

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

BRIDGET C. HOWARD¹, HAYDEN MCROBBIE¹, DENNIS PETRIE², DANIEL BARKER^{3,4}, COLIN MENDELSON⁵, JACK ANDERSON¹, RON BORLAND⁶, FELIX NAUGHTON⁷, PIOTR TUTKA⁸, NICK ZWAR^{9,10}, ANTHONY SHAKESHAFT¹, CORAL GARTNER¹¹, ROBYN RICHMOND¹⁰, WAYNE HALL¹², RICHARD P. MATTICK¹, MICHAEL FARRELL¹, RYAN J. COURTNEY¹

¹National Drug and Alcohol Research Centre, UNSW Sydney, Sydney, Australia, ²Centre for Health Economics, Monash Business School, Monash University, Caulfield, Australia, ³Hunter Medical Research Institute, New Lambton Heights, Australia, ⁴School of Medicine and Public Health, University of Newcastle, Newcastle, Australia, ⁵No affiliation, ⁶School of Psychological Sciences, University of Melbourne, Melbourne, Australia, ⁷Behavioural and Implementation Science Group, School of Health Sciences, University of East Anglia, Norwich, United Kingdom, ⁸Department of Experimental and Clinical Pharmacology, University of Rzeszow, Rzeszow, Poland, ⁹Faculty of Health Sciences and Medicine, Bond University, Gold Coast, Australia, ¹⁰School of Population Health, Faculty of Medicine and Health, UNSW Sydney, Sydney, Australia, ¹¹School of Public Health, Faculty of Medicine, The University of Queensland, Brisbane, Australia, ¹²The National Centre for Youth Substance Use Research, The University of Queensland, Brisbane, Australia.

Presenter's email: <bridget.howard@unsw.edu.au>

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 ≤ 5 ppm 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.*

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