

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

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<b>Registration date</b> 23/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/03/2016	<b>Condition category</b> Surgery	<input type="checkbox"/> 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 that 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 child's anxiety, behaviour and pain or their parents anxiety have been improved through 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 child's 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 parent's 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

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## Contact information

### Type(s)

Scientific

### Contact name

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## 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 child's operation) than those in the control group
3. There will be significantly positive correlation among children's anxiety level, emotional manifestation, and postoperative pain
4. There will be significantly positive correlation between children's 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**

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**Sponsor type**

Government

**Website**

[http://www.nmrc.gov.sg/content/nmrc\\_internet/home.html](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?
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<a href="#">Protocol article</a>	protocol	01/02/2014	Yes	No
<a href="#">Results article</a>	results	01/05/2015	Yes	No
<a href="#">Results article</a>	results	01/07/2015	Yes	No