



Participant Information Sheet (PIS)

Pilot Randomised Controlled Trial on Very Low Nicotine Content (VLNC) cigarettes and Illicit Tobacco Use (VLNC tobacco Use Trial)

Name of researchers: Professor Chris Bullen, Dr. Pyi Pyi Phy, Professor Natalie Walker, Dr Alana Cavadino, Dr Braden Te Ao

Kia ora,

We are a group of researchers from the University of Auckland (Waipapa Taumata Rau).

We wish to understand your views around very low nicotine content (VLNC) cigarettes, and your likely behaviour if such cigarettes were the only tobacco products available in New Zealand.

To help you make a decision about participating in the study, we ask that you read this information sheet.

What are Very Low Nicotine Content (VLNC) cigarettes?

The usual strength cigarettes that you may be currently using may contain approximately 5 to 10 mg of nicotine per gram of tobacco. VLNC cigarettes are those with ~95% less nicotine than regular cigarettes, which is less than 0.5 mg of nicotine per gram of tobacco. The cigarettes are not available in New Zealand yet; however, the US Food and Drugs Administration approved VLNC cigarettes in the US on 23 December 2021.

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What is the type of this study?

This is a pilot study.

What is the aim of this study?

The aim of this study is to conduct a pilot study to find out if we can interest people in taking part in a trial involving smoking and understand how they may behave if such cigarettes were the only tobacco available in New Zealand.

Why have I been selected?

You have been selected because you meet the requirements below:

- You are a person who currently smokes cigarettes (defined as someone who has smoked more than 100 factory-made cigarettes and/or roll-your-own (RYO) cigarettes in their lifetime and currently smokes at least once a month)
- You live in New Zealand
- You are aged ≥ 18 years
- You are able to provide consent
- You are willing to smoke a VLNC cigarette
- You are willing to travel to the study site.
- You are able to read and write in English.

You cannot take part in this study if you have any of the following conditions:

- You are pregnant or breastfeeding
- You are currently using smoking cessation medication (including using e-cigarettes daily for the last month)
- You have ever smoked VLNC cigarettes

Where will the study take place?

The study will occur in the Grafton campus of the University of Auckland in Auckland.

How long will the study take?

The study will be completed on a single day over a one-hour period.

How many people will be recruited into the study?

We are hoping to recruit 30 people.

In what language will the study be conducted?

We will conduct the study in English. Unfortunately, due to the limited resources, we are not able to provide the interpretation or translation of the study materials to Te Reo Māori other languages.

What is involved if I take part?

If you are eligible and agree to participate, you will be asked to sign the separate Consent Form on the study day. The study will involve you smoking one cigarette for 30 minutes. You will need to bring a pack of your usual brand cigarette on the study day.

You will first be asked to fill in the baseline information using the paper-based form (Form B), which could take about 15 minutes. We will ask about your smoking history, alcohol, and cannabis use history as part of the data collection.

After that, you will be allocated (at random - like the toss of a coin) to one of three groups – Group 1: Smoking a VLNC cigarette and viewing health messages about VLNC cigarettes.

Group 2: Smoking one of your own cigarettes and viewing health messages about VLNC cigarettes

Group 3: Smoking one of your own cigarettes

Immediately after the cigarette is finished, you will be asked to complete a short questionnaire (paper-based form C).

You will be offered stop-smoking support: a free Advice to Client letter for low-cost NRT (subject to a \$5 dispensing fee) and written information on available stop-smoking support in your area.

Will I be paid to be involved in this study?

Yes, at the end of the study, you will be offered a \$100 voucher in recognition for your time and transport costs to come to the study site and take part.

How long will I be in the study for?

Once you arrive at the study site, the research activities should take no more than one hour.

What are the benefits and risks of this study?

Possible benefits

Your participation will help us to understand the practical challenges of doing a trial using VLNC cigarettes, the acceptability and usefulness of the study processes and materials. We will also offer you support to stop smoking, if you express an interest in doing so, which would benefit your health and help you financially.

Possible risks

Inhaling cigarette smoke of any sort carries significant health risks, including cancer and lung and heart diseases. The VLNC cigarettes used in this study are licensed for sale in the US. This study poses no additional risk than if you were not taking part in the study and continuing your usual cigarettes.

We do not expect any serious risks. In the unlikely event of an emergency, study investigators will call appropriate medical services by dialling 111. The University of Auckland Human Participants Ethics Committee will also be informed within three working days.

Will the information about me be kept confidential?

All information that you provide will remain strictly confidential. No material that could personally identify you will be used in any reports on this study. The data will be kept securely at the School of Population Health, the University of Auckland, and destroyed after 6 years according to the national research guidelines. All electronic records will be password-protected. All future use of the information collected will be strictly controlled in accordance with the Privacy Act 1994.

A unique registration number will be used to keep participant's information confidential. The central computer will generate this unique registration number (participant ID). We will use the registration number, date of birth, and initials for paper-based Form B and Form C to avoid confusion with other participants. We will then enter those data into the online REDcap survey. A designated data manager in our research group will securely maintain the list of participant

codes and corresponding identifiers in the Trial Master File (TMF), which will be securely stored in the School of Population Health. All personal identifiers such as date of birth and initials will not be used during the online data entry process, and only the registration number will be kept, ensuring the anonymity of the de-identification of the data.

In case of emergencies, we may need to re-identify your information. As this is a pilot trial, we are interested in evaluating the extent to which participants correctly understand the questions and complete the forms.

Personal details and any potentially identifying information will be carefully coded and de-identified. This means that specific identifiers, such as unique product names or distinctive personal experiences, will be generalized or removed during data analysis. Data will be securely stored and only accessible to authorized personnel. Your consent will be available only to the research members who signed the confidentiality agreement form. Consent forms will not be accessible to anyone outside the research team. The data will be stored securely for six years, per the University of Auckland's Research Code of Conduct. After this, they will be destroyed through the confidential document destruction service at the University of Auckland.

When will the results be available?

The results will be available in the second half of 2026. If you consent to participate in the study, you will also be asked if you would like to be sent a copy of the study's overall results.

Will the results be published?

The data collected as part of this study may be used in a medical journal article; however, the publication will not include any personal details or any potential identifying information.

Right to Withdraw from Participation

Your participation is entirely voluntary (your choice). You do not have to take part. If you choose not to take part in this study, you will not be affected in any way. You may withdraw from the study at any time without having to give a reason.

Who do I contact if I have any questions or concerns

If you have any further questions or queries about the study, please do not hesitate to contact the Principal Investigator, Professor Chris Bullen, at c.bullen@auckland.ac.nz

You could also contact the head of the General Practice and Primary Care Department of the University of Auckland, Professor Sue Wells, at s.wells@auckland.ac.nz

For any queries regarding ethical concerns, you may contact the Chair, The University of Auckland Human Participants Ethics Committee, Office of Research Strategy and Integrity, The University of Auckland, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 ext.83711. Email: humanethics@auckland.ac.nz.

Approved by the University of Auckland Human Participants Ethics Committee on xxx ... for three years. Reference Number ...

Please keep this sheet for your information.

Thank you for taking the time to read about this study.

Revision Chronology:	Date	Type
PIS V1.0	18 /01/2025	Original
PIS V2.0	05/02/2025	Amendment
PIS V3.0	06/03/2025	Amendment