ISRCTN17731903 https://doi.org/10.1186/ISRCTN17731903

# Feasibility study of e-cigarettes in periodontitis

**Submission date**
19/09/2016

**Recruitment status**
No longer recruiting

**Registration date**
27/09/2016

**Overall study status**
Completed

**Last Edited**
10/10/2023

**Condition category**
Oral Health

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

## Plain English summary of protocol

Background and study aims
Tobacco smoking is well known to have negative effects on oral health. In particular, smoking dramatically increases the risk of developing gum (periodontal) disease, which can lead to tooth loss. Dentists therefore play a role in helping patients to stop smoking and provide stop smoking advice to their patients. Electronic cigarettes (e-cigarettes) are increasing in popularity and there is growing evidence they may be an effective way to help people give up smoking. With several million users of e-cigarettes in the UK it is important that dentists understand the role they may play in helping their patients to stop smoking. However, there is no research to show their usefulness within the dental setting and any potential effects for oral health, particularly periodontal health. The aim of this study is to investigate the effect of e-cigarettes on periodontal health, in order to find out whether a large scale study would be possible.

Who can participate?
Smokers over 18 years old who have been diagnosed with severe, long-term gum disease.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive usual stop smoking advice from the dentist. Participants in the second group receive usual stop smoking advice from the dentist as well as an e-cigarette starter kit and brief training on how to use it. Participants in both groups then receive normal periodontal therapies delivered over several appointments. A sample of the participants is also asked to attend 1-3 additional visits so they can be interviewed about their experiences in the study. The amount of participants taking part is recorded in order to find out whether a larger scale study would be possible.

What are the possible benefits and risks of participating?
As participants in this study receive periodontal therapies, they may see significant improvements to their gum health. Participants also benefit from receiving help with quitting smoking, which will hopefully help reduce smoking levels which is beneficial for general and oral health. There are no known risks involved with participating.

Where is the study run from?
Newcastle Dental Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2015 to November 2018

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

Who is the main contact?
Dr Richard Holliday
richard.holliday@newcastle.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Richard Holliday

### ORCID ID
https://orcid.org/0000-0002-9072-8083

### Contact details
D4.016
Newcastle Dental Hospital
Richardson Road
Newcastle Upon Tyne
United Kingdom
NE2 4AZ
+44 191 233 6161 (ext 26812)
richard.holliday@newcastle.ac.uk

# Additional identifiers

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

### Protocol serial number
CPMS 32034

# Study information

### Scientific Title
A mixed methods feasibility study of electronic cigarette use by patients with periodontitis

### Study objectives
The aim of this study is to assess the viability of delivering and studying an e-cigarette intervention prior to a definitive study.

### Ethics approval required

Old ethics approval format

## Ethics approval(s)
North East - Tyne & Wear South Research Ethics Committee, 03/08/2016, ref: 16/NE/0219

## Study design
Randomized; Interventional; Design type: Treatment, Prevention, Complex Intervention

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Specialty: Oral and dental health, Primary sub-specialty: Oral and dental public health; UKCRC code/ Disease: Oral and Gastrointestinal/ Diseases of oral cavity, salivary glands and jaws

## Interventions
Following assessment of eligibility and completion of informed consent participants will be randomised to one of two groups, in a 1:1 ratio using random permuted blocks. The randomisation allocation schedule will be generated by a statistician with no other involvement in the study to achieve concealment of allocation.

Control group: Participants receive standard stop smoking advice from the dentist. This involves the '3 A's': Ask, Advise, Act technique and the option of a referral to Newcastle stop smoking services.

Intervention group: Participants receive the same standard stop smoking advice from the dentist as the control group but are also given an e-cigarette starter kit and given brief training on its use.

For all participants, follow up involves normal periodontal therapies delivered over several appointments.

A sample of the participants will be asked to attend 1-3 additional visits for qualitative interviews about their experiences in the study.

## Intervention Type
Other

## Primary outcome(s)
Feasibility outcomes:
1. Eligibility rate will be measured by examining screening records at the end of the study
2. Patients' willingness to enter the trial will be measured by established by examining screening records at the end of the study and by the qualitative interviews
3. Recruitment rate will be measured by recording the number of eligible participant who consent to participate in the study by 12 months
4. Participation biases will be established by examining the screening/ recruitment data at the end of the study
5. Retention rate will be established by recording the number of participants who remain in the

study until the end of follow up
6. Randomised group contamination rates (i.e. the extent of cross-over between the two arms of the trial) will be established by recording the e-cigarette use of all participants over the duration of the study
7. Periodontal Inflammed Surface Area [PISA] will be measured at baseline, 3-months and 6-months
8. Periodontal Epithelial Surface Area [PESA] will be measured at baseline, 3-months and 6-months
9. Pocket Probing Depths [PPDs]) will be measured at baseline, 3-months and 6-months
10. Distribution of microbiome is assessed using subgingival plaque samples at baseline, 3-months and 6-months
11. Distributional properties of the inflammatory biomarkers is assessed using subgingival plaque samples at baseline, 3-months and 6-months
12. Participant compliance with e-cigarette use is measured by self-reported feedback, weekly data collection and qualitative interviews
13. Tobacco smoking and e-cigarette usage is measured by self-reported feedback, weekly data collection and biochemical measurers
14. Participant behaviour regarding the use of the e-cigarette is established by qualitative interviews
15. A Qualitative Process Evaluation will establish the views of participants on the provision of e-cigarettes and to finalise the exact characteristics of an e-cigarette intervention for the future definitive study for this patient group

### Key secondary outcome(s))
There are no secondary outcome measures

### Completion date
30/11/2018

## Eligibility

### Key inclusion criteria
1. Aged over 18 years old
2. Smoker of burnt tobacco (≥10 factory-made cigarettes/day or 7 g [0.25 oz] loose tobacco or 14 hand-rolled cigarettes/day)
3. Not currently using an EC, or not used one for more than two days in the last 30 days
4. Be willing and able to come to the Dental Clinical Research facility in the Newcastle Dental Hospital for the required study visits
5. Minimum of 20 natural teeth (excluding third molars)
6. Diagnosed with severe chronic periodontal disease having interproximal pocket probing depths (PPDs) of ≥5 mm at ≥8 teeth and BOP scores ≥30%
7. Have read, understood and signed an informed consent form

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
80

### Key exclusion criteria
1. Having used an e-cigarette for more than 2 days in the last 30 days
2. Infectious or systemic diseases that may be unduly affected by participation in this study
3. Haemodynamically unstable patients hospitalised with severe arrhythmias, myocardial infarction, cerebrovascular accident
4. Suffering from Phaeochromocytoma
5. Suffering from uncontrolled hyperthyroidism
6. Liver or Kidney problems
7. Chronic Obstructive Pulmonary Disease
8. Patients taking the medication Adenosine
9. Lack of capacity to be able to consent to the research project and/or inability to follow study instructions
10. Participation in a dental research study within the previous 20 days
11. Pregnant by medical history, or nursing
12. Received any non-surgical periodontal therapy other than a routine scale and polish in the last 6 months
13. Currently undergoing or requiring extensive dental, orthodontic or implant treatment, or treatment for peri-implantitis

Eligibility Criteria requiring further discussions with individual participants:
1. Asthma (Severity needs to be assessed. Patient made aware that NRT better than smoking but best to use NRT as a short term stop smoking treatment).
2. Long term throat disease (Severity needs to be assessed. NRT use may exacerbate symptoms)
3. Stomach Ulcer, duodenal ulcer, irritation or inflammation of the stomach or throat (NRT may exacerbate symptoms)
4. Patient with diabetes mellitus will be advised to monitor their blood glucose more closely when initiating treatment. They will be advised to discuss this with their doctor or diabetic nurse.
5. Patients taking medications metabolised by CYP 1A2 and that have a narrow therapeutic window can be affected by stopping smoking. Patients taking theophylline, clozapine and ropinirole will be asked to see their doctor to discuss changing the dose prior to starting the quit attempt.

### Date of first enrolment
20/09/2016

### Date of final enrolment
19/09/2017

## Locations

### Countries of recruitment

United Kingdom

England

**Study participating centre**
**Newcastle Dental Hospital**
Richardson Road
Newcastle upon Tyne
United Kingdom
NE2 4AZ

# Sponsor information

**Organisation**
Newcastle Upon Tyne Hospitals NHS Foundation Trust

**ROR**
https://ror.org/05p40t847

# 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

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

## IPD sharing plan summary

Other

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 04/06/2019 | 10/06/2019 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Statistical Analysis Plan | | 04/06/2019 | 10/10/2023 | No | No |