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E-cigarette support for smoking cessation: Identifying the effectiveness of intervention components in an online randomised optimisation experiment

Submission date
17/10/2022

Recruitment status
No longer recruiting

Registration date
21/10/2022

Overall study status
Completed

Last Edited
21/09/2023

Condition category
Other

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

Plain English summary of protocol

Background and Study aims
Although smoking in the UK is decreasing it remains one of the most avoidable causes of death and disease (96,000 deaths per year). E-cigarettes (EC) could help reduce the number of smokers and they are the most popular method for quitting smoking. However, about half of smokers who try EC (also known as 'vaping') don't continue to use them because they are not satisfying enough. Vapers often say that finding the right device, nicotine strength and flavour are essential for stopping smoking and many vape shops offer some support to help smokers stop smoking by switching to vaping. Not all smokers want to buy an EC from a vape shop though and sometimes the type of advice can be confusing or overwhelming. Online stores offer even less help for smokers trying to switch. This study will test different ways of supporting people who buy an EC online to completely switch to vaping and stop smoking. These different ways of supporting people will be compared to what smokers usually do - i.e. make their own choice about what to buy with no support or advice.

Our previous work has helped us to identify promising approaches that might help smokers to switch to vaping. These could all be easily used online so that they could help more smokers. These are individual (tailored) advice on the choice of device, nicotine strength and flavour. We would also look at the effect of brief information about the reduced harm of vaping compared to smoking. The technical and behavioural support for stopping smoking would be sent by mobile phone text messages. Using a method known as the multiphase optimisation strategy which allows us to test the effects of a large number of treatments separately, we will test whether these treatments work, which works best and if some of them work better when combined with others.

Who can participate?
Adult smokers interested in stopping smoking

What does the study involve?
The study will be advertised on social media. Participants will follow a link to the study website and will answer a set of initial questions about themselves and their smoking. If eligible to take part, participants will see an information sheet detailing what will be involved and will be asked to complete a consent form. This includes agreeing to be contacted again by the researchers in 3 months' time. They will then be presented with questions asking about themselves, their smoking habits, dependence and motivation to quit and, past and present experiences of using an EC. After answering these questions, they may or may not receive advice about one or more particular product(s) to buy and/or receive information about ECs and/or text message support. The advice given will be 'tailored' depending on how people answer the questions and will be sent via email and presented on the study webpage. A voucher code and link to an online EC shop will then be sent by email where people can use the voucher (to the value of £50) to purchase a free EC starter kit.

Participants will provide an e-mail address and mobile telephone number so that text messages can be received to help them use their EC to quit smoking. The telephone number will also be used to prompt participants to complete some more questions about their smoking and EC use after 3-months, at which point, they will be provided with a £10 Amazon voucher.

What are the possible benefits and risks of participants?
Participants will receive a voucher of £50 that covers the costs of one EC (with a charger), an atomiser compatible with their EC and approximately 1 to 2 weeks of e-liquid supply. After this, participants will need to purchase their own e-liquid. They will also be emailed a code for a £10 Amazon voucher for completing the 3-month follow-up survey. As a smoker, participants may benefit further by quitting smoking using an EC. They may also be provided with brief information on smoking and the use of ECs to help them quit including links to the NHS website which contains quit-smoking advice and information on ECs. As this is an online study, participants will not incur any travel or other financial costs. The time it takes to complete the study may differ between participants, but we expect it to take around 20-30 minutes to complete the online questions and 10 minutes to complete the online questions after 3 months. This study was an online study and the only possible risk was the time commitment to completing the study.

Where is the study run from?
Centre for Addictive Behaviours Research at London South Bank University in collaboration with researchers from the University of East Anglia (UEA) and the University of College London (UCL) (UK)

When is the study starting and how long is it expected to run for?
October 2019 November 2020

Who is funding the study?
Medical Research Council (MRC) (UK)

Who is the main contact?
Dr Catherine Kimber (Research Fellow), kimberc3@lsbu.ac.uk (UK)
Prof Lynne Dawkins (Principle Investigator), dawkinl3@lsbu.ac.uk (UK)

Contact information

Type(s)

Public

Contact name
Dr Catherine Kimber

ORCID ID
https://orcid.org/0000-0001-9994-8640

Contact details
London South Bank University
103 Borough road
London
United Kingdom
SE1 0AA
+44 (0) 207 815 5463
kimberc3@lsbu.ac.uk

Type(s)
Principal investigator

Contact name
Prof Lynne Dawkins

ORCID ID
https://orcid.org/0000-0003-1236-009X

Contact details
London South Bank University
Division of Psychology
London
United Kingdom
SE1 0AA
+44 (0)20 7815 5422
dawkinl3@lsbu.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

An online randomised experiment to identify effective tailored interventions on flavours, device, nicotine strength, and text message support and brief information to assist smokers to stop smoking using e-cigarettes (TASSE)

Acronym
TASSE

Study objectives
There is increasing evidence that e-cigarettes (EC) are an effective smoking cessation aid when combined with behavioural support. There is further evidence for digital tailored interventions as cost-effective approaches that can increase smoking cessation rates. Experimental work also suggests the addition of a 'nicotine fact sheet' can improve smokers' risk perceptions related to EC. However, multifaceted approaches to delivering 'tailored advice' for smoking cessation combining various key evidenced-based components are lacking. The aim of this study is to use a Multiphase Optimisation Strategy (MOST) to determine which of five, or a combination thereof, EC-orientated intervention components is associated with self-reported cessation over the previous 4-weeks at 12-week follow-up.

The five intervention components will be:
1. Tailored advice on EC device
2. Tailored advice on e-liquid nicotine strength
3. Tailored advice on e-liquid flavour
4. E-cigarette written information
5. Text message support

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/01/2020, London South Bank University Ethics Panel (103 Borough road, London, SE1 0AA, UK; +44 (0) 207 815 5422; sasethics@lsbu.ac.uk), ref: ETH1920-0043

Study design
Randomized factorial-design study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
Conditions will be randomised in Qualtrics using the Randomizer function. Randomisation will occur after participants complete the baseline measures and provided their contact details. Thereafter, Qualtrics will randomly present 1 of the 32 conditions - each generated an equal number of times. Each recommendation will be displayed at the end of the baseline survey and, sent via email along with a direct link to the EC store and their unique voucher code to make

their online purchase.
The intervention components are:
1. 'Advice on device' will be tailored using three five-point Likert scale items with the options "strongly disagree to strongly agree" scoring from 1 to 5:
1.1. "The e-cigarette must be small"
1.2. "I prefer to be able to see lots of vapour, including when exhaling" (reverse-scoring 5 to 1)
1.3. "The technicalities of the e-cigarette put me off"
Participants scoring between 3 and 7 across the three items will be recommended to purchase a tank system e-cigarette device (Arc 5) which is typically associated with a greater volume of aerosol. Those scoring between 8 and 11 will be assigned a tank system pen-like device (Tornado EX2), and a refillable pod system (Skope-P) will be recommended for those who score 12 or more.

2. 'Advice on nicotine strength' will be determined from participants' answers to the question 'How soon after waking do you smoke your first cigarette?' an item making up both the Fagerström Test for Cigarette Dependence [FTCD] and Heaviness of Smoking Index [HIS]. Those who smoke within 30 minutes of waking will be recommended starting on 18mg/ml nicotine concentration, whilst those who smoke within 30-60 minutes and after 60 mins of waking will be recommended 14mg/ml and 10mg/ml, respectively.

3. 'Advice on flavour' will be tailored using the following: "Do you smoke more menthol cigarettes than regular tobacco cigarettes?". Those answering 'Yes' will be recommended menthol flavour, and those answering 'No' will be directed to a question using items that assess taste preferences (i.e. "In your attempt to quit smoking, do you want something that tastes like smoking or a complete change?" – with the options "Yes I want something that tastes like smoking" resulting in being assigned tobacco and "No I want a complete change" resulting in being recommended fruit flavour).

4. 'Text messages' (70 + 2 instructional) will be sent to those allocated to the text message condition using Simple Mail Transfer Protocol (SMTP) via PageOne Communications LTD, twice daily for the first two weeks, one a day for the following four weeks, then every other day for four weeks, finally one a week for 2 weeks. These cover both, technical advice and behavioural support related to e-cigarette use, as well as some generic smoking cessation texts taken from the iQuit in Practice message bank.

5. 'Brief information' on relative harms, in the form of a CRUK one-page infographic factsheet to allay safety concerns and misperceptions of harm, will be emailed to participants.

All participants who are randomised will be included in the primary analysis with the exception of those classified as protocol violations (i.e. who completed the baseline survey more than once). Participants lost to follow-up will be coded as smoking in line with this aspect of the Russell Standard of smoking (although we will not biochemically validate the self-report at this stage). Abstinence will be defined as self-reported no smoking (not a single puff) for the previous 4-weeks (regardless of current e-cigarette use).

Intervention Type
Behavioural

Primary outcome(s)
Complete abstinence over the last 4-weeks, measured using survey questions at the 12-week follow-up on an intention-to-treat basis

Key secondary outcome(s))
All secondary outcomes will be measured using survey questions at 12 weeks post-randomisation:
1. The proportion of participants who reported complete abstinence from smoking over the previous 7 days
2. The proportion of participants who reported 50% or greater smoking reduction in baseline cigarette consumption
3. Adherence to recommendations measured by asking participants at follow-up, whether they had purchased the device, the nicotine strength and the flavour that was recommended. Participants will be also asked if they had received the email with the information on relative harms, if they had read it and whether they had blocked the text messages (all answers: yes/no).

Completion date
19/11/2020

Eligibility

Key inclusion criteria
1. Aged 18 years old and over
2. Daily smoker
3. UK resident
4. Fluent in English
5. Interested in quitting smoking
6. Interested in using an EC
7. Currently have access to a mobile phone
8. Able to make an online purchase

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1214

Key exclusion criteria
1. Currently using an EC daily (exclusively or as a dual user)
2. Unable or unwilling to be contacted in 3 months' time
3. Any affiliation with the tobacco or EC industries

Date of first enrolment
01/04/2020

Date of final enrolment
19/10/2020

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Medical Research Council

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in the publicly available London South Bank University Repository (LSBU) Research Open (https://openresearch.lsbu.ac.uk/). Shared data will be a fully anonymised dataset with baseline data and 12-week follow-up data in SPSS format and accompanying syntax for the analyses reported and the full paper. Data will be available when the report is accepted for publication and the data will be available indefinitely, for Logistic Regression analysis using IBM SPSS. Consent was obtained and as part of the consent, participants agreed to the sharing of their data. There were no legal restrictions on the sharing of these data.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/07/2023	21/09/2023	Yes	No
Protocol article		09/06/2022	17/10/2022	Yes	No
Participant information sheet		12/12/2019	20/10/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes