Hygiene-therapists undertaking the RDE of lowrisk NHS dental patients (pilot)

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/04/2018		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
30/04/2018		[X] Results		
Last Edited 13/08/2021	Condition category Oral Health	Individual participant data		
13/00/2021	Oracical			

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

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Contact details

NWORTH Clinical Trials Unit Bangor United Kingdom LL57 2PZ

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 GDPs', 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 plague 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?
Results article		01/02/2021	13/08/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V2	30/09/2017	30/04/2018	No	Yes
Participant information sheet	version V1	02/03/2018	30/04/2018	No	Yes
Participant information sheet	version V3	07/11/2017	30/04/2018	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version V4	02/03/2018	30/04/2018	No	No