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.

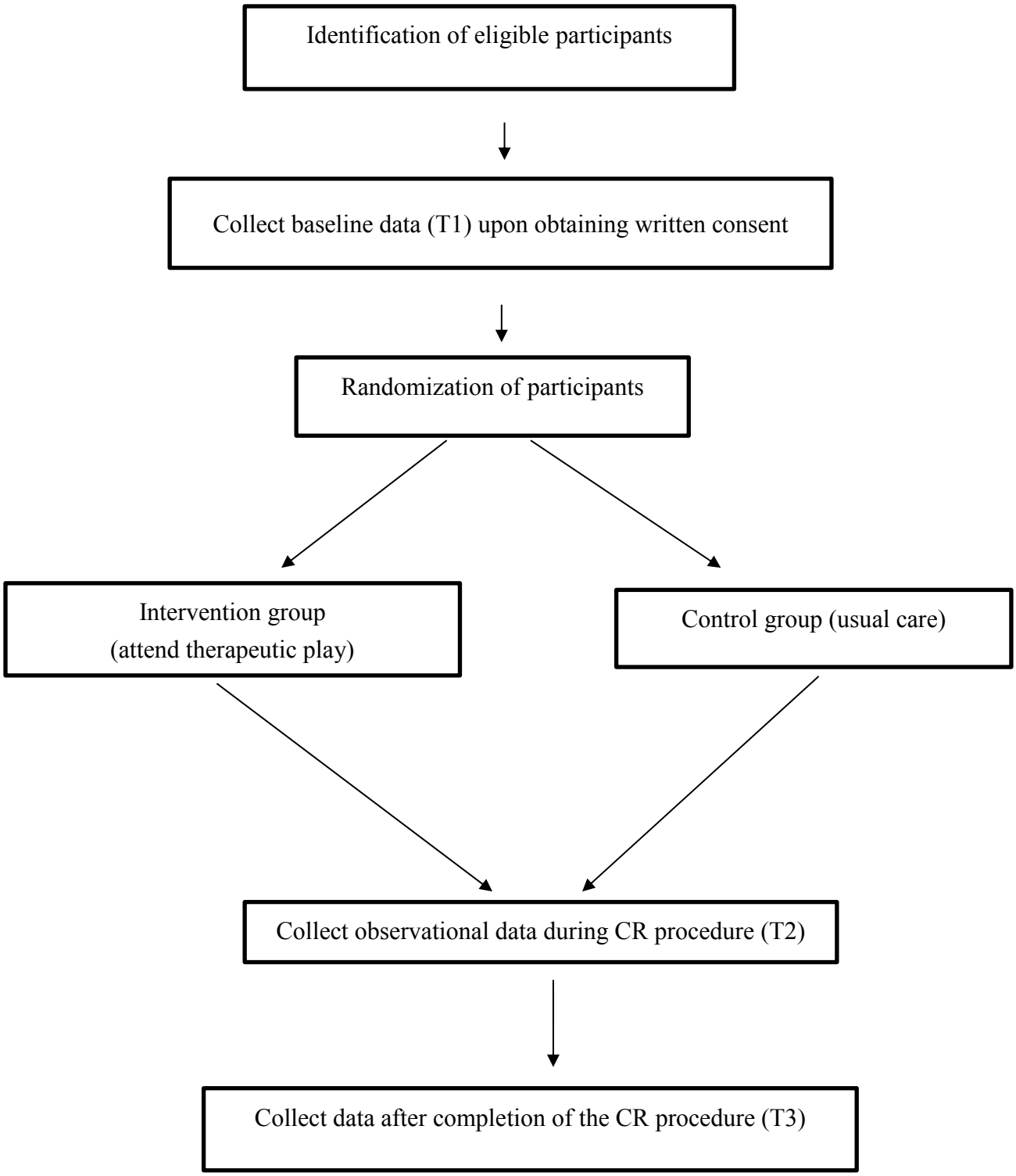
Aims

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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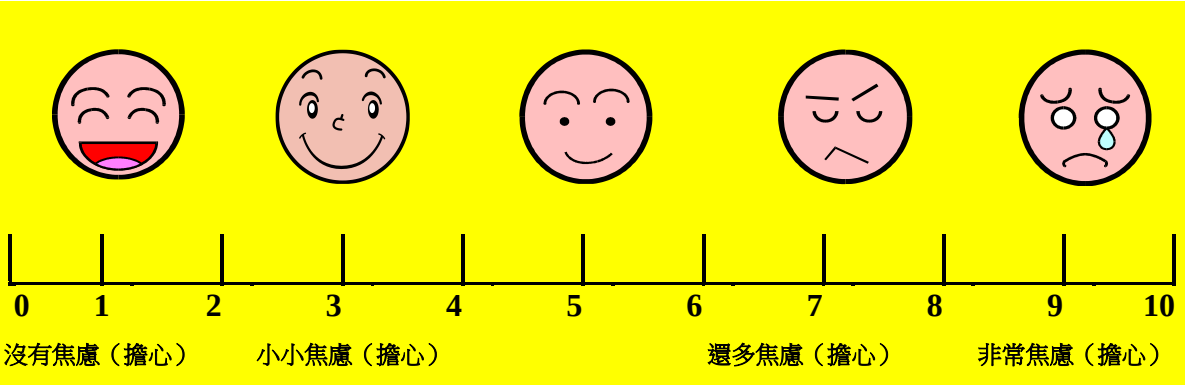
Appendix I

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