Adding a vaporised nicotine product to standard behavioural treatment for low-socioeconomic status smokers: A study protocol for a randomised controlled trial

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Background

- The public health community is divided about the efficacy of vaporised nicotine products (VNPs) for smoking cessation.
- Low-socioeconomic status (low-SES) smokers discontinue current smoking cessation medications prematurely.
- Little is known about the acceptability, efficacy and safety of VNPs among low-SES smokers who are motivated to quit.

Aim

- To evaluate the efficacy and cost-effectiveness of VNP use compared to an oral form of nicotine replacement therapy (NRT) for smoking cessation in Australian low-SES smokers wanting to quit smoking.

Method

Setting and study design

- Computer generated two group block randomised open-label trial with allocation concealment.
- Participants will be randomly allocated to either: (i) control group (NRT) or (ii) intervention group (VNP).
- All participants will be offered Quitline telephone support.
- Eight weeks free treatment: 4mg NRT gum or lozenge; 11mg/mL e-liquid + VNP device.

Inclusion criteria	Exclusion criteria
• ≥18 years of age • Government welfare benefit • Current daily smoker • Wanting to quit • Willing to use NRT/VNP • Able to give verbal consent • Access to a telephone • Willing to complete study interviews	• Pregnant or breastfeeding • Using cessation medications • Participating in another program • Allergic to study medications • Hospitalised for heart attack or stroke in last 3-months • Unstable angina or asthma

Participants

- A total of 868 participants will be randomised (464 per arm).

Data collection

- Recruitment: Quitline services and via print and social media advertisements.
- Interviews: baseline and 7-month follow-up conducted via Contract Research Organisation (CRO).
- Safety and adherence data: two check-in calls conducted by research team and 7-month follow-up interview by CRO.
- Health economics: data linkage with Government health records.

Participant reimbursement

- $50 for 7-month follow-up and biochemical verification completion.

Study flow diagram

Recruitment
- Advertisements: smokers will call trial coordinating centre (TCC);
- Quitline referrals: interested smokers referred to TCC

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Screening and consenting – TCC
- Assesses eligibility criteria/health conditions and obtains verbal consent

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Authorise enrolment – Study Clinician
- Screen participant files, check audio recordings, consultation via telephone (as required) and provide enrolment approval

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Baseline interview – CRO
- Baseline data collection and randomisation
- Set quit date and provide treatment instruction

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Medication dispensing – TCC
- Allocated treatment sent via mail

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Check-in calls – TCC
- Two check-in calls (at two and four weeks post medication dispensing) to assess smoking status, adherence and safety

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Follow-ups – CRO
- Final follow-up: 7-months post randomisation

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Biochemical verification – TCC
- Carbon Monoxide (CO) monitoring for those who meet primary outcome

Outcomes

Primary

- Carbon monoxide (CO) verified 6-months continuous abstinence at 7-month follow-up; and
- Exhaled CO level of ≤9 ppm confirmed abstinent.

Secondary

- Self-reported point prevalence abstinence, acceptability and adherence to treatment, safety, quality of life, number of cigarettes smoked and continued use of cessation aids.

Implications

- The study will provide: i) evidence for the role of VNPs in cessation; ii) the cost-effectiveness of VNPs compared to standard care; and iii) the safety of VNP use compared to oral NRT.
- Increasing cessation rates for low-SES smokers is a public health priority.
- Outcomes will assist Australian and international policy-makers to make evidence-informed decisions.

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