

The acceptability and effectiveness of a computer-based oral health intervention for children undergoing caries treatment under general anaesthesia

Submission date 24/06/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/08/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/03/2020	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

In the UK, an increasing number of children suffering from tooth decay are being treated under general anaesthesia in hospitals every year. In addition, reports have suggested that almost one quarter of these children end up needing the same treatment again despite proper examination and rigorous treatment. Dental problems is one of the most common reasons for young people being admitted to hospital in the UK. Treating tooth decay under general anaesthesia usually involves multiple tooth extractions and is both costly and distressing. It is also entirely preventable with good oral hygiene and by cutting down on sugary food and drinks. Research done by King's College London has shown that giving advice to children and their parents on how to prevent further tooth decay during the medical pre-assessment visit (a visit prior to the surgery to ensure the child is fit for it) might be considered both acceptable and helpful. Using interactive media as a teaching aid has been suggested by parents as something that would appeal to children. The aim of this study is to compare being given oral health advice through a computer interactive game with being given the same advice verbally by a dental nurse.

Who can participate?

Children between the ages of four and ten due to have tooth extractions under general anaesthesia, accompanied by their parents.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 are given advice on oral hygiene in the form of a computer game. Group 2 are given the same advice verbally from an oral hygiene trained dental nurse. Both groups also receive fluoride varnish treatment, which has been proven to provide extra protection against tooth decay when used in addition to daily brushing. All children and parents taking part are asked to fill in a questionnaire regarding their diet and dietary knowledge before and after being given advice. Children are also asked to take home tooth brushing and snack diaries to see how they look after their teeth.

What are the possible benefits and risks of participating?

A possible benefit of taking part is a greater knowledge of good oral hygiene. There are no anticipated risks. We will follow ethical and legal practice and all information about the participants will be handled in confidence and will remain anonymous throughout.

Where is the study run from?

Kings College Dental Institute (UK)

When is the study starting and how long is it expected to run for?

October 2013 to December 2014

Who is funding the study?

Kings College London (UK)

Who is the main contact?

Professor Marie Hosey

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The acceptability and effectiveness of a computer-based oral health intervention for children undergoing caries treatment under general anaesthesia: A randomized controlled trial

Study objectives

There is no difference in the acceptability or effectiveness of a computer-based oral health intervention and standard verbal advice delivered by a trained dental nurse.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London - Dulwich; 05/08/2013; ref. 11/LO/0220

Study design

Single-centre randomized single-blind controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Prevention of dental caries

Interventions

1. Intervention group (video game): receives oral health advice via a video game (delivered on an iPad), also receives fluoride varnish application.
2. Control group (verbal advice): receives oral health advice verbally from a trained dental nurse, also receives fluoride varnish application.

Both interventions (video game, verbal advice) will be applied only once, at the medical pre-assessment clinic prior to the child's general anaesthesia. A follow up appointment will be arranged for participants from both groups approximately three months after the surgery.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Acceptability of intervention: Parent and child satisfaction with the intervention as indicated using a Visual Analogue Scale (VAS), where 0 is not satisfied at all and 10 is very satisfied.
2. Child dietary knowledge: Measured by a Child picture Food Quiz at three points: Baseline Immediately post-intervention, and 3 months later.
3. Child dietary practices reported by parents: using the 'children dietary questionnaire' (CDQ) at baseline and after 3 months.
4. Child reported snack selection: measured by snack diaries given after intervention and returned on the day of general anaesthesia procedure.
5. Child reported Tooth brushing frequency: measured by tooth brushing diaries given after intervention and returned on the day of general anaesthesia procedure.

Secondary outcome measures

Childs acceptability of fluoride varnish: indicated using a Visual Analogue Scale (VAS). where 0 is not satisfied at all and 10 is very satisfied.

Overall study start date

01/10/2013

Completion date

31/12/2014

Eligibility

Key inclusion criteria

1. Scheduled for treatment of dental caries under general anaesthesia
2. Four to ten years old
3. Doesn't suffer from any learning difficulties or medical conditions complicating oral health status
4. An English speaker
5. Accompanied by a parent/guardian able to provide consent

Participant type(s)

Patient

Age group

Child

Lower age limit

4 Years

Upper age limit

10 Years

Sex

Both

Target number of participants

128 total, 64 in each group

Key exclusion criteria

1. Referred for treatment of other dental conditions.
2. Younger than four years or older than ten years.
3. Has a medical condition affecting oral health, or those with learning difficulties.
4. Doesn't speak English.
5. Accompanied by an adult that cannot give consent.
6. Parents/children that refuse to participate in the study.

Date of first enrolment

01/10/2013

Date of final enrolment

31/12/2014

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

King's College Dental Institute

London

United Kingdom

SE5 9RS

Sponsor information**Organisation**

Kings College London (UK)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

University/education

Funder Name

King's College London (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	28/05/2015		Yes	No
Results article	results	01/11/2017		Yes	No