



The stress-reducing effects of therapeutic play on children undergoing cast-

removal procedure

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Final Report

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Executive Summary

Introduction: Children commonly display stressed behaviour in clinical settings even during painless medical procedures such as cast-removal. Psychological preparation of the children through therapeutic play may help them gain a sense of self-control and experience a lower level of anxiety, which may consequently ease the performance of medical procedures. However, the comprehensive value of Hospital Play Specialists' services - in terms of the impact on the children, families, and medical institution as a whole - remains largely unexplored in the literature.

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

Methodology: A two-arm randomized controlled trial was carried out in an orthopaedic outpatient clinic in a regional public hospital. Children aged 3 to 12 undergoing cast-removal procedure were invited to participate. Eligible children were randomly allocated to either the intervention or control groups. The intervention group received therapeutic play intervention provided by Hospital Play Specialists, whereas the control group received standard care only. Participants were assessed on three occasions: before, during, and after completion of the castremoval procedure. Outcome measures included children's anxiety level, emotional manifestation, heart rate, as well as the duration of the procedure. The satisfaction ratings of parents and cast-removal technicians with respect to therapeutic play services were also examined.

Results and Outcomes: From August 2015 to January 2017, a total of 208 subjects participated in the study. One hundred and three participants were assigned to the intervention group, and 105 formed part of the control group. Results revealed that children aged 3–7 in the intervention group demonstrated a statistically significant reduction in anxiety levels (p=0.01)

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compared with those in the control group. In addition, children in the intervention group exhibited fewer negative emotional manifestations (p<0.001). The mean difference in the rise of heart rate before and during the procedure was 2.6 beats/minute in the intervention group and 8.4 beats/minute in the control group (p=0.008). The length of procedures was shorter in the intervention group (269 seconds) than in the control group (296 seconds). Nonetheless, the difference is insignificant. Parents and cast-removal technicians in the experiential group also reported higher level of satisfaction (p<0.001) with respect to the procedures than those in control group.

Conclusions: This study provides empirical evidence to support that therapeutic play effectively reduces anxiety and negative emotional manifestations among children undergoing cast-removal procedures. The findings highlight the need to integrate therapeutic play intervention to children undergo cast-removal procedures.

Main Body

Introduction

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

Cast room procedures, which include cast removal, cast application, and pin removal, cause anxiety in children. The sustain injuries of the children, added together with the unfamiliar environments and equipment used during the procedures likely provoke anxiety and fear for children of any age. These psychological burden of children not only make the procedures difficult to perform effectively and efficiently, it may also impose medical risk to patients. Katz and colleagues (2001) reported an extreme case of death in a child having history of cardiomyopathy during the cast room procedure. Moreover, the anxiety of children also likely reduce parent's satisfaction to the care provided.

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 wellbeing 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). Li, Chung, Ho, and Kwok (2016) found that hospitalized children who received therapeutic play exhibited fewer negative emotions and experienced lower levels of anxiety than those did not receive it. Care providers should consider the human rights of children, and provide age-appropriate information to aid understanding of the disease and the interventions employed. Previous studies (Christian et al., 2011; Nyugen & Thaller, 2008) indicated that medically trained professionals were the main providers delivering play therapy as pre-operative preparation for paediatric clients. However, the sustainability of the intervention was in doubt because of the shortage of medical staff (Smith, Murray, McBride, C& McBride-Henry, 2011). As a result, play specialists (Child Life Services, 2014) are good candidates to deliver therapeutic play in an effective manner.

In the United States, play specialists are registered as child life specialists who have strong backgrounds in child development and who promote effective behaviour management through play, preparation, education and self-expression activities (Child Life Services, 2014). They act as advocates of children and family, educators using age-appropriate medical preparation, and partners with the medical team and social workers to meet the children's emotional and developmental challenges. In North America, the Child Life Council has 5000 members. Brewer, Gleditsch, Syblik, Tietjens, & Vacik (2006) evaluated the effectiveness of therapeutic play managed by child life specialists in a double-blind intervention study. The findings showed that child life preparation with role rehearsal and medical play could lower anxiety levels in children following elective day surgery. Additionally, a randomized controlled trial found that psychosocial services provided by the child life specialists could enhance satisfaction, not only to children but also in the parents and healthcare providers (Tyson, Bohl, & Blickman, 2014). The efficacy of child life services 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, Bivins, O'Brien, & Gonzalez del Rey, 2005; Tyson et al., 2014). Further objective data-gathering studies on the scope of procedures for which child life services are effective in an out-patient setting is crucial.

The comprehensive value of play specialist services - in terms of impact on the child, family and medical institution as a whole in paediatric orthopaedic cast room remains largely unexplored in the literature. Our literature search revealed no reports of prospective and randomized controlled studies of comprehensive play specialists among Chinese children, let alone among Hong Kong Chinese. In Hong Kong, hospital play services are being offered by the Playright Children's Play Association. Well-trained hospital play specialists (HPS) deliver therapeutic play - including but not limited to preparation play and distraction play - to children undergoing medical treatment in various units of hospitals.

Aims

The aim of this study was to examine the impact of the therapeutic play provided by HPS in reducing anxiety and negative emotional maniefestation of paediatric patients during castremoval (CR) procedures in an orthopaedic out-patient clinic in Hong Kong. The satisfaction ratings of parents and healthcare providers in respect of these services were also be examined.

Objectives

The objectives were to examine the effectiveness of therapeutic play intervention in

- 1. reducing children's anxiety levels;
- 2. reducing children's negative emotional manifestations;
- 3. reducing length of procedure;
- 4. improving the satisfaction of parents and technicians in respect of the procedures.

Methods

Design

A two-arm randomized controlled trial was employed. Eligible children undergoing the CR procedure were randomly allocated to either the intervention or control groups in a 1:1 ratio.

The child and accompanying parent in the intervention group received therapeutic play intervention provided by the HPS, and the control group received standard care only. All participants were assessed on three occasions: before, during, and after completion of the CR procedure. The study protocol was shown in Figure 1.



CR = cast-removal; HPS = hospital play specialist

Figure 1. The Study Protocol

Settings

This study was 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 CR procedures monthly. The standard of regimen in this OPD did not include therapeutic play services. The cast technicians attended to paediatric patients every Wednesday afternoon. They received limited training on the developmental needs of children in their profession.

Sample

Children and their accompanying parents, who were waiting for the cast room procedure, were 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 were excluded if they (i) had a cast removed within 3 months and (ii) had neurological or developmental problems as shown on the medical record.

The rationale for selecting 3–12-year-old 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 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. According to Erickson (1963), children in the same age group fall in the same stage of psychosocial development.

Randomization of participants to the intervention or control groups 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 was prepared in advance by an independent statistician using computer generated random codes. The group allocation of the recruited children was 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 was determined to detect at least a medium effect size of Cohen's d =0.5 between the intervention and control groups. According to Cohen (1992), 64 subjects in each group was 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 for the intervention and control groups per stratum by age (3–7 and 8–12 years) would be recruited.

Intervention

An experienced HPS conducted all interventions in the study during her regular shift. She individualized the therapeutic activities based on children's needs and their psycho-cognitive development (Erikson, 1963; Piaget, 1963). Duration and type of intervention was varied but usually be completed within 30 minutes. In general, 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 was 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 HPS is skilled in translating hospital jargon into ordinary language and in giving explanations in terms that suit the developmental level of the child (Brown & Wilson, 1997). The preparation phase was implemented individually, with their parents, in a service room. Information about the procedure was 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 were

introduced 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 were also be given to promote the coping strategies of the children.

Part II: rehearsal of the procedure

After verbal explanation, a demonstration of the CR procedure was conducted, using a doll, by the HPS. Examples of such a demonstration were:

- 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 were asked to role-play how he or she would respond to the procedure after the demonstration given by the HPS. During the session, parents and children were encouraged to raise their concerns or ask any questions about the procedure. This provided an opportunity for the HPS to correct any misconceptions. The preparation intervention usually took 10–15mins to complete.

Distraction Play

The HPS continued giving support to the children and parents throughout the CR procedure by giving distraction play intervention. The aim was 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 depended on the HPS's assessment findings and the children's choices (Doellman, 2003). Parental presence and involvement were supported, and praise was given to any successful self-control exhibited by the child. The conclusion of the procedure was indicated by offering the child a reward (e.g. stickers).

Measurements

A visual analogue scale (Appendix I)

A visual analogue scale (VAS) was used to assess the anxiety levels of children aged 3 and 7 years old. 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 3 and 7 was asked to indicate their levels of anxiety by moving a pointer over the line. As children aged 3 to 4 may have limited verbal expression, their accompanying parent(s) was also invited to rate the anxiety levels of their children, 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 (Bringuier, Dadure, Raux, Dubois, Picot, & Capdevila, 2009).

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

The CSAS-C is 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 three-point Likert scale with total scores ranging from 10 to 30. Higher scores indicate greater anxiety levels (Li & Lopez, 2007). The psychometric properties of the short form has been tested and found to correlate highly with the scores obtained from the full form (r = 0.92), with good internal consistency (r = 0.83) and convergent validity that differentiate state anxiety of children under various situations. Factorial structure of the short form was also confirmed using exploratory and confirmatory analyses (Li, Wong, & Lopez, 2008). The Cronbach's alpha coefficient of this scale in this study was 0.80 to 0.88.

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

The emotional behaviours of children during CR procedures were 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). The Cronbach's alpha coefficient of this scale in this study was 0.86.

Satisfaction Scale

Two questionnaires in English, developed by Tyson and colleagues (2014), were adopted to measure parents' (Appendix IV) and cast technicians' (Appendix V) satisfaction levels. The original questionnaire for the parent is a 10–item scale to measure parents' satisfaction with the child life services. Each item is rated by a 5-point scale ranging from 1 = strongly disagree to 5 = strongly agree. A higher score indicates a higher level of 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'. The perception of the cast technician on the service was 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'.

The research nurse worked with the research team to translate the English questionnaire into a Chinese version, with reference to a back-translation method recommended by Brislin (1986). After the translation process, the translated version was reviewed by a panel of expert professionals for semantic and content equivalence. The semantic equivalence is rated on a 4-point Likert scale, with '1' representing 'not appropriate' and '4' representing 'most appropriate'. The content equivalence was evaluated by Content Validity Index (CVI) which is a 4-point rating scale (1=not relevant, 2=somewhat relevant, 3=quite relevant, and 4=very relevant). The CVI is the percentage of total items rated by the experts as either three or four. A total CVI score of 80% or higher is considered to be an indication of good content validity. In this study, 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 (Polit & Beck, 2013). 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.

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 to be objective and definitive indicators for indirect assessment of anxiety level in children in previous studies (Panda, Bajaj, Pershad, Yaddanapudi, & Chari, 1996; Li & Lopez 2006).

Time counting device

A standard time watch was used to measure the length of the CR procedure, from the time the technician approaches the child until the child leaves the cast room after the completion of the procedure.

A demographic sheet (Appendix VI)

A questionnaire developed by the research team was used to measure the sociodemographic 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 was also obtained.

The cast technician's demographic information including age, sex and years of working experience was also collected by the research nurse.

Data Collection Procedure

Children having their casts removed were identified outside the cast room of the study OPD by the RN. For the child met the inclusion criteria for recruitment, permission for the child to participate was obtained from the accompanying parent. The RN conducted the interview with consenting parent–child pairs in a private room. The children of the consenting parents in both groups were asked to indicate how anxious they were by filling in 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) (Li & Lopez, 2007). The RN acquired 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 was also 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 received standard care in the CR room A, whereas those in the Intervention group additionally received therapeutic play intervention conducted by the HPS in the CR room B. The parents and children were 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 took 1-minute recording of the child's heart rate two times: (1) when the cast technician started sawing the cast of the child and (2) immediately after the cast has been removed. The RN then rated the child's signs of distress from the time the saw touches the cast until the limb was free from the cast, by means of the CEMS (Li & Lopez, 2005). The length of the whole CR procedure for each child was also recorded by the RN. The HPS documented the timing, duration, and nature of play for each child in a log book. After the completion of the CR procedure, The RN asked the parents and the cast technician to fill in their respective satisfaction scales to reflect their perceptions of the delivery of the CR procedure 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). For the children aged under 5, the parents were asked to rate the VAS scale for them. The RN gave a \$30 dollar coupon to the parent upon completion of data collection.

A pilot study on 5 pairs of eligible parent-child dyad were 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 helped the research team to refine or revise the

study plan (Polit & Beck, 2013). The pilot study indicated that the recruitment, implementation and data collection process was appropriate. No modification was needed in the definitive trial. Table 1 showed the data collection of the study.

			1
	Pre-test data	Observational	Post-test
	upon consent	data during	data after
	given (T1)	procedure (T2)	completion
			of the
			procedure
			(T3)
			(15)
Demographic and clinical variables	Х		
VAS anxiety scale for children 3–7 years	Х		Х
old;			
The short form of the Chinese version of			
the State Anxiety Scale for Children			
(CSAS-C) for children aged 8–12			
Children's Emotional Manifestation Scale		Х	
1 minute heart rate recorded by an	Х	Х	Х
automatic heart rate monitoring machine.			
Parent satisfaction scale			Х
Staff satisfaction scale			x
Length of procedure		Х	

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

Data analysis

All data was analysed using IBM SPSS for Windows, Version 22. Descriptive statistics such as mean, standard deviation, medium, inter-quartile range, frequency and percentage, as

appropriate, were used to present the participants' socio-demographics and outcome measurements. Pearson's chi-squared test and student's *t*-test were used as appropriate for comparing the baseline differences between the two groups. Generalized estimating equations (GEE) model was used to compare the outcome measures across time between the two groups. GEE model accounts for intra-correlated repeated measures data and accommodated missing data, provided the data are missing at random. All statistical analyses were two-sided and level of significance was set at 0.05.

Ethical Conduct

Ethical approval was sought from the Ethical Committees of the study institutions. The study was conducted in compliance of the principles of the Declaration of Helsinki. The purpose and details of the study were clearly provided to the participants and their accompanying parents before the RN obtained their written consent (Appendix VII). The confidentiality and anonymity of any data collected was also be assured. Participants and parents were informed that the quality of care would not be affected by their participation status.

Results

Demographic and clinical characteristics of the children and their family

From August 2015 to January 2017, a total of 209 patients and their accompanying parents were approached and screened for the eligibility. 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 accompanying parents were recruited. Of the 208 patients, 105 were in the control group and 103 were in the intervention group. Their mean age was 7.7 (SD=3.0) and 7.5 (SD=2.9), respectively. Among the participants in the control group, 52.4% (n=55) were between 3-7 years old, the majority of them were males (64.8%), accompanied by mothers (49.5%) with a secondary school level education (60.0%). About two

third (63.8%) of them had more than one hospital admission, and the majority of them (83.8%) were applied with arm long cast.

For the participants in the intervention group, more than half of them (50.5%) were between 3-7 years old. The majority of them were males (65.0%), accompanied by mother (52.4%) with a secondary educational level (62.1%). Near 70% of them had more than one time of hospital admissions. A majority of them (79.6%) had an arm long cast. The location of casts indicated that the most common fractures for children were within the upper extremity. No significant difference was noted between the control and intervention groups in terms of their demographics and clinical characteristics. For the CR technicians, most of them were male, older than 40 years old and with more than five years of experiences. There was no significant difference in the demographics of CR technicians between the two groups. Table 2 showed the demographics and clinical characteristics of the participants and the demographic characteristics of the CR technicians.

Table 2: Socio-demographics and clinical characteristics of the participants (n=208) and castremoval 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%)	
\geq 3	12 (11.4%)	22 (21.4%)	
Type of casts			
Arm long	88 (83.8%)	82 (79.6%)	0.684 °
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.

Demographic characteristics of the children underwent an additional pin removal

Among the 208 participants, 38 of them underwent an additional pin removal procedures (Table 3). No significant difference was observed between the intervention and control groups in terms of their age and sex distribution.

Table 3: Demographic characteristics of the participants underwent an additional pin removal procedure (n=38).

Characteristics	Control (n=21)	Intervention (n=17)	p-value #
Children and their family			
Age of the child (years) †	7.8 (2.5)	6.6 (2.7)	0.159 ^a
Age group			
3-7 years	10 (47.6%)	9 (52.9%)	0.827 ^b
8 – 12 years	11 (52.4%)	8 (47.1%)	
Sex of the child			
Female	5 (35.2%)	7 (35.0%)	0.529 ^b
Male	16 (64.8%)	10 (65.0%)	

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

^b Pearson chi-square test;

Outcomes across times between the intervention and control groups

Generalized estimating equations (GEE) model was used to compare the outcome measures across time between the intervention and control groups. The mean and standard deviation of the VAS, state anxiety, emotional manifestation scores, the heart rate of children, and the duration as well as the satisfaction scores of parents and CR technicians towards the procedures are presented in Table 4.

Table 4:	Outcome measures	across time	between th	e intervention	and control §	groups

	Control	Intervention	p-value
Among those children aged between 3 and 7 years (N=107)	<u>(n=55)</u>	<u>(n=52)</u>	
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
Among those children aged between 8 and 12 years (N=101)	<u>(n=50)</u>	<u>(n=51)</u>	
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
Among all children (N=208)			
Children's emotional manifestation scale (range:5 – 25)	<u>(n=105)</u>	<u>(n=103)</u>	
T2 (during CR procedure) †	9.7 (3.9)	7.6 (2.4)	<0.001 ^b
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
T3 (after CR procedure)	93.7 (14.9)	88.8 (15.6)	0.070 ^a

Parent satisfaction score (range: 10 - 50)

T3 (after CR procedure)	42.6 (6.9)	46.6 (5.1)	$<\!\!0.001 \ ^{\rm b}$
CR technician satisfaction score (range: 8– 40)			
T3 (after CR procedure)	31.7 (4.3)	34.3 (3.6)	<0.001 ^b
Duration of procedure (mins)	4.6 (2.2)	4.1 (2.3)	0.072 ^b

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.

^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

Anxiety level

Children aged between 3 and 7 years

The VAS was used to assess the anxiety levels of children aged 3–7. For children in the intervention group, their mean anxiety scores reduced from 35.4 to 27.6 after the CR procedures. However, the anxiety scores of children in the control group increased from 34.0 to 46.3. Statistical significant differences (p=0.010) were noted between the two groups. Figure 1 showed the mean VAS anxiety scores among those children aged 3-7 years old at before and the end of CR procedure.



Figure 1: Mean VAS anxiety scores among those children aged between 3 and 7 years at before and the end of CR procedure between the intervention and control groups

Accompanying parent(s) with children less than 5 years old 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 the CR procedure (r = 0.36) and after the CR procedure (r = 0.50).

Children aged between 8 and 12 years

For children aged between 8 and 12 years, reduction of anxiety scores were noted in both the intervention and control group after the CR procedures. The anxiety scores of children in the intervention group reduced from 18.0 to 15.3, whereas the control group reduced from 17.4 to 15.9. However, no statistical significant difference was noted between the two groups (p=0.171). Figure 2 showed the mean scores of State Anxiety Scale for children those aged between 8 and 12 years at before and the end of CR procedure.



Figure 2: Mean scores of State Anxiety Scale for Children among those children aged between 8 and 12 years at before and the end of CR procedure between the intervention and control groups

Emotional Manifestation during Cast-removal Procedures

The emotional manifestation of children during the CR procedures was measured using the Children's Emotional Manifestation Scale. Higher scores indicate more negative emotional behaviours. The mean scores of the control group were (SD=3.9) and the intervention group were 7.6 (SD=2.4). Statistical significant differences (p<0.001) were found between the two groups, indicating participants in the intervention group exhibited less negative emotional manifestation during the CR procedures. Figure 3 showed the mean scores of Children's Emotional Manifestation Scale during the CR procedures between the two groups.



Figure 3: Mean scores of Children's Emotional Manifestation Scale during the CR procedures between the intervention and control groups

Change in Heart Rate

A standard automatic heart rate monitoring machine was used to measure children's heart rates to assess their physiological responses before, during, and after the CR procedures. Results found that there was a trend of increase in heart rate before and during the CR procedures (Figure 4). The mean heart rate of the intervention and control group increased by 8.4 and 2.6 beats/ minute, respectively. Significant differences were noted between the two groups (p=0.008), indicating that participants in the intervention group experienced lower levels of anxiety than those in the control group.



Figure 4: Mean heart rate per minute before, during and at the end of CR procedure between the intervention and control groups

Children underwent an additional pin removal procedures

Three-eight children underwent an additional pin removal procedures after cast-removal. The results showed that the mean scores of emotional manifestation and heart rate of children were higher in the pin removal procedures than in the cast-removal procedures. However, these parameters were similar between the intervention and control groups (Table 5).

Table 5: Outcomes across time between the intervention and control groups in the pin removal procedure

	Control	Intervention	
	(n=21)	(n=17)	p-value
Children underwent pin removal (N=38)			
Children's emotional manifestation scale (range:5 – 25)			
T2 (during CR procedure) [†]	14.3 (5.0)	11.9 (3.6)	0.09 ^b
Heart rate (per minute)			
T1 (before CR procedure)	94.9 (13.3)	94.6 (13.1)	
T2 (during CR procedure)	100.0 (16.5)	100.0 (17.7)	0.87 ^a
T3 (after CR procedure)	97.0 (16.5)	93.2 (18.1)	0.50 ^a

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.

^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

Satisfaction level

Parent

The mean satisfaction scores rated by parents in the intervention group 46.6 (SD=5.1) were higher than that in the control group 42.6 (SD=6.9). Significance differences were noted between the two groups (p<0.001), indicating that parents in the intervention group were more satisfied with the care provided to their children. Figure 6 showed the mean parent satisfaction score after CR procedure between the intervention and control groups



Figure 5: Mean parent satisfaction score after CR procedure between the intervention and control groups

Cast-removal technician

The mean satisfaction scores rated by the CR technician in the intervention group 34.3 (SD=3.6) were higher than that in the control group 31.7 (4.3). Significant differences were noted between the two groups (p<0.001), indicating the CR technician in the intervention group were more satisfied with the CR procedures than those in the control group. Figure 6 showed the mean CR technician satisfaction score after CR procedure between the intervention and control groups.



Figure 6: Mean CR technician satisfaction score after CR procedure between the intervention and control groups

Duration of procedure

Despite the mean duration (minutes) to perform the CR procedures were shorter in the intervention group 4.1 (SD=2.3) than in the control group 4.6 (SD=2.2), no statistical significant difference was noted between the two groups. Figure 7 showed the mean duration of CR procedure between the intervention and control groups.



Figure 7: Mean duration of CR procedure between the intervention and control groups

Discussion

It is common for children to display stressed behaviour in clinical settings, even during painless medical procedures. CR procedures are known to promote anxiety (Katz, Fogelman, Attias, & Baron, 2001), especially in children in whom negative emotional manifestations are commonly observed during CR. Addressing psychological needs of this vulnerable group is important aspects of care but it has always been neglected and overlooked. This study aimed to examine the effects of therapeutic play in reducing anxiety and negative emotional manifestation among Hong Kong Chinese children undergoing CR procedures in an orthopedic out-patient clinic. Our results revealed that most children presented some degree of anxiety before the procedures. The use of saw and the fluctuating level of high-frequency noise accounted for the major source of anxiety (Katz et al., 2001), which not only render the procedures difficult for patients and CR technician but also reduce the satisfaction level of parents towards the procedures. Anxiety has also been reported to result in harmful consequences to the patient as well (Katz et al., 2001).

Various strategies have been employed to alleviate the anxieties of paediatric patients during cast room procedures. Heart rate and mean arterial blood pressure were commonly used as physiological outcome indicators for anxiety. Carmichael and Westmoreland (2005) examined the use of ear protection in reducing anxiety during CR in children. They found that children with ear protectors had significant lower increase of pulse rate than those without ear protectors. However, no significant difference was observed between these children with respect to mean arterial blood pressure. Notably, some young children are averse to wearing the protectors. Liu and colleagues (2007) investigated the effects of music in 69 children aged 10 years or younger undergoing cast room procedures, such as cast application and removal. They found that the heart rates of children exposed to lullaby music were not significantly

different from those of children who were not during the CR procedures. Thus, considering other ways to alleviate anxiety in children is necessary.

Therapeutic play is considered as an effective intervention for the reduction of anxiety and distress among hospitalized children (Li et al., 2016). A recent systematic review (Silva, Austregésilo, Ithamar, Lima, 2017) on 14 articles found that therapeutic play is commonly employed in children undergoing invasive procedures, such as elective surgery, vaccination, blood collection, and dental treatment in inpatient settings. However, although most of these studies demonstrated positive changes in the behavior of children who participated in therapeutic play session and reduction in their anxieties, these studies did not use random assignment to allocate subjects into intervention or control group. Moreover, the beneficial effects of therapeutic play on institutions or care provider were seldom explored.

This study expanded previous studies and examined the effects of therapeutic play intervention on CR procedures in patients, parents, and institutions as a whole. A randomized controlled design was employed such that the cause and effect relationships among variables can be established (Polit, & Beck, 2013). The findings showed changes in the anxiety scores of children aged 3 to 7 years after the procedures. The anxiety scores of children in the intervention group decreased after the CR procedures. By contrast, the anxiety levels of children who did not undergo therapeutic play intervention increased. These results suggested that therapeutic play can effectively assist children to cope with stressful CR procedures and reduce their anxiety levels. In fact, HPS, who are experts in communicating with children, assisted children to cope with unfamiliar procedure by simple and child-friendly approaches. During the therapeutic play session, the HPS explained and stimulated the CR procedures, which allowed the children to understand the procedures. These approaches helped the children to prepare for the procedures psychologically. As the children were familiarized themselves with the CR procedure, they would expect that the procedures to generate noises but not pain. These preparation assisted the children such that they had enhanced sense of control over the procedures and minimized the adverse effects of children's experiences.

In children aged 8 to 12 years, the children in the interventional group had larger reductions in their anxiety scores than those in the control group after the procedures, although the difference between these groups was non-significant. The results were inconsistent with those of a previous study that suggested that older hospitalized children benefit from the therapeutic play intervention (Ziegler & Prior, 1994; Li et al., 2008). One possible explanation for the nonsignificant findings is that older children had better understanding on CR procedures than younger children. According to Piaget's theory (1963), children of 8–12 years can mentally manipulate information to solve problems. As they may have obtained information about the CR procedures in other means, such as books, internet, and friends, they might feel less anxious about the upcoming procedures. Moreover, compared with younger children, older children likely have a better use of coping strategies and better control of their emotions even at stressful situations. Nevertheless, further study is needed to determine other effective methods for the children in this developmental stage.

Overall, children who received the therapeutic play intervention exhibited significantly fewer negative emotional manifestation than those who did not receive it. This is further supported by the fact that the mean increase in heart rates before and during the procedure was lower in the intervention group than in the control group. During the procedures, the CR technician would make use of the saw to cut the cast, and fluctuating noise would be produced. Children commonly felt distressed by the noise and worried about that the saw would cut their skin (Katz et al., 2001). Nevertheless, as the HPS provided suitable and age-appropriated distraction to the children in the intervention group, the attentions of the children were diverted from the anxiety-provoking procedures to playful interactions. Thus, they exhibited less negative emotional behavior. However, for those children without any distraction, they might

have focused on the whole procedure and thus exhibited more negative emotions and have increased anxiety levels even after the procedure.

With regard to the pin removal procedures, no significant differences was observed between the groups in terms of emotional manifestation and change in heart rate. The nonsignificant findings may be attributed to the small number of children who underwent these procedures. Thus, a larger sample is necessary to determine the effectiveness of therapeutic play intervention in this procedure. Nevertheless, the non-significant findings may also be due to the fact that pin removal procedures caused trauma and fear on children. It also likely to result in some discomforts especially when the pins were being removed from the skin. Other kinds of distraction play strategies that can distract and alleviate the negative emotional manifestation in children during pin removal should be explored.

Consistent with previous study (Schlechter, Avik, & Demello, 2016), parents of children in the intervention group provided statistically significant favorable responses to the questionnaire provided after the CR procedures were performed on their respective children. The result indicated that they were more satisfied with the care and therapeutic play intervention compared with parents of children who received standard care only. The satisfaction of parents in the intervention group likely increased because they also experienced the positive influence of play on their children, particular reduction in anxiety and improved cooperation with the procedures (Li & Lopez, 2008). The positive correlations in the VAS ratings of children aged under five years further suggested that parents also perceived their children to be less anxious after the therapeutic play intervention.

Some technician may have concerns that the CR procedures would be impeded and prolonged because therapeutic play intervention is implemented during the procedures. However, the findings suggested that the duration of procedure was relatively shorter in the intervention than in the control group, although the differences were non-significant.

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Nevertheless, the duration in the intervention group decreased, likely because the children were psychological prepared for the procedures and thus were more cooperative. In fact, children who are less anxious are easier to manage in clinical situations (Schreiber, Cunningham, Kunkov, & Crain, 2006). As a result, it may account for the increased satisfaction of CR technicians in procedures facilitated by HPS.

In summary, therapeutic play intervention is effective in reducing anxiety and negative emotional manifestation among children undergoing CR procedures. The therapeutic play intervention was conducted smoothly in the outpatient clinic, demonstrating that it can be integrated to current clinical setting to ease the psychological burden of children undergoing medical procedures. It also positively affected the satisfaction levels of parents and health care provider toward the procedures. The findings suggested that the intervention not only is useful during cast removal procedures but also has beneficial effects on children, parents, and medical institutions as a whole. However, with the shortage of manpower, implementing therapeutic play intervention in clinical settings is difficult. Moreover, most of health care providers lacking training in such intervention. The findings highlighted that HPS play an important part in the health care team which contribute to improve patient care, satisfaction and overall experiences of children and their family.

Limitations

The results of current study should be interpreted in the light of several limitations. First, children were recruited from a single clinical setting. Therefore the generalizability of findings of this study may be limited. Second, both the patients and outcome assessor were not blinded to the study. However, due to the nature of the therapeutic play intervention, blinding of patients and outcome assessors were difficult. Nevertheless, the lack of blinding would not necessarily contribute to a source of bias because children are unlikely to change their

behaviours even when they know they are participating in a certain intervention (Silva, Austregésilo, Ithamar, & Lima, 2017). Moreover, different strategies were employed to minimize the potential biases. For examples, children were assigned to different cast rooms and isolated from other patients at the time of the intervention regardless whether or not they were randomized to have therapeutic play intervention. Besides, 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 experienced some degree of anxiety and exhibit negative emotional manifestation during the CR procedures. The consequences of stress appear to be substantial, and thus the importance of assisting children to cope with stress effectively and reduce its impact is highlighted. The gap in literatures is addressed by providing empirical evidence on the benefits of therapeutic play intervention on children, family and medical institution during CR procedures. The findings show that therapeutic play interventions provided by HPS is effectively reduce the anxiety levels and negative emotional manifestation among Hong Kong Chinese children undergoing CR procedures. Such positive outcomes also translate to an improvement into the satisfaction levels of parents and CR technicians toward the procedures. The findings highlight the importance of providing and integrating therapeutic play intervention into standard care. Such intervention ensures that holistic and quality care is provided to ease the psychological burden of the patients. Furthermore, it also provided evidence on the significance of the work conducted by HPS in routine care of children undergoing medical procedures, and their contribution to the health care team.

Implications

The findings validated the value of therapeutic play provided by the HPS that can inform future service development. First, it emphasizes the need to integrate therapeutic play intervention into routine care to children undergo CR or other medical procedures. Therapeutic play should be considered as an essential component of paediatric health care and an integral part in enhancing the quality of health care delivery. The positive impact of such services on parents' and health care providers' satisfaction likely generalizable to other clinical settings. Second, it highlights the significant role taken by HPS in providing therapeutic play intervention. In fact, most hospitals specializing in paediatric care in the United States, Canada, and other Western countries employed HPS to provide evidence-based and age-appropriated interventions such as therapeutic play to reduce psychological burden that accompany hospitalization or other health care experiences in children. Despite this study provide promising evidence that HPS play a significant role in providing therapeutic play intervention to children, no HPS position is available in hospitals in Hong Kong at present. The therapeutic play services in this study were provided by HPS in the Playright Children's Play Association, a non-profit making organization that receive no direct subsidy from the Government.

Taken together, it is recommended that the Hospital Authority in Hong Kong should advocate the importance of play in the clinical settings including outpatient clinic and allocate adequate resources to secure a child-friendly play environment for children. It is also important to establish positions for HPS and employ them to facilitate the integration of therapeutic play into routine care for children of all age to provide holistic and integrated health care to the children. In fact, the provision of such services is a quality benchmark of an integrated child health delivery system. Although extra resources will be required, it is believed that the benefits of such action on patients, parents, and institutions as a whole far outweigh the additional costs.

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Dissemination

The findings of this study will be presented at international and local conferences. Discussion of the implications of the findings with clinical staff and officials of the Hospital Authority will be taken place.

Publication

- Wong, C. L., Ip, W.Y., Chan, C. W. H., Kwok, M. C., Wong, P. F., Choi, K. C., Chair, S. Y., & Ng, K. W. (2017, May). *The stress-reducing effects of therapeutic play on children undergoing cast-removal procedure.* Poster session presented at the Hospital Authority Convention 2017, Hong Kong.
- Wong, C. L. (2017, February). The best partner in a stressful medical procedure: Play. Paper presented at the Imagining the Future: Community Innovation and Social Resilience in Asia, The Chinese University of Hong Kong, Hong Kong.

Appendix I

A 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<u>圈</u> 出最能表達你<u>現時感覺</u>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<u>現時感覺</u>的字句圈出來就可以了。

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

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Appendix III

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		Non-verbal				
	Verbal interaction	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

Please circle the number that corresponds with your level of agreement

(1=strongly disagree to 5=strongly agree)

		Strongly	Disagree	Neutral	Agree	Strongly
		disagree				agree
1.	The procedure was explained using language my child could understand.	1	2	3	4	5
2.	My child's emotional needs were met.	1	2	3	4	5
3.	Staff showed concern for my child's comfort.	1	2	3	4	5
4.	I knew what to do to help my child.	1	2	3	4	5
5.	Staff showed concern for my questions and worries.	1	2	3	4	5
6.	Staff respected my knowledge of my child.	1	2	3	4	5
7.	I am satisfied with the care provided to my child.	1	2	3	4	5
8.	I would recommend this hospital to others.	1	2	3	4	5
9.	Staff were friendly and helpful.	1	2	3	4	5
10	. Staff worked together well to care for my child.	1	2	3	4	5

Appendix V

Staff Satisfaction Scale

Please circle the number that corresponds with your level of agreement

(1=strongly disagree to 5=strongly agree)

	Strongly	Disagree	Neutral	Agree	Strongly
	disagree				agree
1. The child had an understanding of what was going	1	2	3	4	5
to happen.					
2. The child was cooperative.	1	2	3	4	5
3. The child's emotional needs were met.	1	2	3	4	5
4. The child engaged in distraction.	1	2	3	4	5
5. The parent understood how to help their child.	1	2	3	4	5
6. The procedure environment was well suited to the	1	2	3	4	5
child's need.					
7. I am satisfied with the care we provided to this	1	2	3	4	5
child.					
8. The family is satisfied with the care provided to	1	2	3	4	5
their child.					

Appendix VI

A Demographic and Clinical Data Sheet

1.	Age of children:
2.	Sex of children: F /M
3.	Reason for cast application:
4.	Number of hospital admission for children:
5.	Accompany parent: Father / mother , others; Sex; Age;
6.	Accompany parent's educational level: no schooling/ primary /secondary/college or university
7.	Accompany parent's working status:
	housewife/worker/technician/professional/others
8.	CR Technician: Sex; Age; years of working experience

THE END

Appendix VII



香港中文大學

醫學院

那打素護理學院

遊戲治療對兒童接受石膏拆除程序的有效性研究

研究說明

研究目的

本研究是由香港中文大學及威爾斯親王醫院聯合主辦。其研究目的是探討醫院遊戲治療師對兒童 在骨科門診接受石膏拆除程序所提供遊戲活動的影響。

研究計劃

研究對象為三至十二歲的兒童並等候石膏拆除程序、家長和兒童均懂得講廣東話及閱讀中文。

研究分為干預及對照組別,用隨機抽樣形式進行。

參與對照組別的兒童會接受日常一般的治療程序,而干預組別的兒童會被安排在石膏拆除之前和 進行期間接受遊戲活動。

所有兒童在石膏拆除之前、過程中及之後會接受問卷調查。在石膏拆除的過程中及之後,我們會 觀察兒童的心跳,以及評估其情緒反應。整個程序需時約三十分鐘。 每位參與研究的家長在程序完成後,均填寫一份滿意度問卷調查。

每位參與的兒童將獲發放現金港幣 30 元以作為感謝參與。

現附上研究說明和同意書供閣下閱讀及考慮。如閣下同意參與這項研究,請把同意書簽妥。

我們謹衷心感謝閣下的參與,而參與這次研究完全是自願性質的。閣下有權隨時詢問任何問題, 及拒絕參與。在研究開始之前或期間,閣下是有權拒絕或退出這項研究,而這做法並不會影響閣 下的孩子在醫院內所得到的醫療和護理服務。所得資料均以保密處理及只供學術研究之用。研究 資料將會被妥善儲存,而未得參加者及研究主任的允許,任何人士均不能取用。如有需要,閣下 有權取得個人資料,以及得悉研究結果。

如閣下有任何疑問或查詢,請致電本研究主任聯絡:

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<u>父母、兒童同意書</u>

本人已取得此資料副本作為記錄。

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