Abstract of thesis entitled

An evidence-based protocol for reducing pain and anxiety during blood taking of child and adolescent psychiatric inpatients

Submitted by

Leung Ka Yan

For the degree of Master of Nursing

at The University of Hong Kong

in July 2016

Blood taking is a common procedure in medical treatment in child and adolescent psychiatric inpatients. It is a useful means to monitor a patient’s physical condition, drug administration, side effects of drugs, and therapeutic drug dosage. However, pain induced during the blood taking procedure can lead to distress and fear in patients, especially in children and adolescents. There are many types of pain
reducing methods but no relevant evidence-based guidelines are available for their use in the psychiatric inpatients setting.

The objective of this study was to systemically review the current literature on the effectiveness of pain reducing methods during blood taking among children and adolescents. Data were extracted from 14 articles. Data from the selected studies were extracted in order to establish a table of evidence. Moreover, quality assessment of the selected articles was performed. An evidence-based protocol for reducing pain and anxiety during blood taking drawing in child and adolescent psychiatric inpatients was developed and its feasibility and transferability to the target setting and clients was determined.

Based on the data reviewed in this study, a distraction method for reducing pain and anxiety during blood collection is proposed. The target setting is a child and adolescent psychiatric ward in a local public hospital and the target clients are aged from 6 to 12. The implementation potential of the proposed innovation is high because of its transferability, feasibility and cost-effectiveness. Based on the data, an evidence-based practice protocol will be developed to guide nurses on the use of the distraction method for reducing pain and anxiety during blood taking in child and
adolescent psychiatric inpatients. In order to improve the quality of nursing care by reducing pain and anxiety levels during blood taking, it is recommended that this approach should be established in the practice of all public hospitals.
An evidence-based protocol for reducing pain and anxiety during blood taking of child and adolescent psychiatric inpatients

by

Leung Ka Yan

BSc(Hons) NURS, R.N.P.

A dissertation submitted in partial fulfillment of the requirements for

the Degree of Master of Nursing

at The University of Hong Kong

July 2016
Declaration

I declare that this thesis thereof represents my own work, except where due acknowledgement is made, and that it has not been previously included in a thesis, dissertation or report submitted to this University or to any other institution for a degree, diploma or other qualifications.

Signed

Ms. Leung Ka Yan
Acknowledgements

I would like to express my sincere gratitude to my supervisor, Dr. Athena Hong Wai Lin, for her valuable guidance, advice and encouragement in this year. She inspired me a lot in completing the dissertation with enrichment of content and enhancement of my thinking process. I could accomplish the dissertation because of her generous assistance.

In addition, I offer my heartfelt blessings to my beloved one, family and friends, colleagues for their sincere support, love and understanding throughout the period of my study.

At last, I would like to take this opportunity to thank The University of Hong Kong for providing me with a good learning environment and giving me the chance to fulfill my wish of obtaining a Master Degree.
# Table of Contents

Declaration ........................................................................................................... i  
Acknowledgements ................................................................................................. ii  
Table of Contents ................................................................................................. iii  
List of Table .......................................................................................................... viii  
List of appendix ..................................................................................................... ix  
Abbreviations ....................................................................................................... x  

## CHAPTER 1: INTRODUCTION  
1.1 Background ................................................................................................. 1  
1.2 Affirming the need ....................................................................................... 2  
1.3 Objectives and Significance ......................................................................... 6  

## CHAPTER 2: CRITICAL APPRAISAL  
2.1 Search and Appraisal Strategies ................................................................. 8  
2.1.1 Inclusion and Exclusion Criteria for Study Selection ......................... 8  
2.1.2 Search Strategies .................................................................................... 9  
2.1.3 Appraisal Strategy ................................................................................ 9  
2.2 Results ......................................................................................................... 10
2.3 Summary and Synthesis

CHAPTER 3: IMPLEMENTATION POTENTIAL AND CLINICAL GUIDELINES

3.1 Transferability

3.1.1 Target Setting

3.1.2 Target Population

3.1.3 Philosophy of Care

3.1.4 Number of Clients that will Benefit from the Innovation

3.1.5 Time for Implementation and Evaluation

3.2 Feasibility

3.2.1 Freedom of Implementation

3.2.2 Interference with Staff Function

3.2.3 Administrative support and Organizational climate

3.2.4 Consensus and Resistance

3.2.5 Support from other disciplines

3.2.6 Skills Needed

3.2.7 Equipment and facilities

3.2.8 Measurement Tools

3.3 Cost-Benefit Ratio
4.2.1.1 Setting ................................. 47
4.2.1.2 Study design and sampling .................. 47
4.2.1.3 Sample Size .............................. 47
4.2.1.4 Subjects .................................. 47
4.2.1.5 Collection of data ........................... 47
4.2.1.6 Assessment of feasibility ..................... 48
4.2.1.7 Assess for acceptability and nurse compliance 48
4.2.1.8 Refining .................................. 48
4.2.2 Timelines for the Pilot Study .................... 49
4.3 Evaluation Plan .................................. 49
4.3.1 Outcome measurements .......................... 49
4.3.2 Timelines for the Evaluation Plan .................. 51
4.3.3 Sample size .................................... 51
4.3.4 Data analysis ................................... 52
4.3.5 Effectiveness of the innovation ..................... 52
4.4 Basis for Implementation .......................... 53

CHAPTER 5: CONCLUSION ........................... 55

TABLE .......................... 56

APPENDIX .......................... 60
List of Table

Table 1 Material Cost of implementation (per year) ------------------------------ 56
Table 2 Nonmaterial Cost for staff training ------------------------------------- 57
Table 3 Estimated cost of the innovation ---------------------------------------- 58
Table 4 Cost-benefits Ratio for Implementation of Distraction Cards --------- 59
# List of Appendix

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PRISMA 2009 Flow Diagram</td>
<td>60</td>
</tr>
<tr>
<td>2</td>
<td>Table of Evidence</td>
<td>61</td>
</tr>
<tr>
<td>3</td>
<td>Methodology Quality Appraisal</td>
<td>63</td>
</tr>
<tr>
<td>4</td>
<td>Details of the Guideline</td>
<td>71</td>
</tr>
<tr>
<td>5</td>
<td>Child and Adolescent Psychiatric Inpatients Blood Taking Record</td>
<td>78</td>
</tr>
<tr>
<td>6</td>
<td>Satisfactory Survey for Healthcare Providers</td>
<td>79</td>
</tr>
</tbody>
</table>
Abbreviations

Advanced Practice Nurse (APN)
Castle Peak Hospital (CPH)
Children's Anxiety and Panic Scales (CAPS)
Children Fear Scales (CFS)
Chief of Service (COS)
Department Operations Manager (DOM)
Department of Child and Adolescent Psychiatry (CAP)
Enrolled Nurse (Psychiatric) (ENP)
High-density-lipoprotein (HDL)
Low-density lipoprotein (LDL)
Medical Officer (MO)
New Territories West Cluster (NTWC)
Nursing Officer (NO)
Practice Nurse (Psychiatric) (APNP)
Registered Nurse (Psychiatric) (RNP)
Scottish Intercollegiate Guideline Network (SIGN)
Second generation antipsychotics (SGA)
Statistical Package for Social Science (SPSS)
Tuen Mun Hospital (TMH)
Ward Manager (WM)
Wong Baker FACES (WB-FACES)
CHAPTER 1: INTRODUCTION

1.1 Background

Pain is an unpleasant sensation or emotion triggered by stimulation of the nervous system (International Association for the Study of Pain, 1979). It is a subjective feeling and can be experienced by people of all ages. Medical procedures which result in pain are very common in the hospital setting. Needle-related-procedures are the most prevalent and are the major source of patient pain, especially in children (Cummings et al., 1996). According to Duff (2003), blood taking is a stressor and source of painful experience to children admitted to hospital. This procedure may cause children to become fearful of needles and may lead to them becoming uncooperative in their care.

Phlebotomy, blood taking/drawing from a vein for diagnostic purposes or treatment, is one of the most common procedures in hospital setting. In the following text, the following terms related to blood taking such as phlebotomy, venipuncture (venipuncture), blood letting, blood drawing and blood sampling, will be regarded as having the same meaning.

The painful experience may lead to patient anxiety when undergoing those procedures again. Therefore, the reduction of the sensation of pain and anxiety involved in the procedure is crucial. This can lead to improved patient cooperation
and a smoother process during the procedure.

For an in-ward setting, blood taking will always be ordered upon admission and also later for monitoring purposes. In children and adolescents in the psychiatric in-patient setting, blood taking procedures will take place for baseline monitoring, as a reference for the physical condition of the patient and also assessing the general state of health before, after and during treatment.

1.2 Affirming The Need

As mentioned, blood collection is a common procedure in medical treatment, even in the psychiatric in-ward setting. Blood taking for monitoring physical condition, prescribed drugs and their side effects are the most common reasons for having blood taking in the psychiatric setting. For example, a large body of clinical data shows that atypical (second generation) antipsychotics (SGA) will cause an increase in blood glucose, serum triglyceride, and low-density lipoprotein (LDL) levels, as well as a decrease in high-density-lipoprotein (HDL) levels revealing the adverse metabolic adverse effects associated with SGA use (American Diabetes Association et al., 2004). Also, drug-induced agranulocytosis might also arise in some patients taking SGA (Cohen & Monden, 2013, Gaszner, Makkos, & Kosza, 2002), and recent studies revealed the late
onset of drug-induced agranulocytosis (Nongpiur, Praharaj, Sarkar & Das, 2012; Raja, Azzoni & Maisto, 2011). In addition to SGA, mood stabilizers and antiepileptics are drugs commonly used in psychiatric medicine and often require careful monitoring for their therapeutic range and toxicity (Taur, Kulkarni, Gogtay, & Thatte, 2013; Baumann et al., 2005). Therefore, regular blood monitoring is recommended in the psychiatric setting. All these drugs are also prescribed to child and adolescent psychiatric patients. Thus, blood taking is a relatively frequent procedure in the child and adolescent psychiatric in-ward setting.

The child and adolescent psychiatric in-ward setting provides in-patient treatment for children and adolescents under the age of 18 with mental health problems. Every day patients in these wards undergo blood taking procedures. Most of these patients demonstrate distress and fear of needle-related procedures including blood collection. Research has also revealed that needle-fear is predominant among children and up to 93% of children experiencing needle-related stress (Ives & Melrose, 2010). By clinical observation, it is noticed that children (aged 6-12) struggled more in blood collection procedures than adolescents (aged 13-18). In clinical practice, physical restraint may be used to stabilize the patient during the procedure. This kind of fear or stress may relate to prior painful and negative experiences the elevated anxiety in
children. Needle-related procedures including blood taking are the main source of pain for children causing anxiety, distress and fear in the hospital setting (Cummings et. al., 1996; Inal & Kelleci, 2012).

There is no doubt that early negative experiences may lead to a lifelong fear of situations associated with blood collection. Pain may cause a fear of needles in children, and lead to a resistance to related medical procedures in future (Wong, Chia, Yam, Teodoro, & Lau, 2004) and even to avoidance of treatment (Spielberg et al., 2003). Thus, applying pain management to reduce the fear and anxiety during blood collection is important in nursing practice (Rogers & Ostrow, 2004).

Pain management in blood taking procedures has been widely studied and can be mainly divided into pharmacological and non-pharmacological approaches (Taddio et al., 2010). Many studies have shown that pharmacological approaches are effective in reducing pain during phlebotomy (Rogers & Ostrow, 2004; Arendts et al., 2008; Gilboy & Hollywood, 2009). However, pharmacological approaches will be excluded in this thesis as application of all types of drug, even through the use of topical creams are required to have a prescription by a medical officer in Hong Kong practice. If pain management for blood taking procedures can be carried out as part of routine nursing
care, it will be much more flexible and easy to carry out in non-pharmacological approaches. In fact, non-pharmacological approaches are regarded as useful in improving a child’s experience of painful procedures (Wang et al., 2008). This includes hypnosis, distraction, and guided imagery (Rogovik & Goldman, 2007; Russell & Smart, 2007). Literature has shown these methods are safe, inexpensive and effective for short painful procedures (Wang et al., 2008; Prabhakar et al., 2007; Bellieni et al., 2006).

The literature review identified a full-text systematic review on these non-pharmacological approaches with the title of 'Psychological interventions for needle-related procedural pain and distress in children and adolescents in 2013 (Uman et al., 2013). Also, a narrative review was recently published, but the full-text could not be accessed. There is now a need for a systematic review of the field as new evidence of the use of the distraction method for reducing needle-related procedural pain and anxiety was not included in the 2013 review. According to Uman et al. (2013), distraction is an effective method for directing children's attention away from pain stimulation. There are difference distraction techniques which are easily administered in the ward setting. Hartling et al. (2013) showed that music was effective when used for relieving pain and distress in children during intravenous access. Inflating a balloon
also showed a positive impact on reducing pain during phlebotomy (Sahiner & Bal, 2015). The use of a kaleidoscope is also a beneficial method for pain and anxiety relief during phlebotomy in children (Canbulat et al., 2014). Additionally, distraction cards are effective for dealing with pain during phlebotomy (Canbulat et al., 2014; Inal et al., 2012).

**1.3 Objectives and Significance**

Blood taking is a painful invasive procedure commonly experienced by patients in hospital, and the condition is more prominent in child and adolescent patients. Effective pain management during blood taking procedures in children and adolescent patients is not only important for their immediate comfort, but also facilitates the whole treatment process. These benefits make pain management important for nurses and even health care providers.

In Hong Kong, there is no routinely used systematic method for reducing the pain and anxiety of children during blood taking. In addition, there is no formal practice in pain management in blood taking procedures in the children and adolescents psychiatric ward.
The objectives of this dissertation are:

i. To evaluate current evidence for reducing pain and anxiety during blood taking in child and adolescent psychiatric inpatients;

ii. To develop an evidence-based protocol for reducing pain and anxiety during blood taking in child and adolescent psychiatric inpatients;

iii. To assess the transferability and feasibility of implementing the pain and anxiety reduction protocol in the child and adolescent psychiatric in-patient setting in Hong Kong;

iv. To develop implementation strategies and an evaluation plan for reducing pain and anxiety during blood taking procedures in local child and adolescent psychiatric in-patient settings.

As mentioned, needle-related procedures are the main cause of painful experiences in child patients. This kind of discomfort and pain experienced during needle-related procedures such as blood taking process may affect the patients willingness to cooperate in their treatment programme afterwards. It is significant that nursing interventions can be provided to reduce the pain and anxiety in child patients during the blood taking process.
CHAPTER 2: CRITICAL APPRAISAL

2.1 Search and Appraisal Strategies

In this chapter, a detailed description of the literature searching process from identifying keywords to the selection of potential studies will be provided. The identified studies will be further rated according to their level of evidence while valuable data extracted from the selected studies will then be used to draw conclusions and make recommendations.

2.1.1 Inclusion and Exclusion Criteria for Study Selection

Studies were included if:

i. the target population were children and adolescents under the age of 18 years

ii. distraction methods for pain reduction during blood taking was carried out

Studies were excluded if:

i. Pharmacological approaches were used

ii. Additional expensive equipment was needed

iii. Parental reassurance was involved

iv. Specific skills were needed.
2.1.2 Search Strategies

From September 2015 to December 2015, a literature review was conducted by using the Pubmed, Cochrane Library, and PsycINFO databases. The following keywords identified by using MESH were included: phlebotomy, bloodletting, pain, distraction method. To eliminate irrelevant articles, records were excluded after title and abstract examination. Duplicated articles were excluded. The reference lists from the eligible studies were also screened to identify other potential studies. By searching of reference lists of eligible studies and relevant reviews, one further article was added.

Since the pharmacological approaches pain reduction are not well suited to clinical practice in Hong Kong, methods related to the application of topical anesthetic creams were also excluded. Additionally, procedures requiring expensive equipment were excluded as they may not be feasible to implement in the ward setting. In addition, methods focused on parental reassurance were excluded.

2.1.3 Appraisal Strategy

Critical appraisal of the eligible studies was done according to the Scottish Intercollegiate Guideline Network (SIGN) methodology checklist for randomized
controlled trials (SIGN, 2011). The question statement, randomization, concealment method, blinding, similarity between groups, validity and reliability, drop-out rate, intention to treat analysis, and study site comparability were considered in the quality assessment. “+++” was scored if all or most of the criteria were fulfilled, meaning that the conclusion of study would be very unlikely to be altered by bias and regarded as a high quality study. “+” was be scored if some of the criteria were fulfilled, meaning that the conclusion of the study would be unlikely to be altered and was regarded as an acceptable level of quality. “-“ was scored if few or none of the criteria were fulfilled and the conclusion would be likely altered and regarded as an unacceptable level of quality.

2.2 Results

By using the Pubmed database 159 articles can be searched using the keywords above. Combined with the 11 articles identified in the Cochrane Library and 6 articles identified by PsycINFO, together with one article identified through reference lists of eligible studies, a total 177 articles were identified. After 12 duplicates were removed, 165 articles were screened. 111 articles were then excluded, and 54 full-text articles were assessed for eligibility. A further 40 articles were excluded of which 30 were related to pharmacological approaches, 3 needed expensive equipment, 2 focused on
parental techniques, 1 required hypnosis skills, and 4 were not related to normal blood
taking procedures. Finally, 14 articles were identified (Appendix 1).

In these 14 articles, the distraction method used for reducing pain during blood
taking included distraction cards, listening to music, use of a kaleidoscope, balloon
inflation, a rubber ball, TV, and structured psychological consultation. Four of the
recently published articles showed the distraction cards were beneficial; two showed
balloon inflation and two showed watching TV have a positive impact; one showed that
a rubber ball and one showed that structured psychological consultation is effective.
Three of the articles also showed music is effective in reducing pain during blood
collection. However, the method of delivering music was variable; live musicians,
choice by a music therapist, and also cartoon music were all employed. The
effectiveness of a kaleidoscope was unclear (Carlson, 2000).

In the table of evidence (Appendix 2), Canbulat et al. (2014) revealed the
distraction cards were the most effective method for reducing in pain and anxiety during
blood taking in the kaleidoscope and the control group. In this randomized clinical
trial, a total of 188 children aged 7-11 years old with a mean age of 8.8 ± 1.5 years were
recruited, consisting of 95 females (50.5%) and 93 males (49.5%). 63 participants
were randomized into a no intervention control group, with 63 participants in a
distraction cards group (cards would be given and questions about the cards would be
asked throughout the whole process) and 62 participants were in the kaleidoscope group
(the kaleidoscope would be given before the blood collection process and continued
until the end). Two outcomes were measured as pain and anxiety by the Wong Baker
FACES (WB-FACES) and Children Fear Scales (CFS) respectively. WB-FACES was
carried out by self-reported, parent-reported and observer-reported observations after
the procedure, and CFS was parent-reported and observer-reported. Although both
the distraction card group and the kaleidoscope group showed a lower pain level than
controls, the most effective method was the distraction card methods (p = 0.02) by self-
reported, p < 0.01 by parent-reported and observer-reported data comparing to the
control group. For the pain level, the larger effect size of the distraction cards group
and the control group by WB-FACES were 0.65, 1.26 and 1.76. For anxiety levels,
the most effective method was the distraction card method with p < 0.01 in the
CFS compared to the control group. The effect size of the distraction cards group and
the control group by CFS was large, at 1.05 and 1.50 respectively.

As reported by Sahiner & Bal (2015), a prospective randomized controlled trial
was carried out with a total of 120 children aged 6-12 (mean age: 9.1 ± 1.6 years),
comprising 57 females (47.5%) and 63 males (52.5%). Participants were randomized into groups of three distraction methods employed; distraction cards, listening to cartoon music, balloon inflation and a control group with 30 participants in each group. The intervention was continued until the end of the blood taking procedure. Thus, distraction cards were given to the distraction cards group participants and questions were asked before the procedure till the procedure was completed. In music group, 15 minutes of cartoon music was played and participants would be asked which cartoons the music came from. In the balloon inflation group, the balloons were inflated before the procedure till the procedure completed. The routine blood taking procedure was conducted in control group. The WB-FACES for pain and CFS for anxiety level were assessed by parent-reported and observer-reported data. The distraction cards group showed reduced pain levels compared with the control group, with medium effect sizes of self-, parent- and observer-reported data as 0.68, 0.56, and 0.61 respectively. The difference between groups in the self-reported data is significant (p = 0.04) in the self-report. The anxiety levels reported by observers were significantly different in the distraction card group compared with controls (p = 0.032) with an effect size in parent- and observer-reported data of 0.36 and 0.30 respectively.
The study of Inal & Kelleci (2012) is a prospective randomized controlled trial. It consisted of 123 children aged 6-12 with a mean age of 9.36 ± 1.96 years. The population comprised 61 females (49.6%) and 62 males (50.4%). Participants were then randomly assigned into a distraction card group (n=61) and a no intervention control group (n = 62). The distraction was applied by distributing the cards and asking related questions during the whole blood collection process. Parent- and observer-reported Children's Anxiety and Pan Scales (CAPS) were used to assess the patient anxiety levels. Self-, parent- and observer-reported pain was assessed by the Faces Pain Scale-Revised (Inal & Kelleci, 2012). The group shown distraction cards showed significant differences in pain levels reported by self, parents and observers with p = 0.00 for each type of reporting and large effect sizes of 1.45, 1.35 and 1.36 respectively. Also, parent- and observer-reported differences in anxiety were significantly different in distraction cards group with p = 0.00 large effect sizes of 2.02 and 1.94, respectively.

Finally, a quasi-experimental study (Alhani et al., 2010) was included. This study enrolled 42 participants from three centres, comprised of 17 females (40.5%) and 25 males (59.5%). Twenty-one participants were assigned to a distraction picture group
(mean age 13.86 ± 3.19) and another 21 participants from another 2 centres were assigned into the control group (mean age 14.81 ± 3.51). Two pictures were provided to participants before each venipuncture and participants were asked to identify the differences between the pictures and provide their answer after the procedure. WB-FACES was used to assess self-reported pain levels. Although data showed that in the intervention group there was a significantly decrease in pain intensity (p = 0.003), the effect size of 0.29 was very small. Also the difference of pain reduction between the intervention group and control group was significant after distraction (p=0.007), but the effect size was also small at only 0.23.

After completing the SIGN checklist (Appendix 3), two articles scored ++ (Canbulat et al., 2014; Inal & Kelleci, 2012); and other two articles scored + (Sahiner & Bal, 2015; Alhani et al., 2010).

To summarize the appraisal results, distraction is a useful method for reducing pain and anxiety in children during the blood taking process. The use of distraction cards is regarded as the most effective distraction method compared to a kaleidoscope, balloon inflation, and listening to cartoon music.
2.3 Summary and Synthesis

The included studies all demonstrated the effectiveness of using distraction cards for reducing pain and anxiety levels in children during blood taking.

In the following section, each of the selected studies will be synthesized by the study design, subject characteristics, intervention, controls, outcome measures, and methodological quality.

Study design

Three studies are in randomized clinical trials (RCT) (Canbulat et al., 2014; Sahiner & Bal, 2015; Inal & Kelleci, 2012) and one is a quasi-experimental study (Alhani et al., 2010). The RCTs have the randomized allocation of intervention group(s) and a control group. However, the Alhani et al. study (2010) only assigned the participants from the same centre into the same groups. This may be because it is easier to handle and carry out the interventions. However, no further information was provided about any differences between the three chosen centres in the Alhani et al. study. There may be self-selected differences before application of the intervention and there is therefore a high potential for selection bias. The three RCTs all stated the
randomization was performed on the basis of a computer generated table of random numbers. This approach can help to avoid and minimize systematic bias.

Additionally, the Alhani et al. study consists of 3 pretest sessions without distraction applied and 9 sessions with distraction applied during the venipuncture procedure. Evaluation was performed immediately after each session. For the other three RCT studies, only a single session was evaluated, with no course of sessions. In the RCTs evaluation was also performed immediately after each blood taking procedure.

Subject characteristics

Some studies have reported that pain rating is influenced by demographic variables such as gender and age (Cohen, 2008). These studies involved children mainly aged 6-12 with a mean age of 8.8-9.36 (Canbulat et al., 2014; Sahiner & Bal, 2015; Inal & Kelleci, 2012) undergoing blood taking procedures. Alhani et al. (2010) had a wider range of participants, aged 10 - 21, with a mean age of 13.86 (intervention group), and 14.81 (control group). All four studies had similar male to female ratio of approximately 1:1. There were no significant differences between the intervention and control groups in each study. Thus, pain and anxiety levels should not be influenced by demographic variables such as gender and age.
Two of the selected studies were done at the Phlebotomy station in Children’s Hospital (Canbulat et al., 2014; Sahiner & Bal, 2015). One study was done in a pediatric clinic (Inal & Kelleci, 2012), and another one was done in three haemodialysis centres of Children's hospitals (Alhani et al., 2010). The source of participants from haemodialysis centres might be different from the other three studies, as the participants would not be undergoing one-off venipuncture procedures. Their treatment would be likely to require much more frequent venipuncture than patients in the other studies.

Canbulat et al. (2014) and Sahiner & Bal (2015), the participants were children from 7 to 11 years and 6-12 years of age respectively, who requested blood tests and with consent from their parents were recruited as study participants. Both studies might have a wider range of patient groups. In these studies, there was less bias in the recruitment process and the results should be more generalizable. In Inal & Kelleci's study (2012), 6-12 year-old patients who requested a blood test were recruited, excluding the neuro-developmentally delayed, those with verbal difficulties, hearing or visual impairments, those who have taken analgesic medication within 6 hours, or have a history of syncope due to blood draws. Since exclusion criteria were set, that could only allow a focus on participants with a normal physical state the results might be only
relevant to children with a normal physical state. In Alhani et al. (2010), the criteria for patient recruitment were 10-21 years old with hemodialysis at least twice a week and at least in their third month of hemodialysis (in order to ensure the hemodialysis process was done with the venipuncture), able to read and write Persian, and with consent of both patient and parent. Thus, the results might cast doubt on the applicability of its findings to my own practice.

Pre-procedural anxiety was taken into account for differences between intervention and control groups. In Canbulat et al. (2014) and Sahiner & Bal (2015), self-reported, parent-reported and observer-reported data were used to assess pre-procedural anxiety levels. In Inal & Kelleci’s (2012), both parent-reported and observer-reported data were used to determine pre-procedural anxiety levels. All three studies showed no significant difference in anxiety level between the intervention and control groups before the intervention. Alhani et al. (2010) could not be compared, as anxiety was not measured in this study. Thus, a limitation of Alhani et al. (2010) is that the psychological condition of participants before blood taking could affect the results of the study. In addition, there was the limitation that hemodialysis patients might have other disease-related factors affecting their psychological condition and which result in potential effects on the pain assessment results.
Sample size

For the RCTs combined, a large sample size of 120-188 participants was reached. However, only a comparatively small sample size of 42 participants was involved in Alhani et al.’s study (2010) resulting in less ability to generalize the result, even though the participants were recruited from three different centres. No dropped out participants were identified in the four studies.

Intervention

Distraction cards were an important intervention in the RCTs (Canbulat et al., 2014; Sahiner & Bal, 2015; Inal & Kelleci, 2012). Three methods of using distraction cards were used under the same procedure. Visual cards of 5 cm x 8 cm dimensions with different pictures and shapes were prepared. The cards were given to children just before the phlebotomy and the distraction procedure was continued until the phlebotomy was completed. Throughout the process, two nurses with at least 5 years of experience in pediatric care were involved. One nurse was responsible for the phlebotomy works for the whole study and the blood taking process was performed within 1 to 5 minutes. The other nurse was responsible for the distraction procedure that involved asking a series of questions related to the pictures. For example, asking
children to count the objects in the pictures and identifying the objects in the pictures.

If the first attempt of blood taking was not successful, a second attempt was tried in the distal part of the same arm and the distraction procedure was continued till the blood taking process was complete.

For this intervention, people were assigned for each phlebotomy. This could be easily arranged in the child psychiatric ward setting as it is just like usual practice in blood collection procedures. Also, this intervention is affordable as the preparation of the distraction cards is inexpensive.

In Alhani et al.’s study (2010), the distraction procedure was performed in a similar way to the RCTs. Distraction pictures were given to children before the phlebotomy process. Children were requested to identify the difference between the pictures after the blood drawing procedure. However, in this study the venipuncture procedures were performed by three different personnel, and it was not possible to judge how variation in their skills would affect outcome.

**Controls**

For the control groups, the routine blood taking procedure was applied in all four
studies.

Outcome measures

All four studies used pain level as the primary parameter. Anxiety levels were measured only in the three RCTs (Canbulat et al., 2014; Sahiner & Bal, 2015; Inal & Kelleci, 2012), but not in the Alhani et al. study (2010). All the measurement tools used in the studies are well established, reliable and validated.

WB-FACES was used for pain level assessment by Canbulat et al., Sahiner & Bal and Alhani et al.. This test uses a scale from 0 to 10, with six cartoon faces representing a neutral expression (0 = very happy/no pain) to a crying face (10 = hurts as much as you can imagine). This scale has been validated (Hockenberry & Wilson, 2009).

FPS-R was used for pain level assessment by Inal & Kelleci. This scale has a scale from 0 to 10 consisting of six cartoon faces from neutral expression (0 = no pain) to a screaming face (10 = severe pain). It is a well-accepted measure (Stinson et al., 2006), with strong psychometric properties in children ages 4 to 17 years (Tsze et al., 2013).
CFS was used for anxiety level assessment by Canbulat et al., and Sahiner & Bal. It is a scale ranging from 0 to 4, showing five cartoon faces ranging from a neutral expression (0 = no anxiety) to a frightened face (4 = severe anxiety) (McMurtry et al., 2011).

Inal & Kelleci used CAPS to evaluate levels of anxiety and pain. This approach comprises two sets of scales from 0-5, with one scale for anxiety and the other for pain levels. Inal & Kelleci, only used the set with five cartoon faces ranging from a neutral expression (0 = no anxiety) to a frightened face (5 = severe anxiety). This tool is also widely used and well established for in the evaluation of pain and anxiety in children (Meyerhoff et al., 2001).

Data Collection

For the three RCT studies, the pain and anxiety measurement tools were explained to both the participants and their parents before randomization so as to ensure they fully understood the use of the measurement tool.

In the three RCT studies pain levels were evaluated by self-, parent- and observer-reported data. The three parties were blinded to each other’s responses.
For anxiety levels, only the parent and observer were responsible for the report in the RCT studies. However, only self-reported data was used by Alhani et al. (2010).

Methodological quality

Although randomization using a computer generated table of random numbers were mentioned in the three RCTs, the method of concealment and blinding about treatment allocations were not mentioned. Failure to conceal the allocation sequence may cause distortion of the results. In these studies, the participants and the nurse cannot be blinded. However, blinding could be applied for parents and observers to minimize the bias from reporting. However, because the sample sizes in the RCTs were large the data can be regarded as high quality, with a greater chance of generalization.

In terms of effect size, Canbulat et al. (2014) and Inal & Kelleci (2012) showed the most significant effect of using the distraction cards for reducing pain and anxiety during blood taking. In contrast, Alhani et al. (2010) showed a relatively low quality of data due to the study design, sample size, the effect size and also the levels of significance which were observed.

By comparing the study design, subject characteristics, intervention, controls,
outcome measures, and methodological quality of the four studies, Canbulat et al. (2014) and Inal & Kelleci (2012) revealed adequate evidence supporting the use of distraction cards as a method to reduce pain and anxiety during blood taking. Canbulat et al. (2014) studies enrolled participants aged from 7-11 years old and Inal & Kelleci (2012) enrolled participants aged 6-12 years old. Thus, to conclude the above summaries and synthesis, the distraction cards method was the most effective method for reducing pain and anxiety during blood taking in children aged 6-12. There are no studies especially focused on the psychiatric setting. The target population in the reviewed studies did not have any specific diagnosis mentioned and it was assumed that the result would not be affected by the diagnosis. The effects of the sensory alterations and uncooperative clients that would take place during psychiatric diagnosis will be discussed in the next chapter. This proposed innovation will be a systematic method to reduce pain and anxiety during blood taking in child and adolescent psychiatric in-patients in Hong Kong.
CHAPTER 3: IMPLEMENTATION POTENTIAL AND CLINICAL GUIDELINES

In the previous chapter, a critical appraisal of methods to reduce pain and anxiety of child patients during blood taking procedures was performed. In this chapter, the implementation potential of the method will be assessed through examination of transferability, feasibility and the cost-benefit ratio. Also, clinical guidelines will be developed with details of the background of the clinical issue, target setting, target population and evidence-based recommendations.

3.1 Transferability

To evaluate transferability of the method, the target setting, target population, philosophy of care, the number of clients who would benefit from the innovation, and the time frame for implementation and evaluation will be considered.

3.1.1 Target Setting

The distraction card method for reducing pain and anxiety during blood taking is proposed for use in Child and Adolescent Psychiatry ward under the governance of the New Territories West Cluster (NTWC) Hospital Authority. This is one of the four public hospitals with Child and Adolescent Psychiatry in-patient services in Hong Kong.
It is a mixed gender ward which provides 20 beds.

In the reviewed studies, the innovations were performed on the setting of a phlebotomy station in children hospital, a pediatric clinic and a haemodialysis centre at a children’s hospital (Canbulat et al., 2014; Sahiner & Bal, 2015; Inal & Kelleci, 2012; Alhani et al., 2010). Although the settings were slightly different from the proposed setting, the blood taking skills and other necessary requirements are similar to those used in the research studies. Thus, the innovation can be applied in the proposed setting.

3.1.2 Target Population

The target population for the proposed innovation are children aged from 6 to 12 who need to undergo blood taking procedures. The actual age of the clients in the target setting includes all ages under 18. The target population in the research were children aged from 6 to 21 who needed blood drawing. However, the majority of the target population in the reviewed studies were aged 6 to 12. Thus, the target population will be set as children aged from 6 to 12.

Since the target population in the reviewed studies had not been assigned with a
specified diagnosis, it was supposed that no diagnosis would affect the result. To eliminate the effect of sensory alterations and uncooperative clients in the psychiatric ward, the target population of the proposed innovation will exclude clients who are diagnosed with learning disabilities, are not willing to cooperate, or have verbal difficulties, and hearing or visual impairments. The population of the reviewed studies are therefore similar to the population in the proposed study.

3.1.3 Philosophy of Care

The proposed setting is under the governance of NTWC of the Hospital Authority, which is responsible for managing the public hospitals services in Hong Kong. NTWC adopts the vision of “your preferred healthcare provider” and the mission statement “We are committed to providing people-oriented healthcare services and an environment conducive to staff wellness and the Values of “People FIRST”” representing fairness, innovation, respect, safety and teamwork (NTWC, 2016).

Pain management has a significant impact on patient experience in the hospital setting. To enhance pain management in NTWC, a Policy on Pain Management has been established in alignment with international health care standards and assessments tools for pain (NTWC Cluster Clinical Governance Committee, 2014a). The policy
applies to all admitted patients in NTWC, except patients admitted to the antenatal and labour wards, and pediatric service for patients younger than 3 years old. Under the health care standards, the patients’ right to appropriate assessment and management of pain are promoted (NTWC Cluster Clinical Governance Committee, 2014a). Since the distraction cards method can effectively relieve procedural pain during blood draws, this innovation is in consensus with the philosophy of care of the NTWC.

3.1.4 Number of Clients that will Benefit from the Innovation

According to the statistics on Key Performance Indicators for Department of Psychiatry, the target population for this innovation had 109 admissions from January 2015 to December 2015. Out of the 109 admissions, 65 cases (around 60%) were within the target age range of 6 to 8 and 100% of these underwent blood drawing for the purpose of baseline monitoring. Also, 69.2% of these patients stayed at the hospital for over one month and required monthly blood monitoring for various reasons. These numbers do not take into account those patients who needed weekly blood monitoring due to monitoring of prescribed medications. Based on these numbers it is estimated that a minimum 110 patients will benefit from the innovation each year.

3.1.5 Time for Implementation and Evaluation
The proposed development schedule of the innovation will be divided into preparation, implementation and evaluation phases. This process will take approximately 14 months. In the preparation phase, guidelines and an implementation plan will be prepared and developed (4 weeks); the innovation may take 3 months to be approved; a further 2 weeks will be needed for purchasing the equipment; staff training will be provided over a 4-weeks period of time; the final part of the preparatory phase will consist of a pilot study and pilot evaluation for 2 months for final amendment of the innovation before implementation. The implementation phase will proceed over a 6-months period. The data will be collected before and immediately after use of the innovation. For the evaluation phase, 2 weeks will be needed for further data analysis and evaluation of the innovation.

3.2 Feasibility

In the following section, feasibility of the proposed innovation will be assessed in terms of freedom of implementation, interference of staff function, administrative support and organizational climate, consensus and resistance, support from other disciplines, skills needed, equipment and facilities, and measurement tools.

3.2.1 Freedom of Implementation
It is important for the nurse to have the autonomy to decide whether the innovation should be carried out or terminated (Polit, 2008). According to the reviewed studies, the distraction cards method is a safe, non-invasive and effective method for reducing pain and anxiety in child clients during blood taking. Also, medication is not involved and a doctors’ prescription is not needed. Nurses should use their professional judgement on carrying out the innovation based on the clients’ psychiatric diagnosis and cooperativeness.

3.2.2 Interference with Staff Function

The proposed innovation will not interfere with current staff functions. Basically, at least two staff are needed for every routine practice in blood taking procedures. Sometimes, even 4-5 staff are needed to handle clients with higher anxiety levels in usual practice. For the proposed innovation, two staff will be involved in the whole process. One is responsible for the blood taking procedure and the other one is responsible for carrying out the distraction method. Thus, no extra manpower and workload will be needed. If the children are unable to follow the distraction card instructions from staff (e.g., they cannot stop crying), time could be allowed for the child to rest before the second attempt at blood taking is made. If it was still unsuccessful, the nurses would exclude that client from the innovation and routine
practice would be resumed.

3.2.3 Administrative support and Organizational climate

Administrative support will be gained in order to implement the innovations. The proposed innovations will be fully explained to the related administrative staff including the general manager of nursing, the department operating manager, ward manager, nurse officer and all nursing staff in the ward.

To promote evidence based practice, a Journal Club has been established in CPH. This emphasizes the nurse’s role in conducting evidence based practice in the clinic. Also, academic activities will be held in child and adolescent psychiatric team in order to share knowledge in the clinical practice of different disciplines. Thus, the organizational climate will support the new innovation and suggestions to implement the innovation most effectively will be obtained through these activities.

3.2.4 Consensus and Resistance

Consensus from all staff in the target setting will be obtained before the implementation of the new innovation. Apart from the supportive organizational and team climate, all staff in the target setting are welcome to make suggestions and
improvements. The total number of staff in the target setting is only 9 and all of them are well educated with bachelor’s degrees or with a post-graduate registered certification. Thus, the staff are familiar with evidence-based practice and this is a well-accepted approach. No foreseeable resistance or uncooperativeness from the staff is expected.

3.2.5 Support from other disciplines

In addition to nursing, support from other disciplines is essential in order to implement the new innovation smoothly. The concerned parties are mainly doctors, the medical officer and the phlebotomist. The innovation will be explained to these staff groups as well.

Doctors will support the innovation for streamlining the process of blood drawing among 6-12 year old children. It used to be necessary to wait for blood monitoring results to prescribe medication, while small children are usually not cooperative in blood taking. The innovation aims at reducing the pain and anxiety during blood taking among 6-12 year old children. Nevertheless, time can be saved for obtaining baseline blood investigation.
There will be no change of the nature or procedure in the daily work of the phlebotomist, but a nurse will be assigned to conduct the distraction method to divert clients’ attention. As a result, for the innovation will make blood collection procedures easier to conduct.

3.2.6 Skills Needed

The innovation procedure is simple. No special skills or techniques are needed, except for distribution of the distraction cards to the clients before blood taking, and following the cue card to ask the client questions about the cards. Therefore, no complicated and time-consuming training is needed. The details of the innovation will be taught and demonstrated during monthly ward meetings. Nursing staff do not need to be released from other practice activities to learn about and implement the innovation.

3.2.7 Equipment and facilities

The equipment needs for implementation of the innovation include distraction cards, the equipment and room for blood taking, and measuring tools. The equipment and room for blood taking are available in the target setting. No other equipment needs to be purchased for the innovation.
3.2.8 Measurement Tools

Measuring tools will be applied just before and immediately after blood taking. WB-FACES will be used for pain level assessment and the Children Fear Scale (CFS) will be used for anxiety level assessment. In NTWC, WB-FACES is available for use of pain assessment (NTWC Cluster Clinical Governance Committee, 2014b). For anxiety level assessment, there are no formal measuring tools in NTWC. Therefore, it will be necessary to prepare the CFS.

3.3 Cost-Benefit Ratio

In order to implement the new innovation smoothly and successfully, cost and benefit analysis has been performed as described in the sections below with Table for the calculation.

3.3.1 Potential Risks of the Innovation

The use of the distraction card method instead of holding the target clients tightly or even restraining them during the blood taking process, will reduce the risk of blood drawing. Patients in the psychology ward may struggle and increase the danger of needle stick injuries. However, no such incidence rates of this type of risk were
mentioned in the reviewed studies. Thus, the risk involved in introduction of the innovation is very low.

3.3.2 Potential Benefits of the Innovation

There are potential benefits of the innovation not only from the patient point of view, but also from the nurse’s point of view. Firstly, according to the reviewed studies, the innovation can reduce the pain and anxiety of the target population during the blood taking process. Secondly, the innovation will eliminate the sense of fear which occurs when restraint is used during the blood taking process. Thirdly, early treatment can be promoted through facilitating baseline blood investigations, or drug levels could be easily obtained without struggling with clients. Fourthly, the better pain control and the less struggling that occurs during blood taking results in more rapid analysis of blood and better treatment in which may ultimately reduce the length of hospitalization time. Fifthly, the higher autonomy nurses get, the more job satisfaction they will achieve.

3.3.3 Risks of Maintaining Current Practices

If the current practice is maintained, target clients will continue to suffer from pain and anxiety during blood draws. Also, diagnosis and treatment may be delayed. If
children are not co-operative and keep on refusing to help, extra staff may be called in to hold the children or restraint may be needed. If restraint is needed for blood taking procedures, it is difficult to achieve a good rapport between clients and their nurses.

3.3.4 Material Costs

The main source of material costs associated with implementing the innovation will be mainly the distraction cards, blood taking materials and the evaluation tools. There will be no special setup costs for the innovation. Therefore, the costs will be calculated on one-year basis and a total HK $1523.6 will be needed. These costs are tabulated in Table 1.

3.3.5 Nonmaterial Costs

Nonmaterial costs include the training costs during the preparation phase, and staff and venue costs for carrying out the innovation during the implementation phase. During the preparation phase, an innovation team will be formed by an Advance Practice Nurse (Psychiatric) (APNP) and a Registered Nurse (Psychiatric) (RNP) for developing the guidelines and implementation plan. Other staff in target setting will all attend a training session. Moreover, all training sessions and meetings will be held in the hospital compound. No extra costs will be included for this. The total non-
material costs are HK $4905.8 and are shown in Table 2.

3.3.6 Estimated Cost of the Innovation

The estimated cost of the innovation is the sum of material costs and the nonmaterial costs which is a total of HK $6429.4. However, there are some hidden costs (development of blood drawing skills, the training venue and software for data analysis) as shown in Table 3.

3.3.7 Cost-benefit Ratio of the Implementation of the Innovation

As stated previously, the earlier blood monitoring results are obtained, the earlier diagnosis and treatment can be prescribed thus reducing the length of patient stay. The cost staying for one day in a psychiatric ward is presently HK $1940 (Hospital Authority, 2016). Based on this assumption, if patients can be discharged one day earlier they can save HK $1940, a net gain of HK $1881.6 per person. This benefit of the proposed innovation outweighs the cost of the proposed innovation (Table 4). Thus, the innovation is recommended.

3.4 Evidence-Based Practice Guidelines

The development of practice guidelines is one of the most important parts of the
translational process, which will be done according to the best evidence available (Polit & Beck, 2008). The Scottish Intercollegiate Guideline Network (SIGN) 50: A Guideline Developer's Handbook (SIGN, 2011), will be used to grade the levels of evidence and strength of recommendations in the guidelines. The detailed guidelines were prepared based on the literature review and critical appraisal in Chapter 1 and 2, and are shown in Appendix 4.
CHAPTER 4: IMPLEMENTATION PLAN

The cost-benefit analysis in Chapter 3 showed that the innovation is transferable, feasible and economically favorable. Also, evidence-based practice guidelines were developed. In this chapter, an implementation plan will be described that will be divided into a communication plan, a pilot study plan, an evaluation plan which provides the basis for implementation of innovation.

4.1 Communication Plan

Throughout the communication plan, stakeholders are the key people to be involved in the innovation. Thus, stakeholders will be identified first and the communication process will be established according to different stakeholders.

4.1.1 Stakeholders

People who may be affected by the innovation can be regarded as stakeholders (Burns and Grove, 2005). All stakeholders are important for the effective implementation of the innovation, and feedback and information will be collected from them for refining the guidelines. Stakeholders identified include the Chief of Service (COS), Department Operations Manager (DOM), Ward Manager (WM), Medical Officer (MO), Nursing Officer (NO), Advanced Practice Nurse (APN), Nursing staff
and clients.

4.1.1.1 Concerns of Stakeholders

Among the stakeholders mentioned, the COS and the DOM are very important. The COS is the policy and decision maker in the service, and approves budgets. The DOM provides administrative support and can relocate resources for the innovation. Thus, the transferability, feasibility and the cost-benefit ratio will be in their key interests as they are responsible for the operation, development and the sustainability of the service in the target settings.

On a practical level, the WM is the person who can facilitate the logistical arrangements in the ward. The WM is responsible for maintaining sufficient manpower to the service and the management of the ward. Therefore key concerns of the WM will be ensuring sufficient manpower for the innovation and the implementation of the innovation in the ward. Thus, the WM can arrange nursing manpower for the implementation of the innovation.

MOs are informed to know what nursing procedure is being done on their clients. Frontline staff like NO/APNs and nursing staff are also essential stakeholders.
NO/APNs are the key staff for the identification of potential problems related to the innovation and also provide supervision to the innovation. All nursing staff in ward are conductors of the innovation who are responsible for giving feedback on the innovation. The main concern of frontline staff will be the identification of potential problems during application of the innovation and how to perform the innovation.

Clients are the service receivers. As the target participant is only 6-12 years-old, most concerns may come from their parents and they may focus on the potential risks involved in the innovation compared to current practice.

4.1.2 Communication Process

The communication process relates to how to explain and get support from different stakeholders. The first person to contact will be decided and a communication channel will be set up. Also, the focus of the discussions will be identified according to stakeholder concerns.

4.1.2.1 First contact person

The WM will be the first person to be contacted as the WM is the direct supervisor of the ward. All details about the innovations will be presented to the WM. The
concepts of the innovation with the benefits highlighted will be clearly explained to WM by the proposer of the innovation. Without the support of the WM, the concept of the innovation cannot be further delivered to the senior hierarchy in the service.

4.1.2.2 Establishment of the Innovation Team

An innovation team will be set up as mentioned in Chapter 3. An APN and a RN will be responsible for the presentation of the innovation to different stakeholders in the hospital hierarchy. The need for changes on current practice will be emphasized. The foreseeable obstacles and related solutions should be figured out by this team.

4.1.2.3 Communication with Senior Staff

Once the innovation has the support of the WM, the innovation concept will firstly be presented by the WM to the DOM and the COS. After initial permission has been obtained, a further presentation will be arranged to explain the innovation focused on the supporting evidence and potential benefits to the DOM and the COS by the innovation team during a management meeting. Comments and concerns will be welcomed and afterwards pilot tests will be done.

4.1.2.4 The Ongoing Process
This is the process that provides a bridge from initiation of the innovation to sustained change. The ongoing process be divided into three stages: initiation, guiding, and sustaining.

Initiation

The proposer will share their experience of blood collection in child and adolescent psychiatric patients with the APN/NO. The concept of using the distraction method during blood taking will be discussed. The effectiveness and benefits to our settings will be considered. Also, potential problems related to current practice and the potential risk of the innovation will be examined. An innovation team of comprised of an APN/NO and a RN will be set up.

The key role of the innovation team will be to promote the innovation by presenting the proposed innovation to different stakeholders, as well as developing evidence-based guidelines based on the reviewed studies and feedback from stakeholders. As mentioned previously, the innovation team is responsible for presenting the innovation to the DOM and the COS during management meetings. After the innovation is preliminarily accepted by the DOM and the COS, a formal proposal would be made by the innovation team. The proposal would then be sent for
formal approval by the COS, the DOM and the ethics approval board (it may take six weeks to obtain the approval).

Guiding phase

Before the pilot phase can be started a guiding phase will be performed to obtain support from different parties.

Support from Nursing staff

To obtain support from the nursing staff the innovation team will distribute the information on how to use the distraction card method during blood taking. This will take 15 minutes during lunch hour ward meeting which is attended by all the nursing staff on the ward. Demonstration and role play will be used to show how to apply the innovation. To ensure the skills are learned by all the nursing staff, they will be required to perform a return demonstration. The evidence-based guidelines will be printed out and kept in the nursing station for reference. A suggestion box will be setup for collecting comments, concerns and identifying problems regarding the new innovation.

Support from clients
Before the innovation can be implemented, the procedure will be explained to clients. Feedback will be collected from the client after the procedure. Also, measuring tools for assessment of pain and anxiety levels will be applied before and immediately after the innovation.

Sustaining phase

Finally, to maintain the innovation over an extended period of time, the so-called sustaining phase will be applied. In order to sustain the innovation, the compliance by nursing staff should be continuous. However, opinions and suggestions by frontline staff are always welcome so as to make improvement to the guidelines and sustain the innovation

4.2 Pilot Study Plan

A pilot study will be used to test the feasibility of the innovation. It is an important component of the innovation before large scale implementation in order for the workflow of the guideline to be properly tested. Staff opinions will be valuable at this moment and the proposed guidelines will be revised if needed. The plan to explore the feasibility of implementation will be discussed.
4.2.1 Plan for exploring the feasibility

4.2.1.1 Setting

The setting is the child and adolescent psychiatric ward located in NTWC.

4.2.1.2 Study design and sampling

The pilot test will use a quasi-experimental design. Pain and anxiety levels will be measured. Convenience sampling will be used.

4.2.1.3 Sample Size

For the pilot study, 20 clients will be recruited.

4.2.1.4 Subjects

Child and adolescent psychiatric patients aged from 6 to 12 who require blood taking. The pilot test will also exclude clients who are diagnosed with learning disabilities (used to be called mental retardation); are not willing to cooperate; or have verbal difficulties, hearing or visual impairments.

4.2.1.5 Collection of data

Collection of data will be performed just before and immediately after the
innovation. WB-FACES will be used for pain level assessment (NTWC Cluster Clinical Governance Committee, 2014) and the Children Fear Scale (CFS) will be used for assessment of anxiety levels.

4.2.1.6 Assessment of feasibility

During the pilot study, the availability of the equipment (i.e. distraction cards) will be predicted. Also, the guidelines will be placed in nursing station.

4.2.1.7 Assess for acceptability and nurse compliance

Frontline nurses will be invited to complete a self-reported survey which will be collected after the pilot phase of the innovation in order to assess its acceptability, competence, the level of workload, and express other comments regarding the distraction cards method.

4.2.1.8 Refining

At the end of the pilot study, data collection from clients and self-reported surveys from nurses will be gathered. The innovation team will review these data and feedback. Potential problems, obstacles to the workflow and any other suggestions will be discussed. The guidelines will be revised within two weeks after data collection.
The revised guidelines will be sent for approval by the hospital ethics committee.

4.2.2 Timelines for the Pilot Study

It is estimated around 10 clients will be needed for blood drawing each month and that 20 clients will be needed for the pilot study. Thus, two months will be needed for recruiting clients for the pilot study. Since data collecting will be performed during every blood taking procedure with the innovation, no extra time is needed to add to the timeline. Two weeks will be needed for guideline revision after data collection. Therefore, finally 2.5 months will be needed to complete the pilot study and analyze the data.

4.3 Evaluation Plan

The evaluation Plan aims to review the effectiveness of the innovation by outcome measurements.

4.3.1 Outcome measurements

In the proposed innovation, the primary patient outcome will be the pain score. Nurses will measure the pain level by using the WB-FACES which is one of the pain level assessment methods used in NTWC (NTWC Cluster Clinical Governance
Committee, 2014). Also, WB-FACES was validated for use in children and provided high agreement with a visual analog scale (Anthony & Schanberg, 2007; Garra et al., 2010).

The secondary patient outcome will be their anxiety level as measured by the Children Fear Scale (CFS). This has been validated for use in children (McMurtry et al., 2011). Both the assessments will be carried out immediately before and after the innovation.

The healthcare provider outcomes will be staff satisfaction by the nursing staff. This will be assessed using a self-reported survey which contains 5-point Likert scale from strongly disagree (1) to strongly agree (5). The mean score will be calculated with a higher score representing greater nurse satisfaction about the innovation.

The system outcomes will be the cost of the innovation and the actual utilization rate of the innovation. The cost will be calculated by the ward steward. All the material costs and compensation hour records for staff costs will be included. The number of clients who used the innovation will be counted and presented in monthly statistics by the ward steward. Finally, demographic data will be collected for statistical
4.3.2 Timelines for the Evaluation Plan

The primary patient outcome and the secondary patient outcome will be measured just before and immediately after each innovation. The healthcare provider outcome will be obtained in the middle and at the end of the implementation phase. The system outcome will be counted at the end of the implementation phase. Also, the demographic data will be collected before every application of the innovation.

4.3.3 Sample size

In the statistical analysis, a two tailed t-test will be used to assess the reduction of pain levels in child and adolescent psychiatric inpatients during blood taking. The sample size of the patient group will be calculated based on the method of Russ Lenth (2011). The effective sample size is 84 by using 5% margin of error and 80% power. According to the nature of the innovation, there will be no dropout rate. Usually, there are 10 children needed for routine blood monitoring each month. Thus, there will be approximately 10 patients each month that will benefit from the innovation. Therefore, if the effective sample size is 84, the intervention period will continue for about 8.5 months.
4.3.4 Data analysis

The objective of the innovation is to reduce the pain level and anxiety level of the clients. Data will be entered into a computer database and analyzed by IBM Statistical Package for Social Science (SPSS) software (version 22). A two tailed t-test will be used to evaluate both pain score and anxiety levels are reduced after applying the innovation.

4.3.5 Effectiveness of the innovation

*Pain level*

The pain level will be measured by the Numeric Rating Scale. The baseline pain level before and after application of the innovation will be measured. The innovation will be regarded as effective if 80% of the clients report less pain after use of distraction cards method during blood taking.

*Anxiety level*

The anxiety level will be also measured by the Numeric Rating Scale. The baseline of anxiety before and after application innovation will be measured. Again, the innovation will be regarded as effective if 80% of the clients report less anxiety after
using the distraction cards method.

**Staff satisfaction**

To determine the level of staff satisfaction, the result in week 17 (middle of the implementation phase) and week 34 (end of the implementation phase) will be estimated with a 95% confidence interval.

Costs will be determined by adding all costs including the setup costs, material costs and personnel costs. The estimate of the utilization rate will also be determined by using a 95% confidence interval.

### 4.4 BASIS FOR IMPLEMENTATION

The basis for implementation is to evaluate whether the innovation will continue to be adopted or not. The innovation team will hold the evaluation meeting with the COS and the DOM together with the WM after all data has been collected and analysis completed. The participants of the meeting will discuss the results of the data analysis. Reduction of one score of pain level in the WB-FACES pain assessment tool compared to the current practice will be regarded as the minimum acceptable reduction in pain and would be considered as a significant difference. Similarly, a one point reduction
in anxiety level would be considered significant.
CHAPTER 5: CONCLUSION

Pain gives an unpleasant experience to our clients. The innovation brings benefit to both patients and the healthcare provider by reducing the pain and anxiety during blood taking procedure. When clients are more satisfied with their care, there will be less complaints. In addition, with the increased quality of nursing care, the reputation of the hospital may also increase. The effectiveness of the innovation outcome can be evaluated through the above measurements. Though the evaluation plan described it can be determined whether the distraction cards method is effective in reducing pain and anxiety during blood taking procedure in child and adolescent psychiatric inpatients.
Table 1 Material Cost of implementation (per year)

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distraction cards (4” X 3”)</td>
<td>HK $863.6</td>
</tr>
<tr>
<td>- 5 pack with 25 different cards (HK $583.7)</td>
<td></td>
</tr>
<tr>
<td>- delivery (shipping) fee (HK $280.5)</td>
<td></td>
</tr>
<tr>
<td>Blood taking material</td>
<td>HK $440</td>
</tr>
<tr>
<td>- vacutainer, 21G needle, gauze, alcohol prep and</td>
<td></td>
</tr>
<tr>
<td>adhesive plaster (HK $4 X 110 headcounts)</td>
<td></td>
</tr>
<tr>
<td>Evaluation tool</td>
<td>HK $220</td>
</tr>
<tr>
<td>- photocopying fee (HK $0.5 per sheet)</td>
<td></td>
</tr>
<tr>
<td>- pre- and post- measurement for both WB-FACES and</td>
<td></td>
</tr>
<tr>
<td>CFS</td>
<td></td>
</tr>
<tr>
<td>- 110 (headcounts) X HK $0.5 (per sheet) X 2 (pre- and</td>
<td></td>
</tr>
<tr>
<td>post- WB-FACES measurement) X 2 (pre- and post-</td>
<td></td>
</tr>
<tr>
<td>CFS measurement)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>HK $1523.6</td>
</tr>
</tbody>
</table>

Remarks: WB-FACES = Wong Baker FACES; CFS = Children Fear Scale
<table>
<thead>
<tr>
<th>Item</th>
<th>Monthly Salary</th>
<th>Hours</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovations team</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>APNP</td>
<td>HK $ 47235</td>
<td>2hrs X 5 = 10hrs #</td>
<td>HK $2684</td>
</tr>
<tr>
<td>(Hourly Pay: HK $ 268.4)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RNP (5 years experienced)</td>
<td>HK $ 34180</td>
<td>2hrs X 5 = 10hrs #</td>
<td>HK $1942</td>
</tr>
<tr>
<td>(Hourly Pay: HK $ 194.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff training *</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RNP X 5 (10 years experienced)</td>
<td>HK $ 45130</td>
<td>0.5 hrs</td>
<td>HK $128.2</td>
</tr>
<tr>
<td>(Hourly Pay: HK $ 256.4)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RNP X 1 (5 years experienced)</td>
<td>HK $ 34180</td>
<td>0.5 hrs</td>
<td>HK $ 97.1</td>
</tr>
<tr>
<td>(Hourly Pay: HK $ 194.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ENP X 1 (new graduated)</td>
<td>HK $ 19160</td>
<td>0.5 hrs</td>
<td>HK $ 54.5</td>
</tr>
<tr>
<td>(Hourly Pay: HK $ 108.9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>HK $4905.8</td>
</tr>
</tbody>
</table>

Remarks:

# 2 hours meeting for 5 times

*Other 7 Staff will attend the 0.5 hours training (10 years experienced RNP x 5; 5 years experienced RNP x 1; new graduated ENP X 1)
Table 3 Estimated cost of the innovation

<table>
<thead>
<tr>
<th>Category</th>
<th>Estimated Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Cost</td>
<td>HK $1523.6</td>
</tr>
<tr>
<td>Nonmaterial Cost</td>
<td>HK $4905.8</td>
</tr>
<tr>
<td>Hidden cost</td>
<td>Uncountable cost.</td>
</tr>
<tr>
<td>- blood taking skills</td>
<td></td>
</tr>
<tr>
<td>- venue for training</td>
<td></td>
</tr>
<tr>
<td>- software for data analysis</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>HK $6429.4</td>
</tr>
</tbody>
</table>
Table 4 Cost-benefits Ratio for Implementation of Distraction Cards

<table>
<thead>
<tr>
<th>Estimated Expenses</th>
<th>Potential Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Cost/ per patient)</td>
<td>(Benefit/ per patient)</td>
</tr>
<tr>
<td>Material Cost</td>
<td>Decreased hospital charge and doctor’s fee = HK$ 1940</td>
</tr>
<tr>
<td>= HK $1523.6/ 110 headcount</td>
<td></td>
</tr>
<tr>
<td>= HK $13.9</td>
<td></td>
</tr>
<tr>
<td>Non-material Cost</td>
<td></td>
</tr>
<tr>
<td>= HK $4905.8/110 headcount</td>
<td></td>
</tr>
<tr>
<td>= HK $ 44.6</td>
<td></td>
</tr>
<tr>
<td>Total = HK $58.4</td>
<td>Total = HK$ 1940</td>
</tr>
</tbody>
</table>

Net gain = Total potential benefits - Total estimated expenses

= HK $ 1940 - $58.4

= HK $ 1881.6
Appendix 1 - PRISMA 2009 Flow Diagram

- Records identified through PubMed database searching (n = 159)
- Records identified through Cochrane Library database searching (n = 11)
- Records identified through PsycINFO database searching (n = 6)
- Additional records identified through reference lists of eligible studies (n = 1)

Records after duplicates removed (n = 165)

Records screened (n = 165)

Records excluded (n = 111)

Full-text articles assessed for eligibility (n = 54)

Studies included in qualitative synthesis (n = 14)

Full-text articles excluded, With Pharmacological approaches (n = 30), extra expensive equipment (n = 3), focus on parental reassurance (n = 2), hypnosis skills (n = 1), not related to routine blood taking procedure (n = 4).
### Appendix 2 Table of Evidence

<table>
<thead>
<tr>
<th>Citation / Design (Study quality)</th>
<th>Sample characteristics</th>
<th>Intervention</th>
<th>Control</th>
<th>Outcomes (Assessment time)</th>
<th>Effect size (Intervention - Control)</th>
</tr>
</thead>
</table>
| Canbulat, Inal, & Sönmezer (2014) / RCT(++) | mean age = 8.8 ± 1.5 years (range, 7–11 years)  
female = 95, 50.5%  
& male = 93, 49.5% | distraction cards (n=63)  
- questions about the cards was asked  
- before phebotomy until the end of the procedure | No intervention (n=63) | 1. Pain  
- WB-FACES (0-10)  
- by self-,parent-, observer-reported  
2. Anxiety  
- CFS (0-4)  
- by parent-, observer-reported | 1. self-reported: $p = .002$, $d = 0.65$  
parent- reported: $p = <.001$, $d = 1.26$  
observer-reported: $p = <.001$, $d = 1.76$  
2. parent- reported: $p = <.001$, $d = 1.05$  
observer-reported: $p = <.001$, $d = 1.50$ |
| Sahiner & Bal (2015)/ RCT (+) | mean age: 9.1 ± 1.6 years (range: 6–12 years)  
female = 57 (47.5%)  
and male = 63 (52.5%) | distraction cards (n=30)  
- before the phlebotomy and continued until the procedure completed  
- cards were given to children | No intervention(n=30) | 1. Pain  
- WB-FACES (0-10)  
- by self-,parent-, observer-reported  
2. Anxiety  
- CFS (0-4) | 1 self-reported: $p=0.04$, $d = 0.68$  
parent- reported: $d = 0.56$  
observer-reported: $d = 0.61$  
2. parent- reported: $d = 0.36$  
observer-reported: $p= 0.032$, $d = 0.30$ |
<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Distraction</th>
<th>No intervention</th>
<th>1. Pain</th>
<th>2. Anxiety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inal &amp; Kelleci (2012)/ RCT (++)</td>
<td>Mean age: 9.36 ± 1.96 (6–12 yrs old) female = 61 (49.6%) and male = 62 (50.4%)</td>
<td>distraction cards (n=61) - questions about the cards were asked</td>
<td>No intervention(n=62)</td>
<td>1. Pain - Faces Pain Scale-Revised (0-10) - by self-, parent-, observer-reported</td>
<td>2. Anxiety - Children's Anxiety and Pain Scales (0-5) - by parent-, observer-reported</td>
</tr>
<tr>
<td>Alhani, Shad, Anoosheh &amp; Hajizadeh (2010)/ quasi-experimental study (+)</td>
<td>Mean age (Case group): 13.86 ± 3.19; Mean age (control group): 14.81 ± 3.51 [10-21 years old] female = 17 (40.5%) and male = 25 (59.5%)</td>
<td>Distraction pictures (n=21) - after venipuncture patient had to tell the differences between the pictures</td>
<td>No intervention(n=21)</td>
<td>1. Pain - WB-FACES (0-10) -by self-report - evaluate after 3 pretest session and 9 posttest session with intervention</td>
<td>1. intervention group: p =0.03, d =0.29 Between intervention group and control group: p = .007, effect size = 0.23</td>
</tr>
</tbody>
</table>

RCT= Randomized controlled trial; SD = standard deviation; WB-FACES =Wong Baker FACES; CFS= Children Fear Scale; sig. diff.= significant difference; NS = no significantly difference, d= effect size
Appendix 3 Methodology Quality Appraisal

Study identification  (Include author, title, year of publication, journal title, pages)

<table>
<thead>
<tr>
<th>SECTION 1: INTERNAL VALIDITY</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>In a well conducted RCT study…</td>
<td></td>
</tr>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question. <em>The aim of study was clearly stated.</em></td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised. <em>It was randomized on the basis of a computer generated table of random numbers into three equal groups.</em></td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used. <em>Not mentioned</em></td>
<td>Yes ☐ No ☑ Can’t say ☐</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
<td>Yes ☐ No ☑ Can’t say ☐</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial. <em>No significant differences between the intervention groups and control groups</em></td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way. <em>Wong Baker FACES (WB-FACES) Pain Rating Scale Children Fear Scale (CFS)</em></td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Kaleidoskop group 0% Distraction Cards group 0% Control group 0%</td>
</tr>
<tr>
<td>1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). <em>100% of the participants had completed the study.</em></td>
<td>Yes ☑ No ☐ Can’t say ☐ Does not apply ☐</td>
</tr>
<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites. <em>Study was conducted in a phlebotomy station of a Children hospital.</em></td>
<td>Yes ☐ No ☑ Can’t say ☐ Does not apply ☑</td>
</tr>
</tbody>
</table>
| 2.1 | How well was the study done to minimise bias?  
*Code as follows* | High quality (++)
Acceptable (+)
Unacceptable – reject 0 |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td><em>The sample size is large, but blinding is not mentioned in the article. In fact, blinding of observer and parents can be applied.</em></td>
</tr>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes</td>
</tr>
<tr>
<td>2.4</td>
<td><strong>Notes.</strong> Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.</td>
<td><em>Distraction cards rather than kaleidoscope and no intervention were found to be the most effective method for pain and anxiety relief for children during phlebotomy.</em></td>
</tr>
</tbody>
</table>
### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Yes ☑  No ☐</td>
</tr>
<tr>
<td>The aim of study was clearly stated.</td>
<td>Can’t say ☐</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td>Yes ☑  No ☐</td>
</tr>
<tr>
<td>It was randomized on the basis of a computer generated table of random numbers into four equal groups.</td>
<td>Can’t say ☐</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Yes ☐  No ☑</td>
</tr>
<tr>
<td>Not mentioned</td>
<td>Can’t say ☐</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept ‘blind’ about treatment allocation. not mentioned</td>
<td>Yes ☐  No ☑</td>
</tr>
<tr>
<td></td>
<td>Can’t say ☐</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Yes ☑  No ☐</td>
</tr>
<tr>
<td>No significant differences between the intervention groups and control groups</td>
<td>Can’t say ☐</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes ☑  No ☐</td>
</tr>
<tr>
<td></td>
<td>Can’t say ☐</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes ☑  No ☐</td>
</tr>
<tr>
<td>Wong Baker FACES, Children Fear Scale</td>
<td>Can’t say ☐</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Distraction Cards: 0% Music: 0% Balloon inflation: 0% Control: 0%</td>
</tr>
<tr>
<td>1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). 100% of the participants had completed the study.</td>
<td>Yes ☑  No ☐</td>
</tr>
<tr>
<td></td>
<td>Can’t say ☐</td>
</tr>
<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>Yes ☐  No ☑</td>
</tr>
<tr>
<td>Study was conducted in a phlebotomy unit of a Children hospital.</td>
<td>Can’t say ☐</td>
</tr>
</tbody>
</table>

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

65
### 2.1 How well was the study done to minimise bias?

*Code as follows*

- High quality (++)
- Acceptable (+)
- Unacceptable – reject

### 2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?

The sample size is acceptable, but no concealment and blinding.

### 2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?

YES

### 2.4 Notes

Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

*The distraction card group had significantly lower pain levels than the control group. All the forms of distraction significantly reduced pain and anxiety perception.*
**Study identification**  

Include author, title, year of publication, journal title, pages


### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study…**

<table>
<thead>
<tr>
<th></th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question. <em>The aim of study was clearly stated.</em></td>
</tr>
<tr>
<td></td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
</tbody>
</table>
| 1.2 | The assignment of subjects to treatment groups is randomised.  
*It was randomized on the basis of a computer generated table of random numbers into two equal groups.*  |
|   | Yes ☑ No ☐ Can’t say ☐ |
| 1.3 | An adequate concealment method is used.  
*Not mentioned*  |
|   | Yes ☐ No ☑ Can’t say ☐ |
| 1.4 | Subjects and investigators are kept ‘blind’ about treatment allocation.  |
|   | Yes ☑ No ☐ Can’t say ☐ |
| 1.5 | The treatment and control groups are similar at the start of the trial.  
*No significant differences between the intervention groups and control groups*  |
|   | Yes ☑ No ☐ Can’t say ☐ |
| 1.6 | The only difference between groups is the treatment under investigation.  |
|   | Yes ☑ No ☐ Can’t say ☐ |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way.  
*Faces Pain Scale- Revised, Children’s Anxiety and Pain Scales*  |
|   | Yes ☑ No ☐ Can’t say ☐ |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?  |
|   | Distraction cards group: 0%  
Control group: 0%  |
| 1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).  
*100% of the participants had completed the study.*  |
|   | Yes ☑ No ☐ Can’t say ☐  
Does not apply ☐ |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites.  
*Study was conducted in a Pediatric Clinic*  |
|   | Yes ☐ No ☐ Can’t say ☐  
Does not apply ☐ |

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
</table>
| 2.1 | How well was the study done to minimise bias?  
*Code as follows*  |
|   | High quality (++))☑ |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | The sample size is large, but blinding is not mentioned in the article. In fact, blinding of observer and parents can be applied. |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |
| 2.4 | **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. |
|     | *Distraction group significantly lower pain levels and lower anxiety levels than the control group during the blood draw procedure.* |
Study identification  (Include author, title, year of publication, journal title, pages)

SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question. <em>The aim of study was clearly stated.</em></td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised. <em>21 patients from one centre were assigned to the intervention group and other 21 patients from other two centre were assigned to control group.</em></td>
<td>Yes ☐ No ☑ Can’t say ☐</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>not relevant</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
<td>not relevant</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial. <em>No significant differences between the intervention groups and control groups</em></td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way. <em>Wong Baker FACES</em></td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Distraction picture: 0% Control: 0%</td>
</tr>
<tr>
<td>1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). <em>100% of the participants had completed the study.</em></td>
<td>Yes ☑ No ☐ Can’t say ☐ Does not apply ☐</td>
</tr>
<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites. <em>Study was conducted in three pediatric hemodialysis centre</em></td>
<td>Yes ☐ No ☑ Can’t say ☑ Does not apply ☐</td>
</tr>
</tbody>
</table>

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

| 2.1 How well was the study done to minimise bias? *Code as follows* | Acceptable (+) ☑ |
| 2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you | The sample size was small and no randomization was done. The effect size is relatively small. |

69
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
</tr>
<tr>
<td>2.4</td>
<td><strong>Notes.</strong> Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.</td>
</tr>
</tbody>
</table>

Distraction program can decrease the pain caused by venipuncture in adolescents undergoing hemodialysis.
Appendix 4 Details of the Guideline

Title

An evidence-based protocol for reducing pain and anxiety during blood taking of child and adolescent psychiatric inpatients

Background

- Pain is an unpleasant sensation and emotion
- Needle-related-procedures are the most prevalent and main source of pain of patient, especially in children (Cummings et al., 1996).
- Blood taking is one of the most common procedure in hospital setting.
- Painful experience may lead to anxiety of patient taking those procedures again.
- Effective pain management during blood taking procedure in child and adolescent patients is not only important for their immediate comfort, but also facilitating the whole treatment process.
- Distraction cards are effective for dealing with pain during blood taking (Canbulat et al., 2014; Inal et al., 2012).
- There is no clinical protocol for reducing pain and anxiety of children during blood taking in child and adolescent psychiatric ward.

Aim

- To guide nurses on the use of distraction method for reducing pain and anxiety during blood taking in Child and adolescent psychiatric inpatients

Objective

The objectives of this Protocol are to:
- To summarize the clinical evidence for using of distraction method for reducing pain and anxiety during blood taking
- To formulate clinical practice instructions for using of distraction method for reducing pain and anxiety during blood taking based on the best evidence available
- To streamline and standardize the using of distraction method for reducing pain and anxiety during blood taking in Child and adolescent psychiatric ward

**Target Setting**
- Child and adolescent psychiatric ward located in Tuen Mun Hospital (TMH) under the umbrella of Department of Child and Adolescent Psychiatry (CAP), Castle Peak Hospital (CPH) and the governance of New Territories West Cluster (NTWC).

**Target Population**
- Child and adolescent psychiatric patients aged from 6 to 12 needed for blood taking
- exclude clients who are diagnosed learning disability (used to be called mental retardation); or are not willing to cooperate; or had verbal difficulties, hearing or visual impairments..

**Guideline Development**
- Scottish Intercollegiate Guideline Network (SIGN) 50: A Guideline Developer's Handbook (SIGN, 2011) was used to grade the levels of evidence and strength of recommendations in the guideline.
- Research question: What is the effectiveness of distraction method for reducing...
pains and anxiety during blood taking of child and adolescent psychiatric inpatients?

- Literature Review:
  - Searching Strategies
    - Database: Pudmed, Cochrane Library and PsycINFO
    - Key words identified by using MESH was included: phlebotomy, bloodletting, pain, distraction method
    - Searching refined to 6-12 years old Child
  - Appraisal Strategies (SIGN, 2004)

<table>
<thead>
<tr>
<th>LEVELS OF EVIDENCE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Meta-analyses, systematic reviews, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>High quality systematic reviews of case control or cohort or studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal</td>
</tr>
<tr>
<td>2+</td>
<td>Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2-</td>
<td>Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Non-analytic studies, e.g. case reports, case series</td>
</tr>
</tbody>
</table>
Expert opinion

Search Results: 14

- Implementation Potential Assessment: Transferability, Feasibility and Cost-benefit Ratio

Recommendations

- SIGN 50: A Guideline Developer's Handbook (SIGN, 2011) was used to grade the strength of recommendations in the guideline.

- Grade of Recommendation

<table>
<thead>
<tr>
<th>Grade</th>
<th>Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results</td>
</tr>
<tr>
<td>B</td>
<td>A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+</td>
</tr>
<tr>
<td>C</td>
<td>A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++</td>
</tr>
<tr>
<td>D</td>
<td>Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+</td>
</tr>
<tr>
<td></td>
<td><strong>Good practice points</strong></td>
</tr>
</tbody>
</table>

- Recommendation 1.0 – Target
**Children aged 6 to 12 should be suitable for using distraction cards method.**

(Grade A Recommendation)

- There are two studies involved participants from 6-12 years old (Sahiner & Bal, 2015) (1-) (Inal & Kelleci, 2012) (1+) and one study from 7–11 years old (Canbulat, Inal, & Sönmezer, 2014) (1+). Another involved a wider range from 10-21 years old (Alhani, Shad, Anoosheh & Hajizadeh, 2010) (2++).

- **Recommendation 2.0 - Manpower**

  At least two staff should be needed: one for conducting blood taking procedure and one for conducting the distraction methods. (Grade A Recommendation)

  - 2 staff are involved during the whole process one is for blood taking and another one is for carrying out the distraction (Canbulat, Inal, & Sönmezer, 2014) (1+); (Inal & Kelleci, 2012) (1-); (Sahiner & Bal, 2015) (1+).

- **Recommendation 3.0 - Equipment**

  Vacutainer and 21 G needle are recommended for blood taking process.

  (Grade A Recommendation)

  - Vacutainer and 21 G needle were selected to use in the studies (Canbulat, Inal, & Sönmezer, 2014) (1+); (Inal & Kelleci, 2012) (1-); (Sahiner & Bal, 2015) (1+).

- **Recommendation 4.0 - Equipment**

  The distraction cards with colored picture should give to target clients.

  (Grade A Recommendation)

  - Distraction cards consisted of various pictures and shapes were used as a distraction method in the reviewed studies (Canbulat, Inal, &

- **Recommendation 5.0 - Time**

The distraction procedure should begin before the phlebotomy and continue until the procedure completed. (Grade A Recommendation)

- Distraction methods continued from the beginning of the first attempt until the end of the last attempt (Canbulat, Inal, & Sönmezer, 2014) (1+); (Inal & Kelleci, 2012) (1-); (Sahiner & Bal, 2015) (1+); (Alhani, Shad, Anoosheh & Hajizadeh, 2010) (2++)

- **Recommendation 6.0 - Process**

Targets are recommended to examine the distraction cards carefully. (Grade A Recommendation)

- In this distraction method, target was carefully examined the cards (Canbulat, Inal, & Sönmezer, 2014) (1+); (Inal & Kelleci, 2012) (1-); (Sahiner & Bal, 2015) (1+); (Alhani, Shad, Anoosheh & Hajizadeh, 2010) (2++).

- **Recommendation 7.0 - Process**

Nurse responsible for carrying out the distraction card methods should ask questions related to the picture on the cards for target to answer. (Grade A Recommendation)

- A nurse asked some questions about those cards are to be answered by the target (Canbulat, Inal, & Sönmezer, 2014) (1+); (Inal & Kelleci, 2012) (1-); (Sahiner & Bal, 2015) (1+); (Alhani, Shad, Anoosheh & Hajizadeh, 2010) (2++)

- **Recommendation 8.0 - Evaluation**
A post-intervention assessment should be done immediately after the innovation. (Grade A Recommendation).

- It can effectively reveal the effect of distraction card method on reducing pain and anxiety during blood taking (Canbulat, Inal, & Sönmez, 2014) (1+); (Inal & Kelleci, 2012) (1-); (Sahiner & Bal, 2015) (1+); (Alhani, Shad, Anoosheh & Hajizadeh, 2010) (2++).
Appendix 5 Child and Adolescent Psychiatric Inpatients Blood Taking Record

Please Tick the appropriate Box

Age: ☐6 ☐7 ☐8 ☐9 ☐10 ☐11 ☐12

Sex: ☐Male ☐Female

Size of Cannula: ☐20GA ☐22GA ☐24GA ☐Others:_________

Location of blood taking: ☐Antecubital ☐Hand ☐Others:_________

Pain Score (before): ___________ Pain Score (after): ___________

Anxiety Score (before): ___________ Anxiety Score (after): __________

Wong-Baker Face Scale

Children’s Fear Scale

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Children's Fear Scale Faces" /></td>
<td><img src="image" alt="Children's Fear Scale Faces" /></td>
<td><img src="image" alt="Children's Fear Scale Faces" /></td>
<td><img src="image" alt="Children's Fear Scale Faces" /></td>
<td><img src="image" alt="Children's Fear Scale Faces" /></td>
</tr>
</tbody>
</table>
Appendix 6

Satisfactory Survey for Healthcare Providers - The Use of Distraction Cards to Reduce Pain & Anxiety during blood taking of child and adolescent psychiatric inpatients.

Please circle your answer.

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>No Comment</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>I think this innovation can reduce Client’s pain.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2.</td>
<td>I think this innovation can reduce Client’s anxiety.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3.</td>
<td>I think this innovation do not place a burden to healthcare providers.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4.</td>
<td>I think I am competent in doing this procedure.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5.</td>
<td>I feel comfortable in doing this procedure.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>6.</td>
<td>I support this innovation.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Please return to collection box in nursing station after completion.
REFERENCE


venepuncture. *Paediatric Nursing*, 21(8), 14-19.


IASP Subcommittee on Taxonomy. (1979). Pain term; a list with definitions and notes on usage; recommended by the subcommittee on taxonomy. *Pain*, 6, 249-252.


Pediatric Infectious Disease Journal, 20, 57–62.


Raja, M., Azzoni, A., & Maisto, G. (2011). Late onset neutropenia associated with


