STUDY SYNOPSIS

Study Title: The Quit Smoking Study - Vaporised nicotine products (VNP) versus nicotine replacement therapy (NRT) for tobacco smoking cessation among low-socioeconomic status (SES) smokers: a randomised controlled trial (RCT)

Funding: National Health and Medical Research Council

Aim: To evaluate the cost-effectiveness and safety of vaporised nicotine products (VNPs) plus text message behavioural support compared with oral nicotine replacement therapy (NRT) plus text message behavioural support for smoking cessation in Australian low-SES daily smokers.

Relevance: Findings from this trial will provide much needed data to guide healthcare providers' and policy makers' decision making on the value of VNPs as smoking cessation aids.

Inclusion Criteria	Exclusion Criteria
• 18 years of age or older • Receiving a government pension or allowance (proxy for low-SES) • Are a current daily smoker • Interested in quitting smoking and using the study products • Willing to make a quit attempt in the next two weeks • Have a mobile that can receive text messages • Available for follow-up over a 7-month period • Can speak English and provide consent	• Participating in another quit smoking program • Using a quit smoking medication or product • Diagnosed with unstable angina • Hospitalized for stroke, heart attack or another heart-related condition in the last 2 weeks • Pregnant, breastfeeding or planning to become pregnant in the next 7 months • Deemed medically unfit by the study clinician

Procedure. This study is being undertaken in Sydney and the wider catchment region and will recruit 1058 participants. The Trial Coordinating Centre (TCC) is located at the University of New South Wales, Sydney, Randwick Campus.

Screening and consenting. All interested smokers will be contacted by the research team at the TCC via telephone. The initial screening call will include eligibility checking, electronic (or hard copy) consent and baseline interview scheduling. A Study Doctor will assess eligibility, authorize enrolment and issue randomized participants in the VNP group with a prescription.

Baseline telephone interview and randomisation. All baseline interviews will be conducted by an independent contract research organisation (CRO). After baseline interview, participants will be randomised to either treatment.

Treatment conditions. There are two conditions, VNP and NRT, that will be equally matched in access to free mailed treatment. Participants in the VNP group will receive 8-week supply of nicotine e-liquid and two different vaporisers (a tank and pod device). Participants in the NRT group will receive 8-week supply of either nicotine gum or lozenge (4mg). Both treatment groups will receive text message behavioural quit support.

Safety monitoring. Adverse event data will be collected at two check-in calls during the active treatment phase, and also at the final follow-up interview. A study clinician, UNSW research team, and an independent Data Safety Monitoring Board (DSMB) will oversee participants' safety, medication use, and safety data collection.

Follow-up interviews. All follow-up interviews will be conducted by an independent CRO. The interviewers conducting the follow-up interviews will be blinded to the treatment allocations. The follow-up interview will occur 7-months post trial enrolment. Participants will receive $40 for completing the follow-up interview.

Primary outcome. Biochemically verified six-months continuous abstinence, measured at 7-months post-randomisation. Participants meeting six-months continuous abstinence will be asked to complete a voluntary CO breath test. Participants will receive $40 for completing the test.

For schematic representation of trial methodology, please see Study Flow Diagram below:

Study flow diagram