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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
17/03/2017		[_] Protocol		
Registration date	Overall study status Completed	[] Statistical analysis plan		
23/03/2017		[X] Results		
Last Edited 06/07/2021	Condition category Mental and Behavioural Disorders	[_] 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

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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

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?
<u>Results article</u>		01/06/2021	06/07/2021	Yes	No