ISRCTN14140672 https://doi.org/10.1186/ISRCTN14140672

# Exploring the use and uptake of e-cigarettes for homeless smokers

**Submission date**
25/09/2018

**Recruitment status**
No longer recruiting

**Registration date**
07/11/2018

**Overall study status**
Completed

**Last Edited**
07/01/2022

**Condition category**
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**

Background and study aims

Smoking rates in the UK are now the second lowest in Europe (after Sweden), but homeless smokers are still 4 times more likely to smoke. They are also less likely to try to stop smoking and if they do, are less likely to succeed. E-cigarettes are now the most popular method of quitting, with some studies suggesting they may help people to stop smoking. For those on low incomes, however, the price for a starter kit may put people off. Supplying free e-cigarette starter kits at centres that homeless smokers already go to may help smokers to reduce the number of cigarettes they smoke, and eventually stop. This study will explore whether supplying free e-cigarette starter kits to smokers accessing homeless centres is a good idea and look at the best ways to do this. If enough people sign up for the study, continue to use the e-cigarette and cut down their smoking or quit completely, we can be confident that it would be worthwhile running a larger study to explore whether e-cigarettes help homeless smokers to stop smoking. We will share our findings with the smokers who took part and the homeless centres we work with, as well as making our findings available online and via social media and press releases.The main goal of the study is to make a decision as to whether to proceed to a larger trial and how best to run this trial. If we do run a full trial we will assess whether providing free e-cigarette starter kits to homeless smokers is a good way of helping smokers to quit.

Who can participate?

Adults who are daily smokers (confirmed by homeless centre staff and then exhaled CO at recruitment), are currently accessing homeless centre services, and are actively engaging with the service.

What does the study involve?

Our study will take place in four homeless centres across the UK: two in the e-cigarette group and two in a control group ('usual care' advice to quit and signposting to the stop smoking service). At the start of the study, 120 smokers (30 at each centre) will complete questionnaires about their current smoking and their health and will breathe into a breathalyser which measures carbon monoxide (CO) – a harmful toxicant caused by smoking. Those in the e-cigarette group will be given a starter kit and 4 weeks supply of e-liquid and support to use it. We will see everyone in the study again at 4, 12 and 24 weeks to ask them about their quit attempts, current smoking, e-cigarette use, health and CO level. Those in the control group will

be given information about quitting smoking and how to access their local stop smoking service and will be seen at the same time points but will not receive the free e-cigarette. We will interview 24 participants (12 in each group) including some who completed andsome who did not complete the study, and 12 service centre staff (6 in each group) between weeks 4 and 8.We will use the information from this study to decide whether a larger trial is possible and worthwhile. To do this we will measure: willingness of smokers to take part; whether they complete study measures; if they are still using e-cigarettes at each follow up time point; how many quit smoking or reduce the number of cigarettes they smoke; and the cost of providing free e-cigarettes to smokers. We will gather information to see how smokers and staff at homeless centres engage with the study and will interview some smokers who complete and some who drop out as well as staff to explore their views on using, and supporting the use of, e-cigarettes.

What are the possible benefits and risks of participating?
Stopping smoking is one of the best things one can do to improve their health. Homeless centres may consider adopting this approach to reduce inequalities and the impact of diseases caused by smoking in this vulnerable group.
There are no known risks to participants taking part in this study.

Where is the study run from?
4 independent homeless centres - one in Northampton, one in Edinburgh and two in London.

When is the study starting and how is it expected to run for?
October 2018 to March 2020

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

Who is the main contact?
Dr Sharon Cox
coxs15@lsbu.ac.uk

### Study website
https://www.journalslibrary.nihr.ac.uk/programmes/phr/174429/#/

## Contact information

### Type(s)
Scientific


### Contact name
Dr Sharon Cox

### ORCID ID
http://orcid.org/0000-0001-8494-5105

### Contact details
Centre for Addictive Behaviours Research
London South Bank University
103 Borough Road
London

United Kingdom
SE1 0AA
0207 815 5467
coxs15@lsbu.ac.uk

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
PHR Project:17/44/29

# Study information

### Scientific Title
Exploring the uptake and use of electronic cigarettes provided to smokers accessing homeless centres: a feasibility study

### Study objectives
The aim of this study is to undertake a feasibility cluster randomised controlled trial to evaluate the effectiveness of supplying free e-cigarette (EC) starter kits for smoking cessation to smokers accessing homeless centres.
This study aims to address the following questions:
1. What percentage of smokers accessing homeless centres consent to participate?
2. What percentage of smokers attend follow up appointments and continue to use EC during and after the free supply period?
3. What factors promote continued engagement with the study and what are the facilitators and barriers to EC use?
4. Do service centre staff support the study and what level and type of information and training do they require?
5. What percentage of smokers in the two study arms stop smoking or reduce their tobacco consumption by at least 50% at 4, 12 and 24 weeks?
6. How feasible is it to collect data on contacts with health care services within this population as an input to an economic evaluation in a full randomised controlled trial?
7. How much does it cost to provide free EC on a per person basis?
The following objectives will allow us to answer the research questions above:
1. Assess willingness of smokers to participate in the feasibility study to estimate recruitment rate and inform recruitment strategies for a future trial
2. Assess participant retention in the intervention and control groups and the percentage that are still using EC at each follow up time point
3. Examine the perceived value of the intervention and facilitators and barriers to engagement via qualitative interviews with participants
4. Assess service providers' capacity to support the study and the type of information and training required
5. Assess preliminary evidence of the potential effectiveness 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 randomised controlled trial
7. Estimate the cost of providing free e-cigarettes on a per person basis

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
London South Bank University, 05/08/2018, reference: 1821

## Study design
Interventional prospective cohort four-centre feasibility cluster randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Cluster randomised trial

## Study setting(s)
Other

## Study type(s)
Other

## Participant information sheet
Not available in web format, please use contact details to request participant information sheet

## Health condition(s) or problem(s) studied
Tobacco cessation amongst homeless adults residing in four locations across Great Britain

## Interventions
This is a four-centre feasibility cluster randomised controlled trial. Two of the homeless centres are accommodation units (St Mungo's) and two are not (Hope Centre and Nidry Street, Salvation Army). Thus we will pair and match the centres on accommodation provision with one of the St Mungo's centres being paired with The Hope Centre and one with the Salvation Army. The St Mungo's centres will be randomised to EC, the other to the control (usual care (UC)) arm, with the accompanying pair allocated to the other arm. Allocation will be determined via coin toss. Participants in the EC arm will be provided with a starter kit comprising a tank-style refillable EC with a choice of nicotine strength e-liquid (2 options) and flavours (4 options). They will receive an explanation of how to use the product and a 'guide to e-cigarettes' fact-sheet. E-liquids will be supplied for four weeks at weekly intervals by centre staff. Evidence suggests that smokers successfully transition to vaping with higher nicotine e-liquids, thus we have opted for the 2 higher strength e-liquids (12 and 18 mg/mL). Evidence also suggests that smokers have different preferences regarding flavours, so a choice of flavours will be offered (e.g. tobacco, menthol, fruit & bakery). 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. Homeless centre staff will provide participants with five 10ml bottles of e-liquids per week (approx. 7mL a day) in accordance with the upper level reported in the recent UK national survey.
Those in the control group (usual care) will be recruited in the same way as intervention group (EC) participants and will receive the same study information sheet and consent form. After

seeing the researcher to provide baseline information and being informed they are in the UC group, participants will be referred to the keyworker to receive brief advice to quit, and a 'help-quit' leaflet including information about the location and opening hours of the local stop smoking service (SSS). Paper copies of the help-quit leaflet (with SSS contact details) will be available as posters/flyers at homeless centres.
Control participants will be seen at baseline and followed up at the same time points (4, 12 and 24 weeks) using the same measures as the intervention group. We will monitor uptake /recruitment rate to the control group and the percentage available for follow up. All participants (intervention and control) will be offered a £15 voucher for each follow up and a further £15 voucher for interviews.

### Intervention Type
Other

### Primary outcome measure
1. Uptake to the study, measured by the number of participants consenting at the baseline
2. Retention, measured at each follow-up timepoint (4, 12 and 24 weeks) by:
2.1. The number of participants still using the e-cigarette in the intervention group
2.2. The number of participants in each arm completing assessment measures
3. Service providers' capacity to support the study assessed using qualitative interviews at 12 weeks post-recruitment
4. CO-validated quit rates, assessed by CO breath levels after 1, 3 and 6 months
5. Number of cigarettes smoked, measured by the self-reported number of cigarettes per day at each follow-up time point
6. Utilisation of primary and secondary health care services via self-report questionnaire at each time point (baseline, and 4, 12 and 24 weeks)
7. Resources used in the delivery of the intervention 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.This will be assessed at all time points (baseline, and 4, 12 and 24 weeks)

### Secondary outcome measures
N/A

### Overall study start date
01/10/2018

### Completion date
31/03/2020

## Eligibility

### Key inclusion criteria
1. Aged 18 and over
2. Self-reported daily smoking (confirmed by homeless centre staff and 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**
120

**Total final enrolment**
80

**Key exclusion criteria**
1. Currently using another smoking cessation aid
2. Pregnant
3. Unable to consent
4. Not known to centre staff

**Date of first enrolment**
01/01/2019

**Date of final enrolment**
30/05/2019

# Locations

**Countries of recruitment**
England

Scotland

United Kingdom

**Study participating centre**
**London South Bank University**
103 Borough Road
London
United Kingdom
SE1 0AA

**Study participating centre**
**University of Stirling**
Stirling

United Kingdom
FK9 4LA

## Sponsor information

**Organisation**
London South Bank University

**Sponsor details**
103 Borough Road
London
England
United Kingdom
SE1 0AA

**Sponsor type**
University/education

**Website**
www.lsbu.ac.uk

**ROR**
https://ror.org/02vwnat91

## Funder(s)

**Funder type**
Government

**Funder Name**
Public Health Research Programme

**Alternative Name(s)**
NIHR Public Health Research Programme, PHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

## Publication and dissemination plan
We plan to disseminate our findings via international conferences, with key stakeholders and policy makers and researchers. We will also feed our results back to the service centres involved. Our results will also be available via the funders (NIHR) website.

## Intention to publish date
30/12/2020

## Individual participant data (IPD) sharing plan
The data will be preserved and available for sharing for at least 5 years following the acceptance for publication of the main findings of the study. The data collected are intended to benefit the general public; we will therefore preserve all data resulting from the study (with the exception of personal data) and make it publically available with as few restrictions as possible. Once the data has been finalized, it will be deposited in LSBU's open repository: http://researchopen.lsbu.ac.uk/
It will be given an 18 month embargo period, during which access will be restricted. Upon acceptance of the main finding of the study in an open access journal, the embargo will be lifted and the data will be freely open to all. The dataset will comprise anonymised data from all participants across baseline and each follow up time point and will be archived in SPSS, excel and CSV formats. This should maximize the data's accessibly and ease of use. The data will be given a CC-BY license, which will require any future user to acknowledge the investigators in any subsequent publications arising from use of the data. We will ensure that our participants provide consent to share their anonymised data and we will screen and clean the data to ensure there are no direct identifiers to participants.

## IPD sharing plan summary
Stored in repository

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 01/05/2021 | 07/01/2022 | Yes | No |