ISRCTN18265148 https://doi.org/10.1186/ISRCTN18265148

Preparatory information for children undergoing general anaesthesia

Submission date 29/11/2013	**Recruitment status** No longer recruiting
Registration date 29/11/2013	**Overall study status** Completed
Last Edited 19/11/2018	**Condition category** Oral Health

✓ Retrospectively registered
✓ Protocol added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Marie Therese Hosey

ORCID ID
http://orcid.org/0000-0003-1178-4106

Contact details
Kings College Dental Institute
Bessemer Road
Denmark Hill
London
United Kingdom
SE5 9RS
-
m.t.hosey@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
10006

Study information

Scientific Title
Improving access to preparatory information for children undergoing general anaesthesia for surgical dental procedures and their families

Study hypothesis
Phase III evaluation will use a double-blind three-armed RCT design. The clinical trial will recruit up to 210 children and will compare the web-based version of the package against standard care and another non-medical game. Distress will be assessed through evaluation of the childs behaviour during the visit and parental reports of physical and psychological morbidity. The views of parents and children will be sought; the mode of usage of the web-based package will be automatically recorded and the impact on the service e.g. recovery time and throughput will be reported. At least 53 in each group will be required for 90% statistical power.

The Phase III study primary outcome measures: (1) patient experience: acceptance of anaesthetic induction; child co-operation/distress; reduction of peri- and post-operative morbidity; child and family satisfaction and (2) service improvement: anaesthetic time /improvement in throughput. Measures will be administered at baseline, at the time of the GA treatment visit and then at 48 hours and 1 week later.

Ethics approval required
Old ethics approval format

Ethics approval(s)
10/H0802/41

Study design
Randomised interventional double-blind three-armed trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

Condition

Topic: Oral and Gastrointestinal, Generic Health Relevance and Cross Cutting Themes; Subtopic: Oral and Gastrointestinal (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Oral & Dental, Anaesthetics

Interventions
The clinical trial will compare the web-based version of the package against standard care and another non-medical game.

Online serious game intervention will include: modelling appropriate behaviour, coping skill teaching, provision of information in a developmentally appropriate manner and parent involvement (how to help their child get the most out of the intervention and what they can do themselves to improve their childs GA experience).

Study Entry: Multiple Randomisations

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Blind observer VAS scores of behaviour at anaesthetic induction
2. Child cooperation and dist

Secondary outcome measures
Automatic recording of internet package usage will occur.

Overall study start date
04/07/2012

Overall study end date
31/12/2013

Eligibility

Participant inclusion criteria
1. Consent to participate
2. Literate in English
3. Own a PC with internet access
4. No previous experience of general anaesthesia
5. Target Gender: Male & Female; Upper Age Limit 7 years; Lower Age Limit 5 years

Participant type(s)
Patient

Age group
Child

Lower age limit

5 Years

Upper age limit
7 Years

Sex
Both

Target number of participants
Planned Sample Size: 210; UK Sample Size: 210; Description: Based on acceptance of anaesthetic induction measured using a Visual Analogue Scale

Participant exclusion criteria
1. Do not consent to participate
2. Prior experience of GA
3. No PC ownership
4. Child has learning disability

Recruitment start date
04/07/2012

Recruitment end date
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Kings College Dental Institute
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (UK)

Sponsor details
NICU, Denmark Hill
London

England
United Kingdom
SE5 9RS

Sponsor type
Hospital/treatment centre

Website
http://www.kch.nhs.uk/

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme Grant Codes: PB-PG-1208-17227

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	11/06/2014		Yes	No
Results article	results	07/09/2017		Yes	No
Results article	results	01/02/2018		Yes	No
Results article	results	01/11/2018		Yes	No
HRA research summary			28/06/2023	No	No