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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

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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 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 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

Study type(s)
Other

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 childs GA experience).

Study Entry: Multiple Randomisations

Intervention Type

Other

Phase
Not Applicable

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

Key secondary outcome(s))
Automatic recording of internet package usage will occur.

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
7 years

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
King's College Hospital NHS Foundation Trust (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, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/09/2017		Yes	No
Results article	results	01/02/2018		Yes	No
Results article	results	01/11/2018		Yes	No
Protocol article	protocol	11/06/2014		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes