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Effects of therapeutic play on children undergoing cast-removal procedures: a randomised controlled trial

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Complete List of Authors:	Wong, Cho Lee; The Chinese University of Hong Kong, Faculty of Medicine, The Nethersole School of Nursing Ip, Wan Yim; The Chinese University of Hong Kong, Faculty of Medicine, The Nethersole School of Nursing Kwok, Blondi Ming Chau; Playright Children's Play Association Choi, Kai Chow; The Chinese University of Hong Kong, Faculty of Medicine, The Nethersole School of Nursing Ng, Bobby King Wah; The Chinese University of Hong Kong, Faculty of Medicine, Department of Orthopaedics & Traumatology Chan, Carmen Wing Han; The Chiniese University of Hong Kong, Faculty of Medicine, The Nethersole School of Nursing
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Authors:

Wong CL, Ip WY, Kwok BMC, Choi KC, Ng BKW, Chan CWH.

Authors' information:

Correspondence to CL Wong:

Cho Lee Wong

PhD, RN

Assistant Professor

The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China

Room 824, Esther Lee Building, The Chinese University of Hong Kong, Hong Kong.

Telephone number: (852) 3943 8166

Fax number: (852) 2603 5269

Email: jojowong@cuhk.edu.hk

Wan Yim Ip

PhD, RN

Associate Professor (Retired)

The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China

Email: wanyimip@cuhk.edu.hk

Kwok Blondi Ming Chau

BN, RN

Manager (Community & Hospital)

Playright Children's Play Association, Hong Kong, China

Email: blondi@playright.org.hk

Kai Chow Choi

PhD

Senior Research Fellow

The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China

Email: kchoi@cuhk.edu.hk

Bobby King Wah Ng

M.D.

Clinical Professional Consultant of Orthopaedics & Traumatology

Department of Orthopaedics & Traumatology, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China

Email: bobng@ort.cuhk.edu.hk

Carmen Wing Han Chan

PhD, RN

Vice-Director of Education / Professor

The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China

Email: whchan@cuhk.edu.hk

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Abstract

Objectives: To examine (i) the effectiveness of therapeutic play in reducing anxiety and negative emotional manifestations among children undergoing cast-removal procedures; (ii) the satisfaction of parents and cast technicians with cast-removal procedures.

Design: A randomised controlled trial.

Setting: An orthopaedic outpatient department of a regional teaching hospital in Hong Kong.

Participants: Children (n=208) aged 3-12 undergoing cast removal procedure were invited to participate.

Interventions: Eligible children were randomly allocated to either the intervention (n=103) or control group (n=105). The intervention group received therapeutic play intervention, whereas the control group received standard care only. Participants were assessed on three occasions: before, during, and after completion of the cast removal procedure.

Outcome measures: Children's anxiety level, emotional manifestation, and heart rate. The satisfaction ratings of parents and cast technicians with respect to therapeutic play intervention were also examined.

Results: Children aged 3-8 in the intervention group demonstrated a statistically significant reduction in anxiety levels ($p=0.01$) and exhibited fewer negative emotional manifestations ($p<0.001$) than the control group. Parents and technicians in the intervention group also reported a higher level of satisfaction ($p<0.001$) with the procedures.

Conclusion: Therapeutic play effectively reduces anxiety and negative emotional manifestations among children undergoing cast-removal procedures. The findings highlight the importance of integrating therapeutic play into standard care.

Trial Registration: Centre for Clinical Research and Biostatistics: CUHK_CCT00465.

Strengths and limitations of this study:

- This study was one of the first randomised controlled trial to examine the effects of therapeutic play on children undergo cast-removal procedures, building the evidence base of therapeutic play.
- A limitation was recruiting children from a single clinical setting so that the generalisability of the findings may be restricted.
- The strength of this study included employing both subjective and objective outcome measures to evaluate the impact of therapeutic play on the psychological state of a child.

Introduction

It is common for children to display stressed behaviour in clinical settings even during painless medical procedures such as cast removal.[1 2] The original injuries sustained by the children, added to the unfamiliar environment and the equipment used during the procedures, are likely to provoke anxiety and fear in children of any age. The psychological burden on children not only makes the procedures difficult to perform effectively and efficiently, but may also impose medical risks.[1 3] Moreover, anxiety in the children also reduces parents' satisfaction with the care provided.[4] Various strategies such as the use of ear protection or musical lullabies have been used but have not proved very effective.[5 6] Other interventions to reduce anxiety levels in children coping with cast removal (CR) procedures should be explored.

Therapeutic play is a set of structured activities designed according to the subject's age, cognitive development and health-related issues, to promote emotional and physical well-being in hospitalised children.[7] Li and colleagues suggested that hospitalised children who engaged in therapeutic play exhibited fewer negative emotions and experienced lower levels of anxiety than those did not.[8] A recent systematic review of 14 articles found that therapeutic play was commonly employed for children undergoing invasive procedures, such elective surgery, vaccination, blood collection or dental treatment in in-patient settings, with positive changes in the behaviour of those who participated in play sessions and a reduction in their anxieties.[9] However, some of these studies were limited by the lack of random assignment of subjects into intervention or control groups. Besides, the efficacy of therapeutic play interventions is yet to be determined, as the studies reported were mainly based on clinical observation and most of the play manuals, which should have set out specific procedures to improve fidelity, were not fully described.[10-12] Objective studies to gather data on the scope of procedures are clearly necessary.

Moreover, the beneficial effects of therapeutic play on institutions or care providers were seldom explored.

Our literature search revealed no reports of prospective and randomised controlled studies on therapeutic play among children undergoing cast-removal procedures. The comprehensive value of therapeutic play in paediatric orthopaedic cast rooms - in their impact on the children, parents and medical institution as a whole - remains largely unexplored in the literature. This study aimed to examine the effectiveness of therapeutic play in reducing anxiety and negative emotional manifestations among children undergoing cast-removal procedures. The satisfaction ratings of parents and cast technicians in respect of the cast-removal procedures were also to be examined.

Theoretical Framework

Lazarus and Folkman's theory of stress and coping theory was used to guide this trial.[13] They suggest that stress is a relationship between a person and the environment that the person finds taxing or exceeding resources. It is well known that cast-removal procedures is stressful for children.[1,2] Children likely feel stress and anxiety if they perceived a lack of control over the medical procedure.[8] Therapeutic play works by helping children to prepare for the procedure and thereby assist them to regain a sense of self-control to cope with the procedure.[13, 14] It is reasoned that children undergoing therapeutic play intervention will be more likely to cope with cast removal procedures and feel less stress and anxiety.

Methods

Design

A two-arm parallel randomised controlled trial was employed.

Setting

The study was conducted in the orthopaedic outpatient department (OPD) of a regional teaching hospital in Hong Kong, where the OPD cast room performs approximately 20 CR procedures monthly. The standard regimen in this OPD did not include therapeutic play intervention.

Participants

Children

Children and their accompanying parents who were waiting for the cast room procedure were invited to participate in the study if: (i) the child was 3–12 years of age; and (ii) the parents were able to speak Cantonese and read Chinese. Children were excluded if they: (i) had had a cast removed within the previous 3 months; or (ii) had neurological or developmental problems as shown on the medical record.

The rationale for selecting 3–12 year olds was that the number of children having cast room procedure within this age range in Hong Kong was higher than for other age groups. In fact, according to Piaget's (1963) theory of cognitive development, children from 3-7 belong to the same pre-operational stage, while those between 8 -12 belong to the concrete operational stage.[15] Children in the same age group will be at the same stage of psychosocial development.[16]

The sample size of the study was determined to detect an effect size of Cohen's d =0.6 between the intervention and control groups with reference to previous therapeutic play studies.[17-18] Forty-four subjects in each group were sufficient to detect an effect of 0.6 with 80%

power at 5% level of significance. Taking into account of up to a 20% attrition rate and stratified the study by age, 53 children each would be recruited for the intervention and control groups per stratum by age (3–7 & 8–12 years).

Accompany parents and cast technicians

All accompany parents and cast technicians involved in the cast-removal procedures were invited to assess their satisfaction for the procedures.

Randomisation

Eligible children undergoing the CR procedure were randomly allocated to the intervention or control groups in a 1:1 ratio. Randomisation were stratified by the two age groups, 3–7 and 8–12 years. Serially numbered opaque sealed envelopes containing the grouping identifier (intervention or control) for each age group were prepared in advance by an independent statistician using computer-generated random codes. The group allocation of the children recruited was assigned according to their ages and sequence of enrolment in the study, and the grouping identifier contained in the corresponding numbered envelopes.

Control Group: Standard Care

Participants in the control group received standard care without therapeutic play intervention. Standard care included the nurse explaining why and what would be done and saying comforting and supportive words during the procedures.

Intervention Group: Therapeutic Play

In addition to the standard care, children in the intervention group also received therapeutic play intervention. The interventions were conducted by the hospital play specialist (HPS). To ensure therapeutic play interventions were provided according to the children's needs and psycho-cognitive development,[15-16] the research team met with the HPS to set up the research protocol (supplementary file). The content of the therapeutic play had two main components: preparation and distraction forms of play.[19] The duration of intervention was about 30 minutes.

Preparation play

Preparation play was conducted before the CR procedure a. A demonstration of the CR procedure was conducted using a doll. The demonstration included:

- Showing a dummy circular-saw cast cutter with appropriate sound effects
- Playing with a doll and explaining how the cast was cut open by the circular saw
- Reassuring children that the saw would not cut their skin if they followed the instruction not to move
- Explaining that, when the cast was cut, the child might feel vibration or tingling, notice a certain warmth and see chalky dust flying
- Describing the use of spreaders and scissors to finish removing the cast
- Explaining how, after the cast was open, the skin might appear scaly and dirty and the limb feel a little stiff when first moved; also that the arm or leg might seem light because the cast had been heavy.

During the demonstration, the children were asked to touch and play with the doll and material, and role-play how they would respond to the procedure after the demonstration. The preparation play usually took 10–15 minutes to complete.

Distraction play

Throughout the CR procedure, support was given to children by introducing distraction play. The aim of the distraction play was to divert children's attention away from the medical procedure. Methods of distraction included visual or auditory distraction, deep breathing exercises, tactile stimulation, counting/singing or other verbal interaction. The choice of method depended on the children's choices.[20] The parents' presence and involvement were supported, and the children were praised for any act of successful self-control. The conclusion of the procedure was indicated by offering the children a reward (e.g. stickers).

Outcome measures

Visual analogue scale

A visual analogue scale (VAS) was used to assess the anxiety levels of children between 3 and 7. The VAS consists of a 10-cm horizontal line anchored by the words 'not worried' (low score) at one end and 'very worried' (high score) at the other, with drawings of different facial expressions spaced along the line. Children aged between 3-7 were asked to indicate their levels of anxiety by moving a pointer over the line. As children of 3 or 4 may have limited verbal expression abilities, their parents were also invited to rate the anxiety levels of their children. The VAS is a widely used scale which has been found to be a reliable and valid tool for measuring children's subjective feelings.[21]

The short-form Chinese version of the State Anxiety Scale for Children (CSAS-C)

The CSAS-C is a 10-item self-report scale measuring the anxiety levels of children aged 8-12 in busy clinical setting.[17] It is a three-point Likert scale with total scores ranging from 10 to 30,

with higher scores indicating greater anxiety levels.[17] The psychometric properties of the short form have been tested and found to correlate highly with the scores on the full form (r = 0.92), with good internal consistency (r = 0.83) and convergent validity that differentiate the state anxiety of children in various situations. Factorial structure of the short form was also checked using exploratory and confirmatory analyses.[22] The Cronbach's alpha of the scale in this study was 0.80 to 0.88. [23-24]

Children's Emotional Manifestation Scale (CEMS)

The emotional behaviour of children during CR procedures was documented by using the CEMS, developed by Li and Lopez in 2005. It comprises five observable emotional forms of behaviour, categorised as 'facial expression', 'vocalisation', 'activity', 'interaction' and 'level of co-operation'. The CEMS score is obtained by reviewing the descriptions of behaviour in each category and selecting the number that most closely represents the behaviour observed at the time the subject experiences the most distress. Each category is scored from one to five. Observable forms of behaviour in each category of the CEMS are explained in detail with an operational definition, so that the observer, a research nurse in this study, using the scale has relatively clear-cut criteria for assessment. The sum of the numbers obtained for each category is the total score, which will be between 5-25, higher scores indicating the manifestation of more negative (distressed) emotional behaviour. The evaluation of the psychometric properties of the CEMS demonstrated adequate reliability and validity.[25] The Cronbach's alpha of the scale in this study was 0.86.[23-24]

Satisfaction scale for parent and cast technician

Two questionnaires in English, developed by Tyson and colleagues (2014),[12] were adopted to measure parents' and cast technicians' satisfaction levels. The original questionnaire for parents is a 10–item scale to measure their satisfaction with the child life services. Each item is rated on a five-point scale ranging from 1 = strongly disagree - 5 = strongly agree, higher scores indicating higher levels of satisfaction. Example of the statement used is 'My child's emotional needs were met'. The perception of the cast technician was examined by eight items, with each being rated on a scale from 1 = strongly disagree - 5 = strongly agree. Example of the statement used is 'the child engaged in distraction'. The researcher translated the questionnaire into Chinese, using the back-translation method recommended by Brislin (1986).[26] The translated version was reviewed by a panel of expert professionals for semantic and content equivalence. The scale level of semantic equivalence for the parents' satisfaction and cast technician satisfaction was 95% and 92%, respectively, indicating that the translated version was a correct reflection of the original version.[27] The CVI of the parent's satisfaction level scale was 0.90 and cast technician's satisfaction level scale was 0.94, indicating the content of the translated scale were equivalent to the original version. The Cronbach's alpha of both scales in this study was 0.90.

Heart rate monitoring

A standard automatic heart rate monitoring machine, available in the study hospital, was used to measure children's heart rates to assess their physiological responses to CR procedures. Children's heart rates have been considered objective and definitive indicators for an indirect assessment of children's anxiety levels in previous studies.[28]

A demographic sheet

The socio-demographic and clinical variables of parents and children were collected. The items for children include age, sex, reason for cast application and number of hospital admissions. The accompany parent's age, sex, educational level and working status was also obtained. The cast technician's demographic information, including age, sex and years of work experience, was also collected by the research nurse.

Data collection

Children having their casts removed were identified outside the cast room of the study OPD by a research nurse. Permission for a child meeting the recruitment criteria to participate was obtained from the accompanying parent. The research nurse conducted the interview with consenting parent–child pairs in a private room. The children in both groups were asked to indicate how anxious they were by completing either the VAS anxiety scale (for children between 3–7 years old) or the short form of the CSAS-C (for children aged between 8–12).[17] The rearch nurse obtained demographic and clinical data from the parents. She also asked the parents of children aged under 5 to use the VAS scale to indicate their child's perceived anxiety level. Children's heart rates were also monitored for one minute at the end of the interview, using a standard automatic monitor.

According to the subject allocation scheme, children in the control group received standard care in CR room A, while the intervention group additionally received a therapeutic play intervention conducted by the HPS in CR room B. The parents and children were asked during the informed consent process not to discuss the purpose of the study with cast technicians in the cast room.

In the CR room, the research nurse took two one-minute recordings of the child's heart rate: (1) when the cast technician started sawing the cast; and (2) immediately after the cast had been removed. The research nurse then rated the child's signs of distress from the time the saw touched the cast until the limb was free of it, by means of the CEMS.[25] She also recorded the length of the whole CR procedure for each child. After the CR procedure, the research nurse asked the parents and the cast technician to fill in their respective satisfaction scales to reflect their perceptions of how the CR procedure had been delivered. The children were asked to recall their level of anxiety throughout the procedure by filling in either the VAS anxiety scale (for those between 3-7) or the short form of the CSAS-C (for those between 8-12).[17] Parents were asked to rate the VAS scale for children under 5.

Data analysis

All data were analysed by means of IBM SPSS for Windows, Version 22. Descriptive statistics were used to present the participants' socio-demographics and outcome measurements. Pearson's chi-squared test and the student's *t*-test were used as appropriate to compare baseline differences between the two groups. A generalised estimating equations (GEE) model was used to compare the outcome measures across time between the two groups. The model accounts for intra-correlated repeated measures data and accommodates missing data, provided it is missing at random. All statistical analyses were two-sided, with the level of significance set at 0.05.

Results

Demographic and clinical characteristics of the children and their families

From August 2015 - January 2017, a total of 209 patients and their accompanying parents were screened and approached. However, one of them declined to participate in the study because they were in a hurry and had to leave the clinic at once after the procedure. Therefore, a total of 208 participants and their accompany parents were recruited. Of these, 105 were allocated to the control group and 103 to the intervention group (Figure 1). Their mean ages were 7.7 (SD 3.0) and 7.5 (SD 2.9), respectively. There was no significant difference in the demographic or clinical characteristics of the two groups ($p>0.05$) (Table 1).

Anxiety levels

Children aged between 3 and 7

The mean anxiety scores of children aged 3-7 in the intervention group decreased from 35.4 to 27.6 after the CR procedures. By contrast, the anxiety levels of children who did not take part in therapeutic play increased from 34.0-46.3. Statistically significant differences ($p=0.010$) were noted between the two groups (Table 2).

Accompanying parent(s) with children under 5 were invited to rate the anxiety levels of their children using VAS. The results showed that there were statistically moderate to high correlations between the children and their parent's rating before ($r = 0.36$) and after the CR procedure ($r = 0.50$).

Children aged between 8 and 12

The anxiety scores of children in the intervention group fell from 18.0-15.3, and in the control group from 17.4-15.9. However, no statistically significant difference was noted between the two groups ($p=0.171$) (Table 2).

Emotional manifestation during cast-removal procedures

The mean emotional manifestation scores of the intervention group were 7.6 (SD 2.4) and of the control group 9.7 (SD 3.9). Statistically significant differences ($p<0.001$) were found between the two groups, indicating that the intervention group exhibited fewer negative emotional manifestations during the CR procedures (Table 2).

Changes in heart rate

A trend of increasing heart rate was noted before and during the CR procedures for both comparative groups. The mean heart rate of the intervention and control groups increased by 2.6 and 8.4 beats/minute, respectively. Significant differences were noted between the two groups ($p=0.008$), indicating that the intervention group experienced lower levels of anxiety than the control group (Table 2).

Satisfaction levels of parents and cast technicians

Significantly higher satisfaction scores ($p<0.001$) were noted by parents of the intervention group (46.6, SD 5.1) and the control group (42.6, SD 6.9), as well as by the CR technician with the intervention (34.3, SD 3.6) and control groups (31.7, SD 4.3) (Table 2).

Duration of procedure

Although the mean time (in minutes) taken to perform the CR procedure was shorter in the intervention 4.1 (SD 2.3) than in the control group 4.6 (SD 2.2), no statistically significant difference was noted between the two (Table 2).

Discussion

This study expanded previous studies and examined the effects of a therapeutic play intervention on CR procedures in patients, parents and institutions. A randomised controlled design was employed such that the cause and effect relationships among variables could be established.[27] Findings suggest that therapeutic play effectively assists children aged 3-7 to cope with stressful CR procedures and reduces their anxiety levels. Moreover, children who received the intervention exhibited significantly fewer negative emotional manifestations than those who did not.

Most children in this study presented some degree of anxiety before the procedures, the use of a saw and the fluctuating level of high-frequency noise probably accounting for most of the anxiety.[1 29] Previous studies employed ear protection [5] or lullaby-type music [6] to reduce anxiety in children during CR, while heart rate and mean arterial blood pressure were used as physiological outcome indicators of anxiety, respectively. However, no significant difference was noted in these parameters in either study.

The positive results of the present study are further supported by the fact that the mean increase in heart rates before and during the procedure was lower in the intervention than in the control group. A possible explanation may be that the therapeutic play assisted children to cope with an unfamiliar procedure. During the play session, the HPS explained and simulated the CR procedures, which allowed the children to understand them. As the children were familiarised with the procedure, they would expect it to generate noise but not pain. These preparations assisted the children in such a way that they had an enhanced sense of control over the procedure, minimising the adverse effects of the experience.[6] As suitable and age-appropriate distraction were provided to the intervention group, the children's attention was diverted from the anxiety-

provoking procedure to playful interaction. They therefore exhibited less negative emotional behaviour. However, children without any distraction might have focused on the whole procedure and thus exhibited more negative emotions and increased anxiety levels, even after it was all over.

Nevertheless, although children of 8-12 in the intervention group had larger reductions in their anxiety scores than those in the control group after the procedure, the difference between the groups was non-significant. The results were in conflict with those of a previous study suggesting that older hospitalised children benefit more from the play intervention.[21 30] One possible explanation for the non-significant findings is that older children have a better understanding of CR procedures than younger children. According to Piaget (1963),[15] children of 8–12 can mentally manipulate information to solve problems. As they may have obtained information about the CR procedure from other sources, such as books, the internet or friends, they might feel less anxious about the forthcoming procedure. Moreover, compared with younger children, older children probably have better coping strategies and better control of their emotions, even in stressful situations. Nevertheless, further study is needed to determine other effective methods for children at this developmental stage.

Consistent with a previous study,[31] the result indicated that parents of children in the intervention group were more satisfied with the care and play intervention than those of children receiving standard care only. The satisfaction of parents in the intervention group is likely to have increased because they also experienced the positive influence of play on their children, particularly the reduction in anxiety and improved cooperation with the procedure. [32] The positive correlations in the VAS ratings of children under 5 further suggested that parents also perceived their children to be less anxious after the intervention.

Some cast technicians might have concerns that the CR procedures would be impeded and prolonged because the play intervention was implemented at the same time. However, the findings suggest that the duration of the entire procedure was shorter in the intervention than in the control group, although the differences were non-significant. Nevertheless, the duration in the intervention group did decrease, probably because the children were psychologically prepared and were thus more cooperative. In fact, children who are less anxious are easier to manage in clinical situations,[33] which may account for the increased satisfaction of CR technicians in procedures assisted by HPS.

Limitations

The results of the current study should be interpreted in the light of several limitations. First, children were recruited from a single clinical setting. The generalisability of the findings may therefore be restricted. Second, neither patients nor outcome assessors were blinded to the study. However, because of the very nature of the intervention, blinding of patients and outcome assessors would have been difficult, and the lack of blinding would not necessarily contribute to a source of bias because children are unlikely to change their behaviour even when they know they are participating in a certain intervention.[9] Moreover, different strategies were employed to minimise the potential bias. For example, children were assigned to different cast rooms and isolated from other patients at the time of the intervention, regardless of whether or not they were randomised to the play intervention group. Also, subjective and objective outcome measures were used to evaluate the impact of therapeutic play on the psychological state of a child.

Conclusions

This study confirms the findings of previous work that children experience some degree of anxiety and exhibit negative emotional manifestations during medical procedures. The consequences of stress appear to be substantial, and thus the importance of assisting children to cope effectively with it and reduce its impact is highlighted. A gap in the literature is addressed by providing empirical evidence on the benefits of therapeutic play for children, family and medical institution during CR procedures. The findings show that a play intervention effectively reduces anxiety levels and negative emotional manifestations among children undergoing CR procedures. Such positive outcomes also translate into an improvement in the satisfaction levels of parents and CR technicians with the procedures. Play is universal and similar intervention can be adopted in other settings or medical procedures. The findings highlight the importance of providing and integrating therapeutic play into standard care. Such an intervention ensures that holistic and quality care is provided to ease the psychological burden of the patients. Furthermore, it contributes to improve patient care, satisfaction and overall experience of children and their families.

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Figure Legends

Figure 1: The CONSORT diagram of this study

Footnotes

Contributors: Wan Yim and King Wah conceived and designed the study. Cho Lee and Wing Han obtained ethical approval. Ming Chau supervised data collection. Cho Lee supervised the data analysis and wrote the paper. Kai Chow provided statistical support and analysed the data. Ming Chau and Wing Han helped revising the manuscript. All authors have given final approval of the version to be published.

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Patient consent: Obtained.

Ethics approval: This study was approved by the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (2015.005-T).

Provenance and peer review: Not commissioned; externally peer reviewed.

Data sharing statement: Not additional data are available.

Table 1: Socio-demographics and clinical characteristics of the participants (n=208) and cast-removal technicians (n=12)

Characteristics	Control (n=105)	Intervention (n=103)	p-value #
Children and their family			
Age of the child (years) †	7.7 (3.0)	7.5 (2.9)	0.699 [a]
Age group			
3 – 7 years	55 (52.4%)	52 (50.5%)	0.784 [b]
8 – 12 years	50 (47.6%)	51 (49.5%)	
Sex of the child			
Female	37 (35.2%)	36 (35.0%)	0.965 [b]
Male	68 (64.8%)	67 (65.0%)	
Accompanied by			
Mother only	52 (49.5%)	54 (52.4%)	0.797 [b]
Father only	29 (27.6%)	26 (25.2%)	
Both parents	14 (13.3%)	10 (9.7%)	
Mother/father together with other relatives	6 (5.7%)	6 (5.8%)	
Other relatives	4 (3.8%)	7 (6.8%)	
Highest education attainment of the accompanied family			
Primary or below	8 (7.6%)	7 (6.8%)	0.944 [b]
Secondary	63 (60.0%)	64 (62.1%)	
College or above	34 (32.4%)	32 (31.1%)	
Number of hospital admission			
0	38 (36.2%)	31 (30.1%)	0.063 [b]
1	30 (28.6%)	36 (35.0%)	
2	25 (23.8%)	14 (13.6%)	
≥ 3	12 (11.4%)	22 (21.4%)	
Type of casts			
Arm long	88 (83.8%)	82 (79.6%)	0.684 [c]
Arm short	6 (5.7%)	7 (6.8%)	
Leg long	9 (8.6%)	13 (12.6%)	
Leg short	2 (1.9%)	1 (1.0%)	
CR technician (n=12)			
Sex			
Female	32 (30.5%)	30 (29.1%)	0.831 [b]
Male	73 (69.5%)	73 (70.9%)	
Age (years)			
< 30	16 (15.2%)	9 (8.7%)	0.319[b]
30 – 40	34 (32.4%)	39 (37.9%)	
> 40	55 (52.4%)	55 (53.4%)	
Years of experience			
< 2	14 (13.3%)	9 (8.7%)	0.315 [b]
2 – 5	47 (44.8%)	41 (39.8%)	
> 5	44 (41.9%)	53 (51.5%)	

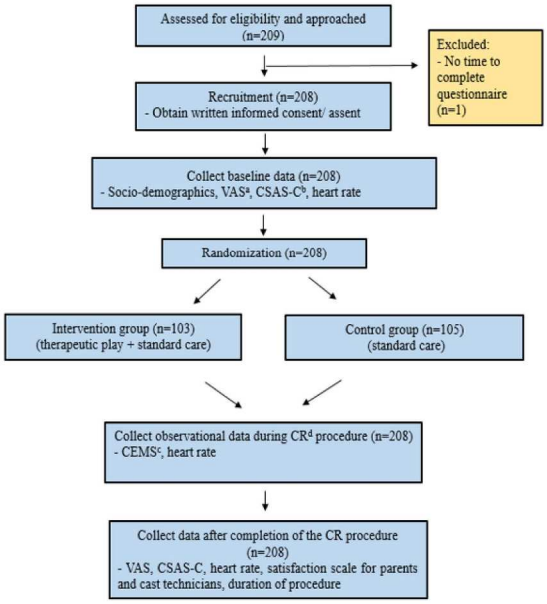
Data of variables marked with † are presented as mean (standard deviation), otherwise as frequency (%).
[a] Independent t-test;

[b] Pearson chi-square test;
[c] Fisher's exact test.

Table 2: Outcome measures across time between the intervention and control groups

	Control	Intervention	p-value	Effect size #
Among those children aged between 3 and 7 years (N=107)	**(n=55)**	**(n=52)**		
VAS anxiety scale (range: 0 – 100)				
T1 (before CR procedure)	34.0 (30.0)	35.4 (32.7)		
T3 (after CR procedure)	46.3 (37.3)	27.6 (28.6)	0.010 [a]	0.50
Among those children aged between 8 and 12 years (N=101)	**(n=50)**	**(n=51)**		
State Anxiety Scale for Children (CSAS-C) (range: 10 – 30)				
T1 (before CR procedure)	17.4 (4.0)	18.0 (3.5)		
T3 (after CR procedure)	15.9 (4.7)	15.3 (3.9)	0.171 [a]	0.27
Among all children (N=208)				
Children's emotional manifestation scale (range:5 – 25)	**(n=105)**	**(n=103)**		
T2 (during CR procedure) [†]	9.8 (3.9)	7.6 (2.4)	<0.001 [b]	0.69
Heart rate (per minute)				
T1 (before CR procedure)	87.6 (14.2)	86.7 (13.6)		
T2 (during CR procedure)	96.0 (16.2)	89.3 (15.5)	0.008 [a]	0.36
T3 (after CR procedure)	93.7 (14.9)	88.8 (15.6)	0.070 [a]	0.25
Parent satisfaction score (range: 10 – 50)				
T3 (after CR procedure)	42.6 (6.9)	46.6 (5.1)	<0.001 [b]	0.65
CR technician satisfaction score (range: 8 – 40)				
T3 (after CR procedure)	31.7 (4.3)	34.3 (3.6)	<0.001 [b]	0.66
Duration of procedure (mins)	4.6 (2.2)	4.1 (2.3)	0.072 [b]	0.25

Data of variables marked with [†] are presented as median (inter-quartile range), otherwise as mean (standard deviation)
[†] Nature log-transformed before subjected to independent t-test
[#] Cohen's d effect size
[a] P-value testing for differential change of heart rate at the underlying time point with respect to T1 by using GEE model;
[b] Independent t-test



Note:

[a] VAS: Visual Analogue Scale

[b] CSAS-C: The short form Chinese version of the State Anxiety Scale for Children

[c] CEMS: Children's Emotional Manifestation Scale

[d] CR: Cast-removal

The CONSORT diagram of this study

210x297mm (300 x 300 DPI)

Title of proposal: The stress-reducing effects of therapeutic play on children undergoing cast-removal procedure.

Background

It is common for children to display stressed behaviour in clinical settings, even during painless medical procedures such as cast-removal. Many behavioural and physiological manifestations of anxiety in children are associated with their compliance with the medical procedures and thus the recovery outcomes (Felder-Puig et al., 2003) and the quality of care (Tyson, Bohl, & Blickman, 2014). Researchers (Li, Lopez, & Lee, 2007) has pointed out that lack of self-control and limited cognitive capabilities are two main factors associated with children's anxiety and that psychosocial preparation of the children through therapeutic play could help them gain a sense of self-control and achieve lower anxiety levels.

Therapeutic play is a set of structured activities that are designed according to the subject's age, cognitive development and health-related issues, to promote emotional and physical well-being in hospitalized children (Vessey & Mahon, 1990). Extensive studies have supported therapeutic play as an effective pre-operative preparation for both children and parents in reducing fear and anxiety (Christian, Russ, & Short, 2011; Nyugen, & Thaller, 2008). Care providers should consider the human rights of children, and provide age-appropriate information to aid understanding of the disease and the interventions employed.

Brewer et al. (2006) evaluated the effectiveness of therapeutic play in a double-blind intervention study. The findings showed that preparation with role rehearsal and medical play could lower anxiety levels in children following elective day surgery. Additionally, a recent randomized, controlled trial (RCT) (Tyson et al., 2014) found that therapeutic play could enhance satisfaction, not only to children but also in the parents and healthcare providers. However, the efficacy of therapeutic play are yet to be determined because the reported studies were based mainly on clinical observations and most of the play manuals, which should have set out specific procedures and improved fidelity, were not fully described (Brewer et al., 2006; Stevenson et al., 2005; Tyson et al., 2014). Researchers have emphasized the need for further objective data-gathering studies on the scope of procedures in an out-patient setting.

In summary, the comprehensive value of therapeutic play—in terms of impact on the child, family and medical institution as a whole—remains largely unexplored in the literature. Our literature search revealed no reports of prospective and randomized controlled studies of the

effectiveness of therapeutic play among Chinese children undergoing cast-removal procedures, let alone among Hong Kong Chinese.

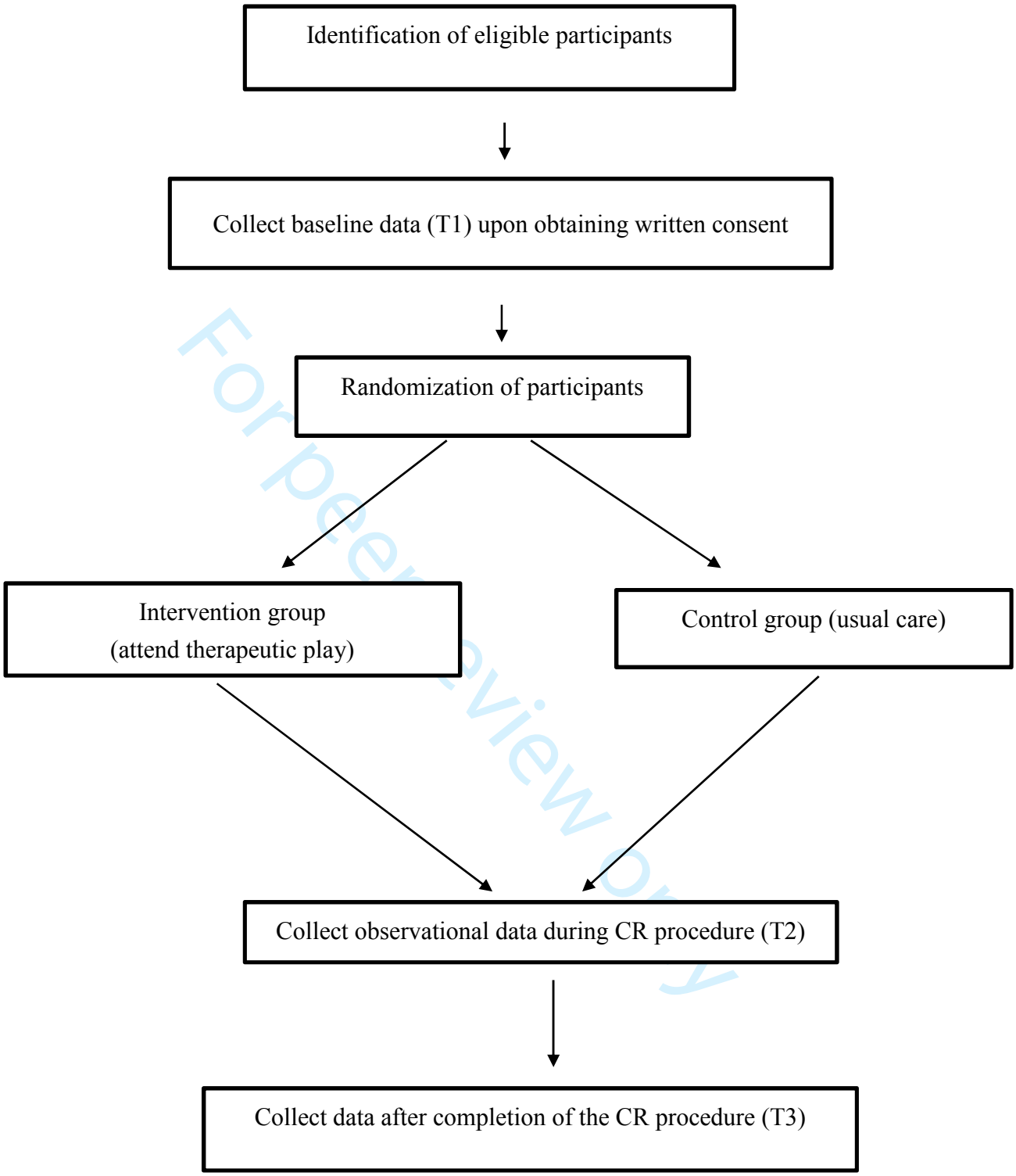
Aims

The aim of this study is to examine the impact of the therapeutic play on the psychological stress of paediatric patients during cast-removal (CR) procedures in an orthopaedic out-patient clinic in Hong Kong. The satisfaction ratings of parents and healthcare providers in respect of these services will also be examined.

Methods

Design

This is a two-arm randomized controlled trial. Eligible children undergoing the CR procedure will be randomly allocated to either the experimental or control groups in a 1:1 ratio. The child and accompanying parent in the experimental group will receive therapeutic play intervention, and the control group will receive routine care only. All participants will be assessed on three occasions: before, during, and after completion of the CR procedure. Please refer to Figure 1 for the study protocol.



CR = cast removal

Figure 1. Study Protocol

Research Hypotheses

The research objectives are to examine whether, in CR procedures, there are significant differences between the Intervention and Control groups in:

1. children's anxiety levels
2. children's emotional distress levels
3. children's heart rates
4. length of procedure
5. satisfaction levels of parents and technicians in respect of the procedures.

Settings

This study will be conducted in the orthopaedic out-patient department (OPD) of a regional teaching hospital in Hong Kong. A cast room in the OPD performs approximately 20 cast-removal procedures monthly. At the time of this proposal, the standard of regimen in this OPD does not include therapeutic play services. The cast technicians attend to paediatric patients every Wednesday afternoon. They receive limited training on the developmental needs of children in their profession.

Sample

Children and their accompanying parents, who are waiting for the cast room procedure, will be invited to participate in the study if (i) the children are 3–12 years of age and (ii) the parents are able to speak Cantonese and read Chinese. Children will be excluded if they have had a cast removed within 3 months and demonstrate obvious neurological or developmental problems during cognitive assessment by a play specialist.

The rationale for selecting 3–12-year-old is that the number of children having cast room procedure within this age range in Hong Kong is higher than for other age groups. In fact, according to Piaget's (1963) theory of cognitive development, children from 3 to 7 years of age belong to the same pre-operational stage, while those in the age range 8–12 years belong to the concrete operational stage. In addition, according to Erickson (1963), children in the same age group fall in the same stage of psychosocial development. Accordingly, randomization of participants to the experimental (E) or control (C) groups will be stratified by the two age groups: 3–7 and 8–12 years. Serially numbered opaque sealed envelopes containing the grouping identifier (E or C) for each age group will be prepared in advance by an independent statistician using computer generated random codes. The group allocation of the recruited children will be

assigned according to their ages and sequence of enrolment in the study and the grouping identifier contained in the corresponding numbered envelopes.

The sample size of the study is determined to detect at least a medium effect size of Cohen's d = 0.5 between the experimental and control groups. According to Cohen (1992), 64 subjects in each group will be sufficient to detect a medium effect of 0.5 with 80% power at 5% level of significance. Taking into account of up to a 15% attrition rate and stratified the study by age, seventy-five children each will be recruited for the experimental and control groups per stratum by age (3–7 and 8–12 years).

Interventions

The research team discuss the study protocol and an experienced hospital play specialist (HPS) will conduct all interventions in the study during her regular shift. Each child who is assigned to the Intervention group will receive an initial assessment, who will individualize the therapeutic activities based on children's psycho-cognitive development (Erikson, 1963; Piaget, 1963) and general condition. Duration and type of intervention will be varied, based on the assessment of the child's needs, but will usually be completed within 30 minutes. The content of the therapeutic play has two main components: preparation play and distraction play (Blaine, 1999).

Preparation Play

Preparation play consisting of two parts of intervention will be conducted before the CR procedure:

Part I: information given

The children and parents should be well prepared by information supplied about the procedure and the choices of behaviour management. The hospital jargon were translated into ordinary language and in giving explanations in terms that suit the developmental level of the child (Brown et al., 1997). The preparation phase will be implemented individually, with their parents, in a service room. Information about the procedure will be provided, such as: (i) Why must the procedure be done? (ii) Where will the procedure take place? (iii) What will be happening? and (iv) How will it feel? Multiple coping strategies will also be introduced, so as to allow the parent and child to choose the one appropriate to them (Stephens, Barkey, & Hall, 1999); for example: (i) whether or not to watch the procedure, (ii) to pick something nice to think about and (iii) to sing a song. Choices of age-appropriate toys with specified playing activities will also be given to promote the coping strategies of the children.

Part II: rehearsal of the procedure

After verbal explanation, a demonstration of the cast-removal procedure will be conducted, using a doll. Examples of such a demonstration are:

- Show a dummy circular-saw cast cutter with appropriate sound effect
- Play with a doll and explain how the cast is cut open by the circular saw
- Reassure the child that the saw will not cut his or her skin if he or she follows the instruction not to move
- Explain that, when the cast is cut, the child may feel vibrations or tingling, feel warmth, and see chalky dust flying
- Describe the use of spreaders and scissors to finish removing the cast
- Explain how, after the cast is open, the child's skin may appear scaly and dirty and the child's arm or leg may be a little stiff when he or she first tries to move it; also that the arm or leg may seem light because the cast was heavy.

Each child will be asked to role-play how he or she would respond to the procedure after the demonstration. During the session, parents and children will be encouraged to raise their concerns or ask any questions about the procedure. The preparation intervention will usually take 10–15mins to complete.

Distraction Play

Support will be given to the children and parents throughout the cast-removal procedure by giving distraction play intervention. The aim is to focus children's attention away from the medical procedure. Methods of distraction include visual distraction, auditory distraction, deep breathing exercises, tactile stimulation, counting/singing or verbal interaction. The choice of the distraction method the children's choices (Doellman, 2003). Parental presence and involvement will be supported, and praise will be given to any successful self-control exhibited by the child. The conclusion of the procedure will be indicated by offering the child a reward (sweets or stickers).

Measures

A visual analogue scale (Appendix I)

A visual analogue scale (VAS) will be used to assess the anxiety levels of children aged 3–7. The VAS is a 10 cm horizontal line anchored by the words "not worried" (low score) at one end and "very worried" (high score) at the other, with different facial expressions drawn along the line. Children aged between 5 and 7 will be asked to indicate their levels of anxiety by moving a

pointer over the line. Accompanying parent(s) will rate the anxiety levels of children aged 3–4, with higher scores indicating greater anxiety. The VAS is a widely used scale which is found to be a reliable and valid tool for measuring subjective feelings of children aged 5 to 7 (Bringuier *et al*., 2009).

The short form of the Chinese version of the State Anxiety Scale for Children (CSAS-C) (Appendix II)

The CSAS-C was a 10-item self-report scale to measure the levels of anxiety among children aged 8-12 in busy clinical settings (Li & Lopez, 2007). The content validity of the scale has been empirically tested and the Cronbach's alpha value was 0.83. This is a 3-point Likert scale with total scores ranging from 10 to 30. Higher scores indicate greater anxiety levels (Li & Lopez, 2007).

Children's Emotional Manifestation Scale (CEMS) (Appendix III)

The emotional behaviours of children during CR procedures will be documented using the CEMS. The CEMS was developed by Li and Lopez in 2005. It comprises five observable emotional behaviours, categorized as 'Facial expression', 'Vocalization', 'Activity', 'Interaction' and 'Level of Co-operation'. The CEMS score is obtained by reviewing the descriptions of behaviour in each category and selecting the number that most closely represents the observed behaviour at the time the subject experiences the most distress. Each category is scored from one to five. Observable behaviours in each category of the CEMS are explained in detail with an operational definition, so that the observer, a research nurse (RN) in this study, using this scale has relatively clear-cut criteria for assessment. The sum of the numbers obtained for each category is the total score, which will be between 5 and 25. Higher scores indicate the manifestation of more negative (distressed) emotional behaviours. The evaluation of the psychometric properties of the CEMS demonstrated adequate inter-rater reliability, high internal consistency, good content validity and excellent convergent validity (Li & Lopez, 2005).

Satisfaction Scale

Two questionnaires in English, developed by Tyson and colleagues (2014), will be adopted to measure parents' (Appendix IV) and cast technicians' (Appendix V) satisfaction levels. The RN will work with the research team to translate the English questionnaire into a Chinese version, with reference to a back-translation method recommended by Brislin (1970).

The original questionnaire for the parent is a 10–item scale to measure parents' satisfaction with the child life services. Each item will be rated by a 5-point scale ranging from 1 = strongly

disagree to 5 = strongly agree. A higher score indicates a higher level of the satisfaction. Examples of the statements used are 'My child's emotional needs were met' and 'I am satisfied with the care provided to my child' (Appendix IV). The perception of the cast technician on the service will be examined by eight items, with each being rated on a scale from 1 = strongly disagree to 5 = strongly agree. Examples of the statements used are 'The child was co-operative' and 'The child engaged in distraction' (Appendix V).

Heart rate monitoring

A standard automatic heart rate monitoring machine, available in the study hospital, will be used to measure children's heart rates to assess their physiological responses to CR procedures. Children's heart rates have been considered to be objective and definitive indicators for indirect assessment of anxiety level in children in previous studies (Augustin & Hains 1996; Panda *et al*. 1996; Li & Lopez 2007).

A demographic sheet

A questionnaire developed by the research team will be used to measure the socio-demographic and clinical variables of the parent and their child. The items for children include age, sex, reason for cast application and number of hospital admissions. The accompany parent's age, sex, educational level and working status will also be obtained.

The cast technician's demographic information including age, sex and years of working experience will also be collected by the RN.

Data Collection Procedure

Children having their casts removed will be identified outside the cast room of the study OPD by the RN. If the child meets the inclusion criteria for recruitment, permission for the child to participate will be obtained from the accompanying parent. The RN will then conduct the interview with consenting parent–child pairs in a private room. The children of the consenting parents in both groups are asked to indicate how anxious they are by filling in either the VAS anxiety scale (for children between 5–7 years old) or the short form of the CSAS-C (for children aged between 8–12) (Li & Lopez, 2007). The RN will acquire demographic and clinical data from the parents. She will also ask the parents of children aged under 5 to use the VAS scale to indicate their child's perceived anxiety level. Children's heart rates will also be monitored for 1 minute, using a standard automatic heart rate monitoring machine at the end of the interview.

According to the subject allocation scheme, children in the Control group will receive routine care in the CR room A, whereas those in the Intervention group will additionally receive

therapeutic play intervention conducted by the HPS in the CR room B. The parents and children will be asked not to discuss the purpose of the study with cast technician in the cast room during the informed consent process.

In the CR room, the RN will take the 1-minute recording of the child's heart rate when the cast technician starts sawing the cast of the child. The RN will also rate the child's signs of distress from the time the saw touches the cast until the limb is free from the cast, by means of the CEMS (Li & Lopez 2005). The length of the whole CR procedure for each child will also be recorded by the RN. The timing, duration, and nature of play for each child will be documented in a log book. After the completion of the CR procedure, The RN will take the child's heart rate for 1 min and then ask the parents and the cast technician to fill in their respective satisfaction scales to reflect their perceptions of the delivery of the CR procedure.
The RN will give a $30 dollar coupon to the parent upon completion of data collection.

A pilot study on 5 pairs of eligible parent-child dyad will be performed to assess the feasibility of the data collection plan and to pre-test the questionnaires. The respondents' comments on and impressions of the pilot study will help the research team to refine or revise the study plan (Polit *et al*., 2013). Please refer to the outline of data collection in Table 1.

Table 1. The plan of data collection by the research nurse

	Pre-test data upon consent given (T1)	Observational data during procedure (T2)	Post-test data after procedure (T3)
Demographic and clinical variables	X		
VAS anxiety scale for children 3–7 years old; The short form of the Chinese version of the State Anxiety Scale for Children (CSAS-C) for children aged 8–12	X		X
Children's Emotional Manifestation Scale		X	
1 minute heart rate recorded by an automatic heart rate monitoring machine.	X	X	X
Parent satisfaction scale			X

Staff satisfaction scale			X
Length of procedure		X	

Data Analysis

All data will be analysed using IBM SPSS for Windows, Version 22. Descriptive statistics such as mean, standard deviation, medium, inter-quartile range, frequency and percentage, as appropriate, will be used to present the participants' socio-demographics and outcome measurements. Pearson's chi-squared test and student's *t*-test will be used as appropriate for comparing the baseline differences between the two groups. Generalized estimating equations (GEE) model will be used to compare the outcome measures across time between the two groups. GEE model can account for intra-correlated repeated measures data and accommodated missing data, provided the data are missing at random. All statistical analyses are two-sided and level of significance will be set at 0.05.

Ethical Issues

Ethical approval will be sought from the Ethical Committees of the University and the study hospital prior to conducting the study. The purpose and details of the study will be clearly provided to the accompanying parents before the RN obtains their written consent. Maintenance of confidentiality and anonymity of data gained will also be assured. Participants will be informed that the quality of care will not be affected by their participation status. Please refer to the details of the information sheet and consent form in Appendix VII.

Timeline

Timetable of the 20-month project

Month	**1**	**2**	**3**	**4–16**					**17**	**18**	**19**	**20**
RN training & literature review	★	★										
Questionnaires development & pilot study		★	★									
Data collection				★	★	★	★	★	★	★		
Data entry & data analyses									★	★	★	
Report writing											★	★

Note: Based on recruiting 20 cases per month

Significance

Removal of casts is a frightening procedure for children (Johnson et al., 1975), and studies on psychosocial care for children receiving the procedure are limited. This is the first study of this kind among Hong Kong Chinese children in an orthopaedic out-patient clinic. The findings will inform policy makers on the development and inclusion of therapeutic play interventions in paediatric out-patient healthcare settings.

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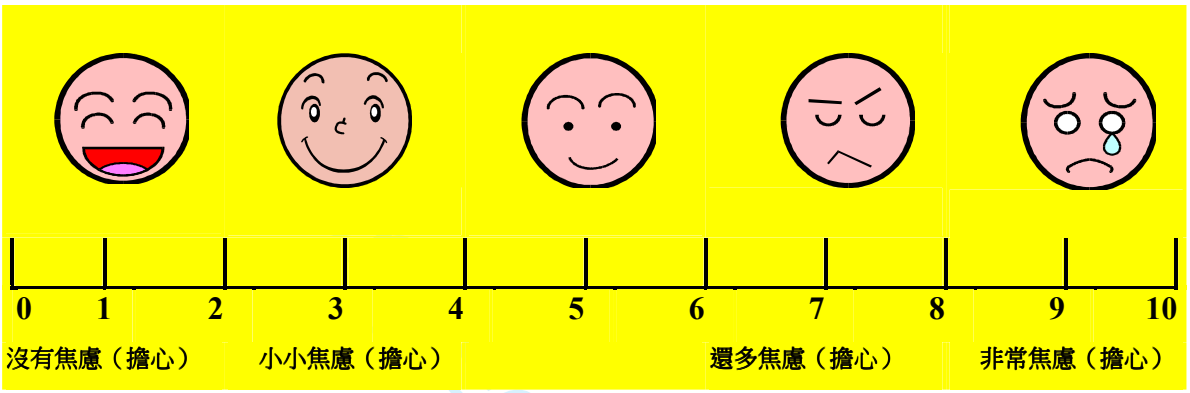
Appendix I

A 10-point level Visual Analogue Scale (VAS)



Appendix II

Short-Form of the Chinese version of the State Anxiety Scale

以下是一些男孩子和女孩子用來形容自己的句子。請小心閱讀每一句，然後在每句子的右方*圈出*最能表達你*現時感覺*的字句。答案是沒有分對或錯的。不要花太多時間在任何句子上，只要將最能表達你*現時感覺*的字句圈出來就可以了。

1. 我感到.....	十分愉快	愉快	不愉快
2. 我感到.....	十分不安	不安	無不安
3. 我感到.....	十分緊張	緊張	不緊張
4. 我感到.....	十分平靜	平靜	不平靜
5. 我感到.....	十分輕鬆	輕鬆	不輕鬆
6. 我感到.....	十分擔心	擔心	不擔心
7. 我感到.....	十分害怕	害怕	不害怕
8. 我感到.....	十分快樂	快樂	不快樂
9. 我感到.....	十分煩惱	煩惱	不煩惱
10. 我感到.....	十分開心	開心	不開心

---------- 此問卷到此完 ----------

Appendix 3

The Children Emotional Manifestation Scale

	1	2	3	4	5	Scored
Facial Expression						
Vocalization	No Crying	Watery eyes	Whimpering	Crying	Hard Crying or Non-stop Screaming	
Activity	Calm	Annoying	Irritable	Restlessness	Agitation	
Interaction	Verbal interaction	Non-verbal response only	Avoid interaction	Mild verbal protest	Strong verbal protest	
Level of Co-operation	Active participation	Passive participation	Withdrawal	Extreme resistance	Disruptive behaviour	

Appendix IV

Parent Satisfaction Scale (Chinese version)

家長滿意程度調查

香港中文大學現在正進行一項關於拆除石膏程序的研究，希望了解病人家屬和職員對這項服務的滿意程度。以下是關於剛才拆除石膏過程的相關問題，請為每條問題圈出符合你的同意程度的號碼。答案純屬個人意見，沒有標準答案。

(1 = 非常不同意；5 = 非常同意)

		非常不同意	不同意	中立	同意	非常同意
1	整個程序用了我的孩子能明白的語言去講解。	1	2	3	4	5
2	我孩子的情緒有被照顧到。	1	2	3	4	5
3	職員有關顧到我的孩子是否感到舒適。	1	2	3	4	5
4	我知道要怎樣做去幫助我的孩子。	1	2	3	4	5
5	職員有關顧到我的疑問和憂慮。	1	2	3	4	5
6	職員尊重我對我孩子的理解。	1	2	3	4	5
7	我對我孩子所受到的照顧感到滿意。	1	2	3	4	5
8	我會推薦這個服務給其他人。	1	2	3	4	5
9	職員都是友善和樂於幫忙的。	1	2	3	4	5
10	職員們好好地共同合作去照顧我	1	2	3	4	5

	的孩子。					

Parent Satisfaction Scale

These are the questions in regards to the process of pop removal, please rate each question on scale 1-5

		STRONGLY DISAGREE	DIS-AGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
1	Appropriate wordings was used to let my kid to understand the process.	1	2	3	4	5
2	My kid's emotion was looked well after by the team.	1	2	3	4	5
3	Staff concerned about the comfortability of my kid.	1	2	3	4	5
4	I knew how to assist with my kid.	1	2	3	4	5
5	Staff concerned about my questions and worries.	1	2	3	4	5
6	Staff respect my knowledge to my kid.	1	2	3	4	5
7	I satisfied with the care received from the team.	1	2	3	4	5
8	I would recommend this hospital to others.	1	2	3	4	5
9	Staff were friendly and willing to help.	1	2	3	4	5
10	Staff cooperated well to care my kid.	1	2	3	4	5

Appendix IV

Staff Satisfaction Scale (Chinese version)

職員滿意程度調查

香港中文大學現在正進行一項關於拆除石膏程序的研究，希望了解病人家屬和職員對這項服務的滿意程度。以下是關於剛才拆除石膏過程的相關問題，請為每條問題圈出**符合你的同意程度**的號碼。**答案純屬個人意見**，沒有標準答案。

(1 = 非常不同意；5 = 非常同意)

		非常不同意	不同意	中立	同意	非常同意
1	孩子明白到甚麼事情將會發生。	1	2	3	4	5
2	孩子表現得合作。	1	2	3	4	5
3	孩子的情緒有被照顧到。	1	2	3	4	5
4	孩子的注意力已被分散。	1	2	3	4	5
5	家長明白怎樣去幫助他們的孩子。	1	2	3	4	5
6	進行拆除石膏程序的環境符合孩子的需要。	1	2	3	4	5
7	我對我們團隊所供給這個孩子的照顧感到滿意。	1	2	3	4	5
8	家人對於孩子所受到的照顧感到滿意。	1	2	3	4	5

Staff Satisfaction Scale

These are the questions in regards to the process of pop removal, please rate each question on scale 1-5

		STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
1	The kid understood what would happen next.	1	2	3	4	5
2	The kin was cooperative.	1	2	3	4	5
3	The kid's emotion was looked well after by the team.	1	2	3	4	5
4	The kid was distracted.	1	2	3	4	5
5	Parents knew how to help with their kids	1	2	3	4	5
6	The venue for POP removal was appropriate to kids' needs	1	2	3	4	5
7	I am satisfied with the cared provided to the kid.	1	2	3	4	5
8	Kid's family was satisfied with the care received by the kid.	1	2	3	4	5

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	21

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	16
	13b	For each group, losses and exclusions after randomisation, together with reasons	16
Recruitment	14a	Dates defining the periods of recruitment and follow-up	16
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	16
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	20
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	20
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	22
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Effects of therapeutic play on children undergoing cast-removal procedures: a randomised controlled trial

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Authors:

Wong CL, Ip WY, Kwok BMC, Choi KC, Ng BKW, Chan CWH.

Authors' information:

Correspondence to CL Wong:

Cho Lee Wong

PhD, RN

Assistant Professor

The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China

Room 824, Esther Lee Building, The Chinese University of Hong Kong, Hong Kong.

Telephone number: (852) 3943 8166

Fax number: (852) 2603 5269

Email: jojowong@cuhk.edu.hk

Wan Yim Ip

PhD, RN

Associate Professor (Retired)

The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China

Email: wanyimip@cuhk.edu.hk

Kwok Blondi Ming Chau

BN, RN

Manager (Community & Hospital)

Playright Children's Play Association, Hong Kong, China

Email: blondi@playright.org.hk

Kai Chow Choi

PhD

Senior Research Fellow
The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China
Email: kchoi@cuhk.edu.hk

Bobby King Wah Ng
M.D.
Clinical Professional Consultant of Orthopaedics & Traumatology
Department of Orthopaedics & Traumatology, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China
Email: bobng@ort.cuhk.edu.hk

Carmen Wing Han Chan
PhD, RN
Vice-Director of Education / Professor
The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China
Email: whchan@cuhk.edu.hk

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Abstract

Objectives: To examine (i) the effectiveness of therapeutic play in reducing anxiety and negative emotional manifestations among children undergoing cast-removal procedures; (ii) the satisfaction of parents and cast technicians with cast-removal procedures.

Design: A randomised controlled trial.

Setting: An orthopaedic outpatient department of a regional teaching hospital in Hong Kong.

Participants: Children (n=208) aged 3-12 undergoing cast removal procedure were invited to participate.

Interventions: Eligible children were randomly allocated to either the intervention (n=103) or control group (n=105) and stratified by the two age groups (3–7 and 8–12 years). The intervention group received therapeutic play intervention, whereas the control group received standard care only. Participants were assessed on three occasions: before, during, and after completion of the cast removal procedure.

Outcome measures: Children's anxiety level, emotional manifestation, and heart rate. The satisfaction ratings of parents and cast technicians with respect to therapeutic play intervention were also examined.

Results: Findings suggested that therapeutic play assists children aged 3-7 to reduce anxiety levels with mean differences between the intervention and control group was -20.1 (95% CI: -35.3 to -4.9; p=0.01). Overall, children (aged 3-7 and 8-12) in the intervention groups exhibited fewer negative emotional manifestations than the control group with a mean score difference -2.2 (95% CI: -3.1 to -1.4; p<0.001). Parents and technicians in the intervention group also reported a higher level of satisfaction with the procedures than the control group with a mean score difference

of 4.0 (95% CI: -5.6 to 2.3; p<0.001) and 2.6 (95% CI: 3.7 to 1.6; p<0.001), respectively.

Conclusion: Therapeutic play effectively reduces anxiety and negative emotional manifestations among children undergoing cast-removal procedures. The findings highlight the importance of integrating therapeutic play into standard care, in particular for children in younger age.

Trial Registration: The Chinese Clinical Trials Registry: ChiCTR-IOR-15006822.

Strengths and limitations of this study:

- This study was one of the first randomised controlled trial to examine the effects of therapeutic play on children undergo cast-removal procedures, building the evidence base of therapeutic play.
- A major limitation was the lack of blinding of outcome assessor. Another limitation was recruiting children from a single clinical setting so that the generalisability of the findings may be restricted.
- The strength of this study included employing both subjective and objective outcome measures to evaluate the impact of therapeutic play on the psychological state of a child.

Introduction

It is common for children to display stressed behaviour in clinical settings even during painless medical procedures such as cast removal.[1 2] The original injuries sustained by the children, added to the unfamiliar environment and the equipment used during the procedures, are likely to provoke anxiety and fear in children of any age. The psychological burden on children not only makes the procedures difficult to perform effectively and efficiently, but may also impose medical risks.[1 3] For instance, an extreme case of death in a child having history of cardiomyopathy during the cast room procedure has been reported.[1] Moreover, anxiety in the children also reduces parents' satisfaction with the care provided.[4] Various strategies such as the use of ear protection or musical lullabies have been used but have not proved very effective.[5 6] Other interventions to reduce anxiety levels in children coping with cast-removal (CR) procedures should be explored.

Therapeutic play is a set of structured activities designed according to the subject's age, cognitive development and health-related issues, to promote emotional and physical well-being in hospitalised children.[7] The therapeutic play activities may include scrapbooking, storytelling, doll demonstration, and art activities. Li and colleagues suggested that hospitalised children who engaged in therapeutic play exhibited fewer negative emotions and experienced lower levels of anxiety than those did not.[8] A recent systematic review of 14 articles found that therapeutic play was commonly employed for children undergoing invasive procedures, such as elective surgery, vaccination, blood collection or dental treatment in in-patient settings, with positive changes in the behaviour of those who participated in play sessions and a reduction in their anxieties.[9] However, some of these studies were limited by the lack

of random assignment of subjects into intervention or control groups. Besides, the efficacy of therapeutic play interventions is yet to be determined, as the studies reported were mainly based on clinical observation and most of the play manuals, which should have set out specific procedures to improve fidelity, were not fully described.[10-12] Future study that adopt a robust randomized controlled design and delineate the scope of play procedures is clearly necessary.

Our literature search revealed no reports of prospective and randomised controlled studies on therapeutic play among children undergoing CR procedures, let alone among Hong Kong Chinese. Most importantly, the comprehensive value of therapeutic play in paediatric orthopaedic cast rooms - in their impact on the children, parents and medical institution as a whole - remains largely unexplored in the literature. This study aimed to examine the effectiveness of therapeutic play in reducing anxiety and negative emotional manifestations among children undergoing cast-removal procedures. The satisfaction ratings of parents and cast technicians in respect of the cast-removal procedures were also to be examined.

Theoretical Framework

Lazarus and Folkman's theory of stress and coping theory was used to guide this trial.[13] They suggest that stress is a relationship between a person and the environment that the person finds taxing or exceeding resources. Coping is a constantly changing cognitive and behavioural effort to manage stressful situations. The two types of strategy used to cope with stress are problem-focused and emotional-focused coping. When individuals perceive that they cannot change the threatening situation, they will resort to emotion-focused coping. [13] It is well known that cast-removal procedures is stressful for children.[1,2] Children likely feel stress and anxiety if they perceived a lack

of control over the medical procedure.[8] Therapeutic play works by helping children to prepare for the procedure and thereby assist them to regain a sense of self-control to cope with the stressful procedure.[13, 14] As a result, it is reasoned that children undergoing therapeutic play intervention will be more likely to cope with cast removal procedures and feel less stress and anxiety.

Methods

Design

A two-arm parallel randomised controlled trial was employed.

Setting

The study was conducted in the orthopaedic outpatient department (OPD) of a regional teaching hospital in Hong Kong, where the OPD cast room performs approximately 20 CR procedures monthly. The standard regimen in this OPD did not include therapeutic play intervention.

Participants

Children

Children and their accompanying parents who were waiting for the cast room procedure were invited to participate in the study if: (i) the child was 3-12 years of age; and (ii) the parents were able to speak Cantonese and read Chinese. Children were excluded if they: (i) had had a cast removed within the previous 3 months; or (ii) had neurological or developmental problems as shown on the medical record.

The rationale for selecting 3-12 year olds was that the number of children having cast room procedure within this age range in Hong Kong was higher than for other

age groups. According to Piaget's (1963) theory of cognitive development, children from 3-7 belong to the same pre-operational stage, while those between 8-12 belong to the concrete operational stage.[15] Children in different age group are at the different stage of psychosocial development and likely respond to cast-removal procedures and therapeutic play differently.[16] Therefore, children were stratified according to their age group (3-7 and 8-12).

The sample size of the study was determined to detect an effect size of Cohen's d =0.6 on the outcomes of anxiety level and emotional manifestation between the intervention and control groups with reference to previous therapeutic play studies[17-18] for guiding the selection of a minimum detectable effect. By using the power analysis software GPower 3.1, 45 subjects in each group were sufficient to detect an effect of at least 0.6 with 80% power at 5% level of significance. Taking into account of up to a 15% attrition rate and stratified the study by age, 53 children each would be recruited for the intervention and control groups per stratum by age (3–7 & 8–12 years).

Accompany parents and cast technicians

All accompany parents and cast technicians involved in the cast-removal procedures were invited to assess their satisfaction for the procedures.

Randomisation

Eligible children undergoing the CR procedure were randomly allocated to the intervention or control groups in a 1:1 ratio. Randomisation were stratified by the two age groups, 3–7 and 8–12 years. Serially numbered opaque sealed envelopes containing the grouping identifier (intervention or control) for each age group were

prepared in advance by an independent statistician using computer-generated random codes. The group allocation of the children recruited was assigned according to their ages and sequence of enrolment in the study, and the grouping identifier contained in the corresponding numbered envelopes.

Control Group: Standard Care

Participants in the control group received standard care without therapeutic play intervention. Standard care included the nurse explaining why and what would be done and saying comforting and supportive words during the procedures.

Intervention Group: Therapeutic Play

In addition to the standard care, children in the intervention group also received therapeutic play intervention. The interventions were conducted by an experienced and well-trained senor hospital play specialist (HPS). The HPS has more than five years of experience in delivering therapeutic play - including preparation play and distraction play - to children undergoing medical treatments in various units of hospitals. To ensure therapeutic play interventions were provided according to the children's needs and psycho-cognitive development,[15-16] the research team met with the HPS to set up the research protocol (supplementary file). The content of the therapeutic play had two main components: preparation and distraction forms of play.[19] The duration of intervention was about 30 minutes.

Preparation play

Preparation play was conducted before the CR procedure. A demonstration of the CR procedure was conducted using a doll. The demonstration included:

- Showing a dummy circular-saw cast cutter with appropriate sound effects
- Playing with a doll and explaining how the cast was cut open by the circular saw
- Reassuring children that the saw would not cut their skin if they followed the instruction not to move
- Explaining that, when the cast was cut, the child might feel vibration or tingling, notice a certain warmth and see chalky dust flying
- Describing the use of spreaders and scissors to finish removing the cast
- Explaining how, after the cast was open, the skin might appear scaly and dirty and the limb feel a little stiff when first moved; also that the arm or leg might seem light because the cast had been heavy.

During the demonstration, the children were asked to touch and play with the doll and material, and role-play how they would respond to the procedure after the demonstration. The preparation play usually took 10–15 minutes to complete.

Distraction play

Throughout the CR procedure, support was given to children by introducing distraction play. The aim of the distraction play was to divert children's attention away from the medical procedure. Methods of distraction included visual or auditory distraction, deep breathing exercises, tactile stimulation, counting/singing or other verbal interaction. The choice of method depended on the children's choices.[20] The parents' presence and involvement were supported, and the children were praised for any act of successful self-control. The conclusion of the procedure was indicated by offering the children a reward (e.g. stickers). The children did not know that they would receive reward in advance.

Primary outcome measures

Anxiety

Visual analogue scale

A visual analogue scale (VAS) was used to assess the anxiety levels of children between 3 and 7. The VAS consists of a 10-cm horizontal line anchored by the words 'not worried' (low score) at one end and 'very worried' (high score) at the other, with drawings of different facial expressions spaced along the line. Children aged between 3-7 were asked to indicate their levels of anxiety by moving a pointer over the line. As children of 3 or 4 may have limited verbal expression abilities, their parents were also invited to rate the anxiety levels of their children. The VAS is a widely used scale which has been found to be a reliable and valid tool for measuring children's subjective feelings.[21]

The short-form Chinese version of the State Anxiety Scale for Children (CSAS-C)

The CSAS-C is a 10-item self-report scale measuring the anxiety levels of children aged 8-12 in busy clinical setting.[17] It is a three-point Likert scale with total scores ranging from 10 to 30, with higher scores indicating greater anxiety levels.[17] The psychometric properties of the short form have been tested and found to correlate highly with the scores on the full form (r = 0.92), with good internal consistency (r = 0.83) and convergent validity that differentiate the state anxiety of children in various situations. Factorial structure of the short form was also checked using exploratory and confirmatory analyses.[22] The Cronbach's alpha of the scale in this study was 0.80 to 0.88. [23-24]

Children's Emotional Manifestation Scale (CEMS)

The emotional behaviour of children during CR procedures was documented by using the CEMS, developed by Li and Lopez in 2005. It comprises five observable emotional forms of behaviour, categorised as 'facial expression', 'vocalisation', 'activity', 'interaction' and 'level of co-operation'. The CEMS score is obtained by reviewing the descriptions of behaviour in each category and selecting the number that most closely represents the behaviour observed at the time the subject experiences the most distress. Each category is scored from one to five. Observable forms of behaviour in each category of the CEMS are explained in detail with an operational definition, so that the observer, a research nurse in this study, using the scale has relatively clear-cut criteria for assessment. The sum of the numbers obtained for each category is the total score, which will be between 5-25, higher scores indicating the manifestation of more negative (distressed) emotional behaviour. The evaluation of the psychometric properties of the CEMS demonstrated adequate reliability and validity.[25] The Cronbach's alpha of the scale in this study was 0.86.[23-24]

Secondary outcome measures

Satisfaction scale for parent and cast technician

Two questionnaires in English, developed by Tyson and colleagues (2014),[12] were adopted to measure parents' and cast technicians' satisfaction levels. The original questionnaire for parents is a 10–item scale to measure their satisfaction with the child life services. Each item is rated on a five-point scale ranging from 1 = strongly disagree - 5 = strongly agree, higher scores indicating higher levels of satisfaction. Example of the statement used is 'My child's emotional needs were met'. The perception of the cast technician was examined by eight items, with each being rated on a scale from 1 = strongly disagree - 5 = strongly agree. Example of the statement

used is 'the child engaged in distraction'. The researcher translated the questionnaire into Chinese, using the back-translation method recommended by Brislin (1986).[26] The translated version was reviewed by a panel of expert professionals for semantic and content equivalence. The scale level of semantic equivalence for the parents' satisfaction and cast technician satisfaction was 95% and 92%, respectively, indicating that the translated version was a correct reflection of the original version.[27] The content validity index of the parent's satisfaction level scale was 0.90 and cast technician's satisfaction level scale was 0.94, indicating the content of the translated scale were equivalent to the original version. The Cronbach's alpha of both scales in this study was 0.90.

Heart rate monitoring

A standard automatic heart rate monitoring machine, available in the study hospital, was used to measure children's heart rates to assess their physiological responses to CR procedures. Children's heart rates have been considered objective and definitive indicators for an indirect assessment of children's anxiety levels in previous studies.[28]

Anxiety produced due to CR procedures likely manifested as an increase in heart rate in children.

A demographic sheet

The socio-demographic and clinical variables of parents and children were collected. The items for children include age, sex, reason for cast application and number of hospital admissions. The accompany parent's age, sex, educational level and working status was also obtained. The cast technician's demographic information,

including age, sex and years of work experience, was also collected by the research nurse.

Data collection

Children having their cast-removal would be arranged to wait outside the cast room of the study OPD in a separate timeslot. They would be identified by a research nurse in the waiting area. Permission for a child meeting the recruitment criteria to participate was obtained from the accompanying parent. The research nurse conducted the interview with consenting parent–child pairs in a private room. The children in both groups were asked to indicate how anxious they were by completing either the VAS anxiety scale (for children between 3–7 years old) or the short form of the CSAS-C (for children aged between 8–12).[17] The rearch nurse obtained demographic and clinical data from the parents. She also asked the parents of children aged under 5 to use the VAS scale to indicate their child's perceived anxiety level. Children's heart rates were also monitored for one minute at the end of the interview, using a standard automatic monitor.

According to the subject allocation scheme, children in the control group received standard care in CR room A, while the intervention group additionally received a therapeutic play intervention conducted by the HPS in CR room B. The parents and children were asked during the informed consent process not to discuss the purpose of the study with cast technicians in the cast room.

In the CR room, the research nurse took two one-minute recordings of the child's heart rate: (1) when the cast technician started sawing the cast; and (2) immediately after the cast had been removed. The research nurse then rated the child's signs of distress from the time the saw touched the cast until the limb was free of it, by means

of the CEMS.[25] She also recorded the length of the whole CR procedure for each child. After the CR procedure, the research nurse asked the parents and the cast technician to fill in their respective satisfaction scales to reflect their perceptions of how the CR procedure had been delivered. The children were asked to recall their level of anxiety throughout the procedure by filling in either the VAS anxiety scale (for those between 3-7) or the short form of the CSAS-C (for those between 8-12).[17] Parents were asked to rate the VAS scale for children under 5.

Data analysis

All data were analysed by means of IBM SPSS for Windows, Version 22. Appropriate descriptive statistics were used to present the participants' socio-demographics and outcome measurements. A generalised estimating equations (GEE) model was used to compare each of the repeated outcome measures across time between the two groups. The model can account for intra-correlated repeated measures data and produce effect estimates even in the presence of missing data, provided they are missing at completely random. All statistical analyses were two-sided, with the level of significance set at 0.05.

Patient and Public involvement

Development of research question and outcome measures were based on the facts that many children reported anxiety during the cast removal procedures. Patients were not involved in the design, subject recruitment, and the conduction of the study. The findings will be disseminated to the study participants by publishing the study as an original article. A satisfaction survey was conducted involving the parents of the

participants to assess whether the participants experienced any burden during the intervention.

Results

Demographic and clinical characteristics of the children and their families

From August 2015 - January 2017, a total of 209 patients and their accompanying parents were screened and approached. However, one of them declined to participate in the study because they were in a hurry and had to leave the clinic at once after the procedure. Therefore, a total of 208 participants and their accompany parents were recruited. Of these, 105 were allocated to the control group and 103 to the intervention group (Figure 1). Their mean ages were 7.7 (SD 3.0) and 7.5 (SD 2.9), respectively. The demographic and clinical characteristics of the two groups were comparable and are shown in Table 1.

Anxiety levels

Children aged between 3 and 7

The mean anxiety scores of children aged 3-7 in the intervention group as measured by VAS anxiety scale decreased from 35.4 to 27.6 after the CR procedures. By contrast, the mean anxiety levels of children who did not take part in therapeutic play increased from 34.0 to 46.3. The difference in mean changes between the two groups as estimated by the group by time interaction term by using GEE was -20.1 (95% CI: -35.3 to -4.9; p=0.010) (Table 2).

Accompanying parent(s) with children under 5 were invited to rate the anxiety levels of their children using VAS. The results showed that there were moderate to high correlations between the children and their parent's rating before (r = 0.36, 95%

CI: 0.0 to 0.65; p<0.05) and after the CR procedure (r = 0.50, 95% CI: 0.13 to 0.74; p<0.01).

Children aged between 8 and 12

The mean anxiety scores of children in the intervention group as measured by CSAS-C fell from 18.0 to 15.3, and in the control group from 17.4 to 15.9. The difference in mean changes between the two groups as estimated by using GEE was -1.1 (95% CI: -2.8 to 0.5; p=0.171). (Table 3).

Emotional manifestation during cast-removal procedures

The mean emotional manifestation scores of children aged 3 - 7 and 8 - 12 in the intervention group were significantly lower than the control group (Table 2 and Table 3). Overall, the mean emotional manifestation scores of the intervention group were 7.6 (SD 2.4) and of the control group 9.8 (SD 3.9) with a mean difference of -2.2 (95% CI: -3.1 to -1.4; p<0.001), indicating that children in the intervention group, on average, exhibited fewer negative emotional manifestations during the CR procedures comparing with those children in the control group (Table 4).

Changes in heart rate

No significant difference in heart rate was noted between the intervention and control group among children aged 3 and 7 years old (Table 2). In contrast, significant difference was found before and during CR procedure between the intervention and control group among children aged 8 and 12 years old (Table 3). Among all children, a trend of increasing heart rate was noted before and during the CR procedures for both groups. The mean heart rate of the intervention and control groups increased by

2.6 and 8.4 beats/minute, respectively with a difference in mean changes between the two groups as estimated by using GEE was -5.9 (95% CI: -10.3 to -1.5; p=0.008), indicating that the children in the intervention group might experience lower levels of anxiety than those in the control group (Table 4).

Satisfaction levels of parents and cast technicians

Among all children, the satisfaction scores of parents in the intervention group (46.6, SD 5.1) were higher than the control group (42.6, SD 6.9) with a mean difference of 4.0 (95% CI: 5.6 to 2.3; p<0.001). Similarly, the satisfaction scores of CR technician in the intervention group (34.3, SD 3.6) were higher than those in the control group (31.7, SD 4.3) with a mean difference of 2.6 (95% CI: 3.7 to 1.6; p<0.001). (Table 4).

Duration of procedure

Among all children, the mean time (in minutes) taken to perform the CR procedure was shorter in the intervention 4.1 (SD 2.3) than in the control groups 4.6 (SD 2.2) with a mean difference of -0.56 (95% CI: -1.17 to 0.05; p=0.072). (Table 2).

Discussion

This study expanded previous studies and examined the effects of a therapeutic play intervention on CR procedures in patients, parents and institutions. A randomised controlled design was employed such that the cause and effect relationships among variables could be established.[27] Findings suggest that therapeutic play effectively assists children aged 3-7 to cope with stressful CR procedures and reduces their

anxiety levels. Overall, children who received the intervention exhibited significantly fewer negative emotional manifestations than those who did not.

Most children in this study presented some degree of anxiety before the procedures, the use of a saw and the fluctuating level of high-frequency noise probably accounting for most of the anxiety.[1 29] Previous studies employed ear protection [5] or lullaby-type music [6] to reduce anxiety in children during CR, while heart rate and mean arterial blood pressure were used as physiological outcome indicators of anxiety, respectively. However, no significant difference was noted in these parameters in either study.

The positive results of the present study are further supported by the fact that the mean increase in heart rates before and during the procedure was lower in the intervention than in the control group. A possible explanation may be that the therapeutic play assisted children to cope with an unfamiliar procedure. During the play session, the HPS explained and simulated the CR procedures, which allowed the children to understand them. As the children were familiarised with the procedure, they would expect it to generate noise but not pain. These preparations assisted the children in such a way that they had an enhanced sense of control over the procedure, minimising the adverse effects of the experience.[6] As suitable and age-appropriate distraction were provided to the intervention group, the children's attention was diverted from the anxiety-provoking procedure to playful interaction. They therefore exhibited less negative emotional behaviour. However, children without any distraction might have focused on the whole procedure and thus exhibited more negative emotions and increased anxiety levels, even after it was all over.

Nevertheless, although children of 8-12 in the intervention group had larger reductions in their anxiety scores than those in the control group after the procedure,

the difference between the groups was non-significant. The results were in conflict with those of a previous study suggesting that older hospitalised children benefit more from the play intervention.[21 30] One possible explanation for the non-significant findings is that older children have a better understanding of CR procedures than younger children. According to Piaget (1963),[15] children of 8–12 can mentally manipulate information to solve problems. As they may have obtained information about the CR procedure from other sources, such as books, the internet or friends, they might feel less anxious about the forthcoming procedure. Moreover, compared with younger children, older children probably have better coping strategies and better control of their emotions, even in stressful situations. Nevertheless, further study is needed to determine other effective methods for children at this developmental stage.

Consistent with a previous study,[31] the result indicated that parents of children in the intervention group were more satisfied with the care and play intervention than those of children receiving standard care only. The satisfaction of parents in the intervention group is likely to have increased because they also experienced the positive influence of play on their children, particularly the reduction in anxiety and improved cooperation with the procedure.[32] In fact, parental perception played an important role on child's coping with various conditions such as cancer or other medical procedures.[33] The positive correlations in the VAS ratings of children under 5 further suggested that parents also perceived their children to be less anxious after the intervention. However, further study could also include self-report questionnaire not only on satisfaction but also examine the mediating role of parents play in the distraction intervention.

Some cast technicians might have concerns that the CR procedures would be impeded and prolonged because the play intervention was implemented at the same

time. However, the findings suggest that the duration of the entire procedure was shorter in the intervention than in the control group, although the differences were non-significant. Nevertheless, the duration in the intervention group did decrease, probably because the children were psychologically prepared and were thus more cooperative. In fact, children who are less anxious are easier to manage in clinical situations,[34] which may account for the increased satisfaction of CR technicians in procedures assisted by HPS.

Limitations

The results of the current study should be interpreted in the light of several limitations. First, children were recruited from a single clinical setting. The generalisability of the findings may therefore be restricted. Second, neither patients nor outcome assessors were blinded to the study. However, because of the very nature of the intervention, blinding of patients and outcome assessors would have been difficult. Although children are unlikely to change their behaviour even when they know they are participating in a certain intervention, [9] however, lack of blinding may contribute to an importance source of bias because the assessors know the group allocation of children which likely affect their ratings of children's emotional manifestation during the CR procedures. Nevertheless, different strategies were employed to minimise the potential bias. For example, children were assigned to different cast rooms and isolated from other patients at the time of the intervention, regardless of whether or not they were randomised to the play intervention group. Also, subjective and objective outcome measures were used to evaluate the impact of therapeutic play on the psychological state of a child. Finally, there might be other factors that affect children's anxiety level and play predisposition such as children'

coping styles or temperament, or parent's anxiety level and symptomatology towards cast-removal procedure. Future study should take these factors into account and consider to include the assessment of children's coping style or parents' anxiety level as well.

Conclusions

This study confirms the findings of previous work that children experience some degree of anxiety and exhibit negative emotional manifestations during medical procedures. The consequences of stress appear to be substantial, and thus the importance of assisting children to cope effectively with it and reduce its impact is highlighted. A gap in the literature is addressed by providing empirical evidence on the benefits of therapeutic play for children, family and medical institution during CR procedures. The findings show that a play intervention effectively reduces anxiety levels and negative emotional manifestations among children undergoing CR procedures. Such positive outcomes also translate into an improvement in the satisfaction levels of parents and CR technicians with the procedures. Play is universal and similar intervention can be adopted in other settings or medical procedures. It may also adopt to reduce anxiety and improve motor abilities of children that underwent invasive procedures.[35] The findings highlight the importance of providing and integrating therapeutic play into standard care. Such an intervention ensures that holistic and quality care is provided to ease the psychological burden of the patients. Furthermore, it contributes to improve patient care, satisfaction and overall experience of children and their families.

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Figure Legends

Figure 1: The CONSORT diagram of this study

Footnotes

Contributors: Wan Yim and King Wah conceived and designed the study. Cho Lee and Wing Han obtained ethical approval. Ming Chau supervised data collection. Cho Lee supervised the data analysis and wrote the paper. Kai Chow provided statistical support and analysed the data. Ming Chau and Wing Han helped revising the manuscript. All authors have given final approval of the version to be published.

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Competing interests: No conflict of interest has been declare by all the authors.

Patient consent: Obtained.

Ethics approval: This study was approved by the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (2015.005-T).

Provenance and peer review: Not commissioned; externally peer reviewed.

Data sharing statement: Not additional data are available.

Table 1: Socio-demographics and clinical characteristics of the participants (n=208) and cast-removal technicians (n=12)

Characteristics	Control (n=105)	Intervention (n=103)
Children and their family		
Age of the child (years) †	7.7 (3.0)	7.5 (2.9)
Age group		
3 – 7 years	55 (52.4%)	52 (50.5%)
8 – 12 years	50 (47.6%)	51 (49.5%)
Sex of the child		
Female	37 (35.2%)	36 (35.0%)
Male	68 (64.8%)	67 (65.0%)
Accompanied by		
Mother only	52 (49.5%)	54 (52.4%)
Father only	29 (27.6%)	26 (25.2%)
Both parents	14 (13.3%)	10 (9.7%)
Mother/father together with other relatives	6 (5.7%)	6 (5.8%)
Other relatives	4 (3.8%)	7 (6.8%)
Highest education attainment of the accompanied family		
Primary or below	8 (7.6%)	7 (6.8%)
Secondary	63 (60.0%)	64 (62.1%)
College or above	34 (32.4%)	32 (31.1%)
Number of hospital admission		
0	38 (36.2%)	31 (30.1%)
1	30 (28.6%)	36 (35.0%)
2	25 (23.8%)	14 (13.6%)
≥ 3	12 (11.4%)	22 (21.4%)
Type of casts		
Arm long	88 (83.8%)	82 (79.6%)
Arm short	6 (5.7%)	7 (6.8%)
Leg long	9 (8.6%)	13 (12.6%)

Leg short	2 (1.9%)	1 (1.0%)
CR technician (n=12)		
Sex		
Female	32 (30.5%)	30 (29.1%)
Male	73 (69.5%)	73 (70.9%)
Age (years)		
< 30	16 (15.2%)	9 (8.7%)
30 – 40	34 (32.4%)	39 (37.9%)
> 40	55 (52.4%)	55 (53.4%)
Years of experience		
< 2	14 (13.3%)	9 (8.7%)
2 – 5	47 (44.8%)	41 (39.8%)
> 5	44 (41.9%)	53 (51.5%)

Data of variables marked with † are presented as mean (standard deviation), otherwise as frequency (%).

Table 2: Outcome measures across time between the intervention and control groups among those children aged between 3 and 7 years (N=107)

	Control (n=55)	Intervention (n=52)	p-value	Effect size (95% CI) #
VAS anxiety scale (range: 0 – 100)				
T1 (before CR procedure)	34.0 (30.0)	35.4 (32.7)		
T3 (after CR procedure)	46.3 (37.3)	27.6 (28.6)	0.010 [a]	0.50 (0.11 , 0.88) [c]
Children's emotional manifestation scale (range:5 – 25)				
T2 (during CR procedure) †	10.6 (4.7)	8.1 (2.9)	0.002 [b]	0.62 (0.23 , 1.01)
Heart rate (per minute)				
T1 (before CR procedure)	88.7 (14.9)	88.6 (14.5)		
T2 (during CR procedure)	95.8 (17.7)	89.8 (16.6)	0.081 [a]	0.33 (-0.05 , 0.71) [c]
T3 (after CR procedure)	97.2 (15.6)	90.0 (17.2)	0.051 [a]	0.37 (-0.01 , 0.75) [c]
Parent satisfaction score (range: 10 – 50)				
T3 (after CR procedure)	42.5 (6.7)	47.3 (3.3)	<0.001 [b]	0.89 (0.49 , 1.28)
CR technician satisfaction score (range: 8 – 40)				
T3 (after CR procedure)	31.5 (5.0)	33.9 (3.7)	0.007 [b]	0.54 (0.15 , 0.92)
Duration of procedure (mins)	4.8 (2.2)	4.2 (2.0)	0.126 [b]	0.30 (-0.08 , 0.68)

Data of variables marked with † are presented as median (inter-quartile range), otherwise as mean (standard deviation)

† Nature log-transformed before subjected to independent t-test

Cohen's d effect size

[a] P-value testing for differential change of heart rate at the underlying time point with respect to T1 by using GEE model

[b] Independent t-test

[c] The Cohen's d effect size corresponds to the standardized mean difference of the mean changes at the underlying time point with respect to T1 between the intervention and control groups

Table 3: Outcome measures across time between the intervention and control groups among those children aged between 8 and 12 years (N=101)

	Control (n=50)	Intervention (n=51)	p-value	Effect size (95% CI) #
State Anxiety Scale for Children (CSAS-C) (range: 10 – 30)				
T1 (before CR procedure)	17.4 (4.0)	18.0 (3.5)		
T3 (after CR procedure)	15.9 (4.7)	15.3 (3.9)	0.171 [a]	0.27 (-0.12 , 0.66) [c]
Children's emotional manifestation scale (range:5 – 25)				
T2 (during CR procedure) [†]	9.0 (2.6)	7.0 (1.4)	<0.001 [b]	0.93 (0.51 , 1.33)
Heart rate (per minute)				
T1 (before CR procedure)	86.3 (13.4)	84.8 (12.6)		
T2 (during CR procedure)	96.2 (14.4)	88.7 (14.5)	0.037 [a]	0.41 (0.01 , 0.80) [c]
T3 (after CR procedure)	89.9 (13.1)	87.5 (13.8)	0.720 [a]	0.07 (-0.32 , 0.46) [c]
Parent satisfaction score (range: 10 – 50)				
T3 (after CR procedure)	42.8 (7.1)	46.0 (6.5)	0.020 [b]	0.47 (0.07 , 0.86)
CR technician satisfaction score (range: 8 – 40)				
T3 (after CR procedure)	31.8 (3.5)	34.8 (3.5)	<0.001 [b]	0.83 (0.42 , 1.24)
Duration of procedure (mins)	4.4 (2.2)	3.9 (2.5)	0.314 [b]	0.20 (-0.19 , 0.59)

Data of variables marked with [†] are presented as median (inter-quartile range), otherwise as mean (standard deviation)

[†] Nature log-transformed before subjected to independent t-test

[#] Cohen's d effect size

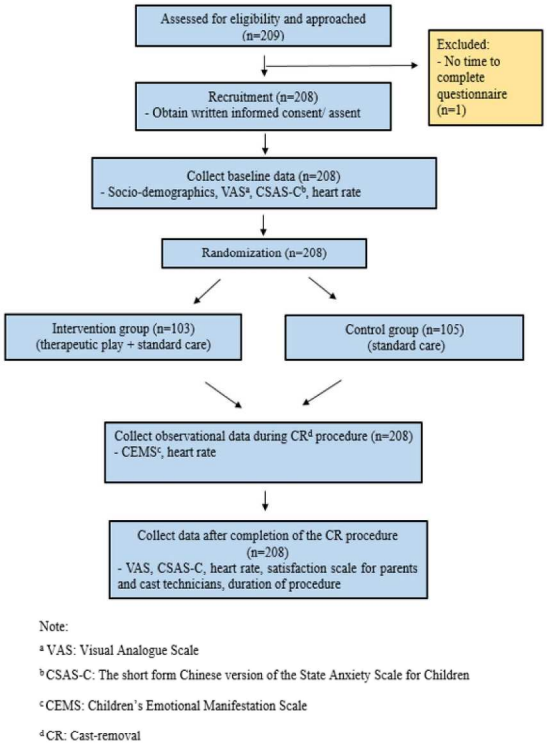
[a] P-value testing for differential change at the underlying time point with respect to T1 by using GEE model

[b] Independent t-test
[c] The Cohen's d effect size corresponds to the standardized mean difference of the mean changes at the underlying time point with respect to T1 between the intervention and control groups

Table 4: Outcome measures across time between the intervention and control groups

	Control	Intervention	p-value	Effect size (95% CI) #
Among all children (N=208)				
Children's emotional manifestation scale (range:5 – 25)	**(n=105)**	**(n=103)**		
T2 (during CR procedure) †	9.8 (3.9)	7.6 (2.4)	<0.001 [b]	0.69 (0.41 , 0.69)
Heart rate (per minute)				
T1 (before CR procedure)	87.6 (14.2)	86.7 (13.6)		
T2 (during CR procedure)	96.0 (16.2)	89.3 (15.5)	0.008 [a]	0.36 (0.09 , 0.64) [c]
T3 (after CR procedure)	93.7 (14.9)	88.8 (15.6)	0.070 [a]	0.25 (-0.02 , 0.52) [c]
Parent satisfaction score (range: 10 – 50)				
T3 (after CR procedure)	42.6 (6.9)	46.6 (5.1)	<0.001 [b]	0.65 (0.38 , 0.93)
CR technician satisfaction score (range: 8 – 40)				
T3 (after CR procedure)	31.7 (4.3)	34.3 (3.6)	<0.001 [b]	0.66 (0.38 , 0.94)
Duration of procedure (mins)	4.6 (2.2)	4.1 (2.3)	0.072 [b]	0.25 (-0.02 , 0.52)

Data of variables marked with † are presented as median (inter-quartile range), otherwise as mean (standard deviation)
† Nature log-transformed before subjected to independent t-test
# Cohen's d effect size
[a] P-value testing for differential change at the underlying time point with respect to T1 by using GEE model
[b] Independent t-test
[c] The Cohen's d effect size corresponds to the standardized mean difference of the mean changes at the underlying time point with respect to T1 between the intervention and control groups



The CONSORT diagram of this study

210x297mm (300 x 300 DPI)

Title of proposal: The stress-reducing effects of therapeutic play on children undergoing cast-removal procedure.

Background

It is common for children to display stressed behaviour in clinical settings, even during painless medical procedures such as cast-removal. Many behavioural and physiological manifestations of anxiety in children are associated with their compliance with the medical procedures and thus the recovery outcomes (Felder-Puig et al., 2003) and the quality of care (Tyson, Bohl, & Blickman, 2014). Researchers (Li, Lopez, & Lee, 2007) has pointed out that lack of self-control and limited cognitive capabilities are two main factors associated with children's anxiety and that psychosocial preparation of the children through therapeutic play could help them gain a sense of self-control and achieve lower anxiety levels.

Therapeutic play is a set of structured activities that are designed according to the subject's age, cognitive development and health-related issues, to promote emotional and physical well-being in hospitalized children (Vessey & Mahon, 1990). Extensive studies have supported therapeutic play as an effective pre-operative preparation for both children and parents in reducing fear and anxiety (Christian, Russ, & Short, 2011; Nyugen, & Thaller, 2008). Care providers should consider the human rights of children, and provide age-appropriate information to aid understanding of the disease and the interventions employed.

Brewer et al. (2006) evaluated the effectiveness of therapeutic play in a double-blind intervention study. The findings showed that preparation with role rehearsal and medical play could lower anxiety levels in children following elective day surgery. Additionally, a recent randomized, controlled trial (RCT) (Tyson et al., 2014) found that therapeutic play could enhance satisfaction, not only to children but also in the parents and healthcare providers. However, the efficacy of therapeutic play are yet to be determined because the reported studies were based mainly on clinical observations and most of the play manuals, which should have set out specific procedures and improved fidelity, were not fully described (Brewer et al., 2006; Stevenson et al., 2005; Tyson et al., 2014). Researchers have emphasized the need for further objective data-gathering studies on the scope of procedures in an out-patient setting.

In summary, the comprehensive value of therapeutic play—in terms of impact on the child, family and medical institution as a whole—remains largely unexplored in the literature. Our literature search revealed no reports of prospective and randomized controlled studies of the effectiveness

of therapeutic play among Chinese children undergoing cast-removal procedures, let alone among Hong Kong Chinese.

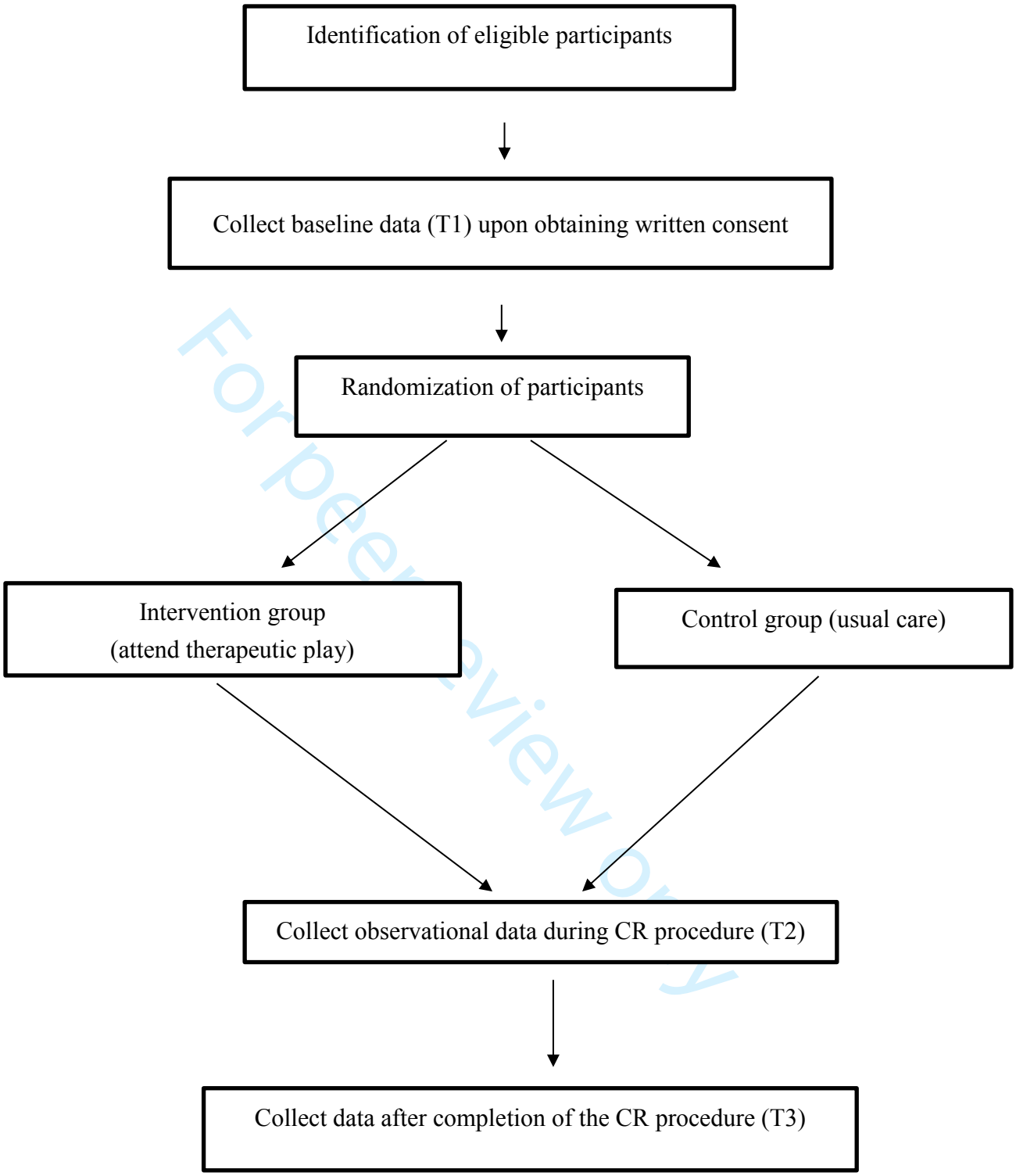
Aims

The aim of this study is to examine the impact of the therapeutic play on the psychological stress of paediatric patients during cast-removal (CR) procedures in an orthopaedic out-patient clinic in Hong Kong. The satisfaction ratings of parents and healthcare providers in respect of these services will also be examined.

Methods

Design

This is a two-arm randomized controlled trial. Eligible children undergoing the CR procedure will be randomly allocated to either the experimental or control groups in a 1:1 ratio. The child and accompanying parent in the experimental group will receive therapeutic play intervention, and the control group will receive routine care only. All participants will be assessed on three occasions: before, during, and after completion of the CR procedure. Please refer to Figure 1 for the study protocol.



CR = cast removal

Figure 1. Study Protocol

Research Hypotheses

The research objectives are to examine whether, in CR procedures, there are significant differences between the Intervention and Control groups in:

1. children's anxiety levels
2. children's emotional distress levels
3. children's heart rates
4. length of procedure
5. satisfaction levels of parents and technicians in respect of the procedures.

Settings

This study will be conducted in the orthopaedic out-patient department (OPD) of a regional teaching hospital in Hong Kong. A cast room in the OPD performs approximately 20 cast-removal procedures monthly. At the time of this proposal, the standard of regimen in this OPD does not include therapeutic play services. The cast technicians attend to paediatric patients every Wednesday afternoon. They receive limited training on the developmental needs of children in their profession.

Sample

Children and their accompanying parents, who are waiting for the cast room procedure, will be invited to participate in the study if (i) the children are 3–12 years of age and (ii) the parents are able to speak Cantonese and read Chinese. Children will be excluded if they have had a cast removed within 3 months and demonstrate obvious neurological or developmental problems during cognitive assessment by a play specialist.

The rationale for selecting 3–12-year-old is that the number of children having cast room procedure within this age range in Hong Kong is higher than for other age groups. In fact, according to Piaget's (1963) theory of cognitive development, children from 3 to 7 years of age belong to the same pre-operational stage, while those in the age range 8–12 years belong to the concrete operational stage. In addition, according to Erickson (1963), children in the same age group fall in the same stage of psychosocial development. Accordingly, randomization of participants to the experimental (E) or control (C) groups will be stratified by the two age groups: 3–7 and 8–12 years. Serially numbered opaque sealed envelopes containing the grouping identifier (E or C) for each age group will be prepared in advance by an independent statistician using computer generated random codes. The group allocation of the recruited children will be assigned according to their

ages and sequence of enrolment in the study and the grouping identifier contained in the corresponding numbered envelopes.

The sample size of the study is determined to detect at least a medium effect size of Cohen's d = 0.5 between the experimental and control groups. According to Cohen (1992), 64 subjects in each group will be sufficient to detect a medium effect of 0.5 with 80% power at 5% level of significance. Taking into account of up to a 15% attrition rate and stratified the study by age, seventy-five children each will be recruited for the experimental and control groups per stratum by age (3–7 and 8–12 years).

Interventions

The research team discuss the study protocol and an experienced hospital play specialist (HPS) will conduct all interventions in the study during her regular shift. Each child who is assigned to the Intervention group will receive an initial assessment, who will individualize the therapeutic activities based on children's psycho-cognitive development (Erikson, 1963; Piaget, 1963) and general condition. Duration and type of intervention will be varied, based on the assessment of the child's needs, but will usually be completed within 30 minutes. The content of the therapeutic play has two main components: preparation play and distraction play (Blaine, 1999).

Preparation Play

Preparation play consisting of two parts of intervention will be conducted before the CR procedure:

Part I: information given

The children and parents should be well prepared by information supplied about the procedure and the choices of behaviour management. The hospital jargon were translated into ordinary language and in giving explanations in terms that suit the developmental level of the child (Brown et al., 1997). The preparation phase will be implemented individually, with their parents, in a service room. Information about the procedure will be provided, such as: (i) Why must the procedure be done? (ii) Where will the procedure take place? (iii) What will be happening? and (iv) How will it feel? Multiple coping strategies will also be introduced, so as to allow the parent and child to choose the one appropriate to them (Stephens, Barkey, & Hall, 1999); for example: (i) whether or not to watch the procedure, (ii) to pick something nice to think about and (iii) to sing a song. Choices of age-appropriate toys with specified playing activities will also be given to promote the coping strategies of the children.

Part II: rehearsal of the procedure

After verbal explanation, a demonstration of the cast-removal procedure will be conducted, using a doll. Examples of such a demonstration are:

- Show a dummy circular-saw cast cutter with appropriate sound effect
- Play with a doll and explain how the cast is cut open by the circular saw
- Reassure the child that the saw will not cut his or her skin if he or she follows the instruction not to move
- Explain that, when the cast is cut, the child may feel vibrations or tingling, feel warmth, and see chalky dust flying
- Describe the use of spreaders and scissors to finish removing the cast
- Explain how, after the cast is open, the child's skin may appear scaly and dirty and the child's arm or leg may be a little stiff when he or she first tries to move it; also that the arm or leg may seem light because the cast was heavy.

Each child will be asked to role-play how he or she would respond to the procedure after the demonstration. During the session, parents and children will be encouraged to raise their concerns or ask any questions about the procedure. The preparation intervention will usually take 10–15mins to complete.

Distraction Play

Support will be given to the children and parents throughout the cast-removal procedure by giving distraction play intervention. The aim is to focus children's attention away from the medical procedure. Methods of distraction include visual distraction, auditory distraction, deep breathing exercises, tactile stimulation, counting/singing or verbal interaction. The choice of the distraction method the children's choices (Doellman, 2003). Parental presence and involvement will be supported, and praise will be given to any successful self-control exhibited by the child. The conclusion of the procedure will be indicated by offering the child a reward (sweets or stickers).

Measures

A visual analogue scale (Appendix I)

A visual analogue scale (VAS) will be used to assess the anxiety levels of children aged 3–7. The VAS is a 10 cm horizontal line anchored by the words "not worried" (low score) at one end and "very worried" (high score) at the other, with different facial expressions drawn along the line. Children aged between 5 and 7 will be asked to indicate their levels of anxiety by moving a pointer over the line. Accompanying parent(s) will rate the anxiety levels of children aged 3–4, with higher

scores indicating greater anxiety. The VAS is a widely used scale which is found to be a reliable and valid tool for measuring subjective feelings of children aged 5 to 7 (Bringuier *et al*., 2009).

The short form of the Chinese version of the State Anxiety Scale for Children (CSAS-C) (Appendix II)

The CSAS-C was a 10-item self-report scale to measure the levels of anxiety among children aged 8-12 in busy clinical settings (Li & Lopez, 2007). The content validity of the scale has been empirically tested and the Cronbach's alpha value was 0.83. This is a 3-point Likert scale with total scores ranging from 10 to 30. Higher scores indicate greater anxiety levels (Li & Lopez, 2007).

Children's Emotional Manifestation Scale (CEMS) (Appendix III)

The emotional behaviours of children during CR procedures will be documented using the CEMS. The CEMS was developed by Li and Lopez in 2005. It comprises five observable emotional behaviours, categorized as 'Facial expression', 'Vocalization', 'Activity', 'Interaction' and 'Level of Co-operation'. The CEMS score is obtained by reviewing the descriptions of behaviour in each category and selecting the number that most closely represents the observed behaviour at the time the subject experiences the most distress. Each category is scored from one to five. Observable behaviours in each category of the CEMS are explained in detail with an operational definition, so that the observer, a research nurse (RN) in this study, using this scale has relatively clear-cut criteria for assessment. The sum of the numbers obtained for each category is the total score, which will be between 5 and 25. Higher scores indicate the manifestation of more negative (distressed) emotional behaviours. The evaluation of the psychometric properties of the CEMS demonstrated adequate inter-rater reliability, high internal consistency, good content validity and excellent convergent validity (Li & Lopez, 2005).

Satisfaction Scale

Two questionnaires in English, developed by Tyson and colleagues (2014), will be adopted to measure parents' (Appendix IV) and cast technicians' (Appendix V) satisfaction levels. The RN will work with the research team to translate the English questionnaire into a Chinese version, with reference to a back-translation method recommended by Brislin (1970).

The original questionnaire for the parent is a 10–item scale to measure parents' satisfaction with the child life services. Each item will be rated by a 5-point scale ranging from 1 = strongly disagree to 5 = strongly agree. A higher score indicates a higher level of the satisfaction. Examples of the statements used are 'My child's emotional needs were met' and 'I am satisfied with the care provided to my child' (Appendix IV). The perception of the cast technician on the service will be

examined by eight items, with each being rated on a scale from 1 = strongly disagree to 5 = strongly agree. Examples of the statements used are 'The child was co-operative' and 'The child engaged in distraction' (Appendix V).

Heart rate monitoring

A standard automatic heart rate monitoring machine, available in the study hospital, will be used to measure children's heart rates to assess their physiological responses to CR procedures. Children's heart rates have been considered to be objective and definitive indicators for indirect assessment of anxiety level in children in previous studies (Augustin & Hains 1996; Panda *et al*. 1996; Li & Lopez 2007).

A demographic sheet

A questionnaire developed by the research team will be used to measure the socio-demographic and clinical variables of the parent and their child. The items for children include age, sex, reason for cast application and number of hospital admissions. The accompany parent's age, sex, educational level and working status will also be obtained.

The cast technician's demographic information including age, sex and years of working experience will also be collected by the RN.

Data Collection Procedure

Children having their casts removed will be identified outside the cast room of the study OPD by the RN. If the child meets the inclusion criteria for recruitment, permission for the child to participate will be obtained from the accompanying parent. The RN will then conduct the interview with consenting parent–child pairs in a private room. The children of the consenting parents in both groups are asked to indicate how anxious they are by filling in either the VAS anxiety scale (for children between 5–7 years old) or the short form of the CSAS-C (for children aged between 8–12) (Li & Lopez, 2007). The RN will acquire demographic and clinical data from the parents. She will also ask the parents of children aged under 5 to use the VAS scale to indicate their child's perceived anxiety level. Children's heart rates will also be monitored for 1 minute, using a standard automatic heart rate monitoring machine at the end of the interview.

According to the subject allocation scheme, children in the Control group will receive routine care in the CR room A, whereas those in the Intervention group will additionally receive therapeutic play intervention conducted by the HPS in the CR room B. The parents and children will be asked not to discuss the purpose of the study with cast technician in the cast room during the informed consent process.

In the CR room, the RN will take the 1-minute recording of the child's heart rate when the cast technician starts sawing the cast of the child. The RN will also rate the child's signs of distress from the time the saw touches the cast until the limb is free from the cast, by means of the CEMS (Li & Lopez 2005). The length of the whole CR procedure for each child will also be recorded by the RN. The timing, duration, and nature of play for each child will be documented in a log book. After the completion of the CR procedure, The RN will take the child's heart rate for 1 min and then ask the parents and the cast technician to fill in their respective satisfaction scales to reflect their perceptions of the delivery of the CR procedure.
The RN will give a $30 dollar coupon to the parent upon completion of data collection.

A pilot study on 5 pairs of eligible parent-child dyad will be performed to assess the feasibility of the data collection plan and to pre-test the questionnaires. The respondents' comments on and impressions of the pilot study will help the research team to refine or revise the study plan (Polit *et al*., 2013). Please refer to the outline of data collection in Table 1.

Table 1. The plan of data collection by the research nurse

	Pre-test data upon consent given (T1)	Observational data during procedure (T2)	Post-test data after procedure (T3)
Demographic and clinical variables	X		
VAS anxiety scale for children 3–7 years old; The short form of the Chinese version of the State Anxiety Scale for Children (CSAS-C) for children aged 8–12	X		X
Children's Emotional Manifestation Scale		X	
1 minute heart rate recorded by an automatic heart rate monitoring machine.	X	X	X
Parent satisfaction scale			X
Staff satisfaction scale			X

Length of procedure		X	

Data Analysis

All data will be analysed using IBM SPSS for Windows, Version 22. Descriptive statistics such as mean, standard deviation, medium, inter-quartile range, frequency and percentage, as appropriate, will be used to present the participants' socio-demographics and outcome measurements. Pearson's chi-squared test and student's *t*-test will be used as appropriate for comparing the baseline differences between the two groups. Generalized estimating equations (GEE) model will be used to compare the outcome measures across time between the two groups. GEE model can account for intra-correlated repeated measures data and accommodated missing data, provided the data are missing at random. All statistical analyses are two-sided and level of significance will be set at 0.05.

Ethical Issues

Ethical approval will be sought from the Ethical Committees of the University and the study hospital prior to conducting the study. The purpose and details of the study will be clearly provided to the accompanying parents before the RN obtains their written consent. Maintenance of confidentiality and anonymity of data gained will also be assured. Participants will be informed that the quality of care will not be affected by their participation status. Please refer to the details of the information sheet and consent form in Appendix VII.

Timeline

Timetable of the 20-month project

Month	**1**	**2**	**3**	**4–16**					**17**	**18**	**19**	**20**
RN training & literature review	★	★										
Questionnaires development & pilot study		★	★									
Data collection				★	★	★	★	★	★	★		
Data entry & data analyses									★	★	★	
Report writing											★	★

Note: Based on recruiting 20 cases per month

Significance

Removal of casts is a frightening procedure for children (Johnson et al., 1975), and studies on psychosocial care for children receiving the procedure are limited. This is the first study of this kind among Hong Kong Chinese children in an orthopaedic out-patient clinic. The findings will inform policy makers on the development and inclusion of therapeutic play interventions in paediatric out-patient healthcare settings.

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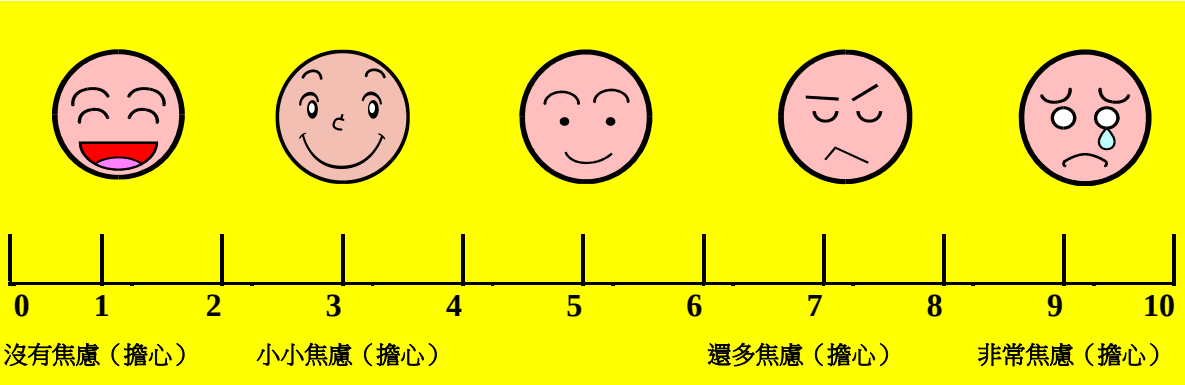
Appendix I

A 10-point level Visual Analogue Scale (VAS)



Appendix II

Short-Form of the Chinese version of the State Anxiety Scale

以下是一些男孩子和女孩子用來形容自己的句子。請小心閱讀每一句，然後在每句子的右方*圈出*最能表達你*現時感覺*的字句。答案是沒有分對或錯的。不要花太多時間在任何句子上，只要將最能表達你*現時感覺*的字句圈出來就可以了。

1. 我感到.....	十分愉快	愉快	不愉快
2. 我感到.....	十分不安	不安	無不安
3. 我感到.....	十分緊張	緊張	不緊張
4. 我感到.....	十分平靜	平靜	不平靜
5. 我感到.....	十分輕鬆	輕鬆	不輕鬆
6. 我感到.....	十分擔心	擔心	不擔心
7. 我感到.....	十分害怕	害怕	不害怕
8. 我感到.....	十分快樂	快樂	不快樂
9. 我感到.....	十分煩惱	煩惱	不煩惱
10. 我感到.....	十分開心	開心	不開心

---------- 此問卷到此完 ----------

Appendix 3

The Children Emotional Manifestation Scale

	1	2	3	4	5	Scored
Facial Expression						
Vocalization	No Crying	Watery eyes	Whimpering	Crying	Hard Crying or Non-stop Screaming	
Activity	Calm	Annoying	Irritable	Restlessness	Agitation	
Interaction	Verbal interaction	Non-verbal response only	Avoid interaction	Mild verbal protest	Strong verbal protest	
Level of Co-operation	Active participation	Passive participation	Withdrawal	Extreme resistance	Disruptive behaviour	

Appendix IV

Parent Satisfaction Scale (Chinese version)

家長滿意程度調查

香港中文大學現在正進行一項關於拆除石膏程序的研究，希望了解病人家屬和職員對這項服務的滿意程度。以下是關於剛才拆除石膏過程的相關問題，請為每條問題圈出符合你的同意程度的號碼。答案純屬個人意見，沒有標準答案。

(1 = 非常不同意；5 = 非常同意)

		非常不同意	不同意	中立	同意	非常同意
1	整個程序用了我的孩子能明白的語言去講解。	1	2	3	4	5
2	我孩子的情緒有被照顧到。	1	2	3	4	5
3	職員有關顧到我的孩子是否感到舒適。	1	2	3	4	5
4	我知道要怎樣做去幫助我的孩子。	1	2	3	4	5
5	職員有關顧到我的疑問和憂慮。	1	2	3	4	5
6	職員尊重我對我孩子的理解。	1	2	3	4	5
7	我對我孩子所受到的照顧感到滿意。	1	2	3	4	5
8	我會推薦這個服務給其他人。	1	2	3	4	5
9	職員都是友善和樂於幫忙的。	1	2	3	4	5
10	職員們好好地共同合作去照顧我的孩子。	1	2	3	4	5

Parent Satisfaction Scale

These are the questions in regards to the process of pop removal, please rate each question on scale 1-5

		STRONGLY DISAGREE	DIS-AGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
1	Appropriate wordings was used to let my kid to understand the process.	1	2	3	4	5
2	My kid's emotion was looked well after by the team.	1	2	3	4	5
3	Staff concerned about the comfortability of my kid.	1	2	3	4	5
4	I knew how to assist with my kid.	1	2	3	4	5
5	Staff concerned about my questions and worries.	1	2	3	4	5
6	Staff respect my knowledge to my kid.	1	2	3	4	5
7	I satisfied with the care received from the team.	1	2	3	4	5
8	I would recommend this hospital to others.	1	2	3	4	5
9	Staff were friendly and willing to help.	1	2	3	4	5
10	Staff cooperated well to care my kid.	1	2	3	4	5

Appendix IV
Staff Satisfaction Scale (Chinese version)
職員滿意程度調查

香港中文大學現在正進行一項關於拆除石膏程序的研究，希望了解病人家屬和職員對這項服務的滿意程度。以下是關於剛才拆除石膏過程的相關問題，請為每條問題圈出符合你的同意程度的號碼。答案純屬個人意見，沒有標準答案。

(1 = 非常不同意；5 = 非常同意)

		非常不同意	不同意	中立	同意	非常同意
1	孩子明白到甚麼事情將會發生。	1	2	3	4	5
2	孩子表現得合作。	1	2	3	4	5
3	孩子的情緒有被照顧到。	1	2	3	4	5
4	孩子的注意力已被分散。	1	2	3	4	5
5	家長明白怎樣去幫助他們的孩子。	1	2	3	4	5
6	進行拆除石膏程序的環境符合孩子的需要。	1	2	3	4	5
7	我對我們團隊所供給這個孩子的照顧感到滿意。	1	2	3	4	5
8	家人對於孩子所受到的照顧感到滿意。	1	2	3	4	5

Staff Satisfaction Scale

These are the questions in regards to the process of pop removal, please rate each question on scale 1-5

		STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
1	The kid understood what would happen next.	1	2	3	4	5
2	The kin was cooperative.	1	2	3	4	5
3	The kid's emotion was looked well after by the team.	1	2	3	4	5
4	The kid was distracted.	1	2	3	4	5
5	Parents knew how to help with their kids	1	2	3	4	5
6	The venue for POP removal was appropriate to kids' needs	1	2	3	4	5
7	I am satisfied with the cared provided to the kid.	1	2	3	4	5
8	Kid's family was satisfied with the care received by the kid.	1	2	3	4	5

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	21

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	16
	13b	For each group, losses and exclusions after randomisation, together with reasons	16
Recruitment	14a	Dates defining the periods of recruitment and follow-up	16
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	16
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	20
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	20
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	22
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Effects of therapeutic play on children undergoing cast-removal procedures: a randomised controlled trial

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Complete List of Authors:	Wong, Cho Lee; The Chinese University of Hong Kong, Faculty of Medicine, The Nethersole School of Nursing Ip, Wan Yim; The Chinese University of Hong Kong, Faculty of Medicine, The Nethersole School of Nursing Kwok, Blondi Ming Chau; Playright Children's Play Association Choi, Kai Chow; The Chinese University of Hong Kong, Faculty of Medicine, The Nethersole School of Nursing Ng, Bobby King Wah; The Chinese University of Hong Kong, Faculty of Medicine, Department of Orthopaedics & Traumatology Chan, Carmen Wing Han; The Chiniese University of Hong Kong, Faculty of Medicine, The Nethersole School of Nursing
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Title: Effects of therapeutic play on children undergoing cast-removal procedures: a randomised controlled trial

Authors:

Wong CL, Ip WY, Kwok BMC, Choi KC, Ng BKW, Chan CWH.

Authors' information:

Correspondence to CL Wong:

Cho Lee Wong

PhD, RN

Assistant Professor

The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China

Room 824, Esther Lee Building, The Chinese University of Hong Kong, Hong Kong.

Telephone number: (852) 3943 8166

Fax number: (852) 2603 5269

Email: jojowong@cuhk.edu.hk

Wan Yim Ip

PhD, RN

Associate Professor (Retired)

The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China

Email: wanyimip@cuhk.edu.hk

Kwok Blondi Ming Chau

BN, RN

Manager (Community & Hospital)

Playright Children's Play Association, Hong Kong, China

Email: blondi@playright.org.hk

Kai Chow Choi

PhD

Senior Research Fellow
The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China
Email: kchoi@cuhk.edu.hk

Bobby King Wah Ng
M.D.
Clinical Professional Consultant of Orthopaedics & Traumatology
Department of Orthopaedics & Traumatology, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China
Email: bobng@ort.cuhk.edu.hk

Carmen Wing Han Chan
PhD, RN
Vice-Director of Education / Professor
The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong, China
Email: whchan@cuhk.edu.hk

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Abstract

Objectives: To examine (i) the effectiveness of therapeutic play in reducing anxiety and negative emotional manifestations among children undergoing cast-removal procedures; (ii) the satisfaction of parents and cast technicians with cast-removal procedures.

Design: A randomised controlled trial.

Setting: An orthopaedic outpatient department of a regional teaching hospital in Hong Kong.

Participants: Children (n=208) aged 3-12 undergoing cast removal procedure were invited to participate.

Interventions: Eligible children were randomly allocated to either the intervention (n=103) or control group (n=105) and stratified by the two age groups (3–7 and 8–12 years). The intervention group received therapeutic play intervention, whereas the control group received standard care only. Participants were assessed on three occasions: before, during, and after completion of the cast removal procedure.

Outcome measures: Children's anxiety level, emotional manifestation, and heart rate. The satisfaction ratings of parents and cast technicians with respect to therapeutic play intervention were also examined.

Results: Findings suggested that therapeutic play assists children aged 3-7 to reduce anxiety levels with mean differences between the intervention and control group was -20.1 (95% CI: -35.3 to -4.9; p=0.01). Overall, children (aged 3-7 and 8-12) in the intervention groups exhibited fewer negative emotional manifestations than the control group with a mean score difference -2.2 (95% CI: -3.1 to -1.4; p<0.001). Parents and technicians in the intervention group also reported a higher level of satisfaction with the procedures than the control group with a mean score difference

of 4.0 (95% CI: -5.6 to 2.3; p<0.001) and 2.6 (95% CI: 3.7 to 1.6; p<0.001), respectively.

Conclusion: Therapeutic play effectively reduces anxiety and negative emotional manifestations among children undergoing cast-removal procedures. The findings highlight the importance of integrating therapeutic play into standard care, in particular for children in younger age.

Trial Registration: The Chinese Clinical Trials Registry: ChiCTR-IOR-15006822.

Strengths and limitations of this study:

- This study was one of the first randomised controlled trial to examine the effects of therapeutic play on children undergo cast-removal procedures, building the evidence base of therapeutic play.
- A major limitation was the lack of blinding of outcome assessor. Another limitation was recruiting children from a single clinical setting so that the generalisability of the findings may be restricted.
- The strength of this study included employing both subjective and objective outcome measures to evaluate the impact of therapeutic play on the psychological state of a child.

Introduction

It is common for children to display stressed behaviour in clinical settings even during painless medical procedures such as cast removal.[1 2] The original injuries sustained by the children, added to the unfamiliar environment and the equipment used during the procedures, are likely to provoke anxiety and fear in children of any age. The psychological burden on children not only makes the procedures difficult to perform effectively and efficiently, but may also impose medical risks.[1 3] For instance, an extreme case of death in a child having history of cardiomyopathy during the cast room procedure has been reported.[1] Moreover, anxiety in the children also reduces parents' satisfaction with the care provided.[4] Various strategies such as the use of ear protection or musical lullabies have been used but have not proved very effective.[5 6] Other interventions to reduce anxiety levels in children coping with cast-removal (CR) procedures should be explored.

Therapeutic play is a set of structured activities designed according to the subject's age, cognitive development and health-related issues, to promote emotional and physical well-being in hospitalised children.[7] The therapeutic play activities may include scrapbooking, storytelling, doll demonstration, and art activities. Li and colleagues suggested that hospitalised children who engaged in therapeutic play exhibited fewer negative emotions and experienced lower levels of anxiety than those did not.[8] A recent systematic review of 14 articles found that therapeutic play was commonly employed for children undergoing invasive procedures, such as elective surgery, vaccination, blood collection or dental treatment in in-patient settings, with positive changes in the behaviour of those who participated in play sessions and a reduction in their anxieties.[9] However, some of these studies were limited by the lack

of random assignment of subjects into intervention or control groups. Besides, the efficacy of therapeutic play interventions is yet to be determined, as the studies reported were mainly based on clinical observation and most of the play manuals, which should have set out specific procedures to improve fidelity, were not fully described.[10-12] Future study that adopt a robust randomized controlled design and delineate the scope of play procedures is clearly necessary.

Our literature search revealed no reports of prospective and randomised controlled studies on therapeutic play among children undergoing CR procedures, let alone among Hong Kong Chinese. Most importantly, the comprehensive value of therapeutic play in paediatric orthopaedic cast rooms - in their impact on the children, parents and medical institution as a whole - remains largely unexplored in the literature. This study aimed to examine the effectiveness of therapeutic play in reducing anxiety and negative emotional manifestations among children undergoing cast-removal procedures. The satisfaction ratings of parents and cast technicians in respect of the cast-removal procedures were also to be examined.

Theoretical Framework

Lazarus and Folkman's theory of stress and coping theory was used to guide this trial.[13] They suggest that stress is a relationship between a person and the environment that the person finds taxing or exceeding resources. Coping is a constantly changing cognitive and behavioural effort to manage stressful situations. The two types of strategy used to cope with stress are problem-focused and emotional-focused coping. When individuals perceive that they cannot change the threatening situation, they will resort to emotion-focused coping. [13] It is well known that cast-removal procedures is stressful for children.[1,2] Children likely feel stress and anxiety if they perceived a lack

of control over the medical procedure.[8] Therapeutic play works by helping children to prepare for the procedure and thereby assist them to regain a sense of self-control to cope with the stressful procedure.[13, 14] As a result, it is reasoned that children undergoing therapeutic play intervention will be more likely to cope with cast removal procedures and feel less stress and anxiety.

Methods

Design

A two-arm parallel randomised controlled trial was employed.

Setting

The study was conducted in the orthopaedic outpatient department (OPD) of a regional teaching hospital in Hong Kong, where the OPD cast room performs approximately 20 CR procedures monthly. The standard regimen in this OPD did not include therapeutic play intervention.

Participants

Children

Children and their accompanying parents who were waiting for the cast room procedure were invited to participate in the study if: (i) the child was 3-12 years of age; and (ii) the parents were able to speak Cantonese and read Chinese. Children were excluded if they: (i) had had a cast removed within the previous 3 months; or (ii) had neurological or developmental problems as shown on the medical record.

The rationale for selecting 3-12 year olds was that the number of children having cast room procedure within this age range in Hong Kong was higher than for other

age groups. According to Piaget's (1963) theory of cognitive development, children from 3-7 belong to the same pre-operational stage, while those between 8-12 belong to the concrete operational stage.[15] Children in different age group are at the different stage of psychosocial development and likely respond to cast-removal procedures and therapeutic play differently.[16] Therefore, children were stratified according to their age group (3-7 and 8-12).

The sample size of the study was determined to detect an effect size of Cohen's d =0.6 on the outcomes of anxiety level and emotional manifestation between the intervention and control groups with reference to previous therapeutic play studies[17-18] for guiding the selection of a minimum detectable effect. By using the power analysis software GPower 3.1, 45 subjects in each group were sufficient to detect an effect of at least 0.6 with 80% power at 5% level of significance. Taking into account of up to a 15% attrition rate and stratified the study by age, 53 children each would be recruited for the intervention and control groups per stratum by age (3–7 & 8–12 years).

Accompany parents and cast technicians

All accompany parents and cast technicians involved in the cast-removal procedures were invited to assess their satisfaction for the procedures.

Randomisation

Eligible children undergoing the CR procedure were randomly allocated to the intervention or control groups in a 1:1 ratio. Randomisation were stratified by the two age groups, 3–7 and 8–12 years. Serially numbered opaque sealed envelopes containing the grouping identifier (intervention or control) for each age group were

prepared in advance by an independent statistician using computer-generated random codes. The group allocation of the children recruited was assigned according to their ages and sequence of enrolment in the study, and the grouping identifier contained in the corresponding numbered envelopes.

Control Group: Standard Care

Participants in the control group received standard care without therapeutic play intervention. Standard care included the nurse explaining why and what would be done and saying comforting and supportive words during the procedures.

Intervention Group: Therapeutic Play

In addition to the standard care, children in the intervention group also received therapeutic play intervention. The interventions were conducted by an experienced and well-trained senor hospital play specialist (HPS). The HPS has more than five years of experience in delivering therapeutic play - including preparation play and distraction play - to children undergoing medical treatments in various units of hospitals. To ensure therapeutic play interventions were provided according to the children's needs and psycho-cognitive development,[15-16] the research team met with the HPS to set up the research protocol (supplementary file). The content of the therapeutic play had two main components: preparation and distraction forms of play.[19] The duration of intervention was about 30 minutes.

Preparation play

Preparation play was conducted before the CR procedure. A demonstration of the CR procedure was conducted using a doll. The demonstration included:

- Showing a dummy circular-saw cast cutter with appropriate sound effects
- Playing with a doll and explaining how the cast was cut open by the circular saw
- Reassuring children that the saw would not cut their skin if they followed the instruction not to move
- Explaining that, when the cast was cut, the child might feel vibration or tingling, notice a certain warmth and see chalky dust flying
- Describing the use of spreaders and scissors to finish removing the cast
- Explaining how, after the cast was open, the skin might appear scaly and dirty and the limb feel a little stiff when first moved; also that the arm or leg might seem light because the cast had been heavy.

During the demonstration, the children were asked to touch and play with the doll and material, and role-play how they would respond to the procedure after the demonstration. The preparation play usually took 10–15 minutes to complete.

Distraction play

Throughout the CR procedure, support was given to children by introducing distraction play. The aim of the distraction play was to divert children's attention away from the medical procedure. Methods of distraction included visual or auditory distraction, deep breathing exercises, tactile stimulation, counting/singing or other verbal interaction. The choice of method depended on the children's choices.[20] The parents' presence and involvement were supported, and the children were praised for any act of successful self-control. The conclusion of the procedure was indicated by offering the children a reward (e.g. stickers). The children did not know that they would receive reward in advance.

Primary outcome measures

Anxiety

Visual analogue scale

A visual analogue scale (VAS) was used to assess the anxiety levels of children between 3 and 7. The VAS consists of a 10-cm horizontal line anchored by the words 'not worried' (low score) at one end and 'very worried' (high score) at the other, with drawings of different facial expressions spaced along the line. Children aged between 3-7 were asked to indicate their levels of anxiety by moving a pointer over the line. As children of 3 or 4 may have limited verbal expression abilities, their parents were also invited to rate the anxiety levels of their children. The VAS is a widely used scale which has been found to be a reliable and valid tool for measuring children's subjective feelings.[21]

The short-form Chinese version of the State Anxiety Scale for Children (CSAS-C)

The CSAS-C is a 10-item self-report scale measuring the anxiety levels of children aged 8-12 in busy clinical setting.[17] It is a three-point Likert scale with total scores ranging from 10 to 30, with higher scores indicating greater anxiety levels.[17] The psychometric properties of the short form have been tested and found to correlate highly with the scores on the full form (r = 0.92), with good internal consistency (r = 0.83) and convergent validity that differentiate the state anxiety of children in various situations. Factorial structure of the short form was also checked using exploratory and confirmatory analyses.[22] The Cronbach's alpha of the scale in this study was 0.80 to 0.88. [23-24]

Children's Emotional Manifestation Scale (CEMS)

The emotional behaviour of children during CR procedures was documented by using the CEMS, developed by Li and Lopez in 2005. It comprises five observable emotional forms of behaviour, categorised as 'facial expression', 'vocalisation', 'activity', 'interaction' and 'level of co-operation'. The CEMS score is obtained by reviewing the descriptions of behaviour in each category and selecting the number that most closely represents the behaviour observed at the time the subject experiences the most distress. Each category is scored from one to five. Observable forms of behaviour in each category of the CEMS are explained in detail with an operational definition, so that the observer, a research nurse in this study, using the scale has relatively clear-cut criteria for assessment. The sum of the numbers obtained for each category is the total score, which will be between 5-25, higher scores indicating the manifestation of more negative (distressed) emotional behaviour. The evaluation of the psychometric properties of the CEMS demonstrated adequate reliability and validity.[25] The Cronbach's alpha of the scale in this study was 0.86.[23-24]

Secondary outcome measures

Satisfaction scale for parent and cast technician

Two questionnaires in English, developed by Tyson and colleagues (2014),[12] were adopted to measure parents' and cast technicians' satisfaction levels. The original questionnaire for parents is a 10–item scale to measure their satisfaction with the child life services. Each item is rated on a five-point scale ranging from 1 = strongly disagree - 5 = strongly agree, higher scores indicating higher levels of satisfaction. Example of the statement used is 'My child's emotional needs were met'. The perception of the cast technician was examined by eight items, with each being rated on a scale from 1 = strongly disagree - 5 = strongly agree. Example of the statement

used is 'the child engaged in distraction'. The researcher translated the questionnaire into Chinese, using the back-translation method recommended by Brislin (1986).[26] The translated version was reviewed by a panel of expert professionals for semantic and content equivalence. The scale level of semantic equivalence for the parents' satisfaction and cast technician satisfaction was 95% and 92%, respectively, indicating that the translated version was a correct reflection of the original version.[27] The content validity index of the parent's satisfaction level scale was 0.90 and cast technician's satisfaction level scale was 0.94, indicating the content of the translated scale were equivalent to the original version. The Cronbach's alpha of both scales in this study was 0.90.

Heart rate monitoring

A standard automatic heart rate monitoring machine, available in the study hospital, was used to measure children's heart rates to assess their physiological responses to CR procedures. Children's heart rates have been considered objective and definitive indicators for an indirect assessment of children's anxiety levels in previous studies.[28]

Anxiety produced due to CR procedures likely manifested as an increase in heart rate in children.

A demographic sheet

The socio-demographic and clinical variables of parents and children were collected. The items for children include age, sex, reason for cast application and number of hospital admissions. The accompany parent's age, sex, educational level and working status was also obtained. The cast technician's demographic information,

including age, sex and years of work experience, was also collected by the research nurse.

Data collection

Children having their cast-removal would be arranged to wait outside the cast room of the study OPD in a separate timeslot. They would be identified by a research nurse in the waiting area. Permission for a child meeting the recruitment criteria to participate was obtained from the accompanying parent. The research nurse conducted the interview with consenting parent–child pairs in a private room. The children in both groups were asked to indicate how anxious they were by completing either the VAS anxiety scale (for children between 3–7 years old) or the short form of the CSAS-C (for children aged between 8–12).[17] The rearch nurse obtained demographic and clinical data from the parents. She also asked the parents of children aged under 5 to use the VAS scale to indicate their child's perceived anxiety level. Children's heart rates were also monitored for one minute at the end of the interview, using a standard automatic monitor.

According to the subject allocation scheme, children in the control group received standard care in CR room A, while the intervention group additionally received a therapeutic play intervention conducted by the HPS in CR room B. The parents and children were asked during the informed consent process not to discuss the purpose of the study with cast technicians in the cast room.

In the CR room, the research nurse took two one-minute recordings of the child's heart rate: (1) when the cast technician started sawing the cast; and (2) immediately after the cast had been removed. The research nurse then rated the child's signs of distress from the time the saw touched the cast until the limb was free of it, by means

of the CEMS.[25] She also recorded the length of the whole CR procedure for each child. After the CR procedure, the research nurse asked the parents and the cast technician to fill in their respective satisfaction scales to reflect their perceptions of how the CR procedure had been delivered. The children were asked to recall their level of anxiety throughout the procedure by filling in either the VAS anxiety scale (for those between 3-7) or the short form of the CSAS-C (for those between 8-12).[17] Parents were asked to rate the VAS scale for children under 5.

Data analysis

All data were analysed by means of IBM SPSS for Windows, Version 22. Appropriate descriptive statistics were used to present the participants' socio-demographics and outcome measurements. A generalised estimating equations (GEE) model was used to compare each of the outcome measures across time between the two groups. Specifically, the GEE model was used to estimate the mean change on each outcome between group with adjustment for the baseline group difference and accounting for autocorrelation of the outcome across time. All statistical analyses were two-sided, with the level of significance set at 0.05.

Patient and Public involvement

Development of research question and outcome measures were based on the facts that many children reported anxiety during the cast removal procedures. Patients were not involved in the design, subject recruitment, and the conduction of the study. The findings will be disseminated to the study participants by publishing the study as an original article. A satisfaction survey was conducted involving the parents of the

participants to assess whether the participants experienced any burden during the intervention.

Results

Demographic and clinical characteristics of the children and their families

From August 2015 - January 2017, a total of 209 patients and their accompanying parents were screened and approached. However, one of them declined to participate in the study because they were in a hurry and had to leave the clinic at once after the procedure. Therefore, a total of 208 participants and their accompany parents were recruited. Of these, 105 were allocated to the control group and 103 to the intervention group (Figure 1). Their mean ages were 7.7 (SD 3.0) and 7.5 (SD 2.9), respectively. The demographic and clinical characteristics of the two groups were comparable and are shown in Table 1.

Anxiety levels

Children aged between 3 and 7

The mean anxiety scores of children aged 3-7 in the intervention group as measured by VAS anxiety scale decreased from 35.4 to 27.6 after the CR procedures. By contrast, the mean anxiety levels of children who did not take part in therapeutic play increased from 34.0 to 46.3. The difference in mean changes between the two groups as estimated by the group by time interaction term by using GEE was -20.1 (95% CI: -35.3 to -4.9; p=0.010) (Table 2).

Accompanying parent(s) with children under 5 were invited to rate the anxiety levels of their children using VAS. The results showed that there were moderate to high correlations between the children and their parent's rating before (r = 0.36, 95%

CI: 0.0 to 0.65; p<0.05) and after the CR procedure (r = 0.50, 95% CI: 0.13 to 0.74; p<0.01).

Children aged between 8 and 12

The mean anxiety scores of children in the intervention group as measured by CSAS-C fell from 18.0 to 15.3, and in the control group from 17.4 to 15.9. The difference in mean changes between the two groups as estimated by using GEE was -1.1 (95% CI: -2.8 to 0.5; p=0.171). (Table 3).

Emotional manifestation during cast-removal procedures

The mean emotional manifestation scores of children aged 3 - 7 and 8 - 12 in the intervention group were significantly lower than the control group (Table 2 and Table 3). Overall, the mean emotional manifestation scores of the intervention group were 7.6 (SD 2.4) and of the control group 9.8 (SD 3.9) with a mean difference of -2.2 (95% CI: -3.1 to -1.4; p<0.001), indicating that children in the intervention group, on average, exhibited fewer negative emotional manifestations during the CR procedures comparing with those children in the control group (Table 4).

Changes in heart rate

No significant difference in heart rate was noted between the intervention and control group among children aged 3 and 7 years old (Table 2). In contrast, significant difference was found before and during CR procedure between the intervention and control group among children aged 8 and 12 years old (Table 3). Among all children, a trend of increasing heart rate was noted before and during the CR procedures for both groups. The mean heart rate of the intervention and control groups increased by

2.6 and 8.4 beats/minute, respectively with a difference in mean changes between the two groups as estimated by using GEE was -5.9 (95% CI: -10.3 to -1.5; p=0.008), indicating that the children in the intervention group might experience lower levels of anxiety than those in the control group (Table 4).

Satisfaction levels of parents and cast technicians

Among all children, the satisfaction scores of parents in the intervention group (46.6, SD 5.1) were higher than the control group (42.6, SD 6.9) with a mean difference of 4.0 (95% CI: 5.6 to 2.3; p<0.001). Similarly, the satisfaction scores of CR technician in the intervention group (34.3, SD 3.6) were higher than those in the control group (31.7, SD 4.3) with a mean difference of 2.6 (95% CI: 3.7 to 1.6; p<0.001). (Table 4).

Duration of procedure

Among all children, the mean time (in minutes) taken to perform the CR procedure was shorter in the intervention 4.1 (SD 2.3) than in the control groups 4.6 (SD 2.2) with a mean difference of -0.56 (95% CI: -1.17 to 0.05; p=0.072). (Table 2).

Discussion

This study expanded previous studies and examined the effects of a therapeutic play intervention on CR procedures in patients, parents and institutions. A randomised controlled design was employed such that the cause and effect relationships among variables could be established.[27] Findings suggest that therapeutic play effectively assists children aged 3-7 to cope with stressful CR procedures and reduces their

anxiety levels. Overall, children who received the intervention exhibited significantly fewer negative emotional manifestations than those who did not.

Most children in this study presented some degree of anxiety before the procedures, the use of a saw and the fluctuating level of high-frequency noise probably accounting for most of the anxiety.[1 29] Previous studies employed ear protection [5] or lullaby-type music [6] to reduce anxiety in children during CR, while heart rate and mean arterial blood pressure were used as physiological outcome indicators of anxiety, respectively. However, no significant difference was noted in these parameters in either study.

The positive results of the present study are further supported by the fact that the mean increase in heart rates before and during the procedure was lower in the intervention than in the control group. A possible explanation may be that the therapeutic play assisted children to cope with an unfamiliar procedure. During the play session, the HPS explained and simulated the CR procedures, which allowed the children to understand them. As the children were familiarised with the procedure, they would expect it to generate noise but not pain. These preparations assisted the children in such a way that they had an enhanced sense of control over the procedure, minimising the adverse effects of the experience.[6] As suitable and age-appropriate distraction were provided to the intervention group, the children's attention was diverted from the anxiety-provoking procedure to playful interaction. They therefore exhibited less negative emotional behaviour. However, children without any distraction might have focused on the whole procedure and thus exhibited more negative emotions and increased anxiety levels, even after it was all over.

Nevertheless, although children of 8-12 in the intervention group had larger reductions in their anxiety scores than those in the control group after the procedure,

the difference between the groups was non-significant. The results were in conflict with those of a previous study suggesting that older hospitalised children benefit more from the play intervention.[21 30] One possible explanation for the non-significant findings is that older children have a better understanding of CR procedures than younger children. According to Piaget (1963),[15] children of 8–12 can mentally manipulate information to solve problems. As they may have obtained information about the CR procedure from other sources, such as books, the internet or friends, they might feel less anxious about the forthcoming procedure. Moreover, compared with younger children, older children probably have better coping strategies and better control of their emotions, even in stressful situations. Nevertheless, further study is needed to determine other effective methods for children at this developmental stage.

Consistent with a previous study,[31] the result indicated that parents of children in the intervention group were more satisfied with the care and play intervention than those of children receiving standard care only. The satisfaction of parents in the intervention group is likely to have increased because they also experienced the positive influence of play on their children, particularly the reduction in anxiety and improved cooperation with the procedure.[32] In fact, parental perception played an important role on child's coping with various conditions such as cancer or other medical procedures.[33] The positive correlations in the VAS ratings of children under 5 further suggested that parents also perceived their children to be less anxious after the intervention. However, further study could also include self-report questionnaire not only on satisfaction but also examine the mediating role of parents play in the distraction intervention.

Some cast technicians might have concerns that the CR procedures would be impeded and prolonged because the play intervention was implemented at the same

time. However, the findings suggest that the duration of the entire procedure was shorter in the intervention than in the control group, although the differences were non-significant. Nevertheless, the duration in the intervention group did decrease, probably because the children were psychologically prepared and were thus more cooperative. In fact, children who are less anxious are easier to manage in clinical situations,[34] which may account for the increased satisfaction of CR technicians in procedures assisted by HPS.

Limitations

The results of the current study should be interpreted in the light of several limitations. First, children were recruited from a single clinical setting. The generalisability of the findings may therefore be restricted. Second, neither patients nor outcome assessors were blinded to the study. However, because of the very nature of the intervention, blinding of patients and outcome assessors would have been difficult. Although children are unlikely to change their behaviour even when they know they are participating in a certain intervention, [9] however, lack of blinding may contribute to an importance source of bias because the assessors know the group allocation of children which likely affect their ratings of children's emotional manifestation during the CR procedures. Nevertheless, different strategies were employed to minimise the potential bias. For example, children were assigned to different cast rooms and isolated from other patients at the time of the intervention, regardless of whether or not they were randomised to the play intervention group. Also, subjective and objective outcome measures were used to evaluate the impact of therapeutic play on the psychological state of a child. Finally, there might be other factors that affect children's anxiety level and play predisposition such as children'

coping styles or temperament, or parent's anxiety level and symptomatology towards cast-removal procedure. Future study should take these factors into account and consider to include the assessment of children's coping style or parents' anxiety level as well.

Conclusions

This study confirms the findings of previous work that children experience some degree of anxiety and exhibit negative emotional manifestations during medical procedures. The consequences of stress appear to be substantial, and thus the importance of assisting children to cope effectively with it and reduce its impact is highlighted. A gap in the literature is addressed by providing empirical evidence on the benefits of therapeutic play for children, family and medical institution during CR procedures. The findings show that a play intervention effectively reduces anxiety levels and negative emotional manifestations among children undergoing CR procedures. Such positive outcomes also translate into an improvement in the satisfaction levels of parents and CR technicians with the procedures. Play is universal and similar intervention can be adopted in other settings or medical procedures. It may also adopt to reduce anxiety and improve motor abilities of children that underwent invasive procedures.[35] The findings highlight the importance of providing and integrating therapeutic play into standard care. Such an intervention ensures that holistic and quality care is provided to ease the psychological burden of the patients. Furthermore, it contributes to improve patient care, satisfaction and overall experience of children and their families.

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Figure Legends

Figure 1: The CONSORT diagram of this study

Footnotes

Contributors: Wan Yim and King Wah conceived and designed the study. Cho Lee and Wing Han obtained ethical approval. Ming Chau supervised data collection. Cho Lee supervised the data analysis and wrote the paper. Kai Chow provided statistical support and analysed the data. Ming Chau and Wing Han helped revising the manuscript. All authors have given final approval of the version to be published.

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Patient consent: Obtained.

Ethics approval: This study was approved by the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (2015.005-T).

Provenance and peer review: Not commissioned; externally peer reviewed.

Data sharing statement: Not additional data are available.

Table 1: Socio-demographics and clinical characteristics of the participants (n=208) and cast-removal technicians (n=12)

Characteristics	Control (n=105)	Intervention (n=103)
Children and their family		
Age of the child (years) †	7.7 (3.0)	7.5 (2.9)
Age group		
3 – 7 years	55 (52.4%)	52 (50.5%)
8 – 12 years	50 (47.6%)	51 (49.5%)
Sex of the child		
Female	37 (35.2%)	36 (35.0%)
Male	68 (64.8%)	67 (65.0%)
Accompanied by		
Mother only	52 (49.5%)	54 (52.4%)
Father only	29 (27.6%)	26 (25.2%)
Both parents	14 (13.3%)	10 (9.7%)
Mother/father together with other relatives	6 (5.7%)	6 (5.8%)
Other relatives	4 (3.8%)	7 (6.8%)
Highest education attainment of the accompanied family		
Primary or below	8 (7.6%)	7 (6.8%)
Secondary	63 (60.0%)	64 (62.1%)
College or above	34 (32.4%)	32 (31.1%)
Number of hospital admission		
0	38 (36.2%)	31 (30.1%)
1	30 (28.6%)	36 (35.0%)
2	25 (23.8%)	14 (13.6%)
≥ 3	12 (11.4%)	22 (21.4%)
Type of casts		
Arm long	88 (83.8%)	82 (79.6%)
Arm short	6 (5.7%)	7 (6.8%)
Leg long	9 (8.6%)	13 (12.6%)

Leg short	2 (1.9%)	1 (1.0%)
CR technician (n=12)		
Sex		
Female	32 (30.5%)	30 (29.1%)
Male	73 (69.5%)	73 (70.9%)
Age (years)		
< 30	16 (15.2%)	9 (8.7%)
30 – 40	34 (32.4%)	39 (37.9%)
> 40	55 (52.4%)	55 (53.4%)
Years of experience		
< 2	14 (13.3%)	9 (8.7%)
2 – 5	47 (44.8%)	41 (39.8%)
> 5	44 (41.9%)	53 (51.5%)

Data of variables marked with † are presented as mean (standard deviation), otherwise as frequency (%).

Table 2: Outcome measures across time between the intervention and control groups among those children aged between 3 and 7 years (N=107)

	Control (n=55)	Intervention (n=52)	p-value	Effect size (95% CI) #
VAS anxiety scale (range: 0 – 100)				
T1 (before CR procedure)	34.0 (30.0)	35.4 (32.7)		
T3 (after CR procedure)	46.3 (37.3)	27.6 (28.6)	0.010 [a]	0.50 (0.11 , 0.88) [c]
Children's emotional manifestation scale (range:5 – 25)				
T2 (during CR procedure) †	10.6 (4.7)	8.1 (2.9)	0.002 [b]	0.62 (0.23 , 1.01)
Heart rate (per minute)				
T1 (before CR procedure)	88.7 (14.9)	88.6 (14.5)		
T2 (during CR procedure)	95.8 (17.7)	89.8 (16.6)	0.081 [a]	0.33 (-0.05 , 0.71) [c]
T3 (after CR procedure)	97.2 (15.6)	90.0 (17.2)	0.051 [a]	0.37 (-0.01 , 0.75) [c]
Parent satisfaction score (range: 10 – 50)				
T3 (after CR procedure)	42.5 (6.7)	47.3 (3.3)	<0.001 [b]	0.89 (0.49 , 1.28)
CR technician satisfaction score (range: 8 – 40)				
T3 (after CR procedure)	31.5 (5.0)	33.9 (3.7)	0.007 [b]	0.54 (0.15 , 0.92)
Duration of procedure (mins)	4.8 (2.2)	4.2 (2.0)	0.126 [b]	0.30 (-0.08 , 0.68)

Data of variables marked with † are presented as median (inter-quartile range), otherwise as mean (standard deviation)

† Nature log-transformed before subjected to independent t-test

Cohen's d effect size

[a] P-value testing for differential change of heart rate at the underlying time point with respect to T1 by using GEE model

[b] Independent t-test

[c] The Cohen's d effect size corresponds to the standardized mean difference of the mean changes at the underlying time point with respect to T1 between the intervention and control groups

Table 3: Outcome measures across time between the intervention and control groups among those children aged between 8 and 12 years (N=101)

	Control (n=50)	Intervention (n=51)	p-value	Effect size (95% CI) #
State Anxiety Scale for Children (CSAS-C) (range: 10 – 30)				
T1 (before CR procedure)	17.4 (4.0)	18.0 (3.5)		
T3 (after CR procedure)	15.9 (4.7)	15.3 (3.9)	0.171 [a]	0.27 (-0.12 , 0.66) [c]
Children's emotional manifestation scale (range:5 – 25)				
T2 (during CR procedure) [†]	9.0 (2.6)	7.0 (1.4)	<0.001 [b]	0.93 (0.51 , 1.33)
Heart rate (per minute)				
T1 (before CR procedure)	86.3 (13.4)	84.8 (12.6)		
T2 (during CR procedure)	96.2 (14.4)	88.7 (14.5)	0.037 [a]	0.41 (0.01 , 0.80) [c]
T3 (after CR procedure)	89.9 (13.1)	87.5 (13.8)	0.720 [a]	0.07 (-0.32 , 0.46) [c]
Parent satisfaction score (range: 10 – 50)				
T3 (after CR procedure)	42.8 (7.1)	46.0 (6.5)	0.020 [b]	0.47 (0.07 , 0.86)
CR technician satisfaction score (range: 8 – 40)				
T3 (after CR procedure)	31.8 (3.5)	34.8 (3.5)	<0.001 [b]	0.83 (0.42 , 1.24)
Duration of procedure (mins)	4.4 (2.2)	3.9 (2.5)	0.314 [b]	0.20 (-0.19 , 0.59)

Data of variables marked with [†] are presented as median (inter-quartile range), otherwise as mean (standard deviation)

[†] Nature log-transformed before subjected to independent t-test

[#] Cohen's d effect size

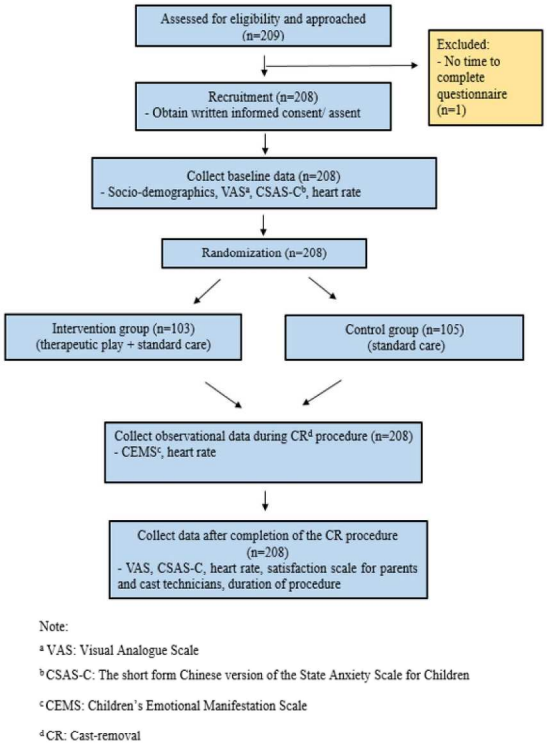
[a] P-value testing for differential change at the underlying time point with respect to T1 by using GEE model

[b] Independent t-test
[c] The Cohen's d effect size corresponds to the standardized mean difference of the mean changes at the underlying time point with respect to T1 between the intervention and control groups

Table 4: Outcome measures across time between the intervention and control groups

	Control	Intervention	p-value	Effect size (95% CI) #
Among all children (N=208)				
Children's emotional manifestation scale (range:5 – 25)	**(n=105)**	**(n=103)**		
T2 (during CR procedure) †	9.8 (3.9)	7.6 (2.4)	<0.001 [b]	0.69 (0.41 , 0.69)
Heart rate (per minute)				
T1 (before CR procedure)	87.6 (14.2)	86.7 (13.6)		
T2 (during CR procedure)	96.0 (16.2)	89.3 (15.5)	0.008 [a]	0.36 (0.09 , 0.64) [c]
T3 (after CR procedure)	93.7 (14.9)	88.8 (15.6)	0.070 [a]	0.25 (-0.02 , 0.52) [c]
Parent satisfaction score (range: 10 – 50)				
T3 (after CR procedure)	42.6 (6.9)	46.6 (5.1)	<0.001 [b]	0.65 (0.38 , 0.93)
CR technician satisfaction score (range: 8 – 40)				
T3 (after CR procedure)	31.7 (4.3)	34.3 (3.6)	<0.001 [b]	0.66 (0.38 , 0.94)
Duration of procedure (mins)	4.6 (2.2)	4.1 (2.3)	0.072 [b]	0.25 (-0.02 , 0.52)

Data of variables marked with † are presented as median (inter-quartile range), otherwise as mean (standard deviation)
† Nature log-transformed before subjected to independent t-test
# Cohen's d effect size
[a] P-value testing for differential change at the underlying time point with respect to T1 by using GEE model
[b] Independent t-test
[c] The Cohen's d effect size corresponds to the standardized mean difference of the mean changes at the underlying time point with respect to T1 between the intervention and control groups



The CONSORT diagram of this study

210x297mm (300 x 300 DPI)

Title of proposal: The stress-reducing effects of therapeutic play on children undergoing cast-removal procedure.

Background

It is common for children to display stressed behaviour in clinical settings, even during painless medical procedures such as cast-removal. Many behavioural and physiological manifestations of anxiety in children are associated with their compliance with the medical procedures and thus the recovery outcomes (Felder-Puig et al., 2003) and the quality of care (Tyson, Bohl, & Blickman, 2014). Researchers (Li, Lopez, & Lee, 2007) has pointed out that lack of self-control and limited cognitive capabilities are two main factors associated with children's anxiety and that psychosocial preparation of the children through therapeutic play could help them gain a sense of self-control and achieve lower anxiety levels.

Therapeutic play is a set of structured activities that are designed according to the subject's age, cognitive development and health-related issues, to promote emotional and physical well-being in hospitalized children (Vessey & Mahon, 1990). Extensive studies have supported therapeutic play as an effective pre-operative preparation for both children and parents in reducing fear and anxiety (Christian, Russ, & Short, 2011; Nyugen, & Thaller, 2008). Care providers should consider the human rights of children, and provide age-appropriate information to aid understanding of the disease and the interventions employed.

Brewer et al. (2006) evaluated the effectiveness of therapeutic play in a double-blind intervention study. The findings showed that preparation with role rehearsal and medical play could lower anxiety levels in children following elective day surgery. Additionally, a recent randomized, controlled trial (RCT) (Tyson et al., 2014) found that therapeutic play could enhance satisfaction, not only to children but also in the parents and healthcare providers. However, the efficacy of therapeutic play are yet to be determined because the reported studies were based mainly on clinical observations and most of the play manuals, which should have set out specific procedures and improved fidelity, were not fully described (Brewer et al., 2006; Stevenson et al., 2005; Tyson et al., 2014). Researchers have emphasized the need for further objective data-gathering studies on the scope of procedures in an out-patient setting.

In summary, the comprehensive value of therapeutic play—in terms of impact on the child, family and medical institution as a whole—remains largely unexplored in the literature. Our literature search revealed no reports of prospective and randomized controlled studies of the effectiveness

of therapeutic play among Chinese children undergoing cast-removal procedures, let alone among Hong Kong Chinese.

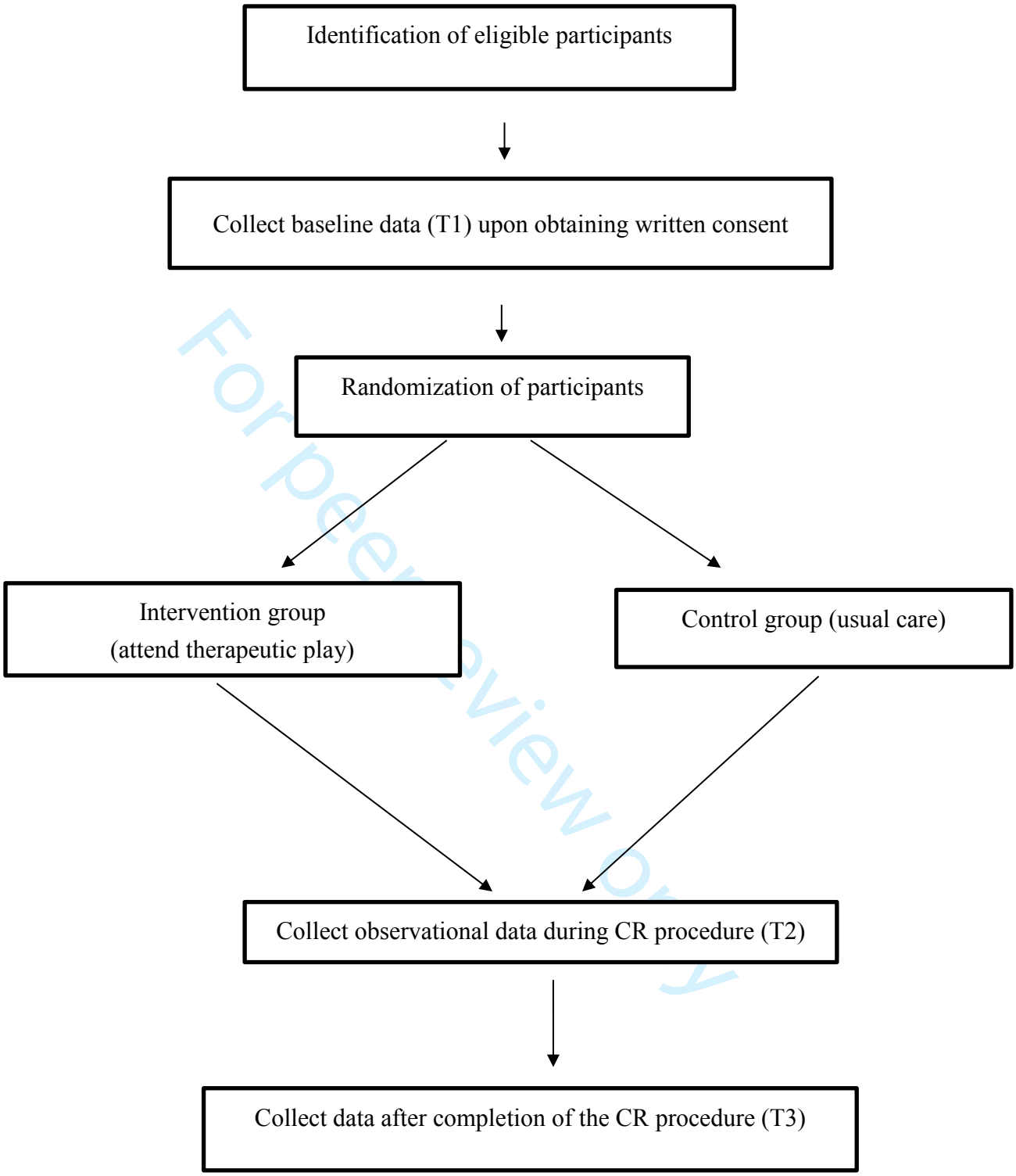
Aims

The aim of this study is to examine the impact of the therapeutic play on the psychological stress of paediatric patients during cast-removal (CR) procedures in an orthopaedic out-patient clinic in Hong Kong. The satisfaction ratings of parents and healthcare providers in respect of these services will also be examined.

Methods

Design

This is a two-arm randomized controlled trial. Eligible children undergoing the CR procedure will be randomly allocated to either the experimental or control groups in a 1:1 ratio. The child and accompanying parent in the experimental group will receive therapeutic play intervention, and the control group will receive routine care only. All participants will be assessed on three occasions: before, during, and after completion of the CR procedure. Please refer to Figure 1 for the study protocol.



CR = cast removal

Figure 1. Study Protocol

Research Hypotheses

The research objectives are to examine whether, in CR procedures, there are significant differences between the Intervention and Control groups in:

1. children's anxiety levels
2. children's emotional distress levels
3. children's heart rates
4. length of procedure
5. satisfaction levels of parents and technicians in respect of the procedures.

Settings

This study will be conducted in the orthopaedic out-patient department (OPD) of a regional teaching hospital in Hong Kong. A cast room in the OPD performs approximately 20 cast-removal procedures monthly. At the time of this proposal, the standard of regimen in this OPD does not include therapeutic play services. The cast technicians attend to paediatric patients every Wednesday afternoon. They receive limited training on the developmental needs of children in their profession.

Sample

Children and their accompanying parents, who are waiting for the cast room procedure, will be invited to participate in the study if (i) the children are 3–12 years of age and (ii) the parents are able to speak Cantonese and read Chinese. Children will be excluded if they have had a cast removed within 3 months and demonstrate obvious neurological or developmental problems during cognitive assessment by a play specialist.

The rationale for selecting 3–12-year-old is that the number of children having cast room procedure within this age range in Hong Kong is higher than for other age groups. In fact, according to Piaget's (1963) theory of cognitive development, children from 3 to 7 years of age belong to the same pre-operational stage, while those in the age range 8–12 years belong to the concrete operational stage. In addition, according to Erickson (1963), children in the same age group fall in the same stage of psychosocial development. Accordingly, randomization of participants to the experimental (E) or control (C) groups will be stratified by the two age groups: 3–7 and 8–12 years. Serially numbered opaque sealed envelopes containing the grouping identifier (E or C) for each age group will be prepared in advance by an independent statistician using computer generated random codes. The group allocation of the recruited children will be assigned according to their

ages and sequence of enrolment in the study and the grouping identifier contained in the corresponding numbered envelopes.

The sample size of the study is determined to detect at least a medium effect size of Cohen's d = 0.5 between the experimental and control groups. According to Cohen (1992), 64 subjects in each group will be sufficient to detect a medium effect of 0.5 with 80% power at 5% level of significance. Taking into account of up to a 15% attrition rate and stratified the study by age, seventy-five children each will be recruited for the experimental and control groups per stratum by age (3–7 and 8–12 years).

Interventions

The research team discuss the study protocol and an experienced hospital play specialist (HPS) will conduct all interventions in the study during her regular shift. Each child who is assigned to the Intervention group will receive an initial assessment, who will individualize the therapeutic activities based on children's psycho-cognitive development (Erikson, 1963; Piaget, 1963) and general condition. Duration and type of intervention will be varied, based on the assessment of the child's needs, but will usually be completed within 30 minutes. The content of the therapeutic play has two main components: preparation play and distraction play (Blaine, 1999).

Preparation Play

Preparation play consisting of two parts of intervention will be conducted before the CR procedure:

Part I: information given

The children and parents should be well prepared by information supplied about the procedure and the choices of behaviour management. The hospital jargon were translated into ordinary language and in giving explanations in terms that suit the developmental level of the child (Brown et al., 1997). The preparation phase will be implemented individually, with their parents, in a service room. Information about the procedure will be provided, such as: (i) Why must the procedure be done? (ii) Where will the procedure take place? (iii) What will be happening? and (iv) How will it feel? Multiple coping strategies will also be introduced, so as to allow the parent and child to choose the one appropriate to them (Stephens, Barkey, & Hall, 1999); for example: (i) whether or not to watch the procedure, (ii) to pick something nice to think about and (iii) to sing a song. Choices of age-appropriate toys with specified playing activities will also be given to promote the coping strategies of the children.

Part II: rehearsal of the procedure

After verbal explanation, a demonstration of the cast-removal procedure will be conducted, using a doll. Examples of such a demonstration are:

- Show a dummy circular-saw cast cutter with appropriate sound effect
- Play with a doll and explain how the cast is cut open by the circular saw
- Reassure the child that the saw will not cut his or her skin if he or she follows the instruction not to move
- Explain that, when the cast is cut, the child may feel vibrations or tingling, feel warmth, and see chalky dust flying
- Describe the use of spreaders and scissors to finish removing the cast
- Explain how, after the cast is open, the child's skin may appear scaly and dirty and the child's arm or leg may be a little stiff when he or she first tries to move it; also that the arm or leg may seem light because the cast was heavy.

Each child will be asked to role-play how he or she would respond to the procedure after the demonstration. During the session, parents and children will be encouraged to raise their concerns or ask any questions about the procedure. The preparation intervention will usually take 10–15mins to complete.

Distraction Play

Support will be given to the children and parents throughout the cast-removal procedure by giving distraction play intervention. The aim is to focus children's attention away from the medical procedure. Methods of distraction include visual distraction, auditory distraction, deep breathing exercises, tactile stimulation, counting/singing or verbal interaction. The choice of the distraction method the children's choices (Doellman, 2003). Parental presence and involvement will be supported, and praise will be given to any successful self-control exhibited by the child. The conclusion of the procedure will be indicated by offering the child a reward (sweets or stickers).

Measures

A visual analogue scale (Appendix I)

A visual analogue scale (VAS) will be used to assess the anxiety levels of children aged 3–7. The VAS is a 10 cm horizontal line anchored by the words "not worried" (low score) at one end and "very worried" (high score) at the other, with different facial expressions drawn along the line. Children aged between 5 and 7 will be asked to indicate their levels of anxiety by moving a pointer over the line. Accompanying parent(s) will rate the anxiety levels of children aged 3–4, with higher

scores indicating greater anxiety. The VAS is a widely used scale which is found to be a reliable and valid tool for measuring subjective feelings of children aged 5 to 7 (Bringuier *et al*., 2009).

The short form of the Chinese version of the State Anxiety Scale for Children (CSAS-C) (Appendix II)

The CSAS-C was a 10-item self-report scale to measure the levels of anxiety among children aged 8-12 in busy clinical settings (Li & Lopez, 2007). The content validity of the scale has been empirically tested and the Cronbach's alpha value was 0.83. This is a 3-point Likert scale with total scores ranging from 10 to 30. Higher scores indicate greater anxiety levels (Li & Lopez, 2007).

Children's Emotional Manifestation Scale (CEMS) (Appendix III)

The emotional behaviours of children during CR procedures will be documented using the CEMS. The CEMS was developed by Li and Lopez in 2005. It comprises five observable emotional behaviours, categorized as 'Facial expression', 'Vocalization', 'Activity', 'Interaction' and 'Level of Co-operation'. The CEMS score is obtained by reviewing the descriptions of behaviour in each category and selecting the number that most closely represents the observed behaviour at the time the subject experiences the most distress. Each category is scored from one to five. Observable behaviours in each category of the CEMS are explained in detail with an operational definition, so that the observer, a research nurse (RN) in this study, using this scale has relatively clear-cut criteria for assessment. The sum of the numbers obtained for each category is the total score, which will be between 5 and 25. Higher scores indicate the manifestation of more negative (distressed) emotional behaviours. The evaluation of the psychometric properties of the CEMS demonstrated adequate inter-rater reliability, high internal consistency, good content validity and excellent convergent validity (Li & Lopez, 2005).

Satisfaction Scale

Two questionnaires in English, developed by Tyson and colleagues (2014), will be adopted to measure parents' (Appendix IV) and cast technicians' (Appendix V) satisfaction levels. The RN will work with the research team to translate the English questionnaire into a Chinese version, with reference to a back-translation method recommended by Brislin (1970).

The original questionnaire for the parent is a 10–item scale to measure parents' satisfaction with the child life services. Each item will be rated by a 5-point scale ranging from 1 = strongly disagree to 5 = strongly agree. A higher score indicates a higher level of the satisfaction. Examples of the statements used are 'My child's emotional needs were met' and 'I am satisfied with the care provided to my child' (Appendix IV). The perception of the cast technician on the service will be

examined by eight items, with each being rated on a scale from 1 = strongly disagree to 5 = strongly agree. Examples of the statements used are 'The child was co-operative' and 'The child engaged in distraction' (Appendix V).

Heart rate monitoring

A standard automatic heart rate monitoring machine, available in the study hospital, will be used to measure children's heart rates to assess their physiological responses to CR procedures. Children's heart rates have been considered to be objective and definitive indicators for indirect assessment of anxiety level in children in previous studies (Augustin & Hains 1996; Panda *et al*. 1996; Li & Lopez 2007).

A demographic sheet

A questionnaire developed by the research team will be used to measure the socio-demographic and clinical variables of the parent and their child. The items for children include age, sex, reason for cast application and number of hospital admissions. The accompany parent's age, sex, educational level and working status will also be obtained.

The cast technician's demographic information including age, sex and years of working experience will also be collected by the RN.

Data Collection Procedure

Children having their casts removed will be identified outside the cast room of the study OPD by the RN. If the child meets the inclusion criteria for recruitment, permission for the child to participate will be obtained from the accompanying parent. The RN will then conduct the interview with consenting parent–child pairs in a private room. The children of the consenting parents in both groups are asked to indicate how anxious they are by filling in either the VAS anxiety scale (for children between 5–7 years old) or the short form of the CSAS-C (for children aged between 8–12) (Li & Lopez, 2007). The RN will acquire demographic and clinical data from the parents. She will also ask the parents of children aged under 5 to use the VAS scale to indicate their child's perceived anxiety level. Children's heart rates will also be monitored for 1 minute, using a standard automatic heart rate monitoring machine at the end of the interview.

According to the subject allocation scheme, children in the Control group will receive routine care in the CR room A, whereas those in the Intervention group will additionally receive therapeutic play intervention conducted by the HPS in the CR room B. The parents and children will be asked not to discuss the purpose of the study with cast technician in the cast room during the informed consent process.

In the CR room, the RN will take the 1-minute recording of the child's heart rate when the cast technician starts sawing the cast of the child. The RN will also rate the child's signs of distress from the time the saw touches the cast until the limb is free from the cast, by means of the CEMS (Li & Lopez 2005). The length of the whole CR procedure for each child will also be recorded by the RN. The timing, duration, and nature of play for each child will be documented in a log book. After the completion of the CR procedure, The RN will take the child's heart rate for 1 min and then ask the parents and the cast technician to fill in their respective satisfaction scales to reflect their perceptions of the delivery of the CR procedure.
The RN will give a $30 dollar coupon to the parent upon completion of data collection.

A pilot study on 5 pairs of eligible parent-child dyad will be performed to assess the feasibility of the data collection plan and to pre-test the questionnaires. The respondents' comments on and impressions of the pilot study will help the research team to refine or revise the study plan (Polit *et al*., 2013). Please refer to the outline of data collection in Table 1.

Table 1. The plan of data collection by the research nurse

	Pre-test data upon consent given (T1)	Observational data during procedure (T2)	Post-test data after procedure (T3)
Demographic and clinical variables	X		
VAS anxiety scale for children 3–7 years old; The short form of the Chinese version of the State Anxiety Scale for Children (CSAS-C) for children aged 8–12	X		X
Children's Emotional Manifestation Scale		X	
1 minute heart rate recorded by an automatic heart rate monitoring machine.	X	X	X
Parent satisfaction scale			X
Staff satisfaction scale			X

Length of procedure		X	

Data Analysis

All data will be analysed using IBM SPSS for Windows, Version 22. Descriptive statistics such as mean, standard deviation, medium, inter-quartile range, frequency and percentage, as appropriate, will be used to present the participants' socio-demographics and outcome measurements. Pearson's chi-squared test and student's *t*-test will be used as appropriate for comparing the baseline differences between the two groups. Generalized estimating equations (GEE) model will be used to compare the outcome measures across time between the two groups. GEE model can account for intra-correlated repeated measures data and accommodated missing data, provided the data are missing at random. All statistical analyses are two-sided and level of significance will be set at 0.05.

Ethical Issues

Ethical approval will be sought from the Ethical Committees of the University and the study hospital prior to conducting the study. The purpose and details of the study will be clearly provided to the accompanying parents before the RN obtains their written consent. Maintenance of confidentiality and anonymity of data gained will also be assured. Participants will be informed that the quality of care will not be affected by their participation status. Please refer to the details of the information sheet and consent form in Appendix VII.

Timeline

Timetable of the 20-month project

Month	**1**	**2**	**3**	**4–16**					**17**	**18**	**19**	**20**
RN training & literature review	★	★										
Questionnaires development & pilot study		★	★									
Data collection				★	★	★	★	★	★	★		
Data entry & data analyses									★	★	★	
Report writing											★	★

Note: Based on recruiting 20 cases per month

Significance

Removal of casts is a frightening procedure for children (Johnson et al., 1975), and studies on psychosocial care for children receiving the procedure are limited. This is the first study of this kind among Hong Kong Chinese children in an orthopaedic out-patient clinic. The findings will inform policy makers on the development and inclusion of therapeutic play interventions in paediatric out-patient healthcare settings.

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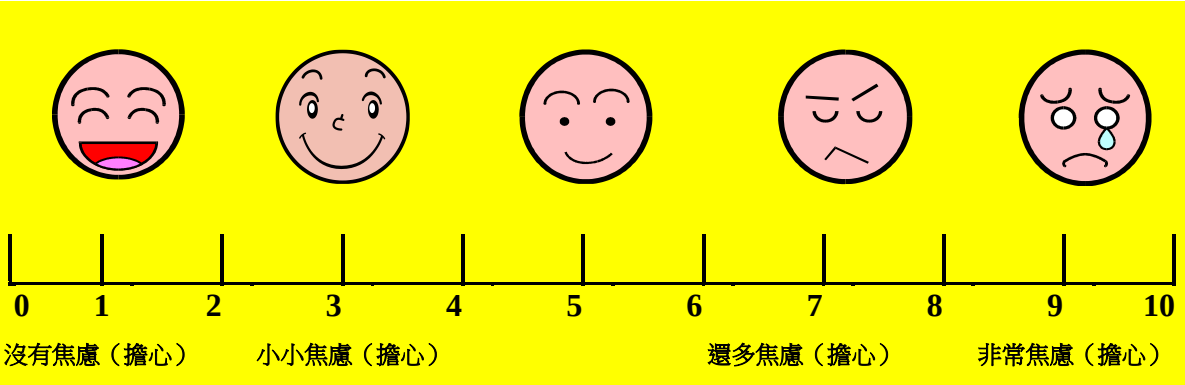
Appendix I

A 10-point level Visual Analogue Scale (VAS)



Appendix II

Short-Form of the Chinese version of the State Anxiety Scale

以下是一些男孩子和女孩子用來形容自己的句子。請小心閱讀每一句，然後在每句子的右方*圈出*最能表達你*現時感覺*的字句。答案是沒有分對或錯的。不要花太多時間在任何句子上，只要將最能表達你*現時感覺*的字句圈出來就可以了。

1. 我感到.....	十分愉快	愉快	不愉快
2. 我感到.....	十分不安	不安	無不安
3. 我感到.....	十分緊張	緊張	不緊張
4. 我感到.....	十分平靜	平靜	不平靜
5. 我感到.....	十分輕鬆	輕鬆	不輕鬆
6. 我感到.....	十分擔心	擔心	不擔心
7. 我感到.....	十分害怕	害怕	不害怕
8. 我感到.....	十分快樂	快樂	不快樂
9. 我感到.....	十分煩惱	煩惱	不煩惱
10. 我感到.....	十分開心	開心	不開心

---------- 此問卷到此完 ----------

Appendix 3

The Children Emotional Manifestation Scale

	1	2	3	4	5	Scored
Facial Expression						
Vocalization	No Crying	Watery eyes	Whimpering	Crying	Hard Crying or Non-stop Screaming	
Activity	Calm	Annoying	Irritable	Restlessness	Agitation	
Interaction	Verbal interaction	Non-verbal response only	Avoid interaction	Mild verbal protest	Strong verbal protest	
Level of Co-operation	Active participation	Passive participation	Withdrawal	Extreme resistance	Disruptive behaviour	

Appendix IV

Parent Satisfaction Scale (Chinese version)

家長滿意程度調查

香港中文大學現在正進行一項關於拆除石膏程序的研究，希望了解病人家屬和職員對這項服務的滿意程度。以下是關於剛才拆除石膏過程的相關問題，請為每條問題圈出符合你的同意程度的號碼。答案純屬個人意見，沒有標準答案。

(1 = 非常不同意；5 = 非常同意)

		非常不同意	不同意	中立	同意	非常同意
1	整個程序用了我的孩子能明白的語言去講解。	1	2	3	4	5
2	我孩子的情緒有被照顧到。	1	2	3	4	5
3	職員有關顧到我的孩子是否感到舒適。	1	2	3	4	5
4	我知道要怎樣做去幫助我的孩子。	1	2	3	4	5
5	職員有關顧到我的疑問和憂慮。	1	2	3	4	5
6	職員尊重我對我孩子的理解。	1	2	3	4	5
7	我對我孩子所受到的照顧感到滿意。	1	2	3	4	5
8	我會推薦這個服務給其他人。	1	2	3	4	5
9	職員都是友善和樂於幫忙的。	1	2	3	4	5
10	職員們好好地共同合作去照顧我的孩子。	1	2	3	4	5

Parent Satisfaction Scale

These are the questions in regards to the process of pop removal, please rate each question on scale 1-5

		STRONGLY DISAGREE	DIS-AGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
1	Appropriate wordings was used to let my kid to understand the process.	1	2	3	4	5
2	My kid's emotion was looked well after by the team.	1	2	3	4	5
3	Staff concerned about the comfortability of my kid.	1	2	3	4	5
4	I knew how to assist with my kid.	1	2	3	4	5
5	Staff concerned about my questions and worries.	1	2	3	4	5
6	Staff respect my knowledge to my kid.	1	2	3	4	5
7	I satisfied with the care received from the team.	1	2	3	4	5
8	I would recommend this hospital to others.	1	2	3	4	5
9	Staff were friendly and willing to help.	1	2	3	4	5
10	Staff cooperated well to care my kid.	1	2	3	4	5

Appendix IV
Staff Satisfaction Scale (Chinese version)
職員滿意程度調查

香港中文大學現在正進行一項關於拆除石膏程序的研究，希望了解病人家屬和職員對這項服務的滿意程度。以下是關於剛才拆除石膏過程的相關問題，請為每條問題圈出符合你的同意程度的號碼。答案純屬個人意見，沒有標準答案。

(1 = 非常不同意；5 = 非常同意)

		非常不同意	不同意	中立	同意	非常同意
1	孩子明白到甚麼事情將會發生。	1	2	3	4	5
2	孩子表現得合作。	1	2	3	4	5
3	孩子的情緒有被照顧到。	1	2	3	4	5
4	孩子的注意力已被分散。	1	2	3	4	5
5	家長明白怎樣去幫助他們的孩子。	1	2	3	4	5
6	進行拆除石膏程序的環境符合孩子的需要。	1	2	3	4	5
7	我對我們團隊所供給這個孩子的照顧感到滿意。	1	2	3	4	5
8	家人對於孩子所受到的照顧感到滿意。	1	2	3	4	5

Staff Satisfaction Scale

These are the questions in regards to the process of pop removal, please rate each question on scale 1-5

		STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
1	The kid understood what would happen next.	1	2	3	4	5
2	The kin was cooperative.	1	2	3	4	5
3	The kid's emotion was looked well after by the team.	1	2	3	4	5
4	The kid was distracted.	1	2	3	4	5
5	Parents knew how to help with their kids	1	2	3	4	5
6	The venue for POP removal was appropriate to kids' needs	1	2	3	4	5
7	I am satisfied with the cared provided to the kid.	1	2	3	4	5
8	Kid's family was satisfied with the care received by the kid.	1	2	3	4	5

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	6
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	21

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	16
	13b	For each group, losses and exclusions after randomisation, together with reasons	16
Recruitment	14a	Dates defining the periods of recruitment and follow-up	16
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	16
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	20
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	20
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	22
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.