ISRCTN13288677 https://doi.org/10.1186/ISRCTN13288677

Can electronic cigarettes and nicotine replacement treatment help reduce smoking in smokers who struggle to quit?

Submission date
17/03/2017

Recruitment status
No longer recruiting

Registration date
23/03/2017

Overall study status
Completed

Last Edited
06/07/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Current treatments for smokers do not typically address the behaviours and sensations associated with the act of smoking (e.g. handling a cigarette, inhaling, taste and feel of smoke on the throat). Electronic cigarettes (EC) are battery-operated devices that attempt to mimic the act of smoking and so provide these effects. EC can alleviate urges to smoke, but it is not known whether they are as effective at helping smokers who want to cut down on their smoking and quit as the existing stop-smoking medicines (e.g. nicotine replacement treatment (NRT)). The aim of this study is to compare the effectiveness of two different stop-smoking strategies: an electronic cigarette (EC) or a nicotine-replacement product (NRT).

Who can participate?
People at least 18 years old, who have failed to stop smoking with stop-smoking services and/or products in the past

What does the study involve?
Information is collected about participants' smoking, mood and health, and the amount of carbon monoxide (CO) in their breath is measured (this shows how much smoke they inhale). Participants are then randomly allocated to use EC or NRT for at least 4 weeks. All participants are contacted by phone at weeks 1, 4 and 24 and asked questions about their mood, smoking and the use of their allocated product. Those who have reduced their smoking by 50% or more at weeks 4 and 24 are invited to the clinic for a CO reading and are given £10 towards the travel cost.

What are the possible benefits and risks of participating?
Participants receive either NRT or EC with behavioural support which they might find beneficial in helping them to quit or reduce their smoking. No risks are expected from using EC or NRT. Neither contain tobacco, and therefore do not deliver the many harmful substances found in normal cigarettes. As a result they pose no increased risk compared to normal cigarettes. The

most common side effects that people report experiencing when using EC or NRT are mouth and throat irritation, nausea and sleep disturbance. The EC provided are not currently licensed as a medicine, but they are regulated as a consumer product.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
January 2017 to January 2018

Who is funding the study?
Cancer Research UK

Who is the main contact?
Ms Marzena Orzol
m.orzol@qmul.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Marzena Orzol

Contact details
Health and Lifestyle Research Unit
2 Stayner's Road
London
United Kingdom
E1 4AH
+44 (0)207 882 8227
m.orzol@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
QMERC2016/65

Study information

Scientific Title
Can electronic cigarettes and nicotine replacement treatment help reduce smoking in smokers who struggle to quit? A pilot randomised control trial

Acronym
EC-CRUK

Study objectives
The aim of the study is to examine over six months the smoking behaviour of smokers unable to stop smoking with conventional methods who are randomised to two harm-reduction strategies: an electronic cigarette of their choice or a nicotine-replacement product of their choice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Queen Mary Ethics of Research Committee (Panel E), 22/02/2017, ref: QMERC2016/65

Study design
Pilot single-centre randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Smoking cessation

Interventions
Participants will be invited to attend two appointments as follows:
Visit 1 - Screening for eligibility, baseline data collection and randomisation. Smokers attend to confirm eligibility, have questions answered, and provide consent. Baseline data collected. Participants randomised to EC or NRT, select products of their choice and receive instructions on how to obtain them. Continue to smoke ad-lib.

Visit 2 – Preparation
Smokers bring allocated product to the session, receive advice on use, test and start product use. Commitment to not using unallocated products for the next four weeks. Smoking reduction counselling will be provided.

Participants will be randomised to two different study arms: NRT group and e-cigarette group. Randomisation (1:1 in blocks of 20) will be undertaken using computer generated randomisation

codes that will be prepared in advance. Codes will be sealed in opaque envelopes that will be marked with a randomisation number. Randomisation numbers will be allocated sequentially. The staff randomising the participant will open the envelope and enter the allocation onto the clinical record form (CRF).

NRT group product details
Those allocated to the NRT group will be shown and explained the NRT products available and encouraged to choose a product or product combination that suits their needs. They will receive a letter of recommendation (LOR) as per standard practice and collect their chosen products at local pharmacies. Product use will be supervised and adjusted (if required) as part of the behavioural support package. As per local standard practice, NRT will be provided for up to 8 weeks.

EC group product details
Those allocated to the EC group will be shown and explained different EC products commonly used and asked to obtain the product of their choice either using a voucher for up to £35 to purchase EC at a local vape shop, purchase from other suppliers and claim a refund of up to £35 upon providing a valid receipt, or choose from a limited selection at the smoking cessation clinic. They will be encouraged to try different products and liquids if the first purchase does not meet their needs, but after the initial purchase, participants will fund further supplies themselves (this is to mimic the provision of starter packs, an approach that is most likely to be used by routine services).

Participants will be contacted by phone at 1 week, 4 weeks and 24 weeks after the initial screening session when their smoking behaviour and NRT/e-cigarette use will be assessed. Those who will report ≥50% smoking reduction will be invited to provide a CO reading in the clinic.

Intervention Type
Behavioural

Primary outcome measure
Cigarette consumption per day, assessed by self-report in the follow up survey created for the purpose of the study at 1, 4 and 24 weeks post quit date/preparation date. Those who will report ≥50% smoking reduction will be validated with a CO reading in the clinic.

Secondary outcome measures
1. Use of allocated harm reduction strategies
2. Strategy ratings
3. Changes in smoking behaviour
4. Proportion of people still using allocated strategy at 6 months
All measured by the follow up survey created for the purpose of the study at 1, 4 and 24 weeks post quit date/preparation date

Overall study start date
01/01/2017

Completion date
01/01/2018

Eligibility

Key inclusion criteria
1. 18 years or older
2. Able to provide written informed consent
3. History of failed quit attempts using stop smoking medications and/or stop smoking services
4. Willing to use their allocated harm-reduction strategy for at least 4 weeks

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Total final enrolment
135

Key exclusion criteria
1. Women who are pregnant or breastfeeding
2. Unable to read/write/understand English
3. Currently using EC or any stop smoking products
4. Taking part in other interventional research
5. Have a strong preference to use or not to use NRT or EC

Date of first enrolment
04/04/2017

Date of final enrolment
04/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Mary University of London
Health and Lifestyle Research Unit
London

United Kingdom
E1 4AH

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Joint Research Management Office
5 Walden Street
London
England
United Kingdom
E1 2EF

Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The study results will be:
1. Published in a peer-reviewed medical journal, in Open Access format
2. Presented at international conferences on tobacco control and public health (e.g. Society for Research on Nicotine and Tobacco (SRNT) Annual Conference; European Respiratory Society Annual Congress)
3. Translated for the lay audience in collaboration with our Patient Group and communicated through the QMUL press office and the UK Centre for Tobacco and Alcohol Studies in a range of press and digital formats
4. Communicated in lay format through various electronic cigarette consumer organisations (e.g. the Electronic Cigarettes Consumer Association of the UK)
5. Integrated into national and international guidelines and training programmes for smoking cessation specialists
6. Directly communicated to key government, NHS, and public health stakeholders
7. Communicated over specialist tobacco control networks (e.g. SRNT, Association for the Treatment of Tobacco Use and Dependence)

Intention to publish date

30/06/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Anna Phillips (a.phillips@qmul.ac.uk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	06/07/2021	Yes	No