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The effectiveness of an educational intervention on the outcomes of parents and their children who undergo inpatient elective surgery

Submission date
10/02/2014

Recruitment status
No longer recruiting

Registration date
11/03/2014

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Inadequate pain management after an operation is a major issue due to the heavy workload of nurses. Involving parents in managing their childs postoperative pain has benefits for both the child and their parents. However, this requires parents to be knowledgeable about pain and pain reduction strategies that could support their child. Previous studies have shown that parents often experience a lack of knowledge of pain relief strategies and misconceptions regarding pain medication. Education is regarded as one of the most important strategies to change a persons knowledge, attitudes, and behaviour. However, only limited studies have reported the usefulness of providing education, information and coping skills training to parents in changing their knowledge level, attitudes, and behaviour towards pain management. No previous studies have been conducted to find out the effectiveness of an educational intervention (using a parent pain management education booklet in combination with a video, with or without face-to-face teaching), to improve parental knowledge, attitudes and pain management practices, in using pain medication and non-drug-related methods for their children who undergo a surgery in Singapore. This study aims to develop a pain management educational program for parents and to examine the direct effects of the educational intervention on various factors related to pain management. The study will also analyse pain management-related costs.

Who can participate?
162 pairs of parents and their 6-14-year-old children undergoing inpatient elective surgery in the participating hospital can take part in this study.

What does the study involve?
Parents will be randomly allocated to one of three groups. Intervention group 1 will receive routine care plus a booklet and video with one hour of face-to-face teaching of the following contents to parents with the help of the booklet and video: the cause of pain, a childs reaction, pain assessment and management by using pain medications and non-pharmacological pain relief methods. Intervention group 2 will receive routine care plus the booklet and video without

face-to-face teaching. The control group will only receive routine care. The routine care (pre-operation pain education to parents) includes the leaflet about general pain management to their children. The change of parents knowledge and attitude about pain and pain management and their use of strategies for their childs postoperative pain management, as well as childrens postoperative pain intensity and their satisfaction with pain management, and parents satisfaction with their childrens pain management will be measured at the start and at 6, 12 and 24 hours after surgery. Data will be collected by a trained research assistant.

What are the possible benefits and risks of participating?
Participants in the intervention groups will receive an educational intervention. Information obtained from this study may benefit parents to improve their knowledge, attitude and behaviour related to pain management, and may therefore benefit their children. There is no risk or any discomfort for participants in this study. The only inconvenience will be the time spent filling in a questionnaire and receiving one hour face-to-face teaching.

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?
The study started in September 2013 and will run for 2 years.

Who is funding the study?
Ministry of Health, Singapore.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HSRG11MAY022

Study information

Scientific Title
The effectiveness of an educational intervention on the outcomes of parents and their children who undergo inpatient elective surgery: a randomized controlled trial

Study objectives
The hypotheses of this study were set as follows:
1. When compared with the control group, parents in the intervention groups who receive the educational intervention (with or without face-to-face teaching) will report a significantly higher level of knowledge and more positive attitudes related to pain medication and non-pharmacological methods; use more pain relief strategies for their children with a significant difference; report a significantly lower level of postoperative pain of their children; and report a significantly higher satisfaction level with their childrens postoperative pain management.
2. Children whose parents are in the intervention groups will report a significantly lower level of postoperative pain intensity and significantly higher satisfaction level with pain management.
3. There is a reduction of pain management related costs in the intervention groups than in the control group.
4. There is no difference between the two intervention groups regarding the efficacy of the educational intervention on the primary and secondary outcomes as well as pain management related costs.
5. There is a significant correlation in pain scores between the Numerical Rating Scale (NRS) and the Tong Numerical Rating Scale (TNRS) and a significant correlation in pain scores between test and retest by using the TNRS with 15 minutes interval.

Ethics approval required
Old ethics approval format

Ethics approval(s)
SingHealth Centralized Institutional Review Board (CIRB), 14/01/2013, Ref: 2013/016/A

Study design
Randomized controlled three-group pretest and repeated posttests 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
Parents and their children in all three groups will receive routine preparation of surgery provided by the participating hospital in this study. Parents and their children who are assigned to the control group will receive the routine preparation for surgery only. Parents and their children who are assigned to intervention group 1 will receive one-hour individual face-to-face teaching with the help of a booklet and video regarding pain assessment and pain management, such as pain medication and non-pharmological methods (e.g., deep breathing, massage and distraction) for pain management. Parents and their children who are assigned to intervention group 2 will receive the booklet and video regarding pain assessment and pain management (the same as intervention group 1) for self-learning.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
The primary outcome measures are parents knowledge, attitude and behaviour related to pain management. The instruments used to measure these outcomes are described below.

1. Pain Management Knowledge and Attitudes (PMKA) questionnaire for parents will be used in this study to measure parents' knowledge and attitudes toward their children's postoperative pain and pain management. The PMKA consists of two sections which are answered on a five-point Likert Scale. The first section comprises of five questions measuring parental perceived adequacy of knowledge related to their child's postoperative pain and pain management. The second section comprises of seven questions measuring parental attitudes toward their child's postoperative pain and pain management using a five-point Likert Scale. An additional set of five questions in the second section seeks to understand parents attitudes towards pain medication. The scale indicated a good validity of scale-content validity index at 0.85. Measured at baseline (around 7-10 days before the operation) and around 24 hours after the operation.
2. A modified Parents Use of Pain Relief Strategies (PUPRS) questionnaire for parents (17 items) will be used to measure parents use of different pain relief strategies for their childs pain management. The PUPRS indicated good internal consistency with Cronbachs alpha values of 0.93. Measured at around 24 hours after the operation.

Secondary outcome measures
The secondary outcome measures are childrens postoperative pain intensity and their satisfaction with pain management, their parents satisfaction with their childrens pain

management, and pain management related costs as well as the validity and reliability of the Tong Numerical Rating Scale (TNRS). The instruments used to measure these secondary outcomes are described below:

1. A 10-point Numerical Rating Scale (NRS) and Tong Numerical Rating Scale (TNRS) will be used to assess childrens postoperative pain intensity by children and their parents. The NRS for pain is a one-item scale that measures pain intensity on a horizontal line from 0 (no pain) to 10 (worst imaginable pain). The TNRS is a newly developed pain scale which combines a Numerical Rating Scale from 0 (no pain) to 10 (extreme pain) with the size of cartoon Tong to show pain intensity for children. The participants will be asked to mark a point above the number that most represented their pain intensity during the interview on the NRS and TNRS, respectively, with a 15-minute interval between the usages of the two scales to avoid any possible contamination of the two scales. In addition, the two scales will be randomly selected as priority sequence for each participant. The concurrent validity and test-retest reliability of TRNS will be tested in the pilot study. The NRS will also be used as a gold standard to test concurrent validity of TNRS in this study. The NRS will be used at around 6, 12, and 24 hours after the operation. The TNRS will be used at around 24 hours after the operation. For the first 30 participants in this study, test-retest of TNRS will be conducted at around 24 hours after the operation. Thus, the concurrent validity of the TNRS will be calculated with the NRS and test-retest reliability of the TNRS will also be calculated.
2. A 6-point Ordinal Descriptive Scale (ODS) for assessing satisfaction with postoperative pain management of children (1 item) and their parents (1 item) will be used to assess their self-reported level of satisfaction with postoperative pain management. Measured at around 24 hours after the operation.
3. Pain management related cost evaluation during hospitalization and intervention related cost (for researcher use) will be used for assessing the pain medication bill size during hospitalization, and the costs of the intervention, such as the costs of booklet and video, telephone calls, and time for face-to-face teaching. Pain management related cost evaluation within 2 weeks after discharge (for parents use) will be used to assess the costs due to postoperative pain within 2 weeks after discharge from the KKH, such as the severity of their childs pain, whether they visit GPs and/or the emergency department, strategies used for pain relief, and costs before and after subsidy within 2 weeks after discharge from hospital due to postoperative pain. Calculated during hospitalization and 2 weeks after discharge from hospital.

Overall study start date
01/09/2013

Completion date
31/12/2015

Eligibility

Key inclusion criteria
The inclusion criteria for children include:
1. Age between 6 and 14 years old
2. Is scheduled for an elective surgery in the participating wards
3. Will be hospitalised for at least 1 day postoperatively
4. Is able to speak English or Chinese (Mandarin)

The inclusion criteria for parents include:
1. Main caregiver of the child who meets the inclusion criteria
2. Able to communicate and read in English or Chinese (Mandarin)

Participant type(s)
Patient

Age group
Other

Sex
Both

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

Total final enrolment
152

Key exclusion criteria
The exclusion criteria for children include:
1. Having cognitive and learning disabilities identified from their medical records
2. Having a chronic pain related condition

The exclusion criteria for parents include:
1. Guardians of the child
2. Not the main caregiver of the child in the hospital

Date of first enrolment
01/09/2013

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Singapore

Study participating centre
Level 2
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117597

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Funder(s)

Funder type
Government

Funder Name
Ministry of Health (Singapore), Award No.: HSRG11MAY022

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?
Results article	results	01/07/2018	17/12/2020	Yes	No