Exploring the uptake and use of electronic cigarettes provided to smokers accessing homeless centres: a four-centre cluster feasibility study

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Scientific Summary

At current times, smoking prevalence is at a historic low in the UK. Smoking prevalence rates have dropped across all socioeconomic-status groups but remain considerably higher in adults with difficult lives including those with poor mental health and substance use comorbidities. Adults experiencing homelessness represent one group where prevalence rates, even at the minimum estimate, are four times higher than the national average. Tobacco related diseases are a leading cause of death amongst

this group. However, smokers from this population are not well represented within health services including stop smoking services, despite a desire to quit which is no different to those who are not homeless. E-cigarettes (EC) are now the most popular quit method in England and there is increasing evidence for their efficacy within trials alongside behavioural support and effectiveness at a population level. The efficacy of EC for quitting or reducing smoking have not been tested within a homeless population. This feasibility study with embedded qualitative process evaluation was undertaken as a precursor to a main trial which would explore the efficacy of EC for smokers accessing homeless centres compared with usual care (UC).

Seven key objectives were examined to inform a future trial. 1: Assess willingness of smokers to participate in the study to estimate recruitment rates and inform a future trial. 2: Assess participant retention in the intervention and control groups. 3: Examine the perceived value of the intervention, facilitators and barriers to engagement and influence of local context. 4: Assess service providers' capacity to support the study and the type of information and training required. 5: Assess the potential efficacy of supplying free EC starter kits. 6: Explore the feasibility of collecting data on contacts with health care services within this population as an input to an economic evaluation in a full RCT. 7: Estimate the cost of providing the intervention and usual care.

This was an 18-month mixed method study delivered across four homeless centres; two centres in the EC cluster, and 2 in the usual care cluster. A cluster design was adopted following the advice of our Public and Patient Involvement (PPI) and centre staff in order to reduce contamination and disharmony between participants allocated to different conditions. Recruitment took place between January and June 2019. Usual care (UC) participants received advice to quit and were signposted to the local Stop Smoking Service. EC intervention participants received a starter kit and 4-weeks supply of e-liquid, provided at weekly intervals. Follow-up assessments were conducted at 4, 12 and 24 weeks. Outcome measures were the proportion of eligible individuals agreeing to take part and returning for follow-up, the proportion who still had and who were still using ECs at each follow-up, participants' experience of the study, service providers ability to support the study, smoking cessation at each follow-up point. We also collected health care utilisation data in order to pilot the health economics questionnaires and also recorded the resources used in the delivery of the study in order to estimate cost.

Eighty of the 153 (52%) eligible participants invited were successfully recruited; 48 (56%) in the EC arm and 32 (50.5%) in the UC arm) and recruitment was most successful in day centres. Retention rates were 75%, 63% and 59% respectively at 4, 12 and 24 weeks and retention were higher in the EC vs UC arm (24-week retention = 73% vs. 38%). The difference between arms was largely due to poor retention rates at the Edinburgh site and there were higher levels of baseline co-morbidities (physical and mental illness and substance misuse) in the UC vs. EC arm. Of those who could be followed up, the CO validated sustained abstinence rate at 24 weeks was 3/35 (11%) for the EC arm and 0/12 (0%) for the UC arm. Assuming that all those with missing follow-up data were smoking (ITT), the 24-week sustained abstinence rate was 6.25% (3/48) in the EC arm vs. 0/32 (0%) in the UC arm.

Qualitative interviews with a sub-sample of participants and staff showed perceived value of the EC intervention was high. Barriers to engagement were participants' personal and psychological difficulties and cannabis use. Facilitators were participants' desire to change, free EC and social dynamics. Staff capacity to support the study was generally good although some mentioned that they would like more support and guidance around how to approach potential participants about recruitment**.** Almost all participants who were present at follow-up visits completed data collection for healthcare service and health-related quality of life measure. However, whilst it was feasible to collect information relating to the cost of delivery in the EC arm collecting data from staff about their contact time when delivering the intervention was not possible in the UC arm In total, the mean costs of the EC intervention, including training and delivery, were £114.42 (SD £22.89) based on data from 43 participants in the EC arm. It was not possible to estimate costs for the UC arm.

Reasonable study recruitment and retention rates with promising acceptability were observed. This is a hard-to-treat population but with careful consideration around the study design and further public involvement a future trial may be feasible.

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Registration: The protocol was registered at the Research Registry: researchregistry4346; registration date: 21/08/2018 and ISRCTN14140672: registration date: 07/11/2018

The study protocol can be found online at:

https://njl-admin.nihr.ac.uk/document/download/2025909.