

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

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| Submission date 17/03/2017 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 23/03/2017 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 06/07/2021 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> 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
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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 $\geq 50\%$ smoking reduction will be invited to provide a CO reading in the clinic.

Intervention Type

Behavioural

Primary outcome(s)

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 $\geq 50\%$ smoking reduction will be validated with a CO reading in the clinic.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

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

ROR

<https://ror.org/026zzn846>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

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 |