

Is photographic evidence a valuable aide to oral hygiene advice in 9-16 year olds?

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/10/2014	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0043189395

Study information

Scientific Title

Study objectives

To find out whether giving patients photographic evidence of their own poor oral hygiene /appearance of teeth when they smile motivates 9-16 year olds to improve their tooth brushing and oral health behaviour.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Oral Health: Oral hygiene

Interventions

A randomised controlled trial with two study groups:

1. Group 1: standard intervention (control) including manual toothbrush and standardised oral and written tooth brushing instruction based on the bass technique
2. Group 2: as with standard intervention with the addition of standardised photographic evidence of the subjects oral health status and instructions how best to use this.

All paperwork to be used by subjects reviewed by focus group through PPI for B&D service.

Procedure:

1. Define whether patient fits inclusion criteria
2. Gain written photographic consent for inclusion in trial
3. Assign to group 1 or 2 in random fashion
4. Initial appointment: initial questionnaire (demographic data, i.e. age, sex, is appearance

important to you, etc.); measure modified plaque and bleeding indices (how much tartar and bleeding from teeth and gums). If assigned to group 2 take initial standard set of photos and give set plus instructions (to put them on bathroom mirror) to subject. If group 1 a single photograph of anterior view showing incisors, to both groups give written oral hygiene instructions.

5. Review at 6 weeks - measure plaque and bleeding indices and take new set of photos appropriate to group, and if group 2 give set to patient

6. Review at 12 weeks - measure plaque and bleeding indices and take final photos and give final questionnaire (how did they use the information given, what was most helpful)

Analysis:

1. For each subject analyse any changes in plaque and bleeding scores and for group 2 compare the standardised initial and review photos for both groups by measuring the change in gingival height from a fixed point on the lower central incisors (i.e., has there been any reduction in swelling to the gums) to give an accurate measure of actional improvements (rather than the kids just brushing hard before coming to the clinic) in oral hygiene. This latter measure will give significance to the results.

2. Maintain record of photographic costs and find information for similar volumes using alternatives, e.g. digital photography, i.e. is it financially viable to use photos for this purpose in clinics.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/12/2006

Completion date

01/07/2007

Eligibility

Key inclusion criteria

1. Patients with visible plaque (tartar) levels on three or more tooth surfaces (i.e., a minimum plaque score of 3)
2. Attending Barking and Dagenham Special Needs and Community Dental Service
3. Aged between 9 - 16 years
4. Who have the ability to brush their own teeth unsupervised
5. Have no conditions that would contraindicate measuring the bleeding from the gums

Participant type(s)

Patient

Age group

Child

Lower age limit

9 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

Both groups up to 30

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/12/2006

Date of final enrolment

01/07/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Upminster Dental Clinic

Upminster

United Kingdom

RM14 3DH

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall
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United Kingdom
SW1A 2NL
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Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Barking and Dagenham Primary Care Trust and Havering Primary Care Trust (UK)

Funder Name

Own account

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