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Do e-cigarettes help smokers quit when not accompanied by intensive behavioural support?

Submission date	Recruitment status	[X] Prospectively registered
04/08/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/08/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/02/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol
Current plain English summary as of 16/03/2021:

Background and study aims
The researchers recently completed a large trial which showed that e-cigarettes (EC) are more effective in helping smokers quit than nicotine replacement treatments, such as patches or chewing gum. EC and NRT were used within the specialist stop-smoking services and accompanied by weekly support sessions with smoking cessation advisors. Stop-smoking services are very important, especially for highly dependent smokers. However, attendance requires time and effort and under 5% of smokers attend such treatment. Less intensive treatments are likely to be less effective, but they can be expected to reach more smokers and thus help more people. The researchers propose to conduct the next trial that will show whether, and to what extent, EC can help smokers quit with less intensive support (either with telephone support or no support). The trial results will determine whether public health messages need to encourage all smokers interested in switching to EC to attend stop-smoking services, or whether those that cannot or do not wish to attend intensive programs can benefit from simpler options. Provided the interventions works, the researchers also want to see what would help NHS staff to refer smokers to this new way of helping smokers, and smokers to use it.

Who can participate?
Adult daily smokers who are motivated to stop smoking. They must own a mobile phone and have an email address and be willing to try either automated support messagesor an e-cigarette with or without telephone support. They should be happy to receive follow up calls and be able to read/write/understand English. People who are pregnant or currently using an e-cigarette cannot take part.

What does the study involve?
The researchers propose to test two approaches that provide EC starter packs: either with five weekly support telephone calls from an EC helpline; or just with initial one-off telephone advice. This will be compared with the NHS Smokefree programme that provides automated support for 28 days, with advice on coping with cravings, using medications and other aids, encouragement to attend local stop-smoking services, and motivational messages. This is currently the most economical approach in use.

A total of 1,170 smokers will be allocated, by chance, to one of these three study treatments and the researchers will record how many have stopped smoking 6 and 12 months later. Those who have quit smoking will attend for a breath test to confirm this. Participants who do not provide this information or do not pass the breath test will be counted as non-quitters.
The project will also include a qualitative sub-study. Doctors and nurses often do not know much about EC, and like everyone else, they see contradictory media stories. Many do not feel comfortable discussing EC but may welcome an option to refer smokers interested in EC to an approved EC helpline that can provide information, assess smokers, and hand out EC starter packs as appropriate, whether with or without further telephone support. The trial above will show whether the helpline would help smokers quit; the sub-study will identify barriers and facilitators to health professionals referring smokers to it and smokers using it. Doctors and nurses (as well as smokers who did and did not take part in the main study) will be interviewed, so that if the intervention is found effective, the researchers can identify the best ways of putting it into practice.

What are the possible benefits and risks of participating?
Participants can benefit from the study as they will receive support to stop smoking. The researchers do not foresee any risk of taking part in this study. EC are a consumer product regulated under the Tobacco Products Directive (TPD). The researchers will be providing a TPD-approved EC starter pack to participants but they will be able to purchase a different EC and/or e-liquid if the one provided does not work for them. There is little doubt they are much safer than normal cigarettes, and they have been shown to help people quit smoking.

Where is the study run from?
Participants will be recruited mainly from hospitals and GP practices across the UK by the Clinical Research Network. The study is being organised by Queen Mary University of London (QMUL). Researchers from QMUL will provide the study treatment and conduct follow-up calls.

When is the study starting and how long is it expected to run for?
September 2020 to January 2025

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

Who is the main contact?
Dr Katie Myers Smith
katie.smith@qmul.ac.uk

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Previous plain English summary:

Background and study aims
The researchers recently completed a large trial which showed that e-cigarettes (EC) are more effective in helping smokers quit than nicotine replacement treatments, such as patches or chewing gum. EC and NRT were used within the specialist stop-smoking services and accompanied by weekly support sessions with smoking cessation advisors. Stop-smoking services are very important, especially for highly dependent smokers. However, attendance requires time and effort and under 5% of smokers attend such treatment. Less intensive treatments are likely to be less effective, but they can be expected to reach more smokers and thus help more people. The researchers propose to conduct the next trial that will show whether, and to what extent, EC can help smokers quit with less intensive support (either with

telephone support or no support). The trial results will determine whether public health messages need to encourage all smokers interested in switching to EC to attend stop-smoking services, or whether those that cannot or do not wish to attend intensive programs can benefit from simpler options. Provided the interventions works, the researchers also want to see what would help NHS staff to refer smokers to this new way of helping smokers, and smokers to use it.

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What does the study involve?
The researchers propose to test two approaches that provide EC starter packs: either with five weekly support telephone calls from an EC helpline; or just with initial one-off telephone advice. This will be compared with the NHS Smokefree Quit Now online programme that provides e-mails and/or texts daily for 28 days with advice on coping with cravings, using medications and other aids, encouragement to attend local stop-smoking services, and motivational messages. This is currently the most economical approach in use.
A total of 1,170 smokers will be allocated, by chance, to one of these three study treatments and the researchers will record how many have stopped smoking 6 and 12 months later. Those who have quit smoking will attend for a breath test to confirm this. Participants who do not provide this information or do not pass the breath test will be counted as non-quitters.
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September 2020 to May 2024

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

Who is the main contact?
Dr Katie Myers Smith
katie.smith@qmul.ac.uk

Study website
https://www.qmul.ac.uk/wiph/centres/centre-for-public-health-and-policy/health-and-lifestyle-unit/research-projects/do-e-cigarettes-help-smokers-quit-when-not-accompanied-by-intensive-behavioural-support/

Contact information

Type(s)
Scientific

Contact name
Dr Katie Myers Smith

ORCID ID
http://orcid.org/0000-0003-1837-3924

Contact details
2 Stayner's Road
London
United Kingdom
E1 4AH
+44 (0)2078828230
katie.smith@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HTA - NIHR129627

Study information

Scientific Title
Do e-cigarettes help smokers quit when not accompanied by intensive behavioural support? A multi-center randomised controlled trial

Acronym
Vapeline

Study objectives
Modern refillable e-cigarettes combined with weekly face-to-face support sessions have been shown to be more effective in helping smokers quit than nicotine replacement treatments also combined with this behavioral support. In this study, the researchers want to answer whether e-cigarettes are effective without this intensive behavioural support. They hypothesise that less intensive treatments are likely to be less effective. However, if such treatments can be disseminated on a larger scale and reach more smokers, they can make important contributions to public health.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/12/2020, South West - Central Bristol Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 104 8029; centralbristol.rec@hra.nhs.uk), ref; 20/SW/0179

Study design
Multi-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled 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

Interventions
Current interventions as of 16/03/2021:

Participants will be randomised to one of three interventions (detailed below). Randomisation (1:1:1) in permuted blocks will be undertaken using a web-based application. There are no stratification factors. As there are three treatment groups, the study may use blocks of a minimum size of 9 and a maximum of 18. The trial statistician will produce the randomisation list, which will be embedded into an application that only reveals the next treatment assignment once a participant has been entered into the database.

1. Control: NHS Smokefree programme
This is an automated stop-smoking treatment package based on 28 days of supportive messages. It is a part of the NHS web-based Live Well programme to which HCPs would ideally refer all smokers. The website https://www.nhs.uk/live-well/quit-smoking/take-steps-now-to-stop-smoking provides information on health benefits of stopping smoking, advice and resources including local SSS, and an option to enroll in the Smokefree programme. The Smokefree programme sends automated motivational messages (e.g. emails) each day for 28 days with practical advice and motivational messages. Participants will be enrolled in the programme by the study team and will select a TQD on which the programme will start. They will be asked not to use EC for at least the first four weeks post-TQD but will be able to follow any other Live Well and automated message advice including accessing stop-smoking medications and attending local SSS, as these elements are a part of usual care. Participants can request to stop the messages at any time.

2. E-cigarette starter pack with no ongoing support (EC)
Participants will receive instructions on EC use over the phone. It will be explained to them that they will receive a starter pack of refillable EC by post and they will be asked to set up a target quit day (TQD) within a few days of the expected EC delivery. The package will contain the device, USB lead, 5 spare atomisers, two 10ml bottles of tobacco and a fruit flavoured e-liquid (18 mg/ml nicotine), instructions on how to use the EC and advice on sourcing their own future supplies via reputable vape shops or suppliers online. Once the starter pack is received, participants will be asked to purchase further EC supplies of their choice themselves.

3. EC starter pack with helpline support (EC+)
Participants will receive the same intervention as the EC arm, but they will also receive 5 supportive phone calls; one on the agreed TQD and then weekly for four weeks. They will also be encouraged to call the helpline if they have any questions and require additional support. The weekly calls will aim to resolve any EC related issues and questions, provide motivational support, and guide participants through the quitting process (call duration will be monitored).

The study will aim to use a refillable EC that is similar to the type used in a previous EC trial (One Kit - Innokin, UK Ecig Store), and one that is compliant with UK regulations, and not produced by a tobacco company.

Follow-up:
All participants will be followed up at 4 weeks, 6 months and 12 months post-TQD.

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Previous interventions:

Participants will be randomised to one of three interventions (detailed below). Randomisation (1:1:1) in permuted blocks will be undertaken using a web-based application. There are no stratification factors. As there are three treatment groups, the study may use blocks of a minimum size of 9 and a maximum of 18. The trial statistician will produce the randomisation list, which will be embedded into an application that only reveals the next treatment assignment once a participant has been entered into the database.

1. Control: NHS Quit Now programme (QN)
QN is an automated stop-smoking treatment package based on texts and e-mails. It is a part of the NHS web-based Live Well programme to which HCPs would ideally refer all smokers. The website https://www.nhs.uk/live-well/quit-smoking/take-steps-now-to-stop-smoking provides

information on health benefits of stopping smoking, advice and resources including local SSS, and an option to enroll in QN. QN sends three or four texts and/or an e-mail each day for 28 days with practical advice and motivational messages. Participants will be enrolled in QN by the study team according to their preference regarding texts and/or emails and will select a TQD on which the programme will start. They will be asked not to use EC for at least the first four weeks post-TQD but will be able to follow any other Live Well and QN advice including accessing stop-smoking medications and attending local SSS, as these elements are a part of usual care. Participants can request to stop the texts or unsubscribe to the emails at any time.

2. E-cigarette starter pack with no ongoing support (EC)
Participants will receive instructions on EC use over the phone. It will be explained to them that they will receive a starter pack of refillable EC by post and they will be asked to set up a target quit day (TQD) within a few days of the expected EC delivery. The package will contain the device, USB lead, 5 spare atomisers, two 10ml bottles of tobacco and a fruit flavoured e-liquid (18 mg/ml nicotine), instructions on how to use the EC and advice on sourcing their own future supplies via reputable vape shops or suppliers online. Once the starter pack is received, participants will be asked to purchase further EC supplies of their choice themselves.

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The study will aim to use a refillable EC that is similar to the type used in a previous EC trial (One Kit - Innokin, UK Ecig Store), and one that is compliant with UK regulations, and not produced by a tobacco company.

Follow-up:
All participants will be followed up at 4 weeks, 6 months and 12 months post-TQD.

Intervention Type
Mixed

Primary outcome measure
Sustained smoking cessation at 6 months post-TQD. This is measured by asking participants if they have smoked since their TQD at the 6-month follow-up. To be counted as a 'quitter', participants must report smoking no more than five cigarettes since two-weeks post-TQD with no smoking in the previous week, validated by carbon monoxide (CO) reading of < 8ppm. Participants lost-to-follow-up will be counted as smokers.

Secondary outcome measures
1. Validated sustained abstinence rates measured by asking smoking status and taking a carbon-monoxide reading at 12 months post-TQD
2. Validated sustained abstinence rates between 6 and 12 months, measured by asking smoking status and taking a carbon-monoxide reading at 6 and 12 months
3. Self-reported 7-day point-prevalence abstinence, measured by asking smoking status in last 7 days at 4 weeks, 6 months and 12 months post-TQD
4. Cigarette consumption in non-abstainers by vaping status, measured by questionnaire at four weeks, 6 and 12 months

5. Frequency and severity of urges to smoke and withdrawal symptoms, measured by questionnaire at 4 weeks post-TQD.
6. Weight, measured by asking weight at 4 weeks, 6 months and 12 months post-TQD
7. Respiratory symptoms, measured by questionnaire, at 4 weeks, 6 months and 12 months post-TQD
8. Treatment adherence and ratings, measured by questionnaire at 4 weeks (and 6 and 12 months for EC arms)
9. Adverse reactions to EC, measured by questionnaire at 4 weeks, 6 and 12 months post-TQD
10. Cost-effectiveness of the interventions, measured by questionnaires at baseline, 6 and 12 months
11. Smokers' and health-care professionals views and opinions of the helpline, measured by one-off qualitative interviews separate to the main trial

Overall study start date
01/09/2020

Completion date
25/01/2025

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Daily smoker
3. Motivated to stop smoking
4. Owns a mobile phone
5. Willing to try either an online and/or texting treatment package or EC with or without telephone support and to receive follow-up calls
6. Able to read/write/understand English
7. Has an email address (added 16/03/2021)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1,170

Total final enrolment
1170

Key exclusion criteria

1. Pregnancy
2. Current (at least weekly) use of EC

Date of first enrolment
01/09/2021

Date of final enrolment
14/11/2023

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Queen Mary University of London
2 Stayners Road
London
United Kingdom
E1 4AH

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Bradford Teaching Hospital NHS
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre

Gateshead Health NHS Foundation Trust
Queen Elizabeth Hospital
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Homerton University Hospital NHS Trust
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre
University of Edinburgh
Usher Institiute
Old Medical School
Teviot Place
Edinburgh
United Kingdom
EH8 9AG

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Joint Research Management Office (JRMO)
Queen Mary Innovation Centre
Lower Ground Floor
5 Walden Street
London
England
United Kingdom
E1 2EF
+44 (0)20 7882 5555
research.governance@qmul.ac.uk

Sponsor type
University/education

Website

http://www.qmul.ac.uk/

ROR
https://ror.org/026zzn846

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
The protocol and statistical analysis plan will be published on the funder's website (NIHR) when finalised.

The study will be disseminated via conference reports, publications, and if the findings justify this, Public Health dissemination events. The research team collaborates with Public Health England (PHE), NHS Health Scotland, Action on Smoking and Health (ASH) and the National Centre for Smoking Cessation Training (NCSCT), among others, and will work with these organisations to disseminate any research findings of interest to key stakeholders. They will ensure that findings are highlighted to the Department of Health and Social Care, devolved governments and health charities, as appropriate. They will also liaise with their PPI expert on assisting with lay dissemination of the study results.

Intention to publish date
01/09/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Katie Smith (katie.smith@qmul.ac.uk). The data will become available after the study results have been published. The data will be available for 5 years. Anonymised data will be shared with researchers with an interest and expertise in the field. Any analyses will be permitted but those requesting data will need to submit a proposal for review and approval by the study team.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0		21/09/2022	No	Yes
HRA research summary			28/06/2023	No	No