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

Submission date	Recruitment status	Prospectively registered
28/09/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/09/2007	Completed	Results
Last Edited	Condition category	Individual participant data
14/06/2011	Oral Health	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

Changes in oral debris (cleanliness).

Key secondary outcome(s))

Inter- and intra-examiner variability.

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 years

Upper age limit

6 years

Sex

Not Specified

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

United Kingdom

England

Study participating centre C/O Research and Effectiveness Department

Bristol United Kingdom BS2 8HW

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

United Bristol Healthcare NHS Trust

Funder Name

NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration