ISRCTN11421435 https://doi.org/10.1186/ISRCTN11421435

The effectiveness of therapeutic play intervention on outcomes of children undergoing inpatient elective surgery

Submission date
10/10/2014

Recruitment status
No longer recruiting

Registration date
23/10/2014

Overall study status
Completed

Last Edited
29/03/2016

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Children undergoing inpatient elective surgeries (surgery in hospital that has been arranged in advance rather than medical emergencies) often feel stressed and anxious. If the child feels very anxious, it can affect their ability to cope with surgery, make them behave uncooperatively towards healthcare providers and affect how well they recover afterwards. They can become emotional, crying and protesting loudly as they are being anaesthetised. The pain experienced after surgery can also feel worse if the child feels anxious about it. Parents can also experience a considerable amount of anxiety when their child has an operation and if a child senses a parents anxiety, it can make their own anxiety worse. It is therefore important to find a way (intervention) that will ease the anxiety felt by both the parents and the child in order to make the experience less stressful. Research has shown than therapeutic play can reduce the amount of anxiety felt by children in hospital, but there have not been many studies yet that have explored how therapeutic play might reduce anxiety in children about to have elective surgery. The results from the studies that have taken place have been inconsistent in terms of whether either the childs anxiety, behaviour and pain or their parents anxiety have been improved though therapeutic play. In addition to this, factors such as the types of surgery performed or pain medication given were not controlled in any of them. Here, we are going to perform a rigorous, experimental study to examine the effects of a therapeutic play intervention on children about to have inpatient elective surgery and their parents while controlling for possible confounding factors.

Who can participate?
Children aged between 6-14 years undergoing inpatient elective surgery in a public hospital and their parents.

What does the study involve?
Participants (child and parents) are randomly allocated into one of two groups. Those in group 1 are assigned to a control group and are given routine care. Those in group 2 are assigned to the experimental group and are given routine care and a 1 hour therapeutic play intervention. This includes watching a video, looking at photos of an operating theatre and a demonstration of

what happens using a doll. For both groups, the childs feeling of anxiety, how they behave and the pain they experience after the operation is assessed 3-7 days before the operation, on the day of the surgery and around 24 hours after the operation. The parents feeling of anxiety is measured at the same time.

What are the possible benefits and risks of participating?
There is no risk to participating in this study. The only inconvenience will be the time spent filling in three questionnaire surveys and the one-hour therapeutic play intervention (experimental group only).

Where is the study run from?
KK Women and Children Hospital (Singapore)

When is the study starting and how long is it expected to run for?
November 2011 to October 2014

Who is funding the study?
Ministry of Health, National Medical Research Council New Investigator Grant 2011 (Singapore)

Who is the main contact?
Dr He Hong-Gu
nurhhg@nus.edu.sg

Contact information

Type(s)
Scientific

Contact name
Dr Hong-Gu He

Contact details
Alice Lee Centre for Nursing Studies
Yong Loo Lin School of Medicine
National University of Singapore
Level 2, Clinical Research Centre
Block MD11, 10 Medical Drive
Singapore
Singapore
117597
+65 (0) 6516 7448
nurhhg@nus.edu.sg

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NMRC/NIG/1056/2011

Study information

Scientific Title
The effectiveness of therapeutic play intervention on outcomes of children undergoing inpatient elective surgery: a randomized control trial

Study objectives
1. Children in the experimental group will report significantly lower levels of pre- and post-operative anxiety, fewer negative emotion manifestations before the anesthesia induction and less postoperative pain than those in the control group
2. Parents with a child in the experimental group will report significantly lower levels of anxiety (before and after their childs operation) than those in the control group
3. There will be significantly positive correlation among childrens anxiety level, emotional manifestation, and postoperative pain
4. There will be significantly positive correlation between childrens and their parents anxiety level

Ethics approval required
Old ethics approval format

Ethics approval(s)
SingHealth Centralized Institutional Review Board (CIRB), ref: 2011/734/A

Study design
Randomized controlled two-group pretest and repeated post-tests single-blind experimental design

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Perioperative care

Interventions

Eligible participants (child and his/her parent in dyad) will be randomly assigned into either a control group (receiving routine care) or an experimental group (receiving 1-hour therapeutic play intervention plus routine care) by the research randomizer. A single-blind technique will be adopted, where a research assistant, who will be responsible for data collection (e.g. observation of emotional behaviours by Childrens Emotional Manifestation Scale), will be not aware of the treatment allocation of the participants.

The intervention group will be provided a therapeutic play intervention which includes watching a video entitled 'Preparing for your operation' at the participating hospital, viewing photos of operating theatre environment and equipment, doll demonstration of pre-operation procedures as well as anaesthesia induction to the child and his/her parent (e.g., obtaining vital signs, cardiac monitoring, anaesthesia, and intravenous therapy), and returned demonstration.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. Childrens perioperative anxiety: measured by the State Anxiety Scale for Children (SAS-C) at baseline (3-7 days before operation), on the surgery day, and around 24 hours after the operation
2. Negative emotional manifestations: measured by the Childrens Emotional Manifestation Scale (CEMS) before the induction of anaesthesia
3. Postoperative pain: measured by the Numeric Rating Scale (NRS) around 24 hours after the operation

Secondary outcome measures
Parents perioperative anxiety: measured by the State Anxiety Scale for Adults (SAS-A) at baseline (3-7 days before operation), on the surgery day, and around 24 hours after the operation

Overall study start date
01/11/2011

Completion date
30/10/2014

Eligibility

Key inclusion criteria
Children:
1. Age between 6 and 14 years old
2. Will undergo an inpatient elective surgery
3. Able to communicate verbally and be literate in either English or Chinese
4. Are accompanied by their parents (either mother or father or both) during the perioperative period

Parents:
1. Main caregiver of the child who meets the inclusion criteria
2. Able to communicate verbally and be literate in either English or Chinese

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
106 pairs of parents and their 6-14-year-old children who undergo inpatient elective surgery

Key exclusion criteria
Children:
1. Having past experience of surgery
2. Having cognitive and learning disabilities identified from their medical records
3. Having a chronic illness and/or pain that requires special medical care

Parents:
1. Guardians of the child
2. Those who have past experiences of their child undergoing surgery

Date of first enrolment
01/11/2011

Date of final enrolment
30/10/2014

Locations

Countries of recruitment
Singapore

Study participating centre
National University of Singapore
Singapore
Singapore
117597

Sponsor information

Organisation
Ministry of Health (Singapore)

Sponsor details
11 Biopolis Way Helios
#09-10/11
Singapore
Singapore
138667
+65 (0) 6325 8130
moh_nmrc@moh.gov.sg

Sponsor type
Government

Website
http://www.nmrc.gov.sg/content/nmrc_internet/home.html

ROR
https://ror.org/00mrhvv69

Funder(s)

Funder type
Government

Funder Name
Ministry of Health, National Medical Research Council New Investigator Grant 2011 (Singapore) (Award No.: NMRC/NIG/1056/2011)

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	01/02/2014	Yes	No
Results article	results	01/05/2015	Yes	No
Results article	results	01/07/2015	Yes	No