

Abstract of the thesis entitled

**The Use of Massage Therapy to Improve Pain Control for Patients with
Metastatic Cancer**

Submitted by

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Pain, the most common and distressing symptoms, afflicts most cancer patients. Despite the availability of several pharmacological interventions and the existence of well-known guidelines for cancer pain management, pain related to metastatic cancer continues to be undertreated. Inadequate management of cancer pain arouses physical and emotional distress, and result in poor quality of life. Massage is an integrative modality that has been recognized as an adjunctive therapy in caring cancer patients. It provides systematic, manual manipulations on soft tissues and muscles. Several studies have documented the beneficial effect of massage in reducing pain among cancer patients. However, the application of massage has not been well adopted in our clinical practice. A translational research study was launched to review the evidence in applying massage in a clinical setting and the effectiveness of applying massage in cancer patients.

The objective of this dissertation is to apply the best evidence to clinical practice in order

to reduce the severity of pain experienced by patients with metastatic cancer. A search of three databases including PubMed, CINAHL (via EBSCOhost) and ProQuest (British Nursing Index and psyINFO) were conducted to identify eligible studies related to massage in pain relief for metastatic cancer patients. Quality of the retrieved studies was assessed and criticized using the appraisal checklist of SIGN (2008). The derived evidences were summarized and synthesized. An evidence-based guideline of massage therapy in relieving pain among metastatic cancer patients was developed based on the evidence from the reviewed literatures and results of the quality assessment. The implementation potential of the guideline was assessed in relation to the target setting, target audience, transferability of findings, feasibility and cost-benefit analysis of proposed guideline. The assessment revealed a high transferability of findings into practice. It was feasible to implement the proposed guideline in the target setting and the target audience. Approval from the hospital administrators was required before implementing the guideline. The implementation plan therefore included the communication plan with stakeholders and formulation of a Communication Committee. A pilot study was also required to assess the effectiveness and potential barriers associated with the guideline. Evaluation on the clinical outcomes, patients and staff satisfaction, and staff compliance were included in the evaluation plan. Regarding to the result findings and evidence from studies, the proposed massage innovation, besides the usual pharmacological interventions, is considered as effective in reducing pain among patients with advanced cancer.

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with Metastatic Cancer**

by

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A thesis submitted in partial fulfillment of the requirement for
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Declaration

I declare that this dissertation 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:

HUNG NGA TING

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Chapter 1: Introduction

Pain is the most common and distressing symptoms experienced by patients with cancer. It is described as “unpleasant sensory and emotional experience associated with tissue damages” in the study of the international Association for the Study of Pain (Liu & Fawcett, 2008). Studies have shown the effectiveness of using non-pharmacological treatment in relieving pain for advanced cancer patients. The background, affirming needs and their significance and objectives will be discussed in this chapter.

1.1 Background

Pain affects majority of cancer patients. A high prevalence of pain experience is always reported in patients with advanced or metastatic phase of cancer (64%) and patients on anticancer treatment (59%) (van den Beuken-van Everdingen et. al., 2007). There are 30% to 50% of cancer patients who suffer from chronic pain, and 90% patients with metastatic cancer experience severe pain at the end of life (Liu & Fawcett, 2008). Patients with metastatic cancer are more likely to have pain compared to those without metastasis. Pain associated with advanced cancer cause physical and emotional distress which leading to minimize functional ability and quality of life (Kutner et. al., 2008). A successful pain management is necessary to relieve pain and improve mobility, healing as well as quality of life among cancer patients.

Definition of Cancer Pain

Cancer pain is always defined as a multidimensional experience that involves physical, emotional, spiritual and social dimensions (Liu & Fawcett, 2008). The pain can be cancer-associated or treatment-related. Cancer-associated pain can be directly due to the involvement of tumor cells. They can be classified into somatic, visceral or neuropathic origin. Neuropathic pain involves tumor infiltration in nerve plexuses and damage to nerve tissue. Approximately 30% to 50% of cancer patients experience neuropathic pain which is less responsive to systemic opioids analgesic (Chen et. al., 2006). Visceral pain is caused by distortion or compression of solid organs and inflammation of viscera and connective tissues (Chen et. al., 2006). Somatic pain is usually referred to the involvement of muscles, connective tissues and joints (Chen et. al., 2006), while bony involvement accounts for 34% to 45% of cancer patients and results in intolerable pain (Jane et. al., 2011).

Integration of non-pharmacologic analgesic therapies for pain control

Currently, the well-known 3-steps analgesic ladder guidelines in pain management are recommended by World Health Organization (WHO) for patients with cancer. Despite existence of this published guidelines and effective treatments are available for 70% to 90% cases, there are still 40% cancer pain remains under-treated internationally (Apolone et. al., 2006; Aiello-Laws et. al, 2009). Uncontrolled cancer-associated pain can lead to physical and psychological distress. Nowadays, cancer patients are increasingly interested in adjunct

alternative therapies rather than medicine only to relieve their pain (Grealish et. al., 2000).

The principle of non-pharmacological method for pain management is to minimize pain perception among cancer patients by decreasing pain intensity, increasing pain tolerance, and maximize individual adaptive pain behavior (Gatlin & Schulmeister, 2007).

Affirming the needs

Pharmacologic methods are the dominant strategy in managing pain for metastatic cancers in ward setting. Opioid analgesic is commonly used because of its high efficacy and absence of specific organ toxicity (Falkensteiner, Mantovan, Muller & Them, 2011). However, cancer-associated pain is still inadequately treated and hence results in poor quality of life among metastatic cancer patients. The greatest barrier in pain control is the misconception on the use of analgesics. Sometimes patients are reluctant to report pain because they fear of addiction or dose tolerance (Gatlin & Schulmeister, 2007), and the side effects of analgesic such as nausea, vomiting, drowsiness, confusion, respiratory distress and urinary retention (Falkensteiner et. al., 2011), which may limit the use of analgesics. Pain is always considered as nursing-sensitive outcome (Aiello-Laws, et. al, 2009) for hospitalized patients because pain can be directly affected by nursing intervention. Effective pain management is undoubtedly a crucial issue in nursing care intervention.

Massage Therapy

Massage is an integrative modality that has been recognized as an adjunctive supportive care in managing cancer-related pain. It is defined as the “hand motions practiced on the individual body surface with a therapeutic goal” (Wilkie et. al., 2000). It is a systematic application of pressure to skin through direct manipulation such as rubbing, kneading or rolling of soft tissues and muscles (Gatlin & Schulmeister, 2007).

Physiologic and psychological effects of massage in pain relief

It had been found that massage could significantly lower blood pressure and heart rate (Smith, Kemp, Hemphill & Vojir, 2002), improve blood and lymph circulation, reduce edema, relieve muscle spasms and pain, and promote relaxation (Wilkie et. al., 2000). In western country, over 70% hospices offer massage services and 26% of cancer patients received massage therapy as one of their management on cancer pain (Liu & Fawcett, 2008). As most analgesics have its ceiling dose, the use of massage therapy can reduce analgesic medication use and also the chance of using strong opioids. Several studies indicated the beneficial and potential effects of massage therapies to reduce pain in advanced cancer patients. It is suggested that massage can alleviate 40% cancer pain in cancer patients at varying stages (Cassileth & Vickers, 2004). Other studies also indicated massage therapy could be effective, especially in the short term effects. A significant therapeutic effect with immediate massage-related improvement in pain intensity was 35% to 38%, 20% to 37% in mood and

22% to 29% in muscle relaxation in a 45-minute full-body massage (Jane et. al., 2011). It is believed that massage therapy provides a safe, non-invasive, inexpensive adjunct in pain management.

The local needs of massage therapy as a nursing intervention for pain management

Despite massage therapy is pervasive complementary strategy used world-wide in reducing pain among cancer patients, there is no clear and workable evidence-based guideline for nursing practice within clinical setting in Hong Kong. The lack of comprehensive standardized protocol also limits the introduction of massage therapy to eligible cancer patients. Traditionally, massage therapy is often offered by licensed massage therapists who are professionally trained to assist relaxation, relieve muscular aches and pain. It is important for massage therapists to have knowledge about cancer and metastasis in order to determine what techniques can be used safely and effectively when they are treating patients with cancer (Walton, 2000, as cited in Gecesdi, 2002). However, there is limited massage therapist who is adequately trained to provide services for cancer patients and most therapists may not familiar with the disease progress, treatment stage and other contradiction of cancer patients as nurses do. An ideal way is to integrate nurse-led massage therapies into nursing practice to assure all hospitalized cancer patients have a safe and effective treatment to ease their pain symptom as a result in promoting individual well-being and hence a better quality of life. Since not every cancer patients are suitable for the implementation of massage therapy due to certain

condition, such as advanced osteoporosis, bone fracture, burns, deep vein thrombosis, eczema, open wounds, phlebitis and skin infection (Ernst et al., 2006, as cited in Liu & Fawcett, 2011), a safe and effective massage therapy guideline should be well-established before any implementation to patients. Integration of massage therapies may become an important part of nursing care in hospital settings and even involve in patients discharge plan as palliative care in home setting for both cancer patients and their caregivers. Family member, who plays a main role in care-giving, is an essential resource for a touch-based care intervention (Collinge, Macdonald & Walton, 2012). Caregivers can learn simple methods that not only to provide comfort and relaxation to cancer patients safely but also to ease the burden of distress and helplessness among caregivers when they accompany with cancer patients in such a difficult stage.

1.2 Research Question and Objectives

How effective is massage therapy in alleviating pain for adult patients with metastatic cancer in Hong Kong?

Objectives of the dissertation

1. To investigate the effectiveness of using massage therapy in pain control among patients with metastatic cancers.
2. To perform a literature search and quality assessment for the effectiveness of massage therapy on cancer patients.

3. To develop a standardized and evidence-based guideline for using massage therapy as an adjunctive treatment to relieve metastatic cancer pain symptoms.
4. To assess the transferability and feasibility of the proposed protocol.
5. To design an implementation plan and evaluate the effectiveness of massage therapy on ward setting level.

Significance

Pain affects most cancer patients particularly in metastatic stage of the disease. An effective and evidence-based pain management protocol will be benefit to patients, nurses and families.

From patients' perspective

It is suggested that massage may have positive effect in pain relief. It provides an immediate or short-term reduction in pain intensity and promote muscle relaxation (Grealish, Lomasney & Whiteman, 2000; Kutner et. al., 2008 & Wilkie et.al., 2000). Less opioid analgesic will be used due to better control of cancer-related pain. In addition, patients may experience improved quality of life when pain is alleviated and are more likely to manage their daily living successfully at this critical phase of life.

From nurses' perspective

Caring touch is considered as an essential element of a good nursing care (Collinge, MacDonald & Walton, 2012). An evidence-based guideline on massage can standardize

nursing practices. Massage can be perceived as a form of communication and healing touch (Grealish et. al., 2000) that used by nurses who have been technically trained. Through massage procedure, nurses can build up a better rapport with their patients and provide high quality nursing care.

From families' perspective

Spouse, partner or other family members in a care-giving role are an important resource in touch-based supportive care. Teaching family caregivers with simple methods can safely provide comfort and relaxation to cancer patients (Collinge, MacDonald & Walton, 2012).

Caregivers training in simple touch techniques may have potential to empower caregivers with skills to reduce helplessness and help maintaining an optimal level of intimacy with cancer patients (Collinge, MacDonald & Walton, 2012). Simple massage techniques can be taught by nurses and massage can be provided by caregivers to cancer patients at home environment after discharge.

Chapter 2: Critical Appraisal

Searching process of relevant evidence and data summary will be presented in this chapter. The level of evidence of identified studies will be rated according to their study design and methodology quality based on the definition of Scottish Intercollegiate Guidelines Network (SIGN, 2008) while the key findings are discussed and evidence are synthesized.

2.1 Search Strategies

Identification of Studies

A search of PubMed, CINAHL (via EBSCOhost) and ProQuest (British Nursing Index and psyINFO) database were conducted to identify eligible studies on 10th August 2013. An integrated search term was used by the combination of several keywords, including “massage”, “massage therapy”, “therapeutic massage”, “Cancer”, “Metastatic cancer”, “Advanced cancer” and “pain”. There was no restriction on the years or language of publication. Studies were included regarding to the inclusion criteria as listed while those were excluded if they met the exclusion criteria.

Study Selection Criteria

Inclusion Criteria

1. Randomized Control Trails (RCT) or clinical trails
2. Adult patients aged 18 years old or above diagnosed with metastatic cancer

3. Studies relating to full-body or foot massage therapy
4. Primary outcome of studies focus on pain control or relaxation

Exclusion Criteria

1. Studies relating to reflexology and aroma massage therapy
2. Patients just received surgery or currently on chemotherapy or radiotherapy

Results

After searching with the keywords and matching the selection criteria as indicated, there were 44 journal studies retrieved from three databases. 10 studies retrieved after screening title and abstract. Only studies with full-text were retained. Reference lists of the selected studies were also screened for any relevant studies. All duplicated studies were eliminated. Finally, a total of six studies (four randomized controlled trails and two quasi-experimental pretest and posttest studies) were identified. There was no study retrieved after screening the reference list of the identified literature. Details of the search history are summarized in Appendix 1.

Data Extraction

All key data was extracted from selected studies and presented in the table of evidence. Each table of evidence consists of patient characteristics, intervention and control group, outcome measure, and effect size. Outcome measures from selected studies included

immediate or sustained changes in pain intensity, relaxation response and change in mood status. The tables of evidence are presented in Appendix 2.

2.2 Appraisal Strategies

Appraisal checklist of SIGN (2013) was used to critique and appraise the quality of all selected studies. The level of evidence of identified studies was rated according to study design and methodology quality based on the guideline of SIGN (2008). Appraisal checklists of all six selected studies are presented in Appendix 3 and 4.

Study Characteristics

The six identified studies were published in English and between 2000 to 2013. Four were randomized control trials (RCT) (Kutner, et.al., 2008; Jane, et. al., 2011; Toth, et. al., 2013 & Wilkie, et. al., 2000) while the remaining two were quasi-experimental pretest and posttest study (Cassileth & Vickers, 2004 & Grealish, Lomasney & Whiteman, 2000).

In order to investigate the effects of massage therapy among cancer patients, four randomized control trials and one quasi-experimental study (Grealish, Lomasney & Whiteman, 2000) had compared massage intervention to control groups. The remaining study only compared the intervention effect from the baseline in pre- and post-intervention intervals (Cassileth & Vickers, 2004). Wilkie (2000) and Toth (2013) compared the effects of massage intervention and usual care on pain intensity among patients with terminal cancers in hospice

or home setting and metastatic cancers at home respectively. Jane (2011) investigated the efficacy of massage therapy on pain intensity, mood status, muscle relaxation and sleep quality among patients with bony metastases. Kutner (2008) and Wilkie (2000) not only evaluated the efficacy of massage in reducing pain experience, but also explored the effects of massage on analgesic doses and quality of life among advanced cancer patients.

Sample Size

Among the four identified RCT studies, the sample size varied from 29 to 380. On the other hand, a larger sample size ranged from 87 to 1290 was noted in those two identified quasi-experimental pretest and posttest studies. Sample size was calculated by using a power of 80% in the study of Grealish, Lomasney & Whiteman (2000)

Quality assessment of identified studies

The quality of studies was assessed by SIGN with rating scores from 1++ to 4, where 1++ represents the highest quality and 4 is the lowest. “++, + & -” indicates the risk of bias with “++” is the lowest risk of bias and “-” is the highest (Appendix 5). All six reviewed studies had addressed an appropriate and clearly-focused question on the effectiveness of massage therapy in cancer-associated pain among patients with advanced or metastatic cancers. Two out of six studies examined the effects of massage through pretest and posttest study designs without randomization (Cassileth & Vickers, 2004 & Grealish, Lomasney &

Whiteman, 2000). These two studies were scored 2++ because of the very low risk of bias (SIGN, 2008). The remaining four studies (Jane, et. al., 2011; Kutner, et. al., 2008; Toth et. al., 2013 & Wilkie et. al., 2000) had designed randomized assignment in allocating their participants into either massage or control groups. All four RCT studies were scored from 1++ to 1+ (SIGN, 2008). The contents of these four RCT studies were assessed as follow.

Among four RCTs (Jane, et. al., 2011; Kutner, et. al., 2008; Toth et. al., 2013 & Wilkie et. al., 2000), only two of them (Jane, et. al., 2011 & Kutner, et. al., 2008) mentioned clearly the method of randomization. In the study of Jane (2011), they used a computerized minimization program to generate the randomization sequence according to variables such as gender, age, ethnicity, analgesics and symptom distress for the randomization process. On the other hand, Kutner (2008) used a randomized sequence block design that produced by a SAS system and then stratified participants regarding to the study site. For the remaining two RCTs (Toth et. al., 2013 & Wilkie et. al., 2000), since the method of randomization had not described in detail, they should not be rated in a very high level of quality. Method of concealments was not mentioned clearly in all four RCTs studies.

Patients blinding was only indicated clearly in studies of Kutner (2008) and Wilkie (2000). Despite patients were told to be provided non-pharmacological treatments that aim to improve symptom distress in the study of Toth (2013), this was not considered as blinding method. However, it is not possible to completely blind patients to massage intervention

because massage involves manipulating soft tissue areas of participants' bodies. Participants in the intervention arms might be aware of the massage therapy and perceived a better beneficial effect of massage than those in control arms. This might have contributed to the significant difference in pain intensity between massage and control groups in four RCT studies.

The dropout rate of four reviewed RCT studies varied from 2% to 48% (Kutner, et.al., 2008; Jane, et. al., 2011; Toth, et. al., 2013 & Wilkie, et. al., 2000) while no participant dropout before the studies completed in both quasi-experimental studies (Cassileth & Vickers, 2004 & Grealish, Lomasney & Whiteman, 2000). The high attrition rate (48%) was noted in Wilkie (2000) mainly due to death and rapid deterioration of diseases. The drop-out rate among remaining four RCTs was low, except in Kutner (2008) drop-out rate approached to 30% because of the longer study period for examining the sustained effects of massage.

There were five different pain measurement scales used in the reviewed studies, including Visual Analog Scale (VAS), Memorial Pain Assessment Card (MPAC), agency's Pain Assessment Tool (PAT), Skilled Nursing Visit Report form (SNVR) and Brief Pain Inventory (BPI). VAS with 0-10 pain scale was used in three studies (Cassileth & Vickers, 2004; Jane, et. al., 2011 & Toth, et. al., 2013) except Grealish, Lomasney and Whiteman (2000) used VAS in 0-100mm scale for pain measurement. Wilkie (2000) used both PAT and SNVR in measuring immediate pain intensity but only PAT was used in measuring long-term

pain intensity due to the lack of documented data on the worst, least and tolerable pain level on the SNVR form. Kutner (2008) used BPI to measure the sustained change in pain level and used MPAC to measure the immediate change in pain. All pain assessment tools and 0 to 100mm scale have been shown to be valid and reliable among cancer populations.

2.3 Summary of Data

Patients Characteristics

The mean age of participants among identified studies ranged from 50 to 65 years old. Majority of participants experienced pain associated with metastatic cancer or advanced cancer with stage III or IV from various types of cancer, mainly included breast, lung, colorectal, pancreatic and prostate cancers.

Only three studies reported the baseline pain intensity among participants (Cassileth & Vickers, 2004; Kutner, et. al., 2008 & Jane, et. al., 2011). Most of these participants experienced moderate to severe pain with pain score higher or equal to 4 on 0-10 scale.

Study participants were recruited from either oncology units or hospices where provide care to cancer patients. Most participants were recruited during hospitalization. However, outpatients who were referred by health professional in a cancer center were also participated in the study of Cassileth & Vickers (2004).

Intervention

Five out of six studies provided full-body massage therapies with duration between 15 to 60 minutes (Cassileth & Vickers, 2004; Kutner, et. al., 2008; Jane, et. al., 2011; Toth, et. al., 2013 & Wilkie, et. al., 2000) as the major intervention while foot massage and light touch massage were also provided in the study of Cassileth & Vickers (2004). Massage was most commonly applied to patients' head, neck, back, gluteus muscle, arms, hands, lower legs and feet in the full body massage intervention. Besides, 10-minutes massage was applied to foot only in the study of Grealish, Lomasney and Whiteman (2000).

Swedish/classic massage was used in six studies, methods included gentle effleurage, light petrissage, compression, myofascial trigger point release and nerve stroke. In Grealish, Lomasney and Whiteman's study (2000), slow gentle stroke, rhythmic lifting and squeezing and circular movement around joints were applied to ankle, feet and lower legs. Positioning for massage therapy were mentioned in two RCTs (Kutner, et.al., 2008 & Jane, et.al., 2011), there were more than 50% massage sessions provided with patients in supine, and the remainders were in prone and side-lying position.

In majority, massage was delivered during patient hospitalization, except three studies provided massage in patients' home (Cassileth & Vickers, 2004; Toth et.al., 2013 & Wilkie et.al, 2000). Licensed massage therapists who were trained in caring patients with advanced cancers provided massage to patients in four studies (Cassileth & Vickers, 2004; Kutner, et. al.,

2008; Toth, et. al., 2013 & Wilkie, et. al., 2000), while in the remaining two studies, massage therapy was provided by registered nurses who were trained in massage therapy (Jane, et. al., 2011; Grealish, Lomasney & Whiteman, 2000).

Contraindications for massage therapy

All reviewed studies except Cassileth & Vickers (2004) and Wilkie et.al. (2000) indicated condition which is contradictory to massage. Patients were restricted to massage therapy if they had platelet count below 10,000 or on anticoagulant therapy, active spinal cord compression syndrome, deep vein thrombosis, body area with inflammation or infection, identified open wound or bruise, or having surgery on the day of massage intervention. Massage would be avoided over the site of metastasis which had been marked prior to the massage intervention.

Time of Data Collection

The outcome data relevant to pain intensity was collected immediately post-treatment in five studies (Cassileth & Vickers, 2004; Kutner, et. al., 2008; Jane, et. al., 2011; Toth, et. al., 2013 & Wilkie et.al., 2000). Participants were followed up and data collected at 20-minutes interval after intervention in Grealish, Lomasney & Whiteman (2000) and Jane (2011). Moreover, participants were also followed up and data was collected on weekly basis to examine a longer effect of intervention in 3 studies (Kutner, et. al., 2008; Toth, et. al., 2013 & Wilkie et. al., 2000).

Effects of massage therapy on pain

Findings from the reviewed studies examined the immediate, short-term and long-term effects of massage therapy in reducing pain intensity.

- *Immediate effect on pain control*

Four RCTs showed an immediate decrease in pain intensity after half (Wilkie, et. al., 2000) or at the end of the full-body massage ($p < 0.05$). Three studies showed significant immediate effects for patients with baseline pain score ≥ 4 on 0-10 scale of VAS (Cassileth & Vickers, 2004 & Jane, et. al., 2011) and MPAC (Kutner, et.al, 2008). Pain reduced immediately with 1.87 points decreased on 0-10 pain scale of MPAC, which is clinically significant ($p < 0.0001$) in study of Kutner et. al. (2008). A difference of 1.6 to 2.2 points ($p < 0.00$) on 0-10 pain scale of VAS was reported immediately after massage therapy in three different time points (Jane et. al., 2011).

- *Short-term effect on pain control*

Short-term effect in pain reduction was measured at 10-20 minutes (Grealish, Lomasney & Whiteman, 2000; Jane, et. al., 2011) and 2-5 hours (Cassileth & Vickers, 2004) after massage therapy. There were 40.2% (95% CI) and 47.8% (95% CI) pain reduction among patients experienced mild pain and with pain score ≥ 4 in VAS 0-10 scales respectively (Cassileth & Vickers, 2004). Pain also decreased significantly among patients at 20 minutes

($p=0.0001$) in the study of Grealish, Lomasney & Whiteman after using foot massage only (2000).

- *Long-term effect on pain control*

Persisting benefits over 48 hours only observed in outpatients who received massage therapy at home (Cassileth & Vickers, 2004). There was no evidence showed any longer-term effect of massage among inpatients. Although the study of Jane (2011) demonstrated a longer-term improvement in pain after massage, the beneficial effect of massage in pain reduction decreased from 40% immediately after massage therapy to 35% after 16-18 hours of massage therapy. Moreover, there was no significant difference in pain intensity between massage group and control group in the study of Kutner (2008) after one week follow-up. The use of simple touch as the control condition in Kutner's study, which is also considered to have healing purpose, appeared to have beneficial effect that is similar to massage over time. In addition, statistically non-significant long-term effect of massage was reported ($p>0.26$) in the remaining three studies (Grealish et. al., 2000; Toth et. al., 2013; Wilkie et. al., 2000). Therefore, longer term effects of massage cannot be concluded.

2.4 Data Synthesis

The effects of massage therapy on different duration were measured, in which massage was showed to have immediate relief in pain intensity significantly in all six studies. However, short-term and long-term effects in pain relief were not prominent. The beneficial effect of massage in pain was reduced gradually when time passed. Based on the findings from the identified studies, massage was believed to be suitable for all types of cancer even with bony metastasis. After retrieving data from all six studies, recommendations regarding the use of massage therapy in pain control among advanced cancer patients are synthesized as follow.

Informed consent

Although massage therapy is a non-invasive procedure, the needs of informed consent before initiating massage therapy were mentioned in five out of six studies (Grealish, Lomasney & Whiteman, 2000; Kutner, et.al., 2008; Jane, et. al., 2011; Toth, et. al., 2013 & Wilkie, et. al., 2000). It is essential to obtain consent from patients because of the advanced nature of diseases.

Assessment before initiating massage therapy

All studies highlighted conditions that are contradictory to massage therapy. Patients' condition such as skin integrity, platelet counts (Jane et. al., 2011; Kutner et. al., 2008; Toth et. al., 2013) and site of metastasis (Toth et.al., 2013) should be assessed before massage therapy.

Massage should be avoided over body areas with known recent inflammation or infection, wound or bruise, known unstable spinal cord and metastatic sites (Jane et. al., 2011; Kutner et. al., 2008 & Toth et.al., 2013).

Massage method

Swedish massage also referred to as classical massage was used as the main massage type in all reviewed studies. Standardized massage techniques and the use of acupressure points should be clearly mentioned in the proposed guideline. However, massaged body area, pressure intensity, rhythm, rate/frequency of each massage stroke should be personalize and modified according to patients' acceptability, skin fragility/edema and postural limitation (Jane, et. al., 2011 & Kutner, et.al., 2008).

Massage duration

Although longer term effect of massage therapy was not statistically significant, an average 30 to 45 minutes standard massage therapy was showed to have immediate and short-term effects in pain improvements, particularly for those with pain score higher than or equal to 4 in VAS 0-10 scale (Cassileth & Vickers, 2004; Kutner et.al., 2008; Jane et. al., 2011; Toth et. al., 2013; Wilkie et.al., 2000). In view of this, massage therapy in average duration of 30 minutes is considered for the therapeutic effects of massage in pain relief while not disturbing routine function of ward setting.

Time interval for massage therapy

Massage was suggested to perform in the evening time with few interruptions of medical related procedures. Regarding the frequency of massage therapy, four out of six studies (Grealish, Lomasney & Whiteman, 2000; Jane et. al., 2011; Toth et. al., 2013; Wilkie et.al.,2000) indicated massage was provided in two to three times per week while the remaining two (Cassileth & Vickers, 2004; Kutner et.al., 2008) suggested massage could be provided as patients' request. In the study of Cassileth & Vickers (2004), the effect of massage therapy was showed to increase ($p = 0.001$) for each additional treatment. Therefore, in order to maximize patients' satisfaction but not interrupt ward routine activities, daily massage therapy can be considered if patient request and with pain score above 4 in VAS.

Patients positioning

A comfortable position for massage therapy is important for patients due to their weakness and advanced stage of diseases. Supine, prone and side-lying positions were the most preferable in majority cancer patients (Jane, et. al., 2011& Kutner, et.al., 2008).

Positioning patients to a comfort posture before massage can enhance relaxation and therefore optimize therapeutic effects of massage in pain relief.

Swedish massage training for nurses

Massage was provided by either licensed massage therapists (Cassileth & Vickers, 2004; Kutner et.al., 2008; Toth et. al., 2013 & Wilkie et.al.,2000) or well-trained registered nurses

(Grealish, Lomasney & Whiteman, 2000 & Jane, et. al., 2011) in reviewed studies. This suggested that nurses with optimal training in Swedish massage are feasible in providing massage therapy for advanced cancer patients. Moreover nurses are the most ideal person to provide massage therapy in clinical setting as they are experience enough in taking care of patients with various disease stages. They are more competent in managing sudden physical deterioration of advanced cancer patients.

Education for family caregivers

Massage was provided at home environment in three out of six studies (Cassileth & Vickers, 2004; Toth et.al., 2013 & Wilkie et.al, 2000). Patients experienced persisting benefit even after 24 hours of massage therapy which provided at home (Cassileth & Vickers, 2004). The main reason may be due to a longer massage provided, more comfortable and less interruption at home environment. Besides, Swedish massage is the baseline training in most massage schools (Collinge, Macdonald & Walton, 2012) and it is relatively easy to learn. Through involvement and education of family caregivers by experienced nurses, massage is feasible to provide in home setting.

2.5 Conclusion

The findings from six reviewed studies examined the efficacy of massage therapy in reducing pain and provided evidence for the potential beneficial effect of massage therapy on patients with metastatic cancer. Massage therapy was suggested as an adjunctive therapy for

the management of pain due to its lesser adverse effect. Adverse effects were only showed as infrequent, similar in both intervention and control group, and did not appear to be study-related (Kutner et al., 2008; Toth et al., 2013). No adverse effects directly related to massage therapy were reported from all reviewed studies. Therefore massage therapy, besides the usual pharmacological method, is considered as effective in decreasing pain among patients with metastatic cancer.

Chapter 3: Translation and Application

The impacts of cancer pain and evidence supporting a non-pharmacological intervention in relieving pain among metastatic cancer patients have been explored in the previous chapters. In the following chapter, the implementation potential of proposed innovation will be assessed. The evidence will then be translated into practice and an evidenced-based guideline will be developed.

3.1 Implementation Potential

3.1.1 Target Setting

The target setting is medical ward of a Catholic private hospital in Hong Kong. The medical wards of this private hospital can be divided into general and triage wards. There are 5 general medical wards and 1 triage ward. Each medical ward has 24 beds, while triage ward has only 17 beds including 4 isolation rooms. All medical wards are mixed wards. Patients are admitted to different wards regarding to their age, condition as well as the room classification.

3.1.2 Target Audience

The target audiences are adult cancer patients who experience advanced cancer-related pain from various types of cancer in the target setting.

3.1.3 Transferability of Findings

The characteristics of target population between the reviewed studies and target setting were compared in order to assess the transferability of the evidence-based innovation into clinical

practice. The patients in the reviewed studies were between 18 to 88 years of age, with mean age ranged from 50 to 65 years old. In target setting, all patients are at age 18 years or above and most of them are at 60 to 80 of age. Moreover, patients in reviewed studies suffered lung, breast, pancreas, prostate and colorectal cancers. All were diagnosed with metastases. The types and stage of diagnosed cancers are similar to the target audience. All patients participated in the studies hospitalized and experienced certain level of cancer-associated pain, which are similar to those in the target setting.

Despite official statistic regarding the number of target population is limited, it is estimated that there are 34 new cases admitted for cancer-associated complication per month in the target setting. It is estimated that 367 patients may suffer cancer-related pain per year. Therefore, a large population will benefit from the new innovation if massage therapy is going to implement in the target setting.

The philosophy of care of the target hospital is providing loving, dedicated and high quality services to patients. The use of massage therapy aims at reducing pain and improving quality of life, which fulfill the mission and goal of the target hospital. Introducing a non-pharmacological innovation is greatly beneficial to metastatic cancer patients, not only reduce pain physically, but also minimize emotional distress induced by cancer and maximize individual functional ability. A high quality patient-centered nursing care can therefore be provided.

Duration of implementing massage therapy (MT) in the target hospital will last for 27

weeks, including 2 weeks in setting up a committee for planning and launching the program, 2 weeks for staff training, 4 weeks for running a pilot trial, 1 week for revising the protocol after the trial, and 16 weeks for implementing MT. Evaluation for the entire innovation will last for 2 weeks after the implementation period. A 27-week implementation period is workable and appropriate for transferring an evidence-based practice into the clinical setting.

3.1.4 Feasibility of the Innovation

Massage therapy is a non-invasive and safe treatment which requires clinical decision and judgment of nurses in the target setting. Nurses are responsible in administration, modification and termination of the massage therapy according to their knowledge and patient's condition. In order to provide high quality nursing care, hospital Managing Director, General Manager (GM) of nursing division and Senior Nursing Officers in the hospitals agree to support practice that is evidence-based.

Barriers such as attitude among nursing staffs and patients in response to the new innovation may affect the feasibility of implementation. Patients may concern about the safety and effectiveness of massage for advanced cancer, while the use of massage in pain control may increase nurses' workload. There are three massage sessions per week for each patient, and each massage session will take 30 minutes for nurse to complete the entire procedure. The time required for massage therapy is much longer than providing conventional pharmacological intervention. Although, majority nurses agree complementary treatment likes massage does help

in relieving unsolved cancer pain and cause less unpleasant side effects, nurses may be resistant to allocate extra time in providing massage in a limit of manpower per shift. Consensus and acceptance among nursing staff and patients will be enhanced if detail of massage therapy is clearly explained.

Resistance from administrative level on the use of massage therapy would be low. Since the target hospital is now under reform and redevelopment in order to provide excellence service to the public. Evidence-based practice that can promote high quality patients care will be supported by administrators. The massage practice not only improves overall healthcare quality, but also promotes hospital reputation in the community.

In order to improve staff compliance and the standard of nursing care, 4 sessions of 1.5 hour-training will be offered to 12 nurses. The training program will provide basic concept on Swedish massage maneuvers and explain the standard use of massage therapy to nurses. MT will be a cost-effective innovation once nursing staff are properly trained. Besides, visual analog scale in 0-10 scale will be used to measure pain level before and after massage innovation, where 0 = no pain and 10 = most pain. This numeric rating scale is already well-established and currently in use in the target hospital.

3.1.5 Cost-benefit analysis of the innovation

Risks and potential benefits, implementation costs include both material and nonmaterial costs of the proposed innovation will be discussed in the following paragraphs.

Risks of implementation of massage therapy

Since massage therapy is still not commonly used as an adjunctive intervention in local hospitals and insufficient knowledge on massage therapy among cancer patients, patients may be reluctant to try massage as complementary therapy for pain control. There was a common misunderstanding that massage may accelerate tumor growth and metastasis (Falkensteiner et al., 2011; Liu & Fawcett, 2007). In fact, there was no evidence that showed that massage could promote cancer metastasis (Joske et al., 2006, as cited in Liu & Fawcett, 2007). Although patients may be exposed to certain adverse events such as bruising, swelling of massaged muscles, dislodging of thromboses and pulmonary emboli in patients with deep vein thrombosis (Liu & Fawcett, 2007), no serious adverse events of massage were reported from the reviewed studies. Therefore, caution and pre-treatment assessment should be taken for patients who have conditions contraindicated to massage. Modification of massage techniques is also required for patients with bony metastases or coagulation problems in order to avoid the occurrence of potential adverse events. Screening for contraindications and careful assessment will be reinforced for nurses during the training sessions in order to minimize the risk of MT.

Potential benefits result from implementation of massage therapy

Massage provides a positive effect on alleviating pain, encouraging relaxation and promoting quality of life among advanced cancer patients. Massage helps to improve individual well-being by interrupting the cycle of physical and emotional distress that result from cancer pain (Kutner,

et. al., 2008). The use of massage provides similar analgesic effect (Wilkie, et. al., 2000) but does not produce side effects that commonly occur with medication. Using MT as adjunctive to conventional care is effectively decrease pain, promote relaxation and enhance patients' satisfaction.

On the other hand, nurses' satisfaction can be enhanced because they have a higher autonomy to make judgment for the application of massage to patients after obtaining the massage qualification. Better communication and rapport with patients can be established through provision of massage which is an effective way that nurses deliver a caring message to their patients. Moreover, an effective and evidence-based practice can further enhance the standard of care and build up institutional reputation in the community.

Risks of maintaining current practices

Systemic pharmacologic intervention likes opioids are typically used in relieving pain among cancer patients in the target setting. However the relatively high cost and its side effects may limit the usage. Patients suffer from cancer-related pain continue to be undertreated due to the fear of addiction or adverse side effects of opioids such as respiratory distress, nausea, vomiting and constipation (Gatlin & Schulmeister, 2007). This results in prolonged hospitalization, increase medical expenses and poor quality of life.

Costs for implementing massage therapy

Cost is an important determinant when implementing a new innovation. Training on massage therapy will be provided to nurses before implementation. Two senior nurses will be allocated from each medical ward, and therefore total twelve nurses will participate in 4 training sessions. Training will be provided by a resident physician who was trained in massage therapy and obtained the massage therapist qualification. The resident physician will serve as key trainer and consultant in massage therapy. All nurses will attend 4 training sessions and each session will last for 1.5 hours. Certificate will be given to nurses who achieve 80% attendance and pass the test at the end of the session. Only certified nurses will provide MT in target settings. 6 copies DVDs on massage therapy will be distributed to target settings for supplementary information for nurses. The estimated total training cost includes the cost of DVDs and lecture notes will be approximately \$18,818 (Appendix 6). The estimated implementation costs for massage therapy will be \$ 18,838 which including the training cost and information sheets on MT for patients (Appendix 7). A 30-minute full body massage will be provided to each eligible patient, while unscented massage oil is optional with respect to patient's preference and nurse's adjustment. Individual massage oil will be purchased to patient upon use. The cost of the massage oil is \$100/bottle and each patient may require 2 bottles massage oil for 3 massage sessions. The estimated costs for using MT for each patient will be \$507.5/week, while the costs for opioid intervention are \$5,488/week for patient who requires around-the-clock (Q4H) opioid

analgesic for relieving moderate to severe pain (Appendix 8). The estimated cost saved will be around \$2,236.5/week for patients using MT as adjunctive intervention as the use of opioid intervention may be reduced, e.g. 3 times/day (Appendix 9).

Besides the material costs, staff morale and workload should be carefully considered for implementing a new innovation. At the initial phase of the implementation, nurses may feel stress and frustrated because they may not be competent with the new skill required for the massage procedure. The stress may influence nurse's daily performance and hence decrease their productivity. On the other hand, massage treatment may increase nurse's workload since it is a time-consuming procedure. This may affect team-spirit and morale among nurses. Therefore, support from nursing officer and colleagues are crucial during implementation process. Through case sharing in briefing session between shifts in the first month of implementation can strengthen up staff morality and work competency.

To conclude, massage therapy has a high transferability, feasibility and cost-benefit ratio. This evidence-based practice should be considered to implement among the target population for their greatest benefit.

3.2 Evidence-based guideline for the use of massage therapy in pain control for advanced cancer patients

Based on the retrieved evidence from the systematic review and analysis, guideline for the use of massage therapy in advanced cancer patients is developed.

Aim

The purpose of the protocol is to guide nurses on the use of massage therapy in reducing pain intensity for patients with advanced cancers during hospitalization.

Objectives

The objectives of this protocol are to:

1. Formulate evidence-based instructions on the use of massage therapy
2. Decrease pain, increase circulation and promote physiological relaxation through full-body massage
3. Optimize pain management by a safe and cost-effective practice

Target Population

Massage therapy will be provided to adult patients who admitted to the medical wards with diagnosed of metastatic cancers and suffer from cancer-related pain with score ≥ 4 in VAS, 0-10 scale. However, patients have contraindications to massage therapy as follow should be excluded:

- Low platelet count ($\leq 10,000/\text{mm}^3$) or on anticoagulant therapy

- Active spinal cord compression syndrome, e.g back pain, paralysis of limbs/decreased sensation below the level of compression, urinary or fecal incontinence
- Deep vein thrombosis
- Body areas with inflammation, infection, identified open wound or bruise from any part of body
- Have surgery on the day of massage therapy and within 5 days post-operation

Keys to the Quality of Recommendation

The levels of evidence were graded according to the Scottish Intercollegiate Guidelines Network (SIGN, 2008), while grades of recommendation are rated regarding to the level of evidence of the retrieved studies and the applicability to the target population.

The recommendation guideline consists:

1. Assessment
2. Massage Intervention
3. Evaluation

ASSESSMENT

Recommendation 1

The general condition of patients and significant observation related to skin integrity, edema, wound, bruise, ports, catheters, or tubes should be assessed before each massage session. (*Grade of recommendation: A*)

Specific precautions should be followed before initiating massage therapy due to the advanced stage of cancer. Patient's conditions that contraindicate to massage should be avoided, including known inflammation, infection, unstable spinal cord and metastatic sites. (Kutner et al., 2008) (1++); (Jane et. al., 2011; Toth et. al., 2013) (1+)

Recommendation 2

Nurses should assess patients' ability to turn and their most comfortable position before massage. (*Grade of recommendation: A*)

Patients have to position themselves comfortably in their beds (Greaslish, Lomasney & Whiteman, 2000) (2++). A comfort position can enhance relaxation and maximize massage therapeutic effect in relieving pain. The most comfortable position was lying supine, prone and lateral as reported in studies (Jane et.al., 2011; Kutner et.al., 2008) (1+; 1++). Massage should also be modified in patients with postural limitations (Kutner et.al., 2008) (1++).

MASSAGE INTERVENTION

Recommendation 3

Obtaining informed consent from patients before massage intervention is necessary.

(Grade of recommendation: A)

Due to the complexity of metastatic cancers, patients may decline massage intervention because of the safety concern (Jane et. al., 2011) (1+), lack of interest or refuse to participate (Wilkie et. al., 2000) (1+). Participation for the massage intervention should be voluntary (Greaslish, Lomasney & Whiteman, 2000) (2++).

Recommendation 4

Patients are advised to have as minimum clothing as possible during massage treatment.

(Grade of recommendation: A)

Massage is a direct hands-on and skin-to-skin manipulation on individual body surface. It can be given over clothing with pajamas, light clothing (Kutner et. al., 2008) (1++) or even unclothed (Wilkie et. al., 2000) (1+).

Recommendation 5

Unscented massage lotion or baby oils can be used on all skin surfaces for the massage session. (Grade of recommendation: A)

The use of unscented oil is mainly to facilitate the massage movement (Greaslish, Lomasney & Whiteman, 2000) (2++) and serves as skin lubricant (Jane et. al., 2011; Wilkie et.

al., 2000) (1+). Patients may selectively use unscented oil as regarding to their preference.

Recommendation 6

Each massage should include the following selected strokes for a designate amount of time:

(Grade of recommendation: A)

1. **Effleurage.** Smooth, rhythmic, gliding stroke conforming to the contours of the body by using nurse's whole palm or tips of fingers, 5 to 10 times.
2. **Light petrissage.** Rolling, squeezing and kneading of patients' fingers and thumb lightly and slowly by using nurse's tips of thumbs or three middle fingers, 5 to 10 times.
3. **Nerve stroke.** Very light brushing of skin with nurse's fingers or full hand, optional or 3 to 5 times.
4. **Light compression.** Fingertips are used to lightly compress selected areas of tension using only mild to moderate pressure. The selected areas can be the plantar surfaces, shoulders, palms and possibly to the sacral area, for 0 to 15 seconds duration.
5. **Myofascial trigger point release.** Concentrated finger pressure to painful localized areas or muscles to relieve spasm and pain, optional or 0 to 20 seconds.

(Greaslish, Lomasney & Whiteman, 2000; Jane et. al., 2009 & 2011; Kutner et. al., 2008;

Wilkie et.al., 2000) (2++; 1+; 1++; 1+)

Recommendation 7

Massage to head, neck, back, gluteus muscles and the four extremities should be involved in each session. (*Grade of recommendation: A*)

The most frequently massaged areas of body were the back or upper back in the reviewed studies (Jane et. al., 2011; Kutner et. al., 2008; Toth et. al., 2013; Wilkie et.al., 2000) (1+; 1++; 1+; 1+), while head and neck were the sequent common massaged areas (Jane et. al., 2011 & Toth et. al., 2013) (1+). Gluteus muscles, arms, hands, lower legs (Jane et. al., 2011; Wilkie et.al., 2000) (1+) and feet (Greaslish, Lomasney & Whiteman, 2000) (2++) were also the frequently massaged areas.

Recommendation 8

At least three sessions of massage therapy for 20-30 minutes duration should be provided weekly during patient hospitalization. (*Grade of recommendation: A*)

A significant improvement in pain was noted after three sessions of 30-minute massage therapy. Small and medium effect size for pain intensity average score was 0.47 and 0.97 (Kutner et. al., 2008) (1++). The effect size for pretest and posttest of pain intensity was also noted as 0.97 in 20-minutes interval after massage therapy (Jane et. al., 2011) (1+).

Recommendation 9

Each massage session are advised to deliver in the evenings before the administration of regular analgesics. (*Grade of recommendation: A*)

Evenings are comparatively quiet with few interruptions for medically related procedures within a day. Patients mostly preferred massage in the evening when distraction and interruptions were less likely (Greaslish, Lomasney & Whiteman, 2000; Jane et. al., 2011) (2++; 1+). It is certainly that the therapeutic effect in pain improvement is only due to massage when delivering before analgesic administration (Jane et. al., 2011) (1+).

EVALUATION

Recommendation 10

Baseline pain intensity should be collected before massage intervention. (*Grade of recommendation: A*)

Pre-test pain intensity was collected as baseline in all reviewed studies (Cassileth & Vickers, 2004; Greaslish, Lomasney & Whiteman, 2000; Jane et. al., 2011; Kutner et.al., 2008;Toth et. al., 2013; Wilkie et.al., 2000) (2++; 2++; 1+; 1++;1+;1+). It is essential to obtain the baseline score in order to compare the changes in pain after the intervention.

Recommendation 11

The Brief Pain Inventory (BPI) short form can be used to assess the effectiveness of MT. (*Grade of recommendation: A*)

BPI has been used as outcome measure in patients with advanced cancer (Kutner et.al., 2008; Toth et.al., 2013) (1++; 1+). The location of pain, average levels of pain within the past 24 hours and the current levels of pain are measured.

Chapter 4: Implementation Plan

In this chapter, an implementation plan and evaluation plan will be discussed after an evidence-based guideline has been developed in the previous chapter. The implementation plan for the guideline includes communication plan with potential stakeholders and a pilot study trial.

4.1 Communication plan

The communication plan starts with identification of the important stakeholders of the guideline, and then describes the process of communication with corresponding stakeholders in order to obtain supports for the proposed innovation.

4.1.1 Identification of Stakeholders

The key stakeholders are identified according to three levels, the users of the guidelines, the management of the department and the administration of the hospital.

Users of the guideline

The users of the guideline mainly are the nurses working in the medical units and cancer patients who experience pain. Nurses are the one who will provide the proposed intervention to advanced cancer patients in their settings, while patients are the target audience of the proposed intervention. Besides nurses, physicians in the target settings are also included as they are the responsible person to prescribe the proposed intervention. Therefore, both nurses and physicians in the target settings are the key persons required to have the optimal understanding for the entire proposed innovation. The details of the innovation should also be explained clearly to

patients who involve in the intervention.

Management of the department

Nursing Officers of the medical wards and Senior Nursing Officers who supervise all medical units are the major decision makers for supporting and approving the implementation of the proposed innovation. They are the key persons in developing, formulating and implementing policy and standards within the nursing scope. Therefore, adequate support from these nursing leaders is essential in initiating a change and implementing a new innovation.

Administration of the hospital

In order to obtain an approval for the implementation of innovation, supports from General Manager (GM) and hospital Managing Director are crucial because they are the key persons to make the final decision on hospital policy. The proposed innovation must obtain their approval before implementation.

4.1.2 Communication plan with stakeholders

To initiate an innovation, effective communication is essential in order to gain adequate collaboration and supports from nursing leaders and administrators.

Communication in initiating the change

First of all, Nursing Officer in the target ward will be the first person to be approached. She has a higher authority in policy that related to nursing practice. An individual meeting will be held in ward, the content of the communication will focus on introducing the proposed

innovation and explaining the significance of massage in pain improvement. Aims of the innovation, details of the guideline, expected barriers and solutions for the implementation plan will be discussed in the meeting. Evidence from the literature will be explained and information like cost-benefit of the proposed innovation will be presented by using tables and charts.

After obtaining support from Nursing Officer in target setting, the next step is to communicate with Managing Director, General Manager and Senior Nursing Officers in the management and administrative level. A formal group meeting will be arranged with a well-organized written proposal and powerpoint. The proposal will include the aim and objective of the guideline, evidence on the effectiveness of massage in pain relief among cancer patients, the benefit of the innovation on hospital aspect, the implementation potential and detailed schedule for the entire innovation. Comparison on current practice and the innovation, the need of change as well as the program budget will be discussed and explained in details.

Communication in guiding the change

After getting approval for implementing the innovation by Managing Director and administrators, a Communication and Quality Management Committee for massage therapy on cancer patients will be formed for planning and launching the innovation. One administrator, two Nursing Officers, one resident physician with massage therapist license and two senior frontline nurses will be recruited to the Committee. Meetings will be held for discussing and preparing implementation as well as launching training sessions on massage therapy for nurses.

In-charged nurses in medical units will be announced the proposed innovation through internal e-mail. They will be informed for the plan and the content of the innovation, so that they can facilitate the implementation process in target setting. Electronic copy of guideline protocol will be distributed to in-charged nurses after reviewing by the Committee. In-charged nurses will be instructed to read through the protocol first and share with nursing staff in target setting in briefing session of shifts. Meanwhile, memo and circular for the innovation with detailed time schedule will be distributed among nurses in the target setting to read and sign. The progress of innovation will be announced through internal E-newsletter to all nurses and physicians in the target hospital.

Communication in sustaining the change

Briefing and training of massage therapy will be provided to nurses in medical units in different period of time. Nursing Officers in medical units will be invited to arrange nurses to attend the training sessions. The resident physician will serve the key person for any enquiry of massage therapy during training sessions. 6 DVDs with detailed descriptions for the theory of massage therapy and application of massage maneuvers will be distributed for reference. Skills and knowledge will be assessed by a competent test at the end of the training sessions in order to ensure nurse's competency on the new innovation. Revisions on the new guideline will be made in a monthly meeting that held by the Communication and Quality Management Committee.

4.2 Pilot study plan

A small scale preliminary study will be performed in order to assess the feasibility of the innovation before implementation. It provides a framework for proposed guideline and assists in identification of logistic problems which might encounter using proposed innovation. A pilot study of the proposed innovation will be carried out to a small number of cancer patients in medical units, the data collected from the study can help to determine whether the proposed guideline is realistic and workable. Modification of the guideline and budget planning for a larger-scaled implementation are necessary after the pilot study.

The objectives of this pilot study are:

- i) To determine the feasibility of implementing the guideline
- ii) To assess the clinical effectiveness of the innovation
- iii) To identify any difficulties might occur during implementation
- iv) To assess nurses compliance of the guideline
- v) To assess the level of satisfaction among nurses and patients about the innovation

Study setting, target population and intervention

The study will be conducted in target medical units by the nurses who completed the training sessions for massage therapy in a 4-week period. During a 4-week period, patients admitted to the medical units will be screened for eligibility. Patients who are i) 18 years old or above and ii) diagnosed with metastasis from all types of cancers and suffering from pain will be recruited to

the study. Convenience sampling will be adopted and it is estimated to recruit thirty patients for this pilot study. Thirty-minute massage will be provided when patients are in pain or at least 3 times per week during patients' hospitalization, while massage modalities and techniques will be based on the proposed guideline.

Ethical consideration

Ethical approval for the innovation will be obtained by the Hospital Ethics Committee. The risks and benefits will be assessed by the Ethics Committee to ensure patients' rights and privacy are protected. Procedure of the innovation and the possible complications will be explained by massage nurses. Information sheets in Chinese or English version will be distributed to eligible patients for details. Written consent from patients will be obtained before initiating the massage therapy. Consent from relatives is also acceptable if patients are not able to sign because of worsen physical condition. Patients will be allowed to terminate the massage at anytime or withdraw from the study if they cannot tolerate the procedure.

Outcome measures

In the pilot study, nurses will assess pain by using the Brief Pain Inventory (BPI) Short Form (Appendix 10). The BPI was developed by the Pain Research Group of the World Health Organization Collaborating Center for Symptom Evaluation and Cancer Care (Kumar, 2011). It has been used as an outcome measure in patients with advanced cancer (Kumar, 2011). The BPI scale will assess the worst, least, average and the current pain levels. The location of pain will

also be assessed using graphic representation of a front and back views of human figure. Both assessment tools are retrieved from the reviewed studies. Nurses will provide complete documentation for all pain-related treatments, including the use of analgesic medication, duration of massages, location of treatments as well as any potential adverse effects from massage. All clinical data will be collected by the Communication and Quality Management Committee for evaluation and revisions of the guideline.

Nursing compliance and patients' satisfaction

Nurses' satisfaction during implementation may greatly affect nursing compliance of the proposed innovation. Since massage therapy is comparatively time-consuming and increased workload may influence nurses' willingness in following the guideline, members of the Communication and Quality Management Committee will then visit the unit once a week during the study period to provide backup and supports to frontline nurses. Nurses who participate in the study will be asked about the difficulties they encountered during the study, comments on any logistic problems, their satisfaction regarding to workload and the treatment. On the other hand, to assess the feasibility and the effectiveness of massage, patients will be asked to report on their satisfaction towards massage treatment using a brief questionnaire (Appendix 11).

Chapter 5: Evaluation Plan

Evaluation is an essential assessment for the implementation of a new innovation. It provides evidence to stakeholders on the achievement of the targeted goal as well as the effectiveness of the innovation. Outcome benefits regarding to patients, healthcare providers and hospital will be discussed as follows.

5.1 Identifying Outcomes

Patient Outcomes

The primary outcome of the innovation is to reduce pain among cancer patients. The patient outcomes therefore determine the effectiveness of the guideline. Baseline and post-treatment pain level will be assessed before and after the intervention in order to compare any significant difference in pain severity. The Brief Pain Inventory Short Form (BPI-short form) (Kumar, 2011) will be used to assess the effectiveness of the massage therapy. Patients' satisfactory on using massage in pain control will be assessed by post-questionnaire. All outcomes will be documented by nurses in medical units. The Communication and Quality Management Committee will then assess and evaluate the data to determine the effectiveness of guideline.

Nurse Outcomes

Skills and knowledge among nurses will directly influence the effectiveness of the guideline. Therefore, skills and knowledge competent tests will be assessed by the Committee

after the training sessions to ensure nurses have optimal knowledge and skills in massage therapy before launching the innovation. Only nurses who pass the tests will be certified and allowed to implement massage therapy on cancer patients. Besides, nursing compliance will be also assessed by the Committee in a weekly visit. Nurses' satisfactory level towards massage therapy will be assessed through a self-reported questionnaire in the last week of the implementation (Appendix 12).

Hospital Outcomes

The costs and utilization of the innovation can greatly affect the operation system of the guideline. The actual costs for the entire innovation will be calculated to control the budget. The utilization of massage therapy and its adverse events should be assessed by the Committee.

5.2 Nature and Number of clients involved

The selection criteria for eligible patients in the evaluation will be similar to those reported in the reviewed studies. The inclusion criteria are i) adults who diagnosed of advanced cancers and ii) with pain score ≥ 4 in VAS, 0-10 scales. For patients who have low platelet count ($\leq 10,000/\text{mm}^3$), active spinal cord compression syndrome, skin lesion, bruise and surgery will be excluded.

The sample size calculation is based on the studies of Jane et.al. (2011) & Kutner et.al. (2008). A two-tailed t-test will be used to determine the reduction in pain level, with alpha value significance level of 0.05 and a power of 80%. 20% drop out rate is allowed. The sample size

required for the evaluation is 34 patients.

5.3 When and How often to take measurements

The innovation will be implemented for sixteen weeks, starting from 1 September 2014. Measurement will take place in different parties, including patients, nurses and hospital. Patients' pain level and pain location (Q1-6 in BPI short-form) will be measured before massage. The measurement on pain level and the degree of pain relief (Q6-9 in BPI short form) will be measured 20-minute after completing the massage treatment. The use of analgesic medication during a week will also be documented. All data will be recorded by nurses. Moreover, patients' satisfaction towards the massage innovation will be measured by questionnaire which can be completed by patients before discharge. On the other hand, nurses' satisfaction on the massage guideline will be measured by self-reported questionnaires which will be distributed during the last week of implementation period. Nurses will be asked for the problems and difficulties they encountered during the implementation and providing suggestions on further improvement for the massage guideline. Both patients and staff questionnaires will be collected by the member of Communication and Quality Management Committee after the implementation period. Measurement on the hospital expense including material and nonmaterial expenses will be evaluated by the Committee during the implementation period. The average time used for providing massage to each patient and the necessity of additional manpower will be also assessed. All clinical and operational data will be collected by the Committee for data analysis.

The analysis process will last for 2 weeks after implementation.

5.4 Data Analysis

Descriptive statistics will be used to analysis patient demographics and pain characteristics. Statistical Package for Social Sciences (SPSS) will be used for data analyses. Outcomes included the severity of pain, use of medication, satisfactory level from patients and nurses will be collected and analyzed. A two-tailed t-test will be performed to test the significance and determine whether the level of pain can be reduced after the implementation.

Effectiveness of innovation

Guideline effectiveness is determined on the basis of the outcomes achievement. The guideline will be considered as effective if the following outcomes are achieved.

Patient clinical outcomes

The effectiveness of the guideline will be determined by comparing the findings in studies and the target setting. According to the figures from studies, the guideline is effective if 80% of patients report a reduction in pain intensity with 2 or more points in numerical 0-10 rating scales after massage intervention (Cassileth & Vickers, 2004; Jane et. al., 2011; Toth et. al., 2013).

Besides pain level, reduction in analgesics used is expected after 3 sessions of MT.

Knowledge and compliance among nurses

Nurse's knowledge and competency on massage intervention can greatly affect their compliance. Skills and knowledge on massage intervention will be assessed after the training.

The training courses are said to be effective if each nurse obtained $\geq 95\%$ achievement in the tests. Moreover, 99% nursing compliance should be achieved for an effective innovation. Nurses' knowledge and skill on massage intervention will be assessed through randomly selected audit during implementation period by members of the Communication and Quality Management Committee.

Patient and nurse satisfactory level

Satisfaction towards massage intervention is a great concern on the effectiveness of the guideline. At least 50% of items in the questionnaires should be rated at score 4 or above (i.e. 4 = agree and 5 = totally agree). Around 70% of patients and nurses should rate for score 4 or above in satisfactory level towards the massage intervention.

The massage innovation will be considered as effective in the target setting if all of the achievements mentioned are made. The evaluation data also provides good evidence on the effectiveness of massage intervention to identified stakeholders.

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Appendix 1

Summary of Bibliographic Database Search Strategy and Results

Search items	Electronic Databases		
	CINAHL via EBSCOhost	PubMed	ProQuest (British Nursing Index &psycINFO)
Search Date	10/8/2013	10/8/2013	10/8/2013
(1) Massage OR massage therapy OR therapeutic massage	770	11109	1556
(2) Cancer OR metastatic cancer OR advanced cancer	29488	2847683	67094
(3) Pain	23166	544958	80432
(1)+(2)+(3)	30	166	63
Limit to clinical trial	15	56	21
Limit to full-body/hand/foot massage and exclude massage listed in exclusion criteria	10	22	12
Total number of articles retrieved after screening of title and abstract	10		
Total number of articles retrieved without overlapping	6		
Articles retrieved from references	0		
Total reviewed articles	6		

Appendix 2:Table of Evidence

Bibliographic citation	Study type	Level of evidence	Patient characteristics	Intervention(s)	Comparison	Length of follow up	Outcome measures	Result
Cassileth& Vickers (2004)	Quasi-experimental, pre& post -intervention, non-randomized study	2++	Patients received integrated medicine therapy with baseline pain score ≥ 4	Standard/ light touch/ foot massage at 20 minutes for inpatients & 60 minutes for outpatients (n= 1290)	Baseline score before massage intervention	2-5 hours & daily (outpatient only) after treatment	Immediate improvement in pain, anxiety, depression & nausea (VAS,0-10)	<p>Immediate effects</p> <p>(1) Mean change in pain -2.9 (SD\pm2.2 ; p = 0.01)</p> <p>(2) Mean change in anxiety -4 (SD\pm2.4; p = 0.01)</p> <p>(3) Mean change in depression -3 (SD\pm2.3; p = 0.01)</p> <p>(4) Mean change in nausea-3.1 (SD\pm2.4; p = 0.01)</p>

VAS: Visual analogue scale 0-10 scale

Bibliographic citation	Study type	Level of evidence	Patient characteristics	Intervention(s)	Comparison	Length of follow up	Outcome measures	Result
Grealish et.al. (2000)	Quasi-experimental, pre& post-intervention, over 3 consecutive nights	2++	Adult patients with mean aged at 58.2 years old, diagnosed with cancer in various type, 32 participants with metastasis	10 minutes foot massage (5 minutes per foot) were applied from the base of toes up the foot & lower leg to the knee on 2 massage sessions (MT1&MT2) (n= 87)	Remain in bed & completed a quiet activity (watched TV or read), data was collected after 20-30 minutes (participants randomly assigned to one of three factors-control sessions)	10-20 minutes after massage	(1) Decreased in reported pain (100mm-VAS with verbal anchor: 0- no pain; 100-worst pain) (2) Relaxation: (100mm-VAS; 0-atpeace;100-very tense)& (Mean HR beat/min)	Immediate effects (1)Change in mean pain <u>Control</u> :-0.874mm (p=0.1943) <u>MT1</u> : -9.8mm (p=0.0001) <u>MT2</u> : -9.4mm (p=0.0001) (2)(i) Change in mean relaxation <u>Control</u> :-2.7mm (p=0.0681) <u>MT1</u> : -22.2 (p=0.0001) <u>MT2</u> : -16.5 (p=0.0001) (ii) Decreased in HR <u>Control</u> : 1.6/min(p=0.023) <u>MT1</u> : 3.7/min(p=0.0001) <u>MT2</u> : 2.7/min (p=0.0069)

Bibliographic citation	Study type	Level of evidence	Patient characteristics	Intervention(s)	Comparison	Length of follow up	Outcome measures	Result
Jane et. al. (2011)	Pretest and posttest 5-day, 2-group, RCT	1+	Taiwanese patient with mean age at 50 years old; radiologically diagnosed with evident bone metastatic via bone scan and experiencing moderate metastatic bone pain with intensity ≥ 4 on 0-10 scale.	45-minute full-body massage for 3 consecutive sessions (n=36)	45-minute social attention intervention provide similar amount of time and attention as MT (n=36)	Every 20 minutes & 16-18 hours after MT in daily basis	<p>Primary: (1) Intervention effect in (PPI-VAS; 0-10 scale)</p> <p>Secondary: (2) Intervention effect in mood status (mood-VAS; 0-10 scale)</p>	<p>Immediate effect (1) Mean change in pain: <u>MT</u>: -2.2;<u>Control</u>: -0.2 (p<0.01) (2) Mean change in mood: <u>MT</u>: -9.6;<u>Control</u>: -0.1 (p<0.01)</p> <p>Long-term effect (1) Mean change in pain: <u>MT</u>: -1.6;<u>Control</u>: -0.2 (p=0.01) (2) Mean change in mood: <u>MT</u>: -2.8;<u>Control</u>: -1 (p=0.36)</p>

PPI-VAS: Present pain intensity using a vertical visual analogue scale 0-10 scale; MT: Massage Therapy

Bibliographic citation	Study type	Level of evidence	Patient characteristics	Intervention(s)	Comparison	Length of follow up	Outcome measures	Result
Kutner et.al. (2008)	Prospective, 2-group, single-blind RCT	1++	Adults at mean age of 65 years old, with advanced cancer (included lung, breast, pancreas, colorectal & prostate in stage III or IV or bony metastases), pain intensity ≥ 4 on 0-10 scale	Six 30-minute full-body massages over two weeks (n=188)	Six session of simple touch, with placement of both hands on participant for 3 minutes at specific locations bilaterally (n=192)	7 days	<p>Primary</p> <p>(1) Immediate change in pain(MPAC)</p> <p>(2) Sustained change in pain (BPI)</p> <p>Secondary</p> <p>(1) Immediate change in mood (MPAC)</p>	<p>Immediate effect</p> <p>(1) Mean change in pain (MPAC): -1.87(p< 0.0001)</p> <p>(2) Mean change in mood (MPAC): 1.58 (p< 0.0001)</p> <p>Sustained effect</p> <p>(1) Mean change in pain (BPI): -0.33 (p=0.66)</p>

MPAC: Memorial Pain Assessment Card 0-10 scale

BPI: Brief Pain Inventory 0-10 scale

CI: Confidence Interval

Bibliographic citation	Study type	Level of evidence	Patient characteristics	Intervention(s)	Comparison	Length of follow up	Outcome measures	Result
Toth et. al.(2013)	Pre- & post intervention, RCT	1+	Patients at mean age of 55.1 years old with metastatic cancer in all type	3 visits on 15-45 minutes Swedish and non-Swedish massage each over first week (n=20)	(1) 15-45 minutes no-touch intervention by using distraction (n=10) (2) Usual care control group (n=9)	7 days and 30 days after enrollment	(1) Pre & post-treatment change in pain level (VAS; 0-10 scale) (2) Pre & post-treatment change in anxiety (VAS; 0-10 scale)	Immediate effect (1) Mean change in pain <u>MT</u> : -1.4 <u>Control</u> : -0.5 (p =0.04) (2) Mean change in anxiety <u>MT</u> : -2.0 <u>Control</u> : -1.7 (p = 0.72) No change in pain/anxiety in 7 or 30 days follow-ups

Bibliographic citation	Study type	Level of evidence	Patient characteristics	Intervention(s)	Comparison	Length of follow up	Outcome measures	Result
Wilkie et al. (2000)	Pretest and posttest, 3 weeks, randomized controlled pilot study	1+	Adult patients with mean age 63 years had pain associated with lung, breast, prostate, colorectal or other types of cancers	30-45 minutes of full body massage therapy twice a week over a period of two weeks (n=15)	Usual hospice care (n=14)	Every 7 days after the first visit	(1) Reduced average pain intensity (PAT or SNVR)	<p>Immediate effect</p> <p>(1) Mean change of pain intensity <u>MT</u>: -2(p <0.05)</p> <p>Long term effect</p> <p>(1) Mean change of pain intensity <u>MT</u>: -1 (p>0.26) <u>Control</u>: -0.4 (p>0.49)</p>

PAT: agency's Pain Assessment Tool 0-10 scale

SNVR: Skilled Nursing Visit Report form 0-10 scale

Appendix 3: Appraisal Checklists

SIGN Methodology Checklist 2: Controlled Trails		
Study identification (Include author, title, year of publication, journal title, pages)		
Cassileth, B.R., & Vickers, A.J. (2004) Massage Therapy for Symptom Control: Outcome Study at a Major Cancer Center. <i>Journal of Pain and Symptom Management</i> , 28(3), 244-249.		
SECTION 1: INTERNAL VALIDITY		
<i>In a well conducted RCT study...</i>		Does this study do it?
1.1	The study addresses an appropriate and clearly focused question.	Yes
1.2	The assignment of subjects to treatment groups is randomized.	No Quasi-experimental, pre & posttest study design was used
1.3	An adequate concealment method is used.	
1.4	Subjects and investigators are kept 'blind' about treatment allocation.	
1.5	The treatment and control groups are similar at the start of the trial.	Not addressed. It did not reported and mentioned difference between groups
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?	No participants dropout from the study before it completed
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).	Yes
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Yes. Inpatients and outpatients from different hospitals
SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimise bias?	Acceptable (+). Selection bias may interfere with the study outcome due to

		perceived benefit of massage therapy.
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 study sample size was large but without randomization. Recruitment was mainly from referral by health professional or some were self- and family referrals.
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	Yes, majority of participants were recruited from a cancer center and experienced certain level of cancer pain
2.4	The study not only showed there were immediate improvement in symptom scores (decreased in pain and anxiety) following massage therapy, but also provided evidence that Swedish and light touch massage were superior to foot massage in both inpatients and outpatients participants. Persisting benefit was experienced by outpatients across 48 hours of study, suggesting massage may have long-term effects in symptom control.	

SIGN Methodology Checklist 2: Controlled Trails		
Study identification (Include author, title, year of publication, journal title, pages) Grealish, L., Lomasney, A. & Whiteman, B. (2000). Foot Massage, A Nursing Intervention to Modify the Distressing Symptoms of Pain & Nausea in Patients Hospitalized with cancer. <i>Cancer Nursing</i> , 23(3), 237-243.		
SECTION 1: INTERNAL VALIDITY		
In a well conducted RCT study...		Does this study do it?
1.1	The study addresses an appropriate and clearly focused question.	Yes
1.2	The assignment of subjects to treatment groups is randomized.	No Quasi-experimental, pre & posttest study design was used
1.3	An adequate concealment method is used.	
1.4	Subjects and investigators are kept 'blind' about treatment allocation.	
1.5	The treatment and control groups are similar at the start of the trial.	Yes
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?	No participants dropout from the study before it completed
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).	Yes
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 minimise bias?	Acceptable (+).
2.2	Taking into account clinical considerations, your evaluation of the methodology used, and the statistical	Yes. Sample size was calculated to achieve a

	power of the study, are you certain that the overall effect is due to the study intervention?	power of 0.8 and it was large enough
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	Yes. Only foot massage was studied that may not totally reflect the effectiveness of massage therapy in relieving pain if apply to other body sites.
2.4	<p>The study showed significant evidence to support foot massage had significant effect on the symptom of pain that was a direct result of relaxation induced by foot massage. This study only reported an immediate effect in pain control, there was no conclusive effect on a lasting effect of relaxation and symptom relief by foot massage.</p> <p>Involvement of family members to perform foot massage for their loved one was encouraged by the author.</p>	

SIGN		Methodology Checklist 2: Controlled Trails
Study identification <i>(Include author, title, year of publication, journal title, pages)</i> Jane, S.W., Chen, S.L., Wilkie, D.J., Lin, Y.C., Foreman, S.W., Beaton, R.D., Fan, J.Y., Lu, M.Y., Wang, Y.Y., Lin, Y.H.,& Liao, M.N. (2011). Effects of massage on pain, mood status, relaxation, and sleep in Taiwanese patients with metastatic bone pain: A randomized clinical trial. <i>PAIN</i> . 2432-2442.		
SECTION 1: INTERNAL VALIDITY		
<i>In a well conducted RCT study...</i>		Does this study do it?
1.1	The study addresses an appropriate and clearly focused question.	Yes
1.2	The assignment of subjects to treatment groups is randomized.	Yes. Randomization sequence were generated by a computerized minimization program
1.3	An adequate concealment method is used.	Yes
1.4	Subjects and investigators are kept 'blind' about treatment allocation.	No. Project coordinator, participants and interveners were not blinded
1.5	The treatment and control groups are similar at the start of the trial.	Yes
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 subjects completed only T1 session of intervention (3 in social attention, 2 in Massage therapy) Dropped out rate = $5/72 = 7\%$
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).	Yes
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Yes

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1	How well was the study done to minimise bias?	High quality (++) Majority of criteria met
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 statistical power for pain intensity (key outcome for guideline) is 99% and effect size is 0.97. $P \leq 0.001$ at each time point of intervention on pain intensity.
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	Yes, especially when considering bone metastasis.
2.4	Massage therapy outcomes showed significant improvements in pain, mood and muscle relaxation. Among all, the reduction in pain with massage is both statistically and clinically meaningful and effect lasts for at least 16-18 hours post-intervention. Although the sample size not large, the study already showed the beneficial effect of massage therapy for bony metastasis patients. The study also suggested the optimal duration of massage therapy which is essential in designing a guideline.	

SIGN		Methodology Checklist 2: Controlled Trails
Study identification <i>(Include author, title, year of publication, journal title, pages)</i> Kutner, J.S., Smith, M.C., Corbin, J., Hemphill, L., Benton, K., Mellis, B.K., Beaty, B., Felton, S., & Yamashita, T.E. (2008). Massage Therapy vs. Simple Touch to Improve Pain and Mood in Patients with Advanced Cancer: A Randomized Trial. <i>Ann Intern Med.</i> 149(6), 369-379.		
SECTION 1: INTERNAL VALIDITY		
<i>In a well conducted RCT study...</i>		Does this study do it?
1.1	The study addresses an appropriate and clearly focused question.	Yes
1.2	The assignment of subjects to treatment groups is randomized.	Yes. A randomized sequence block design produced by SAS system was used.
1.3	An adequate concealment method is used.	Not addressed
1.4	Subjects and investigators are kept 'blind' about treatment allocation.	Yes
1.5	The treatment and control groups are similar at the start of the trial.	Yes
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?	21.6% did not receive any study treatment 8.4% did not contribute any sustained data outcome
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).	Yes

1.10	Where the study is carried out at more than one site, results are comparable for all sites	Yes
SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimise bias?	High quality (++) Majority of criteria met
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?	Reasonably, even the lack of “usual care” control group but only provide “simple touch” as the control group. Without usual care arm, the differential beneficial effect may not conclusive.
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	Yes.
2.4	This study showed an immediately beneficial effect on pain in massage group. It also revealed massage offer significant improvements in pain and quality of life over time without increasing in total analgesic medication use. Therapeutic massage is feasible in hospice/palliative care setting as an adjunct to usual care.	

SIGN		Methodology Checklist 2: Controlled Trails
Study identification (Include author, title, year of publication, journal title, pages)		
Toth, M., Marcantonio, E.R., Davis, R.B., Walton, T., Kahn, J.R., & Phillips, R.S. (2013). Massage Therapy for Patients with Metastatic Cancer: A Pilot Randomized Controlled Trial. <i>The Journal of Alternative and Complementary Medicine</i> , 1-7.		
SECTION 1: INTERNAL VALIDITY		
In a well conducted RCT study...		Does this study do it?
1.1	The study addresses an appropriate and clearly focused question.	Yes
1.2	The assignment of subjects to treatment groups is randomized.	Poorly addressed. Only stated randomization being used but method of randomization not clearly mentioned.
1.3	An adequate concealment method is used.	Can't say
1.4	Subjects and investigators are kept 'blind' about treatment allocation.	Can't say
1.5	The treatment and control groups are similar at the start of the trial.	Yes
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?	1 patient died during the study in usual care control group. Dropped out= 1/42 = 2%
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).	Yes
1.10	Where the study is carried out at more than one site, results are comparable for all sites	Yes. In patient's home setting

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1	How well was the study done to minimise bias?	Acceptable (+). Details of randomization not mentioned but met most of the criteria
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 overall effect may be due to the study intervention, but patient expectation for a better outcome from massage therapy might have biased the study against the control.
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	Yes. It is applicable to metastatic cancer patients despite in different stage and type of cancer.
2.4	The result of this study suggested the feasibility of applying massage therapy for advanced cancer patients in the home setting and more benefit when provided in the context of palliative care. Massage therapy may have beneficial short-term effects on decreasing pain and improved quality of life of patients with advanced cancer.	

SIGN Methodology Checklist 2: Controlled Trails		
Study identification (Include author, title, year of publication, journal title, pages)		
Wilkie, D.J., Kampbell, J., Cutshall, S., Halabisky, H., Harmon, H., Johnson, L.P., Weinacht, L. & Rake-Marona, M. (2000). Effects of Massage on Pain Intensity, Analgesics and Quality of Life in Patients with Cancer Pain: A Pilot Study of a Randomized Clinical Trial Conducted within Hospice Care Delivery. <i>The Hospice Journal</i> , 15(3), 31-53.		
SECTION 1: INTERNAL VALIDITY		
<i>In a well conducted RCT study...</i>		Does this study do it?
1.1	The study addresses an appropriate and clearly focused question.	Yes
1.2	The assignment of subjects to treatment groups is randomized.	Poorly addressed. Only stated randomization being used but method of randomization not clearly mentioned.
1.3	An adequate concealment method is used.	Can't say
1.4	Subjects and investigators are kept 'blind' about treatment allocation.	Yes. All except 2 hospice staff (secretary and social worker) were blind to subject group assignment
1.5	The treatment and control groups are similar at the start of the trial.	Yes
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?	Attrition rate was 48%; 16 control group patients (28.4%) & 11 massage group patients (19.6%) due to death & physical deterioration
1.9	All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).	Yes

1.10	Where the study is carried out at more than one site, results are comparable for all sites	Yes. Study procedures were completed in patient's home and 3 different nursing homes
SECTION 2: OVERALL ASSESSMENT OF THE STUDY		
2.1	How well was the study done to minimise bias?	Acceptable (+). The study covered most of the criteria but method of randomization not mentioned in details.
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. Most selected instruments provided adequate outcome measurements in determining the immediate and long-term effects of massages given to terminally ill cancer patients
2.3	Are the results of this study directly applicable to the patient group targeted by this guideline?	Yes.
2.4	The study showed significant evidence that massage intervention provided immediate effects in reducing pain intensity and increasing relaxation, and suggest a feasibility to involve family caregivers to learn appropriate techniques and provide massage at home setting.	

Appendix4: Summary of Quality Assessment of Reviewed Studies

	Cassileth & Vickers (2004)	Grealish et.al. (2000)	Jane et. al. (2011)	Kutner et.al. (2008)	Toth et. al. (2013)	Wilkie et al. (2000)
Did the study ask a clearly focused question?	✓	✓	✓	✓	✓	✓
Was this a randomized controlled trial (RCT) and was it appropriately so?	✗ Quasi-experimental, pre & posttest	✗ Quasi-experimental, pre & posttest	✓	✓	✓	✓
Were participants appropriately allocated to intervention and control group?	N/A	N/A	✓	✓	Method of randomization not clearly mentioned	Method of randomization not clearly mentioned
Were participants, staff and study personnel kept 'blind' to treatment allocation?	N/A	N/A	✗	✓	Can't say	✓
Were all of all of the participants who entered the trial accounted for its conclusion?	✓	✓	Drop-out: 7%	21.6% not receive any treatment 8.4% not contribute any sustained data	Drop-out: 2%	Attrition rate: 48% due to death & deterioration of cancer

	Cassileth & Vickers (2004)	Grealish et al. (2000)	Jane et al. (2011)	Kutner et al. (2008)	Toth et al. (2013)	Wilkie et al. (2000)
Were all participants in all groups followed up and data collected in the same way?	✓	✓	✓	✓	✓	✓
Did the study have enough participants to minimize the play of chance?	✓ Large sample size (n=1290)	✓ Large sample size which was calculated to achieve a power of 80%	Can't say	✓ Estimated sample size was calculated to achieve power of 80% and 380 participants recruited	Can't say	Can't say
Were the results precise enough to make a decision?	✓ p=0.001	✓ p= 0.0001	✓ p<0.01	✓ p<0.0001 & 95%CI	✓ p<0.05 & 95%CI	✓ p<0.05
Were all important outcomes considered so the results can be applied?	✓	✓	✓	✓	✓	✓
Level of evidence	2++	2++	1+	1++	1+	1+

Appendix 5

Key to evidence statements and grades of recommendations by SCOTTISH INTERCOLLEGIATE GUIDELINES NETWORK


LEVEL OF EVIDENCE

- 1++ High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
- 1+ Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
- 1- Meta-analyses, systematic reviews, or RCTs with a high risk of bias
- 2++ 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
- 2+ Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
- 2- Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
- 3 Non-analytic studies, e.g. case reports, case series
- 4 Expert opinion

GRADES OF RECOMMENDATIONS

- A** 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
- B** 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+
- C** 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++
- D** Evidence level 3 or 4; *or*
Extrapolated evidence from studies rated as 2+

Good practice points

-  Recommended best practice based on the clinical experience of the guideline development group

Appendix 6

Estimated training cost for the use of massage therapy

Items	Calculation	Amount (HKD)
1) Involvement of a resident doctor(with massage therapist license) provides massage training	1) \$1000 x 4 sessions	1) \$40000
2) 6 DVDs for staff reference	2) \$2 x 6 pieces	2) \$12
3) Cost for lecture notes for 12 nurses	3) \$0.2 x 10 pages x 12	3) \$24
4) 12 registered nurses attended the training session	4) *\$205x 1.5hr x 4 sessions x 12	4) 14,782
Total training cost	*Median wage of registered nurses per hour: $(\$27,694 + \$44,566) / 2 / 4$ weeks/ 44 hours = \$205/hr	\$18,818

Appendix 7

Estimated implementation costs for the use of massage therapy

Items	Calculation	Amount (HKD)
1) MT training cost	1) As appendix 5	1) \$18, 818
2) Information sheet for 100 patients	2) \$0.2 x 100 pages	2) \$20
Total implementation cost		\$ 18,838

Appendix 8

Estimated costs for the use of massage therapy for each patient in a week

Items	Calculation	Amount (HKD)
1) Cost of 30-min massage therapy application	1) \$ 205 x 0.5hr x 3sessions/week	1) \$307.5
2) Unscented massage oil (optional)	2) \$100 x 2bottles	2) \$200
Total material cost		\$ 507.5/week (Material cost will be charged to each patient in the procedure fee)

Estimated cost for pharmacological intervention in a week (e.g. IV morphine Q4H/day)

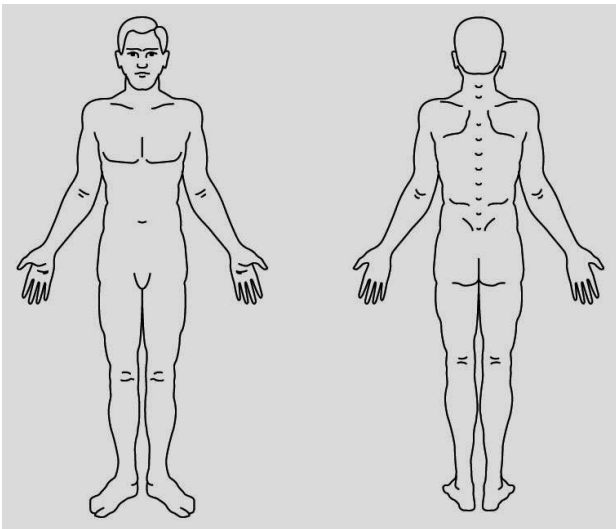
Items	Calculation	Amount (HKD)
1) Medication fee	1) \$114 x 6 x 7days	1) \$4,788
2) Materials for IV injection	2) \$100 x 7days	2) \$700
Total pharmacological cost		\$ 5,488/week

Appendix 9

Estimated cost saved after implementing massage therapy for each patient

Items	Calculation	Amount(HKD)
1) Medication fee (↓ Frequency from Q4H to TDS)	1) \$5,488/2	1) \$2,744
2) Massage therapy	2) \$507.5	2) \$507.5
Total cost for MT as adjunctive intervention	(1) + (2)	\$ 3,251.5/week
Total cost saved from pharmacological intervention after implementing MT	\$5,488 - \$3,251.5	\$ 2,236.5/week

Brief Pain Inventory (BPI) Short Form

<p>Brief Pain Inventory (Short form) Massage Intervention</p>	Hospital No.: _____ I.D. No.: _____ Name:(English) _____ (Chinese) _____ Sex: ____ Age: ____ Ward: ____ Bed: ____
Part I: Pain severity and location of pain	
1. Throughout our lives, most of us have had pain from time to time (e.g. minor headache, sprain, toothache). Have you had pain other than these everyday kinds of pain today? <input type="checkbox"/> Yes <input type="checkbox"/> No	
2. On the diagram, shade in the areas where you feel pain. Put an “X” on the area that hurts the most.	
	
3. Please rate your pain by circling one number that best describes your pain at its WORST in the <u>past 24 hours</u> . 0 1 2 3 4 5 6 7 8 9 10 No pain Worst pain	
4. Please rate your pain by circling one number that best describes your pain at its LEAST in the <u>past 24 hours</u> . 0 1 2 3 4 5 6 7 8 9 10 No pain Worst pain	
5. Please rate your pain by circling one number that best describes your pain on the AVERAGE . 0 1 2 3 4 5 6 7 8 9 10 No pain Worst pain	
6. Please rate your pain by circling one number that tells how much pain you have RIGHT NOW . 0 1 2 3 4 5 6 7 8 9 10 No pain Worst pain	

Part II: Treatments and the degree of pain relief

7. What treatments and medications are you receiving for your pain?

Treatments: _____

Medications: _____

8. Please circle the percentage that most shows how much **PAIN RELIEF** you have received after the treatments and medications.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

No relief

Complete relief

9. Circle one number that describes how pain interfere you in the following categories after treatments

:

I) General activity

0 1 2 3 4 5 6 7 8 9 10

Does not interfere

Completely interferes

II) Mood

0 1 2 3 4 5 6 7 8 9 10

Does not interfere

Completely interferes

III) Sleep

0 1 2 3 4 5 6 7 8 9 10

Does not interfere

Completely interferes

IV) Enjoyment of life

0 1 2 3 4 5 6 7 8 9

Does not interfere

Completely interferes

Remarks: _____

Assessed by: _____

Signature

Name & Rank

Date

Time

Appendix 11

Patients Questionnaire on Using of Massage Intervention

<p>Please “✓” the boxes provided: (5= totally agree, 4= agree, 3= neutral, 2= disagree, 1= totally disagree)</p>					
Satisfaction towards massage intervention	1	2	3	4	5
1) I am satisfied with the massage treatment provided.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2) Massage treatment is useful in reducing pain.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3) I would like to select massage treatment again when I experience pain in the future.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4) The hospital environment is comfortable enough for massage treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5) I am satisfied with the nurse who provides massage treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6) I would like to recommend massage treatment to others who experience pain from cancer.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Comments: _____ _____ _____ _____ _____</p>					
<p>Ward Unit:_____ Bed no.:_____ Date:_____</p>					

Appendix 12

Staff Self-Reported Questionnaire on the Use of Massage Guideline

Please “✓” the boxes provided:

(5= totally agree, 4= agree, 3= neutral, 2= disagree, 1= totally disagree)

Staff satisfaction:	1	2	3	4	5
1) The massage guideline is concise and clear.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2) The massage guideline is easy to follow.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3) Staff training is enough and appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4) The Massage intervention has decreased workload in general.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5) I am satisfied with the instruction and recommendation of the massage guideline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6) I have enough knowledge and skills on massage therapy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7) I am confident enough to provide massage intervention	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8) I am willing to provide massage to patients who are eligible for the massage intervention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9) The innovation has increased nursing autonomy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10) The innovation has increased my sense of achievement.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments:					
11) What problems have you encountered during massage intervention?					

12) Recommendations and solutions for encountered problems:					

Ward Unit:_____ Date:_____					