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INTERVAL Dental Recalls Trial

Submission date
18/08/2008

Recruitment status
No longer recruiting

Registration date
20/08/2008

Overall study status
Completed

Last Edited
23/11/2020

Condition category
Oral Health

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

Plain English summary of protocol

Plain English summary as of 04/10/2018:
Background and study aims
Traditionally dentists encourage the practice of recommending 6 monthly dental check-ups. There is, however, little information to either support or refute this practice, or to advise either patients or dentists of the best dental recall interval for the maintenance of oral health.
The purpose of this study is to investigate and compare the effect of three different arrangements for the timing of dental check-up recall intervals on oral health.

Who can participate?
Adults 18 years of age or older who have visited their dentist in the previous 2 years and who receive all or part of their care as NHS patients.

What does the study involve?
Participants will be randomly allocated to one of three groups:
Group 1: a fixed, 6 month recall interval.
Group 2: an individualised, recall interval based on the patients risk of dental disease.
Group 3: a fixed, 24 month recall interval.

What are the possible benefits and risks of participating?
The results of this study will provide much needed evidence on the best time interval between dental check-ups in order to improve and maintain oral health.

Where is the study run from?
The study is being organised by staff at the INTERVAL Dental Recalls Trial Office at the Dental Health Services & Research Unit, School of Dentistry, University of Dundee. Research groups from NHS Education for Scotland, ACTA, the Universities of King's College London, Aberdeen, Edinburgh, Glasgow, Manchester, Birmingham, Leeds, Cardiff, St. Andrews and UCL are also involved. 50 dental practices were recruited (Scotland, England, Wales & Northern Ireland).

When is the study starting and how long is it expected to run for?
Phase 1, (feasibility study) started on 01/08/2009 and Phase 2 (main trial) started on 01/09/2011. Both Phase 1 and Phase 2 are included in the study which is expected to end 28/02/19.

Who is funding the study?
National Institute for Health Research, UK.

Who is the main contact?
Prof Jan Clarkson
j.e.clarkson@dundee.ac.uk

Previous plain English summary:
Background and study aims
Traditionally dentists encourage the practice of recommending 6 monthly dental check-ups. There is, however, little information to either support or refute this practice, or to advise either patients or dentists of the best dental recall interval for the maintenance of oral health. The purpose of this study is to investigate and compare the effect of three different arrangements for the timing of dental check-up recall intervals on oral health.

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When is the study starting and how long is it expected to run for?
The study started in September 2011 and is expected to run until February 2017.

Who is funding the study?
National Institute for Health Research, UK.

Who is the main contact?
Prof Nigel Pitts
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Study website
https://w3.abdn.ac.uk/hsru/interval/

Contact information

Type(s)

Scientific

Contact name
Prof Jan Clarkson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 06/35/99

Study information

Scientific Title
INTERVAL Dental Recalls Trial (Investigation of NICE Technologies for Enabling Risk-Variable-Adjusted-Length Dental Recalls Trial)

Acronym
INTERVAL

Study objectives
Study hypothesis as of 25/09/2018:
The principal research question is to investigate whether risk-based recall intervals or a fixed-period 24 month recall are more effective and cost effective in maintaining oral health than the traditional fixed-period 6 month recall.

Following successful delivery of a feasibility study from 01/08/2009 to 31/08/2011 and the award of new funding, the main trial is being undertaken during 01/09/2011 to 28/02/2017. HTA extension agreed, current end date is 28/02/19.

Previous study hypothesis:
The principal research question is to investigate whether risk-based recall intervals or a fixed-period 24 month recall are more effective and cost effective in maintaining oral health than the traditional fixed-period 6 month recall.

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Ethics approval required
Old ethics approval format

Ethics approval(s)
Transition to the main trial was approved by Fife and Forth Valley REC on 23/09/2011 (ref: 09 /S0501/1)

Study design
Multi-centre, parallel-group, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
https://w3.abdn.ac.uk/hsru/interval/Public/Download.aspx?ID=34

Health condition(s) or problem(s) studied
Oral health

Interventions
Interventions as of 25/09/2018:
In total, 2,288 participants will be recruited in order to retain 1,735 at 4 years.

This is a 4-year, multi-centre, parallel-group, randomised controlled comparison of three recall intervals: 6-month fixed-period recall, risk-based recall, and 24-month fixed-period recall.

Intervention group 1: 6-month, fixed period dental recall. Participants allocated to this group will attend their dentist at fixed, 6 monthly time intervals for a routine dental check-up. The content of this check-up will remain as per current practice. A recognised definition of a traditional NHS dental check-up is clinical examination, advice, charting including monitoring of periodontal status and report.

Intervention group 2: Risk-variable-adjusted-length recall interval. Participants allocated to the risk-based recall interval group will attend their dentist at time intervals determined by the

evidence-based process outlined in the 2004 National Institute for Health and Clinical Excellence (NICE) guideline on Dental Recall. The recommended stages in establishing the appropriate recall interval are:
a. Establishing the age range
b. Consideration of risk variables
c. Integration and prediction of recall need
d. Discussion
e. Review

Intervention group 3: 24-month, fixed period dental recall. Participants deemed suitable by their dentist for allocation to this group will attend at fixed, 24 monthly time intervals for a routine dental check-up. The content of this check-up is as described for group 1.

Details of Joint Principal Investigator:
Professor Nigel Pitts
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Tel: 020 7188 8094

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Details of Joint Principal Investigator:
Dr Jan Clarkson

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Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary outcome measures as of 25/09/2018:
1. Health related quality of life measured using an annual, self-administered patient questionnaire. Questionnaire will include a global assessment of quality of life using short form Oral Health Impact Profile, a standardised measure of health outcome (EQ-5D). After discussion and consideration a specially developed measure was not required. Removal of relevant text not done due to a clerical error.
2. Periodontal disease assessed by gingival inflammation/bleeding measured according to the Gingival Index of Loe.

All clinical outcomes are measured at 4 years by trained examiners who are blinded to allocation.

Current primary outcome measures as of 29/09/2011:
1. Health related quality of life measured using an annual, self-administered patient questionnaire. Questionnaire will include a global assessment of quality of life using short form Oral Health Impact Profile, a standardised measure of health outcome (EQ-5D) and a specially developed, context-specific, health related quality of life measure.
2. Periodontal disease assessed by gingival inflammation/bleeding measured according to the Gingival Index of Loe.

All clinical outcomes are measured at 4 years by trained examiners who are blinded to allocation.

Previous primary outcome measures included both current outcome measures plus the following point:
2. Caries experience assessed at both the enamel and dentine thresholds using the validated International Caries Detection and Assessment System (ICDAS). The ICDAS criteria measure both early and more advanced stages of caries. For early caries, ICDAS measures the surface changes and potential histological depth of carious lesions by relying on surface characteristics related to the optical properties of sound and demineralised enamel prior to cavitation. All surfaces of all teeth will be examined and the status of each recorded in terms of caries and restorations. This system allows the recording of both preventive and operative care needs.

This has been moved to secondary outcome measures following discussion between funders, peer reviewers and principal investigators and is reflected in the approved main trial protocol

Secondary outcome measures

Secondary outcome measures as of 25/09/2018:
1. Caries experience assessed at both the enamel and dentine thresholds using the validated International Caries Detection and Assessment System (ICDAS). The ICDAS criteria measure both early and more advanced stages of caries. For early caries, ICDAS measures the surface changes and potential histological depth of carious lesions by relying on surface characteristics related to the optical properties of sound and demineralised enamel prior to cavitation. All surfaces of all teeth included will be examined and the status of each recorded in terms of caries. This system allows the recording of both preventive and operative care needs.
2. Plaque measured according to the Silness and Loe Plaque Index, calculus measured according to the Ramfjord Calculus Index and a colour-coded UNC periodontal probe will be used to measure periodontal pocket depth and clinical attachment level. The assessments will be made at 4 years by trained examiners who are blinded to allocation. After discussion it was decided that calculus would be recorded as present or not and that plaque and clinical attachment level would not be measured. This is reflected in the approved main trial protocol.
3. Patient-centred outcomes including dental anxiety, oral health related knowledge, attitudes, and behaviours, use of and reason for use of dental services (including symptoms and pain), and satisfaction with care measured using annual, self-administered questionnaire. Total duration of follow-up: 4 years.
4. Dentist attitude towards the different recall strategies measured using a self-administered questionnaire at month 0 and at 4 years

Current secondary outcome measures as of 27/09/2011:

1. Caries experience assessed at both the enamel and dentine thresholds using the validated International Caries Detection and Assessment System (ICDAS). The ICDAS criteria measure both early and more advanced stages of caries. For early caries, ICDAS measures the surface changes and potential histological depth of carious lesions by relying on surface characteristics related to the optical properties of sound and demineralised enamel prior to cavitation. All surfaces of all teeth will be examined and the status of each recorded in terms of caries and restorations. This system allows the recording of both preventive and operative care needs.
2. Plaque measured according to the Silness and Loe Plaque Index, calculus measured according to the Ramfjord Calculus Index and a colour-coded UNC periodontal probe will be used to measure periodontal pocket depth and clinical attachment level. The assessments will be made at 4 years by trained examiners who are blinded to allocation.
3. Patient-centred outcomes including dental anxiety, oral health related knowledge, attitudes, and behaviours, use of and reason for use of dental services (including symptoms and pain), and satisfaction with care measured using annual, self-administered questionnaire. Total duration of follow-up: 4 years.
4. Dentist attitude towards the different recall strategies measured using a self-administered questionnaire at month 0 and at 4 years

Previous secondary outcome measures included points 2 to 4 only.

Overall study start date
01/08/2009

Completion date
28/02/2019

Eligibility

Key inclusion criteria
Adult patients 18 years of age or older who are dentate, have visited their dentist in the previous 2 years, and receive all or part of their dental care as an NHS patient.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2,288

Total final enrolment
2372

Key exclusion criteria
Patients for whom periodontal probing is contraindicated or who have a medical condition indicating increased risk of bleeding (e.g., history of bacterial endocarditis, bleeding disorder, immuno-compromised).

Date of first enrolment
27/07/2010

Date of final enrolment
31/07/2014

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Dental Health Services Research Unit
Dundee
United Kingdom
DD1 4HN

Sponsor information

Organisation
University of Dundee (UK)

Sponsor details
Research & Innovation Services
11 Perth Road
Dundee
Scotland
United Kingdom
DD1 4HN

Sponsor type
University/education

Website
http://www.dundee.ac.uk

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	07/08/2018	10/09/2019	Yes	No
Results article	results	01/11/2020	23/11/2020	Yes	No