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Enhancing dental health advice

Submission date 09/02/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/05/2022	**Overall study status** Ongoing	
Last Edited 16/12/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Smoking is one of the main risk factors for oral (mouth) diseases, particularly periodontitis (gum disease) and cancer. Although there is evidence that giving up smoking leads to improvements in oral health, there is less evidence about how dental professionals can best support smokers to quit. This trial aims to address this, building on existing evidence by comparing the clinical- and cost-effectiveness and safety of three possible strategies for quitting smoking – nicotine replacement therapy (gum/patches - NRT); E-cigarettes (EC); and very brief advice from a dental professional (VBA). Success will be measured in terms of quit rates and improvement in oral health. The trial will be conducted in 56 NHS dental practices across 7 UK regional hubs in England and Scotland.

Who can participate?
1460 adult regular tobacco smokers will be recruited, with 455 of those with periodontitis going into a sub-group for additional examination and analysis.

What does the study involve?
All study participants will be randomly assigned to receive one of the three strategies described above. Those who are assigned to NRT or EC will be provided with a 12-week supply of NRT, or an EC starter kit. All participants will be followed up at 6 months and 12 months, with those in the periodontitis group having an additional clinical examination at 6 months. We will use a monitor that measures exhaled carbon monoxide to indicate whether the participants have stopped smoking, and for the periodontitis group we will take samples from their mouth and assess other indicators to measure their gum health.

What are the possible benefits and risks of participating?
Benefits:
We do not know whether this study will help to improve your dental health. We hope that the information that we collect from this study will help us develop advice we offer to people in the future.
Risks:
1. Potential adverse events related to study intervention
- Although NRT is an extremely safe medication, there are known minor side effects (or adverse events) associated with it. These adverse events will be recorded and monitored. Study eligibility criteria will exclude those for whom NRT is contraindicated.

2. Discomfort and minor bleeding
- Some types of periodontal assessments (e.g. bleeding on probing) can cause slight discomfort. However, such periodontal assessments are routinely done during dental visits for patients with gum disease (i.e. periodontitis). Therefore, there is no additional increase in risk from these due to participation in the trial.
3. Inconvenience
- There will be a total of 3 visits throughout the trial: baseline study visit will be done during the participant's routine dental visit (only after they agree to take part in the study and written informed consent has been obtained); follow-up visits at 6 months and 12 months which will be scheduled around their normal dental visits to avoid unnecessary visit. A £20 gift voucher will be provided during follow-up visits.

Where is the study run from?
Newcastle Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
February 2022 to April 2026

Who is funding the study?
The trial is being funded by the National Institute for Health Research Health Technology Assessment programme, part of the Department of Health and Social Care (UK)

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

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
2021-005440-30

Integrated Research Application System (IRAS)

1004761

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
09800, IRAS 1004761, CPMS 52707

Study information

Scientific Title
ENHANCE-D: Enhancing Dental Health Advice

Acronym
ENHANCE-D

Study objectives
1. To compare smoking abstinence at 6 months of nicotine replacement therapy or e-cigarettes to usual care and to each other.
2. To compare the periodontal health at 6 months of nicotine replacement therapy (NRT) or e-cigarettes (EC) to usual care and to each other, for those with periodontitis at baseline.
3. To evaluate other parameters of oral health including oral health-related quality of life.
4. To evaluate nicotine dependence, urges to smoke, withdrawal symptoms and longer term smoking abstinence (12 months).
5. To assess costs and benefits in the form of a cost-effectiveness analysis and cost-benefit analysis of NRT and EC in comparison to usual care at 6 months.
6. To estimate participants' preferences for each of the interventions.
7. To compare the adverse event profiles of the interventions.
8. To confirm the acceptability of these interventions and explore experiences.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/03/2022, North East - Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 2071048265; tyneandwearsouth.rec@hra.nhs.uk), ref: 22/NE/0040

Study design
Interventional open-label randomized three-arm parallel-group controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Smoking cessation in dental patients with or without gum disease

Interventions

Control arm
i. Very Brief Advice (VBA)
1. VBA is usual care for smokers in dental settings usually following the 3As: Ask, Advise, Act technique. This will signpost participants to a GP, pharmacy or stop smoking service (SSS). Formal referral can also be completed to SSS, where available.
2. Participants in the control group will be free to use NRT or ECs as they wish but these will not be provided by the dental professional providing the advice, nor specifically recommended. If participants decide to use NRT or EC (on their own decision), they will be recorded at follow up.
3. Conducted at baseline visit, only a 5 minute intervention.
4. Patients will be followed-up for up to 12 months from baseline.

Intervention arms
i. Nicotine Replacement Therapy (NRT)
1. If a participant is randomised to NRT arm, a trained dental professional will provide a single-visit behavioural support intervention including the offer of NRT.
2. 12-week course of combination NRT (patch plus faster acting form such as chewing gum or lozenge), in line with current recommendations.
3. Duration will be 12 weeks if a participant wants to continue NRT after initial 4-week supply.
4. Participants will be followed up for up to 12 months from baseline.
ii. E-cigarette (EC)
1. If a participant is randomised to EC, they will receive the same behavioural intervention as the NRT group along with EC starter kit. The starter kit will include ten, 10ml bottles of e-liquid with a choice of one of four packages of flavour and nicotine concentrations.
2. Participants will be expected to source their own supply of e-liquid after the initial supply and advice will be given as to where to source suitable MHRA registered products.
3. Duration will vary depending on use of EC.
4. Participants will be followed up for up to 12 months from baseline.

Randomisation process
i. Randomisation will be performed using Sealed EnvelopeTM system (a secure, central, 24-hour web-based randomisation system with concealed allocation).
ii. Following completion of informed consent and confirmation of eligibility participants will be randomised to receive VBA, NRT or EC starter kit, in a 1:2:2 ratio using random permuted blocks within strata. Randomisation will be stratified by regional hub (7 levels) and by baseline periodontal status (3 levels: all sextants BPE code ≤2, 1-3 sextants with BPE code 3 or 4, ≥4 sextants with BPE code 3 or 4).

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

NRT (transdermal patch, lozenge and gum)

Primary outcome(s)

Biochemically verified smoking abstinence 6 months after randomisation using a carbon monoxide monitor

Key secondary outcome(s))
To all participants:
1. Continuous biochemically verified smoking abstinence is measured using exhaled Carbon Monoxide (eCO) 12 months
2. Nicotine dependence is measured using Fagerstrom Test for Nicotine Dependence (FTND) at baseline and 6 months
3. Cigarette withdrawal symptoms is measured using Mood and Physical Symptoms Scale (MPSS) at baseline and 6 months
4. Quality of Life related to oral health is measured using Oral Health Quality of Life Assessment (OHQoL-UK) at baseline and 6 months.
5. Oral health is measured using Number of teeth at baseline and 6 months
6. Health economic evaluation (in terms of the following) is measured using Health Utilisation Questionnaire at baseline and 6 months
6.1. Costs to the NHS and participants
6.2. Incremental cost per smoking abstinence
6.3. Net monetary benefits based on participants' willingness-to-pay for the intervention and associated outcomes
6.4. Incremental net benefit

For periodontitis sub-group only
1. Periodontal health is measured using the following at baseline and 6 months
1.1. Percentage of periodontal sites with PPD (Pocket Probing Depths) ≥5 mm
1.2. Periodontal Epithelial Surface Area (PESA)
1.3. Periodontal Inflamed Surface Area (PISA)
2. Oral hygiene is measured using Plaque Index (PI) at baseline and 6 months
3. Gingival health is measured using the following at baseline and 6 months
3.1. Gingival Index [Lobene Modified Gingival Index]
3.2. Bleeding on Probing (BOP)
4. Dry mouth (as part of a routine oral health assessment) is measured using Clinical Oral Dryness Score at baseline and 6 months
5. Current and previous periodontal disease exposure is measured using clinical attachment loss (CAL) at baseline and 6 months

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. Aged at least 18 years old
2. Current regular smoker
3. Willing and able to provide informed consent prior to any trial procedures taking place
4. A basic Periodontal Examination completed within the last 3 months.

Periodontitis subgroup:
5. Minimum of 16 natural teeth (excluding third molars)
6. For sub-group - diagnosis of periodontitis stage II (or greater), grade A/B/C and currently unstable (As diagnosed by the primary care dentist/hygienist/therapist)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Known to be pregnant or currently breastfeeding
2. Enrolled in another interventional research trial which could affect the outcome of this trial
3. Having used an aid to quit smoking or reduce/quit alcohol in the week prior to enrolment
4. Phaeocromocytoma, uncontrolled hyperthrodism, extensive dermatitis/skin disorder
5. Known hypersensitivity to nicotine or any component of the study products
6. Taking one of the following medications:
6.1. Clozapine
6.2. Olanzapine
6.3. Theophylline
6.4. Aminophylline

Date of first enrolment
01/06/2022

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Royal Victoria Infirmary
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Edinburgh Dental Institute
4th Floor
Lauriston Building
Lauriston Place
Edinburgh
Lothian
United Kingdom
EH3 9HA

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

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
In line with General Data Protection Regulation (GDPR), explicit consent must be obtained via the informed consent form from each trial participant to allow data sharing to occur. De-identified data from this trial may be available to the scientific community subject to appropriate ethical approval. Requests for data should be directed to the lead author/Chief Investigator and Clinical Trials Unit (during the course of the trial), and DataNCL (after the study is completed and closed).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes