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Improving the Quality of Dentistry (IQuaD): Study comparing oral hygiene advice and periodontal instrumentation for the prevention and management of periodontal disease in dentate adults attending dental primary care

Submission date
04/07/2011

Recruitment status
No longer recruiting

Registration date
01/08/2011

Overall study status
Completed

Last Edited
10/07/2018

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
It is well known that dental plaque is the main cause of gum disease. Effective oral hygiene (tooth brushing and inter-dental aids) for plaque control and the removal of calculus (tartar) by your dentist or hygienist with a scale and polish are considered necessary to prevent and treat gum disease. However, there is a lack of strong evidence to inform dentists about what type of oral hygiene advice is most beneficial for their patients. There is also a lack of strong evidence to inform dentists about the most effective time interval for providing a scale and polish. The purpose of this study is to investigate and compare the effectiveness and cost- effectiveness of providing personalised oral hygiene advice and/or scale and polish at different time intervals for improving gum health in adults attending general dental practice. The results of this study will provide much-needed evidence on the best type of oral hygiene advice for patients and the most appropriate time interval between scale and polishes in order to prevent and treat gum disease .

Who can participate?
We are asking patients who have attended their dentist at least twice during the previous two years to take part.

What does the study involve?
A study hygienist will examine your teeth and gums to record information about the health of your gums . If this examination reveals gum disease that requires specialist care you will be informed and will not be allocated to a study group. However, we will ask for your permission to follow you up over the three years in the same way as the other study participants. In order to compare routine and personalised oral hygiene advice, your dentist/hygienist has been asked to provide all their patients with either advice as usual (routine) or to base the advice on health status and to demonstrate using appropriate toothbrushes and inter-dental aids (personalised).

Depending on which type of advice your dentist/hygienist has been asked to provide you will receive routine or personalised oral hygiene advice at the first visit and as required at any subsequent visit for a check up or treatment. At this first visit your dentist/hygienist will also provide you with a thorough scale and polish to remove all plaque and deposits of calculus. In order to compare routine and personalised oral hygiene advice and scale and polish at different time intervals, you will be randomly (i.e. by chance) allocated to one of three different time intervals for a scale and polish: six monthly scale and polish; yearly scale and polish; or no scale and polish. The group you are allocated to will be selected by a computer. All participants will receive a £25 gift voucher in recognition of your contribution to the study. Your involvement in the study will be for a period of three years.
At the first visit you will also be asked to complete a confidential questionnaire asking about your views of the service you get from your dental practice, and your attitudes and beliefs towards oral health. You will be asked to complete this questionnaire again at 1 year, 2 years and 3 years after your first visit. It is estimated that each questionnaire will take about 30 minutes to complete. In total you will be asked to complete four questionnaires during the study. Three years after your first check-up appointment you will be asked to attend for a dental examination. This examination will take place in your dental practice. However, the examination will not be carried out by your dentist, but will be carried out by an independent dentist/hygienist who is employed by the study. The study will also compare the number and types of treatments received by patients.

What are the possible benefits and risks of participating?
During the study you will not be asked to see your dentist less frequently. No matter which group you are allocated to if at any time there is a need to provide care for your gums more often, including referral to a specialist, this will be arranged and the treatment recorded. It is possible that you may be allocated to a group where you receive care more often than usual and , if so , your oral health will be monitored more often than usual. Of course you are free to attend your dentist at any time if you develop any dental problems (e.g. toothache) in between check-ups.

Where is the study run from?
The study is being organised by staff at the IQuaD Study Office at the Dental Health Services & Research Unit, University of Dundee and Health Services Research Unit, University of Aberdeen. Research groups from NHS Education for Scotland, the Universities of Newcastle , Edinburgh, Manchester and London are also involved. The study will be carried out in 60 dental practices in Scotland and the North of England.

When is the study starting and how long is it expected to run for?
The study started in August 2011 and will run until December 2016.

Who is funding the study?
The study is funded by the Health Technology Assessment programme of the NHS (UK).

Who is the main contact?
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Study website
https://w3.abdn.ac.uk/hsru/IQuaD/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 09/01/45, 10273

Study information

Scientific Title
Improving the Quality of Dentistry (IQuaD): A multicentre randomised controlled trial comparing oral hygiene advice and periodontal instrumentation for the prevention and management of periodontal disease in dentate adults attending dental primary care

Acronym
IQuaD

Study objectives
The aim of this study is to compare the effectiveness and cost-effectiveness of theoretically based, personalised oral hygiene advice (OHA) or periodontal instrumentation (PI) at different time intervals (no PI; 6 monthly PI or 12 monthly PI) or their combination to routine OHA, for improving periodontal health in dentate adults attending general dental practice.

More details can be found at http://www.hta.ac.uk/project/2300.asp
Protocol can be found at http://www.hta.ac.uk/protocols/200900010045.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Fife and Forth Valley REC approved on 24/03/2011, ref: 10/S0501/65

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Patient information can be found at https://w3.abdn.ac.uk/hsru/IQuaD/Public/DownloadPage.aspx

Health condition(s) or problem(s) studied
Oral and dental hygiene advice

Interventions
1. Dental practices will be randomised (cluster randomisation) to personalised oral hygiene advice (OHA) which will be tailored to the needs of the patient or routine OHA
2. Subsequently participants will be randomised to one of three groups:
2.1. No periodontal instrumentation (PI)
2.2. 6 monthly PI
2.3. 12 monthly PI
3. Participants will be followed up annually by postal questionnaire for 3 years

Intervention Type
Mixed

Primary outcome measure
1. Clinical: Gingival inflammation/bleeding on probing at the gingival margin measured using the Gingival Index of Loe by a trained blinded outcome assessor at baseline and 3 years follow-up
2. Patient centred: Oral hygiene self-efficacy collected annually by questionnaire
3. Economic: Net benefits (mean willingness to pay minus mean costs)

Secondary outcome measures
1. Clinical: Calculus to the Ramfjord Calculus Index and periodontal pocket depth using the colour-coded UNC periodontal probe measured by a trained blinded outcome assessor at baseline and 3 years follow-up; additional periodontal instrumentation and referral
2. Patient centred: dental quality of life, oral health behaviour, knowledge, cosmesis collected annually by questionnaire
3. Economic: Costs to the National Health Service (NHS) and patients, willingness to pay

4. Providers: Beliefs relating to giving oral hygiene advice and maintenance of periodontal health collected by questionnaire at baseline and 3 years follow-up

Overall study start date
01/08/2011

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Adult patients, either sex (more than or equal to 18 years of age) with periodontal health, gingivitis or moderate periodontitis (BPE 0-3) who:
1.1. Are dentate
1.2. Have attended for a check-up at least twice in the previous 2 years
1.3. Receive their dental care in part or fully as an NHS patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 1860; UK Sample Size: 1860

Key exclusion criteria
1. Patients with periodontal disease with a Basic Periodontal Examination (BPE) score of 4 (probing depth > 6mm and/or furcation involvements or attachment loss of 7mm or more) in any sextant on the basis more extensive periodontal care is indicated
2. Patients with an uncontrolled chronic medical condition (e.g. diabetes, immunocompromised)

Date of first enrolment
01/08/2011

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Trial Manager
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
Nethergate
Dundee
Scotland
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DD1 4HN

Sponsor type
University/education

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/10/2013		Yes	No
Results article	results	01/07/2018		Yes	No