

# Hygiene-therapists undertaking the RDE of low-risk NHS dental patients (pilot)

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|--|---|---|
| <b>Submission date</b><br>23/04/2018   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>30/04/2018 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>13/08/2021       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Over one half of all dental 'check-ups' result in no further treatment. The patient is examined by a General Dental Practitioner (GDP) and returned to the recall list for a further 'check-up' in another 6 or 12 months' time. As the oral health of regular dental attenders improves further, it is likely that increasingly more patients will be 'low-risk' and will only require a simple 'check-up' in the future, with no further treatment. The use of the GDP to undertake the routine dental 'check-up' is becoming a costly way of providing care. Research has shown that other less expensive members of the dental team, known as Hygiene-Therapists (H-Ts), are just as good at detecting dental decay, gum disease and oral cancer. Using H-Ts in this way could help free up the GDPs' time to concentrate on more complex cases. It could also free up resources to treat patients who currently don't access care and meet the future challenges for NHS dentistry, like the growing number of house-bound elderly. The aim of this study is to explore this over a 15-month period to inform the design of a larger study.

### Who can participate?

NHS patients aged over 18 who have presented with no more than one active lesion in the last year or required no more than one dental filling due to dental caries within the previous year (as of 04/10/2018)

### What does the study involve?

Participants are randomly allocated to have a check-up with either a dentist or a H-T. At the end of the study their oral health is assessed (gum disease, oral cleanliness and tooth decay). At the same time, interviews explore GDPs', H-Ts' and patients' views to improve understanding about what could work well, how and under which conditions.

### What are the possible benefits and risks of participating?

The results will be used to plan for a full-scale study. Participants receive a £25 (as of 04/10/2018) voucher from the study team for participating in the study.

### Where is the study run from?

1. Cheshire & Merseyside Area Team (UK)
2. Greater Manchester Area Team (UK)

When is the study starting and how long is it expected to run for?  
October 2017 to July 2019

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

Who is the main contact?  
Prof. Paul Brocklehurst

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Paul Brocklehurst

**ORCID ID**  
<https://orcid.org/0000-0003-1878-9030>

**Contact details**  
NORTH Clinical Trials Unit  
Bangor  
United Kingdom  
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## Additional identifiers

**Protocol serial number**  
36996

## Study information

**Scientific Title**  
Can Hygiene-Therapists maintain the oral health of routine low-risk dental recall patients in "high-street" dental practices: a pilot study

**Study objectives**  
Over one half of all dental 'check-ups' result in no further treatment. The patient is examined by a General Dental Practitioner (GDP) and returned to the recall list for a further 'check-up' in another six or twelve months' time. As the oral health of regular dental attenders improves further, it is likely that increasingly more patients will be 'low-risk' and will only require a simple 'check-up' in the future, with no further treatment. The use of the GDP to undertake the routine dental 'check-up' is becoming a costly way of providing care.

Research undertaken by the same team has shown that other less expensive members of the dental team, known as Hygiene-Therapists (H-Ts), are just as good at detecting dental decay, gum disease and oral cancer. Using H-Ts in this way could help free up the GDPs' time to concentrate on more complex cases, pursuant to their skill-set. It could also be a model of care

that could be used to free up resources to treat patients who currently don't access care and meet the future challenges for NHS dentistry, like the growing number of house-bound elderly.

To explore this, a pilot study is proposed over a 15-month period. This will inform the design of a definitive trial.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

East Midlands REC, 09/11/2017, REC ref: 17/EM/0365, IRAS: 226296

### **Study design**

Randomised; Interventional; Design type: Treatment, Diagnosis, Prevention, Process of Care, Management of Care

### **Primary study design**

Interventional

### **Study type(s)**

Prevention

### **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**

The current practice of using dentists to provide 'check-ups' will form the control arm and will be compared to the new model, where dental 'check-ups' and any subsequent treatment will be provided by H-Ts. At the end of the study, differences in oral health will be assessed using accepted measures of 'gum' disease, oral cleanliness and tooth decay. At the same time as the trial, parallel interviews will explore GPs', H-Ts' and patients' views to improve understanding about what could work well, how and under which conditions.

### **Intervention Type**

Other

### **Primary outcome(s)**

Proportion of sites that bleed on probing (measured at six sites per tooth) at 15 months

### **Key secondary outcome(s)**

Measured at 15 months:

1. Proportion of sites that have visible plaque present (measure of oral cleanliness)
2. Proportion of sites with a probing depth that exceeds Code 2 of the Basic Periodontal Examination periodontal probe
3. Number of new decayed and filled teeth
4. Unplanned visits between RDEs
5. Oral health related quality of life (Oral Health Impact Profile)
6. Patient-centred outcomes to explore behaviour change and dental anxiety through the use of validated questionnaires

**Completion date**

31/07/2019

## Eligibility

**Key inclusion criteria**

Current participant inclusion criteria as of 04/10/2018:

1. NHS adult patient (aged at least 18 years of age) on the recall list of the practice
2. Has presented with no more than one active lesion in the last year or required no more than one dental filling due to dental caries within the previous year (defined as "low-risk")
3. Asymptomatic at time of the 'check-up'
4. Have no predisposing medical history that elevates risk status
5. Were seen for their routine recall at least six months ago
6. Dentate or partially dentate

Previous participant inclusion criteria:

1. NHS adult patient (> 18 years of age) on the recall list of the practice
2. Have not presented with any active dental decay or required any dental fillings due to dental caries within the previous two years (defined as "low-risk")
3. Asymptomatic at time of the RDE
4. Dentate or partially dentate

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

217

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/03/2018

**Date of final enrolment**

31/07/2018

## Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

**Cheshire & Merseyside Area Team**

Chester

United Kingdom

CH2 1BQ

## Study participating centre

**Greater Manchester Area Team**

Manchester

United Kingdom

M1 3BN

## Sponsor information

### Organisation

Bangor University

### ROR

<https://ror.org/006jb1a24>

## Funder(s)

### Funder type

Government

### Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/01/79

## Results and Publications

### Individual participant data (IPD) sharing plan

Anonymised data will be stored according to Bangor regulations (Bangor server). See

<https://www.bangor.ac.uk/planning/InfSecGuid.php.en>

## IPD sharing plan summary

Stored in repository

### Study outputs

| Output type                                   | Details    | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               |            | 01/02/2021   | 13/08/2021 | Yes            | No              |
| <a href="#">HRA research summary</a>          |            |              | 28/06/2023 | No             | No              |
| <a href="#">Participant information sheet</a> | version V2 | 30/09/2017   | 30/04/2018 | No             | Yes             |
| <a href="#">Participant information sheet</a> | version V1 | 02/03/2018   | 30/04/2018 | No             | Yes             |
| <a href="#">Participant information sheet</a> | version V3 | 07/11/2017   | 30/04/2018 | No             | Yes             |
| <a href="#">Protocol file</a>                 | version V4 | 02/03/2018   | 30/04/2018 | No             | No              |