Effectiveness, safety and cost-effectiveness of vaporised nicotine products versus nicotine replacement therapy for tobacco smoking cessation in a low-socioeconomic status Australian population: A study protocol for a randomized controlled trial

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Introduction and Aims: In Australia, tobacco smoking rates are significantly higher among low socio-economic status (low-SES) populations.(1) This study evaluates the effectiveness, safety and cost-effectiveness of vaporised nicotine products (VNPs) compared with nicotine replacement therapy (NRT) for smoking cessation among low-SES Australian smokers.

Design and Methods: This is a two-arm, open-label, randomized controlled trial (RCT) conducted at the National Drug and Alcohol Research Centre, University of New South Wales, Australia. Participants are people who smoke daily, are interested in quitting and receive a government pension (N=1058). Participants will be randomized (1:1 ratio) to free: 8 weeks of VNPs (pod [40mg/mL nicotine salt] and tank device [18mg/mL freebase nicotine] in mixed flavours) or 8 weeks of NRT (gum or lozenge; 4mg). Participants receive daily text message behavioural support for 5-weeks. Assessments are undertaken at baseline, two check-in calls within first month and final follow-up at 7-months to ascertain smoking status, treatment adherence and adverse events. The primary outcome is six-month continuous abstinence verified by carbon monoxide breath test of ≤5ppm at 7-month follow-up. Safety and cost-effectiveness of VNPs versus NRT will also be evaluated.

Results: Research in progress, results unavailable at time of submission

Discussions and Conclusions: Further data are required to strengthen certainty of evidence for VNPs aiding smoking cessation, particularly for newer generation pod devices. To our knowledge, this trial is the first to offer choice of VNPs and no comparative effectiveness trial data exists for new pod devices.

Implications for Practice or Policy: If effective, the findings can inform wider implementation of VNPs to aid smoking cessation in a priority group.

Disclosure of Interest Statement: No authors have received financial support from any companies for the submitted work. DP provides advice to the Australian Government Department of Health on funding decisions. CM was the founding chairman of the Australian
Tobacco Harm Reduction Association, a health promotion charity which received funding from the vape industry to establish the charity. NZ is chair of an Expert Advisory Group for the Royal Australian College of General Practitioners smoking cessation guidelines. MF receives unrestricted research funding from Seqirus and Indivior. The study is funded by an Australian National Health and Medical Research Council (NHMRC) grant (APP1127390). The National Drug and Alcohol Research Centre at the University of New South Wales is supported by funding from the Australian Government under the Substance Misuse Prevention and Service Improvements Grants Fund. RC is supported by a NHMRC Career Development Fellowship (1148497).

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