Abstract of thesis entitled

“An evidence-based education program to use massage therapy to reduce pain and anxiety in children with cancers undergoing chemotherapy”

Submitted by

Au Yeung, Fung Yan

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Children with cancers undergoing chemotherapy often face with various kinds of symptoms related to illness and complications; among the most common symptoms and treatments for cancer are pain and anxiety. The use of complementary and alternative medicine (CAM) in US has risen sharply in recent decades for symptom management. Massage therapy was one of the most common CAM therapies which may help children to cope with side effects associated with chemotherapy.

This systematic review aims at assess the effectiveness of massage therapy to reduce pain and anxiety in children with cancer and develop an evidence-based program to use massage therapy.
All the studies in the systematic review mentioned the limitation of study’s results due to small sample size, but still, four of the five studies concluded that massage therapy can improve children’s quality of life and can be effectively implemented for children with cancer to reduce physiological and psychological symptoms related to intensive cancer treatment. Besides, massage therapy provided a positive experience to most children and their parents in the studies.

Massage therapy can be easily implemented and practice by nurses in hospital-setting, however, it was not included as routine practice in Hong Kong. Also, little attention has been drawn on non-life-threatening consequences of pediatric oncology. In conclusion, an evidence-based education programs should develop for implementation of massage therapy for children with cancer in Hong Kong.
An evidence-based education program
to use massage therapy to reduce pain and anxiety
in children with cancers undergoing chemotherapy

by

Au Yeung, Fung Yan

B. Nurs. H.K.U.

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Declaration

I declare that this thesis 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 ………………………………………………………………………………………………

Au Yeung, Fung Yan
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Contents

Declaration.................................................................................................................. i

Acknowledgements................................................................................................. ii

Table of Contents.................................................................................................. iii

Chapter 1.1 Backgrounds........................................................................................ 1

Chapter 1.2 Affirming the Needs............................................................................ 5

Chapter 1.3 Research Question, Objectives & Significance................................. 8

Chapter 2.1 Search & Appraisal Strategies............................................................ 11

Chapter 2.2 Results.................................................................................................. 14

Chapter 2.3 Summary & Synthesis......................................................................... 20

Chapter 3.1 Target Audience & Target Setting...................................................... 28

Chapter 3.2 Implementation Potential................................................................... 30

Chapter 3.3 Developing Evidence-based Practice Guideline for the Education

  Program.................................................................................................................. 39

Chapter 4.1 Communication Plan........................................................................... 41

Chapter 4.2 Pilot Study Plan................................................................................... 46

Chapter 4.3 Evaluation Plan................................................................................... 48

Appendices.............................................................................................................. 55

References.............................................................................................................. 86
An evidence-based education program to use massage therapy to reduce pain and anxiety in children with cancers undergoing chemotherapy

1.1 Backgrounds

In 2010, it is estimated that more than 175,000 children develop cancer annually worldwide (American Cancer Society, 2011). According to The Hong Kong Cancer Registry, there was around 190-200 new cases annually among children and adolescents (0-19 years) in 2007-2011 in Hong Kong. A noteworthy fact over the past 25 years was the survival rates for childhood cancer have risen sharply. In US, the percentage of survival rate for 5 years after diagnosis was greater than 80% of children with cancer, compared with only about 62% of that in the mid-1970s (National Cancer Institute, 2005). The progress in survival rates is largely attributable to improvements in treatments; however, despite advances in early detection and effective treatment, cancer was viewed as one of the most feared diseases (Bagur, et al., 2015; Patrick, et al., 2004), not only because it was associated with death but also its effect on quality of life; the intensified treatments and the repeated pain procedure result in greater physical symptoms and emotional disturbance (Bagur, et al., 2015; Docherty, 2003; Kanitz, et al., 2013).
Children with cancer must face with various kinds of symptoms related to illness and complication related to treatment (Docherty, 2003; Williams, et al., 2006). Among the most common symptoms and treatments for cancer are pain and anxiety (Haun, et al., 2009; Reisi-Dehkordi, et al., 2014; Van-Cleve, et al., 2004). These symptoms may persist or appear, even after treatment ends (National Institute of Health, 2002; Kudubes, et al., 2014). A study found that more than 90% of children with terminal cancer experienced pain and 45% of children experienced anxiety (Goldman, et al., 2006). The International Association for the Study of Pain (IASP) defined pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. The inability to communicate verbally does not negate the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment. Pain is always subjective” (IASP, 2008, section 19). The causes of pain for children with cancer include disease progression with stage metastases; postoperative pain; repeated invasive procedures such as venipuncture, lumbar punctures and bone marrow aspirations and the side effects of chemotherapy. Pain and anxiety can greatly affect children’s quality of life, thus poor prognosis and negative impact on the lives of their families might result (Campbell-Fleming & Williams, 2008; Kudubes, et al., 2014).
In US, the use of complementary and alternative medicine (CAM) in Western medicine has risen sharply in recent decades, up to 84% of children with cancer started to use of CAM after diagnosis (Post-White, et al., 2009) for symptom management. The National Center for Complementary and Alternative Medicine (NCCAM) of the National Institutes of Health (NIH) defines CAM as “a group of diverse medical and health care systems, practices and products that are not presently considered to be part of conventional Western medicine”. CAM is used in conjunction with conventional medicine; for example, massage may be used with analgesic for pain relief (Kemper, et al., 2008).

One of the most common CAM therapies being used by children with cancer was massage (Gottschling, et al., 2014; Hughes, et al., 2008) and nearly half of the university-affiliated pain management centers in US and Canada provided massage therapy (Beider, et al., 2007). Massage therapy has been used through history for a different condition, including medical and surgical aspects (Field, 2002); Chinese pediatric massage was applied as early to Sui/Tang dynasty (581-907AD) while documents proved massage therapy for pediatric patients began in India and has been used for few centuries (Hughes, et al., 2008; Lemanek, et al., 2009). National Cancer Institute (NCI) of the National Institutes of Health (NIH) defines massage therapy is
“a treatment in which the soft tissues of the body are kneaded, rubbed, tapped and stroked; it may help people relax, relieve stress and pain, lower blood pressure and improve circulation; massage therapy is being studied in the treatment of cancer symptoms such as lack of energy, pain, swelling and depression”.
1.2 Affirming the Need

Children with cancer not only suffered from the physical symptoms of their diseases, but they must learn to face anxiety and precarious progress related to cancer and treatment, the anticipation of physical and emotional pain as well as the significant changes implied in living with cancer (Malboeuf-Hurtubise, et al., 2013). The adverse symptoms including nausea, physical pain, anxiety, depression, weight loss and hair loss were experienced throughout the treatment and recovery progress (Haun, et al., 2008).

Children with cancer are risk of significant psychological distress; the prevalence of major depressive disorder, depressive symptoms or anxiety were commonly noted among children with cancer (Fortier, et al., 2014; Kusch, et al., 2000; Moller, et al., 2014) and has been estimated to be between 20 and 32% (Kurtz & Abrams, 2011). According to the National Cancer Institute (NCI), 15% to 25% of cancer patients become depressed or psychologically distress during their illness; the length of stay, reverse isolation during the neutropenic phase and intensified treatment often make the situation worsen.

For children with cancer, pain was commonly enduring (Campbell-Fleming &
Williams, 2008). Cancer pain can greatly affect the quality of life and also their daily life, even during eating and sleeping, which may result in depression and fatigue (Campbell-Fleming & Williams, 2008) and increased pain perception might lead to higher levels of anxiety and lower self-esteem (Fortier, et al., 2014; Varni, et al., 1996). Chronic pain can reduce their tolerance of physical activity and increased risk of psychological distress; the longer the pain remains, the more negative impacts it causes on children with cancer and their families (Woodgate, et al., 2003).

In Hong Kong, the most common way to alleviate children’s anxiety was to provide reassurance and allowed parents to stay with children during intensive chemotherapy; however, the effects of these strategies were limited. Ineffective coping of anxiety might leads to parental distress, anxiety disorder and depression which can influence the children’s ability to cope with the treatment (Post-White, et al., 2009).

Pharmacologic strategies for managing cancer pain are the main stream of practice in Hong Kong, but the side effects of analgesic included fatigue and increased drowsiness which decreased the quality of life; a study showed that pain affects “the physical, psychological, social, and spiritual well-being of the patient” (Hooke, et al., 2007). Besides, children may not receive enough attention or adequate pain relief due
to limited expression or unable to express how they feel and experience (Fortier, et al., 2014; Mertens, 2011), routine massage therapy for pain relief is therefore suggested.

Several studies found that massage therapy provided symptomatic relief (Bishop, et al., 2010), positive psychological effects (Haun, et al., 2009), and decrease pain (Batalha, et al., 2013; Celebioglu, et al., 2013).

Massage therapy was not included as routine practice in Hong Kong despite its many known benefits. Also, little attention has been drawn on non-life-threatening consequences of pediatric oncology. Therefore, there was a necessity to perform a literature review which focuses on the effectiveness of massage therapy for children with cancer in reducing pain and anxiety.
1.3 Research Question, Objectives & Significance

1.3.1 Research Question

My research question is: ‘How effective is massage therapy in reducing pain and anxiety in children with cancers undergoing chemotherapy?’.

1.3.2 Objectives

The objectives of this study are:

1. To review, analyze, and synthesize research evidence on the effectiveness in reducing pain and anxiety in children with cancers undergoing chemotherapy.

2. To develop an evidence-based education program to use massage therapy to reduce pain and anxiety in children with cancers undergoing chemotherapy.

3. To develop an implementation and evaluation plan for the proposed education program.

1.3.3 Significance

Massage therapy was proved to benefit children and decrease suffering during cancer treatment in several studies. A study found that all of the children felt better after massage in terms of physical, mental, and emotion, and the effects of massage therapy lasted from several hours to a day (Post-White, et al., 2009). Several research findings
indicated that massage therapy can improve blood circulation and boost the function of immunization, resolve soft adhesions, relieve pain and anxiety associated with various diseases (Beider & Moyer, 2007; Cassileth & Vickers, 2004; Field, 1995); overall to improve the quality of life of children while undergoing treatment.

When massage therapy was used for adult during chemotherapy treatment, it has been found to reduce anxiety, nausea and stress and improve quality of sleep (Bohlmeijer, et al., 2010; Ironson, et al., 1996).

Parents have expressed that use of massage therapy can reduce the side effects from chemotherapy and radiotherapy, including pain and tiredness (Hughes, et al., 2008).

Studies reported that massage therapy for children with cancer shown significant improvements in cooperative behavior with health care provider and reduce in the level of depression and anxiety which positively influenced overall emotional well-being (Hughes, et al., 2008; Haun, 2009). A study showed that massage for cancer patients could promote positive feeling and a sense of being cared for (Ackerman, et al., 2012). Communication between parents, children and nurses can also be improved during massage.
Nurses must treat children and their parents as equal partners when providing care to them. The clinical implications of the use of massage therapy for children with cancer undergoing chemotherapy include empowering children and their parents to gain control over their disease and treatment plan (Thrane, 2013). Also, massage causes relaxation results in reducing stress and pain in patients, which enhances psychological and physiological well-being (Mazlum, et al., 2013). Massage therapy was a readily learned, cost-effective, and non-pharmacological intervention to reduce pain and anxiety in children with cancer, results in shortening hospital stay which nurses were benefit from reducing the demand of care and workload; also, massage therapy can be easily implemented and practiced by nurses in hospital-setting.
2.1 Search and Appraisal Strategies

2.1.1 Search Strategies

Three electronic databases were searched as provided by the Library of the University of Hong Kong, included the PubMed (Jan 1970 – Aug 2014), CINAHL Plus (Jan 1970 – Aug 2014) and Cochrane Library. Detail of search strategies was shown in Appendix 1.

Numerous of keywords and combinations of the keywords used were: “children”, “pediatric”, “massage”, “touch”, “chemotherapy”, “cancer” and “oncology”.

Inclusion criteria – studies were included for initial review if the following criteria were met:

- English language literature with full-text available
- Randomized controlled trial or Quasi-experimental study
- Massage therapy was used
- Patients below 18 years old and diagnosed with any types of cancer
- Gender and sample size were not limited
Exclusion criteria – studies were excluded if they met any one of the following criteria:

- Massage therapy was used in the study together with any other Complementary Alternative Medicine (CAM) methods
- Study not carried out in clinical setting

2.1.2 Data Extraction

Data was extracted in various aspects and recorded in the Table of Evidence as shown in Appendix 2.

2.1.3 Appraisal Strategies

The level of evidence and the quality of studies were determined by the methodology checklist for controlled trials Scottish Intercollegiate Guideline Network (SIGN). It consisted of two sections, which used to appraise the internal validity and assess the overall standard of the eligible studies.

Section 1 (Internal Validity) used to identified the study for which it was being considered as evidence; a series of aspects regarding the design of RCT was required to consider and to make a judgment as how well the eligible study meets the criteria.
This section consisted of ten questions and each related to an aspect of methodology that research has shown makes a significant difference to the conclusions of a study (SIGN, 2011).

Section 2 (Overall Assessment of the Study) was used to rate the methodological quality of the eligible study. Coding system was applied to indicate the level of evidence, details of coding system can be referred to Appendix 3.
2.2 Results

2.2.1 Search History

An extensive systematic search was conducted on 17\textsuperscript{th} August, 2014; three electronic databases were searched (PubMed, CINAHL Plus and Cochrane Library). The search yielded 113 articles from PubMed (Jan 1970 – Aug 2014), 3 articles from CINAHL Plus (Jan 1970 – Aug 2014) and 12 articles from Cochrane Library after limited search to “clinical trial or RCT”. Thirteen articles yielded based on initial screening of title and abstracts; four were eliminated due to duplication. After detailed literature review, five articles were selected according to defined inclusion and exclusion criteria, which included four RCT and one quasi-experimental study. The reference lists of the selected articles were screened; however, no extra eligible study was found. The search results from each electronic database were shown in Appendix 1.

2.2.2 Table of Evidence

All the relevant data of the eligible studies, including study type, country of study, evidence level, patient characteristics, intervention and control, length of follow up, outcome measures, effect size and source of funding were synthesized and summarized. Detail characteristics of the eligible studies are listed in Appendix 2.
2.2.3 Study Characteristics

Five studies were selected as mentioned above, including four RCT (Batalha, et al., 2013; Haun, et al., 2009; Mazlum, et al., 2013; Mehling, et al., 2011) and one quasi-experimental study (Celebioglu, et al., 2013).

All eligible studies were published between 2009 and 2013. Studies were carried out in different countries, including Iran (Mazlum, et al., 2013), Portugal (Batalha, et al., 2013), Turkey (Celebioglu, et al., 2013) and USA (Haun, et al., 2009; Mehling, et al., 2011).

Three studies did not mention the source of funding (Batalha, et al., 2013; Celebioglu, et al., 2013; Mazlum, et al., 2013;) and two studies (Haun, et al., 2009; Mehling, et al., 2011) were supported by the National Center for Complementary and Alternative Medicine (NCCAM) and the Community Foundation Sonoma County and Santa Rosa California respectively.

Sample size of the studies ranged from 23 to 70; the total sample size across all studies was 209. All participants were pediatric patients (aged from 6 months to 17 years old) and diagnosed with cancer. The mean age of participants were younger than
10 years old in three studies (Celebioglu, et al., 2013; Haun, et al., 2009; Mazlum, et al., 2013), while the other two studies were approximately 11 to 14 years old (Batalha, et al., 2013; Mehling, et al., 2011).

The frequency of massage session provided was varied; participants received massage session three times per week in two studies (Batalha, et al., 2013; Mehling, et al., 2011) and received daily session in one study (Haun, et al., 2009); the remaining two studies provided massage session before intrathecal / bone marrow aspiration (Celebioglu, et al., 2013) and before / after chemotherapy (Mazlum, et al., 2013) respectively.

The massage lasted for 20 to 30 minutes per session in four studies (Batalha, et al., 2013; Haun, et al., 2009; Mazlum, et al., 2013; Mehling, et al., 2011) and 10 to 15 minutes for the remaining study (Celebioglu, et al., 2013).

2.2.4 Methodological Issues

After reviewing the methodological quality of the study and coupled with the study type, level of evidence of the studies were rated; one study achieved a high level of evidence as most of the criteria of SIGN checklist were fulfilled and rated as 1++
(Mehling, et al., 2011), two studies were rated as 1+ as some of the criteria were not adequately described (Haun, et al., 2009; Mazlum, et al., 2013), and the remaining two studies were rated as 1- (Batalha, et al., 2013) and 2++ (Celebioglu, et al., 2013).

Details of the SIGN checklist can be referred to Appendix 4.

All studies address a clearly focused question in terms of PICO format; children with cancer were selected as participants by convenience sampling, participants in experimental group received massage therapy while usual care was used as the comparison (control) group.

Randomization was carried out in four randomized controlled trial; one of the study claimed the use of randomization, but the process was not specifically mentioned (Batalha, et al., 2013) while the other three studies used coin toss (Haun, et al., 2009), randomized number table (Mazlum, et al., 2013) and stratified randomization (Mehling, et al., 2011) for random allocation of participants. For the quasi-experimental study (Celebioglu, et al., 2013), no randomization was carried out, and therefore allocation bias might not adequately minimize.

Only one study reported the use of allocation concealment method by sealed opaque
envelops that contained the computer-generated intervention or usual care group assignment (Mehling, et al., 2011) and the remaining studies did not mention any concealment method (Batalha, et al., 2013; Celebioglu, et al., 2013; Haun, et al., 2009; Mazlum, et al., 2013;).

Double-blinding was not feasible due to the nature of the intervention. Among five selected studies, only one study was single-blinded which the evaluator was blinded (Batalha, et al., 2013); two studies were non-blinded (Haun, et al., 2009; Mehling, et al., 2011) and two studies did not mention the blinding process (Celebioglu, et al., 2013; Mazlum, et al., 2013).

The demographic characteristics (e.g. age, sex, ethnicity, type of cancer) of the participants in intervention group and control group were recorded in four studies (Batalha, et al., 2013; Celebioglu, et al., 2013; Mazlum, et al., 2013; Mehling, et al., 2011) and all of them showed no significant difference between two groups. Only age and gender of the participants were recorded in the remaining study (Haun, et al., 2009) and the mean age and gender distribution were similar between intervention group and control group.
There was no participant dropped out before the study was completed in four of the studies (Batalha, et al., 2013; Celebioglu, et al., 2013; Haun, et al., 2009; Mehling, et al., 2011). The dropout rate of the remaining study was 5.4% which was acceptable and not significant (Mazlum, et al., 2013).
2.3 Summary and Synthesis

2.3.1 Summary

Three studies primarily focused on the effectiveness of massage therapy to reduce adverse physical and psychological symptoms related to chemotherapy (Batalha, et al., 2013; Haun, et al., 2009; Mazlum, et al., 2013) whereas two studies explored massage therapy for pain management during invasive procedures which commonly come across during cancer treatment, such as intrathecal therapy and bone marrow aspiration (Celebioglu, et al., 2013) and hematopoietic cell transplant (Mehling, et al., 2011). All the selected studies considered \( p<0.05 \) as statistically significant differences. One of the studies (Mehling, et al., 2011) also reported the standardized effect sizes due to small sample size (\( n=23 \)), and aim at allow sample-size calculation for further studies.

Affective Dimension

- *Pain* – Three studies (Batalha, et al., 2013; Celebioglu, et al., 2013; Mehling, et al., 2011) have been included pain as outcome measure. Two of the studies (Batalha, et al., 2013; Celebioglu, et al., 2013) used Visual Analogue Scale (VAS) with ranged from 0 (no pain) to 10 (severe pain) to assess the level of pain of the intervention and control group. Batalha et al. assess the intensity of pain before
and after each massage session; the author concluded that all participants present significant lower pain after each massage session (p<0.001); this study also used Brief Pain Inventory (BPI) to evaluate the pain intensity and interference in activities on day 1 and day 6, no statistically significant differences yielded in most daily activities except lower pain interference with the ambulatory capacity between groups between day 1 and day 6 (p<0.05). The other study (Celebioglu, et al., 2013) asked participants or their mother (if participants were younger than 5 years old) to complete VAS at the beginning and at the end of each massage session, the study yielded a statistically significant effect (p<0.05) between the pretest and posttest total mean pain scores in the intervention group. The remaining study (Mehling, et al., 2011) used PedsQL Cancer Module, a 28 items modular quality of life measure, which 2 items were corresponding to pain, to assess the intensity of pain; this study yielded non-significant effect (p=0.37) in the intervention group.

- **Discomfort** – A study (Haun, et al., 2009) that assesses discomfort level yielded significant differences between groups after massage therapy. Discomfort level was measured before and after each massage session; data was collected as a verbal self-report with a scale from 0 (no discomfort) to 4 (maximal discomfort).
Result showed that the intervention group reported significantly less discomfort than that of the control group (p<0.001).

·  **Anxiety** – Three studies (Celebioglu, et al., 2013; Haun, et al., 2009; Mehling, et al., 2011) examines the effect of massage therapy on anxiety and all of them included both parents and participants to report the level of anxiety by different instruments. One of the studies (Celebioglu, et al., 2013) used Visual Analogue Scale (VAS) with ranged from 0 (no anxiety) to 10 (the most anxiety) to assess the level of anxiety. VAS was completed by participant’s mother if they were younger than 5 years old. The difference between groups was not statistically significant (p>0.05) but the difference between the pretest and posttest total mean anxiety scores was found to be statistically significant (p<0.05) in the intervention group. The other study (Haun, et al., 2009) invited participants and/or their parents to complete two questionnaires before and after massage therapy, including the State-Trait Anxiety Inventory for Children (STAIC) and the Child Health Questionnaire-Parent (CHQ-Parent); STAIC was used to assess the level of situational and characteristic anxiety (minimum score: 20 and maximum score: 60) while CHQ-Parent was used to assess the mental health before and after massage therapy. The study result yielded a statistically
significant effect on the reduction of state and trait anxiety (p<0.000) but no significant differences by using CHQ-Parent for psychological health (p=0.308). The remaining study (Mehling, et al., 2011) used the Behavioral Affective and Somatic Experiences Scale (BASES) for the assessment of children’s anxious and depressive behavior during hospitalization, author concluded that no statistically significant between group differences in intervention group and control group.

**Physiological Dimension**

- *Nausea and Vomiting* – Two studies (Mazlum, et al., 2013; Mehling, et al., 2011) examine whether massage therapy might reduce chemotherapy-induced nausea and vomiting. The first study (Mazlum, et al., 2013) used Baxter Animated Rating Face (BARF) scale for participants under 9 years old and Visual Analogue Scale (VAS) for 9 to 18 years old participants to assess the severity of nausea; for the vomiting severity, a four-item rating scale was used in which the severity of vomiting was numbered from 0 (no vomit) to 3 (severe) based on the vomiting episodes. The findings showed a significant statistical differences (p=0.027) for the severity of nausea during 48 hours post-chemotherapy while the other findings showed no significant difference. The other study (Mehling, et
al., 2011) distribute the PedsQL Cancer Module, a 28 items modular quality of life measure for children with versions for different age groups, to assess the severity of physical symptoms (nausea and vomiting); this study yielded p=0.98 which showed no significant improvement in the intervention group.

• **Muscle soreness** – A study (Haun, et al., 2009) have examined massage therapy’s potential to reduce muscle soreness. This study used Face Muscle Soreness Scale with assigned values from 1 (very sore) to 5 (no sore) to assess the level of muscle soreness before and after each session of massage therapy. A significant mean differences were found between the intervention and control group after massage therapy (p<0.001); the mean values of the muscle soreness scores was significantly increased in the intervention group (3.06→4.53) and no significant change noted in the control group (3.18→3.15).

• **Mucositis** – A study (Mehling, et al., 2011) reported that massage therapy might reduce the days of mucositis, which is a common complication of chemotherapy. Nurse’s clinic data was collected during the period of study and result showed participants in intervention group had shorter duration of mucositis (standardized effect size: +0.63; “+” effect size is advantage for intervention group).
Vital signs – One study (Haun, et al., 2009) examine the effect of massage therapy on vital signs readings. Blood pressure, pulse, and respiratory rate were recorded before and after massage therapy; the author concluded that massage therapy affected the respiratory rate of the participants (p<0.000), but no significant differences between the intervention groups and control groups in systolic blood pressure (p<0.442), diastolic blood pressure (p<0.620) and pulse rate (p<0.825).

2.3.2 Synthesis

After reviewing and summarizing the selected eligible studies, four of the selected studies concluded that massage therapy can improve children’s quality of life and can be effectively implemented for children with cancer to reduce physiological and psychological symptoms related to intensive cancer treatment (Batalha, et al., 2013; Celebioglu, et al., 2013; Haun, et al., 2009; Mazlum, et al., 2013). The remaining study (Mehling, et al., 2011) showed no statistically significant differences between groups; one of the reasons might due to target massage session (3 sessions per week) was not reached and only 1.8 massage sessions were provided per week. All the studies mentioned the limitation of study’s results due to the small sample size, but still, massage therapy provided a positive experience to most participants in the
In conclusion, massage therapy was suggested to include in the routine practice and treatment plan for children undergoing chemotherapy; an evidence-based education programs should develop for its implementation.

This education program for applying massage therapy, which focused on reduce pain and anxiety in children with cancers as provided by nurses. Nurses are in a position to provide massage therapy, guidance and support to children during planning and implementation. To support training and education of healthcare provider, booklets distribution, lectures and hand-on training will be provided accordingly. One-to-one tailor-made massage therapy was suggested due to the unique needs of children (i.e. age, diagnosis, site of intravenous access or central venous catheter).

The number of session and duration of the massage therapy might affect the response of the intervention (Mazlum, et al., 2013). By summarizing the selected studies, each massage session was suggested to last for 20 to 30 minutes before chemotherapy (Batalha, et al., 2013; Haun, et al., 2009; Mazlum, et al., 2013; Mehling, et al., 2011); for the younger participants (<10 years), each massage session can last for 10 minutes at the beginning to see the response and step up the duration according to the effects. A longer duration of massage therapy (more than 30 minutes) might not be
appropriate as children’s endurance and compliance rate was limited (Mazlum, et al., 2013).

For the outcome measures, Visual Analogue Scale (VAS) with ranged from 0 (no pain / no anxiety) to 10 (severe pain / the most anxiety) will be applied to assess the level of pain and anxiety separately. This scale showed good acceptability, validity and was suitable for pediatric population (Bailey, et al., 2012; Taddio, et al., 2009). Parents are invited to complete VAS for children younger than 10 years old.

The details of implementation potential and evidence-based guidelines will be discussed in the next chapter.
The previous chapter summarized five eligible studies and showed that the use of massage therapy provided a positive experience to children with cancer in terms of both physical and psychological perspective. However, massage therapy was not included as routine practice in pediatric units in Hong Kong.

In this chapter, the implementation potential of proposed program will be discussed based on its transferability, feasibility and cost-benefit ratio.

3.1 Target Audience and Target Setting

3.1.1 Target Audience

The target audiences are all pediatric patients between 4 to 18 years old who diagnosed with any types of cancer and undergoing treatment, which required long-term hospitalization (> 3 months). Patients under 4 years old were not included in the proposed innovation as they are less cooperated and impatient, massage therapy provided by healthcare provider might not suitable for them. Establish a positive relationship and building rapport with patient are essential before integrating physical touch into patient care. Therefore, patients who need long-term hospitalization were selected as target audience. Informed consent must be obtained from patients and their parents before the start of proposed innovation.
3.1.2 Target Setting

The proposed program will be implemented in a pediatric oncology ward of a public hospital under Hospital Authority in Kowloon Central Cluster in Hong Kong. The hospital provides pediatric service to the population of the central Kowloon region; the inpatient service of Department of Pediatrics has a capacity of 195 beds, in which the pediatric oncology ward provided 30 hospitalization beds for children with cancer under 19 years old. For manpower, there are 1 Ward Manager, 3 Advanced Practice Nurses, 14 Registered Nurses and 2 Enrolled Nurses working in the oncology area.
3.2 Implementation Potential

3.2.1 Transferability of the Findings

3.2.1.1 Similarity of Target Population and Setting

Most of the characteristics of participants in the five reviewed studies were similar to the target population of the proposed program. With regard to age and gender of the participants, both male and female were included in the five reviewed studies and age range of participants of four studies (Batalha, et al., 2013; Celebioglu, et al., 2013; Mazlum, et al., 2013; Mehling, et al., 2011) was around 4 to 18 years old which is comparable to the target population of the proposed program. In addition, the study population of the reviewed studies and that of the proposed program were all diagnosed with cancer and undergoing treatment which required long-term hospitalization. The only difference is that Chinese or Asian was not included in the reviewed studies; the reviewed studies were carried out in both developing and developed countries, including Iran (Mazlum, et al., 2013), Portugal (Batalha, et al., 2013), Turkey (Celebioglu, et al., 2013) and USA (Haun, et al., 2009; Mehling, et al., 2011), but all the results showed a positive experience to children with cancer after the use of massage therapy, therefore, we can conclude that race and ethnicity does not have significant influence to the proposed program.
The proposed program will be conducted in an inpatient setting which was highly comparable to setting of the reviewed studies. Although all the reviewed studies were carried out in Western countries and cultural difference was a considerable factor to the transferability of the findings, Hong Kong was a multicultural city with a unique combination of Traditional Chinese and British Western; therefore, cultural difference will not alter the transferability of the findings.

To conclude, the target population and setting between the reviewed studies and the proposed program shared similar characteristics and background; which enhance the transferability of the findings.

3.2.1.2 Philosophy of Care

The core values of the Kowloon Central Cluster is to provide quality hospital care to patients under the spirit of patient-centered care; professional training and continuous improvement were particularly important to maintain the highest standard of professional competency. All the activities related to improvement of health and well-being of the community were fully support and encouraged. The proposed evidence-based education program which aims to reduce pain and anxiety in children with cancers undergoing chemotherapy; it was closely meet the core values of
patient-centered care. Also, massage therapy was not included as routine practice in pediatric units in Hong Kong as mentioned before; this innovative education program has adopted the core values of the target hospital – professional training and continuous improvement as a guiding principle to achieve success.

### 3.2.1.3 Number of Patients could Benefit from the Innovation

There is a sufficiently large number of patients in the pediatric oncology ward could benefit from the innovation. According to the statistics of the target setting, there were more than 40 patients aged from 4 to 18 years old who diagnosed with cancer and undergoing chemotherapy in 2012-2013.

### 3.2.1.4 Timeframe of the Innovation

The proposed program will last for one year which included three phases – preparation, implementation and evaluation.

The preparation phase will last for two months which include forming of working committees, establish the innovation scope, staff training and acquisition, promotion, cost budgeting, and secure the necessary resources. The working committees will include one Advanced Practice Nurse and two Registered Nurses; they will receive
train-the-trainer course which include four training sessions with two hours per session to standardize the massage techniques. All ranks of nurses are expected to receive training from the trainer within two months.

Implementation of massage therapy to the target audience will carry out in the following nine months, the working committees will monitor the progress and adjust as necessary. Evaluation will be done in the last month of program which aims to improve future planning by learning from experience.

3.2.2 Feasibility

3.2.2.1 Organizational and Administrative Support

The proposed program will be carried out in public hospital of Hospital Authority. “Professional Service, People-centered Care” are the core values of Hospital Authority, nurses are now expected to act as advocate, educator and researcher rather than a “practitioner” only, continuous nursing education and evidence-based practice are highly promoted to excel the quality of care. This evidence-based program which aims at improves patient care outcomes could possibly be support by organization. Evidence-based innovation and patient-centered care were highly recommended by administrators (Chief of Service and Department Operation Manager), it was
foreseeable that the proposed program could be support and encourage by the administrators of Department of Pediatrics.

### 3.2.2.2 Staffing

The concept of massage therapy was relatively new in Hong Kong, especially in the field of pediatric area. There is no doubt that barriers must be existed before implementing a new program and at the initial phase of implementation. Some of the nursing colleagues might show limited interest or does not support the proposed innovation, they might worry about the new innovation might lead to increase workload; also, the effectiveness of the proposed program might cause stress to nurses due to its uncertainty. It is normal that different people will have different and often conflicting desires due to different roles. In order to gain the cooperation of nursing colleagues, the aim and benefits of using massage therapy should be stressed; the details of potential benefit to nurses will be discussed later.

### 3.2.2.3 Potential Friction

As mentioned before, the use of massage therapy for children was not popular in Hong Kong, the challenges of few trial participants in Hong Kong must be explained to patients and their parents before the use of massage therapy. The effectiveness of
the innovation at the beginning phase might frustrate patients, they might expect more than they get, nurse plays a vital role to explain the potential benefits and risks to patients before the use of massage therapy to prevent over-estimation of the effects which results in causing emotional distress.

3.2.2.4 Equipment and Facilities

The ward environment in the target setting is comfortable and relax in which children can receive massage therapy in a safe and friendly atmosphere. The available equipment and facilities in ward are suitable for the innovation, no additional cost was required.

3.2.2.5 Evaluation

The level of pain and anxiety were assessed before and after each session of massage therapy to evaluate the effectiveness of massage therapy. Visual Analog Scale (VAS) will be used to assess the level of pain and State-Trait Anxiety Inventory for Children (STAIC) was chosen to measure the level of anxiety.

3.2.3 Cost / Benefit Ratio of the Innovation

The assessment between cost-benefit ratios of an innovation is one of the key
component and consideration of the planning and implementation process.

3.2.3.1 Potential Benefit

➢ Potential Benefits to Patient

According to findings of the reviewed studies, the use of massage therapy could reduce pain, anxiety, depressive symptoms among children (Kusch, et al., 2000; Moller, et al., 2014) and other side-effects related to chemotherapy for children with cancer. The use of pain killer is expected to reduce after massage therapy applied. Besides, communication between patients and nurses could be improved during massage therapy; patient could also have a sense of being cared for and positive feelings (Ackerman, et al., 2012).

➢ Potential Benefits to Nurse

Improve quality of patient care will possibly lead to increase job satisfaction and staff morale of nurses. Additional advantages included receive well-organized training to provide massage therapy for children, develop professionalism and demonstrate autonomy to carry out an evidence-based innovation. Besides, use of massage therapy can increase children’s compliance and cooperation due to reduce the level of anxiety, thus reducing some of the unnecessary complaints and burden on nurses.
Potential Benefits to Organization

The target hospital joined The Australian Council on Healthcare Standards (ACHS) accreditation since 2009, one of the elements under the 5th edition of the ACHS Evaluation and Quality Improvement Program (EQuIP5) stated that “the organization encourages and adequately governs the conduct of health and medical research to improve the safety and quality of health care”, therefore, implementing the proposed evidence-based innovation could possibly enhance the positive image of the hospital. Another advantage is that reduce in the length of hospitalization and the use of pain killer could eventually leads to cost saving.

3.2.3.2 Potential Cost

The next step is the development of a budget of each important element; we have to consider the potential cost of the use of massage therapy before implementing the proposed innovation. The costs can be divided into material cost and non-material cost.

The only material cost is purchasing the copyright of STAIC to measure the level of anxiety; no extra expenditure is needed as the venue and manpower were already available in the target setting.
The major non-material costs are the staff training fee and time for attending training workshop. The other possible non-material cost includes decrease staff morale due to increasing workload and the license for the use of STAIC measuring tools.

A detailed cost / benefit ratio is listed in Appendix 5.
3.3 Developing Evidence-Based Practice Guideline for the Education Program

3.3.1 Name of the Evidence-Based Practice Guideline for the Education Program

The title of the evidence-based practice guideline is “evidence-based guideline on using massage therapy to reduce pain and anxiety in children with cancer undergoing chemotherapy”.

3.3.2 Aim and Objectives

3.3.2.1 Aim

This evidence-based guideline aimed to provide guidance and educate nurses in pediatric oncology ward when performing massage therapy to children with cancer.

3.3.2.2 Objectives

The objectives of the evidence-based guideline are,

- to promote and raise the awareness of the use of massage therapy for children with cancer in public hospital in Hong Kong
- to guide and assist nurse to perform massage therapy for children with cancer by continuous training
- to reduce the level of pain and anxiety of children with cancer undergoing chemotherapy after massage therapy
3.3.3 Target Group

This guideline intended to provide guidance and education to all the nurses working in pediatric oncology ward when performing massage therapy.

All inpatient children aged 4 to 18 years old undergoing chemotherapy are eligible to receive massage therapy.

3.3.4 Recommendation

The grade of recommendation are given based on the strength of the evidence supported, the details of the grading system as developed by The Scottish Intercollegiate Guidelines Network (SIGN) is listed in Appendix 6.

Informed consent must be obtained from both children and parents before the start of massage therapy. Three sessions of Swedish massage therapy per week with 20 minutes per session is recommended for children with cancer. Visual Analog Scale (VAS) and State-Trait Anxiety Inventory for Children (STAIC) were recommended to use as evaluation tools to assess the level of pain and anxiety. The details of recommendation were listed in Appendix 7.
In this chapter, the implementation plan will be established based on the communication plan, pilot testing and evaluation plan.

4.1 Communication Plan

4.1.1 Identification of Stakeholders

Stakeholders include intended project beneficiaries and those who is related or affected by the project in terms of both positive and negative effects (Brugha & Varvasovszky, 2000). We should include people who are interested in the program, affected by the program and involved in the entire running of the program.

In this proposed program, there are three major types of stakeholders:

- Administrators

  Administrators have a high degree of power to influence the program; they play a key role in providing necessary resources, manpower and support to the proposed program. They are Chief of Service (COS) of Department of Pediatrics, Department Operating Manager (DOM) of Department of Pediatrics and Ward Manager (WM) of pediatric oncology ward.
Physicians

The role of physicians in this proposed program is relatively passive, they do not directly participate in the program; however, they will provide medical support and advises if needed.

Nurses

Nurses are the key players of the proposed program. They provide massage therapy to children with cancer and document the relevant data; and they are likely to be the most influential.

4.1.2 Communication Plan with Stakeholders

In project planning and implementation, the position of the stakeholders is an important factor in determining its success or failure (Brugha & Varvasovszky, 2000); therefore, stakeholders should understand the process, objectives and goals of the program. Communication with all the involved stakeholders is vitally important, not only facilitate the implementation of the program but also help to assess the feasibility of future program direction and improvement.

Communication process should base on a mutual-trusting relationship which required
a high degree of openness; the objectives and process of program should be clearly explained and expression of their concerns is highly encouraged.

As mentioned in Chapter 3, a working committee consists of one Advanced Practice Nurse and two Registered Nurses will establish an evidence-based guideline to education nurses for the use of massage therapy for children with cancer and responsible for the overall coordination. They are also responsible for the regular meeting with the stakeholders.

The communication progress will start with the Ward Manager of pediatric oncology ward as Ward Manager is an effective communicator and accounts for the organizational change (Hewison, 2012). The working committee will present and explain the purpose of the program, the implementation context, the need for the change, analysis the pros and cons of the program, and cost-benefit ratio will also be explained in details.

The proposed program will be refined after discussed with the Ward Manager; a formal meeting with Chief of Service and Department Operating Manager of Department of Pediatrics will arrange subsequently. Ward Manager will also be
invited in this meeting to act as communicator and facilitator. The purpose of this meeting is to gain support and approval from the administrative level of the department; the working committee will present the work plan and timeline of the program to the administrators.

The working committee will introduce the proposed program to the nurses working in pediatric oncology ward after obtaining approval from Chief of Service and Department Operating Manager. Two identical briefing sessions will be conducted for nurses to ensure everyone can participate in the briefing session. Structural empowerment and self-efficacy are important factors that contributed to professional nursing practice (Manojlovich, 2005); the benefits of using massage therapy including greater autonomy and job satisfaction will be stressed. Moreover, literature review, staff training program, implementation plan and the purpose of the program will also include in the briefing session.

All rank of nurses will receive training from working committees within two months to standardize the massage technique. The training session will last for eight hours and held in the conference room in pediatric oncology ward; the theory and technique of massage therapy will include in the training session.
A monthly meeting will be held after implementation of the proposed program; the working committee will invite nurses to engage in monthly meeting to discuss the program progress, identify barriers and resolve conflicts if any. They are encouraged to ask questions and make suggestions at any time during preparation and implementation phase.

The target audiences – pediatric patients between 4 to 18 years old who diagnosed with any types of cancer will be invited to participate in the proposed program. A briefing session will hold before the launch of the proposed program, all the interested patients and their parents are invited to participate in the briefing session.

An anonymous suggestion box will place in a visible area in the ward corridor to collect opinions and suggestions from patients and their parents. The working committee will check the suggestion box regularly; all the suggestion forms will keep in record and for open discussion during monthly meeting to achieve continuous improvement for the program.
4.2 Pilot Study Plan

A pilot testing is a trial run of the proposed program. It can be used to assess the feasibility of the proposed program; it helps to identify potential practical problems and ensure better resources allocation and sufficient time to accomplish the proposed program (Van-Teijlingen & Hundley, 2001). Besides, pilot testing can help to test the data collection instrument and evaluation tools before full implementation of the program.

The goal of the pilot testing is to find out all the possible practical problems by testing the program on a small scale first. The inclusion criteria for the pilot testing is the same as the proposed program, the daily bed statistic of pediatric oncology ward is around 32 to 40 patients, eight patients (20 to 25% of total patients) will be invite to participate in the pilot testing; they are pediatric patients between 4 to 18 years old who diagnosed with any types of cancer and undergoing treatment, which required long-term hospitalization (> 3 months).

The pilot testing will start after informed consent obtained from both the patients and their parents. It will carry out in a pediatric oncology ward of a public hospital in Hong Kong, which is the same setting as that of the proposed program.
The pilot testing will last for four weeks, the working committee will provide participants with two sessions of Swedish massage per week and each session of massage therapy will last for 20 minutes.

The level of pain and anxiety will be evaluated by using Visual Analog Scale (VAS) (Appendix 8) and State-Trait Anxiety Inventory for Children (STAIC) respectively. A simple questionnaire will be given to children and their parents (Appendix 9) to evaluation the level of satisfaction after the last session of massage therapy.

The working committee will held a meeting to evaluate the finding of the pilot study and review the feedback from the target audience which can help to confirm whether or not minor adaptations to the program are necessary.
4.3 Evaluation Plan

Evaluation plan is used to monitor and evaluate the program; the evaluation result was used for program improvement and decision making (Centers for Disease Control and Prevention, 2011).

4.3.1 Identifying Outcomes

4.3.1.1 Patient Outcomes

Two primary outcomes of this proposed program are reducing the level of pain and anxiety for children with cancer by using massage therapy; the level of pain and anxiety can be evaluated by Visual Analog Scale (VAS) (Batalha, et al., 2013; Celebioglu, et al., 2013) and State-Trait Anxiety Inventory for Children (STAIC) (Haun, et al., 2009) respectively.

4.3.1.2 Healthcare Provider Outcomes

A survey (Appendix 10) was administered to nurses by working committees to assess the level of satisfaction; a regular survey can allow working committees to monitor trends in the level of satisfaction over time.
4.3.1.3 System Outcomes

For the system outcomes, the cost and the utilization of the proposed program will be measured to ensure the effectiveness of the proposed program.

4.3.2 The Nature of Participants

The target clients of the proposed program are all pediatric patients between 4 to 18 years old who diagnosed with any types of cancer and undergoing treatment, which required long-term hospitalization (> 3 months). Children who were critically ill, loss of consciousness, history of psychiatric illness and in contact isolation were excluded in the program (Batalha, et al., 2013; Celebioglu, et al., 2013; Mazlum, et al., 2013).

4.3.3 Sample Size Calculation

Calculating an appropriate sample size is an important step to conduct an effective and efficient study; a sample size which is too large, too small or inappropriate will negatively influence the quality and accuracy of the study (Bartleet, et al., 2001).

As there were two major primary outcomes in this proposed program – reduce the level of pain and anxiety for children with cancer, two sample size will be calculated and the larger one will be selected as the optimum sample size. One-tailed sample
t-test is used for estimation.

For the level of pain, with reference to the study of Celebioglu, et al. (2013), the mean value of pain level (by VAS) after massage therapy is 4.00 (no pain: 0, severe pain: 10) with standard deviation 1.7, 20 participants are required if the level of confidence as 95%, power as 80% and expected outcome of pain level is lower than 5.

For the level of anxiety, with reference to the study of Haun, et al. (2009), the mean value of anxiety level (by STAIC) after massage therapy is 23.00 (minimum score: 20, maximum score: 60) with standard deviation 2.83, 14 participants are required if the level of confidence as 95%, power as 80% and expected outcome of anxiety level is lower than 25.

The recruitment period for the study will last for one month and 20 eligible children will be invited to participate in the proposed program.

4.3.4 Data Collection and Date Analysis

Data collection is a progress of gathering information and data analysis is a step to turn collected data into meaningful, useful and accessible information (Centers for
Disease Control and Prevention, 2011). Data analysis was conducted by using SPSS version 21 and descriptive statistics are given as mean, standard deviation and percentage.

4.3.4.1 For Patient Outcomes

The major outcome for the patient is to reduce pain and anxiety after massage therapy.

Visual Analog Scale (VAS) is use to evaluate the level of pain for children (Batalha, et al., 2013; Celebioglu, et al., 2013) before and after each session of massage therapy. VAS is a linear rating scale 100mm in length and ranged from 0 (no pain) to 10 (severe pain); children can specify their level of pain by indicating the position along the line.

The anxiety level of children with cancer will be assessed by using State-Trait Anxiety Inventory for Children (STAIC) before and after each session of massage therapy (Haun, et al., 2009). STAIC measured both situational and characteristic anxiety (minimum score: 20 and maximum score: 60), it has been tested and used over 8,000 studies in diverse pediatric populations (Haun, et al., 2009).
Two-tailed t-test was used to analysis the scores of VAS and STAIC in order to determine whether massage therapy can significantly reduce the level of pain and anxiety of children with cancer.

4.3.4.2 For Nurses Outcomes

A survey (Appendix 10) was administered to nurses by working committees at baseline and then quarterly to assess the level of satisfaction. The survey aims to assess the level of satisfaction of nurses who participated in the proposed program; the survey consist of 12 questions and the level of satisfaction was assessed which based on different aspects, including the working committee, working climate, self-development and morale. Ten questions employ a 5-point Likert score, ranging from 1 (strongly disagree) to 5 (strongly agree) and two open-ended questions are included to encourage recommendation and opinions to the program. The total score ranges from 10 to 50 and a higher score indicates higher satisfactory level.

The working committee will sum up the score of the survey; a score which is higher than 35 will consider as satisfactory. Mean score will be calculated and the changes of the mean score during different period of the implementation phase was compared by using one sample t-test with confidence interval at 95%.
4.3.4.3 For System Outcomes

The utilization rate and attendance rate of the program are record. A children attendance record will be kept by nurses and the dropout rate will be calculated; children who attended less than 75% of total session of massage therapy will count as dropped out.

The cost of the proposed program (both the material cost and non-material cost) will be recorded by the working committee and the cost-benefit ratio will be calculated quarterly.

4.3.5 Basis for an Effective Change of Practice

The major outcome of this proposed program is to reduce the level of pain and anxiety for children with cancer. Massage therapy will considered as effective if the difference between the pre-test and post-test of mean score was found to be statistically significant (p<0.05).

The satisfaction level of the nurses was considered as one of the factors to determine the effectiveness of the program. The program will considered as effective if the mean score of the survey (Appendix 10) is above 35 marks.
Cost-benefit ratio can be used to summarize the overall value in terms of money for a program. The program will be considered cost-effective if the cost-benefit ratio is less than 1, which indicates that the proposed innovation was profitable.
**Appendix 1 – Search History**
(Retrieved on 17th August, 2014)

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- title, abstracts, full papers read
- eliminated duplication with other databases
- screened reference lists of the relevant studies

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### Table 2 - Table of Evidence

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<td>1-2 years old</td>
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<td></td>
<td></td>
<td>received no massage therapy</td>
<td>- usual care for pain management or usual care for symptom control</td>
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<td>- Received 3 sessions of massage</td>
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<td>- mean age: 13.5 years</td>
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#### Notes
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<th>Source</th>
<th>Effect Size</th>
<th>Follow Up</th>
<th>Length of Intervention</th>
<th>Patient Characteristics</th>
<th>Conclusion</th>
<th>Outcome Measures</th>
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| Grant from the National Center for Complementary and Alternative Medicine | | | | Low dose medication adherence | Inpatient (n=9), outpatient (n=7) | Faces Muscle Soreness Scale with assigned values ranging from 1 ("very sore") to 5 ("very good") we used to record muscle soreness.

Discomfort level was recorded on a scale from 0 to 4 (0 being "no discomfort," 4 being "maximal discomfort").

STAI-C (State-Trait Anxiety Inventory for Children) was used to record levels of anxiety (minimum score: 20; maximum score: 60).

1. p<0.001
   a. Intervention Group: Pretest: 3.06 (SD=0.56), Posttest: 4.53 (SD=0.34)
   b. Control Group: Pretest: 3.18 (SD=0.65), Posttest: 3.15 (SD=0.67)

2. p<0.001
   a. Intervention Group: Pretest: 1.90 (SD=0.50), Posttest: 0.13 (SD=0.28)
   b. Control Group: Pretest: 1.93 (SD=0.76), Posttest: 1.92 (SD=0.78)

3. p<0.000
   a. Intervention Group: Pretest: 1.76 (SD=0.43), Posttest: 0.30 (SD=0.27)
   b. Control Group: Pretest: 1.80 (SD=0.72), Posttest: 1.80 (SD=0.73)

4. p<0.01
   a. Intervention Group: Pretest: 2.00 (SD=0.50), Posttest: 1.61 (SD=0.34)
   b. Control Group: Pretest: 2.00 (SD=0.72), Posttest: 2.00 (SD=0.73)

5. p<0.05
   a. Intervention Group: Pretest: 1.50 (SD=0.40), Posttest: 1.20 (SD=0.27)
   b. Control Group: Pretest: 1.50 (SD=0.72), Posttest: 1.50 (SD=0.73)
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<td>After chemotherapy:</td>
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**Outcome Measures**

- 1. **Pain** and nausea mean management (0-3) absolute score/week
- 2. Summary score of the symptom severity (none / a little / somewhat versus "very / a bit" very)
- 3. Duration of fever (days)
- 4. Tumor versus none (0-3)

**Effect Size**

- 1. **Intervention Group:** 1.8 SD=0.5
- 2. **Control Group:** 2 SD=0.6

**Comparison**

- 1. **Intervention Group:** 0.3 (SD=0.4)
- 2. **Control Group:** 0.3 (SD=0.8)
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</tbody>
</table>

Note: The study was conducted in Turkey with children aged 4 to 15 years. The intervention group received one massage session of 10-15 minutes before the IT or BMA procedure, while the control group received standard treatment. VAS (Visual Analog Scale) was used to determine the level of pain and anxiety before and after the IT or BMA procedure. The intervention group showed a significant decrease in pain and anxiety levels compared to the control group. The study was funded by a grant from the International Journal of Nursing Practice, 2014.
<table>
<thead>
<tr>
<th></th>
<th>(SD=2.72)</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Group: 4.55</td>
<td>4.75</td>
<td>Intervention Group:</td>
<td>Posttest:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(SD=2.26)</td>
<td></td>
<td>(SD=2.98)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Appendix 3 – SIGN coding system**

++ All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought very unlikely to alter.

+ Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.

– Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter.

<table>
<thead>
<tr>
<th>Levels of Evidence (SIGN, 2011)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
</tr>
<tr>
<td>1+</td>
</tr>
<tr>
<td>1−</td>
</tr>
<tr>
<td>2++</td>
</tr>
<tr>
<td>2+</td>
</tr>
<tr>
<td>2−</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
</tbody>
</table>
Appendix 4 – SIGN Checklist


<table>
<thead>
<tr>
<th>Section 1: Internal Validity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Yes. P: children with cancer I: received massage therapy C: received no massage therapy and continue usual care O: relieving pain</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomized.</td>
<td>Can’t say. Randomization method was not reported</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Can’t say. Not reported</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept “blind” about treatment allocation.</td>
<td>Yes. Single-blinded study (the evaluator was unaware of group distribution)</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Yes. The size of both intervention and control group were the same; mean age was similar</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes.</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes.</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>0%</td>
</tr>
<tr>
<td>1.9 All the subjects are analyzed in the groups to which they were randomly allocated (often</td>
<td>Yes. All subjects were</td>
</tr>
</tbody>
</table>
referred to as intention to treat analysis). analyzed as in the allocated group

| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Not Applicable. |

### Section 2: Overall Assessment of the Study

| 2.1  | How well was the study done to minimize bias? | Unacceptable (-)  
The study was randomized but method was unknown and concealment method was not reported |
| 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? | Yes.  
The overall effect is due to the study intervention |
| 2.3  | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes. |
| 2.4  | Summarize 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. | Massage Therapy was a useful intervention for pain relief and its interference in the activities of the child/adolescent with cancer; and all participants presented significant pain relief after each massage session. |

### Section 1: Internal Validity

| 1.1 | The study addresses an appropriate and clearly focused question. | Yes. 
P: children with cancer and blood disease 
I: received massage therapy 
C: received no massage therapy 
O: positive physical and psychological effects |
| 1.2 | The assignment of subjects to treatment groups is randomized. | Yes. 
By coin toss “head” – treatment “tail” – control |
| 1.3 | An adequate concealment method is used. | Can’t say. 
Not reported |
| 1.4 | Subjects and investigators are kept “blind” about treatment allocation. | No. 
Non-blinded study |
| 1.5 | The treatment and control groups are similar at the start of the trial. | Yes. 
The size of both intervention and control group were the same; mean age and gender mix were similar |
| 1.6 | The only difference between groups is the treatment under investigation. | Yes. |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. | Yes. |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | 0%. |
| 1.9 | All the subjects are analyzed in the groups to which they were randomly allocated (often | Yes. 
All subjects were |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Not Applicable. |

### Section 2: Overall Assessment of the Study

| 2.1 | How well was the study done to minimize bias? | Acceptable (+) Non-Blinded study and concealment method was not reported |
| 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? | Yes. The overall effect is due to the study intervention |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes. |
| 2.4 | Summarize 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. | Massage Therapy can be effectively implemented within the clinical setting as to reduce psychological and physical distress and can have a positive effect on quality of life for children with cancer. Although randomization was done in this study, but coin toss cannot regarded as a good randomization method. |

**Section 1: Internal Validity**

| 1.1 | The study addresses an appropriate and clearly focused question. | Yes. P: children with cancer I: received massage therapy C: received no massage therapy and continue usual care O: the effectiveness of massage therapy on chemotherapy-induced nausea and vomiting |
| 1.2 | The assignment of subjects to treatment groups is randomized. | Yes. By randomized number table |
| 1.3 | An adequate concealment method is used. | Can’t say. Not reported |
| 1.4 | Subjects and investigators are kept “blind” about treatment allocation. | Can’t say. Not reported |
| 1.5 | The treatment and control groups are similar at the start of the trial. | Yes. The size of both intervention and control group were the same; mean age and gender mix were similar |
| 1.6 | The only difference between groups is the treatment under investigation. | Yes. |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. | Yes. |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | 5.4% |
| 1.9 | All the subjects are analyzed in the groups to | Yes. |
which they were randomly allocated (often referred to as intention to treat analysis). All subjects were analyzed as in the allocated group.

| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Not Applicable. |

**Section 2: Overall Assessment of the Study**

| 2.1 | How well was the study done to minimize bias? | Acceptable (+) Concealment method and any blinding throughout the study was not reported. |
| 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? | Yes. The overall effect is due to the study intervention. |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes. |
| 2.4 | Summarize 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 study showed positive effect of massage therapy on nausea and vomiting; massage therapy can also reduce stress and pain and enhancing psychological and physiological well-being by good control of chemotherapy-induced nausea and vomiting. |

**Section 1: Internal Validity**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question.</td>
</tr>
<tr>
<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomized.</td>
</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used.</td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept “blind” about treatment allocation.</td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial.</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analyzed in the groups to</td>
</tr>
</tbody>
</table>
which they were randomly allocated (often referred to as intention to treat analysis). All subjects were analyzed as in the allocated group.

| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Not Applicable. |

### Section 2: Overall Assessment of the Study

| 2.1 | How well was the study done to minimize bias? | 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? | Yes. The overall effect is due to the study intervention |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes. |
| 2.4 | Summarize 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. | None of the symptoms showed significant improvements in the intervention group in this study, however, children in intervention group had lower overall symptoms burden. The dose of the massage intervention was averaged 1.8 sessions per week only, while the target dose was 3 times per week. |

### Section 1: Internal Validity

| **1.1** | The study addresses an appropriate and clearly focused question. | Yes.  
|         | P: children with cancer undergoing intrathecal therapy or bone marrow aspiration  
|         | I: received massage therapy  
|         | C: standard treatment  
|         | O: reducing pain and anxiety |

| **1.2** | The treatment and control groups are similar at the start of the trial. | Yes.  
|         | The size and demographic characteristics of children in both intervention and control group were similar |

| **1.3** | The only difference between groups is the treatment under investigation. | Yes.  

| **1.4** | All relevant outcomes are measured in a standard, valid and reliable way. | Yes.  

| **1.5** | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | 0%  

| **1.6** | All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Yes.  
|         | All subjects were analyzed as in the allocated group |

| **1.7** | Where the study is carried out at more than one site, results are comparable for all sites. | Not Applicable. |

### Section 2: Overall Assessment of the Study
<table>
<thead>
<tr>
<th></th>
<th>How well was the study done to minimize bias?</th>
<th>High quality (++)</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>Yes. The overall effect is due to the study intervention</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>Summarize 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>Children who received massage therapy have less acute procedural pain arising from IT or BMA than those in the control group and the level of posttest anxiety was also decreased. This study concluded that children with cancer who received massage therapy tended to be more peaceful and comfortable during invasive procedure and treatment.</td>
</tr>
</tbody>
</table>
## Appendix 5 – Cost / Benefit Ratio of the Innovation

### Potential Cost

<table>
<thead>
<tr>
<th>Items</th>
<th>Costs (HKD)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAIC assessment tool</td>
<td>$1,000</td>
<td>includes STAIC Manual, 25 State-Trait Questionnaires and Scoring Key</td>
</tr>
<tr>
<td>Train-the-trainer course (massage therapy)</td>
<td>$900 per person $900 x 3 = $2,700</td>
<td>The working committees will include one Advanced Practice Nurse and two Registered Nurses; they will receive train-the-trainer course which include 4 training sessions with 2 hours per session</td>
</tr>
<tr>
<td>Time spent for attending training course (salary of nurse)</td>
<td>For APN: $400 x 8hrs = $3,200 For RNs: 2 x $200 x 8hrs = $3,200</td>
<td></td>
</tr>
<tr>
<td>Grand Total:</td>
<td>$10,100</td>
<td></td>
</tr>
</tbody>
</table>

### Potential Benefit

<table>
<thead>
<tr>
<th>Items</th>
<th>Costs (HKD)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine Sulphate</td>
<td>$5 per tablet $40 x $5 x 10 = $2000</td>
<td>Assume each patient could take fewer tablets of Morphine (~10) per year on average and ~40 patients in the target setting</td>
</tr>
<tr>
<td>Ward maintenance fee</td>
<td>40 x $4680 = $187,200</td>
<td>The inpatient charge for non-eligible person in Hospital Authority is $4,680 per day, assume that it is the minimal daily maintenance fee for each patient; and each participant could reduce 1 day of admission after intervention due to decreasing in pain and anxiety</td>
</tr>
<tr>
<td>Grand Total:</td>
<td>$189,200</td>
<td></td>
</tr>
</tbody>
</table>

Cost / Benefit Ratio of the Innovation = $10,100 / $189,200 = 0.053
The ratio is less than 1 which indicated that the proposed innovation was profitable.
Appendix 6 – Grade of Recommendation (SIGN, 2004)

The grades of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the 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; 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>
</tbody>
</table>
- ** Recommendation 1.0**

Swedish massage is recommended for children (Grade of recommendation: A)

Swedish massage can reduce the level of pain and anxiety; two (Haun, et al., 2009; Mazlum, et al., 2013) of three reviewed studies (Haun, et al., 2009; Mazlum, et al., 2013; Mehling, et al., 2011) which used Swedish massage as their intervention shown positive result in their findings. (1+, 1+)

- ** Recommendation 2.0**

The duration of massage therapy is recommended as 20 minutes per session (Grade of recommendation: A)

Four reviewed studies (Batalha, et al., 2013; Haun, et al., 2009; Mazlum, et al., 2013; Mehling, et al., 2011) used 20 to 30 minutes massage therapy for children and the remaining study used 10 to 15 minutes massage therapy (Celebioglu, et al., 2013); four of the studies (Batalha, et al., 2013; Celebioglu, et al., 2013; Haun, et al., 2009; Mazlum, et al., 2013) shown significant results in reducing the level of pain and anxiety. (1-, 1+, 1+, 2++)
- **Recommendation 3.0**

Three sessions of massage therapy per week is recommended. (Grade of recommendation: A)

The frequency of massage therapy is recommended as three times per week and is well-supported by the reviewed studies (Batalha, et al., 2013; Haun, et al., 2009; Mehling, et al., 2011). (1-, 1+, 1++)

- **Recommendation 4.0**

Visual Analog Scale (VAS) and State-Trait Anxiety Inventory for Children (STAIC) were recommended to use as evaluation tools to assess the level of pain and anxiety. (Grade of recommendation: B)

The tools used to assess the level of pain for children was Visual Analog Scale (VAS) (Batalha, et al., 2013; Celebioglu, et al., 2013); it was a linear rating scale 100mm in length (Appendix 8), children can simply specify their level of pain by indicated the position along the line. (1-, 2++)

State-Trait Anxiety Inventory for Children (STAIC) was chosen to measure the level of anxiety before and after each session of massage therapy by Haun, et al. STAIC measured both situational and characteristic anxiety, it has been tested and
used over 8,000 studies in diverse pediatric populations (Haun, et al., 2009). (1+)

- **Recommendation 5.0**

  **Obtain informed consent from both children and parents.** (Grade of recommendation: A)

  To reduce dropout rate and gain cooperation by obtaining informed consent from both children and parents before the start of massage therapy (Batalha, et al., 2013; Celebioglu, et al., 2013; Haun, et al., 2009; Mazlum, et al., 2013; Mehling, et al., 2011). (1-, 1+, 1+, 1++, 2++)
Appendix 8 – Visual Analog Scale (VAS)

The visual analog scale (VAS) is a measurement instrument for subjective characteristics or attitudes that cannot be directly measured. Children can specify their level of pain by indicating a position along a continuous line between two end-points (usually 100mm).
Appendix 9 Questionnaire

MASSAGE THERAPY FOR CHILDREN
Evaluation Questionnaire

Name: ____________________ (optional)
Age: ______________________
Gender: _____________________
Number of sessions attended: □ 1-2 □ 3-4 □ 5-6 □ 7-8

<table>
<thead>
<tr>
<th>Quality of massage</th>
<th>☹</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>☺</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information given</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Environment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Friendliness of the staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall satisfaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other recommendations: ______________________________________
___________________________
___________________________
___________________________

Please indicate the body part that you have received massage therapy on the diagram.

~THANK YOU~
## Appendix 10

**Massage Therapy for Children with Cancer - Staff Satisfaction Questionnaire**

Name: _______________ (optional)
Age: __________________
Rank: ________________

Please choose the most appropriate answer.

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) In general, you feel satisfy about the program.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2) The program has clear aims and objectives.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3) The guidelines and educational materials are clear, sufficient and easy to follow.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>Working Committee</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4) The working committee provides adequate support to you during program implementation.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>Working Climate</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5) Your roles and responsibilities in the program are clear.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6) You have enough time to carry out the program.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>Self-development &amp; Morale</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7) You have received appropriate recognition for your contribution.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8) The use of massage therapy for children gives you a sense of personal accomplishment.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Strongly Disagree</td>
<td>Disagree</td>
<td>Neutral</td>
<td>Agree</td>
<td>Strongly Agree</td>
</tr>
<tr>
<td>---</td>
<td>------------------</td>
<td>----------</td>
<td>---------</td>
<td>-------</td>
<td>---------------</td>
</tr>
<tr>
<td>9) You are satisfied with your own morale.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>10) Children generally pleased with the services of massage therapy.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

11. Are you studying any courses about massage therapy?
   □ Yes
   □ No

12. What could be improved regarding the massage therapy for children with cancer?

13. If you have any other comments you could wish to add, please write them in the box below.

Thank you for your responses.
Appendix 11 – PRISMA Flow Diagram

Literature search
Database: PubMed, CINAHL Plus, and Cochrane Library
Limits: English-language articles only

Search results combined (n=128)

Articles screened on basis of title and abstract

Included (n=13)
Excluded (n=115)
Target population – adults: 66
Not cancer-related: 37
Other CAM methods were used: 12

Manuscript review and application of inclusion criteria

Included (n=5)
Excluded (n=8)
Duplication: 4
Other CAM methods were used: 4

Randomized controlled trial (n=4)
Quasi-experimental designs (n=1)
References


Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; Division of Nutrition, Physical Activity, and Obesity, (2011). Developing an effective evaluation plan, 1-108.


