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An investigation into a measure of oral cleanliness and its usefulness in motivating children towards improved oral hygiene

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/09/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/06/2011	**Condition category** Oral Health	[_] Individual participant data [_] 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
N0264192972

Study information

Scientific Title

Study objectives
Our aims in this study are to address firstly the reproducibility of the Grubby score and secondly whether it has a motivating effect on patients.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Oral Health: Oral hygiene

Interventions
The proposed study will take place at the Paediatric Department of the Dental Hospital, Bristol and will include children who come to the Hospital for tooth extraction under General Anaesthesia. These children attend on an initial visit for assessment and then, usually some 5 weeks later, for extractions. Parents will be informed that the investigators are trying to assess the usefulness of oral hygiene instruction in reducing dental plaque levels. Consent will be recorded.

In the first study, the grubby score of each child will be noted down twice: once before and once after they have been sent to the x-ray department, to determine reproducibility. The same assessment will be performed on the same visit by another clinician so as to compare results on the same child and to make conclusions about the inter- and intra-examiner reproducibility.

Children will be randomly separated into two groups.

In the first group the 'Grubby score' of the patients will be assessed by 'sweeping' the surfaces of the nominated teeth with a blunt dental instrument. The grubby score achieved will be revealed and oral hygiene instructions will be provided, tempered to their age and intellectual ability. 'Target' scores (a reduction of 50%) will be set to achieve by a subsequent visit.

For the second group, the Grubby score of the patients will be assessed. The grubby score achieved will not be revealed. Oral hygiene instructions will be provided, tempered to their age and intellectual ability. Target scores will not be set.

Both groups will be told that their tooth-brushing will be re-assessed at the subsequent appointment for general anaesthesia. At the appointment for general anaesthesia, the grubby score will be repeated and the 'test' (first group) told of their achievement in terms of their grubby score and the second group informed in general terms.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Changes in oral debris (cleanliness).

Secondary outcome measures
Inter- and intra-examiner variability.

Overall study start date
01/10/2006

Completion date
01/10/2007

Eligibility

Key inclusion criteria
1. Children aged between five years and six years
2. Ability to co-operate with oral examination
3. Ability to comprehend instructions in English
4. The presence of teeth at the recording sites

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
6 Years

Sex
Not Specified

Target number of participants
Approx 80 patients

Key exclusion criteria
1. Children aged outside five years and six years, 364 days
2. Inability to co-operate with oral examination
3. Inability to comprehend instructions in English
4. The absence of teeth at the recording sites

Date of first enrolment
01/10/2006

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
C/O Research and Effectiveness Department
Bristol
United Kingdom
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Sponsor information

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

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
United Bristol Healthcare NHS Trust

Funder Name
NHS R&D Support Funding

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