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A trial to assess the benefit of offering an e-cigarette starter kit to smokers attempting to stop smoking with varenicline

Submission date
30/07/2018

Recruitment status
Stopped

Registration date
23/08/2018

Overall study status
Stopped

Last Edited
08/07/2022

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Varenicline is a medication used to help people quit smoking, as it helps to prevent nicotine addiction. E-cigarettes are electronic cigarettes, which are often used as an alternative to cigarettes to help people stop smoking. In English stop smoking services (SSS), the use of e-cigarettes along with varenicline has been associated with higher smoking abstinence rates than just using varenicline alone.
This study aims to look at the benefit of offering an e-cigarette starter kit to smokers attempting to quit smoking with varenicline, using carbon monoxide-verified abstinence 9-12 weeks after the quit date.

Who can participate?
Adult smokers interested in stopping smoking who attend SSS in London and opt for treatment with Varenicline and specialised one to one stop smoking support

What does the study involve?
Participants will be randomly allocated to either the intervention group or the control group. Participants in both groups will receive the usual care, which involves varenicline and behavioural support.
Participants in the intervention group will receive, in addition to usual care, a free e-cigarette starter kit. Those in the control group will receive the usual care only.
Over the 12 week period, participants in both groups will be asked to self-report their smoking abstinence and undergo carbon monoxide breath tests to validate this.

What are the possible benefits and risks of participating?
The possible benefit to participants is that taking part in this study may improve their chances of quitting smoking. The possible risk to participants taking part in this study is that e-cigarette use can lead to mouth and throat irritation, nausea and sleep disturbance.

Where is the study run?:
London local authority stop smoking services

When is the study starting and how long is it expected to run for?
July 2017 to July 2023

Who is funding the study?:
1. Global Research Awards for Nicotine Dependence (GRAND, supported by Pfizer) (USA)
2. Cancer Research UK (UK)

Who is the main contact?
Dr Lion Shahab, Senior Lecturer (Department of Behavioural Science and Health)
lion.shahab@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Lion Shahab

ORCID ID
http://orcid.org/0000-0003-4033-442X

Contact details
1-19 Torrington Place
University College London
London
United Kingdom
WC1E 7BH
+442076791895
lion.shahab@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR-2018-180

Study information

Scientific Title
E-cigarettes to Augment Stop Smoking In-person Support and Treatment with varenicline (E-ASSIST): a randomised controlled trial

Acronym

E-ASSIST

Study objectives
Even with the most effective current pharmacotherapy, varenicline, the majority of quit attempts will fail. Observational data from the English stop smoking services (SSS) suggest adding e-cigarettes to varenicline and behavioural support could improve quit success rates in clinical practice. However, there is no randomised trial evidence. This study will assess the efficacy for smoking cessation of offering an e-cigarette starter kit compared with usual care for smokers attempting to stop smoking with varenicline and behavioural support.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University College London Research Ethics Committee, 22/06/2018, 8323/003

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Tobacco smoking cessation

Interventions
Current interventions as of 24/01/2019:
Participants will be computer-randomised in a 1:1 ratio into either the intervention of the control group. This study will be limited to Stop Smoking Services (SSS) within London Local Authorities (LAs) and Cambridgeshire County Council that provide a standard 12 week treatment; therefore, participants will be block-randomised in LAs to ensure an equal distribution of control and intervention participants across services.
Participants in the intervention group will receive the usual care of behavioural support and varenicline, along with an e-cigarette starter kit (compliant with EU regulation) and an information leaflet about e-cigarettes at the end of their pre-quit visit. The starter kit will contain a third generation e-cigarette and e-liquid (choice of nicotine concentration of 6 mg/ml, 12 mg/ml or 18 mg/ml) in tobacco flavour; a lower nicotine concentration will be offered if the initial concentration is perceived to be aversive) which will last for four weeks. Participants will

be given brief in-person advice about how to use e-cigarettes, asked to try the e-cigarette during the session and encouraged to start using e-cigarettes from their target quit-date onwards and to seek out local vape shops to obtain further e-liquid, suited to their individual needs and flavour preference. After this pre-quit visit, participants will receive the same treatment as per standard SSS practice.
Participants in the control group will receive usual care alone (behavioural support and varenicline).
After the pre-quit treatment episode, participants in both conditions will receive the same treatment as per standard SSS practice and use of e-cigarettes (as well as varenicline) will be recorded at subsequent visits until the final follow-up, twelve weeks after the target quit date.
It is anticipated that the study will take 30 months to allow for sufficient time to gain ethical approval and develop intervention material (4 months), to recruit and follow-up participants (24 months) and to transfer data from SSS to the study team (2 months).

Previous interventions:
Participants will be computer-randomised in a 1:1 ratio into either the intervention of the control group. This study will be limited to Stop Smoking Services (SSS) within London Local Authorities (LAs) that provide a standard 12 week treatment; therefore, participants will be block-randomised in LAs to ensure an equal distribution of control and intervention participants across services.
Participants in the intervention group will receive the usual care of behavioural support and varenicline, along with an e-cigarette starter kit (compliant with EU regulation) and an information leaflet about e-cigarettes at the end of their pre-quit visit. The starter kit will contain a third generation e-cigarette and e-liquid (nicotine concentration 18 mg/ml in tobacco flavour; a lower nicotine concentration will be offered if the initial concentration is perceived to be aversive) which will last for four weeks. Participants will be given brief in-person advice about how to use e-cigarettes, asked to try the e-cigarette during the session and encouraged to start using e-cigarettes from their target quit-date onwards and to seek out local vape shops to obtain further e-liquid, suited to their individual needs and flavour preference. After this pre-quit visit, participants will receive the same treatment as per standard SSS practice.
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Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Smoking abstinence, self-reported between weeks 9-12 from the target quit date and validated by an expired air CO concentration of below 10 ppm at week 12

Secondary outcome measures

Current secondary outcomes as of 24/01/2019:
1. CO-validated smoking abstinence between weeks 2-4 from the target quit date, validated using an expired air CO concentration of below 10 ppm
2. Smoking reduction by at least 50% at week 4, assessed by self-reported reduction in cigarettes per day and at least 50% reduction in CO levels from the baseline
3. Retention in SSS, defined as the proportion of attendees who set a target quit date who respond at the 12 week post-quit follow up
4. Adherence to varenicline treatment, defined as the proportion of attendees who set a target quit date who continue using varenicline until the 12 week post-quit follow up
5. The proportion of services approached who agree to deliver the intervention and the proportion of clients within services who agree to take part in the study will be recorded to determine feasibility of intervention implementation
6. For participants that have been in the trial for 6 months, CO –validated smoking abstinence at 6 months following the target quit-date will be measured

Previous secondary outcomes:
1. CO-validated smoking abstinence between weeks 2-4 from the target quit date, validated using an expired air CO concentration of below 10 ppm
2. Smoking reduction by at least 50% at week 4, assessed by self-reported reduction in cigarettes per day and at least 50% reduction in CO levels from the baseline
3. Retention in SSS, defined as the proportion of attendees who set a target quit date who respond at the 12 week post-quit follow up
4. Adherence to varenicline treatment, defined as the proportion of attendees who set a target quit date who continue using varenicline until the 12 week post-quit follow up
5. The proportion of services approached who agree to deliver the intervention and the proportion of clients within services who agree to take part in the study will be recorded to determine feasibility of intervention implementation

Overall study start date
01/07/2017

Completion date
01/07/2023

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Smoker
3. Attending SSS one-to-one specialist support in London LAs
4. Proficient in English
5. Firm target quit date
6. Elect to use varenicline to support quit attempt
7. Willing to try e-cigarettes

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1266

Total final enrolment
92

Key exclusion criteria
1. Pregnant
2. Breastfeeding

Date of first enrolment
01/08/2018

Date of final enrolment
21/12/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Waltham Forest Stop Smoking Service
Waltham Forest Town Hall, Forest Rd
London
United Kingdom
E17 4JF

Study participating centre
Cambridgeshire County Council, CAMQUIT Stop Smoking Service
Scott House
5 George Street
Huntingdon
United Kingdom
PE29 3AD

Study participating centre
London Borough of Croydon Stop Smoking Service
Bernard Weatherill House
8 Mint Walk
Croydon
London
United Kingdom
CR0 1EA

Study participating centre
London Borough of Lewisham Stop Smoking Service
University Hospital Lewisham
Lewisham High St
London
United Kingdom
SE13 6LH

Study participating centre
London Borough of Bexley Stop Smoking Service
2 Watling St
Bexleyheath
London
United Kingdom
DA6 7AT

Study participating centre
London Borough of Enfield Stop Smoking Service
Silver St
London
United Kingdom
EN1 3XA

Sponsor information

Organisation
University College London

Sponsor details

Gower St, Bloomsbury
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

Website
http://www.ucl.ac.uk/iehc/research/behavioural-science-health

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Not defined

Funder Name
Global Research Award for Nicotine Dependence (Supported by Pfizer)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/11/2023

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	Protocol (not peer reviewed)	05/06/2019	03/09/2020	No	No
Results article		23/06/2022	08/07/2022	Yes	No