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Dawkins, Lynne, Soar, Kirstie, Pesola, Francesca et al. (18 more authors) (2025) Smoking cessation for people accessing homeless support centres (SCeTCH): comparing the provision of an e-cigarette versus usual care in a cluster randomised controlled trial in Great Britain. BMC Medicine. 394. ISSN 1741-7015

<https://doi.org/10.1186/s12916-025-04167-y>

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Smoking cessation for people accessing homeless support centres (SCeTCH): comparing the provision of an e-cigarette versus usual care in a cluster randomised controlled trial in Great Britain

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Abstract

Background Smoking rates are exceptionally high among people experiencing homelessness. We aimed to test the effectiveness of an e-cigarette (EC) intervention designed to help people accessing homeless support services to stop smoking.

Methods A two-arm cluster randomised controlled trial. We recruited 32 homeless centres (clusters) across Great Britain. Participants were aged 18+ and known by centre staff to smoke. Randomisation of clusters (1:1; using various block sizes) to EC or usual care (UC) was generated in Stata by the trial statistician, concealed from researchers. Participants in EC clusters received a refillable EC, 4-week supply of e-liquid, and a fact sheet. UC participants received very brief advice on smoking, a support leaflet, and signposting to the stop smoking service. Interventions were delivered by centre staff. The primary outcome was sustained abstinence from smoking from 2 weeks post-baseline through to 24 weeks, verified by carbon monoxide (CO) measurements below 8 ppm. Secondary outcomes included CO-verified 7-day point prevalence abstinence. Analysis was intention-to-treat.

Results Between February 22, 2022, and June 22, 2023, 16 centres were randomised to EC ($n = 239$ participants) and 16 to UC ($n = 238$ participants). In UC, one participant died, and one withdrew consent. Final sample analysed: $n = 239$ (EC); $n = 236$ (UC). Sustained 24-week CO-validated smoking cessation rates were 5/239 (2.1%) with EC vs. 2/236 (0.8%) with UC (aRR: 2.43, 95%CI: 0.51–11.64). Seven-point prevalence abstinence was 15/239 (6.3%) in the EC arm vs. 5/236 (2.1%) in UC (aRR: 2.95, 95%CI: 1.05–8.29). Four adverse events were reported in the EC arm; three deemed EC-related and not serious; one serious and not EC-related.

Conclusions EC did not support sustained smoking abstinence for 24 weeks. Seven-day point prevalence abstinence rates suggest that cessation is possible, but more support may be needed to sustain this.

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Trial registration The trial was preregistered on the ISTCTN registry #18566874. Registration date: 12/10/2021.

Keywords Smoking cessation, Smoking reduction, Homelessness, E-cigarettes, Tobacco harm reduction, Health inequalities, Abstinence, Cluster randomised controlled trial

Background

Homelessness, used here to refer to adults without secure or long-term accommodation, is associated with extremely poor health outcomes compared to those securely housed [1]. Tobacco smoking significantly contributes to these inequalities [2–4]. In the United Kingdom (UK), people experiencing homelessness are up to four times more likely to smoke than the housed population [3, 5], start smoking at an earlier age, and tend to be more heavily dependent on tobacco. The already considerable risks of smoking may be further exacerbated among people experiencing homelessness, who also may engage in potentially risky smoking practices, such as sharing cigarettes, smoking discarded cigarettes, and smoking unfiltered cigarettes [6, 7].

Smoking cessation intervention studies for people experiencing homelessness are limited; most are concentrated in the USA and typically only report short-term abstinence rates (e.g. 7-day point prevalence) [5]. Previous studies have generally focused on behavioural support and/or licenced pharmacotherapies, but report challenges, including low participant engagement, high dropout rates, and low success in achieving smoking cessation [5, 8]. A Cochrane review published in 2020 [8] reported 10 studies involving 1634 participants exploring the potential effectiveness of intensive behavioural support, multi-issue support, contingency management, text messaging, and one study on e-cigarettes (EC; our feasibility study [9]). Evidence was rated as low or very low quality and insufficient to determine treatment effectiveness [8]. Although previously overlooked in the UK, this population has been identified as a high smoking prevalence group in need of intervention [4] and new efforts are focusing on tobacco harm reduction and smoking cessation. People experiencing homelessness are underrepresented in traditional UK smoking cessation services. Additional ways to engage and support people experiencing homelessness are needed.

A significant proportion of those experiencing homelessness demonstrate a desire and motivation to quit [10–12] and are interested in receiving advice on smoking reduction and cessation [11]. However, this is not routinely offered in an accessible way [11]. There is evidence that tailored interventions, designed to provide support at a place already familiar to the individual, with established relationships and a harm reduction focus, may help people to reduce or quit smoking [5, 8, 9, 11, 13]. Our earlier work with people experiencing homelessness showed that e-cigarettes (EC) were the most popular

option for people planning to quit smoking. However, EC were not consistently available via stop smoking services, and the start-up cost was too high for many people [11].

EC are popular quitting aids [14, 15]. There is emerging evidence for their effectiveness for smoking cessation compared with behavioural support, strong evidence compared to nicotine replacement therapies (NRT), and for equivalence to varenicline and cytisine across international trials [16]. We previously conducted a feasibility study of an EC-based intervention designed with, and specifically for, people experiencing homelessness who smoke [9, 13]. Our results showed a full trial was feasible: over half of eligible participants invited to take part were recruited (80/153) in a 5-month period; the EC intervention was acceptable to both staff and participants, retention rates exceeded progression criteria (>50%), and there were low reports of unintended consequences [9, 13].

This paper presents the results from a cluster randomised controlled trial (cRCT). Our primary aim was to measure the effectiveness of an EC starter kit and 4-week supply of e-liquids provided to people who smoked accessing homeless support centres compared with usual care. We used the same procedures and intervention delivery as in our feasibility study [13]. At the time of the trial, usual care (UC) involved very brief advice PLUS (VBA+) [17] and signposting to a local authority stop smoking service (SSS) (who provide behavioural support, licensed NRT, and in some cases, an EC). Secondary aims were to explore smoking reduction across the two arms and document risky smoking practices over time and across arms.

Methods

Study design

A multi-centre, two-arm cluster RCT (cRCT) with mixed-method process evaluation and economic evaluation. Cluster rather than individual randomisation was used to reduce contamination as advised by our PPI group. The cRCT took place in 32 homeless support centres (clusters) across 6 areas of Great Britain: Scotland ($N=6$), Wales ($N=4$), Southwest ($N=2$), East England ($N=7$), Southeast England ($N=6$), and London ($N=7$). These centres range in size, with between 5 and 50 members of staff/volunteers and with daily provision for between 5 and 160 service users. They comprised both independent (e.g. church-affiliated) establishments as well as local centres which formed part of a larger homeless charity network, and/or services commissioned

through local authorities or health boards. They typically provide access to health-care support, computer facilities, financial advice, food, clothing, showers and basic amenities, social support, referrals to outside agencies, and in some cases, accommodation. Centres were eligible if they were not exclusively residential; primarily targeting people experiencing homelessness; not already providing EC; within 2 h travelling distance from the area university; and willing to be randomised to either arm. The protocol was previously published elsewhere [18].

Participants

Participants who smoked and regularly attended one of the 32 centres were informed of the trial by staff and either signed up via the expression of interest (EOI) posters in centres or were introduced to researchers for further information. Inclusion criteria were aged 18+, self-reported daily smoking verified by centre staff, known to staff, and willing and able to provide written consent. Participants did not have to be motivated to quit and there was no agreement that a cessation attempt should be made. Participants were excluded if they were never, or former smokers, currently using a smoking cessation aid, or had a known allergy to any of the e-liquid ingredients (EC arm only).

Self-reported sociodemographic data was collected following written informed consent at baseline.

Randomisation and masking

Centres (clusters) were randomly allocated (1:1) to the EC intervention ($n=16$) or UC ($n=16$) using a predefined randomisation list generated by the trial statistician using Stata version 17. To ensure balance between arms, the randomisation list consisted of block sequences of varying size, withheld from the research team to avoid allocation bias. The tested and validated list was automated into REDCap (an electronic data capture tool hosted at the trials unit Kings College London) by the database programmer. Randomisation was not stratified by region as this may have led to selection bias (i.e. where researchers could predict allocation of final centres based on previous allocations in that region).

We aimed to recruit 15 participants per centre. The intervention the participant received was determined by the arm each centre was randomised to. Researchers and centre staff were blinded to allocation until after centres had consented to participate in the trial and expressions of interest (EOIs) from participants had been gained (where possible). Arm allocation was revealed to centre staff during intervention training and concealed to participants until after consent and baseline assessment.

Procedures

Staff training

Staff in both arms were trained on content following the National Centre for Smoking Cessation and Training (NCSCT) recommendations and on how to deliver the intervention consistently for their centres. Trainees included volunteers, support workers, senior staff, managers, receptionists, housing support officers, and outreach workers, with limited previous health-care training. In the EC arm, staff were provided with evidenced-based information on EC and how to provide EC advice, and a practical demonstration on EC assembly and use. They were also given advice on guiding participant's choice of e-liquid flavour and strength, and when to distribute additional e-liquids. Staff in the UC arm received guidance on delivering VBA + [17] and information about how to signpost clients to the SSS. All staff attending the training received a certificate of attendance. Training sessions took place in person on a group basis in centres and lasted, on average, 2.5 h.

Usual care arm

In line with current best level of provision, our usual care (UC) arm included VBA + [17] on smoking, a quit smoking support leaflet (as per our feasibility study [13]), and signposting to the SSS, including help to facilitate referral if required. UC was delivered by centre staff following consent and baseline assessment with the researcher.

E-cigarette arm

The EC intervention was as per the feasibility study [13] and delivered by centre staff. Participants were provided with a tank-style refillable EC starter kit (PockeX), a choice of nicotine strength e-liquids (12 mg/mL and 18 mg/mL), and flavours (tobacco, menthol, or fruit). The PockeX tank was selected rather than a pod device based on PPI feedback and because, at the time of the study, pods were more expensive and less readily available. An EC factsheet was also provided, an A5 size leaflet containing practical advice and tips from experienced vapers (e.g. 'when refilling, be careful not to overfill to avoid leaks'; 'Avoid feeling pressured and make small changes at your own pace'; 'if you stop tasting one flavour of e-liquid, switch to another, like mint'). E-liquids (up to five 10-mL bottles per week) were supplied for 4 weeks at weekly intervals by staff, along with replacement coils as needed. Participants could try different flavours and nicotine strengths at baseline and were permitted to switch between flavours. EC charging was available, if required, at centres. Replacements were not provided if devices were lost or damaged.

Assessments

Assessments, at baseline and 4, 12, and 24 weeks, were conducted by researchers at the centres. At baseline, self-reported smoking status and time of last cigarette were recorded alongside a carbon monoxide (CO) reading, collected using a calibrated CO monitor. Case record forms (CRFs) were collected and managed using REDCap and included measures of sociodemographic and housing status, alcohol/drug use (yes/no), and mental health diagnosis (yes/no). Smoking history assessment included the Fagerström Test of Cigarette Dependence (FTCD) [19], a six-item scale measuring cigarette dependence (ranging from 0—low to 10—high cigarette dependence); and motivation to quit, using the one item Motivation to Stop Smoking Scale (MTSS [20]), with 7 options (ranging from 1 = I don't want to stop smoking to 7 = I really want to stop smoking and intend to do so in the next month). Risky smoking practices (sharing cigarettes, picking up discarded cigarettes, asking strangers for cigarettes) were each rated on a 4-point scale (not at all, occasionally, regularly, daily). Known adverse effects of EC ($n=13$: nervous, headache, sweaty, weak, nausea, pounding heart, throat/mouth irritation, sleep disturbance, dizziness, shortness of breath, cough, wheezy, and phlegm production) based on previous studies [13, 21, 22] were each rated on a 5-point scale from 1 (not at all) to 5 (extremely). A full description of all study measures is available elsewhere [18].

Follow-up assessments at 4, 12, and 24 weeks were similar to baseline measures minus demographic characteristics. Participants were also asked about their use of EC/NRT (both arms), smoking cessation, and reduction. Those allocated to the EC arm were asked to rate their experience of using the EC across five attributes (hit, pleasant, satisfying, tastes good, helpful for reducing urge to smoke), each on a 5-point scale from not at all to extremely, based on those most commonly reported in our feasibility study [13], and whether they still had the study EC. A translation service was available for people who did not speak or understand English. Trial materials were translated into 12 languages. Participants were compensated with a £15 Love2Shop voucher for each follow-up session completed.

Outcomes

The primary outcome was sustained CO-validated abstinence from smoking to 24 weeks (allowing a 2-week grace period from baseline) using the Russell Standard for smoking cessation trials [23]. A successful quitter was defined as a person who reported 'not a single puff' or 'just a few puffs' at every follow-up, in response to the question 'in the last 2 weeks/2 months/3 months have you smoked?', or if they reported they had smoked no

more than 5 cigarettes (i.e. ≤ 5) cigarettes in total, accompanied by a CO reading of < 8 ppm at every follow-up.

Secondary outcomes were CO-validated (< 8 ppm) 7-day point prevalence abstinence (defined as 'not a single puff' or 'just a few puffs' in the last 7 days), and reduction of at least 50% smoking from baseline to 4, 12, and 24 weeks; and changes in the frequency of self-reported risky smoking practices from baseline to 4, 12, and 24 weeks.

In addition to the prespecified 13 known adverse effects of EC, we also documented adverse events (AEs) reported to researchers by centre staff or participants. Any AE was assessed for seriousness, relatedness, expectedness, and severity. Data on AE, adverse reactions (AR), serious AE (SAE), and serious AR (SARs) were recorded on the CRF and REDCap.

Statistical analysis

Based on our feasibility study [13], 480 participants (i.e. 240 per arm) were required to provide 90% power (intra-class correlation = 0.01, $\alpha = 0.05$, two-tailed) to detect a difference between arms (i.e. 6.25% vs. 0.5% respectively in the EC vs. UC arms). Assuming 15 participants recruited per centre, the feasibility study average, we required 32 centres in total (i.e. 16 per arm). A final sample of 480 also provided 90% power if the cluster size was smaller ($n=12$) or greater ($n=18$) than the planned 15 participants per cluster.

Our analyses were specified in a preregistered statistical analysis plan (SAP). All analyses were intention-to-treat (ITT), i.e. participants were included in their randomised group and those with missing outcomes were treated as smoking as per Russell Standard [23]. Differences in smoking outcomes between arms were assessed using mixed-effect models with random effects for clusters and fixed effect for treatment to compare quit rates across arms. We used the `-gllamm-` command with binomial family and log link to estimate relative risks (RR) and 95% confidence intervals (CI) in Stata; if the model failed to converge, we ran a modified Poisson model with long link and robust standard errors. A Bayes Factor (BF) was calculated for the primary analysis of the primary outcome.

In our SAP, we prespecified that we would adjust for individual- (age, sex, FTCD, and previous quit attempts) and cluster-level characteristics (i.e. region and centre size); however, due to low quit rates, this was not always possible and in some instances, models were adjusted for (a) age, FTCD, and region, or (b) FTCD only (as found to be imbalanced between arms). We present the unadjusted and adjusted RR and their corresponding two-sided 95%CI for smoking outcomes.

Whilst the primary analysis compares the effectiveness of providing EC at centres compared with UC, our SAP specified that we would explore the effectiveness of using EC compared with no use by excluding those identified as contaminators. Contaminators were defined as EC arm participants using NRT or attending SSS, and UC arm participants using EC at any point during the trial. However, due to the small cell size, it was not possible to conduct any formal sensitivity analysis on the impact of contamination.

In the primary analysis, we assumed that missing data = smoking. This is a conservative approach, so we explored alternative scenarios assuming lower quit rates among individuals with missing data. We also conducted complete case analyses adjusted for age, which is associated with the outcome and its missingness.

To compare known adverse effects between study arms, we used ordinal regression models adjusted for baseline scores and standard errors allowing for intra-group correlation.

To explore possible differences in risky smoking practices between arms, we regressed each behaviour separately onto arm, time, and time*arm, adjusting for baseline scores. The models were also adjusted for region and age, which was also associated with missing data. Time was treated as a discrete measure. As risky practices were rare, items were dichotomised (0: not at all vs. 1: occasionally, regularly, or daily) and mixed-effect logistic regression was used with both participants and cluster as random effects to account for the repeated nature of the measure and that participants are nested within clusters [24].

Lastly, we reported the number (%) of participants who reported compliance with their allocated condition (use of EC in EC arm or attending SSS in UC arm) and additional product use (not provided by the trial in the EC arm, or by the SSS in the UC arm). Those not providing information were assumed not to be using additional products.

To conduct adjusted analyses for cessation outcomes, we imputed missing data on relevant covariates using multiple imputation (MI) by chained equation with 25 imputations. The imputation model included the variables used in the analyses and auxiliary variables associated with the covariates of interest or their missingness. Centre was included as a predictor in the MI model and separate models were run for each study arm. All analyses were conducted using Stata version 18 and verified by the independent statistician.

Results

Between February 22, 2022, and June 22, 2023, 477 eligible participants were recruited: 239 in the EC arm vs. 238 in the UC arm across 16 centres in each arm. One centre withdrew consent after randomisation but before recruitment commenced and was therefore excluded and replaced with a new centre (randomised using a biased coin approach). Two participants from the UC arm were excluded from final analyses, one died during the study period whilst another withdrew consent immediately following baseline assessment. The final sample included in the analyses was 475 (239 within 16 clusters EC vs. 236 within 16 clusters UC; Fig. 1).

Baseline participant characteristics are presented in Table 1. Participants were on average 43.7 (SD=11.7) years old, mostly male (83.2%), of white ethnicity (83.4%). Thirty-six percent had stopped education before completion of O-levels/GCSE's or equivalent (36.3%) whilst 6.7% had a higher education qualification. Thirty-seven percent were unable to work due to illness. We also found that 63.0% reported physical illness, 61.5% mental illness, and 81.1% were UK citizens.

Sixty-four percent reported current alcohol use, 50.5% drug use, and 33.7% reported smoking cannabis joints rolled with tobacco. Seventy-two percent reported at least one previous quit attempt. The median number of cigarettes per day (CPD) was 15 (interquartile range, IQR, 10–30), with a mean FCTD dependency score of 5.3 (SD=2.2) and a median baseline CO reading of 16 ppm (IQR: 10–23). Motivation to stop smoking varied with roughly equal numbers reporting 'I don't want to stop' (8.4%) and 'I really want to stop and intend to do so in the next month' (9.5%).

Additional file 1: Table S1 presents the breakdown of missing data in the primary and secondary smoking outcomes. As expected, missing information for the validated sustained abstinence outcome increased over time.

For the primary outcome, sustained CO-validated smoking cessation rates at 24 weeks were 5/239 (2.1%) in the EC arm and 2/236 (0.8%) in the UC arm (see Table 2). This difference did not reach statistical significance (adjusted RR: 2.43, 95%CI: 0.51–11.64). The estimated Bayes Factor (BF = 1.44) indicates that data are inconclusive. For secondary outcomes, self-reported and CO-validated 7-day point prevalence quit rates were higher in the EC vs. UC arm at all time points. There were significant differences in 7-day point prevalence abstinence (both self-reported and CO-validated) at 24 weeks (aRR: 2.95, 95%CI: 1.05–8.29) and 4 weeks (self-reported; aRR: 3.32, 95%CI: 1.34–8.23) and sustained abstinence (self-report) at 4 weeks (aRR: 2.55, 95%CI: 1.17–5.55). No other cessation comparisons reached significance (see Table 2). A significantly higher number of participants in the EC arm

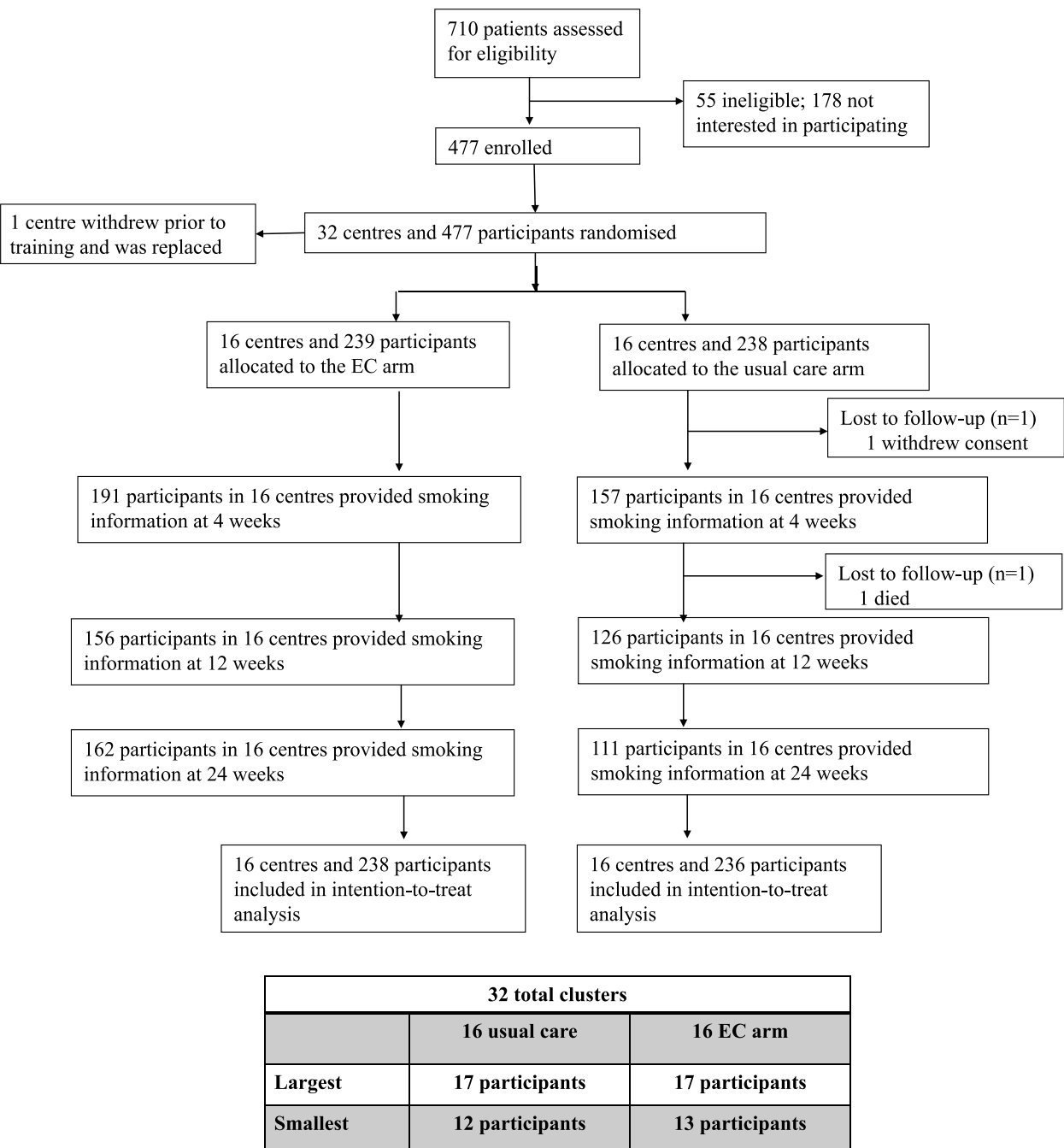


Fig. 1 SCeTCH CONSORT

reduced their smoking by 50% or more at 4 weeks (aRR: 2.55, 95%CI: 1.83–3.54), 12 weeks (aRR: 2.37, 95%CI: 1.68–3.35), and 24 weeks (aRR: 2.02, 95%CI: 1.44–2.84) compared to those in the UC arm (Table 2).

Changes in frequencies of risky practices from baseline to 4, 12, and 24 weeks are presented in Table 3. There was no main effect of intervention on sharing (aOR=1.03, 95%CI: 0.38–2.77), smoking a discarded

cigarette (aOR=0.28, 95%CI: 0.07–1.06), or asking a stranger (aOR=1.61, 95%CI: 0.55–4.77). There was a reduction over time in the proportion of respondents reporting smoking discarded cigarettes ($\chi^2=8.2$, $p=0.02$). We did not detect a reduction over time for sharing cigarettes ($\chi^2=4.6$, $p=0.10$) or asking strangers ($\chi^2=3.8$, $p=0.15$). The time by arm interaction did not reach significance for any risky behaviour (shared

Table 1 Baseline characteristics of the intention to treat population at individual level and cluster (centre) level; the overall sample and by arm (EC versus UC)

	Total population	E-cigarette	Usual care
Participant level	(N = 475)	(N = 239)	(N = 236)
Age ^a	43.7 (11.7)	42.1 (11.0)	45.3 (12.2)
Sex			
Male	395 (83.2)	193 (80.8)	202 (85.6)
Female	77 (16.2)	44 (18.4)	33 (14.0)
Non-binary	1 (0.2)	1 (0.4)	0
Transwoman	1 (0.2)	1 (0.4)	0
Prefer not to say	1 (0.2)	0	1 (0.4)
Occupation			
Employed, studying, or retired	130 (27.4)	58 (24.3)	72 (30.6)
Currently unwell and not working	68 (14.3)	39 (16.3)	29 (12.34)
Unable to work due to illness	177 (37.3)	99 (41.4)	78 (33.2)
Unemployed	99 (20.9)	43 (18.0)	56 (23.8)
Education			
Stopped prior to O-level/GCSE	172 (36.3)	93 (38.9)	79 (33.6)
O-level/GCSE	170 (35.9)	88 (36.8)	82 (34.9)
A-level	100 (21.1)	42 (17.6)	58 (24.7)
University degree	23 (4.9)	13 (5.4)	10 (4.3)
University postgraduate degree	9 (1.9)	3 (1.3)	6 (2.6)
Ethnicity			
White	396 (83.4)	198 (82.9)	198 (83.9)
Long standing illness/disability			
Yes	299 (63.0)	146 (61.1)	153 (64.8)
No	171 (36.0)	92 (38.5)	79 (33.5)
Don't know	5 (1.0)	1 (0.4)	4 (1.7)
Mental illness			
Yes	292 (61.5)	157 (65.7)	135 (57.2)
No	176 (37.0)	80 (33.5)	96 (40.7)
Don't know	7 (1.5)	2 (0.8)	5 (2.1)
UK citizens	385 (81.1)	203 (84.9)	182 (77.1)
Drinks alcohol ^c	305 (64.2)	140 (58.6)	165 (69.9)
Use of other substances ^d	240 (50.5)	118 (49.4)	122 (51.7)
Smoking indices			
Previously tried to quit ^a	340 (71.7)	174 (73.1)	166 (70.3)
N smoked joints with tobacco ^b	160 (33.7)	84 (35.1)	76 (32.2)
CPD (median, IQR)	15 (10–20)	15 (10–20)	15 (10–20)
FTCD (mean, SD) ^a	5.3 (2.2)	5.6 (2.1)	5.0 (2.3)
CO reading ^a	16 (10–23)	17 (11–25)	15 (9–22.5)
Motivation to stop smoking			
I don't want to	40 (8.4)	7 (2.9)	33 (14.0)
I think I should	63 (13.3)	37 (15.5)	26 (11.0)
I want to but haven't thought when	64 (13.5)	34 (14.2)	30 (12.7)
I really want to but don't know when I will	94 (19.8)	41 (17.2)	53 (22.5)
I want to and hope soon	86 (18.1)	46 (19.2)	40 (16.9)
I really want to and intent in the next 3 months	46 (9.7)	25 (10.5)	21 (8.9)
I really want to and intent in the next month	45 (9.5)	29 (12.1)	16 (6.4)
I don't know	34 (7.2)	19 (8.0)	15 (6.4)
Missing	3 (0.6)	1 (0.4)	2 (0.9)

Table 1 (continued)

	Total population	E-cigarette	Usual care
Cluster (centre level)		<i>N</i> = 16	<i>N</i> = 16
Centre size			
0–20		1 (6.3)	2 (12.5)
21–30		5 (31.3)	3 (18.8)
31–50		3 (18.8)	6 (37.5)
50+		7 (43.8)	5 (31.3)
Region			
Scotland		2 (12.5)	4 (25.0)
SE		3 (18.8)	3 (18.8)
EoE		5 (31.3)	2 (12.5)
SW		0	2 (12.5)
London		2 (12.5)	5 (31.3)
Wales		4 (25.0)	0

^a Data not available for all randomised participants^b If, at baseline, they report smoking at least one (1) joint each day on average^c If answered yes to the question ‘how often do you have a drink containing alcohol?’, they respond ‘monthly or less’, ‘2 to 4 times per month’, ‘2 to 3 times per week’, or ‘4+ times a week’^d If they answer yes to the question, ‘In the last month, have you taken any substance other than alcohol’**Table 2** Smoking status outcomes

	EC (<i>N</i> = 239)	UC (<i>N</i> = 236)	RR (95%CI), <i>p</i> -value	aRR (95%CI), <i>p</i> -value
CO-verified sustained abstinence				
4 weeks	12 (5.0)	4 (1.7)	2.96 (0.97–9.06), <i>p</i> = 0.06	2.79 (0.88–8.79), <i>p</i> = 0.08 ^a
12 weeks	7 (2.9)	3 (1.3)	2.30 (0.60–8.82), <i>p</i> = 0.22	2.05 (0.55–7.66), <i>p</i> = 0.29 ^a
24 weeks	5 (2.1)	2 (0.8)	2.47 (0.48–12.62), <i>p</i> = 0.28	2.43 (0.51–11.64), <i>p</i> = 0.27 ^a
Self-reported sustained abstinence				
4 weeks	23 (9.6)	9 (3.8)	2.52 (1.19–5.34), <i>p</i> = 0.02	2.55 (1.17–5.55), <i>p</i> = 0.02 ^a
12 weeks	9 (3.8)	3 (1.3)	2.96 (0.81–10.82), <i>p</i> = 0.10	2.78 (0.76–10.22), <i>p</i> = 0.12 ^a
24 weeks	5 (2.1)	2 (0.8)	2.47 (0.48–12.62), <i>p</i> = 0.28	2.43 (0.51–11.64), <i>p</i> = 0.27 ^a
CO-verified 7-day PP abstinence				
4 weeks	11 (4.6)	3 (1.3)	3.62 (1.02–12.83), <i>p</i> = 0.05	3.40 (0.95–12.14), <i>p</i> = 0.06 ^a
12 weeks	10 (4.2)	5 (2.1)	1.97 (0.68–5.70), <i>p</i> = 0.21	1.84 (0.64–5.24), <i>p</i> = 0.26 ^a
24 weeks	15 (6.3)	5 (2.1)	2.96 (1.09–8.03), <i>p</i> = 0.03	2.95 (1.05–8.29), <i>p</i> = 0.04 ^a
Self-reported 7-day PP abstinence				
4 weeks	20 (8.4)	6 (2.5)	3.29 (1.34–8.06), <i>p</i> = 0.01	3.32 (1.34–8.23), <i>p</i> = 0.01 ^a
12 weeks	11 (4.6)	6 (2.5)	1.81 (0.68–4.82), <i>p</i> = 0.24	1.74 (0.66–4.63), <i>p</i> = 0.27 ^a
24 weeks	15 (6.3)	5 (2.1)	2.96 (1.09–8.03), <i>p</i> = 0.03	2.95 (1.05–8.29), <i>p</i> = 0.04 ^a
Self-reported 50% reduction				
4 weeks	96 (40.2)	42 (17.8)	2.26 (1.65–3.09), <i>p</i> < 0.001	2.55 (1.83–3.54), <i>p</i> < 0.001 ^b
12 weeks	85 (35.6)	40 (17.0)	2.10 (1.51–2.92), <i>p</i> < 0.001	2.37 (1.68–3.35), <i>p</i> < 0.001 ^b
24 weeks	83 (34.7)	40 (17.0)	2.05 (1.47–2.86), <i>p</i> < 0.001	2.02 (1.44–2.84), <i>p</i> < 0.001 ^b

Sustained abstinence defined as continued smoking abstinence with a 2-week grace period and allowing up to 5 ‘slips’; 7-day pp abstinence defined as smoking ‘not a puff’ or ‘just a few puffs’ in the last 7 days

^a Adjusted for age, missing data imputed using Multiple Imputation^b Adjusted for baseline FTCD score, age, and centre size

Table 3 Number (%) of individuals engaging in each risky smoking behaviour at each follow-up by study arm

	Baseline		Week 4		Week 12		Week 24	
	EC (N = 239)	UC (N = 236)	EC (N = 170)	UC (N = 151 ^d)	EC (N = 145)	UC (N = 120)	EC (N = 148)	UC (N = 107)
Shared ^a								
Not at all	115 (48.1)	119 (50.4)	96 (54.5)	89 (59.3)	91 (62.8)	82 (68.3)	95 (64.2)	79 (73.8)
Occasionally	51 (21.3)	47 (19.9)	44 (25.9)	33 (22.0)	33 (22.8)	25 (20.8)	26 (17.6)	18 (16.8)
Regularly	25 (10.5)	30 (12.7)	11 (6.5)	11 (7.3)	9 (6.2)	7 (5.8)	8 (5.4)	6 (5.6)
Daily	48 (20.1)	40 (16.9)	19 (11.2)	17 (11.3)	12 (8.3)	6 (5.0)	19 (12.8)	4 (3.7)
Discarded ^b								
Not at all	162 (67.8)	156 (66.1)	132 (77.6)	106 (70.2)	116 (80.0)	94 (78.3)	119 (80.4)	86 (80.4)
Occasionally	38 (15.9)	38 (16.1)	20 (11.8)	23 (15.2)	12 (8.3)	12 (10.0)	17 (11.5)	10 (9.3)
Regularly	16 (6.7)	27 (11.4)	5 (2.9)	9 (6.0)	4 (2.8)	6 (5.0)	3 (2.0)	6 (5.6)
Daily	23 (9.6)	15 (6.4)	13 (7.6)	13 (8.6)	13 (9.0)	8 (6.7)	9 (6.1)	5 (4.7)
Stranger ^c								
Not at all	165 (69.0)	164 (69.5)	129 (75.9)	121 (80.1)	122 (84.1)	107 (89.2)	121 (81.8)	92 (86.0)
Occasionally	46 (19.2)	47 (19.9)	30 (17.6)	20 (13.2)	11 (7.6)	9 (7.5)	18 (12.2)	12 (11.2)
Regularly	12 (5.0)	15 (6.4)	4 (2.4)	4 (2.6)	6 (4.1)	2 (1.7)	3 (2.0)	0
Daily	16 (6.7)	10 (4.2)	7 (4.1)	6 (4.0)	6 (4.1)	2 (1.7)	6 (4.1)	3 (2.8)

^a Shared: how often have you shared cigarettes (i.e. 'going twos', passing a cigarette/roll up from one person to another)?

^b Discarded: how often have you smoked discarded cigarettes (e.g. picked up from the street/public places)?

^c Stranger: how often have you asked strangers for cigarettes?

^d N = 150 for the variable coding sharing cigarettes

chi(2)=0.3, $p=0.87$; discarded chi(2)=3.1, $p=0.21$; stranger chi(2)=0.7, $p=0.72$).

We explored two scenarios assuming individuals with missing data had lower quit rates than observed in the complete cases (4.2% EC vs. 2.4% UC), i.e. 20% and 50% lower [25]. Additionally, we conducted a complete case analysis. Results from the sensitivity analyses (Additional file 1: Table S2) were in line with the primary analysis (i.e. same direction); however, as in the primary analysis, the 95% CIs were broad indicating a low degree of precision.

Contamination could not be formally explored due to small cell sizes; however, in the EC arm, one of the five (20%) validated abstainers reported using NRT products (i.e. patches and spray) whilst both abstainers in UC reported using an EC.

Ratings of the 13 prespecified known adverse effects are reported in Additional file 1: Table S3. There were no significant differences in ratings between intervention arms. Four adverse events (AE) were reported by 4 participants over the whole study period, all in the EC arm. At 4 weeks, two participants reported one AE each: cough and throat/mouth irritation. Both events were classified as related to product use and not serious. At 12 weeks, no events were recorded. At 24 weeks, two participants reported one AE each: throat/mouth irritation, deemed related to vaping and not serious; and a hospital admission due to DVT caused by intravenous drug use, classified as serious and unrelated to vaping.

Additional file 1: Table S4 summarises the number (%) of respondents who reported compliance with their intervention condition and those using additional products. In the EC arm, 71.5% reported using the study EC at 4 weeks whereas 4.2% of UC participants had attended the SSS. Between 15.9% (4 weeks) and 33.5% (24 weeks) of EC arm participants and 13.1% (at 4 weeks) and 15.5% (24 weeks) of UC participants reported use of additional (non-study) products.

Discussion

This trial found that EC did not support long-term sustained smoking abstinence for 24 weeks in people experiencing homelessness compared to UC, but did suggest a significant benefit of EC vs. UC across secondary smoking cessation and reduction outcomes. Our trial is the first to test EC provision at homeless centres to people who smoke. It is the largest among the limited literature on smoking cessation and homelessness and is the first to use the 'gold standard' primary outcome of sustained CO-validated smoking abstinence to 6 months. Whilst the effect size for the primary outcome was higher than those reported in the Cochrane living systematic review of EC (vs. NRT or behavioural support/no support) [21], the benefit of EC over UC was uncertain due to low quit rates and wide confidence intervals. Our finding is in line with the few other trials that have measured 6-month abstinence in similar groups with high smoking

prevalence [26, 27] highlighting the challenges associated with sustaining smoking cessation among people experiencing disadvantage and with complex health and social needs.

A benefit of EC over UC was observed in our secondary cessation and reduction outcomes. Seven-day point prevalence abstinence at 24 weeks was at least twice as high with EC compared with UC, like other smoking cessation interventions in homeless populations measuring short-term abstinence [5, 8]. Reports of smoking reduction were likewise, more than twice as high in the EC versus the UC group at all follow-up time points. Although this is based on self-report, that 24-week CO-validated and self-reported abstinence rates were identical lends confidence to the accuracy of these measures. Our participants were not necessarily motivated to quit, and as noted elsewhere [10], reduction for many is a more realistic and achievable goal. This discord in personal goals of reduction versus trial goals of abstinence can pose a challenge in terms of definitions of success [28]. Taken together, these findings suggest that more support is needed for people experiencing homelessness to strive towards, and achieve, sustained smoking cessation.

We calculated our sample size based on our feasibility study quit rates (6% for EC; 0% for UC [13]) but 24-week sustained quit rates were lower than expected in the EC group, leading to reduced power to detect a difference in the primary outcome. Why feasibility study quit rates were higher is unclear but could be due to a shift from a smoking- to vaping-oriented culture in one large centre in our earlier study where a significant percentage of clients took part, and several staff members also switched to vaping [9]. In this trial, cluster sizes were 15, with an upper limit of 18, which may limit the critical mass necessary for providing a vaping culture and support. Nevertheless, even in our feasibility study, sustained quit rates were relatively low; different EC devices (e.g. pods), higher nicotine concentrations, and additional guidelines around best practice towards abstinence may improve quit rates. Aside from our feasibility study, only one other trial has explored EC for smoking cessation in adults accessing homeless shelters; quit rates were similarly low but could be improved by adding financial incentives contingent on CO-validated abstinence [29]. These findings suggest that whilst EC may be effective for smoking cessation in the general population [21], multi-pronged interventions with more intensive support may be required for people experiencing homelessness.

We found no changes in the reporting of sharing and asking strangers for cigarettes, but the proportion reporting smoking discarded cigarettes decreased significantly over time in both groups. It is possible that engaging in a trial on smoking (regardless of study arm)

led to greater awareness of potential harms. Another possibility is those who remained in the trial over time were less likely to engage in this practice. Nevertheless, reports of engaging in these practices were lower than in previous studies [6, 7]. This could reflect under-reporting due to shame and stigma or due to the increased focus on transmission of respiratory infection associated with the ongoing COVID-19 pandemic at the time of data collection.

Providing an EC at homeless support centres was acceptable for individuals; over 70% reported using the device provided within the first 4 weeks and reports of adverse effects were low. There were no recorded SAEs. As this was a pragmatic trial exploring the effects of *providing* an EC to people experiencing homelessness, we did not capture detailed data on patterns of use. Elsewhere, daily use has been associated with higher quit rates [30] so further guidance to encourage daily use may have improved abstinence rates, although we note in our process evaluation (reported separately) that restrictions on vaping in centres may have been a barrier to regular use. In the UC arm, only 3% reported that they had attended the SSS, consistent with reports elsewhere that people experiencing disadvantage are less likely to access generic smoking cessation services, favouring 'in-house' provision [11, 31].

SCeTCH is the largest smoking cessation trial for people experiencing homelessness worldwide, the first in Europe, and among only a few to explore the provision of an EC in this population. Previous trials have been mostly US-based and with short follow-up periods [5]. Where follow-up data have been collected at 6 months, cessation outcomes are based on 7-day point prevalence. This is the first to report sustained smoking abstinence over 6 months and we adopted a strict criterion, requiring CO-validated abstinence at all follow-up points, with self-reported smoking of fewer than 5 cigarettes in total (Russell Standard [23]). Although there was uncertainty in our primary outcome, our effect sizes across all outcomes were constant in favouring EC and remained consistent in the complete case analysis and under different missingness assumptions. Our recruitment rates were good at both the cluster and individual level; we successfully recruited for the former and fell short by only $n=3$ for the latter. That 73% of all eligible individuals approached were recruited attests to the interest and willingness among people experiencing homelessness to address their smoking. Cluster RCTs are often at unique risk of bias around identification and recruitment. We attempted to reduce bias by recruiting participants from centres before randomisation of clusters and staff training, by using EOI posters in centres. That enrolment was equitable across arms lends confidence that recruitment

of individuals was not affected by knowledge of the intervention.

Despite these strengths, there were several limitations. Due to the low quit rates, our trial was underpowered to detect an effect of the primary outcome. In turn, we could not always adjust our analysis for individual-level characteristics or conduct sensitivity analysis to explore the effect of any contamination. Our overall retention rate compared favourably to other trials in this population [6, 8] but rates were higher in the EC arm, perhaps reflecting a more positive experience, or greater willingness to return to report positive outcomes [9].

Conclusions

We found that EC did not support long-term sustained smoking abstinence at 24 weeks among people accessing homeless support centres compared to UC although there was a benefit of EC for secondary smoking cessation and reduction outcomes including 7-day point prevalence abstinence at 24 weeks. Sustained abstinence rates are traditionally low with any intervention among people experiencing multiple disadvantage and this appears to be the same with EC, although short-term abstinence and smoking reduction appears achievable. Our findings suggest that additional support over and above EC provision may be needed but how this might be offered in homeless support centres where staff are under pressure and dealing with people with complex difficulties is a challenge.

Given the substantial health inequalities associated with smoking, sustained cessation is a priority for people experiencing homelessness and more intensive support and a systems level approach may be required. Further research is needed to determine the most effective ways of achieving this.

Abbreviations

AE	Adverse event
aOR	Adjusted odds ratio
AR	Adverse reaction
aRR	Adjusted risk ratio
BF	Bayes Factor
EC	E-cigarette
CI	Confidence interval
CO	Carbon monoxide
CPD	Cigarettes per day
cRCT	Cluster randomised controlled trial
CRF	Case record forms
EoE	East of England
EOI	Expression of interest
FTCD	Fagerström Test of Cigarette Dependence
LSBU	London South Bank University
IQR	Interquartile range
ITT	Intention to treat
Mg	Milligram
MI	Multiple imputation
mL	Millilitres

MTSS	Motivation to Stop Smoking Scale
NCSC	National Centre for Smoking Cessation and Training
NRT	Nicotine replacement therapy
PP	Point prevalence
PPI	Patient and public involvement
Ppm	Parts per million
RCT	Randomised controlled trial
REDCap	Research Electronic Data Capture
RR	Relative risk
SAE	Serious adverse event
SAP	Statistical analysis plan
SAR	Serious adverse reaction
SD	Standard deviation
SE	Southeast
SW	Southwest
SSS	Stop smoking service
UC	Usual care
UK	United Kingdom
VBA	Very brief advice

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12916-025-04167-y>.

Additional file 1: Table S1. Missing data for each smoking abstinence and reduction outcome for the whole sample and by arm. Table S2. Sensitivity analyses for the primary outcome—validated sustained abstinence at 24 weeks. Table S3. Known adverse effects by arm. Table S4. Number (%) of participants complying with the intervention and use of additional products.

Acknowledgements

The authors would like to thank the independent statistician for verifying the analysis; members of the Trial Steering Committee; Data Monitoring and Ethics Committee; our PPI group; and all centre staff and participants who contributed to the trial. From July 2023, FP was supported by the Barts Hospital Charity (G-002207).

Authors' contributions

LD, SC, AF, LB, RB, CN, SP, DR, AT, JL PH, and FP, conceptualised, designed the study and obtained funding. DR developed the staff training materials and trained the team on delivery. FP led the statistical analysis. KS and LD have access and verified the data and along with SC and FP were involved in interpretation. LD and SC supervised the trial activities. KS managed the trial activities and led the staff training; the latter was supported by AF, CN, RB, EW, AV, CM, JB, LM, AE and JL. AF, KS, CN and RB led and managed individual area trial activities and research staff. All authors were involved in methodology and EW, LM, AV, CM, JB, AE and BG were responsible for trial delivery and data acquisition. LD, KS and FP drafted the manuscript, with input from all coauthors. KS and BG provided trial administrative support. All authors contributed to reviewing and editing the manuscript, had access to all data reported in the study, had final responsibility for the decision to submit for publication, and read and approved the final manuscript.

Funding

This study was funded by the National Institute for Health and Care Research (NIHR132158). The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

Data availability

The underpinning anonymised data and data dictionary along with the study protocol, Statistical Analysis Plan (SAP), participant information sheet, consent form, Case Record Forms (CRFs), and other study materials are available on the Open Science Framework (OSF) at <https://doi.org/10.17605/OSF.IO/YHMK9> [32].

Declarations

Ethics approval and consent to participate

Ethical approval was granted by London Southbank University (LSBU) ethics committee: ETH2021-0176. The researcher obtained participant consent to (a) take part in the study, (b) be contacted regarding participation in a process evaluation interview, (c) share their anonymised data, and (d) be contacted long term (up to 2 years).

Consent for publication

Not applicable.

Competing interests

FP, AF, RB, EW, LM, DR, AV, CM, JL, JB, AE, PH, AT, SP, JL, BG and SC declare no competing interests. LD has acted as a paid consultant for Johnson & Johnson who manufacturer smoking cessation medications. KS has acted as a paid consultant for ThriveTribe who deliver stop smoking services and Pharmastrat Ltd a healthcare consulting company who deliver stop smoking services. CN has received an honorarium from Vox Media for filming a 'nicotine explainer' on the role of nicotine in addiction. LB is seconded part time to Scottish Government as their Chief Social Policy Adviser and in that role serve as Senior Responsible Officer for the Place and Wellbeing Programme.

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Received: 31 January 2025 Accepted: 27 May 2025

Published online: 01 July 2025

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