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Very low nicotine content (VLNC) tobacco use trial

Submission date	Recruitment status	[_] Prospectively registered
19/03/2025	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/03/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
22/08/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to understand how people who smoke might behave if very low nicotine content (VLNC) cigarettes were the only tobacco available in New Zealand. The researchers want to see if people are interested in participating in a trial involving smoking and to explore their reactions to using VLNC cigarettes.

Who can participate?

Adults aged 18 or older who currently smoke (at least once a month and have smoked more than 100 cigarettes in their lifetime) and live in New Zealand can participate. Participants must be willing to smoke a VLNC cigarette, able to travel to the study site, and able to read and write in English. Pregnant or breastfeeding individuals, those trying to become pregnant in the next three months, those currently using smoking cessation medication, and those who have previously smoked VLNC cigarettes are not eligible.

What does the study involve?

Participants will be randomly assigned to one of three groups:

1. Smoking a VLNC cigarette and viewing health messages about VLNC cigarettes.
2. Smoking one of their own cigarettes and viewing health messages about VLNC cigarettes.
3. Smoking one of their own cigarettes without viewing health messages.

Participants will complete a baseline questionnaire about their smoking history, mental health, and perceptions of tobacco and other nicotine products. They will then follow the study procedures based on their assigned group. After completing the tasks, participants will answer follow-up questions about their smoking preferences, potential use of illicit tobacco, and willingness to quit.

What are the possible benefits and risks of participating?

Participants will receive a $100 voucher for their time and travel costs. They will also receive information on smoking cessation support, including a referral for subsidised nicotine replacement therapy. The study has minimal risks, and participation is voluntary. Participants can withdraw at any time without consequences.

Where is the study run from?
University of Auckland (New Zealand)

When is the study starting and how long is it expected to run for?
September 2024 to December 2026.

Who is funding the study?
University of Auckland (New Zealand)

Who is the main contact?
Prof. Chris Bullen, c.bullen@auckland.ac.nz
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Contact information

Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A pilot randomised trial exploring the intentions of people who smoke, to seek illicit tobacco if very low nicotine content (VLNC) cigarettes were the only tobacco available in New Zealand

Acronym
VeLoNic

Study objectives
It is feasible to conduct a full-scale randomised controlled trial assessing the impact of VLNC cigarette availability and reading health messages about VLNC cigarettes on smoking behaviors and illicit tobacco-seeking intentions, as determined by:
1. Achievable recruitment rates and the time required to recruit participants.
2. Participant attendance and completion of study tasks.
3. Participant comprehension of questionnaires and study procedures.
4. The ability of the study to effectively capture relevant participant responses.
5. Identification of any reported difficulties encountered during the study.
6. Incidence of any reported adverse events related to participation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/03/2025, University of Auckland Human Participants Ethics Committee (UAHPEC) (Level 3, 49 Symonds Street, Auckland, 1010, New Zealand; +64 (09) 373 7599 Ext 83711; humanethics@auckland.ac.nz), ref: UAHPEC28879

Study design
Three-arm parallel-group open-label pilot randomized trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Smoking

Interventions

Participants will be given a hypothetical scenario where all smoked tobacco legally available for purchase in New Zealand has 95% less nicotine than the tobacco they normally smoke. Participants will then be randomised to: 1) smoking a VLNC cigarette and viewing health messages about VLNC cigarettes, 2) smoking one of their own cigarettes and viewing health messages about VLNC cigarettes, or 3) smoking one of their own cigarettes. All data will be collected from each participant within an hour on one day

Intervention Type
Mixed

Primary outcome(s)
The main focus of the trial is to determine whether a larger trial would be feasible to conduct based on the following criteria.
1. Can people be recruited, and how quickly can they be recruited?
This will be measured by
- the number of participants recruited in a month
- the number of participants in each ethnic group (NZ Europeans, Māori, Pacific people, Asian, Middle Eastern/Latin American/African and other ethnicity) as defined by Stat NZ (level 1 classification)
- the number and proportion of participants in priority and non-priority populations. Priority populations are defined as people with self-reported anxiety and/or depression, young people (aged 18-30 years) of low educational attainment or individuals who report heavy alcohol and/or cannabis use (following the same definitions as the CENIC-NZ study.
2. Do people attend the study site on their scheduled day and stay for their required time?
This will be measured by using on-site attendance records.
3. Are the study tasks and questionnaires understandable to participants? Specific questions will be asked in the questionnaire.
4. Are all questions answered? This will be determined by counting the number of unanswered questions in the questionnaire.
5. Did participants highlight any difficulties with the trial?
This will be measured by using the onsite records and feedback from the study participants.
6. Did participants face any adverse events or symptoms after smoking a VLNC cigarette?
This will be measured by using the onsite records and feedback from the participants.

Key secondary outcome(s))
The secondary focus of the trial is to gather data on the likely impact of the tested interventions on potential participant behaviours. The secondary outcome measures will be measured immediately after smoking and reading the health messages on VLNC cigarettes under the hypothetical scenario of all smoked tobacco legally available for purchase in New Zealand having 95% less nicotine than the tobacco they normally smoke. Specifically:
1. Their likelihood of using specific harmful products, measured using a 7-point Likert scale ranging from 0 to 6, where 0 is ‘very unlikely’ and 6 ‘very likely’. These products include:
1.1. VLNC cigarettes.
1.2. Illicit tobacco (i.e., tobacco with regular nicotine levels).
1.3. Homegrown tobacco (i.e., strictly self-grown tobacco. In New Zealand, individuals are allowed to manufacture up to 5kg of home-grown tobacco per adult per year for personal use. This amount translates to approximately 50 to 100 cigarettes per person daily, depending on the tobacco content per each cigarette. However, this tobacco is strictly for personal consumption and cannot be sold or shared).
1.4. Nicotine e-cigarette (vapes).
1.5. Heated tobacco products.

1.6. Nicotine Replacement Therapy (i.e., nicotine gum, patches, or nicotine lozenges or nicotine mouth spray).
1.7. Alcohol.
1.8. Cannabis/Marijuana/ Tetrahydrocannabinol products.
1.9. Other illicit drugs.
1.10. Their desire to quit smoking.
2. Their likelihood to add nicotine to low-nicotine cigarettes or other smoked tobacco was measured using a 5-point scale running from 0 to 4, where 0 is 'never' and 4 is 'daily'.
3. The maximum amount they are willing to pay per VLNC cigarette is measured in New Zealand dollars.
4. If the participants select 1 and above on the 7-point Likert scale for illicit tobacco, the following questions will be triggered:
4.1. The maximum amount you are willing to pay per illicit cigarette, measured in New Zealand dollars.
4.2. The maximum time you would be prepared to travel to get illicit cigarettes, measured in minutes.
4.3. Their reasons for seeking illicit cigarettes to be collected in open field response.
5. The following perception questions will be asked of all the participants:
5.1. Perceptions on general harms of tobacco and vaping: The perceived harm of cigarettes, VLNC cigarettes, and e-cigarettes containing nicotine, and NRT will be measured on a five-point Likert scale (scores will range from 0 to 4, where 0 is "Not at all harmful" and 4 is "extremely harmful").
5.2. Perceptions of Harm: Regular vs. Reduced-Nicotine Cigarettes: Participants' perceptions of harm will be recorded by asking whether they believe cigarettes with 95% less nicotine are more harmful or equally harmful or less harmful or if they don't know, compared to regular cigarettes.

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Currently smoke (defined as people who have smoked more than 100 factory-made cigarettes and/or roll-your-own (RYO) cigarettes in their lifetime and currently smoke at least once a month
2. Live in New Zealand
3. Are aged ≥18 years
4. Are able to provide consent
5. Are able to read and write English
6. Are willing to smoke a VLNC cigarette
7. Are willing to travel to the study site

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Key exclusion criteria
1. Are pregnant/breastfeeding or are women trying to become pregnant in the next three months
2. Are currently using smoking cessation medication (including using e-cigarettes daily for the last month)
3. Have ever smoked VLNC cigarettes

Date of first enrolment
14/03/2025

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
New Zealand

Study participating centre
University of Auckland
School of Population Health
Grafton Campus
Auckland
New Zealand
1010

Sponsor information

Organisation
University of Auckland

ROR
https://ror.org/03b94tp07

Funder(s)

Funder type
University/education

Funder Name
University of Auckland

Alternative Name(s)
University of Auckland, New Zealand, UoA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
New Zealand

Results and Publications

Individual participant data (IPD) sharing plan
Not expected to be made available due to consent not obtained to do so.
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.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	06/03/2025	20/03/2025	No	Yes
Protocol file	version 3	07/03/2025	20/03/2025	No	No