



FREQUENTLY ASKED QUESTIONS 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

General

How can I contact the Break the Habit Study team?

• Phone: 1800 867 071

• Email: breakthehabitstudy@unsw.edu.au

• **Text**: 0428 469 783

What am I agreeing to when I participate in this study?

By participating in this study, you agree to:

- Use allocated study products
- Set a quit date and attempt to quit smoking
- Refrain from using other quit smoking medications while using study products
- Receive text message quit support for the first 12 weeks of the study
- Complete the following assessments:
 - o Baseline telephone interview
 - Two check-in calls
 - Online survey at 4 months
 - Final 12-month follow-up telephone interview
 - Breath test if required
- Provide your contact details
- Allow us to pass on your contact details to the study doctor, third-party text message provider (for quit support), and pharmacy (to receive study products)
- Allow the study doctor and research team to review collected data to ensure accuracy and proper study procedures
- Provide a letter to your GP detailing your involvement in the study (this can be given by you or sent directly by us)

Please refer to page 3 (Section 5) in the Participant Information Sheet for more details.

Are there any costs to be in this study?

No, there are no costs to participate, and you will receive approximately 3 months' worth of study products for free.





When I run out of study products, how do I get more?

Both varenicline and vapes can be obtained at pharmacies in person or online. A prescription is required (except for vapes with less than 2% nicotine strength). Free products will not be supplied after the study period. We will provide you with general instructions on how to obtain more products at the end of check-in call 2 (approximately 10 weeks after study enrolment).

If I don't quit smoking, can I keep participating in the study?

Yes. Regardless of whether you successfully quit, your data is extremely valuable, and you can continue participating.

If I stop using the study products, can I keep participating in the study?

Yes. Even if you stop using the study products, your participation is still important.

Someone I know is interested in the study. Can they participate too?

Yes, if they meet the study requirements. Please direct them to our <u>study webpage</u>, where they can fill out the contact form. We will follow up with them after receiving their details.

What happens with the data I provide?

Your information is securely stored in a password-protected database accessed only by authorized research personnel. Any identifying information will not be included in reports or publications.

How will I receive my reimbursement?

- Bank transfer (via BSB and account number or PayID)
- **Gift card** (sent via email)

Reimbursements may take a few business days to process.

How will the study results be shared?

A summary of results will be sent to participants at the study's completion.

How do I withdraw from the study?

You can withdraw by signing and returning the withdrawal form or notifying the study team by phone, email, or text.

What are the common side effects of quitting smoking?

Nicotine withdrawal symptoms are most severe in the first 2-4 weeks of guitting and may include:

- Anxietv
- Changes in appetite
- Depressed mood
- Difficulty concentrating
- Irritability
- Frustration or anger
- Restlessness
- Sleep disturbances
- Urges to smoke
- Weight gain

These symptoms lessen over time. If concerned, contact the research team or your GP.





If I am concerned about a symptom or side effect, who should I talk to?

You can contact the study team:

• Phone: 1800 867 071

Email: breakthehabitstudy@unsw.edu.au

• **Text**: 0428 469 783

Other resources:

• Poisons Information Centre (24 hours): 131 126

• After Hours GP Helpline: 1800 022 222

If I become pregnant while participating, what should I do?

Stop using all study products immediately and consult your doctor. Notify the study team at 1800 867 071 or breakthehabitstudy@unsw.edu.au. The research team will follow up with you until your pregnancy ends. You can still complete the study surveys and interviews.

Study Products

Varenicline

What is varenicline?

Varenicline (Champix or Pharmacor) is a non-nicotine medication that blocks nicotine receptors in the brain, reducing cravings and withdrawal symptoms. It is most effective when combined with willpower and a quit attempt.

What are the common side effects?

- Nausea
- Disturbed sleep
- Vivid dreams
- Headaches

Tips to reduce side effects:

- · Take after eating and with a glass of water
- Take at the same time each day

Refer to the product information leaflet included in your pack for more details.

What should I do if I miss a dose?

Take the missed dose as soon as you remember. If close to your next dose, skip the missed dose and continue your regular schedule. Do not double the dose.

How should I store varenicline?

Store tablets in a cool, dry place below 25°C, away from moisture and humidity. Keep them in their original packaging.

Nicotine Vaping Products (NVPs)

What is a nicotine vaping product?

NVPs (vapes/e-cigarettes) heat a nicotine liquid into vapor, which is inhaled. They help manage nicotine withdrawal symptoms but must be used with willpower to quit successfully.





How often should I use my vape?

Use it whenever you experience an urge or craving to smoke.

What is the difference between the alt. and the VAPO Rift Pro devices?

- alt.: Uses disposable, pre-filled pods
- VAPO Rift Pro: Uses refillable pods with e-liquid bottles

Both come in tobacco and mint flavours.

Try both to see which works best for you.

What are the common side effects of vaping?

- Throat irritation
- Cough
- Dry throat and mouth

Tips to reduce side effects:

- Drink water regularly
- Inhale slowly into your mouth before deeper into your lungs

Refer to the product leaflet in your pack for more details.

How should I store my vape?

Store all vaping products below 25°C, away from sunlight, and out of reach of children and pets.

Text Message Quit Support Program

What is the text support program?

A 12-week text program that sends motivational quit messages. Messages are more frequent at first and reduce over time.

Who/what is Lou?

Lou is a virtual quit buddy providing motivational support through the text program.

How do I use the text message keyword function?

Text **Lou** any of the following keywords for instant support:

- CRAVE Tips to manage cravings
- **STRESS** Tips to manage stress
- LAPSE or SLIP Support for relapses
- **BORED** Distraction tips
- **SOCIAL** Encouragement for social situations