will receive a hard copy and electronic Services Australia consent form via email and/or text message that seeks your permission authorising the study to access your Commonwealth health information provided by Services Australia for a period of 15 years; see the separate Services Australia Participant Information Document and Participant 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 Services Australia 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 Services Australia data will be destroyed at the end of the study period and will only be used for the purposes of this study. Returning the form is optional, and you can still participate in this study if you choose to decline to. 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. 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 NHMRC.

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 varenicline or using vaping products when you stop smoking may reduce these symptoms.

All study products have some common sides effects.

- For **varenicline,** 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. Varenicline is registered on the Australian Register of Therapeutic Goods (ARTG). The common side effects include nausea, headache, insomnia, and abnormal dreams. Please refer to the product monograph that is included in the study pack that you receive with your study product.
- For **nicotine vaping products,** these products are not medicines and have not been around for long enough 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. The effects of long-term use of vapes remain unknown, and it is recommended that you stop vaping as soon as you feel safe and confident that you won't go back to smoking. Common side effects include nausea, headache, throat irritation, mouth irritation, and cough.

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 867 071.

You can also contact the Poison Information Centre on 131 126 (24 hours support) and the after-hours GP Helpline on 1800 022 222, if you require any urgent support.

You may also be advised to discontinue treatment if the Study Doctor deems that it is not in your best interest.

7. **What are the possible benefits to participation?**
   This study will provide you with free smoking cessation products and additional 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 from this study to benefit others who want help to quit smoking and stay quit.

8. **Can I have other treatments during this research project?**
   You are free to take any medications as required (except quit smoking medications, as outlined above, whilst you are using the study products). You may wish 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. De-identified 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 will be stored in an electronic database on password protected computers. The data will be stored at UNSW in a re-identifiable format for a period of 15 years.

   If you are interested in being contacted in the future about participating in other studies or sharing your data anonymously with other external or internal researchers in future studies, your consent will be obtained during the screening and consenting questionnaire. Your contact details will be stored in a separate password protected computer database at UNSW. Your Services Australia information will not be shared with other researchers for unrelated studies. 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.

10. **How and when will I find out what the results of the clinical trial are?**
    When the study is finished you will be mailed a 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 via email to breakthehabitstudy@unsw.edu.au or our toll-free study number 1800 867 071. 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 clinical trial?

If you do consent to participate, you may withdraw at any time. You can do so by completing the '**Participant Withdrawal Form**' and returning it 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 clinical trial, the researchers will not collect additional information from you, and you will no longer receive any communication from the research team. However, any data that has already been collected until the date of withdrawal will be included and analysed.

12. What should I do if I have further questions about my involvement in the clinical trial?

If you require further information about the study or need to speak to a research team member, please contact our toll-free number 1800 867 071.

13. Study related supports and contacts

Reporting side effects, or any other concerns, you can call 1800 867 071
Poison Information Centre 131 126 (24 hours support)
After hours GP Helpline 1800 022 222

The Break the Habit Study research team can be contacted at the National Drug and Alcohol Research Centre, University of New South Wales, Sydney, NSW 2052**,** via phone on **1800 867 071**, text on **0428 469 783**, or emailed at **breakthehabitstudy@unsw.edu.au**.

The Principal Investigator, Associate Professor Ryan Courtney, can be contacted on **02 9065 7655** or **r.courtney@unsw.edu.au**.

14. What if I have a complaint or any concerns about the clinical trial?

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
iRECS Reference Number	iRECS4324