

Can e-cigarettes assist opiate agonist treatment clients to quit smoking? Results from HARMONY, a multi-site, single-blind RCT of e-cigarettes and NRT

MELISSA JACKSON^{1,2,4}, SAM LAWSON¹, ANTONI PAZESKI¹, BETTINA SWEETMAN¹, EMMA AUSTIN^{1,3}, PAUL HABER^{4,5}, CRAIG RODGERS⁶, TIM HO⁷, RICHARD HALLINAN⁸, NICHOLAS LINTZERIS^{4,9}, ERIN NOLAN¹⁰, CHRISTOPHER OLDMEADOW¹⁰, NADINE EZARD^{4,6,11}, CORAL GARTNER¹², BILLIE BONEVSKI¹³, ADRIAN DUNLOP^{1,3,4}

¹ Drug and Alcohol Clinical Services, Hunter New England Local Health District, Newcastle, New South Wales, Australia, ² School of Psychological Sciences, University of Newcastle, Callaghan, New South Wales, Australia, ³ School of Medicine and Public Health, University of Newcastle, Callaghan, New South Wales, Australia, ⁴ Drug & Alcohol Clinical Research & Improvement Network, St Leonard's, New South Wales, Australia, ⁵ Drug Health Services, Sydney Local Health District, Camperdown, New South Wales, Australia, ⁶ Alcohol and Drug Service, St Vincent's Hospital, Darlinghurst, New South Wales, Australia, ⁷ Drug Health, Western Sydney Local Health District, Parramatta, New South Wales, Australia, ⁸ Drug Health Services, South Western Sydney Local Health District, Liverpool, New South Wales, Australia, ⁹ Drug and Alcohol Services, South East Sydney Local Health District, Surry Hills, New South Wales, Australia, ¹⁰ Hunter Medical Research Institute, New Lambton Heights, New South Wales, Australia, ¹¹ National Centre for Clinical Research on Emerging Drugs/NDARC, UNSW Medicine, Sydney Australia, ¹² School of Public Health, University of Queensland, Herston, Queensland, Australia, ¹³ College of Medicine & Public Health, Flinders University, Bedford Park, South Australia, Australia

Presenter's email: <Mel.Jackson@health.nsw.gov.au>

Introduction and Aims: Most clients (up to 94%) on opiate agonist treatment (OAT) smoke tobacco. Although many are interested in quitting, relapse is common, and few interventions have demonstrated acceptable efficacy for this population. Nicotine containing e-cigarettes may help promote tobacco abstinence and reduce tobacco-related harm in highly nicotine-dependent populations. HARMONY investigated the effectiveness of vaporised nicotine products (VNPs) compared to nicotine replacement therapy (NRT) for smoking cessation in client on OAT.

Design and Methods: This single-blinded parallel-group randomised controlled trial, was conducted across six NSW Local Health Districts, comparing 12-weeks treatment using VNPs to combination NRT in adult clients on OAT wishing to reduce/quit smoking. The primary outcome was self-reported 7-day point-prevalence-abstinence at end-of-treatment.

Results:

500 OAT clients were consented and randomised to treatment (VNP=259, NRT=241). Mean age was 45.6 years (SD 9.7), 308/500 (61.6%) were male, 116/500 (23.2%) identified as Aboriginal or Torres Strait Islander and 193/500 (38.6%) did not complete year 10 education. Mean baseline cigarettes smoked/day was 20.0 (SD 10.2); and 62.6% (313/500) smoke within 5 minutes of waking. Preliminary Bayesian analysis suggests that after 12 weeks treatment, the effect of VNP on abstinence was greater than that of NRT on abstinence. Reported results include between group comparisons of biochemically verified 7-day point prevalence abstinence at end-of-treatment, 30-day continuous abstinence at end-of-treatment and at 12-week follow-up, reduction in cigarettes smoked/day, nicotine withdrawal and craving symptoms, relapse episodes, safety profiles, other substance use, treatment adherence, and study retention.

Discussions and Conclusions: We provide high-quality evidence that VNPs are more effective than NRT for achieving tobacco abstinence for people on OAT. Results add to the

growing body of literature that VNPs provide an effectual and safe treatment for tobacco dependence in high-risk populations. Additional cost-consequence comparisons will provide evidence of future translatability.

Implications for Practice or Policy: Results suggest that VNPs are an effective intervention for decreasing tobacco smoking in opiate treatment populations. They will assist the development of strategies to be implemented across the broader substance use treatment sector.

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