ISRCTN18566874 https://doi.org/10.1186/ISRCTN18566874

E-cigarettes vs usual care for smoking cessation when offered at homeless centres

Submission date
22/04/2021

Recruitment status
No longer recruiting

Registration date
12/10/2021

Overall study status
Completed

Last Edited
23/08/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Around 60% of people who are homeless smoke tobacco; far higher than the UK average of 14.1%. E- cigarettes (EC) are the most popular method of quitting smoking, with some studies suggesting they are more helpful than nicotine gum or patches and are less harmful than smoking. For people on low or no income however, the price of a starter kit is high (~£25). Supplying free EC starter kits at centres for people experiencing homelessness may overcome this problem. In our earlier smaller study, we found that EC starter kits were well received by participants, staff at homeless centres were able to support the study, and we could collect data needed for a full trial. A larger study is now needed to explore whether supplying EC to smokers at homeless centres can help with quitting and whether it offers value for money. This will be the first study in the world to look at this.

Who can participate?
Persons who are current smokes, aged 18 years or above, and currently accessing homeless centre services and actively engaging with the service.

What does the study involve?
Once people have agreed to take part, we will ask them to complete questionnaires asking about their smoking and health. They will also breathe into a breathalyser which measures carbon monoxide (CO), a harmful chemical produced by smoking. This will tell us whether the person has recently smoked. Those in the EC group will be given a starter kit, 4 weeks supply of e- liquids and support to use it. Those in the UC group will be given information and advice about stopping smoking and signposted to the local Stop Smoking Service (SSS). We will see everyone again at 4, 12 and 24 weeks to ask them about their quit attempts, current smoking, EC use, health and CO level.

What are the possible benefits and risks of participating?
There are limited harms from taking part in the study, although some people may not like using an EC or find nicotine medications unpleasant.

Where is the study run from?
London South Bank University (UK)

Our study will take place in 32 centres across six areas in Great Britain: Scotland; Wales; London; South-East England; South-West England and East England.

When is the study starting and how long is it expected to run for?
April 2021 to January 2025

Who is funding the study?
National Institute of Health Research (UK)

Who is the main contact?
Dr Sharon Cox, s.cox@ucl.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR132158, CPMS 50707

Study information

Scientific Title
Effects of e-cigarettes vs usual care for smoking cessation when offered at homeless centres: A multi centre cluster randomised controlled trial

Acronym
SCeTCH

Study objectives
Current study hypothesis as of 11/07/2023:
To compare E-cigarettes versus usual care on biochemically validated 6-month continuous smoking cessation abstinence (as defined by the Russel Standard), and cost-effectiveness.

Previous study hypothesis:
To compare E-cigarettes versus usual care on 6-month continuous smoking cessation abstinence (as defined by the Russel Standard) and cost-effectiveness.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 17/08/2021, London South Bank University Research Ethics Committee (103 Borough Road, London, SE1 0AA, United Kingdom; +44 (0)20 7815 7815; ethics@lsbu.ac.uk), ref: ETH2021-0176

Minor ethical amendment approved 10/02/2023, ref: ETH2223-0142
Minor ethical amendment approved 28/02/2022, ref: ETH2122-0130
Minor ethical amendment approved 19/02/2024, ref: ETH2324-0132*

Study design
Multi-centre two-arm cluster randomized controlled trial for 36-months with embedded process evaluation and economic evaluation

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Smoking cessation for tobacco dependence

Interventions
Current intervention as of 27/07/2022:
Cluster rather than individual randomisation will be used. Hence the clusters/unit of randomisation in the study are the homeless centres. Centres will be allocated either to an e-cigarette (EC) or control (usual care [UC]) arm using permuted block randomisation to ensure balance.

Planned intervention
Delivery of the EC intervention will be as per our feasibility study (Dawkins et al., 2021; Cox et al., 2021). Centre staff will provide EC arm participants with a tank-style refillable EC starter kit (e.g. the PockeX as used in our feasibility study or similar model determined via our PPI work), a choice of nicotine strength e-liquids (12mg/mL & 18mg/mL) and flavours (tobacco, menthol or fruit) and an EC fact-sheet (developed for, and used in, our feasibility study). E-liquids (five 10mL bottles per week) will be supplied for four weeks at weekly intervals by centre staff. Participants will be given time to try different flavours and nicotine strengths at baseline and be permitted to switch between flavours in accordance with documented vaping practices. EC charging will be available at homeless centres. Although signposting and the provision of local SSS details do not form part of the EC intervention (as below), if participants make enquiries regarding their local SSS they can be signposted in the usual way as per homeless centre protocol.

Control/comparator group
In line with the current level of provision for smoking cessation in homeless centres, our control arm will be usual care (UC). This will include very brief advice (VBA) to quit (in the form of an 'NHS choices' leaflet adapted for this population as used in our feasibility study) and signposting to the local SSS, including information about the location and opening hours of the service. Any centres with an established EC 'in house' provision or EC funding stream will be excluded (although this is uncommon). However, support or provision of EC from local SSS will be permitted as this constitutes part of UC. SSS vary widely in terms of services they offer; although all SSS offer NRT and behavioural support, only 11% of local authority funded SSS in England offer EC, whereas others who consider themselves 'e-cigarette friendly' offer support and advice around EC use.

All participants (intervention and control) will be offered a £15 Love2Shop gift card (which cannot be used for tobacco or alcohol purchases) for each follow up appointment attended.

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Previous intervention:
Cluster rather than individual randomisation will be used. Hence the clusters/unit of randomisation in the study are the homeless centres. Centres will be allocated either to an e-cigarette (EC) or control (usual care [UC]) arm. Allocation will be stratified by region (n=5; Scotland, Wales, London, East England, and South East England) using stratified permuted blocks to ensure balance.

Planned intervention
Delivery of the EC intervention will be as per our feasibility study (Dawkins et al., 2021; Cox et al., 2021). Centre staff will provide EC arm participants with a tank-style refillable EC starter kit (e.g. the PockeX as used in our feasibility study or similar model determined via our PPI work), a choice of nicotine strength e-liquids (12mg/mL & 18mg/mL) and flavours (tobacco, menthol or fruit) and an EC fact-sheet (developed for, and used in, our feasibility study). E-liquids (five 10mL bottles per week) will be supplied for four weeks at weekly intervals by centre staff. Participants will be given time to try different flavours and nicotine strengths at baseline and be permitted to switch between flavours in accordance with documented vaping practices. EC charging will be available at homeless centres. Although signposting and the provision of local SSS details do not form part of the EC intervention (as below), if participants make enquiries regarding their local SSS they can be signposted in the usual way as per homeless centre protocol.

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All participants (intervention and control) will be offered a £15 Love2Shop gift card (which cannot be used for tobacco or alcohol purchases) for each follow up appointment attended.

Intervention Type
Mixed

Primary outcome measure
Current primary outcome measure as of 27/07/2022:
Sustained CO validated smoking cessation at 24 weeks using the Russell Standard for cessation trials and intention to treat analysis (i.e. no more than 5 cigarettes since 2 weeks from baseline, validated by expired CO <8ppm. Participants lost to follow-up are treated as non-abstainers).

Previous primary outcome measure:
Sustained CO validated smoking cessation at 24 weeks using the Russell Standard for cessation trials and intention to treat analysis (i.e. no more than 5 cigarettes since 2 weeks post target quit date [TQD] validated by expired CO <8ppm. Participants lost to follow-up are treated as non-abstainers)

Secondary outcome measures
Current secondary outcome measure as of 27/07/2022:
1. Smoking reduction at 24 weeks measured by subtracting the number of cigarettes smoked per day at follow up from the number of cigarettes smoked per day at baseline
2. 7-day point prevalence quit rates at 4, 12 and 24 weeks measured using self reported cigarettes smoked in the last 7-days at follow-up and validated by expired CO <8ppm.
3. Changes in the frequency of risky smoking practices (e.g. sharing cigarettes, smoking discarded cigarettes) from baseline to 4, 12 and 24 weeks measured using self report engagement in these behaviours
4. Cost-effectiveness of the intervention measured using a service use questionnaire and the EQ-5D-5L (service use questionnaire includes NHS and PSS costs, patients' out of pocket expenditure on cessation aids, travel costs when accessing NHS/PSS health care and lost productivity from work for those working) at baseline and each follow up time point (4, 12, 24 weeks)
5. Fidelity of intervention implementation measured using ethnographic observations and a checklist confirming implementation at weeks 3-4
6. Mechanisms of change measured quantitatively via questions (e.g. attitudes and perceptions of e-cigs) inserted into follow-up assessments (via questionnaires) and qualitatively via semi-structure interviews with staff between weeks 4-8 and with participants between weeks 12-24
7. Contextual influences and sustainability measured using semi-structured telephone interviews with staff in the e-cigarette arm between weeks 4-8

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1. Smoking reduction at 24 weeks measured by subtracting the number of cigarettes smoked per day at follow up from the number of cigarettes smoked per day at baseline
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7. Contextual influences and sustainability measured using semi-structured telephone interviews with staff in the e-cigarette arm between weeks 4-8

Overall study start date
23/04/2021

Completion date
31/01/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/07/2023:
1. Persons aged 18 years or older
2. Self-reported daily smoking (confirmed by homeless centre staff and then biochemically verified by exhaled CO at recruitment)
3. Currently accessing homeless centre services and actively engaging with the service (determined by homeless centre staff)
4. Willing and able to provide written consent (a translator can be provided)

Previous inclusion criteria:
1. Persons aged 18 years or older
2. Self-reported daily smoking (confirmed by homeless centre staff and then biochemically verified by exhaled CO at recruitment)
3. Currently accessing homeless centre services and actively engaging with the service (determined by homeless centre staff)

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
480 participants and 32 clusters, 15 people per cluster

Total final enrolment

477

Key exclusion criteria
Current exclusion criteria as of 27/07/2022:
1. Never or former smoker
2. Those currently using a smoking cessation aid
3. Unable to provide written consent at the present time (e.g. due to current intoxication or distress)
4. Not known to centre staff
5. Allergic to any of the e-liquid ingredients (EC arm only)

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Previous exclusion criteria
1. Never and ex-smokers
2. Those currently using another smoking cessation aid
3. Pregnant (although this will be reviewed in light of ongoing evidence)
4. Unable to provide written consent at the present time (e.g. due to current intoxication or distress)

Date of first enrolment
01/02/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
Not to be disclosed
United Kingdom
n/a

Sponsor information

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Sponsor type
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ROR
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Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Our project protocol will be published open access and we will publish at least two papers (one for quantitative findings, one from the process evaluation) in open-access high-quality peer-reviewed journals. We will also attend and present to at least one international conference.

Furthermore, we will disseminate our work via the UK E-cigarette Research Forum (UKECRF) established by Cancer Research UK and PHE. The UKECRF is held three times per year and has closely followed our trajectory of work in this area and we will be able to feed the findings of

this study back to this group via a presentation. The UKECRF is a mixed-method stakeholder engagement meeting including stop smoking practitioners, health care consultants, academics, and policymakers. The majority of the applicants named here have a history of presenting at these meetings. We will disseminate the findings in lay summaries and also through a series of planned impact events which will be free to access and attend - these will planned with our PPI group.

Added 11/07/2023:
The project protocol has been published in an open-access journal: https://pubmed.ncbi.nlm.nih.gov/35194862/

Intention to publish date
01/08/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (London South Bank repository)

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			12/10/2021	No	Yes
Protocol (other)			19/01/2023	No	No
Protocol article		07/03/2022	19/01/2023	Yes	No