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

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SC, AF, JL, CB, AT, DR, IU, SP have no competing interests.

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Abstract

Background

Smoking prevalence is extremely high in adults experiencing homelessness and there is little evidence regarding which cessation interventions work best. This study explored the feasibility of providing free e-cigarette (EC) starter kits to smokers accessing homeless centres in the UK

Objectives

Seven key objectives were examined to inform a future trial. 1: Assess willingness of smokers to participate in the study to estimate recruitment rates. 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 contact with health care services as an input to a main economic evaluation. 7: Estimate the cost of providing the intervention and usual care.

Design

A prospective cohort four-centre pragmatic cluster feasibility study with embedded qualitative process evaluation.

Setting

Four homeless centres. Two residential units in London, England. One day centre in Northampton, England. One day centre in Edinburgh, Scotland.

Intervention

Intervention arm: A single refillable EC was provided with e-liquid provided once a week for four weeks (choice of three flavours: fruit, menthol, tobacco and two nicotine strengths: 12mg/mL or 18mg/mL). Written information for EC use and support. Usual care arm: Written information on quitting smoking (adapted from NHS Choices) and signposting to the local stop smoking service (SSS).

Results

Fifty-two percent of eligible participants invited to take part in the study were successfully recruited (56% in the EC arm; 50.5% in the UC arm; total N=80). Retention rates were 75%, 63% and 59% respectively at 4, 12 and 24 weeks. The qualitative component found perceived value of the intervention was high. Barriers were participant's personal difficulties and cannabis use. Facilitators

were participants' desire to change, free EC and social dynamics. Staff capacity to support the study was generally good. Carbon Monoxide (CO) validated sustained abstinence rates at 24 weeks were 6.25% (3/48) in the EC arm vs. 0/32 (0%) in the UC arm (intention to treat). Almost all participants present at follow-up visits completed measures needed for input into an economic evaluation although information about staff time to support UC could not be gathered. The cost of providing the EC intervention was estimated to be £114.42 per person. Estimated cost could not be completed for UC.

Limitations

Clusters could not be fully randomised due to lack of centre readiness. 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. Staff time supporting UC could not be collected.

Conclusions

The study was associated with reasonable recruitment and retention rates and promising acceptability in the EC arm. Data required for full cost-effectiveness evaluation in the EC arm could be collected but some data was not available in the UC arm.

Future work: Future research should focus on several key issues to help design optimal studies and interventions with this population, including: which types of centres the intervention works best in; how best to retain participants in the study; how to help staff to deliver the intervention and how best to record staff treatment time given the demands on their time.

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Alphabetical list of abbreviations/glossary

CO: Carbon Monoxide

cRCT: Cluster Randomised Control Trial

DHSC: Department of Health and Social Care

EC: Electronic cigarette/s

HRQoL: Health-related quality of life

ICC: Intra cluster correlation coefficient

NIHR: National Institute of Health Research

PPI – Public and Patient Involvement

QALY – Quality-Adjusted Life Year

SSS: Stop Smoking Service/s

UC: Usual care

VAS: Visual analogue scale

Plain English Summary

Smoking rates are exceptionally high among adults experiencing homelessness. Supplying a free e-cigarette (EC) starter kit at homeless centres may be one way to help smokers to quit. This was a small study which explored whether smokers visiting homeless centres would be willing to take part and if they would return to complete questionnaires 6 month later. We also wanted to find out what people thought worked or did not work well for them and whether we could collect information needed to assess cost-effectiveness and success in a larger trial.

We recruited 80 smokers from 4 homeless centres: 48 received an EC and 32 people took part in usual care (UC). UC is defined as signposting to the local Stop Smoking Service (SSS) because this is what is most often available at these centres.

Sixty people (75%) returned to provide follow-up information after 4 weeks; 50 people (63%) came back at 12 weeks; and 47 (59%) came back at 24 weeks. Interviews with participants and staff at the centres showed the study was useful and worthwhile. Although nobody who came back at 24 weeks managed to stop smoking in the UC group, in the EC group 11% (3/35) of those who came back at 24 weeks had quit smoking. We were able to collect the information we needed to assess cost-effectiveness of providing an EC. This was estimated to be £114.43 per person. We could not estimate costs of UC. We found that enough people were interested in taking part that it would be worthwhile running a larger study but this would need to include more people, more centres and explore ways that we could make sure more people came back at 6 months

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.

Background

Smoking prevalence rates have continued to decline in the UK, with fewer young people starting to smoke and greater numbers of people quitting[1]. Smoking has also continued to decline across all socio-economic status groups. However, those from the most disadvantaged groups, such as those presenting with multiple and severe mental illness and substance use comorbidities, present smoking prevalence rates which far exceed groups without[2–5].

Smoking is extremely common amongst adults experiencing homelessness, with prevalence rates ranging from 57- 82%[4]; this is up to four times higher than the UK national average (15.1%)[1].

Smoking is related to premature death and disease and quitting can have a substantial positive impact on reducing harm and increasing life years[6]. In smokers experiencing homelessness, tobacco related disease has been cited as the second single cause of premature death and the single largest cause of death in over 45[7]. Smoking is particularly fatal within this population because of a higher incidence of respiratory infection and disease[8]. These conditions are likely to be exacerbated because of a general likelihood of engaging in practices which increase the risk of developing respiratory infections, for example, smoking discarded cigarettes and sharing cigarettes which act as a vessel for passing viral contaminants[9,10]. Poor respiratory health is also likely to be aggravated by smoking unfiltered and illicit tobacco, dragging harder on cigarettes and taking longer deeper puffs[9]. Beyond the health effects, smoking is also related to several social disadvantages; smokers experiencing homelessness are likely to engage in begging or ask strangers for cigarettes and are reported to spend up to a third of their income on tobacco and cigarettes[11].

Smokers experiencing homelessness have lives which mean that quitting smoking is not a high priority and is also often overlooked by those who support them[12]. There is also some evidence that health and social care professionals are concerned that cessation will exacerbate mental illness and that taking something away, when many of these adults have so little, will be unfair or cruel[13]. While these concerns are understandable, a survey we conducted in 2018 of 286 smokers accessing homeless services in England and Scotland showed that 75% smokers have some desire to quit smoking and 75%

have some history of quitting, however, quit attempts are often unsupported by behavioural support or licensed nicotine medication, and last less than 24 hours[14].

The UK has a clear goal of reducing the harms caused by tobacco smoking; central to this is the reduction of tobacco related health inequalities through improving cessation rates. At the current time however, smokers experiencing homelessness are not well represented within the SSS and cessation support is not mandatory within homeless centres. In the recent Tobacco Control Plan for England[15], the Department of Health and Social Care (DHSC) expresses its commitment to evidence-based innovations to support quitting and will seek to support smokers adopting the use of less harmful nicotine products such as EC. Nevertheless, smoking cessation within the context of homelessness is underexplored within the UK. Our recent systematic review of 53 studies showed that only two cross sectional studies had been conducted in the UK[4] of which one was conducted by our group[14]. Trial evidence from the US shows that there is potential to support cessation in this group. For example, Okuyemi et al.[16] measured the efficacy of motivational interviewing (MI) offered alongside licensed nicotine replacement therapies (NRT) compared to NRT alone. Using intention-to-treat analysis, verified 7-day abstinence rates at week 26 were 9.3% for MI + NRT and 5.6% for NRT alone (P = 0.15). Prior to the work presented here, there were no smoking cessation intervention studies within the UK. In order to reduce the burden of smoking within this population, more evidence of the efficacy of interventions is clearly required.

Our systematic review[4] and PPI work (conducted in 2017, with 7 homeless centres, and 8 interviews from one major homeless charity, and scoping data from 100 participants) helped to shape the design of this study. We were told that the multiple competing needs in this group meant access to support needed to be made easy and appealing in order provide the best chance of engagement. Thus, it was decided that the feasibility study should be embedded within centres that participants were already accessing. Our PPI work also suggested that EC may be particularly appealing to smokers experiencing homelessness because i) smokers in our scoping work were already experimenting with them, ii) they can be framed as a switch rather than a quit (which has connotations of loss) which has been highlighted as an issue of cessation, iii) they can be offered at a location already being visited without a prescription, thus reducing the burden of making further appointments and removing a clinical approach. Taken together the feedback was that EC offer a pragmatic harm reduction approach to smoking cessation, and this is especially important when delivering interventions within the third sector where substance harm reduction is already well established.

An individually randomised trial with allocation to one of two arms (EC vs. UC) was initially considered but our PPI feedback (from staff and clients at homeless centres) strongly advised against this due to potential problems with compliance, contamination and issues of disharmony, e.g. resentment towards staff delivering the intervention that one person had received an EC and another not. Contamination, harmony and protection of staff were important; therefore, our decision was to opt for a feasibility cluster trial.

Here we present a pragmatic four-centre cluster feasibility study exploring the uptake and use of EC to smokers accessing homeless support services. The overall purpose of this research was to evaluate the feasibility of supplying free EC starter kits for smoking cessation to smokers experiencing homelessness at a place which they are already accessing. The UC arm received standard existing treatment: advice to quit, an adapted NHS Choices factsheet for smoking cessation and signposting to the local SSS which offers weekly behavioural support and choice of NRT or varenicline. The EC arm received a starter kit, 4-weeks supply of e-liquid and a fact sheet.

Objectives

To test the feasibility of future trial work, seven objectives were set. Table 1 presents the study objectives and associated outcome measures and whether the objective is specific to the cluster level or across levels.

Table 1: Feasibility study objectives and outcome measures

Objective	**Outcome measure**	**Measured at:**
O1. Assess willingness of smokers to participate in the feasibility study to estimate recruitment rates and inform a future trial.	In both arms, we will record the number of smokers asked to take part and the number who consent.	Across arms
O2. Assess participant retention in the intervention and control groups.	Record a) how many participants complete assessment measures in each arm at each time point b) how many participants still have, and	Across arms

	are still using, e-cigarettes in the intervention group.	
O3. Examine the perceived value of the intervention, facilitators and barriers to engagement and influence of local context.	Qualitative interviews with 4-week completers and non-completers, quitters and smokers (N=24, approx. 6 per site) between weeks 4 and 8 across both arms.	Across arms
O4. Assess service providers' capacity to support the study and the type of information and training required.	Qualitative interviews with keyworkers and front-line staff (N=12; approx. 3 per site) across both arms.	Across arms
O5. Assess the potential efficacy of supplying free EC starter kits	Measure breath CO levels, self-reported quit rates/cigarette consumption and HRQoL (using the EQ-5D-3L) at each follow-up time point.	Across arms
O6. 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.	Record participant utilisation of primary and secondary health care services using a self-report service-use questionnaire at each time point.	Across arms
O7. Estimate the cost of providing the intervention and usual care.	Record all resources used in the delivery including staff costs, e-cigarettes and other costs incurred. Staff will complete a pro forma to record contact time, non-contact time and other resources used in delivery.	Across arms

HRQoL: Health-related quality of life. Carbon Monoxide: CO.

Methods

Trial design

A four-centre cluster feasibility study with embedded qualitative process evaluation. A deviation from our protocol was made to the study design owing to the availability of centres Centres were

counterbalanced in each condition but not randomised (see 'cluster allocation' below. However, participants joined after cluster allocation and allocation was concealed to participants until after the baseline assessment. Recruitment was within a discrete period starting from site initiation at each location (6-weeks).

EC sites offered an EC starter kit at baseline assessment. EC arm is formed of two EC clusters.

UC is defined as offering an adapted NHS Choices fact sheet for smoking cessation and signposting to the local SSS. UC arm is formed of two UC clusters. An illustration of the clusters is outlined in Figure 1.

Consent was taken at baseline by the research team. Follow up data at weeks 4-12 and 24 weeks was also recorded by the research team. Keyworkers delivered the interventions (see details) below.

Participants

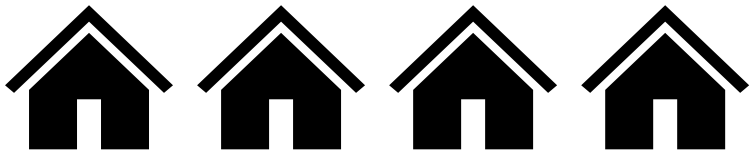
Participants were selected by homeless centre staff based on the inclusion criteria below. Further eligibility checking was performed at baseline by the researcher. Eligibility criteria did not differ between clusters.

Inclusion criteria: Adult smokers (18 and over) accessing homeless support services on a regular basis and also known to staff. Self-reported daily smokers only with smoking status also confirmed by support staff. Smoking status was also biochemically verified by exhaled CO breath test at recruitment. To gain wider representation we did not exclude those who reported mental illness or substance dependence.

Exclusion criteria: non-smokers, or those reporting using another smoking cessation aid at the current time, any one below the age 18 years, reporting pregnancy, or unable to consent e.g. currently intoxicated or unable to speak English; all those not well known to centre staff were ineligible.

Figure 1: the cluster sites

Centre 1 07.01.19- 31.01.19	Centre 2 08.03.19- 25.04.19	Centre 3 18.03.19- 02.05.19	Centre 4 13.05.19- 05.06.19



Usual care

E-cigarette

EC arm: Northampton (Centre 1), and London (Centre 4).
UC arm: Edinburgh (Centre 2), and London (Centre 3).

Description of settings:

Centre 1 (EC cluster): This is a day centre (open Monday to Friday; 8.30am – 1pm) located within Northampton. Staff and volunteers, support workers, keyworkers, social workers and kitchen staff work to provide a range of facilities and programs to serve the practical, physical, and social needs of people experiencing or at risk of homelessness in the area. There is a breakfast and lunch service, training and employment skills programs, and an emergency night shelter (run separately by the local council) for use during periods of inclement weather. The kitchen and day centre are open on Saturday mornings for people who are sleeping rough or in emergency accommodation.

Centre 2 (UC cluster): This is a day centre (open Monday to Friday; 9am – 1pm) located within the city of Edinburgh. It offers breakfast, lunch, shower and clothing facilities as well as spiritual support through chaplaincy and recreational facilities (TV, pool and day trips). Support staff provide crisis intervention advice and assistance with benefits, housing, accessing medical services for physical and mental health and social and life skills emotional support.

Centre 3 (UC cluster): operates three linked sites of supported accommodation in London for people at risk of homelessness. Each site accommodates clients whose needs fall within the parameters of the level of care it is able to provide.

Site 1 has 21 bedsits in 3 adjoining three-and-a-half-storey houses with a shared garden and is staffed 24 hours for people with greater complex needs.

Site 2 has 12 bedsits for male residents who are semi-independent and benefit from support of regular check-ins, health support, and help with advocacy and paperwork. The office staff are available during Monday-Friday between 9-5.

Site 3 has seven units in one four-storey building. The residents are both men and women who are living mostly independently, with the support workers providing advocacy, signposting to services, and on-site management.

Centre 4 (EC cluster): Also located in London, it provides supported accommodation across four linked sites: Staff and volunteers include: keyworkers, complex needs workers, kitchen and maintenance staff.

Site 1 is a 23-unit residential support service for men and women. Single accommodation units are set on two stories and overlook an enclosed communal garden. There is a multi-purpose meeting space in a small unit within the garden where staff run skills classes and social groups. Staff are on-site 24 hours for management and security. Residents have a range of abilities and needs, with an aim to return to independent living. Staff aim to support people to with complex needs through semi-independent living with keyworker support, advocacy, and daily check-ins.

Site 2 is a 13-unit women's only supported accommodation, offering support for women who have been or at risk of becoming homeless. The accommodation provides single occupancy accommodation. There is a shared garden with chickens and a shared communal lounge and kitchen, but no private meeting spaces. Keyworkers provide support sessions within usual 9-5 working hours.

Site 3 is a short stay house and site 4 provides first-night accommodation only (to provide emergency accommodation intended for people who are newly homeless or acutely at risk of rough-sleeping).

The researchers routinely kept reflexive diaries to record observations and reflections about local contexts, as well as notes on psychological impact of working in new and sometimes unpredictable environments where people are reacting to multiple, chronic and/or acute stressors and complex needs. These research notes formed the basis of debriefing meetings and discussions within the research team, in part to be informative of ecological differences between sites as well as to systematise the physical and psychological safety of the researchers.

Interventions

Interventions were delivered at cluster level. Appendix 1 presents the CONSORT flow diagram, which provides a summary of the stages of the study by intervention.

Pre-intervention staff training

The research team provided four education and training sessions to staff in each centre, one to two weeks before recruitment started. The educational content followed National Centre for Smoking Cessation and Training (NCSCT) recommendations, to ensure centre staff had a basic knowledge of the issues which surround smoking and smoking cessation and to optimise the delivery of the EC and UC interventions. The training was developed and led by Dr Debbie Robson (King College, London) with support of the research team (LD, AT, SC, IU and AF); Table 2 presents an overview of the delivery of the staff education and training to 32 staff members across centres. However, not all staff were able to attend the education and training sessions. Also, new staff were employed in some centres during the intervention delivery phase of the study.

Table 2: Outline of the training delivery across centres

	Delivered by:	**Duration**	**Number of staff per training session**	**Materials provided**
EC Arm				
Centre 1	Debbie Robson Allan Tyler Lynne Dawkins	2 hours (plus individual coaching)	12	EC instruction pamphlet
Centre 4	Debbie Robson Allan Tyler Sharon Cox Catherine Kimber	2 hours (plus individual coaching)	8	EC instruction pamphlet
UC Arm				
Centre 2	Debbie Robson Sharon Cox Allison Ford Isabelle Uny	1.15 hours	7	Help to quit leaflet
Centre 3	Debbie Robson Allan Tyler Lynne Dawkins	1.15 hours	5	Help to quit leaflet

UC: Usual care. EC: e-cigarette. Duration refers to the total training time (excluding time to set up). Time for individual coaching was not monitored.

Education and training content for both intervention arms included the following:

1. Prevalence and patterns of smoking among the wider population and people experiencing homelessness
2. Health effects of smoking
3. Benefit of smoking cessation
4. Common misperceptions around smoking cessation within the context of other addictions and mental illness
5. Why this study was important and why it was needed now
6. How to complete the baseline and follow-up forms and what was expected from staff

Additional EC training:

Staff were expected to deliver the intervention and were therefore provided with information on the evidence base of EC use, effectiveness and safety among the wider and population and a rationale about why EC may be useful for this group. Also, within the training session, staff were provided with information about how to deliver correct advice about EC to participants and given a practical hands-on demonstration relating to aspects of EC assembly, how to use the device, charge it, refill the tank, replace coils and battery safety. Including the practical hands-on demonstration meant the EC intervention training took up to 45 minutes longer than the UC training.

The research team in the EC arm provided additional coaching in preparation for each staff member's first two keyworker sessions at baseline, and through shadowing and feedback at ongoing sessions. Ongoing informal training was provided, in the form of question and answer discussions with staff between keyworker sessions and before and after participants' arrival.

Additional UC training:

As above, staff were asked to deliver the UC referral information, so staff were provided with detailed information on the role of SSS, current licensed medications available to smokers within their local SSS and evidence for their effectiveness. Staff were informed that at the time of training, licenced stop smoking medicines alongside behavioural support offered at the SSS was the most effective way of quitting smoking. Details of the centre's local SSS and how to make a referral was also included in the training.

EC Intervention

All participants within the EC cluster (Centres 1 &4) received the same intervention.

Participants were provided with an unboxed Aspire PockeX kit starter kit comprising a tank-style refillable EC with a spare atomiser, charger and wall adapter plug. They were offered five bottles of 10mL e-liquid, choosing from a combination of: a) nicotine strength e-liquid (two options: 12 & 18mg/mL) and b) flavours (three options: tobacco, fruit, menthol). 12 and 18mg/mL nicotine strength e-liquids were chosen based on previous reports from our group and others of high nicotine dependency among smokers experiencing homelessness[14]. The EC brand and e-liquid were decided upon following our PPI work and advice from vapers. Vapers known to the research team who have engaged in other research suggested four of the top selling, easy to use ECs. Upon purchasing these, smokers from one London homeless centre tried the four different ECs and provided feedback on ease of use, nicotine hit and likeability. The Aspire PockeX was consistently rated as the easiest and most satisfying to use. The flavours were recommended by a vape retailer because these are the most popular, in terms of best-selling varieties.

At this time the keyworker showed the participant how to use the device; this included, how to (re)fill the liquid in the tank, how to charge the device, how to inhale and what to expect when first using the device. Participants were also provided with the device instructions, which in response to our PPI feedback, had been retyped in to larger font and a 'Tricks and Tips' from experienced vapers help sheet. Participants were given time to try the device, and experiment with the different flavours and nicotine strengths and were permitted to switch between flavours throughout the follow sessions (Appendix 2 presents the selection of e-liquid flavours and concentrations that were given out by keyworkers). The keyworker recorded the participants' choices of e-liquid and timing of the keyworker session in CRF forms that were kept with the study equipment.

Once per week in the three weeks that followed the baseline meeting, participants met centre staff to report any concerns and collect up to 5 10mL bottles of e-liquid and a new atomiser each week. Ideally, participants met the staff member whom they had met at the baseline session and who had attended the staff training; however, because of staff turnover and time demands this was not always feasible. Staff recorded data on e-liquid and troubleshooting in the CRF. With a larger number of participants attending follow-up appointments at Centre 1, staff adopted a drop-in 'surgery' where waiting participants also interacted with peer advice and support.

Usual care intervention

All participants within the UC cluster (Centres 2 & 3) received the same assessment measures but usual care differed across the two centres within this cluster.

At the end of the baseline assessment, and within the same session, participants were informed of their centre allocation. Participants were then referred to their keyworkers/other centre staff who advised them to consider quitting and provided the fact sheet and an adapted NHS Choices 'help-to-quit' leaflet, this included information about the location and opening hours to SSS local to the centre. Paper copies of the help-to-quit leaflet (with SSS contact details) were available as posters/flyers at homeless centres in the UC condition/cluster. Centre staff were asked to follow up with participants once a week for four weeks to record whether they had made contact with the SSS and to remind them to do so.

Process evaluation

All participants were asked after baseline CRF completion if they would be interested in taking part in the qualitative process evaluation. Individual interviews were conducted in a quiet, private space on homeless centre premises, between weeks four and eight of the trial. A semi-structured topic guide was used to ensure all relevant topics were covered and interviews were digitally recorded with participants' consent.

The participants' guide covered: smoking history; awareness of local SSS; experiences of trial processes; expectations and experiences of vaping (EC arm); and experiences of signposting to SSS (UC arm).

The staff topic guide covered: staff role and trial involvement; existing cessation support for clients; and views and experiences of the trial, processes, and the EC or UC interventions. Both guides covered: unintended consequences and recommendations for improvements.

Incentives for retention

The wider literature on smoking and homelessness has shown that it is common practice to offer a financial incentive to participants and that this improves retention[4]. Regardless of cluster, all participants were compensated with a £15 'Love2Shop' gift card for completing assessments at

baseline, follow-up and the qualitative interview (totalling £75). Staff did not receive a gift card for taking part in the interviews. Participant payment was not contingent on quitting or cutting down and this was stressed to the individuals taking part.

Outcome measures

Table 1 presents the outcomes and associated measures, including the relation to each intervention arm.

Baseline Measures (across clusters)

- Demographic information and homeless status/history.
- Cigarettes smoked per day, smoking history (e.g. length of smoking, previous number of quit attempts, support used) and past and current EC use.
- Severity of tobacco dependence, measured by the Fagerström Test of Cigarette Dependence (Fagerström, 2012) and expired carbon monoxide (CO).
- Motivation to stop smoking, measured by the Motivation to Stop Scale, a 7-level single-item instrument which incorporates intention, desire and belief in quitting smoking[17,18].
- Mental health status, measured using the 9-item Patient Health Questionnaire (PHQ9)[19–21] for depression (total score ranging from 0 to 27 with a higher score indicating greater severity of depression) and the 7-item Generalised Anxiety Disorder (GAD7) questionnaire (total score ranging from 0 to 21 with a higher score indicating greater severity of anxiety)[22,23].
- Alcohol use, measured using the Alcohol Use Disorders Identification Test (AUDIT), a 10-item screening instrument developed by WHO to screen for alcohol problem. Scores range from 0-40 with a score of >8 indicating harmful or hazardous drinking and >13 (females) or >15 (males) indicating alcohol dependence[24].
- Drug use measured using The Severity of Dependence Scale (SDS), a 5-item screening measure of psychological aspects of dependence yielding a total possible score ranging from 0 (no/low dependence) to 15 (high dependence)[25,26].
- General health care and service use measured using an adapted health care and social service utilisation questionnaire.
- Health Related Quality of Life (HRQoL) measured using the EQ-5D-3L, a widely used measure which provides a single value for health status that can be used in the clinical and economic evaluation of an intervention[27,28].

All questionnaires and measures have good psychometric properties and have been used in previous research with vulnerable populations.

Follow-up Data Collection - UC

At weeks 4, 12 and 24, the following information was collected:

- Smoking information: self-reported smoking abstinence; number of cigarettes smoked in the last seven days (to measure 7-day point prevalence abstinence); number smoked per day (in order to calculate smoking reduction from baseline).
- Exhaled CO breath test.
- Engagement with the local SSS (appointments made and attended).
- Use of EC and other tobacco/nicotine containing products.
- General health care and service use; HRQoL; mental health status (GAD7, PHQ9).
- Other drug use/dependence (AUDIT, SDS).
- Direct and indirect staff contact time.

Follow-up Data Collection) – EC

As above and in addition:

- 12 positive effects (e.g. throat hit, satisfaction, pleasant, craving reduction) and 21 negative effects (e.g. mouth/throat irritation, nausea, headache, heartburn) of EC use, self-reported using a Visual Analogue Scales (VAS) and summed to create a percentage score (higher score = higher positive or negative effect) as used in our previous studies[29].
- To further monitor risk and adverse effects (e.g. EC theft, exchanges, use for other substances), were assessed using unintended consequences checklist developed specifically for this trial.

The research team collected all of the baseline and consent data and the 4, 12 and 24-week follow up data.

Feasibility Study Outcome Measures

1. To assess willingness to take part in the study, we recorded a) the number of people who were asked, b) the number eligible, and c) the number who consented, to take part.

2. Retention and engagement were measured by recording a) the proportion of participants who completed assessment measures in each arm at each time point, and b) the proportion of participants: i) still using EC in the intervention group and ii) who had visited the SSS in the UC group.
3. To estimate the parameters for future trial at each follow-up point, we recorded: a) CO-validated sustained abstinence (from 2-weeks post-quit date allowing up to 5 slips); b) CO-validated 7-day point prevalence abstinence (i.e. no smoking at all in the last 7 days); and c) the proportion achieving 50% smoking reduction (calculated by subtracting CPD at follow-up from baseline).
4. To explore the feasibility of collecting data on contact with health care services we recorded participant utilisation of primary and secondary health care services using a self-report questionnaire
5. Staff contact time, non-contact time and other resources used in EC and UC delivery including staff costs, EC and other costs incurred was collected to provide an indicative cost of the intervention.

The research team collected all of the baseline and consent data and the 4, 12 and 24-week follow up data.

Sample size

As this was a feasibility study for a main trial, no formal power calculation based on detecting evidence for efficacy was conducted; the outcomes of study allowed us to calculate the required sample size (and an intra class correlation coefficient ([ICC]) for a possible future definitive cRCT.

As per our published protocol[30], a pragmatically chosen sample size (N=120, n=30 per centre, n = 60 per cluster), was based on our pre-feasibility PPI work and also taking information from published works within similar samples. This information allowed us to identify evidence of feasibility, recruitment rates and any problems with the intervention or research methods. Our pre-feasibility scoping work suggested that the centres had daily contact with between 25 and 120 individuals, of whom 70-90% were likely to be smokers. Other studies in homeless populations have reported follow-up rates ranging between 24% and 88% (depending on the location of visits, provision of incentives & use of prompts[31]. Therefore, we estimated that 50% of those who agree would drop out in the period between consenting to participate and the final follow-up at 24 weeks, leaving an estimated sample size at the final follow-up of 60.

In relation to the qualitative process evaluation, we planned to interview a sub-group of 24 homeless smokers (approximately 6 per centre) and 12 staff members (approx. 3 from each centre). We also aimed to include continuing participants and those who did not complete their 4-week follow-up, as

well as those in the EC and UC arms. This sample size is adequate for collection of qualitative data necessary to assess objectives 3 and 4.

Although there was no formal interim analysis or stopping guidelines, we did specify in our 'project timetable and milestones' that we would assess recruitment and 4-week retention at Centre 1 after 2 months to determine whether to proceed with recruitment at centres 2, 3 and 4.

Cluster Allocation

The centres in Northampton (Centre 1) and Edinburgh (Centre 2) are both day centres, whilst the two London centres (Centre 3 & 4) are residential units. We planned to pair and match centres on accommodation provision; to wit, each one of the residential centres to be paired with one of the day centres. We would then randomly allocate the two London centres; one to the EC arm, the other to the control (UC) arm, with the accompanying pair (day centre) allocated to the other arm.

However, when we were ready to begin recruitment, the centres in London had not confirmed their availability for training and study start date. Thus, centre allocation could not be randomised and therefore deviated from protocol: we started with the centre that was ready to start training and recruitment, which was the centre in Northampton. We allocated this first centre to the EC condition so that we could explore recruitment, 4-week retention and any unintended consequences associated with the intervention to determine whether to proceed with recruitment at centres 2, 3 and 4. Centre 2 (Edinburgh) as the other day centre was therefore allocated to the UC condition. Centres 3 and 4 (London) were allocated to the UC and EC arms respectively. Centre 3 was allocated to UC as it was geographically closer to the researcher who was still collecting follow-up data from centre 1 and we expected lower uptake in the UC condition.

Thus the actual allocation of centres to each arm was non-random, a pragmatic decision based on centre readiness and staff/researcher availability though we balanced potential confounders and differences in environment by ensuring each cluster (EC and UC) contained one day centre and one residential unit.

Allocation concealment mechanism

As this represents feasibility work, a pragmatic approach was taken to the concealment of the intervention. Participants were told of the condition that they had been allocated to only after consent and baseline assessment; this was the same across the clusters. However, because of the nature of the conditions; namely that because those within the EC clusters were provided with a starter pack

and the social dynamics within centres (particularly day centres) were close-knit and interactive, the centre allocation was quickly revealed between participants and also to new participants.

Contamination

Contamination within the context of this design was defined as a participant receiving the intervention delivered by another participating centre, e.g., a participant in UC receiving a free EC starter pack from one of the EC clusters.

Implementation

N/A for this work

Analytical method

This is a feasibility for a trial in preparation for a future cRCT and analyses of effect are not appropriate. Analyses were conducted to evaluate the feasibility study outcomes (Table 1). Similarly, because this is a feasibility for a trial, subgroup analyses are not appropriate.

Table 1 presents the objectives and associated outcome measure for each objective. Objectives 1, 2, 5, 6, & 7 were measured quantitatively, and objectives 3 & 4 through the qualitative process evaluation. Each objective was measured across the whole sample, with the exception of objectives 5 and 7 which relate to efficacy and cost effectiveness of the interventions. Table 3 presents the descriptive data for participant characteristics for the trial, Appendix 3 also presents the data for the subset of participants within the process evaluation.

Baseline demographic data was summarised using frequencies and descriptive statistics and the arms (EC v UC) were compared using t-test/Mann Whitney U test or Fisher's Exact test for continuous and categorical variables respectively. EC effects are summarised descriptively. Changes in mental health status and substance use were explore over time and between arms using repeated measures ANOVA.

Objectives 1 and 2: Participant willingness to take part and retention:

Frequency information regarding the number of smokers who: i) were invited to take part; ii) were eligible to take part; iii) consented/completed the baseline assessment; iv) attended and completed each follow-up.

Objectives 3 & 4: To examine the perceived value of the intervention, facilitators and barriers to engagement and influence of local context, and assess service providers' capacity to support the study and the type of information and training required:

Interviews lasted between 16 and 65 minutes, were transcribed verbatim by professional transcribers, checked for accuracy and entered into NVivo 12 software[32] to facilitate coding and analysis. Data were analysed using thematic analysis[32]. Separate coding frameworks for both participants and staff, with themes initially formed deductively, were developed using the main objectives and interview topics. The qualitative team (AF, IU, AT) conducted a first round of coding with AF, checking all coding for consistency. Through discussion, inductive themes were identified and agreed, leading to a second round of coding. Using an iterative approach, coded themes were then used as the categories for analysis. Data were carefully examined to identify the range and diversity of responses and themes and sub-themes were created and/or refined as appropriate. Findings were interpreted and discussed among the wider team. Quotations were selected to illustrate findings. The study arm for each participant (EC or UC, centre code (01-04) and whether the quote was from a trial participant or staff member are indicated alongside quotes.

Objective 5: Assess the potential efficacy of supplying free EC starter kits

The proportion of participants reporting sustained smoking abstinence, 7-day point prevalence abstinence (both CO verified), and a 50% reduction in smoking in each arm at each follow-up time point were recorded. These variables are presented with the denominator being the number who attended follow-up. Sustained abstinence is also presented and analysed using intention to treat analysis; that is, all those allocated are included in the analysis as belonging to the group to which they were originally allocated and those with missing outcome data were treated as smokers. The intraclass correlation coefficient was calculated by the Fleiss-Cuzick method.

Objectives 6 and 7: To explore the feasibility of collecting data on contact with health care services within this sample as an input to an economic evaluation in a full cRCT and to estimate the cost of providing the intervention and usual care.

The completeness of EQ-5D-3L and service use questionnaires was examined. We used the UK population tariff [33] to convert the results of EQ-5D-3L to utility value. QALYs were then calculated in each arm using the area under the curve plotted from baseline and follow-up points[34]. A set of national weighted average unit costs were extracted from secondary or published sources (see Appendix 4 and 8). The quantities of services reported by participants were multiplied by the respective unit costs to

present a preliminary cost profile. We also present the costs of the programme, including training and delivery, the details of which were recorded by the research team. Results from the health economics component will be used to refine the instruments for a full RCT.

Recruitment

Recruitment and 4-week follow-ups ran sequentially across the three sites in England with 12- and 24-week follow-ups overlapping. Recruitment and data collection in Edinburgh ran in parallel with the second centre in England.

The feasibility study was completed within the planned time frame. However, although we planned to recruit for 4-weeks at each centre, recruitment was extended to 6 weeks in the UC arm. This was a pragmatic decision taken with assistance from the Trial Steering Group, the research team and centre staff. Centre 1 saw high levels of interest in the study and extending the recruitment period to 6 weeks was not required. We did extend capacity within the 4-week window to recruit more participants who were interested in taking part, anticipating potentially lower uptake in smaller centres. Conversely, Centre 2 proved to be a particularly challenging for recruitment due to staff time and competing needs and resources. The research team had to adapt to the conditions of the centre, appointments had to be rescheduled and staff were not always available to assist. Centre 3 was quieter, overlapped with data follow-up at centre 1, and also residents had day time commitments which clashed with recruitment, again the research team needed to be flexible and therefore recruitment was continued over 6-weeks until we reached saturation.

Sampling and recruitment for the qualitative process evaluation

All those enrolled for the trial were asked at baseline about their willingness to take part in the process evaluation interviews and whether they were willing to be contacted at a later date to arrange an interview. After the intervention phase, those who had consented to be contacted were approached by a researcher by telephone, or in person at the homeless centre, and invited to take part. At centre 1, staff identified participants whom they felt would be most willing to take part. Throughout the centres, staff who were supporting the participants and the project were also eligible to take part in an interview. Potential interviewees were provided with a participant information sheet and re-contacted several days later. An interview date and time was arranged for interested participants. Written consent was obtained at the start of the interview.

Purposive sampling was utilised with a pre-determined target to recruit approximately six trial participants and three staff members at each of the four homeless centres. Trial participants were also to be sampled according to a) smoking status at week four of the trial, and b) whether they completed the week four follow-up.

Centre 1 - EC

Recruitment/baseline: 7th to 31st January 2019

4-week follow-up: 4th to 28th February 2019

12-follow-up: 1st to 25th April 2019

24- follow-up: 24th June to 17th July 2019

Centre 2 - UC

Recruitment/baseline: 8th March until 25th April 2019

4-week follow-up: 8th April and 17th May 2019

12-follow-up: 4th June and 25th July 2019

24- follow-up: 23rd August and 10th October 2019

Centre 3 – UC

Recruitment/baseline: 18th March to 2nd May 2019

4-week follow-up: 18th April to 18th May 2019

12-follow-up: 18th June to 18th July 2019

24- follow-up: 10th September to 25th September 2019

Centre 4 – EC

Recruitment/baseline: 13th May to 5th June 2019

4-week follow-up: 10th June to 4th July 2019

12-follow-up: 7th August to 28th August 2019

24- follow-up: 28th October to 20th November 2019

Process evaluation

Interviews were conducted between February and July 2019 by one of a mixed gender team of three full time qualitative researchers experienced in interviewing vulnerable groups (AF, AT, IU).

Results

Baseline data

Baseline data is presented in Table 3: Participant Baseline Characteristics , below**.**

The mean age of the sample was 42.66 years, 65% were male. Participants were primarily white (76.3%) and heterosexual (85%).

Mental illness, health and substance use comorbidities

Seventy-four percent of the sample self-reported a long-standing illness, 38.8% had been previously admitted to hospital due to mental illness, 55% scored 10 or over on the GAD7 indicating presence of Generalised Anxiety Disorder and 60% of participants scored 10 or over on the PHQ9 indicating the presence of major depression.

In relation to alcohol use, 33.8% of participants had an AUDIT score over 8 suggesting that they were drinking at harmful or hazardous levels. SDS, were also high (5), indicating a high prevalence of substance dependence.

Half the participants reported having previously spent time in prison. A significant proportion (38.8%) of the participants, women and men, reported being a victim of domestic violence.

The arms also differed significantly on a number of baseline variables, namely GAD7, SDS, cannabis joints per day, time spent in prison, physical illness and motivation to quit with the UC arm scoring higher in all cases but lower motivation to quit (see Table 3).

Education, employment and housing status

37.6% were educated to A-level/Highers (or equivalent) or above. Employment status varied, 2.5% reported being in current paid employment and 97.5% reported recourse to benefits (social security/benefits). Just over half of the sample (60%) were currently housed in supported accommodation or in a hostel, 8.8% reported sleeping rough.

Cigarette dependence and smoking behaviour

The mean number of cigarettes smoked per day (including roll ups) was 20 (SD=15.33), this is equal to a pack per day in the UK. Mean expired CO breath level was 20.29 ppm (SD=10.04). The FTCD score was 5.51 (SD=2.47). In relation to smoking practices which increase the risk of respiratory infection,

55% reported that they shared cigarettes (24% reported doing this daily), 43% reported that they had smoked discarded cigarettes (6% reported doing this daily).

Motivation to stop smoking (MTSS) varied considerably although, only 6% reported that they did not want to stop smoking, the large majority expressed a desire to quit smoking in the near future.

Differences between the intervention arm

The proportion of participants who had previously spent time in prison or who had a long-standing illness, disability or infirmity was significantly higher in UC compared to those assigned an EC. UC arm participant also scored higher on anxiety and substance dependence, smoked more cannabis joints per day and were less motivated to quit smoking. Given these differences and the differences between centres (see description of settings, p. 18), we conducted sensitivity analyses (One Way ANOVA with post-hoc tests for continuous variables and Fisher's Exact Tests for categorical variables; not per-protocol) to explore differences between the four centres on variables where there was a significant difference between arms. Cannabis smoking and substance dependence scores were significantly higher at the day centre in Edinburgh (centre 2; UC) compared to all other centres (all p's<0.01 for cannabis smoking and all p's<0.05 for SDS) which did not differ from each other. Similarly, anxiety (GAD7) scores were also highest at centre 2 and differed significantly from centre 1 (day centre, Northampton, EC) and 4 (residential centre, London, EC) ($p<0.05$) but not centre 3 (residential centre, London, UC) and centres 1, 3 and 4 did not differ from each other. Motivation to Stop Smoking (MTSS) was significantly higher at centre 1 compared with all other centres ($p<0.01$) which did not differ to each other. A higher proportion of participants from centre 2 had spent time in prison (73% vs 36%, 50% and 56% respectively in centres 1, 3 and 4). The difference between centre 1 and 2 was statistically significant ($p<0.01$). A higher proportion of participants from centres 2 (91%) and 3 (90%) (both UC) reported a long standing illness compared to those at centres 1 (67%) and 4 (44%). Significant differences were observed between centres 2 and 4 and 3 and 4 ($p<0.05$).

Table 3: Participant Baseline Characteristics

	Total N=80	EC arm	UC arm	P value
Age (in years): mean (SD)	42.66 (10.79)	42.75 (10.90)	42.53 (10.78)	.93
Gender: N (%)				.34
Female	28 (35)	19 (40)	9 (28.13)	

Male	52 (65)	29 (60)	23 (71.88)	
Employment status N (%)				.11
Full time school or college	0 (0)	0 (0)	0 (0)	
Paid employment/self-employed	2 (2.5)	2 (4.16)	0 (0)	
Government training scheme	2 (2.5)	1 (2.08)	1 (3.13)	
Unpaid or voluntary work	9 (11.3)	9 (18.75)	0 (0)	
Waiting to work, already obtained	1 (1.3)	1 (2.08)	0 (0)	
Looking for work/training scheme	12 (15.0)	7 (14.58)	5 (15.63)	
Prevented by temporary sickness/injury	5 (6.3)	2 (4.16)	3 (9.38)	
Permanently unable to work	38 (47.5)	21 (43.75)	17 (53.13)	
Unemployed and not looking for work	5 (6.3)	3 (6.25)	2 (6.25)	
Other	6 (7.5)	2 (4.16)	4 (12.5)	
Current sleeping situation (last 7 days): N (%)*				
Sleeping rough on streets/park	7 (8.8)	3 (6.25)	4 (12.5)	.42
Hostel or supported accommodation	48 (60)	31 (64.58)	17 (53.13)	.36
Sleeping on somebody's floor/sofa	3 (3.8)	1 (2.08)	2 (6.25)	.56
Emergency accommodation (refuge, shelter)	9 (11.3)	8 (16.66)	1 (3.13)	.08
B&B or temporary accommodation	2 (2.5)	1 (2.08)	1 (3.13)	1.00
Housed – own tenancy	18 (22.5)	8 (16.66)	10 (31.25)	.17
Other	2 (2.5)	2 (4.16)	0 (0)	.51
Backgrounds: N (%)*				
Spent time in prison	40 (50)	19 (40)	21 (65.63)	**.04**
Spent time in secure/young offender unit	18 (22.5)	9 (18.75)	9 (28.13)	.41
Spent time in local authority care	17 (21.3)	7 (14.58)	10 (31.25)	.10
Spent time in the armed forces	7 (8.8)	3 (6.25)	4 (12.5)	.43
Admitted to hospital due to mental illness	31 (38.8)	18 (37.5)	13 (40.63)	1.00
Been a victim of domestic violence	31 (38.8)	18 (37.5)	13 (40.63)	1.00
Highest level of education: N (%)				.40
School (stopped prior to GCSE/standard grade	24 (30)	17 (35.42)	7 (21.88)	
School (GCSE/Standard grade)	26 (32.5)	13 (27.08)	13 (40.63)	
College (A-level/FE/Highers)	25 (31.3)	15 (31.25)	10 (31.25)	
University (degree level)	4 (5)	3 (6.25)	1 (3.13)	
University (post-graduate, higher level)	1 (1.3)	0 (0)	1 (3.13)	

Ethnicity: N (%)				.64
White	61 (76.3)	35 (72.92)	26 (81.25)	
Asian/Asian British	2 (2.6)	6 (12.50)	2 (6.25)	
Black/Black British	9 (11.4)	2 (4.17))	0 (0)	
Mixed race/multiple ethnic groups	8 (10.2)	5 (10.42)	4 (12.5)	
Sexual Orientation: N (%)				.81
Heterosexual or straight	68 (85)	40 (83.33)	28 (87.5)	
Gay or lesbian	1 (1.3)	1 (2.08)	0 (0)	
Bi-sexual	3 (3.8)	2 (4.16)	1 (3.13)	
Prefer to self-define	3 (3.8)	2 (4.16)	1 (3.13)	
Prefer not to say	3 (3.8)	3 (6.25)	0 (0)	
Missing	2 (2.5)	0 (0)	2 (6.25)	
Immigration Status: N (%)				.68
UK National	74 (92.5)	45 (93.75)	29 (90.63)	
European Economic Area (EEA) national	6 (7.5)	3 (6.25)	3 (9.38)	
Receiving public Funds (Benefits): N (%)				.16
Yes	78 (97.5)	48 (100)	30 (93.75)	
No	2 (2.5)	0 (0)	2 (6.25)	
Long-standing illness, disability, infirmity: N				**.02**
(%)	59 (73.8)	30 (62.5)	29 (90.63)	
Yes	16 (20)	13 (27.08)	3 (9.38)	
No	4 (5)	4 (8.33)	0 (0)	
Prefer to self-define	1 (1.3)	1 (2.08)	0 (0)	
Prefer not to say				
Number of cigarettes/day: mean (SD)	20.07 (15.33)	20.5 (16.78)	19.41 (13.07)	.86
Expired CO: mean (SD)	20.29 (10.04)	19.60 (9.58)	21.31 (10.77)	.46
Number of joints per day: mean (SD)	0.7 (1.69)	0.29 (1.13)	1.73 (2.69)	**.02**
FTCD: mean (SD)	5.51 (2.47)	5.24 (2.53)	6.13 (2.35)	.12
Age started smoking: mean (SD)	15.17 (5.47)	16.02 (6.30)	13.92 (3.72)	.09
Sharing cigarettes: N (%)				.10
Not at all	35 (43.8)	25 (52.08)	9 (28.13)	
Occasionally	18 (22.5)	10 (20.83)	7 (21.88)	

Regularly	7 (8.8)	3 (6.25)	5 (15.63)	
Daily	19 (23.8)	9 (18.75)	11 (34.38)	
Smoke discarded cigarettes: N (%)				.43
Not at all	45 (56.3)	30 (62.5)	15 (46.88)	
Occasionally	22 (27.5)	12 (25)	10 (31.25)	
Regularly	7 (8.8)	3 (6.25)	4 (12.5)	
Daily	5 (6.3)	2 (4.16)	3 (9.38)	
Ask strangers for cigarettes: N (%)				.35
Not at all	47 (58.8)	31 (64.58)	16 (50)	
Occasionally	21 (26.3)	12 (25)	9 (28.13)	
Regularly	5 (6.3)	2 (4.16)	3 (9.38)	
Daily	6 (7.5)	2 (4.16)	4 (12.5)	
MTSS: N (%)				**.04**
I don't want to stop smoking	5 (6.3)	1 (2.08)	4 (12.5)	
I think I should stop but don't really want to	8 (10)	4 (8.33)	4 (12.5)	
I want to stop but haven't thought about	14 (17.5)	6 (12.5)	4 (12.5)	
when	11 (13.8)	3 (6.25)	8 (25)	
I really want to stop but I don't know when I	18 (22.5)	16 (33.33)	5 (15.63)	
will	7 (8.8)	5 (10.42)	3 (9.38)	
I want to stop smoking and hope to soon	14 (17.5)	11 (22.92)	3 (9.38)	
I really want to stop & intend to within 3	3 (3.8)	2 (4.16)	1 (3.13)	
months				
I really want to stop and intend to within 1				
month				
Missing				
Importance of quitting at this attempt: N (%)				.25
Desperately important	13 (16.3)	10 (20.83)	3 (9.38)	
Very important	38 (47.5)	25 (52.08)	15 (46.88)	
Quite important	19 (23.8)	7 (14.58)	10 (31.25)	
Not at all important	8 (10)	5 (10.42)	3 (9.38)	
Determination to quit at this attempt: N (%)				.52
Extremely determined	19 (23.8)	13 (27.08)	6 (18.75)	
Very determined	26 (32.5)	16 (33.33)	10 (31.25)	
Quite determined	24 (30.5)	14 (29.16)	10 (31.25)	

Not at all determined	8 (10.0)	3 (6.25)	5 (15.63)	
Missing	3 (3.8)			
Self-rated chance of quitting				
(1 = very low – 6 = extremely high): mean (SD)	3.74 (1.53)	4.09 (1.21)	3.81 (1.35)	.34
GAD7: mean (SD)	11.22 (7.09)	9.87 (6.86)	13.33 (7.04)	**.04**
PHQ9: mean (SD)	12.93 (8.15)	12.46 (7.97)	13.67 (8.50)	.53
AUDIT: mean (SD)	9.22 (10.20)	9.50 (10.46)	8.80 (9.93)	.77
SDS: mean (SD)	5 (4.81)	3.49 (4.13)	7.44 (4.90)	**<.01**

*Participants could select more than one option. MTSS = Motivation to Stop Smoking Scale: GAD7 = Generalised Anxiety Disorder Questionnaire: PHQ9 = Patient Health Questionnaire; AUDIT = Alcohol Use Disorders Identification Test; SDS = Severity of Dependence Scale; T-tests/Mann Whitney U used for continuous variables. Fishers Exact Test used for categorical variables.

Numbers analysed

Appendix 1 presents the CONSORT flow diagram showing the numbers for each intervention arm.

Objective 1: Assess willingness of smokers to participate in the feasibility study to estimate recruitment rates and inform a future trial.

Outcome: Record the number of smokers asked to take part, and the number who consent.

Across the four centres, 177 participants were initially invited to take part. Of these, 24 were not eligible (16 in the EC arm and 8 in the UC arm). Of the remaining 153 eligible individuals (90 in the EC arm and 63 in the UC arm), 80 consented to take part in the study; 48 (56%) in the EC arm and 32 (50.5%) in the UC arm. Although we did not reach the recruitment goal of 120 that we set ourselves (based on our preliminary scoping work), we did recruit these 80 participants within the originally specified five-month period. Recruitment also differed across centres; the two-day centres were most successful in terms of recruitment (39 consented at centre 1, 22 at centre 2), together accounting for 77.5% of the total sample and there was a waiting list of participants who could not be recruited at centre 1 as the researcher had to move on to the next centre. The residential units had fewer eligible individuals, including fewer smokers, and potential participants were less available due to work or other appointments and less interested in the study. Also, (see discussion for more information), there

was less opportunity to recruit within the residential centres because of centre space and room availability and issues around disturbing residents.

Summary learning points for a future trial

Ensure sufficient researchers are employed on the project to deal with recruitment and limit sites to day centres only.

Objective 2: Assess participant retention in the intervention and control groups.

Outcome: Record a) how many participants complete assessment measures in each arm at each time point, b) how many participants are still using e-cigarettes in the intervention group.

The CONSORT flow diagram presents the participant numbers at recruitment, and follow-up data by intervention (Appendix 1). Within the EC cluster, retention rates were 81%, 69% and 73% at 4, 12 and 24 weeks respectively. Within the UC cluster retention rates were 66%, 53% and 38% respectively at 4, 12 and 24 weeks.

There was a lower rate of attendance within the UC intervention at the 12 and 24-week follow-up. The most common reason for not following up was that participants were no longer attending the services; although exact reasons were not formally documented by the research team, these reasons were highlighted informally via conversations with centre staff.

This difference in retention between arms did not appear to be due to the UC condition per se but rather, to baseline differences which might influence ability to attend follow ups. The UC arm was associated with a higher incidence of criminal background, illness, disability, substance abuse, anxiety, and lower motivation to quit. (see Table 3). This was particularly the case for centre 2 (day centre in Edinburgh; see above) which was also associated with a far lower 24-week retention rate (26%) than centre 3 (residential centre in London; 67%).

We asked all participants in the EC intervention if they were still in possession of the EC that we provided (although they did not have to present it at the appointment), and whether they were still using the EC since the last appointment. Assuming that all those who did not attend follow-up sessions did not still have, or were not still using, the EC, at 24 weeks 46% (22/48) still had the EC that we provided and 56% (27/48) were still using. Table 4 presents the data based on the number of

participants who attended and answered the question at each follow-up. The greatest fall in use was between the 12 and 24-week follow-up, however 63% of those asked self-reported that they were still in possession of the device. Similarly, in relation to use, the greatest fall was between 12 and 24-week follow-up, however of those in attendance at 24-weeks, 79% reported that they were still using an EC, either the device that was provided at baseline or a different one.

Table 4: Data for possession of and use of the EC provided at baseline for participants assigned to the EC clusters. NB: % is from those who attended follow-up only.

EC Intervention	4-week follow-up	12-week follow-up	24-week follow-up
Still have the EC?			
Yes	33 (85%)	28 (82%)	22 (63%)
No	6 (15%)	6 (18%)	13 (37%)
Still using an EC?			
Yes	37 (95%)	30 (91%)	27 (79%)
No	2 (5%)	3 (9%)	7 (21%)

UC: Usual care. EC: E-cigarette. Follow up times are scheduled from the baseline appointment.

Summary learning points for a future trial

Larger numbers, more clusters and official randomisation should reduce baseline differences between groups. Randomisation with stratification by region should also ensure that variables that predict drop out are equally distributed between groups thus reducing the difference in retention across arms. In the event of a future trial, it would be important to consider ways in which retention could be maximised including other ways of maintaining more regular contact with participants, e.g. increasing text and verbal contact between appointments [31].

Objective 3: Examine the perceived value of the intervention, facilitators and barriers to engagement and influence of local context.

Outcome: Qualitative interviews with 4-week completers and non-completers, quitters and smokers (N=24, approx. 6 per site) between weeks 4 and 8 across both arms.

This section presents the findings of 22 in-depth qualitative interviews with a sub-sample of study participants. Given difficulty in contacting most of those participants who had not completed their 4-week follow-up, and with the majority of study participants smoking at week 4, it was not possible to conduct interviews with a good range of completers and non-completers, quitters and smokers as intended. However, there is a good spread of qualitative participants across the four homeless centres and both study arms (see Appendix 3 for the qualitative sample characteristics). Nineteen interviewees (86.4) had completed their week 4 follow-up and three (13.6) had not completed this follow-up. At the week 4 follow-up, 18 of the 22 interview participants (81.8%) were smoking, 1 was abstinent and 3 did not provide smoking information.

We explored participants' experiences of the study in line with research objective three. The findings present six topic summary themes: barriers and facilitators to study and intervention engagement; experiences of the EC intervention; experiences of UC; perceptions of study processes; unintended consequences; and perceived value. Local differences, where they exist, are highlighted in the text. The section ends with a summary of key learning points for a future trial.

<u>Barriers to study and intervention engagement</u>

Participants' personal barriers

Interview narratives highlighted the psychological and emotional vulnerability of many of our participants. Some explained that their mental state, attention difficulties, anxiety around social interaction, and difficulties with appointments, made engaging in treatment programmes challenging.

> *"It is partly my mental health… I do panic about talking to people… It's very hard sometimes, just to sit and explain yourself."* (Participant16, C03, UC)

Several displayed mistrust in authorities and research.

> *"I thought 'oh this definitely a government initiative they're going to run a test on the homeless… maybe they've got a dodgy batch of [e-liquid] and they just want to see if it takes anyone out before they put them up for sale.'"* (Participant02, C01, EC)

While some reported being comfortable providing personal data as part of the study, this was a major concern for others, with particular anxiety around whether data would be shared, *"if I thought my information was being shared, then I wouldn't take part*" (Participant11, C02, UC).

Participants also lacked confidence in their ability to stop smoking and many reported their ideal outcome would be to cut down first, rather than stop straightaway, "*if you can cut down, then you can go that further field*" (Participant09 C02, UC). This was due to their reported reliance on smoking to deal with stress, isolation or boredom. Traditional stop smoking approaches, particularly NRT which was reported to have interacted unpleasantly with substance use or mental health in previous quit attempts, were unappealing for participants. This presented a significant barrier to engagement with local SSS for those in the UC arm.

Cannabis smoking

For participants regularly smoking cannabis mixed with tobacco, most reported wanting to reduce or stop their cannabis consumption, although this presented concerns and was highlighted as especially difficult given the associated pleasure, "*I feel relaxed [smoking cannabis when] I've been wound up all day*" (Participant11, C02, UC). Some noted how cannabis use had drawn them back to smoking in previous quit attempts.

> *"I've quit smoking a couple of times and the thing that always brought me back was smoking weed with the tobacco."* (Participant04, C01, EC)

Two participants, previously dependant on heroin, described reliance on cannabis as a protective factor in abstaining from other substances.

> "I'm an ex-addict, I used to inject heroin etcetera, now I stopped all that and started smoking cannabis and that stopped me taking any other drug." (Participant13, C02, UC)

Participants experiencing mental health distress described that cannabis helped them to cope and were anxious stopping cannabis use would exacerbate their symptoms.

> *"I suffer from a lot of anxiety and depression, so it's just heightened it. It made it worse, trying to stop."* (Participant11, C02, UC)

Facilitators to study and intervention engagement

Opportunity: right time and place

All our interviewees reported desire to stop or reduce their smoking, expressing concerns about finances or health. Whilst most had tried to quit previously, negative experiences with NRT and mainstream routes of support (e.g. GP appointments) meant these approaches were unattractive. This made opting into an incentivised, on-site smoking treatment programme appealing. Many illustrated their receptivity to engaging with support at a place they already attended. Bringing smoking cessation aids and services to participants in their own environments was therefore a key facilitator for engagement.

> *"I just thought if you were coming here and Tuesday is my day off, I'd definitely benefit by taking part… So why not?"* (Participant15, C03, UC)

> *"So I'm glad that this has come along because I don't think, if this hadn't have happened, I would have bothered to give up. I had no plans of giving up, until that day, none."* (Participant 19, C04, EC)

Free e-cigarette starter kit and gift cards

The incentive of receiving a free EC starter kit and/or Love2Shop follow-up gift cards played important roles in study engagement. While the gift cards received for attending follow-up appointments were valued by all participants, they were especially important for facilitating study recruitment for the UC group.

> *"My main incentive – I can't tell lies – is the £15 voucher aye. Why not? If you can come to the centre and make fifteen pounds, well then that is fine. Happy days."* (Participant11, C02, UC)

In the EC arm, the offer of a starter kit capitalised on participants' desire to quit and perceived lack of existing cessation options. Despite some participants' lack of initial enthusiasm for vaping, participants

said it prevailed as worth trying, given the availability and offer of device and e-liquid, especially at a time of financial hardship.

> *"[I] didn't have to go out and buy it you see, you know, 'here it is, just try it.'"* (Participant07, C01, EC)

> *"…the thought of maybe it might work and there's nothing to be lost, there's only something to be gained, you don't have to pay for the device…"* (Participant02, C01, EC)

Providing free starter kits also overcame start-up cost barriers for those who had expressed previous interest in vaping.

> *"I have wanted to do it before but thought it was going to be really costly to start up. I haven't got a spare 30 quid to lay down, ever.* (Participant19, C04, EC)

Social context

Social dynamics facilitated EC intervention engagement. Some participants described becoming strong study and vaping advocates. EC intervention buy-in, particularly from individuals with social status amongst peers, helped raise awareness and interest. Word-of-mouth communication quickly relayed vaping benefits to potential participants.

> *"Everyone I see who smokes I tell them you've got to try it, and I really try and talk them into it. but I'm worried I'm becoming one of those [laughs] people that gives up smoking and just like is a pest. But I want to pester them because it's - I know it's good."* (Particioant19, C04, EC)

> *"…now four or five key people have done it and no one, there was no 'oh are you vaping?'"* (Participant02, C01, EC)

Positive peer influence was especially prevalent at the day drop-in centre (Centre 1), with high demand for the intervention and the creation of a vaping community, characterised by peer advice on equipment and technique, and social vaping norms.

> *"I'll go out, still socially… six or seven of us are vaping away… there's no stigma attached to it anymore. You can just vape happily."* (Participant02, C01, EC)

> *"… they encourage you to stop smoking, you encourage them. So it's a bit of like support in a way. Moral support to try and cut down.*" (Participant03, C1, EC)

A vaping community was not as evident in the residential centre (Centre 4). Generally, in these residential units, the service users we met tended not to mix as much and reported more solitary activity, often staying in their rooms, "*I don't [notice others vaping] …I don't pay any attention to them. I just come in and go out*" (Participant21, C04, EC).

Participants' experiences of the e-cigarette intervention

Participants in the EC arm provided detailed descriptions of their initial expectations, the information and instructions they received, the EC and e-liquids, and their experiences with vaping.

Initial expectations

Most participants had not tried vaping before, reporting little knowledge about EC. Many described their initial scepticism and low expectation that EC would help them to reduce or stop smoking. It was common for participants to think the intervention would not be suited to them. For others, engagement in the study meant going against their negative view on vaping, *"I was anti-vape*" (Participant02, C01, EC).

> *"I did not think for a minute it would fit for me, and work with me at all. I had no hope... hugely low expectations…. I didn't give myself a hope in hell."* (Participant05, C01, EC)

E-cigarette information and instructions

Most participants reported satisfaction with the information provided. Instructions were considered thorough and participants particularly valued the practical demonstration, which included advice on device set-up, maintenance, and use. Some said the practical help leaflets were useful to refer back to.

> "T*hey basically showed me how to use the vape and how to change the liquid… how to charge it… change my coil… what to do when I need to clean the vape out. So it was just a really big help because I didn't really understand anything about vaping and vape pens before."* (Participant03, C01, EC)

E-cigarette device

Perceptions on the device were mixed. Some found it easy to use and liked its compact size, light weight and long-lasting battery. While there were several reports of batteries overheating, this issue was a suspected manufacturer fault. Others reported problems with durability, reporting that the device broke easily when dropped (a common occurrence), resulting in cracks and leaking e-liquid.

> *"I mean I've dropped mine several times… I've sort of repaired it… it's still leaking juice."* (Participant02, C01, EC)

With no money readily available to replace devices or replacement parts, some had used tape to repair their devices. One highlighted the importance accessible and affordable replacement parts.

> *"If you are going to use a vape on a study with vulnerable and homeless people, I would suggest you pick a vape that the parts are more accessible. Because, most of these things you have to go online to get them. And most of these people don't have a bank account, let alone be able to go online."* (Participant01, C01, EC)

E-liquid

Finding a preferred e-liquid was important for continued use and participants had differing preferences. Perceptions on the e-liquid provided were generally positive. Many interviewees said they were satisfied with the variety of flavours, amount, and nicotine content. Experimentation was important for participants to find what suited them best. The flavour options were not liked by all however, and several suggested the study should provide a greater variety. Some described mixing flavours, exchanging flavours with others, and purchasing different flavours.

> *"I think [the variety] covered all bases… I was telling everyone three quarters blueberry or half blueberry and half polar bear and seems to have gone down rather well."* (Participant02, C01, EC)

Some also commented that the available strengths were too high leading to initial adverse effects such as coughing or feeling sick which could put them off continued use.

> "*I shouldn't have started on 18[mg] straight away... I think I went full out too strong…I didn't give myself a chance.* (Participant06, C01, EC)

> *"… the 12[mg]s and 18[mg]s are very high. A lot of people get head rushes and things… I can hit it about twice before nearly passing out. I have to mix mine down."* (Participant04, C01, EC)

Vaping experience

Many interviewees noted their vaping frequency increased over time, with the reported realisation that vaping was helping with smoking reduction and more useful than NRT. Many were pleasantly surprised with these changes and intended to continue.

> *It surprised me… I know 65% [smoking reduction] isn't massive but I've been smoking 30 years. It's a dramatic amount in the short space of time...*" (Participant01, C01, EC)

> *"Well at first… I thought maybe it's just going to be a couple of days thing and then just put it on the side but no I use it every single day…it's helped."* (Participant18, C04, EC)

For some, vaping easily fitted in with existing routines and habits; it was easy to vape and more convenient than rolling a cigarette, especially when outdoors. One noted that vaping helped them to relax. Others found it more difficult to replace certain cigarettes with vaping, i.e. the first one in the morning or after dinner, and some described quickly choosing to smoke if their EC was unavailable or they were experiencing stress.

> *"I probably smoke about 35% cigarettes and 65% vape… It changed for a little bit where I was doing about 50/50, but I was having a well stressful time… if I have a stressful day like I know I'm going to have today, I will have about 5 [cigarettes]."* (Participant01, C01, EC)

Participants' usual care experiences

There was little evidence of engagement with UC among our interviewees. While some said they appreciated the information provided in the help-quit leaflet, many acknowledged they hadn't looked at it since the baseline appointment, "*I'm sorry to say that I didn't actually read through it*" (Participant12, C02, UC).

Only three of our interviewees made contact with local cessation support. When accessing support, participants emphasised that making contact with, or contact being facilitated by, someone they trust, was important. At Centre 2, participants with a methadone prescription reported good relations with the local pharmacist. While one participant obtained a nicotine inhalator this way, another did not obtain support as he was reluctant to speak with anyone else.

> *INT: Have you managed to go to the pharmacy to get some advice on reducing your smoking?*
> *Resp: No because every time I go [pharmacist] is not there.*
> *Int: Okay. But they must have someone else who can do it?*
> *Resp: Aye but I get on well with [pharmacist] so I would rather talk to people that I know.* (Participant13, C02, UC)

At Centre 3, two of our interviewees attended the local SSS accompanied by their keyworker. Without this keyworker support, one participant noted, "*I wouldn't have gone on my own*" (Participant15, C03, UC). Participants who had tried the UC approach were ambivalent about their experiences. The participant who used an inhalator complained of a sore head and nausea, had not found the nicotine delivery satisfying, and had not returned for further advice or support. At Centre 3, participants received a combination of patches and lozenges, however, they were critical of the advice provided and lack of availability of appropriate products.

> *"…they didn't have the appropriate strength to my taste and they gave me a weaker one. But I've tried it maybe four or five days…. I didn't quit smoking completely, but I reduced it like notably."* (Participant15, C03, UC)

One UC interviewees reported greater success by combing NRT with an EC. It was common for UC participants to be interested in EC or to have purchased and used one during the study. Cross-contamination was a feature of the study, as one participant explained:

> *"[Vaping] is helping me – buying my own one… [Researcher] told me that the other places were doing that. I thought 'well, I'll try my own one.' (Participant10, C02, UC)*

Perceptions of study processes

Understanding of the study

Most of our interviewees reported awareness of which study arm they were allocated to prior to the baseline meeting. Some also noted a lack of detailed initial information about the study and its aims. This ties in with staff reports of how they communicated the study (see Objective 4). There were two notable exceptions where EC arm participants likened the baseline assessment to a test, where they perceived the offer of an EC would be "*based on the answers*" (Participant03, C01, EC).

Pragmatic cluster design

Participants' accounts gave some indication of the appropriateness of the pragmatic cluster study design. In Centre 1 some participants perceived resentment from those not able to be recruited because the sample target had been reached, as they observed others receiving a free EC. This, combined with interviewees saying they would have felt "*scorned*" (Participant02, C01, EC) or "*like I'd just wasted my time*" (Participant21, C04, EC) if they had not been allocated an EC after completing the baseline questionnaires, suggests disharmony should both study arms have operated within one centre.

Case report form (CRF)

Some of our interviewees reported issues with the length of the baseline CRF, describing how sitting through a long appointment was difficult, "*it's not as easy for me to just sit, I fidget a lot*" (Participant03, C01, EC). Others described questions alluding to substance use and mental health appeared misplaced within a smoking study, "*why do you want to know about drug history or drinking?*" (Participant18, C04, EC). Some noted emotional difficulty in responding to more sensitive questions.

> *"It was difficult… it just brings back memories of things that – I tried to commit suicide three times… it did stress me a bit, but [researcher] was a nice man and he got me through it and we sat and sorted it out."* (Participant16, C03, UC)

Follow-up appointments

While some interviewees reported no difficulty in attending weekly or the 4-week follow-up appointment, this was problematic for some, who attributed missed appointments to issues such as other commitments, difficulty remembering, hospital admission and being distracted by other life events such as those requiring police involvement. Having no credit on their mobile phone to rearrange, having their phone stolen, and sleep patterns were reasons given for non-completion by our small number of interviewees who had not completed their 4-week follow-up.

Unintended consequences

Use of e-cigarettes to vape other substances

There was minimal evidence from our interview participants that the EC provided through the study was used to consume other substances. Only one interviewee said they had vaped cannabis e-liquid, which they had made, though they reported using this in a device previously purchased, not obtained through the study.

It was, however, common for interviewees across both arms to report anecdotes of other people, not connected to the study, vaping cannabis e-liquid, "…*yeah, people smoke weed in it..."* (Participant01, C01, EC), CBD oil or THC: "…*of course I've heard about it because I'm in [that] lifestyle*…" (Participant09, C02, UC). Additionally, one participant at a UC centre, where no EC had been provided as part of the study, reported to have heard of somebody who had "*cooked up heroin and put it in."* (Participant11, C02, UC). In response to interviewers' enquiries, some participants with a history of drug use speculated on the possibility of using EC to vape other substances.

> *"[I] suppose you could put heroin in an e-cigarette and it would do something. Not so with crack or coke. Don't think there are many drugs you can put in there. Liquid ones, yes.*" (Participant05, C01, EC)

> "*There's a definite similarity to smoking crack in its method and the sucking in… Yes the thought did pop into my head…*" (Participant19, C04, EC)

Love2Shop Gift cards

None of our participant interviews provided evidence that gift cards received for attending follow-up

appointments had been traded for other substances or cash (although there were a small number of informal reports of this occurring from trial participants who did not take part in a qualitative interview.) Rather, the qualitative data highlighted that in most cases participants had used their gift card to buy essentials, most commonly food "*I really need[ed] some food in. I had nothing. I was probably eating about twice a week at that point.*" (Participant05, C01, EC). Some described the gift card as an opportunity to save up or buy something for a family member: "*I can get my child school shoes now.*" (Participant10, C02, UC). One interviewee said they had purchased alcohol with the gift card.

Perceived value of the study and intervention

All participants in the EC arm placed great value on the intervention and the opportunity to try vaping. Even though most had not made a complete switch from smoking to vaping, they described a strong belief in EC as a quitting aid, and valued their increased vaping and tobacco harm reduction knowledge. Many described feeling healthier and better about themselves since starting vaping.

> *"I look in the mirror sometimes and see that I'm progressing, I feel a bit healthier. I'm not always having a cigarette."* (Participant03, C01, EC)

> *"I feel very proud of myself for the first time in ages… and I'm glad that it's had a healthy impact on my life…"* (Participant19, C04, EC)

> *"It does give you confidence… it's made me think, 'I can do something.' Cos my confidence has been knocked a lot. It's good."* (Participant05, C01, EC)

Some believed the EC intervention could be wide reaching in its ability to help disadvantaged smokers, saying it could "*help a lot of people*" (Participant04, C01, EC), and "*potentially save lives*" (Participant02, C01, EC).

> *"You're giving people a chance because you're giving them the equipment so, you know, they're halfway there and then it's up to you… that's a good thing. People, like myself, that would have never thought of buying one."* (Participant05, C01, EC)

Among the UC arm, some participants said they valued how the study made them consider their smoking and appreciated the information on where to access support, *"…even just participating, just*

even the thought that there is help out there to stop smoking is good enough" (Participant08, C02, UC). Most, however, believed EC would have been a more useful and effective approach.

> *"It could have been useful to have been in the half of the study that had electronic cigarettes given to them."* (Participant14, C03, UC)

Overall though, UC participants said they were pleased to have taken part. Across both arms participants valued how the study had enabled them to have their "*voice heard*" (Participant17, C03, UC) in relation to smoking. Some said they liked the thought that the study findings may help other homeless smokers in the future.

> *"I've enjoyed it. It makes me feel important to be part of something that is important*." (Participant19, C04, EC)

Summary learning points for a future trial

Participants' anxieties presented a significant barrier to study engagement. A sensitive and flexible research approach, characterised by participant/researcher trust can help to engage participants.

While cannabis smoking is a barrier to smoking cessation more generally, a future trial would need to consider how best to manage and monitor cannabis use so study objectives are not undermined.

Bringing smoking cessation aids and services to participants in their own environments was a key facilitator for engagement. Gift cards also incentivised participants to engage.

Despite low expectations, participants were willing to engage with the EC intervention. Clear, practical instructions, a durable device with easily accessible parts, and the option of a lower strength nicotine e-liquid may help facilitate use.

UC support was less attractive for participants. Previous negative experiences with NRT and anxieties about engaging with others were barriers to engagement.

Participants' accounts suggest a cluster design is appropriate in homeless settings. Participants may have benefitted from clearer information on the study at the recruitment stage and a shorter CRF. A future study should carefully consider the questions included in the CRF to minimise the burden on participants and reduce potential areas of sensitivity.

There was minimal evidence of unintended consequences, i.e. use of the EC provided to vape other substances or trading of gift cards, however a future study should continue to monitor this closely. However, device breakages were reported (see Harms below).

Perceived value of the study and intervention was high among all participants. Participants' desire to change their smoking behaviour and willingness to engage in the study presents a significant opportunity to engage homeless smokers in smoking discussions and treatment programmes.

Local context had implications for the study on two issues. First, social dynamics at the busy drop-in centre facilitated intervention engagement and vaping social norms. Future EC interventions might therefore benefit from capitalising on peer influence to create a supportive vaping community. Second, centre links and relationships, i.e. with keyworkers or the local pharmacy were a key feature of whether participants in the UC arm engaged with support. Studies should consider the impact of these relationships on UC uptake.

Objective 4: Assess service providers' capacity to support the study and the type of information and training required.

Outcome measure: Qualitative interviews with keyworkers and front-line staff (N=12; approx. 3 per site) across both arms.

This section presents the findings of 12 in-depth qualitative interviews with keyworker and support staff involved in facilitating and supporting the study. This included assisting with recruitment and appointments, setting EC arm participants up with the device, for example showing them how to use the device and helping them choose an e-liquid, providing EC arm participants with weekly EC support and further e-liquid, and providing UC arm participants with brief advice to quit and signposting information for the local SSS. The sample is spread across the four centres (see Appendix 3). We explored their experiences of the study in line with research objective 4. The findings present five key issues: staff assumptions; staff training; communicating the study; staff capacity to support the study;

and perceived value of the study. The section ends with a summary of key learning points for a future trial.

Staff assumptions about smokers experiencing homelessness

Most staff, across centres and study arms, perceived that stopping smoking was not a concern or priority for clients given other issues including mental health, substance use and chaotic lifestyles, *"[smoking is] the less of all the evils*" (Staff01, C01, EC). Other support needs were prioritised as staff believed smoking provided clients with comfort and enjoyment. These assumptions underpinned the lack of discussion about smoking between staff and clients, *"it's not something I would really discuss with them"* (Staff07, C02, UC). Staff had few links to local SSS, little knowledge on smoking cessation and few established processes to support clients.

> *"They have bigger things on their plates to deal with. I'm not going to try take away the one thing that they might enjoy. I'm already working with bigger challenges than that."* (Staff12, C04, EC)

Prior assumptions meant some staff made judgements about which clients, if any, would engage in the study, "*I thought no one would be interested*" (Staff09, C03, UC). Other staff expected EC arm participants to sell their devices. These assumptions, however, were not borne out by their study experiences.

> *"I'm amazed that [devices] have not been sold as far as I know… It was not at all how I expected it to go. It was nice as well because it taught me something – so you don't know everything about these guys. There are still things you can learn."* (Staff12, C04, EC)

Staff training

Prior to study commencement, the research team delivered staff training on smoking prevalence and harm, EC, local SSS, and supporting the study. The training was well received by those who participated in the session and was described as a key facilitator for their engagement with, and belief in, the study; staff felt "*better equipped*" (Staff10, C03, EC) to have more confident discussions with clients on smoking, local SSS and vaping. For many, the training facilitated a change in attitude on the importance of stopping smoking for their clients, alongside greater motivation to discuss smoking.

Some also noted a new understanding of tobacco harm reduction, making the comparison with drug harm reduction.

> *"Doing that training… it made sense because we work with a lot of people with COPD and actually smoking wasn't a priority at all. So the whole study actually has made me rethink… it's the same discussion, part of harm reduction as we have about safer injecting techniques.* (Staff06, C02, UC)

Our staff sample described having limited prior EC experience and initial ambivalence towards EC. Post-training, all reported increased knowledge and interest in EC as a harm reduction and smoking cessation aid. Staff in the EC arms appreciated practical, 'hands-on' EC training, researcher support, and clear, simple handouts. Some said this assisted them in intervention delivery, and also helped alleviate initial nervousness at providing the starter kit and instructions.

> *"The hand out sheets, I think those were the best things. It actually showed you – if you forget, this is what [to do]."* (Staff02, C01, EC)

Timing of training was important. Some staff expressed concerns about remembering information if there was a gap between training delivery and study commencement. Some suggested additional advice on local vape shops and vaping policies would be useful. Aware of some participants' anxiety around providing data, some suggested a better overview of the CRF, to give staff greater understanding of the types of questions and measures used in the study. Some staff noted that more training around facilitating recruitment, approaching participants, and what information should be given to potential participants would be useful in communicating the study (see below).

> *"Going back to the information stage, the recruitment stage. Just having a bit more information available for the staff to be able to use as a bit of a prompt. Or as a consistent communication style for all of them. I think that would be useful."* (Staff04, C01, UC)

Communicating the study

How staff communicated the study to participants was one of two deviations from the feasibility study protocol. As per the protocol, all participants were to receive the same study information at recruitment and complete baseline assessments *before* being told of their allocation to the EC arm or UC. For practical reasons, staff knew whether their centre was allocated to the EC or UC arm. When

facilitating recruitment, our sample of staff in the EC arm reported routinely introducing the study as an EC or 'vape study', where participants would receive a free EC if they signed up.

> *"I just basically told them, 'hey listen, I know you are smoking, are you interested in vaping, they are doing a smoking study, they are probably giving you free vapes if you are wanting to do that.'"* (Staff12, C04, 12)

> *"I did hear some conversations where it was really quite low level, where it was a vape [study] and you are going to get the vape."* (Staff04, C01, EC)

Conversely, our sample of staff in the UC arm said they focused their description of the study on smoking, quitting and local support, and did not suggest that participants would receive an EC.

> *"I'm not sure actually I introduced it really well… Just first asking them if they were a smoker... if they ever think of stopping and if so, that they could meet with [researcher]… you could help them and give them advice on how to stop… I don't think I even mentioned the e-cigarette. I completely forgot about the e-cigarette, because we don't get it."* (Staff07, C02, UC)

Staff capacity to support the study

<u>E-cigarette condition</u>

Few staff capacity issues to support the intervention were described by EC arm staff. There was some initial trial and error with setting up efficient processes, but once resolved, facilitating the intervention was described as straightforward. High demand for the intervention at Centre 1 led the manager to take control of managing referrals and baseline appointments, organising an appointment diary consisting of a main and 'backup' list, *"[Manager] was able to manage it really well from there… just one central point"* (Staff03, C01, EC). This same model was less successful at the smaller, residential units in Centre 4, where there were fewer alternate candidates and less motivation to be disrupted from their ordinary activity.

Staff across centres highlighted that weekly follow-ups, where staff provided participants with e-liquid and vaping support, could be challenging as some participants lost their appointment cards, did not show up at agreed times, or could not be contacted, "*it did happen quite a bit – people missing appointments, turning up late, turning up early*" (Staff03, C01, EC). In Centre 1, implementing a daily vaping 'surgery' overcame some of these difficulties; however, staff said it could still be challenging if

several participants came at once, or did not attend on their set day. Some noted the importance of flexibility if participants approached keyworkers at different times, "*if someone came in the afternoon and I'm free I would issue them the liquids then*" (Staff01, C01, EC). One also noted the importance of maintaining consistency for the follow-up sessions.

> *"So what we did was set up a smoking surgery between 10 and 11 every day. So people could come along, talk to other people that were vaping, and also get help if they needed it…also get their liquids and coils if it was their day to get them."* (Staff03, C01, EC)

Mainly, staff reported responding to participant queries relating to coils *"it was just about changing the coil… that was the main thing"* (Staff11, C04, EC). Some noted requests to help with broken devices and suggested staff having access to spare parts would be useful. Some also noted they had been asked to open e-liquid bottles due to some participants having poor dexterity. Most staff reported receiving few problems with batteries or charging devices. For managing participants' e-liquid supply, some noted that the variety on offer through the study was a good amount, anymore may have overwhelmed participants and staff.

> "*If you give people too much choice, it just becomes a nightmare. So having that restricted number I think was absolutely fine.*" (Staff02, C01, EC).

Usual care condition

There were some challenges for staff supporting the UC arm around recruitment and weekly follow-ups. While some described facilitating recruitment as straightforward, others found this challenging. At the day drop-in Centre 2, staff reported that once the small number of regular clients had agreed to take part, they had difficulty engaging those who were more transient. While the Love2Shop follow-up gift cards had been especially important for facilitating UC recruitment, some expressed discomfort in their reliance on the gift card as an incentive.

> *"It was almost like we were encouraging people to do it because they would get a voucher out of it. But it just felt a bit uncomfortable if I'm honest…"* (Staff06, C02, UC)

Additionally, some reported negative feedback from participants about the length of the baseline CRF and the types of questions, and expressed concern about recruiting some people clients to the study,

"*knowing that actually…it was going to be a challenge for them to answer all those questions*" (Staff06, C02, UC).

Staff signposting UC services and maintaining weekly follow-up contact was the second main deviation from the study protocol. At Centre 3, keyworker staff reported this process worked well. Two staff members had escorted their participating clients to local SSS and had attempted to quit alongside their clients.

> *"I escort clients to the stop smoking van, where they can get nicotine patches, all sorts of paraphernalia to help them stop smoking… [I'm] still going with them to the van. Every Tuesday... we all go for a coffee afterwards as well. So we've turned it into a real social event actually."* (Staff08, C03, UC)

In contrast, at Centre 2 our interviewees reported some capacity issues to complete these tasks due to lack of staff, busy workloads and client demands. Some described dealing with challenges requiring immediate attention, rather than resources to focus on stronger client relationships as a factor. Finding private space for researchers to conduct baseline or follow-up appointments could also be a challenge with rooms often purposed for other support services.

> *"I have found it, personally, really difficult to do the follow-up… You are always on the go and basically I forget... It seems feasible… and then the reality is it hasn't been… maybe because here we don't keywork as such."* (Staff07, C01, UC)

Staff's perceived value of the study

Similar to our participants, staff also placed high value on the study. Across arms, staff appreciated the opportunity to become involved in supporting clients' quit attempts, "*it's really important that we are involved in stuff like this*" (Staff06, C02, UC). Many highlighted that the study had resulted in positive shifts in practice, increasing smoking-related discussions, "*I can't think of any other time we had a conversation about smoking with any other client*" (Staff12, C04, EC).

> *"It's an excellent thing, just being part of this study that is potentially going to inform practice and policies and how we deal with smoking amongst the homeless, it's just immense. The study is going to change the way we do things."* (Staff02, C01, EC)

While staff at the UC centres were positive about the study and pleased to have taken part, "*I feel privileged that we were included in this*" (Staff03, C03, UC), some expressed less enthusiasm for UC cessation support, and disappointment that they had been unable to provide clients with EC, "*I think getting the e-cigs… I think that would be very helpful for people*" (Staff05, C02, UC).

Staff in the EC arm were particularly enthusiastic about the intervention. Many noted positive impacts on their clients' wellbeing. They valued being able to offer clients a tangible, practical tool, rather than just offer stop smoking information. Many reported that the intervention had facilitated client trust and interactions and boosted staff morale.

> *"It has brought them to the centre every day, which is good. Building a bit of trust, which is always a winner."* (Staff03, C01 EC)

> *"I think this is a lot more immediate [than other cessation support]. With the attention deficit some of our clients have got, to be given something tangible – to be given something, not just information, something practical they can use."* (Staff01, C01, EC)

Summary of learning points for a future trial

Staff training was key to changing staff misperceptions about smokers experiencing homelessness and engaging staff in the study. Recommendations to further improve staff training include: consideration of the timing of training in relation to study commencement; advice on local vape shops and policies; a more comprehensive overview of the CRF measures and questions; and greater training on facilitating recruitment.

For a cluster study design, consideration should be given to how best communicate the study to participants, and whether it is practically feasible for participants across arms to be provided with the same information at recruitment.

Staff capacity to support the intervention was good at the EC centres and in one UC centre, suggesting service providers are well placed to offer stop smoking interventions.

Local differences made some study processes more challenging. In one UC centre, lack of adequate staffing numbers, a busy environment, and staff supporting people with acute challenges requiring immediate attention, rather than in keyworker roles, highlighted capacity issues in signposting to usual care and following up participants. Service providers could be further supported by suggesting systems for managing referrals, appointments, signposting and follow-ups, taking into account differences at each site.

Objective 5: Assess the potential efficacy of supplying free e-cigarette starter kits

Outcome measure: Measure breath CO levels, self-reported quit rates/cigarette consumption at each follow-up time point.

Table 5 presents the cessation and smoking reduction outcomes. 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, the 24-week sustained abstinence rate was 6.25% (3/48) in the EC arm vs. 0/32 (0%) in the UC arm.
Seven-day point prevalence rates at 24 weeks were the same as sustained abstinence rates.

Of those who returned for 24-week follow-up (not ITT), the percentage of participants who reported >50% reduction in CPD from baseline was 43% in the EC arm and 25% in the UC arm. The percentage of those with >50% reduction in expired CO was a little lower and similar between groups (EC= 20%; UC= 25%).

Table 5: Frequencies and percentages for smoking related outcome variables at baseline and each follow-up time point for the e-cigarette (EC) and usual care (UC) arms

	EC Arm	**UC Arm**
Sustained abstinence		
4 weeks: N (%)	8/39 (21%)	0 / 21 (0%)
12 weeks: N (%)	2/34 (6%)	0/18 (0%)
24 weeks: N (%)	3/35 (11%)	0/12 (0%)
7-day point prevalence		
4 weeks	7/39 (18%)	0/21 (0%)

12 weeks	5/34 (15%)	0/18 (0%)
24 weeks	3/35 (9%)	0/12 (0%)
50% reduction in CPD		
4 weeks	21/39 (54%)	4/21 (19%)
12 weeks	20/34 (59%)	4/18 (22%)
24 weeks	15/35 (43%)	3/12 (25%
50% reduction in expired CO		
4 weeks	10/39 (26%)	2/21 (10%)
12 weeks	7/34 (21%)	1/18 (6%)
24 weeks	7/35 (20%)	3/12 (25%)

UC: Usual care. EC: E-cigarette. Number of people achieving sustained abstinence refers to abstinence (allowing up to 5 cigarettes) since the baseline appointment at the time of follow up. Number of people achieving 7-day point prevalence refers to abstinence within the 7-days prior to the defined follow-up period. Number of people achieving 50% reduction in CPD (cigarettes per day), calculated as greater than 50% reduction in the number of cigarettes smoked per day. Number of people achieving 50% reduction in CO (carbon monoxide), calculated from deducting CO at baseline.

Intra-class correlation co-efficient

The intraclass correlation coefficient was calculated by the Fleiss-Cuzick method [35] and was estimated to be 0.0157. The intra class correlation coefficient is the 'proportion of the total variance in the outcome attributable to variance between clusters'[35]. Although the estimated ICC is relatively small, neglecting to factor this into the sample size calculation for a full-scale cluster randomised controlled trial would result in reduced statistical power.

Summary of learning points for a future trial

Based on the feasibility average recruitment of 16 per month, it would take 24 months to recruit 384 participants. A main trial would therefore need more (at least double) researchers recruiting and collecting data simultaneously.

The estimation of the intraclass correlation coefficient used the Fleiss-Cuzick method and was not adjusted for individual level baseline measures. In the full trial, the analysis is likely to be by mixed effects models where adjustment for prognostic covariates (e.g. baseline nicotine dependence, number of years smoking) is possible. This adjustment for covariates is likely to reduce cluster level

correlation in outcomes therefore an estimated ICC of 0.01 is used for the sample size calculation for the full trial.

Objective 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.

Outcome measure: Record participant scoring on EQ-5D-3L and utilisation of primary and secondary health care services using a self-report service-use questionnaire at each time point.

The missing information on EQ-5D-3L was mostly due to absence at follow-up visits. Most of those who have attended completed the measure. At baseline, 46 out of 48 participants in the EC arm and 31 out of 32 participants in the UC arm completed EQ-5D-3L. At 4 weeks, all participants in both arms who were followed-up completed it. At 12 weeks, 33 out of 34 attending participants in the EC arm and all 18 attending participants in the UC arm completed it. At 24 weeks, 34 out of 35 attending participants in the EC arm and all 12 in the UC arm did so.

Among the observed cases, no one reported severe problems in mobility in both arms at any time points. The domain with highest percentage of severe problem was anxiety/depression at baseline, 4 and 12 weeks in both arms, followed by pain/discomfort. At 24 weeks, the percentage was similar in the two domains within each arm. The proportion of participants who scored no problem was consistently higher in the EC arm than in the UC arm across all domains and all time points. This led to a consistently higher mean utility score in the EC arm among those who completed the measure **(Table 6).** Among those who completed EQ-5D-3L at all time points, mean QALY was 0.195 (SD 0.097) in the UC group (n=11) and 0.315 (SD 0.120) in the EC group (n=26), over 24 weeks.

Table 6: EQ-5D-3L utility and VAS at each time point, by group

	UC (n=32)			EC (n=48)		
	n	Mean (SD)		n	Mean (SD)	
		Utility	VAS		Utility	VAS
Baseline	31	0.394 (0.362)	57.0 (21.7)	46	0.548 (0.341)	52.7 (20.7)
4 weeks	21	0.330 (0.308)	48.6 (24.7)	39	0.602 (0.346)	61.4 (21.5)
12 weeks	18	0.350 (0.351)	59.3 (22.7)	33	0.683 (0.309)	65.6 (21.3)
24 weeks	12	0.619 (0.238)	61.0 (22.5)	34	0.653 (0.363)	61.8 (21.6)

UC: Usual care. EC: E-cigarette. VAS: Visual Analogue Scale for rating of health today

There were three sections concerning services use: SSS use at follow-ups, smoking cessation help from primary/community healthcare professionals, and general healthcare services. Overall, most of those participants who attended the follow-up visits, completed these sections, with only individual participants had item missing on a few questions.

The attendance of SSS sessions was very low in the UC arm. At 4 weeks, four participants out of 21 contacted SSS. One attended two sessions, three attended one and one did not answer. At 12 weeks, two participants out of 18 contacted SSS, one attended one session and the other attended two. At 24 weeks, two of 12 participants contacted SSS, one attended one session and the other attended two. Using the resource impact template for smoking cessation service [36], the unit cost per session was estimated to be £12.82. In the UC arm, the mean cost of SSS sessions was £3.21 (SD £9.18) at 4 weeks (n=20), £2.14 (SD £6.60) at 12 weeks (n=18), and £3.21 (SD £7.97) at 24 weeks (n=12). In the EC arm, there was no SSS session cost incurred as none of the participants reported attending any session.

At 4 weeks, three of 21 participants in the UC arm used other medications supplied by SSS, including inhaler, patches, and lozenges, with a mean cost of £5.68 (SD £14.30) in the arm. At 12 weeks, two of 18 used patches, lozenges in the UC arm, with a mean cost of £5.43 (£16.01) in the arm. At 24 weeks, one of 12 in the UC arm has used gums and patches, with a mean cost of £3.38 (£11.71) in the arm. None of the attending participants in the EC arm reported using cessation aids supplied by SSS. The majority of them reported using their e-cigarette device only. Among those in the EC arm, who claimed not using any aids supplied by SSS or research team, two reported using other e-cigarette device.

No one reported using varenicline or bupropion. No one purchased any NRT product. The purchase of EC device or e-liquid was reported by a small group of participants in both arms **(Table 7)**. While the number of participants who reported purchase, remained low in the UC arm at all times, the spending was higher than that in the EC arm. In the EC arm, increasing number of participants reported purchase of EC device/e-liquid, after the initial four weeks of the study.

Table 7: Participants' purchase of e-cigarette device and e-liquid at follow-ups, by arm

	UC (n=32)	EC (n=48)

	n of null use	n (range) when use > 0	Missing	n of null use	n (range) when use > 0	Missing
4 weeks	**n=21**			**n=39**		
EC device	17	3 (£10-£75)	1	36	3 (£1-£40)	0
EC e-liquid	15	5 (£5-£168)	1	32	6 (£1-£12)	1
12 weeks	**n=18**			**n=34**		
EC device	17	1 (£10)	0	30	4 (£5-£19)	0
EC e-liquid	15	3 (£39-£448)	0	17	17 (£1-£50)	0
24 weeks	**n=12**			**n=35**		
EC device	10	2 (£40-£100)	0	24	11 (£3-£52)	0
EC e-liquid	10	1 (£288)	2	17	18 (£3-240)	0

UC: Usual care. EC: E-cigarette. EC e-liquid: E-cigarette e-liquid.

There were very few participants receiving smoking cessation help from primary/community care professionals (GP, practice nurse, pharmacist, NHS helpline) and those who did, did not access them frequently. Due to the rare and low frequency of use, the costs of smoking cessation help from primary healthcare professionals were low and, in some cases, null. Especially for the UC arm, from 12 weeks on, there was no one reported any use. The mean costs in the UC arm were £1.45 (SD £6.75) among 31 participants at baseline, and £5.81 (SD £11.83) among 21 participants at 4 weeks. In the EC arm, the mean costs were £3.66 (SD £14.41) among 47 participants at baseline, null cost among 39 participants at 4 weeks, £1.56 (SD £9.09) among 34 participants at 12 weeks, and £2.11 (SD £12.51) among 35 participants at 24 weeks. Overall majority of the costs were contributed by GP advice on smoking cessation.

Very few participants reported getting NRT products, mostly on prescription or from SSS. The participants who had gotten NRT products all came from the UC arm, with only one exception where two participants in the EC arm at 24 weeks also received NRT. In the UC arm, only one or two participants at each follow-up point reported getting NRT on prescription or from SSS. At 12 weeks, one of those reported four packs of patches and four packs of lozenges in total but five packs of each were on prescription or from SSS, causing a discrepancy in quantity. The only one received NRT but not on prescription or from SSS was in the EC arm at 24 weeks. Overall, the costs of NRT on prescription or from SSS were £1.72 (SD £9.59) at baseline (n=31), £4.13 (SD £18.73) at 4 weeks (n=21), £16.30 (SD £51.81) at 12 weeks (n=18) and £11.46 (SD £39.69) at 24 weeks, in the UC arm. In the EC arm, no costs of NRT on prescription or from SSS incurred until 24 weeks (n=35), when it was £0.89 (SD £5.26).

Among the general healthcare and social services asked, some services were used by none or close to none. Among all participants who have answered in this section, no one received any visit from GP at any point of the study. In the UC arm, only one participant received one visit from practice nurse. In the EC arm, at 4 and 12 weeks, there was one participant, respectively, who received one visit from practice nurse, while at 24 weeks, one participant received two. These were likely due to the homeless situation of the participants. No participant accessed maternity service during the study period. Sex health clinic was not visited at all at baseline and 12 weeks. At 4 weeks, one participant in the UC arm visited sex health clinic twice while two participants in the EC arm visited once and four times respectively. At 24 weeks, one participant in each arm visited sex health clinic once. Except for one participant in the EC arm at 12 weeks and one in the UC arm at 24 weeks, no other participants visited an early intervention team. Both participants visited the team only once. No participant in the UC arm stayed in a detox or rehab unit. In the EC arm, one participant stayed in a detox or rehab unit once at baseline and 4 weeks, respectively, while the other stayed twice at 12 weeks.

There were low but constant use of emergency and hospital services in both arms. Although majority of the responding participants did not report any use, a small group of participants visited A & E frequently or had hospital admissions (see Appendix 5). In the UC arm, 4-7 participants visited A & E at different time points. The number of visits ranged from one to nine times. In the EC arm, 5-7 participants visited A & E at different time points. The number of visits ranged from one to six times. Due to the design of the questions, we were unable to tell the number of visits that led to admission. However, in the UC arm, at least five participants at baseline, two at 4 weeks, one at 12 weeks and one at 24 weeks were admitted following the A & E visit. In the EC arm, at least two participants at baseline, three at 4 weeks, and one at 12 weeks were admitted following the A & E visit. The highest number of hospital outpatient appointments was 10 at baseline in the EC arm. The longest hospital stay was 14 days, reported in the UC arm at baseline and 4 weeks, and in the EC arm at 24 weeks.

Most of the participants in both arms received prescriptions. Other more frequently used services included GP, practice nurse and adult mental health team. Ten participants in the UC arm and 14 in the EC arm accessed drug and alcohol service at baseline. This number dropped to almost none afterwards in the UC arm while it remained more or less stable in the EC arm. Similarly, a housing team was visited by nine participants in the UC arm and 12 in the EC arm at baseline. The number of participants in the UC arm used this service then dropped to one at 4, 12 and 24 weeks while in the EC arm, it ranged from 7 to 10 participants at different time points (see Appendix 7).

Due to the ambiguous phrase of the question regarding detox/rehab unit, the meaning of 'visit' was unclear, whether it indicates a period of stay. Consequently, two possible unit costs to quantify the number of use were identified: by day or by week. We could not estimate the unit cost of a simple visit to the facility. Despite this, the overall mean costs of health care service did not differ much because the use of detox/rehab unit was very rare. We therefore reported the higher one of the two (by week) to present a conservative number.

The mean costs among observed cases were consistently higher in the UC arm than in the EC arm **(Table 8)**. The big difference at baseline and 4 weeks was mostly due to the much longer hospital stay in the UC arm. At 12 weeks, although the mean cost of hospital stay was still higher in the UC arm, the mean cost of drug/alcohol service and early intervention team in the EC arm offset part of the difference. At 24 weeks, the mean cost of hospital stay and drug/alcohol service in the EC arm was much higher while the mean cost of A & E, early intervention team and adult mental health team in the UC arm was much higher. However, this comparison has to be taken with caution, as around 30%-60% of the participants in the UC arm lost to follow-up during the study.

Table 8: Costs of healthcare and social services at each time point, by arm

Costs	UC (n=32)		EC (n=48)	
	n	Mean (SD)	n	Mean (SD)
Baseline	31	£1,480 (£3,188)	47	£518 (£754)
4 weeks	21	£1,559 (£4,489)	39	£539 (£987)
12 weeks	18	£957 (£1,849)	34	£682 (£885)
24 weeks	12	£1,207 (£1,494)	35	£1,172 (£1,952)

UC: Usual care. EC: E-cigarettes.

Recommendation for future revision of the questionnaire

The structure and wording of the health-utilisation questionnaire would need to be considered carefully if a full trial were to go head. Some of the questions about health-care utilisation were confusing for participants, repetitive, or not applicable to everyone in the sample. Others (such as A&E admissions) were useful and endorsed by all participants suggesting a more granular follow-up question was needed.

Objective 7: Estimate the cost of providing the intervention and usual care.

Outcome measure: Record all resources used in the delivery including staff costs, e-cigarettes and other costs incurred. Staff will complete a pro forma to record contact time, non-contact time and other resources used in delivery.

The training for the centre staff to deliver standard support in the UC arm and e-cigarette guidance in the EC arm was provided by research team. For the convenience of costing, we divided the training into three components: core component, auxiliary component and extra component.

The core component of the training was the group training programme, which was delivered by centre, two for UC and two for EC. For the UC arm, it was a 1.15 hours programme delivered by four trainers to one centre (seven staff) and three to the other (five staff). The Help to Quit leaflet as used, in-house printed at £0.20 each. For the EC arm, the training was slightly longer, taking 3 hours (including individual coaching). Each member of staff attended the training was provided with an e-cigarette device instruction pamphlet and an e-cigarette helpful tips pamphlet, both in-house printed at £0.20 each. This was similarly delivered by four trainers to one centre (12 staff) and three to the other (8 staff). The demonstration models of e-cigarette were shown to the staff at the ratio of one unit per two trainees during the training and six bottles of e-liquid (three flavours with two strengths each) were also shown. The e-cigarette starter kit was costed at £20 each and e-liquid was £3 per bottle. The research team members who delivered the training were one grade 9, three grade 7 and three grade 6. Their hourly costs, including superannuation and national insurance, were calculated based on the financial records of the project. The staff who received the training held various roles, resulting in varied pay grades. We used the costs information collected from Centre 1 as an estimate for all those involved. The time cost of staff was £13.38 per hour, including superannuation and national insurance. The costs of staff time in delivering the EC training was £1,040.93 in total and UC training was £246.65 in total. There were 20 staff attended EC training and 12 attended UC training. Their staff time costs were therefore £802.80 in the EC group and £184.64 in the UC group. The demonstration e-cigarette kit and e-liquid was re-used for each training. The maximum number of staff for one training was 12. Therefore, the number of demonstration models was estimated to be six. Combining with six bottles of e-liquid, the total costs of e-cigarette and e-liquid were £138.00. The two pamphlets were printed for all 20 staff attending the EC training, costing £8.00 in total. The pamphlets for UC training were printed for 12 staff at £2.40 in total. The costs of core component of the training were £433.70 in UC arm and £1,989.73 in EC arm.

The auxiliary component of the training included travel, accommodation and meals for those delivering and receiving the training. These costs would vary depending on the arrangement of the training programme. In this study, we included the costs of these items if they were claimed in expenses. For travelling, only train journeys were included. Travelling within a city was not taken into account. For the train journeys, the journey duration was estimated using National Rail website [37]. It was then multiplied by the hourly costs of the personnel took that journey. Centres 3 and 4 were in the same city with most of the research team and did not require train travel and therefore the travelling expense and time were not costed. The return train journey to Centre 1 costed £29.30 in ticket and two hours in time. To Centre 2, the return journey costed £118 (one-way £59) in ticket and nine hours in time (4.5 hours one-way). Three team members took a return journey to Centre 1, costing £205.83 in travelling time and £87.90 in train tickets. Two team members went to Centre 2 and had hotel stay. Due to personal arrangements, only one return ticket to Centre 2 was claimed and the other was a one-way ticket. This led to £425.97 in travelling time and £177.00 in train tickets. Their stay costed £500 for accommodation and £40 for meals. The costs of auxiliary component of the training were £293.73 in EC arm and £1,142.97 in UC arm.

The extra component of the training was e-cigarettes given to the staff who were smokers so that they themselves could be familiar with the device. This was not applicable to all staff trained, only four e-cigarette devices were given to the staff in one centre and two in the other during EC training. In total, six e-cigarette devices costed £120.

In total, the training costs for the UC arm were £1,576.66 and for the EC arm £2,403.46. Allocating evenly to participants in each arm, it was £49.27 per participant in the UC arm and £50.07 per participant in the EC arm **(Table 9).**

Table 9: Costs of training breakdown

Costs	UC (n=32)	EC (n=48)
Core component *Delivery of training programme*	£433.70	£1,989.73

Auxiliary component *Travelling, accommodation, meals in relation to training programme*	£1,142.97	£293.73
Extra component *E-cigarette devices given to staff who smoke*	-	£120.00
Total costs of training	£1,576.66	£2,403.46
Mean costs of training per participant	£49.27	£50.07

UC: Usual care. EC: E-cigarettes.

The delivery of intervention in both arms was recorded in the keyworkers form at baseline (visit 0), 1 week post-baseline (visit 1), 2 weeks post-baseline (visit 2) and 3 weeks post-baseline (visit 3). Contact time was costed by multiplying the staff hourly cost by the duration of the contact. The printing cost of 'Helpful tips' pamphlets for the UC arm and e-cigarette device instruction pamphlets and e-cigarette use tips pamphlets for the EC arm was recorded by the research team at £0.20 each.

Due to staff capacity, the data on delivery sessions were not collected in the UC arm. We therefore did not know the attendance of weekly sessions (visit 0-3) and if the pamphlet was given to the participants.

For the EC arm, one participant did not attend any session and did not receive the EC starter kit or e-liquid. The remaining 47 participants attended visit 0 and received an EC starter kit and five bottles of e-liquid. Except for missing answer for one participant, 46 participants also received pamphlets of e-cigarette device instruction and use tips and their mean session duration of visit 0 was 25 minutes (SD 16 minutes, range 7-80). Thirty participants attended visit 1, of which 29 received five bottles of e-liquid and one received two bottles. Except for missing answer for one participant, the mean session duration of visit 1 was 8 minutes (SD 4 minutes, range 1-20). Among the 22 participants who attended visit 2, 20 received five bottles of e-liquid, one received four and one received 10. Except for missing answer for one participant, the mean session duration of visit 2 was 6 minutes (SD 3 minutes, range 1-15). The number of participants who attended visit 3 was also 22, all of which received five bottles of e-liquid. Duration was not recorded for two participants. Among the remaining 20 participants, the mean session duration was 5 minutes (SD 2 minutes, range 2-10).

The mean costs of EC starter kit and e-liquid were £57.46 (SD £19.91) among the 48 participants in the EC arm. The mean cost of pamphlet was £0.39 (SD £0.06) among 47 participants in the arm. The mean costs of sessions were £7.51 (SD £4.60) among 43 participants. The costs of intervention delivery were therefore estimated for 43 participants whose data were complete in this part and it was £64.35

(SD £22.89) per participant. In total, the mean costs of EC intervention, including training and delivery, were £114.42 (SD £22.89) among 43 participants in the EC arm (Table 10).

Table 10: Breakdown of intervention costs, by arm

Costs	UC (n=32)		EC (n=48)	
	n	Mean (SD)	n	Mean (SD)
Training	32	£49.27 (-)	48	£50.07 (-)
EC starter kit + e-liquid	32	-	48	£57.46 (£19.91)
Pamphlet	32	data not available	47	£0.39 (£0.06)
Keyworker session	32		43	£7.51 (£4.60)
Total	**32**	**data not available**	**43**	**£114.42 (£22.89)**

UC: Usual care. EC: E-cigarettes.

Summary of learning points for a future trial

Whilst it was feasible to collect information relating to the costs of delivery in the EC arm, collecting data from staff about contact time was not feasible in the UC arm. If staff are unable to complete this information each time they engage with a research participant, approaching them at a quieter time (e.g. end of follow-up data collection period at each centre) may improve compliance..

Outcomes and estimations

The outcomes relate only to the results as above, which are specific to the feasibility of a full cRCT.

In respect of estimations for a future trial, based on the findings presented here i.e., proportions with sustained CO validated abstinence in each group (6.25% in intervention 0% in usual care) and assuming 0.05 alpha, 90% power and intraclass correlation coefficient of 0.01, a future cRCT would require 12 participants per cluster (the feasibility average), 16 sites per arm, totalling 192 participants per arm, 384 participants across both conditions. This sample size estimate assumes equal cluster sizes. These estimates are not adjusted for attrition as it is anticipated that the primary analysis will be by intention to treat and participants lost to follow up assumed to have relapsed entailing no loss of power.

Ancillary analyses

Substance use and mental illness scores were collected at each follow-up point. Mean (SD) scores for the mental health and substance use measures for those participants who were retained in the study through to the 24-week follow-up are presented in Table 11. GAD7 anxiety and PHQ9 depression scores significantly declined steadily from baseline to the 24-week follow-up, though no causal association can be assumed. A similar decline in alcohol use as measured by the AUDIT scores was also evident, however substance use as measured by the SDS remained stable.

Table 11: Mental health and substance use tables only including the sample of participants who were retained in the study to 24 weeks.

	Total	**EC Arm**	**UC Arm**	**p**
GAD-7 N	37	27	10	Main effect time = .02; main effect group < 0.01
Baseline: Mean (SD)	10.08 (6.91)	8.48 (6.81)	14.40 (5.36)	
4 weeks: Mean (SD)	9.11 (6.81)	7.15 6.38)	14.40 (5.02)	
12 weeks: Mean (SD)	8.27 (7.12)	6.44 (6.54)	13.20 (6.49)	
24 weeks: Mean (SD)	7.54 (6.64)	5.63 (6.34)	12.70 (4.42)	
PHQ-9 N	36	25	11	Main effect time = 0.02
Baseline: Mean (SD)	11.53 (8.26)	10.76 (8.34)	13.27 (8.17)	
4 weeks: Mean (SD)	10.53 (7.62)	9.08 (7.76)	13.82 (6.46)	
12 weeks: Mean (SD)	9.92 (8.03)	8.36 (7.53)	13.45 (8.37)	
24 weeks: Mean (SD)	8.25 (7.38)	7.12 (7.22)	10.82 (7.23)	
AUDIT N	35	24	11	Main effect time = 0.03
Baseline: Mean (SD)	10.60 (11.07)	11.83 (12.15)	7.91 (8.08)	
4 weeks: Mean (SD)	7.86 (9.34)	9.08 (9.76)	5.18 (8.48)	
12 weeks: Mean (SD)	8.57 (9.72)	10.29 (10.37)	4.82 (7.15)	

24 weeks: Mean (SD)	8.00 (8.47)	8.92 (8.83)	6.00 (7.64)	
SDS N	37	27	10	No sig. effects
Baseline: Mean (SD)	3.81 (5.05)	3.15 (4.33)	5.50 (6.52)	
4 weeks: Mean (SD)	3.19 (4.48)	2.81 (4.51)	4.20 (4.49)	
12 weeks: Mean (SD)	3.78 (4.15)	3.35 (4.05)	4.90 (4.41)	
24 weeks: Mean (SD)	3.78 (4.33)	3.23 (4.46)	5.20 (3.82)	

UC: Usual care. EC: E-cigarettes. GAD-7: Generalised anxiety disorder questionnaire. PHQ-9: Patient Health questionnaire V9. AUDIT: Alcohol Use Disorder Identification Test. SDS: Substance dependence severity test.

Reporting against success/progression criteria

In our application, we stated that we would continue without modifications to a full trial if the following success criteria were met:

1) At least 50% of eligible participants can be recruited within a 4-week period.
2) No more than 5% of all recruited participants cross from one arm to the other.
3) At least 50% of all recruited participants complete follow-up assessments

If we didn't meet these success criteria, we planned to assess the reasons for this and consider how these could be improved in a main trial. We stated that if less than 20% of participants complete follow-up assessments, we would consider the main trial unfeasible and would not proceed with a future larger trial application.

Success criteria 1 was met; we recruited 52% of all eligible participants. Although we extended the recruitment period slightly to 6 weeks at some centres, recruitment was completed within the originally specified five-month period and this target was met despite some researchers working part time. Further participants could have been recruited at some centres (mainly centre 1) if we had had the resources. Success criteria 2 was not met; 67% of UC participants reported any use of an EC during the study period. Unfortunately, we did not ask about extent of use so whether it was regular, sustained use remains unclear. Although some EC use was reported, none of the UC participants received the EC intervention as delivered (i.e. a free EC starter kit offered at homeless centres). Contamination across arms can be a problem for many RCTs, however, supported use of an EC is increasingly being incorporated into the 'usual care' offered by SSS and should not, therefore

invalidate our findings. The pragmatic question that will be explored in a main trial (and which this feasibility study sought to provide preliminary evidence for) will be whether the provision of a free EC starter kit offered at a location already being accessed by homeless smokers can increase smoking cessation rates over usual care. Success criteria 3) was fully met; we exceeded 50% retention at each and every follow-up point, however we note that retention did drop below 50% in the UC arm due to poor retention at the Edinburgh site. Given that some of our success criteria were not fully met, we will include an inbuilt pilot study with clear stop/go criteria within our main cRCT.

Harms

At the early phases of the study design, our funders panel and PPI work raised several concerns that for those presenting with substance use disorders or very little income, free e-cigarette devices may be sold, stolen or used for inhaling illicit street trade substances. Therefore, despite a well-intended act of offering an e-cigarette, this could invite several unintended consequences.

In order to systemically monitor risk and the occurrence of unintended consequences we developed a checklist that participants would be asked at each follow-up assessment. The questionnaire is based on our extensive public and patient involvement (PPI), with input from our expert and multi-disciplinary team, our trial steering group and those working within the third sector. This data while recorded retrospectively does not prevent the occurrence of these incidents. The rationale for the inclusion of this checklist was twofold, firstly that we could capture number of times these events occurred, and secondly to offer support if required.

The rationale for each question based on our PPI work is as follows:

1. *Do you still have the e-cigarette that we supplied?*

   To ascertain whether the participant was still in possession of the product that had been supplied to them as part of the study. It was raised during our PPI consultation work that adults who are not securely housed or sharing residences may easily lose their e-cigarette, have it stolen or sell it.

2. (If no) *Since our last meeting has your e-cigarette been lost, stolen, sold, exchanged?*

We are seeking here to gather information as to what happened to the device. Understanding if people are retaining their e-cigarette can help with future planning for more definitive studies or service provision.

3. *If yes, to any of the above, please provide details:*

Free text responses for the participant to elaborate and give the study team more information related to the event. By collecting more detailed information, study teams can try to further mitigate against risks such as theft and understand the nature of the event (e.g., coercive theft) surrounding the incidents.

4. *Have you added any of the following to your e-cigarette?*

A frequent concern when designing the study was that participants may use the e-cigarette for vaping substances other than e-liquid. Here we aim to capture if the e-cigarette is being used for vaping any other substances and which ones.

5. *Have you used the e-cigarette for any other purposes?*

To monitor unforeseen or unpredicted use, we were advised to include this question to capture a broad range of usage.

6. *For you, does the experience of using an -cigarette have any other similarities to drug use (for example, crack)?*

Although not common, in our scoping and PPI work, a small number of clients from homeless centres commented that for them use of a pen-like second generation e-cigarette triggered memories of historic crack cocaine smoking owing to device shape and the sensory aspect of inhalation.

The majority of the participants used the device as intended. Table 12 presents frequency and percentage data at each follow-up point.

Table 12: Frequency and percentage data for the unintended consequences of using an EC checklist

	4-weeks	**12-weeks (since 4wk FU)**	**24-weeks (since 12 wk FU)**

	Yes	No	N/A	Yes	No	N/A	Yes	No	N/A
Still has EC?	33 (41)	6 (7.5)		28 (35)	6 (7.5)		22 (27.5)	13 (16.3)	
EC lost: N (%)	3 (6.3)	36 (75)	9 (18.8)	2 (4.2)	30 (62.5)	16 (33.4)	2 (4.2)	29 (60.4)	17 (35.4)
EC stolen: N (%)	3 (6.3)	36 (75)	9 (18.8)	1 (2.1)	31 (64.6)	16 (33.4)	2 (4.2)	29 (60.4)	17 (35.4)
Sold: N (%)	0	39 (81.3)	9 (18.8)	0	32 (66.7)	16 (33.4)	0	31 (64.6)	17 (35.4)
Exchanged/swapped (%)	1 (2.1)	38 (79.2)	9 (18.8)	0	32 (66.7)	16 (33.4)	0	31 (64.6)	17 (35.4)
Given away N (%)	0	39 (81.3)	9 (18.8)	1 (2.1)	31 (64.6)	16 (33.4)	2 (4.2)	29 (60.4)	17 (35.4)
Broken N (%)	14 (29.3)	25 (52.1)	9 (18.8)	11 (22.9)	20 (41.7)	17 (35.5)	11 (22.9)	21 (43.8)	16 (33.3)
Added substance? N (%)	0	39 (81.3)	9 (18.8)	0	34 (70.8)	14 (29.2)	2 (2.5)	32 (40)	12 (15)
EC used for any other purpose? N (%)	1 (1.3)	38 (47.5)	7 (8.8)	0	34 (42.5)	18 (22.5)	1 (1.3)	33 (41.3)	12 (15)
EC has any similarities to drug use?	1 (1.3)	38 (47.5)	41 (51.2)	2 (2.5)	32 (40)	46 (57.6)	2 (2.5)	32 (40)	46 (57.6)

UC: Usual care. EC: E-cigarettes.

E-cigarette, lost, stolen or exchanged

At 24-week follow-up, 63% still had the EC we provided. Across the follow-up period there were only 7 individual incidence of e-cigarette loss, 6 reported thefts and nobody reported selling their device. Although 1 person did report exchanging their device at 4 weeks and 3 people gave their device away. Other reasons why people did not have their device was because they didn't like it taste or feeling (n = 2) or reported accidentally leaving it elsewhere (n = 5), one person reported having it confiscated upon admission to hospital.

There was a high percentage of breakages, across the follow-up times breakages were reported on average 25% of the time. The most common breakage reported was cracked glass tanks.

Adding of other substances

There were two reports across the follow-up period of adding other substances not intended for vaping. At 24-weeks one person reported adding THC and another CBD oil, however these were added to other devices, not the devices that were provided in this study, suggesting that regular second-generation e-cigarettes as provided here may not be compatible with vaping other substances.

Use of the e-cigarette for any other purposes

At all follow-up appointments, the majority of people said they had not used their device for any other purpose. At 4-week, one person reported using it to mimic vaping without actually switching the device on ("*I put my lips on it*"). There were no reports of unintentional use at 12 weeks. At 24-week follow-up, one person reported using it as both a back scratcher and attempted to use it to light a cigarette.

Similarities to drug use

The majority of participants reported no similarities to drug use experiences. However, two did. One participant noted at all 3 follow-up points that using the device was similar to crack use, and one other reported similarity to smoking cannabis through a 'bong'.

Discussion

Presented here is the first UK feasibility study with an embedded qualitative process evaluation exploring smoking cessation within the context of smokers accessing homeless centres; and the first known trial with adults experiencing homelessness on the use of e-cigarettes for cessation. This report presents data on participant recruitment, retention, engagement, service capacity, perceived value and preliminary efficacy and cost-effectiveness. The initial results are promising, and with careful consideration and future PPI and stakeholder (homeless charity) input, a future trial may be feasible with some changes to the structure and delivery of the intervention. We discuss the facilitators and barriers in more detail below, including recommended changes needed to progress to a main trial.

In relation to **our first objective, recruitment**, of all those who were eligible, just over half of those invited agreed to take part and completed the baseline assessment. Only one person withdrew from the study. Our process evaluation has provided useful information which has helped us to understand how to increase participant trust and therefore willingness to take part in a future trial. One stand out point relates to participant vulnerability and nervousness in taking part in research and sharing personal information. The longer we stayed at centres – especially centres 1 and 2 – the more likely service users were to engage and wished to take part, representing growing trust and a 'snowball effect' as other service users were seen to be taking part and speaking to the research team, though this also had the unintended consequence of 'unblinding' centre allocation. In terms of future work, this highlights the need for the research team to introduce the study to service users as well as staff before baseline assessment. Building trust and offering the opportunity to be seen and be known should, as per our qualitative interviews, decrease any concerns around confidentially and misperceptions about the nature of the study.

In addition to this, the type of centres taking part in this trial and in a future full cRCT is important. Day centres, defined as those which offer services within usual working hours, were the more successful in terms of recruitment compared with residential units. Specifically, the two-day centres (centres 1 and 2) accounted for 77.5% of the total sample. The research team and the participants themselves observed that within the context of these services, a study taking place or a new service being offered was not particularly out of the ordinary. Both of these day centres already offer a range of services and support; thus, our study was within the realm of what was being offered. Furthermore, as noted by our participants when discussing the differences between centres, the day centres offered access to potential participants, who by virtue of their presence at centres, were already engaged with the service. At the residential units there was notably less activity and a significantly lower footfall of potential participants. Contrary to expectations, recruitment and follow-ups were not easier at

residential units as compared to day centres. Residents who were 'at home' would often not respond to door-knocking or would reply that they did not want to be disturbed, whether or not they had scheduled appointments and reminder messages. Offering the service within residential units at times felt more intrusive and this needs to be considered for future studies. It should also be noted that there were fewer smokers within the residential units, and more people were at work. This point is important for considering targeting the most vulnerable smokers; it should not be assumed that because these adults are facing homelessness that the levels of need will be the same across the population.

Centre 1 (EC) was the most successful in terms of recruitment and retention. There were very few limitations to this centre, but it was observed by the researcher that, although its scale was positive for recruitment, it was also often busy and there could be disturbances. Disturbances and commotion were common within both day centres. For example, at Centre 2 (UC), it was common for events outside of the staff/researchers' control (e.g., arguments, drug poisoning, other urgent needs) to take over, making it difficult, or at times impossible, to recruit, collect data and elicit staff support for the study. Despite this, with flexible researchers and a good connection between the research team and the centre staff, these problems were overcome and by extending the recruitment period to 6 weeks rather than 4, we were able to recruit 22 people. Follow-up was difficult at Centre 2 for the reasons outlined above but also because many of the participants were not able to come back for follow-up; many had moved on, or were not visiting the centre during the follow-up period. The lower follow-up rate at Centre 2 compared with Centre 1 may also reflect baseline differences between the groups and the fact that Centre 2 was within a busy national capital city centre with a highly transient population.

The two residential units had the lowest recruitment rates, despite extending our recruitment period. Centre 3 (UC), despite being known as a 'centre', comprised three geographically separate sites and residents did not congregate in the communal spaces much when our researchers were present. Even during periods of good weather, very few people sat in the gardens, often leaving the site or staying in their rooms, in some cases being active at night and sleeping during the day. A number of potential participants were out in the daytime, attending day centres, jobs, part-time education, health appointments, or volunteering. This is in comparison to the bustling environments and continual foot fall of the day centres. In addition to this, with Centre 3 being located at three different locations, the opportunities to 'fill' unattended appointments or serendipitously 'catch' one person whilst waiting for another were fewer than at Centres 1 and 2 where the scale of daily interactions and activities was

greater. Likewise, there were far fewer interactions between residents, so there was less effect from word-of-mouth, even related to the opportunity to receive an incentive gift card.

Similarly, Centre 4 (EC) had four separate sites at three geographically separate locations. Generally, the residents we met who smoked at this centre had consistently complex needs (e.g., substance use and severe mental health comorbidities and side-effects from prescription medications). There were few structured communal interaction events and where these did exist, take-up by residents was low. Participation in activities such as coffee-mornings was moderate but more often attended by people who were already non-smokers. Newly hired staff had already-full workloads with inductions, compulsory training, and patterns of shadowing colleagues, so were not able to prioritise supporting the research as much as had been anticipated at the planning stages. At the women-only accommodation (one site making up centre 4), there were no private meeting rooms for data collection or meetings, so all data collection was conducted in the multi-purpose room. This was challenging at times due to the lack of privacy, as the garden and residents' units were accessed through the multi-purpose room. These are wider considerations which would need to be taken into account for a future trial by planning with centres how the study is needed to run and what the conditions for a 'good assessment' look like.

However, despite some expected and unexpected challenges, that we were able to recruit 80 participants across four centres in a five-month period despite the limited pool of participants at the residential centres, is encouraging. . We are especially encouraged given that our participants presented with a high prevalence of mental illness and illicit substance use.

Retention was also assessed for a future trial. The overall 24-week total retention rate was 59%, this compares well with other studies which have recruited smokers from homeless services[4]. Indeed, here we add to the growing evidence base that despite many competing needs, the majority of our participants were willing to come and speak to the research team. As reflected in our qualitative process evaluation, the financial incentive was instrumental in securing a sufficient number of people within the trial and moving forward the incentive system should remain in place. Financial incentives have been used widely across smoking cessation studies within this environmental context and have also been shown to be a direct measure of increased participation[4].

Results show that 24-week retention rates were higher in the EC arm compared to the UC. There are several explanations for this. Firstly, the EC arm received weekly sessions to provide e-liquid for the

first 4 weeks. This differential level of contact may have encouraged retention in this arm. Nevertheless, this is unlikely to be a key factor given that 4-week retention rates did not differ dramatically between arms (81% vs. 66%). Secondly, baseline characteristics indicate that our UC arm presented with a with greater mental health and substance use comorbidities, both in terms of incidence and severity. This may be a consequence of our non-randomised design, however, the differences across arms appeared to be mainly due to higher levels of anxiety and especially substance dependence and cannabis use at centre 2 in Edinburgh which were significantly higher than at any other centre (which did not differ from each other). This is likely to impact attendance due to competing health and social needs and indeed, this centre was associated with far lower 24 week follow up than the other three. This sample (at centre 2) was also especially transient in nature, and it was difficult to keep in touch with the participants by 24 weeks (some of whom had been hospitalised or incarcerated). Nevertheless, it is encouraging that individuals with such high-level needs were willing to take part and provides proof of concept of the wide-reaching engagement of this study. Future research with this population would need to work closely with PPI representatives in order to explore how participants could be retained in research trials.

However, for those who did return, 6% achieved sustained CO-verified abstinence rate at 24 weeks (intention to treat) in the EC group compared to 0% in the UC group. Cessation rates are low and our sample size is small but these are in-line with other studies conducted in similar settings [16]. Our study is however the first study to also monitor continuous abstinence at 24-week follow-up within this population, the general trend has been to capture 24-hour or 7-day point prevalence at 6-months [4]. Given that we have measured continuous abstinence our results compare favourably to two similar trials using NRT, 4% reported at 26 weeks by Segan et al. [38], and 5.6% and 9.3% 7-day point prevalence at 26 weeks in a larger sample of 430 smokers receiving NRT and motivational interviewing+ NRT at a homeless centre respectively [16].

Importantly, we were able to collect the data from our participants that would be needed for a full cRCT and to include a full economic evaluation (although see below regarding contact time with staff in the UC arm). Amendments can be made to the questionnaires which allow for less extensive intrusion of people's background and current lived circumstances, but at the same time still allow the relevant data on health and demographics to be collected.

Completion rates of HRQoL and general healthcare and social services questionnaires suggest that the use of these measures was feasible whilst indicating potential areas for the refinement of data

collection. More detailed data collection will be included for services used frequently by this population, whereas services with little use can be omitted from the final data collection pro forma.

Self-reported SSS use showed that few participants in the UC arm sought SSS for quitting and they did not ask for help from GP services after 4 weeks. In the EC arm patients did not seek any SSS during the study period and instead used GP services when they were no longer offered help by their keyworkers in the centre.

Overall feedback from participants about the study was positive, as noted above (Harms) there were very few unintended consequences and as noted by the qualitative process evaluation, and the experience of being offered an e-cigarette and use after assistance was well received. Encouragingly the majority of participants reported that they still had and were still using, though not exclusively, at 24-week follow-up. This is an important issue for breaking stereotypes that this may be a group of adults who will not be able to keep in possession of an e-cigarette. There were extra signs of encouragement in the form of participants purchasing their own products, which can be taken as a personal investment in vaping. Around a third reported having purchased their own e-cigarette, this may also explain why the number of participants reporting having used an e-cigarette was greater than the number having been originally supplied.

EC use was also commonly reported in the UC arm; around two thirds reported that they had used, and one third had purchased an EC at some point during the study period However, we did not explore the extent nor the frequency of this use. Use of an e-cigarette is not uncommon in smokers experiencing homelessness [3914] and use and experimentation is prevalent amongst the general population of smokers in Great Britain [40]. As has been reported elsewhere, cluster designs cannot fully mitigate the occurrence of EC use in UC and in fact, EC use is beginning to be supported or actively encouraged in SSS under 'usual care'. Although there was some EC use in our UC group, no participants experienced the EC intervention 'as delivered' in the EC arm (i.e. a free EC starter kit + liquid offered at homeless centres).

Staff capacity to support the study was generally good and staff across three of our four centres reported few issues in the process evaluation interviews. The additional responsibilities placed on staff in the EC arm including initial device set-up, administration of e-liquid and general participant support were met well by the staff in our study. The high value that staff and management placed on the EC intervention likely helped to better engage staff in these processes. Staff training on EC and researcher support were also important in building staff belief in EC as a harm reduction tool and developing their

confidence for EC intervention delivery. This helped staff overcome initial nervousness at supporting participants to use their EC. As the study progressed staff concerns surrounding EC were alleviated, for example, they reported receiving few problems regarding batteries or charging devices and they were able to manage participants' e-liquid supply well during the intervention phase. Although some of our participants would have welcomed a greater variety of e-liquid, staff were content with the quantity of different e-liquids on offer, which needs to strike the right balance between participant choice and staff ability to administer.

Daily challenges for service delivery, particularly those experienced at the busier drop-in centres, highlight that service providers may need further support by providing efficient and effective processes for facilitating the study alongside their usual work. While daily challenges were similar for the drop-in centres (Centres 1 and 2), Centre 1 was better able to support the study through having better resources to draw upon, including staffing and space. Lack of adequate staffing and space presented some challenges for the study at Centre 2. While staff at Centre 1 could cope with and support the high level of interest in the study from clients, staff at Centre 2 were not able to facilitate participant signposting to SSS or follow participants up weekly to check their engagement with SSS and where they were able to, we could not collect data on this. Busy workloads and client demands primarily accounted for reduced capacity for staff to support the study at Centre 2 and alternative ways of capturing contact time in order to fully cost UC would need to be considered if moving to a full trial. However, it is also possible that a lower value placed on the UC intervention may also account for lower staff engagement with these aspects of these study. Service providers could be further supported by suggesting systems for managing referrals, appointments, signposting and follow-ups, taking into account the differences at each site. Training for staff in the usual care arm could also encourage them to see benefits of UC support.

The qualitative interviews found **perceived value** of the study and EC intervention was high among participants. Given participants' reported desire to change their smoking behaviour, irrespective of whether their primary goal was cessation or harm reduction, the chance to engage in smoking-related discussions was welcomed. That this opportunity could be accessed at a place where participants resided or regularly attended, and was incentivised through provision of the EC starter kit and/or Love2Shop gift cards was an added bonus for participants, facilitating their engagement despite low expectations for behaviour change. Those in the EC arm who took part in an interview were particularly enthusiastic about the EC intervention with strong belief in the value of EC as a harm

reduction tool. Social dynamics, especially at Centre 1, where some individuals with social standing became vaping advocates, contributed greatly to this belief. This contrasted with the lower perceived value of the UC approach, which largely stemmed from previous negative experiences of NRT, and likely accounts for the poorer engagement with local SSS. That many in the UC arm expressed interest in EC as a result of the study may also provide an explanation for the level of contamination across study arms.

Limitations

We did not meet the original recruitment target we set ourselves of 120. However, this was a pragmatically chosen target based on our early scoping work and there was potential for further recruitment from some sites if our schedule had permitted it. A second limitation was that we were not able to randomise clusters to condition as planned and this may have led to the differential retention rates which were lower in the UC arm. Our arms also differed on some important baseline characteristics which may have contributed to the lower retention rates at UC sites. This was particularly the case for centre 2 in Edinburgh which differed to the English sites on many of these baseline variables. A fully powered randomised cluster design stratified by region in a main trial should mitigate against baseline differences across groups. Blinding was not possible for the assessment of outcome measures which may have led to assessment bias or reduced effort in attempting to contact some participants for follow-up. Furthermore, staff working at the centres were not blinded to intervention arms and this could potentially have introduced some bias, for example, staffs beliefs around who would be interested and most able to take part, not least beliefs around who would attend and quit. Finally, we were unable to collect information in the UC arm around staff contact time with research participants.

The qualitative process evaluation has some additional limitations. Due to the small sub-sample of trial participants and sample of centre staff, the qualitative findings may not be representative of all our trial participants or staff involved in supporting the study. As above, it is possible that those agreeing to take part in an interview may have held stronger views of the EC or UC intervention, however, many of our interviewees in the UC arm had not engaged with UC support, reflective of the wider trial sample. As such, the qualitative process was not able to fully detect any potential bias across intervention arms. We had difficulty recruiting 4-week non-completers to take part in an interview, primarily as a result of challenges in maintaining contact rather than a reluctance to take part. While interviewing a greater number of non-completers may have identified further barriers to

engagement, interview narratives of the small number of non-completers who did take part were not substantially different to the majority of the sample.

Generalisability

Our data derive from three geographically distinct areas of the UK and from a variety of different centres. The demographics of our are similar to the wider UK population experiencing homelessness (see: https://www.homeless.org.uk/facts/understanding-homelessness/impact-of-homelessness) although the percentage in current employment was lower, and the percentage experiencing long-term physical health problems and using drugs, was higher than reported in the UK homeless population by homeless.org. Based on these facts, and although centre staff recruited those who were known and actively engaging with the services, it does not appear that our sample was any less disadvantaged than the UK homeless population as a whole. The sample is small relative to the numbers of people engaging with the homeless sector but we see no reason why the results and methods here cannot be generalised to other homeless service settings as a potential area for future work. Furthermore, as mentioned above, it is important to stress that our sample included those with both current and historical substance use and mental health comorbidities meaning that our participants presented with the complex needs which one expects within these services. It is encouraging that we are able to reach participants from a wide range of backgrounds with differing levels of needs. Central to DHSC's vision of reducing smoking prevalence rates is directly tackling smoking where tobacco related health inequalities are most felt by driving smoking rates down amongst groups with a high incidence of social disadvantage. This work provides a baseline for that vision. This feasibility provides proof of concept that even amongst adults with complex and competing needs there is a desire to take part in cessation research and attempts to quit are good, our participants did use and hold on to their EC. Encouragingly, overall, the intervention was well accepted and provides a baseline for future work. Specifically findings, suggest that a fully powered cRCT to explore efficacy and cost-effectiveness may be feasible but in order to fulfil this, recruitment across multiple sites must be considered against service provision type and plans for retention need to be explored to increase follow-up rates. A larger trial is important to establish a stronger evidence base for smoking within this population and work towards the shared vision of reducing smoking prevalence within adults experiencing homelessness.

Research recommendations

Objective 1: Recruitment – assess willingness of smokers to participate. The residential units had fewer eligible individuals and potential participants were less available and less interested in taking part in research. **Recommendation:** Any future study should ensure sufficient researchers are employed on the project to deal with recruitment and explore limiting sites to day centres only. This is especially important given the transient nature of the population, staff may need to be responsive to the availability of the participants.

Objective 2: Assess retention and engagement in the EC and UC arms. Retention rates were moderate to good and were comparable to other studies in deprived groups, however one site's poor retention rates negatively skewed retention rates. **Recommendation:** In designing a future trial, we advise based on our findings, that a larger number of clusters with fewer people at each one and official randomisation should help to reduce residual confounding factors between the groups. Randomisation should also ensure that variables predicting drop out are equally distributed between groups thus reducing the difference in retention across arms.

Objective 3: Examine the perceived value of the intervention, facilitators and barriers to engagement.

Perceived value of the intervention was high. Barriers were participant's personal and psychological difficulties especially in relation to answering the questionnaires, a sense of nervousness around research, cannabis use and staff assumptions about smoking. Facilitators were participant' desire to change, lack of existing cessation support, free EC and social dynamics. **Recommendation:** Future studies should make to time to introduce the research team to the participants and outline the project to the service users (all those who access the service, who may or may not take part in the study). Researchers should also identify opportunities to increase trust and build relationships before recruitment. We strongly recommend reconsidering questionnaire burden and intrusiveness; including shortening some questionnaires. Future work should also seek to understand what person centred language would be most appropriate and acceptable with users of homeless services – there is currently a dearth of literature on this.

Specifically for intervention studies which include staff training, from our own experiences, we suggest adding an element to the staff training on fostering a community around the study, highlighting the benefits this brings to motivation. Qualitative work should be designed to fully capture service user and staff views in their experiences of taking part in research studies, including barriers but also facilitators, this would complement our own findings and develop this evidence base.

Objective 4: Assess service providers' capacity to support the study and the type of information and training required. Overall, in the EC arm, staff were well equipped to support the intervention with few capacity issues. Although there was some evidence that staff misremembered key points from the EC training and facts around their use. Some challenges were highlighted in one UC centre, but this is reflective of the unique challenges of this centre and not the UC intervention. **Recommendation:** If a full trial was successfully awarded, planning randomisation and a larger number of clusters should reduce any similar issues. Furthermore, fewer participants at each cluster will the reduce burden on recruitment and follow up at each centre. A future trial should also explore, top-up staff training with smaller, intermittent sessions, especially at EC centres.

Objective 5: Assess the potential efficacy of supplying free EC starter kits. The offer of a free EC starter kit was well accepted by staff and participants. Using ITT analysis, we found sustained 24 week abstinence rates of 0% in the UC arm and 6.25% in the EC arm which provides preliminary evidence of potential efficacy, however, the absolute numbers were small (3/48 in the EC arm and 0/32 in the UC arm). The UC sample size was also lower than expected; the 0% abstinence rates may therefore be an under-estimate of true cessation rates with UC. **Recommendation:** In order to definitively measure efficacy, a future trial with smoking cessation rates as the primary outcome should include more clusters with a fully-powered sample size perhaps using a slightly higher abstinence rate with UC (e.g. 0.5-1%). To fully understand the mechanisms through which change occurs, we recommend an embedded process evaluation which seeks to explore fidelity of implementation and treatment context.

Objective 6: Explore the feasibility of collecting data on contacts with health care services. Almost all participants who were present at follow-up visits completed data collection for healthcare service utilisation and health-related quality of life measures, however as reflected in our interview data, some participants found the nature of these intrusive or overly complicated. **Recommendation:** Alongside experts with lived experience, in any future trial, should consider the structure and wording of the health-utilisation questionnaire.

Objective 7: Estimate the cost of providing the intervention and usual care. Whilst it was feasible to collect information relating to the cost of delivery in the EC arm, collecting data from staff about contact time was not always possible in the UC arm. **Recommendation** Alternative ways of capturing

contact time (or supporting staff to capture contact time) should be considered (e.g. improving reporting mechanisms or collecting data at a quieter time such as the end of follow up data collection period at each centre) in order to fully cost UC.

Conclusion

This study focused on a group of people who are not well considered in traditional smoking cessation treatments and despite some issues around recruitment and retention, there is promising evidence that a full trial may be feasible with iterations to the main trial design and with further discussion with project partners. We observed early signs of acceptability and potential efficacy of offering free EC starter kits. Centre staff were a crucial element in helping people to take part in the study, training helped to support staff in how to be involved in the study and building trust between the researchers and the participants was also key. However, the study was challenging in some sites and parts of the delivery of the study need to be optimised so we can plan a trial which would be likely to progress fully through a clear stop/go criterion. In considering this, and planning to mitigate against future issues, we will explore the findings from the process evaluation alongside the quantitative data, so to help to inform the design of a main trial.

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Contribution of authors

SC conceptualised the study with LD, led the early stage PPI work, led the daily running of the project, led on the writing of this report and contributed to the writing of other outputs.

AF led the qualitative process evaluation and led the Scottish site, she led the writing of the qualitative component and wrote the process evaluation outcomes for this report.

JL led the economic evaluation and contributed to the writing of this report and the economic outcomes for the quantitative paper.

CB led the statistical elements for the study and contributed to the writing of this report.

AT led the data collection at the London and Northampton sites, assisted with data curation and preparation, qualitative data analysis, and has contributed to the writing of all the outputs.

DR prepared and led the staff training for the study and has contributed to the writing of all the outputs.

LB has provided trial expertise throughout the whole study and has contributed to the writing of all the outputs.

PH has provided expertise in smoking cessation; e-cigarette use and trial methodology throughout the whole study and has contributed to the writing of all the outputs.

IU contributed to the data collection and data preparation and curation at the Scottish site, contributed to the analysis of the qualitative data and has contributed to the writing of all the outputs.

SP helped to design the economic evaluation in the early stages of the study and also oversaw the economic evaluation analysis and has contributed to the writing of all the outputs.

LD is the Principal Investigator and conceptualised the study with SC, assisted with the daily project running, oversaw data analysis and writing of all output.

Ethical consent was gained by London South Bank University School of Applied Sciences (REF: SAS 1821 (quantitative component and SAS 1830 qualitative component), and also from University of Stirling.

Other publications and outputs

Two planned publications (process evaluation and quantitative outcomes) are currently in preparation.

Data sharing statement

The fully anonymised data is has been made publicly available by the PI's institute, at the LSBU open repository https://openresearch.lsbu.ac.uk/item/8q255.

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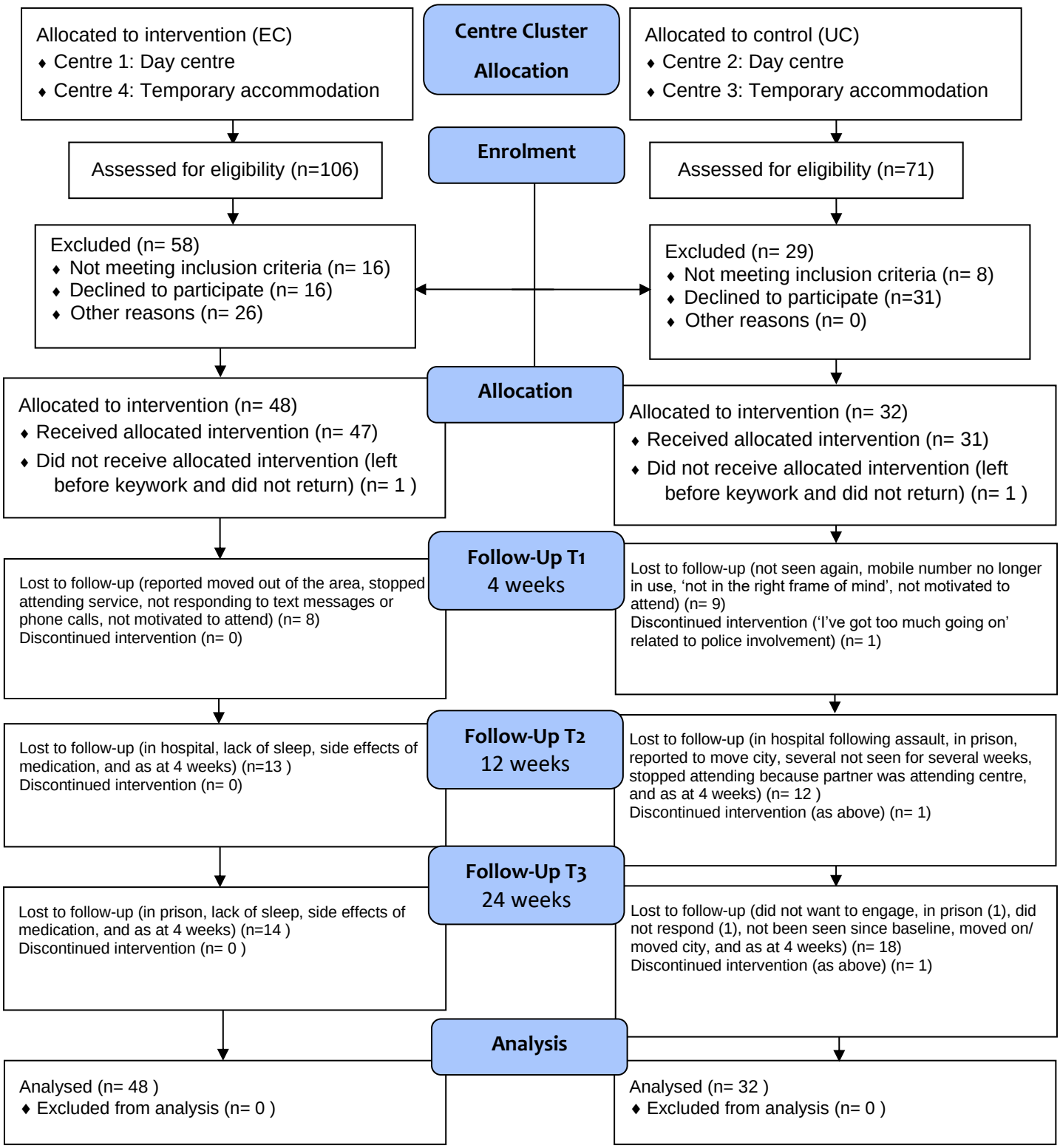
Appendices

Appendix 1 CONSORT flow diagram

CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram



Appendix 2: Participant selection of e-liquid flavours and nicotine concentrations

Flavour & strength	Baseline	Visit 1	Visit 2	Visit 3	TOTAL
Tobacco 18mg	34	10	8	2	**54**
Tobacco 12mg	38	14	13	17	**82**
Menthol 18mg	22	16	17	17	**72**
Menthol 12mg	25	27	17	14	**83**
Fruit 18mg	59	29	17	16	**121**
Fruit 12mg	60	51	42	44	**197**
TOTAL	**238**	**147**	**114**	**110**	**609**

Milligrams are expressed per 100 mL.

Appendix 3: Qualitative process evaluation participant characteristics

	Participants (n=22)	**Staff (n=12)**
Centre and feasibility study arm		
Centre and feasibility study arm		4
Centre 1, EC arm	7 (31.8%)	3
Centre 2, UC arm	6 (27.3%)	3
Centre 3, UC arm	4 (18.2%)	2
Centre 4, EC arm	5 (22.7%)	
Completion at week 4 follow-up		
Completer	19 (86.4%)	
Non-completer	3 (13.6%)	
Smoking at 4-week follow-up	17	
Yes	18 (81.8)	
No	1 (4.5%)	
Missing	3 (13.6%)	
Sex		
Male	13 (59.1%)	
Female	9 (40.9)	
Age (years)		
Mean (SD) (range)	42 (9.4) (26-60)	
Ethnicity		
White UK	13 (59.1%)	
White other	2 (9.1%)	
Mixed white and Caribbean	1 (4.5%)	
Mixed white and African	1 (4.5%)	
Mixed other	2 (9.1%)	
Black African, Black British African	2 (9.1%)	
Black Caribbean, Black British Caribbean	1 (4.5%)	

Where slept last night		
Hostel or supported accommodation	12 (54.5%)	
On someone's sofa or floor	2 (9.1%)	
Emergency accommodation	2 (9.1%)	
B&B accommodation	1 (4.5%)	
Housed – own tenancy	5 (22.7%)	
Long standing illness or disability		
Yes	18 (81.8%)	
No	4 (18.2%)	
Previous mental health hospital admission		
Yes	10 (45.5%)	
No	12 (54.5%)	

UC: Usual care. EC: E-cigarettes. SD: Standard deviation.

Appendix 4: Unit costs of prescribed NRT products

NRT product	Unit cost (2018/19)	Sources
Patches	£26.70/item	(Prescribing Medicines Team 2018, Curtis and Burns 2019) [41,42]
Gum	£13.85/item	
Tablets	£18.70/item	
Inhaler	£0.80/cartridge; £36.40/item	
Lozenge	£14.79/item	
Nasal spray	£15.55/bottle	
Mouthstrip	£10.23/item	

NRT: Nicotine replacement therapies

Appendix 5: Unit costs of smoking cessation and health care services

	Unit cost (2018/19)	Sources
Smoking cessation help from primary care professionals		
GP	£37/10-min session	(Curtis and Burns 2019) [42]
Practice nurse	£8/10-min session	(Curtis and Burns 2019) [42]
Pharmacist	£8/10-min session	(Curtis and Burns 2019) [42]
NHS helpline	£6/call	(Curtis and Burns 2019) [42]
Health care and social services		
A & E	£192/attendances	(NHS England and NHS Improvement 2020) [43]
Outpatient	£144/appointment	(NHS England and NHS Improvement 2020) [43]
Inpatient (nights)	£642/night	(NHS Improvement 2018, NHS England and NHS Improvement 2020) [43,44]
Day case	£752/case	(NHS England and NHS Improvement 2020) [43]
Ambulance (travel)	£257/journey	(NHS England and NHS Improvement 2020) [43]
GP	£34/9.22 min consultation	(Curtis and Burns 2019) [42]
Practice nurse	£11/15.5 min consultation	(Curtis and Burns 2019) [42]

	Unit cost (2018/19)	Sources
GP (home visit)	£79/9.22 min consultation+12 min travel	(Curtis and Burns 2019) [42]
Practice nurse (home visit)	£19/15.5 min consultation+12 min travel	
Prescriptions (NIC+fees)	£20/prescription	(NHS Prescription Service 2019)
Sex health clinic	£263/visit	(NHS England and NHS Improvement 2020)
Drug/Alcohol service	£113/visit	(NHS England and NHS Improvement 2020)
Early intervention	£2721/patient-year	(Curtis and Burns 2019)
Adult mental health team	£155/contact	(NHS England and NHS Improvement 2020)
Crisis team	£87/contact	(NHS England and NHS Improvement 2020)
Maternity service	£232/contact	(NHS England and NHS Improvement 2020)
Detox/Rehab unit	£1114/week £154/day	(Curtis and Burns 2019) [42]
Housing team	£26/visit	(Curtis and Burns 2019) [42]

Appendix 6: Participants' use of emergency and hospital services, by arm

	UC (n=32)			EC (n=48)		
	n of null use	n (range) when use > 0	Missing	n of null use	n (range) when use > 0	Missing
Baseline	**n=32**			**n=48**		
A & E	24	7 (1-2)	1	40	7 (1-3)	1
Of which admitted	-	5 yes	2	-	2 yes, 5 no	0
Outpatient	29	2 (1-1)	1	40	7 (1-10)	1
Inpatient (nights)	25	6 (1-14)	1	46	1 (1)	1
Day case	29	2 (1-1)	1	42	5 (1-4)	1
Ambulance	27	4 (1-2)	1	43	4 (1-2)	1
4 weeks	**n=21**			**n=39**		
A & E	16	3 (2-9)	2	34	5 (1-4)	0
Of which admitted	-	2 yes, 1 no	0	-	3 yes, 2 no	0
Outpatient	20	1 (6)	0	34	5 (1-1)	0
Inpatient (nights)	19	2 (9-14)	0	37	2 (4-4)	0
Day case	20	1 (6)	0	35	4 (1-3)	0
Ambulance	18	3 (3-6)	0	36	3 (1-2)	0
12 weeks	**n=18**			**n=34**		
A & E	15	3 (3-6)	0	28	5 (1-2)	1
Of which admitted	-	1 yes, 1 no	1	-	1 yes, 4 no	0
Outpatient	17	1 (3)	0	30	4 (1-8)	0
Inpatient (nights)	16	2 (1-8)	0	34	0 (-)	0
Day case	15	2 (1-3)	1	31	3 (1-2)	0
Ambulance	16	2 (1-1)	0	34	0 (-)	0
24 weeks	**n=12**			**n=35**		
A & E	8	4 (1-4)	0	28	5 (1-6)	0
Of which admitted	-	1 yes, 2 no	1	-	5 no	0
Outpatient	11	1 (1)	0	33	2 (3-4)	0
Inpatient (nights)	11	1 (1)	0	34	1 (14)	0
Day case	10	2 (1-1)	0	29	6 (1-2)	0
Ambulance	11	1 (2)	0	35	0 (-)	0

UC: Usual care. EC: E-cigarettes. A&E: Accident and Emergency.

Appendix 7: Participants' use of primary and community services, by arm

	UC (n=32)			EC (n=48)		
	n of null use	n (range) when use > 0	Missing	n of null use	n (range) when use > 0	Missing
Baseline	**n=32**			**n=48**		
GP	20	11 (1-4)	1	30	17 (1-4)	1
Practice nurse	23	8 (1-2)	1	40	7 (1-2)	1
Prescriptions	6	25 (1-12)	1	14	33 (1-16)	1
Drug/Alcohol service	21	10 (1-30)	1	33	14 (1-9)	1
Adult mental health team	22	9 (1-30)	1	39	8 (1-4)	1
Crisis team	27	4 (1-30)	1	45	2 (1-1)	1
Housing team	22	9 (1-30)	1	35	12 (1-4)	1
4 weeks	**n=21**			**n=39**		
GP	10	11 (1-14)	0	29	10 (1-2)	0
Practice nurse	15	6 (1-4)	0	35	3 (1-1)	1
Prescriptions	7	14 (1-34)	0	13	25 (1-6)	1
Drug/Alcohol service	18	3 (2-4)	0	25	14 (1-8)	0
Adult mental health team	16	5 (1-4)	0	37	2 (1-1)	0
Crisis team	20	1 (1)	0	39	0 (-)	0
Housing team	20	1 (1)	0	32	7 (1-4)	0
12 weeks	**n=18**			**n=34**		
GP	9	9 (1-5)	0	22	12 (1-5)	0
Practice nurse	13	5 (1-4)	0	28	6 (1-2)	0
Prescriptions	5	13 (1-12)	0	14	20 (1-24)	0
Drug/Alcohol service	18	0 (-)	0	24	10 (1-24)	0
Adult mental health team	13	5 (1-8)	0	29	5 (1-2)	0
Crisis team	17	1 (5)	0	33	1 (1)	0
Housing team	17	1 (1)	0	24	10 (1-8)	0

24 weeks	**n=12**			**n=35**		
GP	3	9 (1-3)	0	22	13 (1-4)	0
Practice nurse	9	3 (1-3)	0	26	9 (1-3)	0
Prescriptions	3	9 (1-24)	0	7	28 (1-60)	0
Drug/Alcohol service	11	1 (1)	0	22	13 (1-26)	0
Adult mental health team	9	3 (1-24)	0	28	7 (1-6)	0
Crisis team	12	0 (-)	0	34	1 (1)	0
Housing team	11	1 (1)	0	25	10 (1-12)	0

UC: Usual care. EC: E-cigarettes. GP: General practitioner.