

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

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

See additional files

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 measure

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

Secondary outcome measures

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

Overall study start date

01/10/2017

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 216; UK Sample Size: 216

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**

England

United Kingdom

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

Sponsor details

c/o Prof. Christopher Burton
School of Healthcare Sciences
Fron Heulog
Bangor
Wales
United Kingdom
LL57 2EF

Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

Journals and presentations to national and international academic conferences, including the International Association of Dental Research and the British Association for the Study of Community Dentistry. The research team also has strong links with policy makers in Europe and they aim to present their findings at a meeting of EU Chief Dental Officers (CDO) (PRB has a direct link with the CDO from Wales, England, Scotland and The Netherlands). The research team will work with dental professional groups including the British Dental Association, British Society of Dental Hygiene-Therapists and the British Association of Dental Therapists. They will also disseminate the results within the commissioning networks in Public Health England, NHS England and to Consultants in Dental Public Health.

Given the strength of the programme in relation to important policy initiatives in England and Wales (Five Years Forward and Prudent Healthcare), direct links will be made with Ministers for Health, through the respective CDOs. The trialists will host a seminar to present the results and discuss their implications.

They will also produce lay summaries of the outputs of the project for presentation on the University website and issue press releases in agreement with NIHR. In addition they want to develop new and novel methods to support dissemination in a more accessible way for a lay audience. One approach will be to record a 'virtual abstract' video to post on University and NHS websites and promulgate via patient networks. The patient group for the study will be directly involved with this and will also create public-friendly summaries of the research.

Intention to publish date

31/07/2020

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?
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
Protocol file	version V4	02/03/2018	30/04/2018	No	No
Results article		01/02/2021	13/08/2021	Yes	No
HRA research summary			28/06/2023	No	No