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

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Declared competing interests of authors: Peter Hajek has received a research grant from and provided consultancy to Pfizer, Inc. (New York, NY, USA). Lynne Dawkins has provided consultancy for the pharmaceutical industry relating to the development of smoking cessation products. Linda Bauld is a member of the National Institute for Health Research Public Health Research funding board.

Published May 2021 DOI: 10.3310/phr09070

Scientific summary

Use of electronic cigarettes in homeless centres Public Health Research 2021; Vol. 9: No. 7 DOI: 10.3310/phr09070

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Scientific summary

Background

At present, smoking prevalence is at a historic low in the UK. Smoking prevalence rates have dropped across all socioeconomic groups but remain considerably higher among adults with difficult lives, including those with poor mental health and substance use comorbidities. Adults experiencing homelessness represent one group in which prevalence rates, even at the minimum estimate, are four times higher than the national average. Tobacco-related diseases are a leading cause of death among this group. However, smokers from this population are not well represented in health services, including stop smoking services, despite a desire to quit that is no different from that of people who are not homeless. Electronic cigarettes are now the most popular quit method in England and there is increasing evidence for their efficacy in trials, alongside behavioural support and effectiveness for smoking has not been tested among a homeless population. This feasibility study with embedded qualitative process evaluation was undertaken as a precursor to a main trial that would explore the efficacy of electronic cigarettes for smokers accessing homeless centres compared with usual care.

Objectives

Seven key objectives were examined to inform a future trial:

- 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 arms
- 3. examine the perceived value of the intervention, facilitators of and barriers to engagement, and influence of local context
- assess service providers' capacity to support the study and the type of information and training required
- 5. assess the potential efficacy of supplying free electronic cigarette starter kits
- 6. explore the feasibility of collecting data on contacts with health-care services among this population as an input to an economic evaluation in a full randomised controlled trial
- 7. estimate the cost of providing the intervention and usual care.

Design and setting

This was an 18-month mixed-methods study delivered across four homeless centres: two centres in the electronic cigarette cluster and two centres in the usual-care cluster. A cluster design was adopted following the advice of our public and patient involvement and centre staff to reduce contamination and disharmony between participants allocated to different conditions. Recruitment took place between January and June 2019.

Interventions

Usual care participants received advice on quitting and were signposted to the local stop smoking service. Electronic cigarette intervention participants received a starter kit and a 4 weeks' supply of e-liquid, provided at weekly intervals. Follow-up assessments were conducted at 4, 12 and 24 weeks.

Outcome measures

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 electronic cigarettes at each follow-up, participants' experience of the study, service providers' ability to support the study, and smoking cessation at each follow-up point. We also collected health-care utilisation data to pilot the health economics questionnaires and recorded the resources used in the delivery of the study to estimate cost.

Results

Eighty of the 153 (52%) eligible participants invited were successfully recruited [48 (56%) in the electronic cigarette arm and 32 (50.5%) in the usual-care arm], and recruitment was most successful in day centres. Retention rates were 75%, 63% and 59% at 4, 12 and 24 weeks, respectively, and they were higher in the electronic cigarette arm than in the usual-care arm (24-week retention rate, 73% compared with 38%, respectively). The difference between arms was largely due to poor retention rates at the Edinburgh site, and there were higher levels of baseline comorbidities (physical and mental illness and substance misuse) in the usual-care arm than in the electronic cigarette arm. Among those who could be followed up, the carbon monoxide-validated sustained abstinence rate at 24 weeks was 8.57% (3/35) for the electronic cigarette arm and 0% (0/12) for the usual-care arm. Assuming that all those with missing follow-up data were smoking (intention to treat), the 24-week sustained abstinence rate was 6.25% (3/48) in the electronic cigarette arm compared with 0% (0/32) in the usual-care arm.

Qualitative interviews with a subsample of participants and staff showed that the perceived value of the electronic cigarette intervention was high. Barriers to engagement were participants' personal and psychological difficulties and cannabis use. Facilitators were participants' desire to change, free electronic cigarettes 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 on health-care service utilisation and health-related quality-of-life measures. However, although it was feasible to collect information relating to the cost of delivery in the electronic cigarette arm, collecting data from staff about their contact time when delivering the intervention was not possible in the usual-care arm. In total, the mean cost of the electronic cigarette intervention, including training and delivery, was £114.42 (standard deviation £22.89) based on data from 43 participants in the electronic cigarette arm.

Limitations

Clusters could not be fully randomised. The originally specified recruitment target was not achieved and recruitment was particularly difficult in residential centres. Blinding was not possible for the measurement of outcomes and it was not possible to estimate costs for the usual-care arm.

Conclusions

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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Trial registration

This trial is registered as ISRCTN14140672, and the protocol is registered as researchregistry4346.

Funding

This project was funded by the National Institute for Health Research (NIHR) Public Health Research programme and will be published in full in *Public Health Research*; Vol. 9, No. 7. See the NIHR Journals Library website for further project information.

Public Health Research

ISSN 2050-4381 (Print)

ISSN 2050-439X (Online)

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This report

The research reported in this issue of the journal was funded by the PHR programme as project number 17/44/29. The contractual start date was in October 2018. The final report began editorial review in May 2020 and was accepted for publication in December 2020. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PHR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health and Social Care.

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