ISRCTN23410641 https://doi.org/10.1186/ISRCTN23410641

Assessing the effectiveness of the Little Journey app at reducing children's anxiety before surgery

Submission date
25/11/2019

Recruitment status
No longer recruiting

Registration date
28/02/2020

Overall study status
Completed

Last Edited
14/12/2021

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Having an operation is a daunting experience, especially as a child. Anxiety begins well before arriving in hospital and is exacerbated by new, unfamiliar environments and people. Researchers have developed a new technique to prepare children for an operation using a smartphone app that can be used at home before coming to the hospital. Children can use the app with a cardboard virtual reality headset to explore the hospital rooms they'll visit on the day of surgery and learn about what will happen from animated characters of staff. The aim of this study is to find out whether this new preparation tool reduces children's anxiety levels before an operation and improves their outcomes after surgery compared to the methods currently used.

Who can participate?
Children between the ages of 3-12, undergoing ambulatory surgery

What does the study involve?
Participants will be randomly allocated to one of two groups. Group 1 will be given a build-your-own virtual reality headset and code to use with the Little Journey app, which they can use in the weeks before their operation. Group 2 will be provided with a build-your-own virtual reality headset to use with a variety of free virtual reality apps. Children in both groups will receive exactly the same care on the day of the operation. On the morning of their surgery, the anaesthetist and surgeon looking after them will visit them on the ward and discuss what will happen. The child will be given a handheld tablet, like an iPad, to play with in the anaesthetic room to help with the 'going to sleep' process. Following their operation, the child will be taken to the recovery room until they are comfortable and awake enough to return to the ward. As part of the research, the researchers will observe the child's behaviours throughout the day of the operation, recording their anxiety levels on the ward before their operation and in the anaesthetic room. Parents are also asked to complete questionnaires assessing their anxiety levels in the pre-assessment clinic and following observation of the 'going to sleep' or induction of anaesthesia process. At the end of the day, before you go home, parents will be given a patient satisfaction survey to complete. Finally, the researchers will telephone and/or email to complete a final questionnaire assessment 2 and 4 weeks later. The child can keep the virtual

reality headset to use as they wish with the freely available virtual reality apps available on the app stores.

What are the possible benefits and risks of participating?
The researchers cannot promise the study will help but the information from this study will help improve the care provided to all children before an operation in the future. It is possible that use of the app could worsen the child's anxiety about the operation. However, the researchers believe this is very unlikely as the app has been developed based on the results of similar studies assessing the best ways to provide information to children before an operation and have received great feedback from children and their parents who have used the app. Potential side effects from using a virtual reality cardboard headset include dizziness, headaches, blurred vision and nausea/vomiting. Based on the pilot study data the researchers expect these to occur in less than 5% of cases and resolve immediately on stopping using the headset.

Where is the study run from?
1. University College London Hospitals NHS Foundation Trust (UK)
2. Plymouth Hospitals NHS Trust (UK)
3. NHS Greater Glasgow and Clyde (UK)
4. Leeds Teaching Hospitals NHS Trust (UK)
5. Barts Health NHS Trust (UK)
6. Guy's and St Thomas' NHS Foundation Trust (UK)
7. York Teaching Hospital NHS Foundation Trust (UK)
8. Brighton and Sussex University Hospitals NHS Trust (UK)
9. King's College Hospital NHS Foundation Trust (UK)
10. Royal United Hospitals Bath NHS Foundation Trust (UK)
11. University Hospitals Bristol NHS Foundation Trust (UK)
12. Nottingham University Hospitals NHS Trust (UK)
13. Manchester University NHS Foundation Trust (UK)
14. Medway NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2019 to July 2021

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Chris Evans
situ.littlejourney@ucl.ac.uk

Study website
https://www.ucl.ac.uk/surgery/research/surgical-interventional-trials-un

Contact information

Type(s)
Scientific

Contact name
Dr Chris Evans

Contact details
Student Investigator
Surgical & Interventional Trials Unit (SITU)
Division of Surgery & Interventional Science
Faculty of Medical Sciences
University College London
Charles Bell House (3rd Floor)
43-45 Foley Street
London
United Kingdom
W1W 7JN
+44 (0)20 7679 9280
situ.littlejourney@ucl.ac.uk

Type(s)
Scientific

Contact name
Prof Ramani Moonesinghe

Contact details
Chief Investigator
Surgical & Interventional Trials Unit (SITU)
University College London
Charles Bell House (3rd Floor)
43-45 Foley Street
London
United Kingdom
W1W 7JN
+44 (0)20 7679 9280
Situ.littlejourney@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
223644

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 41142, IRAS 223644

Study information

Scientific Title

A multi-site randomised controlled trial assessing the effectiveness of the Little Journey app at reducing peri-operative anxiety compared to standard care

Study objectives
This is a phase III multi-centre randomised controlled trial assessing the effectiveness of the Little Journey app: a pre-hospital psychological preparation tool designed for children undergoing ambulatory surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/05/2019, London - Surrey Borders Research Ethics Committee (Research Ethics Committee (REC) London Centre, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 972 2568; nrescommittee.london-surreyborders@nhs.net), REC ref: 19/LO/0255

Study design
Randomised; Interventional; Design type: Prevention, Education or Self-Management, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Peri-operative anxiety

Interventions
Little Journey is a multi-centre, assessor-blinded, two-armed, parallel-group, randomised controlled clinical trial of a virtual reality psychological preparation app in children aged 3-12 years old undergoing ambulatory surgery.

Following screening and recruitment to the trial at the pre-assessment clinic, children will be randomised through use of an online randomisation tool (Sealed Envelope) into either an intervention or control group, stratified by surgical specialty.

Standard care arm (Control):
Participants assigned to the standard care arm will receive standard care from the pre-assessment clinic until discharge. The definition of standard care at each trial site will be recorded through a questionnaire at the SIV, prior to commencement of recruitment to the trial. A typical preparatory pathway in most NHS hospitals would include: meeting a specialist nurse in the preoperative assessment clinic; a preoperative anaesthetic and surgical consultation; interaction with play specialists on the day of surgery; and distraction interventions such as hand-held tablets during the induction of anaesthesia. Participants can undergo either an inhalation or intravenous induction depending on the primary management plan of the anaesthetist in charge.

Participants in the standard care arm will also receive a flat-pack £1.30 virtual reality google cardboard headset. They can take the headset home with them, personalise and decorate it before using it with any of virtual reality apps available to download for free from the app stores.

Intervention arm:
Participants allocated to the intervention arm will receive the same peri-operative management as the standard care arm except for they will also receive an access code enabling them to use the Little Journey app in the weeks leading up to their operation. The researchers suggest the app is used at least once in the 1-2 weeks before surgery but can be used as frequently as the child and/or their parents or carers wish before the operation.

Trial Participant participation:
Patients screened by research staff as being suitable to participate in the research will be sent a patient information sheet at least 48 hours before their Pre-assessment clinic appointment. After undergoing the standard pre-assessment clinic appointment the child and their parents /carers will be approached by a member of research staff to discuss the study further. The child and parents will be given an opportunity to ask questions before, if they are happy to participate, signing a written consent form to participate in the study. The parents/carers will then be asked to complete a questionnaire ascertaining socio-demographic information (5-10 minutes) and a short question assessing parent anxiety levels (1 minute). During this time the research staff will also observe and score the child's anxiety level based on their behaviours (1 minute). Following this, participants will be randomised as described above into either the standard care or Little Journey app arms. An interval of between 2 weeks and 5 months can occur between the pre-assessment clinic and the day of surgery depending on clinical variables and local non-clinical factors.

On the day of the operation, participants will be approached on the morning of surgery. Parents /carers will be asked to complete an assessment of their satisfaction with the preparation information (1 minute) and children's behaviours will again be observed to assess their anxiety levels (1 minute). When ready for their operation, the research staff will observe the child's behaviour in the anaesthetic room, score the child's anxiety levels. Following observing the induction of anaesthesia, parents/carers will be asked to score their own level of anxiety about the operation repeating the assessment tool used at the pre-assessment clinic (1 minute). After the operation when the child has returned back to the ward/waiting area from the recovery room, prior to being discharged home, parents/carers will be asked to complete a questionnaire about the virtual reality headset and app (5-10 minutes) and a short assessment of their satisfaction with care (1 minute).

Following discharge home, parents/carers will be contacted by a member of research staff by telephone at 2 and 4 weeks after surgery to complete a questionnaire assessing the behaviour of their child (5 minutes). After the phone call at 4 weeks their participation in the trial finishes.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Child's anxiety levels measured using modified Yale Paediatric Anxiety Scale – Short form (m-YPAS-SF) at baseline at the pre-assessment clinic (timepoint 1), the ward (timepoint 2) and the anaesthetic room (timepoint 3)

Secondary outcome measures
1. Parent satisfaction with information, measured using a 100 mm Visual Analogue Scale (VAS-IS) on the morning of surgery at timepoint 2
2. Parental anxiety levels measured using Visual Analogue Scale - parent anxiety (VAS-PA) at the pre-assessment clinic (timepoint 1) and immediately prior to observation of the induction of anaesthesia (timepoint 3)
3. Children’s compliance during induction, measured using a 100 mm Visual Analogue Scale - distress (VAS-D) by the independent observer immediately following observing the induction of anaesthesia (timepoint 3)
4. Children’s distress during induction, measured using a 100 mm Visual Analogue Scale - compliance (VAS-C) by the independent observer immediately following observing the induction of anaesthesia (timepoint 3)
5. Parental satisfaction measured using a 100 mm Visual Analogue Scale (VAS-PS) performed by parents/carers at timepoint 5
6. Adverse psychological affects measured using Post-Hospital Behavioural Questionnaire (PHBQ-AS) via email and telephone consultation at 2 and 4 weeks after discharge (timepoint 6)
7. Number of days of work or school missed by the family after the operation due to any adverse behavioural effects, measured via email or telephone consultation at 2 weeks after surgery (timepoint 6)
8. The time taken (minutes) for the induction of anaesthesia, time spent in the recovery room and time to discharge, measured at timepoints 3, 4 and 5
9. Requirement for ward-based premedication to treat preoperative anxiety: the number of children who are given an anxiolytic premedication (name and dose) before anaesthesia, recorded at timepoint 3: anaesthetic room
10. Change in anaesthetic induction plan after child arrives in anaesthetic room: the number of children whose induction technique changes from the planned technique to the actual technique used. This can be from inhalation induction to Intravenous induction and vice versa, recorded at timepoint 3: anaesthetic room
11. Rates of failure to progress with surgery due to anxiety or distress: the number of children who have their surgery cancelled due to anxiety or distress, recorded at timepoint 3: anaesthetic room
12. Requirement for unexpected admission to hospital on the day of surgery: the number of children who are unexpectedly admitted to hospital overnight following surgery (timepoint 5)
13. Need for rescue analgesia in the recovery room: what analgesic medication (name and dose) is given in the recovery room (timepoint 4)
14. Need for rescue anti-emetics in the recovery room: what antiemetic medication (name and dose) is given in the recovery room (timepoint 4)
15. Use of the intervention and side-effects of virtual reality headsets, collected through in-app analytics and a short questionnaire performed on the day of surgery:
15.1. Number of times app used

15.2. Number of animations triggered
15.3. Timing of platform used before surgery
15.4. Prior to discharge home, parents/carers in both trial arms will be asked to complete a short questionnaire assessing if they have used the headset or Little Journey app, and reasons for not using the app. This questionnaire also assesses any side effects experienced when using the VR headset such as dizziness, headaches, blurred vision and if this prevented the participant using the intervention. Finally, the questionnaire assesses if the child/parent/guardian preferred using the application in 2D or 3D mode and the reasons for this.
16. Cost-effectiveness:
16.1. A surrogate marker of staffing costs will be calculated through the recording of time spent by staff in direct face-to-face interaction with participant's and their family. Staff costs will be calculated as per the mid-spine point of their current grade as stated by NHS Employers – agenda for change.
16.2. Equipment costs will be calculated from the number of individual items such as needles and syringes used - excluding surgical equipment used intra-operatively – at any time during their admission
16.3. Drug costs will be calculated based on the volume and dose of pharmacological agents used. , including the amount of volatile anaesthetic used which will be measured through weighing of the vaporiser pre- and post-use induction.
16.4. Additional costs affecting the hospital efficiency such as unplanned admissions, cancellations, delayed discharges or Do Not Attends will be documented and costed for appropriately
16.5. Social-economic costs will be calculated through the number of days of work missed by parents/carers at day 14 and 28

Overall study start date
01/09/2016

Completion date
31/07/2021

Eligibility

Key inclusion criteria
1. Children aged between 3-12 years of age on the date of parental consent to participate in the trial
2. Those undergoing surgery planned to be conducted as a day-case (surgery is defined as any therapeutic procedure taking place under the care of an anaesthetist and surgeon or dentist)
3. Requiring general anaesthetic (must be their first general anaesthetic)
4. American Society of Anesthetists physical status class I-III
Class I: A normal healthy patient
Class II: A patient with mild systemic disease
Class III: A patient with severe systemic disease
5. Both child and parent able to speak/understand one of the languages available on the app (these languages are: English, Polish, Urdu, Arabic, Bengali)

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
Planned Sample Size: 304; UK Sample Size: 304

Key exclusion criteria
1. Children aged less than 3 years of age or more than 12 years' old on the date of parental consent
2. Any child and/or parent that refuses to be part of the study
3. Patients and parents who do not speak one of the languages which are available on the app
4. American Society of Anesthetists physical status class IV-VI
Class IV: A patient with severe systemic disease that is a constant threat to life
Class V: A moribund patient who is not expected to survive without the operation
5. Children undergoing diagnostic procedures (e.g. scans, cardiac catheterisation)
6. Any child with a visual or hearing impairments significant enough to prevent use of the intervention as decided on case-by-case basis

Date of first enrolment
09/09/2019

Date of final enrolment
31/07/2020

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Plymouth Hospitals NHS Trust
Derriford Hospital
Derriford Road
Plymouth
United Kingdom
PL6 8DH

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Trust Offices
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
York Teaching Hospital NHS Foundation Trust
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
Royal Sussex County Hospital
Eastern Road
Brighton
United Kingdom
BN2 5BE

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
University Hospitals Bristol NHS Foundation Trust
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters

Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Medway NHS Foundation Trust
Medway Maritime Hospital
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Sponsor information

Organisation
University College London

Sponsor details
c/o Miss Nikkayla Dixon
Joint Research Office
149 Tottenham Court Road
London
England
United Kingdom
W1T 7DN
+44 (0)2034475274
uclh.randd@nhs.net

Sponsor type
University/education

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0317-20025

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Conference presentation
3. Publication on website
4. The results will form part of Dr Chris Evans PhD thesis
5. The researchers are in the process of submitting their protocol and SAP for publication

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No