

Preparatory information for children undergoing general anaesthesia

Submission date 29/11/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 29/11/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/11/2018	Condition category Oral Health	<input type="checkbox"/> Individual participant data

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

10006

Study information

Scientific Title

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

Study objectives

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 child's 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

Health condition(s) or problem(s) studied

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 child's 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

Completion date

31/12/2013

Eligibility

Key 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

Key exclusion criteria

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

Date of first enrolment

04/07/2012

Date of final enrolment

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