ISRCTN60477608 https://doi.org/10.1186/ISRCTN60477608

# The efficacy of e-cigarettes compared with nicotine replacement therapy, when used within the UK stop smoking service

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|---|---|---|
| **Submission date**<br>02/04/2015 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[X] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>07/04/2015 | **Overall study status**<br>Completed | |
| **Last Edited**<br>24/06/2025 | **Condition category**<br>Mental and Behavioural Disorders | |

**Plain English summary of protocol**
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-electronic-cigarettes-with-nicotine-replacement-therapy-to-stop-smoking-tec

## Contact information

**Type(s)**
Public

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## Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**ClinicalTrials.gov (NCT)**
Nil known

**Protocol serial number**
HTA 12/167/135

# Study information

### Scientific Title
A randomised controlled trial to examine the efficacy of e-cigarettes compared with nicotine replacement therapy, when used within the UK stop smoking service

### Acronym
TEC (Trial of Electronic Cigarettes)

### Study objectives
To determine the 12-month sustained biochemically validated abstinence rates in smokers using electronic cigarettes (EC) compared to smokers using standard nicotine replacement therapy (NRT).

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/12167135

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
NRES Committee London Camden & Islington, 14/LO/2235, 19/12/2014

### Study design
Multicentre pragmatic randomised controlled trial

### Primary study design
Interventional

### Study type(s)
Treatment

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

### Interventions
Smokers who want help to quit smoking will be individually randomised to receive usual care (UC; a choice of NRT combined with usual care behavioural support provided by a Stop Smoking Service) or EC with the same behavioural support.

### Intervention Type
Device

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Electronic cigarettes, nicotine replacement therapy

### Primary outcome(s)

Carbon monoxide (CO) validated sustained abstinence rates at 52 weeks post–target quit date (TQD)

### Key secondary outcome(s))
1. CO validated sustained abstinence rates at 4 and 24 weeks post–TQD
2. 7-day point prevalence abstinence at 4, 24 and 52 weeks
3. Smoking reduction in participants who did not achieve full abstinence
4. Treatment ratings
5. Adverse reactions
6. Cost-efficacy of the interventions

### Completion date
31/03/2018

## Eligibility

### Key inclusion criteria
1. Aged 18 or over
2. Current smoker accessing the stop smoking service
3. Able to read/write/understand English

### Participant type(s)
Other

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
886

### Key exclusion criteria
1. Pregnant or breastfeeding
2. Strong preference to use or not to use NRT or EC in their quit attempt
3. Enrolled in other interventional research
4. Currently using NRT or EC

### Date of first enrolment
15/04/2015

### Date of final enrolment
01/12/2016

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Queen Mary University of London**
United Kingdom
E1 4NS

**Study participating centre**
**Leicester Stop Smoking Service**
United Kingdom
LE1 6TH

**Study participating centre**
**East Sussex Stop Smoking Service**
United Kingdom
TN38 9UH

# Sponsor information

**Organisation**
Queen Mary University of London (QMUL)

**ROR**
https://ror.org/026zzn846

# Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme

### Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan
Not provided at time of registration

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 14/02/2019 | | Yes | No |
| Results article | results | 01/08/2019 | 23/08/2019 | Yes | No |
| Results article | Costs effectiveness | 04/12/2019 | 24/06/2025 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Plain English results | | | 25/02/2020 | No | Yes |
| Protocol file | version 3.0 | 08/04/2015 | 18/08/2022 | No | No |
| Statistical Analysis Plan | version 1.0 | 08/01/2018 | 18/08/2022 | No | No |