



**The Effectiveness of Swedish Massage with Aromatic Ginger Oil  
in Treating Chronic Low Back Pain in Older Adults: A Randomised  
Controlled Trial**

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**The Effectiveness of Swedish Massage with Aromatic  
Ginger Oil in Treating Chronic Low Back Pain in  
Older Adults: A Randomised Controlled Trial**

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Submitted in fulfilment of the requirements of the degree of  
Doctor of Philosophy

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## **Statement of Originality**

This work has not previously been submitted for a degree or diploma in any university. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made in the thesis itself.

Netchanok Sritoomma

11 January 2013

## Synopsis

Chronic low back pain is a common and major health issue, with a high rate of chronic low back pain (CLBP) in older adults. This pain has an impact on functioning, health-related quality of life and the cost of healthcare. Complementary and alternative medicine (CAM) therapies have been employed to manage low back pain, with massage the most popular CAM therapy for this purpose. Swedish massage (SM) and Traditional Thai massage (TTM) appear to relieve lower back pain but their relative effectiveness has not been clearly established. In this study, an essential oil was used to prolong the effects of Swedish massage. Ginger is one of the most popular herbal remedies as it is used as an anti-inflammatory and anti-rheumatic for musculoskeletal pain. However, no study has examined the use of aromatic ginger oil to treat CLBP, and there are also a number of limitations in the research design of reported massage and/or aromatic ginger oil studies.

This study aimed to investigate the effectiveness of Swedish massage with aromatic ginger oil (SMGO) in treating CLBP in older adults compared to TTM in terms of reduction of CLBP intensity, disability improvement, reduction of depression and improvement of quality of life among a group of 140 older people in Thailand experiencing CLBP.

The study was conducted as a randomised controlled trial (RCT) to provide evidence of the effectiveness of SM with 2% aromatic ginger oil compared to TTM in three time periods: immediate (after each of the 10 massages), short term (after six weeks of massage intervention) and long term (at 15 weeks post completion of intervention). One hundred and forty older people with CLBP, who met the inclusion/exclusion criteria and gave signed consent, were randomly assigned into two groups: SMGO (treatment) and TTM (control) groups. The interventions were given twice a week, with 10 sessions of 30-minute massage over five weeks. A pilot study was conducted and the intervention was monitored to verify and identify practical problems and any adverse effects caused by massage procedures. The primary and secondary outcomes were measured at all

three time points using the McGill Pain Questionnaire (MPQ) for pain intensity, Oswestry Disability Questionnaire (ODQ) for functional ability, 12-item Short-Form Health Survey (SF-12v2) for quality of life and Geriatric Depression Scale (GDS) for depression in Thai short form version. To measure immediate effectiveness, the Visual Analogue Scale (VAS) was used pre-post each massage session.

Most participants were female, married, worked in the agricultural sector, and had only a primary school education. The main cause of their back pain was heavy lifting. Medication was the most commonly reported previous treatment for CLBP. There were no significant differences between both groups in terms of demographic and back pain characteristics at baseline. Participants' use of medication and other treatments decreased during the study period.

Data on the relative effectiveness of the two therapies in reducing back pain intensity was the primary outcome of the study. Both types of massage significantly reduced back pain intensity across the period of assessments indicating immediate, short- and long-term effectiveness ( $p < 0.05$ ). There was a statistically significant interaction between intervention type and time with MPQ and VAS ( $p = 0.02$ ), indicating effectiveness in the short and long term: the SMGO group had a greater reduction in back pain intensity than the TTM group on the VAS ( $p = 0.04$ ). However, there was no significant difference between groups in the magnitude of back pain reduction in the period of immediate effectiveness ( $p = 0.85$ ).

In terms of secondary outcomes, both types of massage (SMGO and TTM) led to significant improvements on measures of disability, quality of life and depression across the period of short- and long-term assessments ( $p < 0.05$ ). SMGO was more effective than TTM in reducing disability in both the short and long term ( $p < 0.05$ ), and showed significantly greater improvement of physical quality of life than TTM in the short term ( $p < 0.05$ ). There were no significant differences between the SMGO group and the TTM group in terms of mental quality of life and depression.

This study highlights the effectiveness of aromatic ginger oil for CLBP as it is the first trial to test its use for back pain. The study also developed an appropriate protocol for

SMGO, which was assessed by expert agreement. The study recommends that future trials should consider investigating the effectiveness of aromatic ginger oil in reducing pain intensity. The integration of massage therapy in nursing practice for patients with CLBP in hospitals or aged-care facilities may be used as an optional treatment. A standardized massage protocol and guideline may help nurses or massage therapists in providing holistic care for their patients. The usefulness of massage therapy for CLBP management should be integrated into professional development programs for nurses.

The findings support the conceptual framework of the study. The study concludes that SMGO is more effective than TTM in reducing back pain intensity, disability and quality of life in the short and long term. Recommendations from this study may be helpful in informing the direction and focus of future studies and practice.

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## Dissemination of Study Results

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## **Abbreviation**

1. APM: Acupuncture Massage
2. BMI: Body Mass Index
3. BP: Blood Pressure
4. CAM: Complementary and Alternative Medicine
5. CLBP: Chronic Low Back Pain
6. CO: Colorado
7. HRV: Heart Rate Variability
8. GDS: Geriatric Depression Scale
9. KPCO: Kaiser Permanente Colorado
10. LBP: Lower Back Pain
11. MD: Mean Difference
12. MEPS: Medical Expenditure Panel Survey
13. MPQ: McGill Pain Questionnaire
14. MTrPs: Myofascial Trigger Points
15. NSAIDs: Nonsteroidal Anti-inflammatory Drugs
16. ODQ: Oswestry Disability Questionnaire
17. PPI: the Present Pain Index
18. PPT: Pressure Pain Threshold
19. PRI: the Pain Rating Index
20. PSQI: Pittsburgh Sleep Quality Index
21. RCT: Randomised Controlled Trial
22. SF12v2: The 12-item Short-Form Health Survey
23. SM: Swedish Massage
24. SMGO: Swedish Massage with Aromatic Ginger Oil
25. TTM: Traditional Thai Massage
26. USA: United States of America
27. VAS: Visual Analogue Scale

# **CHAPTER 1**

## **INTRODUCTION**

This chapter provides an introduction to this study. It commences with a definition of chronic low back pain (CLBP) and continues by giving a detailed background of CLBP and defining the significance of this study. Research questions, aims and hypotheses are finally described and the structure of the thesis is outlined.

### **1.1 Definitions of chronic low back pain**

Low back pain (LBP) is defined as localized pain and discomfort experienced below costal margin and above the inferior gluteus folds, with or without referred leg pain (Airaksinen et al., 2006). Chronic low back pain (CLBP) is defined as low back pain persisting for a period of more than 12 weeks (Airaksinen et al., 2006; Andersson, 1999; Bogduk, 2004; Middleton & Pollard, 2005) because most normal connective tissues heal within 6-12 weeks, unless patho-anatomic instability persists (Airaksinen et al., 2006). In addition to the pain, patients typically suffer physical disabilities and psychological distress. They may be unable to work and be depressed (Bogduk & McGuirk, 2002).

### **1.2 Background and significance of study**

CLBP is a disabling condition (Weiner et al., 2006) and a major health problem, with 70 to 85% of people suffering low back pain at sometime in their lives (Andersson, 1999; Furlan et al., 2009). High rates of CLBP have been reported with 26% of respondents experiencing LBP during a three-month period (Deyo et al, 2006) and nonspecific low back pain cited as the fifth most common reason for healthcare provider visits in the United States (Chou et al., 2007).

In Western countries, such as the United States of America, approximately 36% of community-dwelling older people experience a period of back pain every year (Cayea et al., 2006) and 21% of those report frequent moderate to severe pain (Weiner et al., 2003). Similarly, the incidence of LBP among older people in Eastern countries, such as Thailand, has been increasing and is becoming a major health problem. For example, up to 70% of older Thai people experience muscle and back pain (National Statistic Office, Ministry of Information and Technology, 2003). CLBP impairs quality of life, restricts physical activity, reduces psychosocial well-being, and is therefore costly for society (Charoenchai et al., 2006; Rudy et al., 2007). Herman et al. (2008) found that CLBP costs are estimated to be more than 36 billions of dollars per annum in the United States from lost time at workplace and as a result of disability. Deyo et al. (2006) suggested using non-pharmacologic interventions for CLBP when patients do not show improvement with standard treatment.

Complementary and alternative medicine (CAM) consists of five major areas: (1) mind-body interventions (e.g. meditation); (2) biologically based interventions (i.e. vitamins, minerals, herbal medicines and nutritional supplements); (3) body-based interventions (e.g. massage); (4) energy-based interventions (e.g. Reiki); and, (5) alternative medical systems (e.g. Chinese medicine) (National Centre for Complementary and Alternative Medicine, 2007). CAM is most commonly used for chronic conditions including back pain (Cheung & Halcon, 2007; Willison & Andrews, 2004; Wolsko et al., 2003). Massage has been defined as a systematic and scientific manipulation of the soft tissues of the body with rhythmical pressure and stroking for the purpose of obtaining or maintaining health (Weerapong et al., 2005; Wieting et al., 2008). Essentially it is a simple means of providing pain relief through physical and mental relaxation. It is thought to relieve pain through several pathways, including increasing the pain threshold by releasing endorphins (Ernst, 2004) and closing the gate of pain at the spinal cord level (Melzack & Wall, 1996). Massage also promotes a feeling of well-being and a sense of receiving good care (Weerapong et al., 2005; Imamura et al., 2008).

In Asian countries, massage has evolved according to Eastern philosophies, spirituality, theories of energy movement, and clinical practice. By contrast, massage in Western society has developed under the influence of modern medicine and an understanding of

human physiology (Salvo, 2003). Swedish massage exemplifies the Western approach and Thai massage exemplifies the Eastern approach. Swedish massage is classified as superficial massage and consists of five main stroking actions to stimulate the circulation of blood through the soft tissues of the body (Cowen et al., 2006). On the other hand, Thai massage techniques are classified as deep tissue massage with acupressure and follow two lines on the back according to the oriental energy line theory (Chatchawan et al., 2005).

Massage therapy is defined as the use of the hands to physically manipulate the body's soft tissues for the purpose of effecting a desirable change in the individual (Casanelia & Stelfox, 2010). While anatomical and physiological changes within the musculoskeletal system are generally the focus, the emotional, mental and spiritual aspects of the individual may also be affected (Casanelia & Stelfox, 2010). Typical fundamental massage techniques involve basic contact (touch), stroking (effleurage), rubbing (friction), kneading (petrissage), percussion (tapotement), vibration and compression (Casanelia & Stelfox, 2010; Salvo, 2003; Tuchtan et al., 2004). Usually, a lubricant such as an oil or powder is used with Swedish massage techniques. However, massage can be provided without the use of a lubricant as in Thai massage and delivered through clothing (Casanelia & Stelfox, 2010; Tuchtan et al., 2004).

Although essential oils can be used in many ways, massage is the most significant and commonly used method of applying them in aromatherapy because massage combines the therapeutic power of touch with the properties of the oils (Goldberg, 2001). Massage provides an effective way of introducing the oils into the body. The skin absorbs the oils, which are taken into the bloodstream during the relatively short time of the body massage (Goldberg, 2001). Osborn et al. (2001) has also suggested that an essential oil may prolong the effects of massage.

Ginger is one of the most popular herbal remedies and has a long tradition of medicinal use. Ginger (*Zingiber officinales*) belongs to the family of Zingiberaceae (Geiger, 2005). One of ginger's ingredients is gingerols which can convert into 6-paradol, 6-gingerol and 6-shogaol (Yip & Tam, 2008). These compounds have antipyretic and analgesic effects (Thomson et al., 2002). Ginger has been used as an anti-inflammatory

and anti-rheumatic for musculoskeletal pain (Altman & Marcussen, 2001; Srivastava & Mustafa, 1992). Three clinical trials reported the short-term beneficial pain reduction effects of ginger extract taken orally for knee pain or neck pain reduction (Altman & Marcussen, 2001; Bliddal et al., 2000; Thomson et al., 2002) but no study has been found about the use of ginger for back pain.

There are many means of treating CLBP such as surgery, medicines including Nonsteroidal Anti-inflammatory Drugs (NSAIDs), exercise and other complementary and alternative treatments (acupuncture, herbs and massage) (Wheeler, 2010, p.1). However, there are side effects of NSAIDs such as gastric intestinal bleeding or gastric ulcer (Laine, 2001). Furthermore, patients with back pain often have other physical and mental health co-morbidities and this plus use of analgesic are associated with chronicity, increased healthcare utilization and costs (Ritzwoller et.al, 2006). CLBP causes not only pain and suffering for patients, but also depletes healthcare resources (Arcy, 2009). The annual direct medical costs for 16,567 patients who presented with low back pain in the US was \$70,934,545 or, on average, \$357 per person per month (Ritzwoller et.al, 2006). Those with the most episodes of LBP were the lowest users of primary care, but the highest users of all forms of specialty care.

Although LBP affects older people in their physical and emotional status and a large proportion of older people experience a period of LBP in their lives, no study appears to have specifically investigated the effects of Thai massage, Swedish massage and aromatherapy in older age groups. The present study therefore is the first trial to investigate the effectiveness of Swedish massage with aromatic ginger oil in treating chronic low back pain. The literature review conducted for this study shows previous studies have concluded that Swedish massage (SM) and traditional Thai massage (TTM) are equally effective in relieving LBP. However, these studies were found to have some limitations and these are outlined in Chapter 2. The randomised controlled trial (RCT) study described in this thesis was designed to address these limitations by including an appropriate sample size, longer follow-up, standardised intervention and outcome assessments to further investigate the effectiveness of both SM and TTM techniques, and the effectiveness aromatic ginger oil back pain, in treating low back pain. Therefore, the present study aims to gain an understanding of whether chronic

low back pain in older people can be reduced by Swedish massage and aromatic ginger oil, and improve their quality of life.

### **Significance of study**

The high rate of CLBP in older people highlights the importance of this study, which aims to reduce the side effects of this condition and improve the quality of older people's lives. Furthermore, an aging world population also adds to the need to research this population group. This study has relevance to clinical practice as nurses in hospitals or aged care settings can apply back massage to relieve CLBP for their clients and reduce overreliance on medications and this may help to reduce side effects of such medication. Massage can be readily incorporated into the care plans of clients in acute or long-term care once nurses or therapists are trained. The study also explores the longitudinal effect of massage.

This study has the potential to improve our understanding of how the combination of massage and aromatherapy, such as Swedish massage and aromatic ginger oil, can influence physical functioning and psychological well-being of older people with CLBP. Such understanding can be used to improve evidence-based care for aging populations. Furthermore, the treatment may enhance physical functioning and psychological well-being and this may improve the quality of life for older people.

### **1.3 Research aim**

The study aims to examine the effectiveness of Swedish massage with aromatic ginger oil (SMGO) in relieving CLBP in older people compared with traditional Thai massage (TTM). It also aims to examine physical functioning and psychological well-being in relation to both types of massage.

### **1.4 Research question**

What is the effectiveness of Swedish massage with aromatic ginger oil compared with usual massage (traditional Thai massage) for CLBP intensity, physical functioning, psychological well-being and quality of life, in older people with CLBP?

## **1.5 Research hypotheses**

The study hypothesises that:

1. Participants in the SMGO group will demonstrate a greater reduction in pain intensity compared to participants in the TTM group.
2. Participants in the SMGO group will demonstrate a greater improvement in disability compared to participants in the TTM group.
3. Participants in the SMGO group will demonstrate a greater improvement in quality of life compared to participants in the TTM group.
4. Participants in the SMGO group will demonstrate a greater reduction in depression compared to participants in the TTM group.

## **1.6 Thesis framework**

This thesis is organised into six chapters. This chapter has introduced the study and provided an overview of background and significance of the study conducted. The research question, aims and hypotheses of study were also presented.

Chapter 2 reviews studies relevant to the SM and TTM for LBP. As no studies were retrieved that specifically compared Thai and Swedish massage in older people with CLBP, the review was broadened to studies that used Thai massage or Swedish massage to address non-specific lower back pain. Also, no studies were found that reported on the use of ginger to treat back pain so literature on the effectiveness of ginger on other types of pain is addressed in this review.

Chapter 3 addresses the conceptual framework of the study. The chapter explains how massage (Swedish massage and Thai massage) and ginger reduce pain including scientific theories, traditional beliefs, efficacy profiles, and side effects of both massage and ginger. Effects of both Thai massage and Swedish massage from scientific perspectives are presented followed by the traditional beliefs of Thai massage, the effects of ginger, and how aromatherapy works. Finally, the chapter outlines the application of SMGO treatment for CLBP and depicts the conceptual model of the effects of SMGO on CLBP.

Chapter 4 deals with the methodology used in the study in two parts. Part one reviews the background and fundamental principles of RCT, strengths and limitations of RCT. Ethical issues in relation to RCT, quality indicators in RCT, and implementing randomised assignment are also discussed. Part two of the chapter outlines the methodological considerations for the study. The study took place in Thailand and all the instruments applied were standardised Thai versions. The research design, ethical considerations and timeframe are described. A pilot study was conducted prior to starting the actual study to assess the validity and feasibility of the proposed study. The study examined the effectiveness of both SMGO and TTM in three time periods: immediate (after each massage), short term (at completion of six weeks of massage) and long term (at 15 weeks post completion of intervention).

The results of this study are presented in Chapter 5. Part one of chapter 5 reports the response rate achieved in this study, the characteristics of the sample (demographic and back pain characteristics), medication use and adverse effects, and the internal reliability of the measures. Part two presents the analysis of the effectiveness of both types of massage across the immediate, short-term and long-term time periods.

Chapter 6 firstly outlines the strengths of the study and then discusses the significant findings according to the conceptual framework and the contemporary literature, before moving onto a discussion of important demographic issues. The challenges of conducting an RCT are discussed, followed by the implications of the findings for nursing practice. Recommendations for practice, education and research, and limitations of the study, are then presented. The last section of this chapter summarises the study highlights and concludes the study.

## **1.7 Summary**

CLBP is a common condition in older adults and can have a serious impact on both the individual and community, in particular in functional and emotional status, cost and healthcare use, quality of life and self-care behaviour. However, complementary therapies such as SMGO and TTM may help tackle this problem. Both SMGO and

TTM may help to relieve CLBP by enhancing physical functioning and psychological well-being and lead to improving the quality of life for older people.

Previous studies have examined the effectiveness of SM and /or TTM for LBP but those studies are constrained by some limitations. Also, no previous study has examined the use of aromatic ginger oil to treat CLBP. The next chapter reviews and critiques the existing literature on the effectiveness of SM and TTM on LBP and the use of ginger oil extract to treat musculoskeletal pain.

## **CHAPTER 2**

### **LITERATURE REVIEW**

#### **Introduction**

The incidence of low back pain among older people in Thailand has been increasing and is now a major health problem in this group. Up to 70% of Thai older people experience muscle and back pain (National Statistic Office, Ministry of Information and Technology, 2003). This condition may affect the quality of life of individuals and lead to a decline in ability to undertake physical activity (Charoenchai et al., 2006). Several complementary and therapeutic alternatives have been utilized to manage pain. Among these, massage is considered to be an effective remedy to reduce pain in CLBP (Chatchawan et al., 2005; Cherkin et al., 2011).

There is moderate to strong evidence that massage provides relief for CLBP in the short and long term (Imamura et al., 2008). Two rigorous quality trial studies (Franke et al., 2000; Chatchawan et al., 2005) compared two different massage techniques and their effects on CLBP. Franke et al. (2000) compared acupressure as used in Thai massage versus classic massage (Swedish massage), combined with individual or group exercise. The study showed that acupressure was superior to classic massage for low back pain and physical functioning. Chatchawan et al. (2005) compared traditional Thai massage with Swedish massage, assessed using the visual analog scale (VAS). In the Chatchawan et al (2005) study back pain was reduced by more than half in both groups after 3 weeks of treatment and for up to one month afterwards, with no significant difference in VAS between the groups ( $P < 0.05$ ). The overall difference between the two groups and the upper limit of the 95% confidence interval of this difference were less than 1 on the VAS, which is generally considered as the minimum value when looking for a significant clinical difference between groups (Chatchawan et al., 2005). The Chatchawan et al. (2005) study concluded that both treatment types had equal

therapeutic effectiveness in the treatment of patients with back pain associated with myofascial trigger points.

The aim of this chapter is to critique studies examining the effects of Thai massage, Swedish massage and aromatic ginger on CLBP. An appraisal of selected systematic reviews, and research papers published in English in peer reviewed journals between 2000 and 2011 was undertaken. As there were no published trials evaluating the effectiveness of any types of massage for back pain prior to 2000, this was determined to be an appropriate starting date for this review. The major electronic databases e CINAHL, EBSCOhost, MEDLINE, ProQuest, Google scholar, ScienceDirect, MEDSCAPE, PubMed, ProQuest Dissertations and Theses, Australia Digital Theses Program e were searched using the same search strategy. The search terms included the MeSH terms and all databases were searched using a combination of the following key words: Thai massage, Swedish massage, low back pain, chronic low back pain. Reference lists of all relevant articles obtained were checked and additional relevant articles were retrieved. Studies were included if they met the following criteria: participants were adult and older adults with chronic low back pain; study design were randomised controlled trials (RCTs); the primary outcome of interest was back pain intensity and secondary outcomes were any types of physical and/or psychological function; type of interventions were Thai massage and/or Swedish massage compared to each other, usual massage or other treatments such as relaxation therapy and joint mobilization. Studies were excluded when the specific types of Thai or Swedish massage were not detailed.

There were no studies that specifically compared Thai and Swedish massage for older adults with CLBP. Therefore, the review was broadened to studies that used Thai massage or Swedish massage to address non-specific lower back pain. Also, no studies were found that reported on the use of ginger to treat back pain so the effectiveness of ginger on other types of pain was critiqued in this review.

This chapter is divided into four sections. The chapter starts with describing research on the impact of low back pain on older clients. The next section deals with the literature that depicts and critiques the effectiveness of Thai and Swedish massage on low back

pain. The third section, research on the benefits of aromatherapy and the effects of ginger on pain are presented. The last section presents and critiques the complexity of nursing and complementary and alternative medicine research. The sections of Thai massage, Swedish massage and aromatic ginger oil are illustrated with summary tables of the related articles.

## **2.1 The impact of chronic low back pain**

Researchers have reported that CLBP is prevalent in older people and leads to suffering with potentially disabling chronic pain conditions. This pain has a marked effect on functioning and health-related quality of life (Saastamoinen et al., 2006), although the unique impact of CLBP is unknown. Rudy et al. (2007) conducted research to identify the multidimensional factors that distinguish independent community dwelling older adults with CLBP from those who are pain-free. Three hundred and twenty cognitively intact participants (162 with  $\geq$ moderate pain for  $\geq 3$  months, and 158 pain-free) received a comprehensive assessment in four domains: biomedical (pain severity, medical comorbidity, severity of degenerative disc, lumbar flexion), psychosocial (self-efficacy, mood, overall mental health), self-reported function and performance-based function. Significant differences were seen on all 22 measures. All three of the domains examined were significantly different in older adults with CLBP as compared with those who were pain-free. The researchers argued that these results should help to guide investigators who perform studies of CLBP in older adults and practitioners who want an easily adaptable battery of tests for use in clinical settings.

CLBP is debilitating for the patient and costly for society (Weiner, 2010). Although it is one of the most disabling and therapeutically challenging pain conditions afflicting older adults, there is a limited body of research dedicated to defining its impact on function (Hartvigsen et al., 2003). By contrast, there has been extensive research conducted on working-aged adults with CLBP in part due to the costs associated with work-related disability (Rudy et al., 2007).

Ritzwoller et al. (2006) studied the association of co-morbidities, healthcare utilization and costs for patients with back pain and found that physical and mental health co-

morbidities and measures of analgesic use were associated with chronicity, increased healthcare utilization and costs. This study found that the annual direct medical costs for 16,567 patients who presented with low back pain in the US was \$70,934,545, or on average \$357 per person per month. Those with most low back pain episodes were the lowest users of primary care, but the highest users of all forms of specialty care. Given the association of co-morbidities and cost for patients with lower back pain (LBP), management approaches that are effective may prove to be beneficial for patients and the community in general.

Other research reports that back pain is a complex and intractable condition with a variety of adverse consequences including physical disability, psychosocial problems and increased healthcare utilization (Walker et al., 1999; Walker et al., 2004).

In terms of psychological problems, depression is more commonly seen in clients with CLBP than clients with acute, short-term back pain (Deardorff, 2010). Symptoms of depression associated with CLBP include depressed mood, crying spells, depleted self-esteem, lack of self-confidence, disturbance in sleep and social withdrawal (Zepinic, 2009). Carroll et al. (2004) studied whether depression was a risk factor for onset of an episode of troublesome neck and low back pain. A population-based random sample of adults at risk of troublesome (intense and/or disabling) neck or low back pain was surveyed and followed at 6 and 12 months (n=790). The study found an independent relationship between depressive symptoms and onset of an episode of pain. In comparison with the lowest quartile of scores (the least depressed), those in the highest quartile of depression scores had a four-fold increased risk of troublesome neck and low back pain (adjusted HRR 3.97; 95% CI 1.81-8.72). The study concluded that depression is a strong and independent predictor for the onset of an episode of intense and/or disabling neck and back pain. Von Korff and Simon (1996) studied the relationship between pain and depression in 2,384 patients with chronic pain in comparison to 1,003 control subjects. The study found that depressive symptoms were far more common in the pain group, including feeling that everything was an effort, disturbed sleep, worry, and low energy.

Seok et al. (2003) compared CLBP patients with and without emotional depression in terms of their psychosomatic health and clinical outcomes in a cross-sectional and prospective study. The study evaluated 100 patients with CLBP. The patients were classified into three groups (moderately depressed, mild depressed, non-depressed) by the Beck Depression Inventory (BDI) score. All three groups were compared on Pain Disability Index (PDI), Visual Analogue Scale (VAS), Pain Rating Score (PRS) and special diagnostic studies such as MRI and EMG. All subjects took the same conservative treatments for four weeks and were then re-evaluated with PDI, VAS and PRS. The study reported that BDI score was positively and significantly correlated with VAS and PRS ( $P < 0.01$ ). All groups were similar with respect to functional limitation (measured by PDI) and organic lesion (measured by MRI and EMG study) but subjective pain (measured by VAS, PRS) was severe in the depressed group. All groups showed improvement in PDI, VAS and PRS after four weeks of treatment. However, the amount of improvement was greater in the non-depressed group. Therefore, the study concluded that the clinician treating CLBP should be familiar with depressive symptoms routinely and screen for depression.

The previous studies have shown that patients with chronic pain including CLBP frequently have serious psychiatric disturbances – most often, clinical depression. Thus, depression should not be discounted or ignored because of its association with chronic pain. Not all patients with chronic pain have clinical depression, but when depression is present, it influences the pain and may in turn be affected by the level of pain (Rush et al., 2000).

Charoenchai et al. (2006) found that the level of participant's income was statistically relevant to the level of pain ( $p < 0.05$ ) and there was also a significant association between three health behaviors (preventive health behaviors, illness health behaviors, sick role health behaviors) and the level of pain ( $p = 0.0001, 0.005, 0.0001$ ). This study suggested that Thai health care professionals should play a role in changing the health behaviour of patients with low back pain to improve their quality of life.

To sum up, CLBP is a common symptom that can happen at least once in an older person's life (Andersson, 1999). This condition has an effect on all aspects of an

individual's life such as functional status, emotional status, cost and healthcare utilization, quality of life and self care behaviours.

## **2.2 Traditional Thai and Swedish massage effectiveness on low back pain**

Nine papers on the effectiveness of Thai and Swedish massage in treating lower back pain were reviewed. Their main findings are summarized in Table 2.1. All of these papers reported the results of randomised controlled trials. Seven trials tested traditional Thai or Swedish massage compared with other types of therapies (Buttagat et al., 2009; Cherkin et al., 2011; Field et al., 2007; Franke et al., 2000; Hernandez-Reif et al., 2001; Mackawan et al., 2005; Preyde, 2000) and two trials compared traditional Thai and Swedish massage with different outcome measurements (Chatchawan et al., 2005; Cowen et al., 2006).

The primary outcome of most massage therapy trials was pain relief measured using a pain intensity 10-point Visual Analogue Scale (VAS). Another pain scale used was the McGill Pain Questionnaire (MPQ), which consists of two indexes: the Present Pain Index (PPI) and the Pain Rating Index (PRI) to measure pain intensity and quality of pain. The secondary outcome measures are grouped into two major areas: physical functions and psychological measurement. Physical functions included blood pressure (BP), heart rate variability (HRV), disability as measured by Oswestry Disability Questionnaire (ODQ,0-100), back performance as measured by Thoracolumbar spine range of motion (ROM) and lumbar range of motion as measured by the modified Schober test. Psychological measures were patient satisfaction with back care (five-point Likert scale), State Trait Anxiety Inventory (STAI), five-item Mental Health Index of the SF-36 quality of life measurement and the cost of health care services (automated utilization data).

**Table 2.1: The effectiveness of Traditional Thai massage and Swedish massage in treating lower back pain**

Authors/year of publication	Objectives	Methodology					Findings	Limitation
		Design & Sample	Settings	Interventions	Outcome measures	Timing of follow-up		
Buttagat V. et al. (2009)	To investigate the immediate effects of traditional Thai massage (TTM) on heart rate variability and stress-related parameters in patients with back pain associated with myofascial trigger points	Randomized control trial (RCT)  36 patients with chronic low back pain with myofascial trigger points  Average age: 22.6 ± 2.9 yr Female: 55.56 % Pain duration: ≥ 3 months	The Department of Physiotherapy at Khon Kaen University, Thailand	<b>Group 1(treatment ):</b> one 30-min session of TTM onto the back muscles while lying in the prone position during the period between 10.00 h and 13.00 h on the day of the study.  <b>Group 2(Control):</b> lying prone quietly in the same environment and for the same period of time as the treatment group  <b>Groups:</b> G1: TTM, n=18 G2: lying prone, n=18	<ul style="list-style-type: none"> <li>• Heart rate variability (HRV)</li> <li>• Pain intensity and muscle tension:10 cm visual analogue scales (VAS)</li> <li>• Pressure pain threshold (PPT): 3 times for point and then average score (kg/cm<sup>2</sup>)</li> <li>• 20-item State-Trait anxiety inventory (STAI)</li> <li>• Body flexibility: A sit-and-reach box</li> </ul>	Immediately following treatment	TTM was associated with significant increases in HRV, pressure pain threshold (PPT) and body flexibility (p < 0.05) and significant decreases in pain intensity, anxiety and muscle Tension (p < 0.001).  <b>Conclusion</b> Traditional Thai massage can increase heart rate variability, reduce pain and improve stress-related parameters in patients with back pain associated with myofascial trigger points	This study only evaluated the immediate effect of TTM, which may not correlate with a longer term effect

**Table 2.1(Cont.): The effectiveness of Traditional Thai massage and Swedish massage in treating lower back pain**

Authors/year of publication	Objectives	Methodology					Findings	Limitation
		Design & Sample	Settings	Interventions	Outcome measures	Timing of follow-up		
Chatchawan U. et al. (2005)	To verify the effectiveness of traditional Thai massage among patients with back pain associated with myofascial trigger points	<p>Prospective, parallel group, randomized controlled trial (RCT)</p> <p>180 patients with spontaneous back pain with at least one trigger point in either the upper or lower torso</p> <p>Age: average 36_+ 9 yrs Female: 63% Pain duration: &gt;1 month</p>	The Department of Physiotherapy at Khon Kaen University, Thailand	<p>Traditional Thai massage (TTM) or Swedish massage (SM) for 6 sessions during a 3-4 week period, with follow up 1 month later</p> <p><b>Group1:</b> the TTM group received treatment to specific massage points. Each point was pressed with the thumb, finger, palm and elbow beginning with gentle pressure and increasing pressure until the patient reached their pain threshold. Pressure was maintained for 5-10 seconds</p> <p><b>Group 2:</b> comparison group received SM treatments. The pressure held was deep enough to reach into the subcutaneous tissue but not so deep as to reach the patient's pain threshold</p> <p>Both the TTM and SM treatments lasted for 30 minutes, followed by 10 minutes of passive stretching</p> <p><b>Groups:</b> G1: TTM, n=90 G2: SM, n=90</p>	<p><b>Patient-rated outcome measures:</b></p> <ul style="list-style-type: none"> <li>• Pain intensity by visual analogue scale (VAS)</li> <li>• Disability by Oswestry disability questionnaire (ODQ, 0–100)</li> <li>• Patient satisfaction with their treatment (4-point scale)</li> <li>• Side-effects and medication used</li> </ul> <p><b>Back performance:</b></p> <ul style="list-style-type: none"> <li>• Thoracolumbar spine range of motion</li> <li>• Body flexibility: A sit-and-reach box</li> <li>• Pressure pain threshold</li> </ul>	<p><b>Short-term effect</b></p> <p>before and after treatment</p> <ul style="list-style-type: none"> <li>• On day 1</li> <li>• Second week</li> <li>• Third week</li> </ul> <p><b>Long -term effect</b></p> <ul style="list-style-type: none"> <li>• One month after the last treatment</li> </ul>	<p>No statistically significant differences across all outcomes between the TTM and SM treatments</p> <p>Both groups showed over 50% reduction in pain intensity after 3 weeks of treatment</p> <p><b>Conclusion</b> TTM or SM treatment can be used, with equal expected effectiveness, in the treatment of back pain associated with myofascial trigger points</p> <p><b>Recommendation</b> TTM and SM are more widely promoted as alternative primary healthcare treatments for back pain</p>	<p>Participants were not blinded to their treatment groups</p> <p>A 'no-treatment' control group</p>

**Table 2.1(Cont.): The effectiveness of Traditional Thai massage and Swedish massage in treating lower back pain**

Authors/year of publication	Objectives	Methodology					Findings	Limitation
		Design & Sample	Settings	Interventions	Outcome measures	Timing of follow-up		
Cherkin DC. et al. (2011)	To compare the effectiveness of 2 types of massage and usual care for chronic back pain	Parallel-group randomized controlled trial (RCT)  401 patients with nonspecific chronic low back pain  Average age: 47 ± 1 yr Female: 64.33 % Pain duration: ≥ 3 months	An integrated healthcare delivery system in the Seattle Area, USA	<p><b>Group1:</b> Structural massage</p> <p><b>Group2:</b>Relaxation massage (Swedish massage)</p> <p><b>Group3:</b> Continued usual medical care</p> <p>10 massage treatments provided over 10 weeks</p> <p><b>Groups:</b> G1: FM, n=132 G2: SM, n=136 G3: Usual care, n=133</p>	<p><b>Primary outcomes:</b> <b>Roland-Morris Disability Questionnaire</b></p> <ul style="list-style-type: none"> <li>• Dysfunction</li> <li>• Bothersomeness of low back pain</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>• General health status</li> <li>• Satisfaction with back care</li> <li>• Practitioner effects</li> <li>• Co-interventions and subsequent use of massage</li> <li>• Cost of back pain-related healthcare after randomization</li> <li>• Adverse effect</li> </ul>	Baseline and after 10, 26, and 52 weeks by telephone interviewers masked to treatment assignment	<p>The massage groups had similar functional outcomes at 10 weeks. The beneficial effects of relaxation massage on function (but not on symptom reduction) persisted at 52 weeks but were small</p> <p><b>Conclusion</b> Massage therapy may be effective for treatment of CLBP, with benefits lasting at least 6 months. No clinically meaningful difference between relaxation and structural massage was observed in terms of relieving disability or symptoms</p>	Participants were not blinded to treatment

**Table 2.1(Cont.): The effectiveness of Traditional Thai massage and Swedish massage in treating lower back pain**

Authors/year of publication	Objectives	Methodology					Findings	Limitation
		Design & Sample	Settings	Interventions	Outcome measures	Timing of follow-up		
Cowen V. et al. (2006)	To compare and contrast a single general massage treatment, using one of two different styles of massage (TTM &SM), on physiological and psychological outcomes	Randomized control comparative study  53 participants enrolled in the study and were randomly assigned to receive one TM or SM treatment  Average age: 33.7 yrs Female: 71.7 % Pain duration: not reported	Arizona State University, USA	Participants selected a sealed envelope randomly assigning them to 1 of 2 massage groups: <b>Group1:</b> Thai massage <b>Group2:</b> Swedish massage  This study employed a single treatment, random assignment design in order to collect exploratory data on the differences between modalities, the same areas of the body (back, hips, legs, feet, abdomen, arms, hands, upper chest, neck, scalp, head, face) are treated in massage sessions of a 90-min massage.  <b>Groups:</b> G1: SM technique, n=23 G2: TTM technique, n=30	<b>Outcome measures:</b> Physiological (BP, HR,ROM)  Psychological (anxiety and mood) assessments occurred at T1,T2,	Before taking massage (T1), after taking massage immediately (T2), and 48 hours after the massage (T3)	TTM is as effective as SM on general physiological and psychological outcomes	This study only evaluated the immediate effect of both types, which may not correlate with a longer term effect

**Table 2.1(Cont.): The effectiveness of Traditional Thai massage and Swedish massage in treating lower back pain**

Authors/year of publication	Objectives	Methodology					Findings	Limitation
		Design & Sample	Settings	Interventions	Outcome measures	Timing of follow-up		
Field T. et al. (2007)	To evaluate massage therapy versus relaxation therapy effects on chronic low back pain	A randomized between-groups design  30 with low back pain  Average age: 41 years and middle class  Female: 46.67 % Pain duration: ≥ 6 months	Touch Research Institutes, University of Miami School of Medicine  Miami  USA	<b>Group1:</b> Massage therapy -received two 30 min massage therapy sessions per week over 5 weeks by trained massage therapists  <b>Group2:</b> Relaxation therapy (control for potential placebo)  -showed how to use progressive muscle relaxation exercises  Conducted these 30 min sessions at home twice a week for 5 weeks and kept a log on the times they spent in relaxation therapy  <b>Groups:</b> G1: SM technique, n=15 G2: Relaxation therapy, n=15	<b>Pre-post session assessments (immediate effects)</b>  • Profile of Mood States Depression Scale (POMS-D)  • State-Trait Anxiety Inventory (STAI)  • Pain- Visual analogue Scale (VAS)  • ROM-Trunk and Pain flexion  <b>First-last day sessions (longer term effects)</b>  • Sleep Scale  Job productivity and absenteeism	After the sessions on the first and last days of the 5-week study	At the end of the study, the massage therapy group, as compared to the relaxation group, reported experiencing less pain, depression, anxiety and sleep improved trunk and pain flexion performance	The control participants actually practiced muscle relaxation  The small sample size  Lack of a long-term follow-up assessment

**Table 2.1(Cont.): The effectiveness of Traditional Thai massage and Swedish massage in treating lower back pain**

Authors/year of publication	Objectives	Methodology					Findings	Limitation
		Design & Sample	Settings	Interventions	Outcome measures	Timing of follow-up		
Franke A. et al. (2000)	To quantify the effectiveness of Acupuncture massage versus Swedish massage and individual exercise versus group exercise in low back pain sufferers	Randomized control clinical trial in a 2 x 2 factorial design  109 patients who suffered low back pain  Average age: 45 yrs Female: 39 % Pain duration: ≥ 1 year	Forschungs institution, Germany	Acupuncture massage (APM) according to Penzel: treats one unique point with a special vibrating instrument along acupuncture point without needle insertion  Classic massage (SM)  Group 1: APM +individual exercise Group 2: APM + group exercise Group 3: SM+ individual exercise Group 4: SM+ group exercise  <b>Groups:</b> G1,2: n=46 G3,4: n=49	<ul style="list-style-type: none"> <li>• Functional ability/disability (Functional Questionnaire Hanover, FFbH)</li> <li>• Pain intensity (10 cm visual analogue scale, VAS)</li> <li>• Pre/post changes were evaluated by means of 2-way analysis of variance (ANOVA)</li> <li>• Lumbar motility was measured by a 2-inclinometer technique</li> </ul>	Baseline, after treatment	APM showed beneficial effects for both disability and pain compared with SM  Classic massage (SM) did not change function  Mean difference between APM and SM groups: 7.0% (function) and 0.8 cm (VAS)	The measures only relate to physical domain, do not cover mental or psychosocial domain  Differences between groups are not clinically important to justify implementation of acupuncture technique  No long-term follow-up

**Table 2.1(Cont.): The effectiveness of Traditional Thai massage and Swedish massage in treating lower back pain**

Authors/year of publication	Objectives	Methodology					Findings	Limitation
		Design & Sample	Settings	Interventions	Outcome measures	Timing of follow-up		
Hernandez-Reif M. et al. (2001)	To evaluate effectiveness of massage therapy for reducing pain, depression, anxiety and stress hormones, and sleeplessness and for improving trunk range of motion associated with chronic low back pain	A randomized between-groups design.  24 adults with low back pain  Average age: 39.6 years and middle class Female: 54.17 % Pain duration: ≥ 6 months	Touch Research Institutes, University of Miami School of Medicine Miami, USA	<b>Group1:</b> Massage therapy -received two 30-min massage therapy sessions per week over 5 weeks by trained massage therapists  <b>Group2:</b> Relaxation therapy (control for potential placebo) -was shown how to use progressive muscle relaxation exercises including tensing, relaxing muscle. -conducted these 30 min sessions at home twice a week for 5 weeks and kept a log on the times they spent in relaxation therapy  <b>Groups:</b> G1: SM technique, n=12 G2: Relaxation therapy, n=12	<b>Pre–post session assessments (immediate effects)</b> • Profile of Mood States Depression Scale (POMS-D) • State-Trait Anxiety Inventory (STAI) • Pain: Visual analogue Scale (VAS) • ROM: Trunk and Pain flexion  <b>First–last day sessions (longer term effects)</b> • Sleep Scale • Symptom Checklist-90 Revised (SCL-90-R) • Urine samples: cortisol, catecholamine, serotonin (5-HIAA) levels	After the sessions on the first and last days of the 5-week study	The massage therapy group, as compared to the relaxation group, reported experiencing less pain, depression, anxiety and improved sleep  They also showed improved trunk and pain flexion performance, and their serotonin and dopamine levels were higher	Difficult to ensure that the control participants actually complied with the at-home instructions  Small sample size  Lack of a long-term follow-up assessment

**Table 2.1(Cont.): The effectiveness of Traditional Thai massage and Swedish massage in treating lower back pain**

Authors/year of publication	Objectives	Methodology					Findings	Limitation
		Design & Sample	Settings	Interventions	Outcome measures	Timing of follow-up		
Mackawan S. et al. (2005)	To examine the immediate effects of TTM versus joint mobilization on substance P and pain perception in patients with non-specific low back pain	Randomized control comparative study  67 adults with non-specific LBP  Average age: 38.97 ± 7.85 yr Female: 61.19 % Pain duration: ≥ 3 months	The Department of Physiotherapy at Khon Kaen University, Thailand	<b>Group1:</b> TTM on lower back muscles between L2 and L5  <b>Group2:</b> joint mobilization on spinous process of L2–L5 by experienced physiotherapist  -The duration of each treatment was 10 min  <b>Groups:</b> G1: TTM, n=35 G2: Joint mobilization, n=32	<ul style="list-style-type: none"> <li>• The levels of substance P in saliva</li> <li>• Visual analogue scale (VAS)</li> </ul>	Before and 5 minutes after each treatment	There was no significant difference in the level of substance P after treatment between the two groups  TTM group reported less pain than the joint mobilization.  TTM yields slightly more beneficial effects than joint mobilization	Lack of a control group due to ethical concerns  This study only evaluated the short term effect of TTM

**Table 2.1(Cont.): The effectiveness of Traditional Thai massage and Swedish massage in treating lower back pain**

Authors/year of publication	Objectives	Methodology					Findings	Limitation
		Design & Sample	Settings	Interventions	Outcome measures	Timing of follow-up		
Preyde M. (2000)	To compare the effectiveness of comprehensive massage therapy, two separate components of massage therapy (soft-tissue manipulation and remedial exercise with posture education) and a placebo of sham laser therapy for the treatment of sub-acute LBP	Randomized controlled trial.  107 subjects with subacute low back pain  Average age:46 yrs Female: 51% Pain duration: 1 week-8 months	The Health and Performance Centre, University of Guelph, Ontario, Canada	<b>Group1:</b> comprehensive massage therapy (CMT) <b>Group2:</b> soft-tissue manipulation only (STM) <b>Group3:</b> remedial exercise with posture education only (RM) <b>Group4:</b> a placebo of sham laser therapy -Each subject received 6 treatments within approximately 1 month  <b>Groups:</b> G1: CMT, n=25 G2: STM, n=25 G3: RE, n=22 G4: Control group, n=26	<b>Primary outcomes: functional and pain relief</b> <ul style="list-style-type: none"> <li>• The Roland Disability Questionnaire (RDQ)</li> <li>• The McGill Pain Questionnaire (PPI and PRI)</li> </ul> <b>Secondary outcomes: Anxiety and lumbar range of motion</b> <ul style="list-style-type: none"> <li>• The State Anxiety Index (SAI)</li> <li>• The Modified Schober test (lumbar range of motion)</li> </ul>	Baseline, after treatment and at 1-month follow-up	The comprehensive massage therapy group had improved function ( $p < 0.001$ ), less intense pain ( $p < 0.001$ ), decrease in the quality of pain ( $p = 0.006$ ) compared with the other groups  At 1-month follow-up, the reporting no pain in: * 63% of CMT group *27% of SMT group *14% of RM group *0% of the control group	Assessment of outcomes was by physical measures only  Short-term follow-up

### **2.2.1 Traditional Thai massage and Swedish massage on back pain relief**

All of the nine trials that used massage as the intervention (Traditional Thai massage, Swedish massage, structural massage, relaxation massage) reported significantly reduced pain intensity (Buttagat et al., 2009; Chatchawan et al., 2005; Field et al., 2007; Franke et al., 2000; Hernandez-Reif et al., 2001; Mackawan et al., 2005; Preyde et al., 2000).

In terms of a comparison of pain outcome between Traditional Thai massage (TTM) and Swedish massage (SM), Chatchawan et al. (2005) found that pain intensity measured by a Visual Analogue Scale (VAS) among back pain patients with myofascial trigger points (MTrPs) can be reduced by over 50% after only three weeks of treatment with either TTM or SM. MTrPs are hyperirritable spots in skeletal muscle that are associated with palpable nodules and are small contraction knots and a common cause of pain. The results also demonstrated the effectiveness of both TTM and SM massage when followed by passive stretching. Chatchawan et al.'s (2005) study is the only study that has investigated the effectiveness of TTM versus SM in terms of immediate impact (immediately before and after the first treatment on day 1), short-term effects (before and after the third week of treatment) and long-term effects (one month after the last treatment.). This study showed that after the first day of treatment a slightly greater improvement in the Visual Analogue Scale (VAS) was indicated for the SM group when compared to the TTM group. In regards to short- and long-term assessment, this study showed no significant difference in the degree of reduction of pain using the VAS between the groups at the end of three weeks of treatment and a month after the last treatment. However, there was a statistically significant difference between groups (0.4 kg/cm<sup>2</sup>, 95% confidence interval 0.2 to 0.7 kg/cm<sup>2</sup>,  $p < 0.05$ ) in the degree of improvement in the pressure pain threshold (PPT) in long-term effectiveness with patients in the TTM group showing a greater increase in PPT than patients in the SM group. However, findings in three time period of assessments indicated that the VAS improved at approximately the same rate, and with the same magnitude, within each of the two groups. Chatchawan et al. (2005) concluded that both TTM and SM had equal therapeutic effectiveness in the treatment of patients with back pain associated with MTrPs.

Rachlin (1994) suggested that a combination of superficial and deep massage, similar to that of TTM, is the most effective treatment for myofascial trigger points. As myofascial trigger points usually lie in the same area of the back covered by the lines of TTM, Rachlin (1994) argues that the deeper pressure used in TTM should be more effective than SM in breaking down the trigger points, resulting in a greater and more sustained reduction in pain. Additionally, Chatchawan et al. (2005) found that even when SM is correctly applied, with lighter pressure than that used in TTM, the deep stroking and kneading techniques of SM may be able to break down trigger points and muscle adhesions and result in overall relaxation and reduced pain, in a manner comparable to that of TTM.

Buttagat et al. (2009), using the same measure of pain, reported that pain intensity, pressure pain threshold, and muscle tension, all showed significant improvements with Traditional Thai massage for back pain associated with myofascial trigger points in the immediate term (before and immediate assessment after the treatment). Chatchawan et al.'s (2005) study also found the pressure pain threshold was significantly higher in the TTM group compared with the SM group. Field et al. (2007) suggested that massage therapy was more effective than relaxation therapy (muscle relaxation exercise) for reducing pain and anxiety related to LBP. Another study compared the effectiveness of a massage therapy group with three other groups: soft-tissue manipulation, remedial exercise and posture education for subacute low back pain. Preyde's (2000) study found that massage therapy improved disability function and resulted in less intense pain and a decrease in the quality of pain compared with the other groups. Mackawan et al. (2005) examined the immediate effect of TTM and joint mobilization on pain levels and pain perception in non-specific low back pain. The findings suggested that both treatments could temporarily relieve pain. There was no significant difference between the two treatments in levels of substance P, a neuropeptide that has a crucial role in pain signal transmission (Mackawan et al., 2005) and is also useful as an alternative neurochemical correlation with chronic low back pain (Parris et al., 1990). Mackawan et al. (2005) also found that the pain levels as measured by VAS in the TTM group were slightly lower than that of the joint mobilization group ( $p=0.017$ ). Although, most reviewed trials reported that both Swedish and Thai massage can reduce pain levels in patients with

back pain, the trials only tested the effectiveness of massage in the immediate or short term.

### **2.2.2 Traditional Thai massage and Swedish massage on physical functions**

Massage not only reduces pain but also affects other physical functions. A study by Chatchawan et al. (2005) compared the effectiveness of TTM and SM among patients with back pain associated with myofascial trigger points and reported that patients in both massage groups reported improvements in almost all secondary outcome measures: disability measurement, back performance, body flexibility, side effects and medications used, at all post-treatment assessment times. Thai massage improved disability more than Swedish massage in both the short and long term. There were non-significant differences between the effect of TTM and SM on back performance and body flexibility (Chatchawan et.al, 2005). However, both TTM and SM had some side effects, that is, soreness and skin reaction. A trial conducted by Chatchawan et al. (2005) reported that during the treatment period between five and 10 out of 90 patients from each group reported having a little soreness after each treatment; however, those side effects disappeared after 5–10 minutes. In addition, five patients from the SM group reported skin reaction (rashes and pimples) to the massage oil and four of them reported this effect after the last treatment. Chatchawan et al. (2005) also reported that none of the patients used analgesic medications for their back symptoms during the time of this study.

Similarly, in the study by Preyde (2000) it was found that the massage therapy group showed an improvement in disability function ( $P < 0.01$ ) and had a higher score in lumbar range of motion as measured by the Modified Schober Test in the short term (one month) for sub-acute low back pain compared to manipulation, exercise or posture education. Similarly, a study by Hernandez-Reif et al. (2001) found that the massage therapy group experienced immediate changes in trunk flexion and displayed improved trunk flexion for CLBP across the study period (five weeks) compared to a relaxation muscle exercise group. It also showed improved trunk and pain flexion performance, and higher serotonin and dopamine levels. Franke et al. (2000) reported that acupuncture massage therapy had beneficial effects for both disability and pain

compared with Swedish massage in patients with low back pain. However, the studies were still unclear about the effectiveness of Swedish massage for low back pain in relation to the disability and lumbar range of motion in the longer term.

Cherkin et al. (2011) compared the effectiveness of two types of massage (SM and structural massage) and usual medical care for CLBP in terms of relieving disability. The study found that all groups showed improved disability function and decreased symptoms at 10, 26 and 52 weeks. However, there were no significant differences in functional improvement between both massage groups at 10 and 26 weeks. Also, no significant differences in symptoms were observed among the three groups at 26 or 52 weeks. Cherkin et al. (2011) concluded that massage therapy may be effective for treatment of chronic back pain, with benefits lasting at least six months. However, no clinically meaningful difference between relaxation (SM) and structural massage was observed in terms of relieving disability or symptoms. Although Cherkin et al.'s study examined the effectiveness of SM in terms of disability improvement compared with other types of treatments in the long term, it was limited in that participants were not blinded to treatments.

To compare the effects of traditional Thai and Swedish massage for physiological function, Cowen et al. (2006) used physiological assessments (blood pressure, heart rate, range of motion) conducted immediately before and after the single massage intervention. Both treatments included massage to the same areas of the whole body. Significant improvements ( $p < 0.05$ ) after the massage were found in the resting heart rate, ankle plantar flexion, ankle dorsiflexion, and shoulder abduction/rotation. This study reported that Thai massage was as effective as Swedish on general physiological outcomes. It reported that there are benefits associated with a single massage treatment. This result is different from Rachlin (1994) and Chatchawan et al. (2005) whose studies suggested a combination of superficial (Swedish massage) and deep massage (Thai massage) was the most effective treatment for pain relief for back pain associated with myofascial trigger points. However, Cowen et al. (2006) only compared the effectiveness of TTM and SM in the immediate term and studied healthy people, not a back pain group. Cowen et al. (2006) suggested that future research should evaluate the benefits of repeated general TM treatments over the longer term and explore how they

could be used as an alternative therapy or as a complementary treatment for disease or illness.

### **2.2.3 Traditional Thai massage and Swedish massage on psychological functions**

Most massage therapy studies for back pain have researched the effectiveness of massage therapy for physical or physiological function, but only a few studies have investigated the psychosocial effects of massage therapy. A few trials have reported that anxiety or stress can be reduced by massage therapy in the immediate-effect period (Buttagat et al., 2009; Cowen et al., 2006; Field et al., 2007; Hernandez-Reif et al., 2001). Buttagat et al. (2009) found that TTM onto the back muscle for 30 minutes in the prone position was effective in increasing cardiac parasympathetic activity, reducing sympathetic activity, and reducing pain and stress in patients with back pain associated with myofascial trigger points. Anxiety (measured using the State Trait Anxiety Inventory) in the TTM group was significantly ( $P < 0.001$ ) lower than the control group's anxiety level.

Some research has shown that TTM can promote relaxation and decrease stress and anxiety (Chaithavuthi & Muangsiri, 2007; Cowen et al., 2006). The findings of an increased relaxation response and an overall reduction in the defence-arousal (stress) response to TTM were possibly caused by increased parasympathetic and decreased sympathetic activity (Cowen et al., 2006). Other studies report an association between massage and increased levels of serotonin (5HIAA) and dopamine, again indicating modulation of the autonomic nervous system and expected decreased anxiety (Field et al., 2007).

In addition, Cowen et al. (2006) compared TTM and SM using psychological outcomes. The psychological (anxiety and mood) assessments occurred before and after each massage and 48 hours after the massage. This study illustrated that both types of massage improved mood and reduced anxiety. Improvements from before treatment to 48 hours after massage also indicated that the perceived benefits of massage might continue for up to two days. The improvements in anxiety were found for both the State Trait Anxiety Inventory (STAI) and the tension anxiety (TA) factor (Cowen et al., 2006;

Moyer et al., 2004). However, most reviewed trials reported the effectiveness of massage from the psychological view but lacked evidence of the effect on social functioning. These studies also measured the psychological outcomes only in the immediate or short term, and did not include a longer term assessment.

#### **2.2.4 Critique of studies of traditional Thai massage and Swedish massage in treating low back pain**

All the reviewed studies were conducted as randomised controlled trials with independent (unbiased) group allocation and half of the studies reported an intention-to-treat methodology. The findings indicate that both TTM and SM give beneficial effects on back pain relief in a number of physical and psychological functions.

However, there are a number of methodological limitations in design and follow-up assessment. For example, four studies tested the effectiveness of TTM or SM for low back pain (Buttagat et al., 2009; Chatchawan et al., 2005; Cherkin et al., 2011; Mackawan et al., 2005). These trials were limited by the fact that they included no control group, or placebo controls, or no blinding and/or follow-up investigation.

There were two clear limitations (methodology and follow-up investigation) in the Buttagat et al. (2009) trial which tested the immediate effects of TTM on heart rate variability and stress-related parameters in patients with back pain associated with myofascial trigger points. The outcome measurements of the respiratory rates of participants in this study were monitored using the BIOPAC Respiratory Transducer SS5LB, which might have caused some discomfort to the participants due to the fairly constrictive chest band. Another limitation of this study is that it only evaluated the immediate effect of TTM, which might not extend to a longer term effect. The suggestion for future studies would be a more comfortable method for assessing respiratory rate and testing the effect of TTM in the longer term.

The Chatchawan et al. (2005) study also had limitations. It compared the effect of TTM with SM among patients with back pain associated with myofascial trigger points. There was a high compliance rate, and an adequate sample size (n=180). Additionally, all

outcome measures were tested and found to have a very high degree of correlation. Unfortunately, this study lacked a secondary observer to verify outcome measured by the physical therapists so it was not possible to examine the inter-observer reliability of the outcome measures.

The Mackawan et al. (2005) study also had a few limitations in relation to the study design. Researchers examined the immediate effect of TTM versus joint immobilization on substance P level and pain perception in patients with non-specific low back pain. Although, this study was conducted as a randomised controlled trial with independent (unbiased) group allocation (TTM and joint immobilization) and evaluation by one person only, who was blind to treatment group allocation, no control group was included for ethical reasons in comparing treatments. Mackawan et al. (2005) suggested that future studies should use a placebo group (e.g. massage with no pressure) as a control group to give a stronger conclusion about the effectiveness of both treatments.

Another four massage therapy studies for back pain were reviewed. All of the trials reported that massage therapy significantly reduced back pain ( $P=0.001$ ) (Field et al., 2007; Hernandez-Reif et al., 2001; Preyde et al., 2000). However, the trials by Field et al. (2007) and Hernandez-Reif et al. (2001) had small sample sizes and lacked a long-term follow-up assessment. Field et al. (2007) tested lower back pain and sleep disturbance, which were significantly reduced following massage therapy ( $P<0.03$  and  $P<0.01$  respectively). However, this trial had only 30 participants with CLBP and measured the massage effectiveness in the immediate term only. Assessments were made before and after the session on the first and last days of the five-week study. A similar study found that lower back pain was significantly reduced ( $P=0.01$ ) and range of motion significantly increased ( $P=0.02$ ) after massage therapy (Hernandez-Reif et al., 2001). This study had a small sample size with only 24 adults with CLBP. The massage group received two 30-minute massage therapy sessions per week over five weeks delivered by a trained massage therapist. Pain, stress, and range of motion were assessed pre-post treatment sessions on the first and last days of the study to test immediate effectiveness. On the first and last day of the five-week study, the symptom checklist, sleep scale, and urine samples were conducted to measure long-term effectiveness. Both Field et al. (2007) and Hernandez-Reif et al. (2001) reported the

effect of massage therapy in the long term, but this was only five weeks after the first treatment group started treatment.

In conclusion, the literature review of the use of TTM and SM on back pain intensity, physical and psychological functions shows that both TTM and SM are equally effective in relieving lower back pain (Sritoomma et al., 2012). The studies reviewed have limitations in study design, outcome measurements and sample sizes (Sritoomma et al., 2012). Most studies did not assess long-term effectiveness; they only tested the immediate before-after massage effect (Buttagat et al., 2009; Franke et al., 2000; Mackawan et al., 2005). The longest post-treatment assessment investigated outcomes at five weeks post intervention (Chatchawan et al., 2005; Field et al., 2007; Hernandez-Reif et al., 2001; Preyde 2000) and some did not have a control group due to ethical concerns in comparing treatments. The studies conducted by Field et al. (2007) and Hernandez-Reif et al. (2001) had small sample sizes, 30 and 24 respectively. Franke et al. (2000) and Preyde (2000) measured only the physical domain and did not include the mental or psychosocial domains of quality of life. The participants in Cherkin et al.'s (2011) study were not blinded to treatments. Although CLBP mainly affects older people and a significant proportion of older people experience a period of LBP sometimes in their lives, no study to date specifically investigated or compared the effectiveness of Thai and Swedish massage in the older age group. The average age of participants in the studies reviewed was 36–46 years with only a few studies including people aged over 65 years.

## **2.3 The effectiveness of aromatic ginger oil/extract on low back pain**

### **2.3.1 Summary of the findings of ginger studies**

No trials were found that tested the effect of ginger on back pain so this literature review outlines ginger's effectiveness on other musculoskeletal pains (knee pain and osteoarthritis). Three trials examined ginger's effectiveness in reducing pain (Altman & Marcussen, 2001; Bliddal et al., 1999; Haghghi et al., 2005; Yip & Tam, 2008) (see Table 2.2). Bliddal et al. (2000) compared the effect of ginger extract with Ibuprofen in osteoarthritis of the hip or knee in cross-over RCT, with Ibuprofen being found to be

more effective than ginger extract (EV.ext-33) and placebo. This study found that the parameters of pain changed during therapy in all three treatment periods; however, a highly significant difference in efficacy on pain relief was found between the three treatments Ibuprofen>ginger extract>placebo on the Visual Analogue Scale of pain (Friedman test: 24.65,  $P<0.0001$ ). In this cross-over study with a wash out period of one week, no significant difference between placebo and ginger extract could be demonstrated for pain (Siegel-Castellan test), while explorative tests of differences in the first treatment period showed a both Ibuprofen and ginger extract were more effective than placebo (Chi-square,  $P<0.05$ ) (Bliddal et al., 1999). During the study, there were no serious adverse events reported. This study reported that ginger is effective for pain relief and has fewer side effects than Ibuprofen.

In a similar study, Haghghi et al. (2005) tested the effects of ginger extract as an alternative to NSAIDs and as a supplementary drug in the symptomatic treatment of osteoarthritis. The improvement of symptoms including pain, joint swelling and joint motion (defined as reduction in the mean change) was superior to the ginger extract and ibuprofen groups compared to the placebo group. In addition, there was no significant difference in pain using the Visual Analogue Scale (VAS) between the ginger extract and the ibuprofen groups. Haghghi et al. (2005) concluded that ginger extract and ibuprofen were significantly ( $P<0.0001$ ) more effective than the placebo in the symptomatic treatment of osteoarthritis, while there was no significant difference between the ginger extract and ibuprofen groups in a test for multiple comparisons.

Altman and Marcussen (2001) reported that a highly purified and standardized ginger extract had a statistically significant effect on reducing knee pain both on standing ( $P=0.048$ ) and after walking 50 feet ( $P=0.016$ ). There was a good safety profile with ginger, with mild gastro-intestinal upsets as the only adverse event.

All three trials used oral ginger extract treatment for pain relief. However, ginger oil was used in the Yip and Tam (2008) study. The study assessed the efficacy of an aromatic essential oil (1% *Zingiber officinale* and 0.5% *Citrus sinensis*) massage in older people with moderate-to-severe knee pain. Participants in the intervention and placebo groups received a session of 30-35 minutes of aroma-massage on both lower limbs six

times within two to three weeks. The intervention group received massage with ginger essential oil (1% ginger and 0.5% orange oil in olive oil as the base lubricant) plus usual massage. The 0.5% orange essential oil (*Citrus Aurantium*) was added to give a more acceptable odour as it was felt that some participants would find the pungent odour of ginger oil disturbing. Olive oil was selected as the base because it was relatively less costly, and safe for dry and delicate skins compared to other carrier oils. The placebo control group received the massage with olive oil only as well as usual massage, while the control group received no massage but usual massage during the study. However, an equivalent massage session was given to the control group after the study was completed as a service. The same supply of oils and dilutions was used throughout the study. The primary outcome was the knee joint pain intensity measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and a standard 10-cm horizontal Visual Analogue Scale (VAS). The secondary outcomes were knee joint stiffness intensity, physical functioning and quality of life. The findings showed that there were significant mean changes between the three time-points within the treatment groups on three of the outcome measures – knee pain intensity ( $p = 0.02$ ), stiffness level ( $p = 0.03$ ), and enhanced physical function ( $p = 0.04$ ) – but these were not apparent in the between-groups comparison ( $p = 0.48, 0.14$  and  $0.45$  respectively) four weeks after the massage. The improvements in physical function and pain were superior in the intervention group compared with both the placebo and the control group at post one-week time point (both  $p = 0.03$ ) but not sustained at post four weeks ( $p = 0.45$  and  $0.29$ ). However, the changes in quality of life were not statistically significant in difference between the three groups. From this finding, Yip and Tam (2008) concluded that the aroma-massage therapy had potential as an alternative method for short-term knee pain relief. Ginger might possibly be used as an anti-inflammatory and analgesic agent to relieve pain and stiffness for moderate-to-severe knee pain in older people.

The reviewed trials of ginger effectiveness support the finding that ginger has an analgesic anti-inflammatory action and can relieve pain. However, both the effects of oral ginger extract treatment and ginger oil were tested only on knee pain and osteoarthritis in the short term.

**Table 2.2: The effectiveness of ginger in reducing pain**

Authors/year of publication	Objectives	Methodology					Findings	Limitation
		Design & Sample	Settings	Interventions	Outcome measures	Timing of follow-up		
Altman R.& Marcussen C. (2001)	To evaluate the efficacy and safety of a standardized and highly concentrated extract of two ginger species, Zingiber officinale and Alpinia galanga, in patients with osteoarthritis (OA) of the knee	Randomized placebo controlled trial, double-blind, multicentre and parallel-group  247 patients with osteoarthritis of the knee and moderate-to-severe pain  Average age: 65.2+/- 11.4 yrs Female: 62.5 %	Miami Veterans Affairs Medical Center and University of Miami, Florida, USA	Treatment with analgesics and non-steroidal anti-inflammatory drugs (NSAID) was discontinued after a one-week washout period  During the six-week treatment period, patients ingested one capsule twice daily, morning and evening. Each capsule contained 255 mg of EV.EXT 77, extracted from 2,500-4,000 mg of dried ginger rhizomes and 500-1500 mg of dried galanga rhizomes and was produced according to good manufacturing practice (Enrovita Holding, Karlslunde, Denmark).  <b>G1 (treatment):</b> 2,500-4,000 mg Zingiber officinale and 500-1500 mg Alpinia galanga (EV.EXT77) extract <b>G2(control):</b> placebo (Coconut oil)  Acetaminophen 4 mg/day was used as rescue medication and Aspirin for anticoagulation up to 325 mg daily was allowed throughout the study  <b>Groups:</b> G1: EV.EXT77, n=124 G2: Placebo, n=123	<b>Primary outcomes:</b> • Knee pain standing (using WOMAC and VAS)  <b>Secondary outcomes:</b> • Knee pain after walking • Quality of life (SF-36) • Global status • Consumption of rescue medication	After wash-out followed by ginger extract or placebo twice daily for six weeks	A highly purified and standardized ginger extract had a statistically significant (P=0.048) effect in reducing symptoms of OA of the knee. This effect was moderate. There was a good safety profile, with mostly mild GI adverse events in the ginger extract group	Short-term evaluation

**Table 2.2: The effectiveness of ginger in reducing pain**

Authors/year of publication	Objectives	Methodology					Findings	Limitation
		Design & Sample	Settings	Interventions	Outcome measures	Timing of follow-up		
Bliddal H. et al. (1999)	To examine the effect of ginger extracts and Ibuprofen in osteoarthritis	<p>Double-blind, double-dummy, cross-over controlled design</p> <p>56 patients with osteoarthritis of the hip or the knee</p> <p>Average age: 66 yrs Female: 73.21 % Pain duration: average 7.7 yrs</p>	<p>Parker Institute, Frederiksberg Hospital, Copenhagen, Denmark</p>	<p>Treatment with analgesics and non-steroidal anti-inflammatory drugs (NSAID) was discontinued for a one-week washout period</p> <p>The patients were then randomized to three treatment periods of three weeks each, administered t.i.d</p> <p><b>G1 (treatment):</b> 170 mg EV.ext-33 ginger extract <b>G2(control):</b> Ibuprofen 400 mg <b>G3:</b> placebo</p> <p>Acetaminophen was used as rescue medication throughout the study</p> <p>The study was conducted in accordance with Good Clinical Practice (European Guideline for GCP)</p> <p><b>Groups:</b> Numbers of participants in each group not reported</p>	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Knee pain intensity (using WOMAC and VAS)</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Knee stiffness intensity</li> <li>• Physical functioning</li> <li>• Quality of life (SF-36)</li> </ul> <p><b>Assessment of efficacy:</b></p> <ul style="list-style-type: none"> <li>• A 100 mm VAS for pain assessment (primary outcome variable)</li> <li>• Lequesne-index for either hip or knee</li> <li>• Range of motion</li> </ul> <p><b>Assessment of safety:</b></p> <ul style="list-style-type: none"> <li>• Blood test for haemoglobin</li> </ul>	<p>A wash-out period of one week followed by three treatments periods in a randomized sequence, each of three weeks duration</p>	<p>A ranking of efficacy of the three treatment periods: Ibuprofen&gt;ginger extract&gt;placebo was found for VAS of pain and the Lequesne-index.</p> <p>In the cross-over study, no significant difference between placebo and ginger extract could be demonstrated, while explorative tests of differences in the first treatment period showed a better effect of both Ibuprofen and ginger extract than placebo (<math>P&lt;0.05</math>)</p> <p>There were no serious adverse events reported during the periods with medications</p>	<p>In the study a statistically significant effect of ginger extract could only be demonstrated by explorative statistical methods in the first period of treatment before cross-over, while a significant difference was not observed in the study as a whole</p>

**Table 2.2: The effectiveness of ginger in reducing pain**

Authors/year of publication	Objectives	Methodology					Findings	Limitation
		Design & Sample	Settings	Interventions	Outcome measures	Timing of follow-up		
Haghighi M. et al. (2005)	To compare the effects of ginger (zingiber Officinale) extract and buprofen on patients with osteoarthritis	A double-blinded randomized placebo controlled clinical trial  120 outpatients with OA of moderate to severe pain, requiring only the use of NSAIDs  Average age: 58.5 yrs Female: 25.83% Pain duration: Not reported	Rheumatology clinic of Imam Khomeini Hospital  Iran	These patients were randomized into three groups of 40  G1:placebo (PL) G2:ginger extract (GE) G3:ibuprofen (IBP) groups  After a washout period of one week (week 0), patients received either 30 mg ginger extract in two 500 mg capsules, placebo, or three 400 mg ibuprofen tablets daily for one month  Acetaminophen tablet was prescribed as a rescue analgesia during the study  Groups: G1: PL, n=40 G2: GE, n=40 G3: IBP, n=40	<ul style="list-style-type: none"> <li>100-mm VAS for assessing the severity of pain</li> <li>Gelling pain</li> <li>Joint swelling measurements</li> <li>Joint motion slope measurements</li> </ul> <p><b>Statistical analysis</b></p> <ul style="list-style-type: none"> <li>ANOVA</li> <li>Kruskal-Wallis nonparametric test for between-group differences</li> <li>Dunn's correction of the significance level for multiple comparison</li> </ul>	Baseline, A month of treatment	The improvement of symptoms including pain, joint swelling and joint motion was superior to the ginger extract and ibuprofen groups than the placebo group.  There was no significant difference in VAS and gelling pain scores between the ginger extract and the ibuprofen groups.  <b>Conclusion</b> Ginger extract and ibuprofen were significantly ( $P<0.0001$ ) more effective than the placebo in the symptomatic treatment of OA, while there was no significant difference between the ginger extract and ibuprofen groups in a test for multiple comparison	The development of side effects often occur without warning and could be life threatening  A 1-month period of therapy with only one dose of ginger extract applied in this study might not have been adequate for all the effects of ginger extract to be detected  Future studies might look into the dose-response and duration of therapy of a standardized and highly concentrated ginger extract in patients with osteoarthritis

**Table 2.2: The effectiveness of ginger in reducing pain**

Authors/year of publication	Objectives	Methodology					Findings	Limitation
		Design & Sample	Settings	Interventions	Outcome measures	Timing of follow-up		
Yip Y.B. et al. (2008)	To assess the efficacy of an aromatic essential oil (1% <i>Zingiber officinale</i> and 0.5% <i>Citrus sinensis</i> ) massage among the elderly with moderate-to-severe knee pain	A double-blind, placebo-controlled group experimental study design  59 older voluntary persons with knee joint pain  Average age: 73.59 years Female: 79 % Pain duration: average 9.71 years	The Community Centre for Senior Citizens  Hong Kong	<p><b>Group 1:</b> The intervention was six massage sessions with ginger and orange oil over a 3-week period.</p> <p><b>Group 2 :</b> The placebo control group received the same massage intervention with olive oil only</p> <p><b>Group 3:</b> The control group received no massage</p> <p><b>Groups:</b> G1: Massage with ginger &amp; orange oil, n=19 G2: Massage with olive oil, n=17 G3: Conventional treatment, n=17</p>	<p><b>Primary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Knee pain intensity (using WOMAC and VAS)</li> </ul> <p><b>Secondary outcomes:</b></p> <ul style="list-style-type: none"> <li>• Knee stiffness intensity</li> <li>• Physical functioning</li> <li>• Quality of life (SF-36)</li> </ul>	Baseline, post 1-week and post 4 weeks after treatment	<ul style="list-style-type: none"> <li>• There were significant mean changes between the three time-points within the intervention group in knee pain intensity (<math>p = 0.02</math>); stiffness level (<math>p = 0.03</math>); and physical function (<math>p = 0.04</math>)</li> <li>• The improvement of physical function and pain were superior in the intervention group compared others (<math>p = 0.03</math>) but not sustained at post 4 weeks (<math>p = 0.45, 0.29</math>)</li> <li>• The changes in quality of life were not statistically significant for all three groups.</li> </ul> <p><b>Conclusions:</b> The aroma-massage therapy seems to have potential as an alternative method for short-term knee pain relief</p>	<p>The nurse massage therapist was not blind to the types of treatment</p> <p>The awareness of the participants on the effects of ginger in the management of knee pain; they may have incorporated ginger into their daily diet</p> <p>The sample size was beneath enough to reflect real conditions (53 people)</p> <p>The incompleteness of follow-up is a potential weakness</p>

### **2.3.2 Critique of the ginger oil/extract studies**

The reviewed ginger trials had some strengths and limitations in their studies. The strength of the Yip and Tam (2008) study was the inclusion of a placebo control group and blinded measurement. This helped to eliminate the placebo effects and observation bias in outcome measures. Despite this strength, there were potential limitations. Although the nurse massage therapist was not involved in data collection, she was not blinded to the types of treatment being given. It was inevitable that the therapist's awareness of the types of treatment might sensitize the participants on every symptom to the treatment. Secondly, this study may have increased awareness among participants about the use of ginger in managing knee pain so that participants may have incorporated ginger into their daily diet. Additionally, as the net total number of participants was 53, the sample size was below what was required to reflect real conditions. Moreover, the functional abilities of participants may be exaggerated when assessing the functional status of daily activities, as discrepancies between self-reports of functional ability and observation assessments have been found (Miu et al., 2004)

Two limitations are evident in the Haghighi et al. (2005) trial. Firstly, the researcher failed to warn patients about the side effect of NSAID to the gastro-intestinal system. Side effects of NSAID therapy such as gastrointestinal ulceration and ulcer complications often occur without warning and can be life threatening. Secondly, over the one-month period of therapy only one dose of ginger extract was taken and this might not have been adequate for all the effects of ginger extract to be detected. The researchers suggest that future studies might look into the dose-response and duration of therapy.

The few studies investigating the effect of ginger on rheumatic and muscle pain all found that ginger significantly relieved pain (Altman & Marcussen, 2001; Bliddal et al., 1999; Haghighi et al., 2005; Yip & Tam, 2008). However, no study has tested the effectiveness of aromatic ginger oil in treating chronic low back pain. Therefore, there is an opportunity to investigate the effects of ginger in treating other types of pain, especially low back pain.

## **2.4 The complexity of nursing and complementary alternative medicine research**

This section critiques the investigation of complex interventions in nursing including CAM research as this dissertation uses the methodology of RCT to test the effectiveness of massage in treating CLBP.

### **2.4.1 Investigating complex interventions in nursing**

In nursing science, RCT design is a complex endeavor to conduct in a complex clinical environment. Environmental complexity is certainly one of many factors which inhibits the use of RCTs in nursing science (Prescott et al., 1999). However, the complexity of the clinical environment is not unique to nursing as clinical interventions conducted in fields such as medicine and physiotherapy are also complex and continue to be conducted (Blackwood, 2006; Campbell et al., 2007; Medical Research Council, 2008; Richards & Hamers, 2009). (). The complexity of trialing interventions in a clinical setting is as a result of the inherent variation in the populations targeted by such interventions, the number of interactions between components within the experimental and control interventions, the number and variability of outcomes, number and difficulty of behaviours required by those receiving the intervention, and degree of flexibility in the intervention fidelity (Medical Research Council, 2008; Rolfe, 2002).

RCT design has traditionally been used to evaluate new drug treatments. Recently, it has been acknowledged that whilst in theory it may be best practice to carefully develop and test interventions through a phased program of pilot studies, in reality interventions can arise from ‘past practice, existing evidence, theory, an investigator’s interest, policy makers or practitioners, new technology, or commercial interests’ (Medical Research Council, 2008)..

### **2.4.2 Experimental research in nursing**

Experimental research is characterised by the inclusion of a control group to which the intervention group is compared. The classic experimental research design is where one group is exposed to an intervention treatment and the other group is exposed to something that is inert. The research examines the group outcomes to identify if there

are any differences between the treatment and control group. Therefore experimental research offers evidences concerning causation and effect of interventions. If a treatment is tested in a clinical setting it is called a clinical trial. Nurse researchers may use experimental methods to examine for example the factors that determine the assessment of a patient or nursing problem (pain or quality of care) or predict nurses' decision-making regarding interventions (Richards & Hamers, 2009). In a true experiment, there are a number of characteristics: randomisation of the participants, and control and manipulation, so that all factors are controlled (Polit and Beck, 2003; Richards & Hamers, 2009).

Although experimental research is considered to be classic research most nursing research is not experimental as it is difficult to identify all of the variables associated with nursing care that need to be controlled. Furthermore, within nursing practice where social variables can influence treatment it can be difficult to manipulate these types of variables. Furthermore, it can be difficult to conduct random assignment to groups and standardization of research procedures within the clinical setting. Therefore these complexities can reduce the number of experimental studies within nursing practice.

Richards and Hamers (2009) concluded that although nursing research is complex and experiments are artificial, that experimental research in nursing can be overcome by careful methodological processes. which is important for nursing practice as the application of experiments in nursing can produce extremely useful information for practice. Richards and Hamers (2009) emphasized that innovative nursing science needs innovative research and researchers who broaden the horizon by using combinations of innovative and complicated designs, and sometimes go beyond the beaten track of nursing science.

### **2.4.3 Complementary alternative medicine in chronic low back pain**

This study investigated massage therapy which is one of the CAM therapies. CAM is most commonly used for chronic back pain (Cheung & Halcon, 2007; Willison & Andrews, 2004). Among prior users of specific CAM modalities for back pain, massage

was rated most helpful in relieving their current pain whereas users of chiropractic care reported treatment-related significant discomfort, pain or harm (Sherman et al., 2004).

Comparing massage therapy with other alternative therapies in treating LBP six studies (Buttagat et al., 2009; Chatchawan et al., 2005; Field et al., 2007; Hernandez-Reif et al., 2001; Mackawan et al., 2005; Preyde, 2000) reported that both traditional Thai and Swedish massage could reduce back pain intensity. Traditional Thai massage slightly reduced pain compared to joint mobilization while the Swedish massage group had significantly less intense pain and a decrease in the quality of pain compared with soft-tissue manipulation, remedial exercise and posture education for sub-acute low back pain.

Acupuncture is one of the popular alternative therapies and it is used by approximately 2% of adults in the UK for treating back pain (Thomas et al., 2006). According to the National Institute for Health and Clinical Excellence (NICE) guidelines (2009) a course of acupuncture of up to 10 sessions over 12 weeks is offered as a treatment option, according to patient preference (National Institute for Health and Clinical Excellence, 2009). Similarly, the present study intervention session was 10 sessions over 5 weeks. Comparing acupuncture with massage therapy in treating chronic low back pain, Cherkin et al. (2001) compared the effectiveness of acupuncture, massage and self-care education for persistent back pain. The three group intervention had 10 sessions over 10 weeks in each group. Cherkin et al. (2001) concluded that therapeutic massage was effective for persistent low back pain, apparently providing long-lasting benefits. Traditional Chinese Medical acupuncture was relatively ineffective (Cherkin, et al., 2001).

These previous studies have demonstrated favorable use experimental study in nursing and in particular when investigating CAM interventions. Although there are many complexities associated with experimental design use in nursing research these studies have demonstrated excellence through a process of development, feasibility/piloting, evaluation and implementation using standardized research protocols..

## **2.5 Summary**

The literature review has reviewed and critiqued published studies on the effectiveness of SM, TTM on LBP and the effectiveness of aromatic ginger oil/extract in treating musculoskeletal pain. Furthermore, this chapter has critiqued the complexity of conducting experimental research in nursing and in particular in CAM research. Previous studies have concluded that SM and TTM are equally effective in relieving LBP. However, these studies were found to have some limitations. The RCT study described in this thesis was designed to address these limitations by including an appropriate sample size, longer follow-up, standardised intervention and outcome assessments to further test the effectiveness of both SM and TTM techniques, and the effectiveness aromatic ginger oil back pain, in treating low back pain. The next chapter explains how massage (SM and TTM) and aromatic ginger oil/extract can reduce pain. It also outlines the conceptual framework for this study.

## **CHAPTER 3**

### **CONCEPTUAL FRAMEWORK**

#### **Introduction**

Massage and aromatherapy have become the most popular complementary and alternative medicine (CAM) therapies for treating pain, the condition for which CAM therapies are most commonly used (Wolsko et al., 2003). As shown in Chapter Two, most massage or aromatherapy studies have used randomised controlled trial designs to test their effectiveness of these therapies in treating conditions such as pain. The present study investigates the effectiveness of SMGO compared with TTM as a control group for CLBP in Thai older people.

TTM is considered to be the usual massage treatment for low back pain in Thailand (Kulsomboon & Attasit., 2007). TTM is therefore chosen as the control treatment in this current study. TTM generally follows the Sen lines on the body—somewhat analogous to meridians or channels and Indian nadis (Chaithavuthi & Muangsiri, 2007). Since The Thai government has supported traditional Thai medicine as national policy, Thai massage has gained credibility in the eye of the Thai public (Chaithavuthi & Muangsiri, 2007). To control for standard of care and safety practice, The Ministry of Education and The Ministry of Public Health of Thailand have approved numerous massage schools throughout the Kingdom (Chaithavuthi & Muangsiri, 2007). A full body Thai massage session typically lasts two hours or more, and includes rhythmic pressing and stretching of the entire body (Institute for Small and Medium Enterprises Development, 2002). The massage practitioner leans on the recipient's body using hands and usually straight forearms locked at the elbow to apply firm rhythmic pressure (Chaithavuthi & Muangsiri, 2007). There is a standard procedure and rhythm to the massage, which the practitioner will adjust to fit each individual client (Chaithavuthi & Muangsiri, 2007). The cost of TTM is approximate 300-400 Thai baht per 2 hours (Institute for Small and Medium Enterprises Development, 2002).

Thai and Swedish massage are based on different theories. Thai massage includes references to the ten energy lines (Sen Sib), while Swedish massage is based on Western anatomy and physiology. Therefore, this chapter presents the conceptual framework for both types of massage and outlines the properties of ginger relevant to its use in treating pain. Ginger will be used as an aromatic essential oil combined with Swedish massage. Ginger is an anti-inflammatory and analgesic agent with both prostaglandin and leukotriene syntheses inhibitors (Grzanna et al., 2005). It is hypothesised that Swedish massage may be more effective for back pain relief in the immediate, short and long term, if it is combined with the application of ginger oil.

Chapter One provided an overview of the background on the use of Swedish massage and ginger aromatherapy in treating CLBP. Chapter Two reviewed and critiqued studies investigating the effect of Thai versus Swedish massage and aromatic ginger oil/extract on pain, including LBP. This chapter explains how massage (Swedish massage and Thai massage) and ginger reduce pain, including scientific theories, efficacy profiles, traditional beliefs and side effects of both massage and ginger. The effects of both Thai and Swedish massage from scientific perspectives will be presented in the first section of this chapter followed by the traditional beliefs of Thai massage, the effects of ginger, and how aromatherapy works.

### **3.1 Effects and benefits of massage**

#### **General description**

Massage has been defined as a systematic and scientific manipulation of the soft tissues of the body with rhythmical pressure and stroking for the purpose of obtaining or maintaining health (Weerapong et al., 2005; Wieting et al., 2008). Basically, massage is a simple means of pain relief, while at the same time aiding relaxation and promoting a feeling of well-being and a sense of receiving good care (Weerapong et al., 2005; Imamura et al., 2008). Massage for CLBP can be applied either to the lumbar region or to the whole body, depending on patient symptoms and the desired therapeutic effect (Weerapong et al., 2005). Massage, especially Swedish massage, uses a combination of techniques including stroking, effleurage, petrissage, friction, kneading, or hacking. Soft tissue massage has four basic effects on patients: mechanical, physiological, neurological and psychological. Each of these broad areas is considered separately in

this chapter, although they are closely related. The primary effects of massage are mechanical, but they produce physiological and psychological effects in individuals. This chapter describes only the effects of massage on pain, especially in the muscular-skeletal system.

Massage in Asian countries has evolved according to Eastern philosophy, spirituality, theories of energy movement, and clinical practice. Massage in Western society has developed under the influence of modern medicine and physiology (Salvo, 2003). Swedish massage is considered to be a superficial massage (Rachlin, 1994), which consists of five main stroking actions to stimulate the circulation of blood through the soft tissues of the body. Through stroking and kneading, the body's metabolic processes and blood circulation are stimulated, enhancing one's sense of vitality, and combined with active and passive movements of the joints improving range of motion and muscle tone (Ojala, n.d., para.9). The technique of traditional Thai massage is considered a form of deep tissue massage with acupressure. It works as a therapeutic intervention to reduce back pain. Thai massage follows two lines on the back following the Thai massage theory of the ten energy lines (Chatchawan, 2005). The present study tested Swedish massage with aromatic ginger essential oil as a treatment group while TTM was provided as a usual massage control group. The following section demonstrates the effects and benefits of Swedish and Thai massage in back pain relief from scientific perspectives. The mechanisms of massage on the body and mind are then presented from a general viewpoint followed by the beneficial effects of each Swedish massage technique and the theory of Thai massage based on traditional views.

### **How does massage work?**

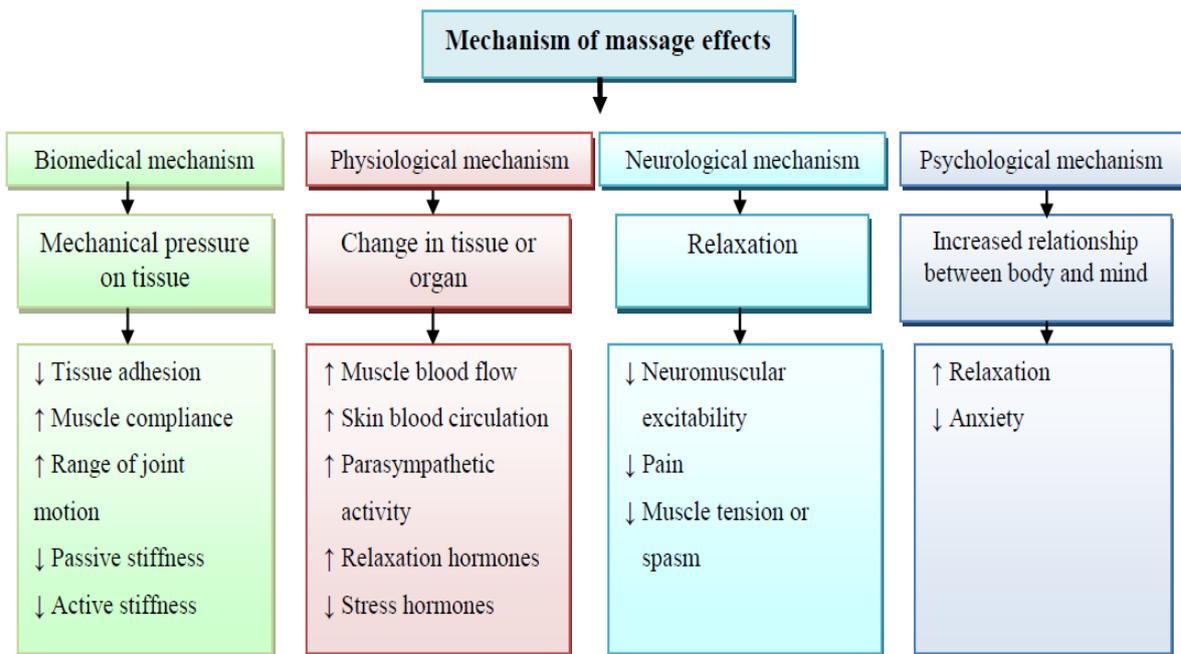
For centuries, human touch has been shown to be emotionally and physically healing. Particular massage techniques may either stimulate or calm the body's muscles and tissues to create a desired effect. When a practitioner massages soft tissue, electrical signals are transmitted both to the local area and throughout the body. These signals, in combination with the healing properties of touch, help heal damaged muscle, stimulate circulation, clear waste products via the lymphatic system, boost the activity of the immune system, reduce pain and tension, and induce a calming effect. Massage may

also enhance well-being by stimulating the release of endorphins (natural painkillers and mood elevators) and reducing levels of certain stress hormones.

### **3.1.1 Mechanism of massage action**

During massage, there is mechanical stimulation of the tissue by means of rhythmically applied pressure and stretching. Pressure compresses soft tissue and distorts the network of nerve-ending receptors. Stretching applies tension to soft tissues and distorts the nerve-ending plexuses of receptors. By enlarging the lumens of blood vessels and lymph vessel spaces these two forces affect capillary, venous, arterial, and lymphatic circulation (Domenico & Wood, 1997).

Soft tissue massage is thought to improve physiological and clinical outcomes of CLBP by offering the symptomatic relief of pain through physical and mental relaxation. Manipulation of affected muscles and fascia may induce local biochemical changes that modulate local blood flow and oxygenation in muscles. These local effects may influence neural activity at the spinal cord segmental level and modulate the activities of sub-cortical nuclei that influence mood and pain perception (Sagar et al., 2007). Massage may also increase the pain threshold through the release of endorphins and serotonin (Hernandez et al., 2001). The gate-control theory predicts that massaging a particular area stimulates large diameter nerve fibres, which have an inhibitory input onto T-cells (first cells in the spinal cord that project into the central nervous system). This may result in decreased T-cell activity, followed by pain relief (Melzack et. al, 1996). Massage may also increase local blood circulation, improve muscle flexibility, intensify the movement of lymph, and loosen adherent connective tissue (Imamura et al., 2008). The effects of massage are mostly produced by more than one mechanism: biomechanical, physiological, neurological and psychological mechanisms (Weerapong et al., 2005). A theoretical model of the mechanisms and their effects is presented in Figure 3.1.



**Figure 3.1: Theoretical model of the expected mechanism of massage**  
 (Weerapong et al., 2005, p.238)

The following section will briefly present the biomedical and physiological mechanisms of massage and demonstrate the neurological and psychological mechanisms broadly and in relation to their effects on pain.

### **3.1.1.1 Biomechanical mechanisms**

Biomedical massage effects come about through mechanical pressure on tissues. Therefore, this section explains how mechanical pressure influences the muscular-skeletal system. Massage involves the application of mechanical pressure on the muscle tissue to decrease tissue adhesion. Increased muscle-tendon compliance is achieved by mobilising and elongating shortened or adhered connective tissue. Improved muscle compliance results in less stiff muscles and tendons (Magnusson, 1998), which is measured by three main measurements: dynamic passive stiffness, dynamic active stiffness and static joint end range of motion (Weerapong et al., 2005).

This section explains how massage has an effect on tissue through skin and the involvement of muscular-skeletal functions. Massage may reduce tissue adhesion and communicate feeling and emotion by touching, stroking and rubbing of the skin. Each technique of massage such as squeezing, pulling, stretching, pressing and rubbing have noticeable mechanical effects on tissue (Domenico & Wood, 1997). For instance, the technique of kneading and wringing would be expected to have a significant mobilizing effect (loosening or stretching) on the skin and subcutaneous and muscle tissue (Domenico & Wood, 1997). However, the slightly increasing pressure of effleurage or stroking affects blood circulation and lymph flow because its movement pushes the venous blood and lymph in the superficial vessel toward the heart (Goldberg, 2001). Each of the manipulation effects is listed in Table 3.1.

**Table 3.1: Therapeutic effects of soft tissue massage**

(Domenico & Wood, 1997, p.68)

<b>Stroke</b>	<b>Effects</b>
<b>Effleurage, Stroking</b> <b>Skin rolling</b>	Stimulation of superficial blood and lymph flow; mobilization of skin and subcutaneous tissue; promotion of local and general relaxation; relief of pain
<b>Kneading, Wringing</b> <b>Picking up</b>	Mobilization of muscle tissue; stimulation of deeper circulation; promotion of relaxation; relief of pain
<b>Hacking, Beating</b> <b>Pounding, Clapping</b>	Stimulation of muscle activity and deep circulation
<b>Clapping, Vibrations</b> <b>Shakings</b>	Mobilization and removal of lung secretions
<b>Deep friction</b>	Mobilization and pain relief in tendons, muscle, ligaments, and joint capsules

Dry tissue creates more friction and is known to lose compliance and elongate less readily when the tissue has good water content. Therefore, the rate of massage should be suitable for the type and condition of the skin tissue (Holey & Cook, 2003). This is of particular importance in an older population.

### **Increasing muscle tone**

Massage also affects skeletal muscle. One of the effects is increasing muscle tone. A healthy muscle always has a certain amount of resting tone, which is a response of the muscle fibres to nervous activity and maintains the muscle in a state of slight, normally imperceptible, contraction. Tone can be increased, especially in postural muscles, by factors such as stress because muscle spindles have sympathetic innervations (Holey & Cook, 2003). Tone is dependent on the interaction between the muscle spindle (sensitive to length and rate of change in length of muscle) and the central nervous system (CNS). Stretching a muscle will stimulate the spindle and cause reflex muscle

contraction, while reflex inhibition of the antagonist occurs. Massage can add an external stimulus to sensory organs and either raise tone by stimulation or reduce it, probably by facilitating an accommodation of the spindle, causing it to 'reset' at a lowered threshold of excitability (Holey & Cook, 2003). The sympathetic supply to muscle spindles means that any influence on the autonomic nervous system (ANS) will affect muscle responses (Braun & Simonson, 2005). Massage techniques have a general relaxation effect in addition to the effect of local massage in changing muscle tone (Field et al., 2007).

### **Improved muscle stiffness and joint motion**

Massage encourages nutrition and development of the muscular system by stimulating its circulation, nerve supply and cell activity (Fritz, 2000). Regular and systematic massage causes the muscles to become firmer and more elastic, while muscles that are too weak to function can be strengthened by active massage treatments (Loving, 1999). Massage also provides a gentle stretching action to both the muscles and connective tissues that surround and support the muscles and many other parts of the body, which helps to keep these tissues elastic (Gao et al., 2010). When muscle is fatigued and sore, it can be revitalized through massage. Massage can improve blood circulation around muscles and it can enhance muscle tone so these actions cause muscles to be more firm and elastic (Loving, 1999).

Muscles that are tightened and shortened often impair joint movement and massage can often improve mobility of joints. The passive range of motions will reveal the gains received from the massage. In addition, active joint movements performed by the client are similar to exercise and can strengthen and firm the muscles (Loving, 1999). Joints are crucial to exercise because joints are moved by the muscles to produce movement. All joints are complicated, and their parts have a way of settling and stiffening when not used (Langlitz, n.d., para. 1). Massage therapists may incorporate joint movement into their treatment when evaluating range of motion. In response to joint movement, the body produces synovial fluid, which cushions and lubricates the synovial joints to keep them healthy (Braun & Simonson, 2005). In this way, massage may reduce muscle stiffness and improve range of motion by passive manipulation.

In conclusion, the mechanical pressure of massage affects the tissues by four means:

1. Manipulation techniques such as touching, stroking, rubbing or pressing pressure on skin can reduce tissue adhesion (Domenico & Wood, 1997).
2. Stretching muscles will stimulate the spindle and cause reflex muscle contraction. Massage is an external stimulus to sensory organs and can either raise muscle tone by stimulation or reduce it (Holey & Cook, 2003).
3. Massage can improve muscle stiffness by stimulating blood circulation, nerve supply and cell activity. It helps muscle to become firmer and more elastic (Fritz, 2000).
4. The passive manipulation of massage improves joint range of motion. Joint response to the massage action is the production of synovial fluid which cushions and lubricates the synovial joint so massage help joints to be healthy (Braun & Simonson, 2005).

#### **3.1.1.2 Physiological mechanisms**

There are two physical effects of massage, mechanical and reflex, which may occur separately or together (Beck,2010; Fritz, 2000). Mechanical effects are direct physical effects of the massage techniques on the tissue. A mechanical response happens as a result of pressure, force and range of motion. Tissues are pulled, lifted, rubbed, compressed and manipulated. Examples of the mechanical responses of pressure are increased blood circulation, and reduced swelling or formation of scar tissue (Salvo, 2003). Reflex effects of massage are indirect responses to touch that affect body function and tissue through the nervous or energy systems of the body. Gentle stimulation of sensory nerve endings in the skin, such as superficial stroking, results in reflex effects, either locally or in distant parts of the body.

#### **Increased muscle blood flow and skin circulation**

The immediate effects of massage are noticeable on the skin, for example increased skin and muscle temperature (Weerapong et al., 2005). Friction and stroking movements heighten blood circulation to the skin and increase activity of the sweat and oil glands. Accompanying the increased flow of blood, there is slight reddening and warming of

the skin. Superficial skin friction raises local heating, and consequently causes hyperemia within the massage area. Local heating increases local blood circulation (Black et al., 2003).

The pumping action of compression and deep stroking during massage can increase the effect of massage. Even light stroking and sustained percussion movements can result in vasodilatation in surrounding areas (Goldberg, 2001; Loving, 1999). Stroking removes dead skin cell, stimulates sweat and sebaceous glands, and improves the suppleness of the skin. Percussion movement also stimulates circulation by shaking deeper tissues (Goldberg, 2001).

Massage, in particular Swedish massage, affects the circulatory system of the body (Loving, 1999). When massaging a particular body part, the blood rushes in, carrying increased oxygen and nutrients needed for injured or stressed areas (Fritz, 2000). This action increases the venous flow of the blood return to the heart and lungs for re-oxygenation and reduces venous pressure. As a result, arterial circulation is increased, and capillary pressure and the fluid filtrating into extracellular space are decreased (Loving, 1999).

### **Increased parasympathetic activity**

The mechanical pressure of massage may stimulate parasympathetic activity as shown by reduced saliva cortisol levels, the stress hormone demonstrating an indirect measure of parasympathetic activity (Field et al, 2007). Changes in hormonal levels (serotonin and cortisol) after massage have been shown in specific conditions such as patients with low back pain (Hernanandez et al., 2001), HIV-positive patients and depressed adolescent mothers (Weerapong et al., 2005). Massage has also been shown to increase parasympathetic activity by reducing heart rate and blood pressure (Buttagat et al., 2009; Corley et al., 1995), increasing relaxation substances such as endorphins and increasing heart rate variability (Delaney et al, 2002).

Diego and Field (2009) studied 20 healthy adults who were randomly assigned to a moderate pressure or a light pressure massage therapy group. Electrocardiography (EKGs) were recorded during a 3-minute baseline during the 15-minute massage period

and during a 3-minute post-massage period. EKG data were then used to derive the high frequency (HF), low frequency (LF) components of heart rate variability, and the low to high frequency ratio (LF/HF) as non-invasive markers of autonomic nervous system activity. This study found that the moderate pressure massage (typical of Thai massage) exhibited a parasympathetic nervous system response characterized by an increase in HF, suggesting increased vagal efferent activity. By contrast, the light pressure massage (typical of Swedish massage) exhibited a sympathetic nervous system response characterized by decreased HF and increased LF/HF.

In summary, massage affects the physiological system, the mechanical response of pressure from massage increases muscle blood flow and skin circulation and stimulates parasympathetic activity. Changes in hormonal level such as serotonin and cortisol after massage give people a feeling of relaxation.

### **3.1.1.3 Neurological mechanisms**

All of the sensory input from the massage process can affect the nervous system as well as the emotional condition of the patient (Braun and Simonson, 2005). Initial interaction with the skin reflexively stimulates a sympathetic nervous response. When the body has verified that the maintained touch does not pose any danger, it stops the sympathetic nervous response (Braun & Simonson, 2005). In approximately 10-15 minutes, sustained touch and massage activates the parasympathetic nervous response of relaxation (Braun & Simonson, 2005). Massage can change the blood level of several neurochemicals and hormones associated with pain (Fritz, 2000). The main neurological effect of massage is relaxing stimulation (Weerapong et al., 2005). It may reduce neuromuscular excitability, pain and muscle spasm.

### **Reduced neuromuscular excitability and muscle spasm**

Massage stimulates sensory receptors and decreases muscle tension by reducing neuromuscular excitability as measured by changes in the Hoffman reflex (H-reflex) amplitude. H-reflex is considered to be the electrical analogue of the stretch reflex (Zehr, 2002). The potent inhibitory effects of massage on neuromuscular excitability might be one of the explanations for reduction of muscle tension or spasm after massage

application. At times, muscles are subjected to nervous stimulation resulting in hypertonicity or spasm, and the over-stimulation of muscle leads to a hyper-excitable motoneuron pool in the muscle. One traditional technique used to relieve a cramp or spasm is passive muscle stretching, but when pain or limitation of joint movement reduces the opportunity for a passive muscle stretch, massage may be applied to relieve a cramp or spasm (Tuchtan et al., 2004).

A study by Morelli (1990) found that massage decreased the Hoffman reflex amplitude during treatment, indicating that massage is effective for the relief of spasm or cramp. One-hand petrissage for 3-6 minutes decreased the H-reflex amplitude, but the amplitude returned to baseline levels immediately after the massage finished. The reduction of the H-reflex amplitude results from a decrease in spinal reflex excitability when massage is applied (Morelli et al, 1991; Sullivan et al, 1991). The inhibitory effects of massage on the soleus H-reflex amplitude did not originate from mechanical stimulation of cutaneous mechanoreceptor so it was predicted that this might originate from muscle or other deep tissue mechanoreceptors (Morelli et al, 1999). Additionally, a study conducted by Goldberg et al. (1992) reported that deep massage had more impact in decreasing H-reflex amplitude than light massage.

### **Effect on pain and sensation**

Pain can be reduced by massage as a primary intervention or as a secondary effect if massage eradicates the cause of pain. Evidence of massage and its effect on pain has been shown in the literature review in the previous chapter. Therefore this chapter describes the pain process and how massage affects pain. Pain is produced by thermal, mechanical or chemical trauma. In addition, damage to tissue causes certain chemicals to be released which can cause pain and damage the tissues even further (Holey & Cook, 2003). There are various substances which are believed to have an indirect effect in producing pain. Acetylcholine, 5-hydroxytryptamine (5-HT), enzymes and prostaglandins can all have algogenic properties (Holey & Cook, 2003). Some of the main neuroendocrine chemicals influenced by massage are presented in Table 3.2,

**Table 3.2: The effects of neuroendocrine chemicals on pain**  
(Fritz, 2000)

<b>Changing neuroendocrine chemicals through massage</b>	<b>The effects of changing neuroendocrine chemicals on pain</b>
<b>Increased dopamine</b>	A pain-relieving chemical involved in voluntary movement.
<b>Increased endorphines</b>	Strong pain-relieving chemical repress all nerve functions to some degree.
<b>Increased enkephalins</b>	Pain relievers involved in sensory integration.
<b>Increased oxytocin</b>	A chemical that raises the pain threshold, stimulates smooth muscle contractions, reduces sympathetic nervous response, and has sedative effects.
<b>Increased serotonin</b>	A chemical that diminishes pain and taste, mood and sleep patterns and arouses smooth muscle contraction.
<b>Decreases cortisol</b>	A natural anti-inflammatory produced in response to stress which can accelerate the collapse of tissue and prevent tissue repair, both of which can cause pain.
<b>Decreases substance P</b>	A neurotransmitter that triggers the pain response

Massage has also been applied in order to relieve pain (Buttagat et al., 2009; Chatchawan et al., 2005; Field et al., 2007; Franke et al., 2000; Hernandez-Reif et al., 2001; Mackawan et al., 2005; Preyde, 2000). The possible responsible mechanisms are neurological (gate-control theory), physiological (biochemical substance) and mechanical (realignment of muscle fibres). Massage may reduce pain by activating the neural-gating mechanism in the spinal cord. Tactile information from massage might stimulate large fast nerve fibres and block the smaller, slower nerve fibres that detect pain. This effect results from local lateral inhibition in the spinal cord and explains why touching the painful area is an effective strategy for relieving pain. Muscle spasm causes muscle pain directly by stimulating mechano-sensitive pain receptors or indirectly by compressing the blood vessels resulting in ischemia (Guyton and Hall, 2000). Massage helps to rearrange muscle fibres and increase microcirculation. The

realignment of fibres helps to reduce muscle spasm which stimulates pain receptors and helps to reduce the pressure on blood vessel (Weerapong et al., 2005).

### **The effects of massage on back pain as measured by decreased substance P and closing the controlled gate of pain**

Substance P levels in saliva have been used in many studies to indicate the severity of chronic pain (Mackawan et al., 2005). Substance P is a neuropeptide that has a crucial role in nociceptive signal transmission. Substance P plays a role in many symptoms that have a pain action such as chronic back pain (Parris et al., 1990), arthritis (Levine et al., 1984), headaches (Marukawa et al., 1996), and inflammatory joint disease (Anichini et al., 1997; Appelgren et al., 1998).

Wright and Sluka (2001) maintain that massage may activate segmental inhibitory mechanisms to suppress pain and that some techniques may activate descending pain inhibitory systems (Goats, 1994), as suggested by gate theory. The main theories regarding the analgesic effects of massage include gate theory and the serotonin hypothesis (Ireland, 2000). Gate theory suggests that pressure receptors are longer and more myelinated than pain fibres, and thus pressure signals from massage are transmitted faster, closing the gate to pain signals. The serotonin hypothesis maintains that massage increases levels of serotonin, a neurotransmitter that modulates the pain control system (Field et al., 1997).

Goats (1994) explained that massage produces short-lived analgesia by activating the pain gate mechanism. Cutaneous mechanoreceptors are stimulated by touch and transmit information within large nerve fibres to the spinal cord. These impulses block the pathway of painful stimuli entering the same spinal segment along small, slowly conducting neurons (Watson, 1981). Therefore, massage is an effective mechanical stimulus and a particularly efficient trigger for the pain gate process. Longer pain control appears to be mediated by the descending pain repression mechanism (Watson, 1982). While unpleasant cutaneous sensations stimulate nuclei within the midbrain, these nuclei generate preliminary activity in the descending spinal tracts that release

endogenous inhibitory neurotransmitters within the spinal segment receiving the painful input. This action reduces the intensity of pain transmitted to the higher centres. Massage can reinforce a naturally occurring discomfort, cause greater release of opiates and accomplish more intense pain repression (Goats, 1994)

Mackawan et al. (2005) found that both traditional Thai massage (deep friction kind of massage) and Swedish massage (superficial massage) influence the same pain chemical mediator and both of them can reduce the level of substance P. These researchers concluded that traditional Thai massage modulates pain transmission at the spinal cord level by closing the gate and inhibiting transmission cell (i.e. T-cells or the first cells in the spinal cord that project into the central nervous system) activity via substantia gelatinosa (SG-cells), stimulating mechanosensitive afferent fibres in muscles and spinal joints that influence SG cells. The action of Thai massage also temporarily decreases the level of pain in biochemical transmission of substance P, so the nerve conductivity to a higher centre is limited (Mackawan et al., 2005).

In summary, massage helps to reduce pain by its effect on the tissues. Massage can interfere with the pain mechanism at the spinal cord level (Holey & Cook, 2003). Massage techniques have a vibratory effect in the tissues, reducing pain through a repetitive mechanical stimulus that prevents pain impulses reaching the brain (Lundeberg, 1983). This is the 'closed pain gate' in pain gate theory. Pain relief occurs before the synapse and is termed 'presynaptic inhibition'. Massage also produces postsynaptic inhibition because of the positive effect it has on limbic system and cerebral cortex (Holey & Cook, 2003; Tuchtan et al, 2004). Massage can produce relaxation and positive psychological effects. Therefore, patients may feel calmer and less anxious. They may feel relaxed and more in control of their physical and emotional state.

Massage assists in relieving pain both in the periphery and in the central nervous system (CNS) by three means (Holey & Cook, 2003; Guyton & Hall, 2000):

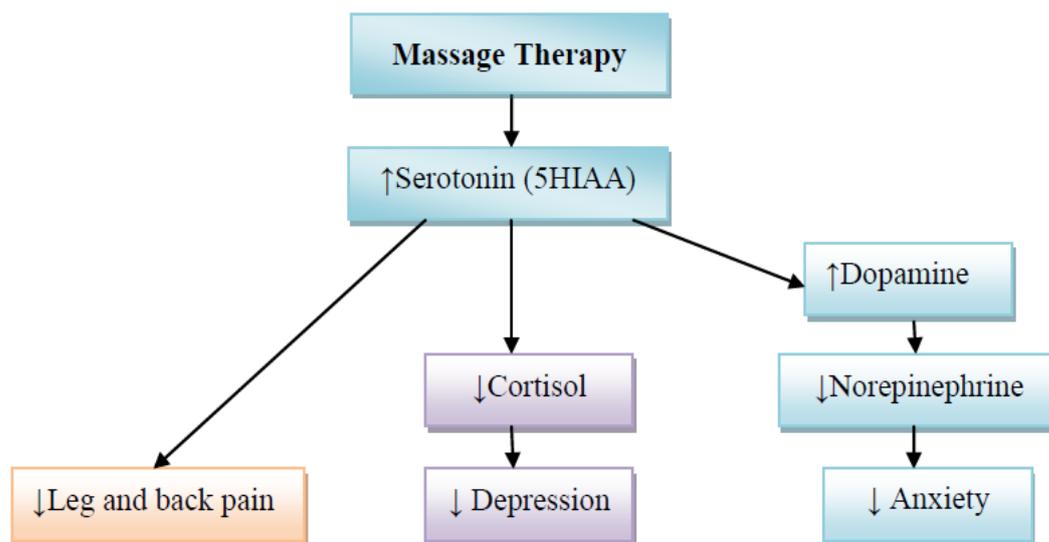
1. The fluid exchange and raised circulation will improve the local chemical environment.

2. It produces presynaptic inhibition by closing the ‘pain gate’ in the dorsal horn of the spinal cord.
3. It causes postsynaptic inhibition through its effect on the limbic system and cerebral cortex.

#### **3.1.1.4 Psychological mechanisms**

Various mechanisms cause a relaxation response from massage. These include an increase in plasma endorphins, decreased arousal level, reduced stress hormone levels or an activation of the parasympathetic response (Delaney et al., 2002). Massage increases the relationship between body and mind (Weerapong et al., 2005). For example, when a person is under a lot of tension, body functions are affected and many symptoms can be exaggerated by stress (Loving, 1999). When massage is given and endorphins are released in the brain, the morphine-like chemicals act as pain reducers so less pain is felt, stress and anxiety are lessened, and the client feels better (Loving, 1999).

Field et al. (2004) created a potential mechanism model underlying massage therapy effects that explains how massage reduces leg and back pain, depression and anxiety. In this model, massage therapy increases serotonin and in turn decreases cortisol and depression. Elevated serotonin (5HT<sub>1A</sub>) may also reduce leg and back pain, as serotonin is noted to decrease substance P and other pain-causing chemicals (Moldofsky, 1982). Additionally, massage is expected to increase dopamine and, in turn, decrease norepinephrine and anxiety (see Figure 3.2) (Field et al., 2004).



**Figure 3.2: Potential mechanisms underlying massage therapy effects**

(Field et al., 2004, p.116)

### **Physical relaxation**

Massage treatments are extremely relaxing. Certain strokes in particular promote physical relaxation; however, the concept of relaxation is not principally a physical one. It is just as much psychological as physiological. For muscles to relax, especially in an entire limb or the whole body, the person must be able to minimize the cortical drive passing to the relevant spinal motor neurons (Domenico & Wood, 1997). Massage helps the muscles relax by stimulating a reflex response of the nervous system. The application of smooth, steady, rhythmical massage can relieve tension and soothe sore muscles. This decrease in muscle tension causes the muscle to become more relaxed and elastic (Larson, 2001).

### **Relief of anxiety and tension (stress)**

Relief of tension through massage is strongly linked to the promotion of relaxation identified previously. A person who has significant anxiety and tension will find it very hard, if not impossible, to relax. As massage promotes relaxation, and also helps to reduce anxiety and tension. This is because relaxation requires psychological release from anxiety and tension. This is one of the main reasons why recreational massage is popular as part of stress reduction programmes (Domenico & Wood, 1997).

One study comparing massage therapy and relaxation therapy effects on lower back pain found that trunk and pain flexion performance were improved by massage therapy and self-reported pain, depression, anxiety and sleep disturbance were decreased (Hernandez et al., 2001). Additionally, Field et al. (2004) found that dopamine and serotonin levels increased following a five-week period of two 30-minute massage per week. The improvement in sleep disturbance that accompanied massage therapy could result in less pain as sleep disturbances are known to increase pain and levels of pain-associated substances such as substance P.

In addition, tactile stimulation from massage to body tissue produces relaxation (Harris & Richards, 2010). This action stimulates complex neurohumoral responses in the hypothalamic-pituitary axis (HPA) to the circuit through the central nervous system pathways so that it is interpreted as a relaxation response (Lawton, 2003). Stress adaptation is regulated by HPA capacity as it produces hormones such as cortisol and endorphins, which decrease sympathetic nervous system activity and increase parasympathetic responses (Moyer et al., 2004). Light massage counteracts the overproduction of cortisol by influencing the secretion of corticotrophin from the HPA (Harris & Richards, 2010). Therefore, cortisol is decreased and relaxation is promoted (Remington, 2002).

In summary, massage involves a psychological mechanism. The applications of smooth, steady, rhythmical massage give physical relaxation and tension relief by stimulating a reflex response of the nervous system. Endorphin and serotonin are released from the brain and in turn decrease cortisol substance.

### **Summary of massage action**

Massage may improve physiological and clinical outcomes in chronic low back pain by offering pain relief through physical and emotional relaxation. Manipulation of affected muscles and fascia may induce local biochemical changes that modulate local blood flow and oxygenation in muscle (Imamura, 2008). These local effects may influence neural activity at the spinal cord segmental level and could modulate the activities of subcortical nuclei that involve emotion and pain perception (Sagar, 2007). Massage may increase the pain threshold through the release of endorphins and serotonin. The gate-

control theory suggests that massaging a particular area stimulates large-diameter nerve fibres, which have an inhibitory input onto T-cells (Imamura, 2008). This may result in decreased T-cell activity, followed by pain relief (Melzack, 1996). Massage may also increase local blood circulation, improve muscle flexibility, and loosen adherent connective tissue (Lee et al., 1990).

### **3.1.2 Benefits of massage**

Thai massage and Swedish massage are effective manipulations for body, mind and emotion. There are some differences between Thai and Swedish massage. Swedish massage is superficial massage that gives a feeling of relaxation while Thai massage is a type of deep massage that is effective for reducing pain as a therapeutic intervention (Chatchawan et al., 2005).

Rachlin (1994) reported that superficial massage, consisting of such techniques as stroking and kneading, is good for general relaxation. Unless the trigger point is identified and eradicated, this type of massage, however, may not provide the patient with lasting pain relief. This may be due to the application of insufficient pressure on the trigger point area to break up adhesions. Trigger points are the hyperirritable spots in skeletal muscle associated with palpable nodules that are small contraction knots and a common cause of pain. Swedish massage uses techniques of stroking and kneading with body oil. The pressure of Swedish massage is enough to reach deep into skin and subcutaneous tissue, but might not go deep enough into the muscle to reach the patient's pain threshold in the way that Thai massage does (Chatchawan et al., 2005). However, some forms of deep massage such as Thai massage techniques of deep friction, compression, ischemic compression can lead to post-massage side effects of soreness and bruising, when applied to the trigger point specifically, with no accompanying treatment of the surrounding back muscles (Rachlin, 1994; Simons et al., 1999).

Chatchawan et al. (2005) suggested that the technique of TTM is a form of deep massage, is gentler in application than other deep massage techniques so it may not elicit the same undesirable side effects while providing better results. TTM is applied to the whole muscle surrounding the myofascial trigger points, and thus it is likely to result

in better overall relaxation and to benefit the patient more than other forms of deep massage, which focus only on the trigger point. Additionally, TTM has been shown to produce effective analgesic effects for releasing trigger points and alleviating pain (Prateepavanich, 1999).

Chaithavuthi and Muangsiri (2007) reported that the spiritual benefits of TTM are based on the elements of life and 'Sen Sib' (ten energy lines), with TTM having a positive impact on the spirit. Pressure applied to each point to arouse the energy through 'Sen Sib', and coupled with a gentle smooth movement during the transition of each sequence, combines with the union of breath between giver and the open-minded recipient. However, both TTM and SM affect the body, mind and emotion and give the physiological, psychological and metaphysical benefits that are presented in Table 3.3.

**Table 3.3: Summary of the benefits of massage**

(Domenico & Wood, 1997; Loving, 1999)

<b>Physiological benefits</b> <b>(effect on the body)</b>	<b>Psychological benefits</b> <b>(effect on the mind)</b>	<b>Metaphysical benefits</b> <b>(effect on the emotion)</b>
<ul style="list-style-type: none"> <li>• Increases blood and lymph flow</li> <li>• Improves circulation</li> <li>• Increases nutrition to tissue</li> <li>• Removes waste products and metabolites</li> <li>• Stimulates the healing process</li> <li>• Relaxes muscle spasms and helps prevent them</li> <li>• Helps to prevent build-up of harmful fatigue products</li> <li>• Improves muscle tone</li> <li>• Stimulates or sedates nervous system</li> <li>• Relieves pain</li> <li>• Increases extensibility of connective tissue</li> <li>• Increases joint movement</li> <li>• Facilitates muscle activity</li> <li>• Promotes local and general relaxation</li> </ul>	<ul style="list-style-type: none"> <li>• Relieves stress, anxiety and tension</li> <li>• Releases endorphins in the brain and promotes a natural feeling</li> <li>• Calms a hyperactive or agitated person</li> <li>• Helps a person get in touch with their body</li> <li>• Elevates the mood for depressed person</li> </ul>	<ul style="list-style-type: none"> <li>• Elevates the spirit</li> <li>• Calms the worried mind</li> <li>• Balances, integrates, and connects the whole being</li> <li>• Puts the person in touch with self</li> <li>• Helps create a state of heightened awareness or reflective state</li> <li>• Shares intent to heal between client and therapist</li> <li>• Brings together hemispheres of brain with body core</li> </ul>

### **3.1.3 Contraindications of massage**

Massage increases blood flow, but this can be a risk if a thrombus is attached to a vessel wall. Mechanical stimulation of the vessel and rising blood flow may cause the thrombus to detach and occlude a vessel (Salvo, 2003). Increasing lymphatic flow via massage can increase the rate at which bacteria or metastases are carried around the body (Holey & Cook, 2003). Furthermore, manipulation of the tissue can cause bleeding in damaged or leaking blood vessels (Holey & Cook, 2003). Manipulation of early healing-tissue processes may damage the fragile cellular and fibrinous network so it will produce delayed healing and even cause excess fibrous tissue. Infection can be introduced into an open wound if the surface is touched by a non-sterile object (Beck, 2010) and massage oil can cause skin allergies or irritations (Sugiura et al., 2000).

According to Beck (2010) and Holely and Cook (2003), massage is contraindicated where there is an open wound surface of skin infection, thrombophlebitis, a healing fracture site, and inflammation of muscle (especially within the last 24-48 hours) and when the patient has cancer.

## **3.2 Swedish massage**

Swedish massage is the systematic and scientific manipulation of soft tissues of the body for the purpose of maintaining good health. Swedish massage is used for a variety of reasons such as deep levels of relaxation, rehabilitation, prevention of an injury and reducing the progression of an illness (Salvo, 2003). Swedish massage is the most widely recognized and commonly used type of massage. It is identified as a gentle and superficial massage and the techniques vary from light to vigorous (Braun & Simonson, 2005). Swedish massage is based on five basic strokes: effleurage (gliding), petrissage (kneading), friction, tapotement (percussion), and vibration, which are administered using a lubricant on the skin (Braun & Simonson, 2005; Cowen, 2005; Holely & Cook, 2003; Salvo, 2003). In Swedish massage five basic strokes are used to manipulate muscles and connective tissue, and promote lymphatic flow and venous return (Fritz, 2000). Effleurage is a gliding stroke used to introduce touch, apply lubricant and warm superficial tissue (Fritz, 2000). Compressive strokes (tapotement and vibration) are used

to stimulate muscle spindle activity and superficial muscle to give benefits such as pain relief, reduced trigger and tender point activity, and increased circulation (Salvo, 2003). Kneading strokes (petrissage and friction) are used to promote circulation and removal of wastes (Cowen, 2005; Goats, 1994; Holey & Cook, 2003). The amount of pressure has an impact on the type as well as the effect. Moderate to deep pressure is considered to have a more positive effect than light pressure, which may be irritating (Field, 1998).

In summary, each Swedish massage technique has different movement and effects (these are described in detail in Appendix A). Swedish massage is widely known as relaxation massage for maintaining health and well-being instead of releasing trigger points of pain from deep tissue massage (Thai massage). However, two strong studies (Chatchawan et al., 2005; Cowen, 2005) support that both Swedish massage and traditional Thai massage have the same outcomes on pain. Therefore, the present study adds aromatic ginger oil as the lubricant with Swedish massage as a means to increase and explore the effect on pain.

### **3.3 Traditional Thai massage**

Traditional Thai massage (TTM) is deep massage with prolonged pressure (5–10 seconds per point) on the muscles along with passive stretching (Mackawan et al., 2005). Pressure point massage along the body's 10 major energy channels or 'sen' lines is believed to release blocked energy, increasing awareness and vitality. Gentle stretching of the joints and muscles relieves tension, enhances flexibility, and induces a deep state of tranquillity (Tapanya, 1990).

A key difference from Western massage is that TTM is applied without oils, and the recipients are fully clothed. Unlike the continuous strokes of Western massage, TTM uses pressure, muscle stretching and compression, practised in gentle, rhythmic, rocking movements (Jotisalikor, 2002). When habitually tensed muscles are massaged, their energy blockages are released, thus resulting in discomfort (Salguero, 2004). This can be remedied by a few more massage sessions (Jotisalikor, 2002).

This following section outlines the theoretical foundations of traditional Thai massage. It is based on two theories: the four elements of life and 'Sen Sib' (ten energy lines) so this section describes the background of Traditional Thai massage and the energy line theory.

### **3.3.1 The basic theory of Traditional Thai massage**

#### **3.3.1.1 The four elements of life**

Traditional Thai medicine follows Buddhist teachings that a human being is comprised of five aggregates 'Panca Khanda', namely body, feelings, recognition, thought and consciousness (Chaithavuthi & Muangsiri, 2007). The five components are compounded in Rupa, or body, the corporeal or concrete form. Enclosed within Rupa are the following:

1. Venada: feeling or sensation – the five senses and mind.
2. Sanya: recognition – the recognition of the recent action and awareness of the action.
3. Sankhara: thought – the process of thought leading to action.
4. Vinyana: consciousness – the consciousness of the senses and emotion.

Additionally, the body is believed to be composed of four elements: earth, water, wind and fire. All four elements of life are interconnected and must be balanced in the following manner (Chaithavuthi and Muangsiri, 2007):

#### **1. The earth element**

The earth element represents 20 organs and parts of the body with solid properties such as hair and nail. Thai massage affects the earth element at the level of the muscles, bones and ligaments.

#### **2. The water element**

The water element represents 12 products of the body's organ such as bile and mucus. Thai massage stimulates the water element to flow through the whole body and helps to maintain healthy function of the organs.

### 3. The wind element

The wind element provides energy for movement in all activity and function. The wind external to the body consists of the air and wind in the atmosphere. Thai massage helps direct the wind element to flow in the right direction to benefit the body.

### 4. The fire element

The fire element consists of the heat and energy of life. This fire element assists the wind and water elements in the body to flow with the right temperature and heat energy. Fire keeps the earth element warm to maintain the body organs in a healthy condition. Thai massage improves circulation and helps maintain the right temperature for the body, benefiting the fire element. A balanced union of all four fundamental elements of the life is considered to be the solution to maintaining good health (Chaithavuthi & Muangsiri, 2007; Tangtrongchir, 1992).

#### **3.3.1.2 Sen (the energy line)**

The philosophical theory of traditional Thai massage is similar to the theory of Ayurvedic massage because both types of massage are based on the life energy channels and the belief that a person's health and well-being relies on the balance of life energy (Balaskas, 2002; Chaithavuthi & Muangsiri, 2007; Jotikalikorn, 2002; Salguero, 2004). Life energy in Thai massage is called 'Prana', which means the wind of life and is known as 'Lom Pran' in Thai. The obstruction of prana flow can cause discomfort or illness (Balaskas, 2002). As 'Sen Sib' is the major energy channel throughout the body, it needs regular maintenance to avoid any blockages (Chaithavuthi & Muangsiri, 2007). Problems arise in the body when energy lines are either blocked or broken, causing an energy imbalance (Salguero, 2004).

Applied TTM helps to remove blockages by working directly with the energy lines to restore their vigour and vitality (Chaithavuthi & Muangsiri, 2007; Salguero, 2004). Massaging along these energy lines can break energy blockage, stimulate the flow of prana and restore general well-being (Jotikalikorn, 2002; Salguero, 2004). Ancient Thais applied pressure on points according to 'Sen Sib' in combination with herbs to treat illness. Some of these pressure points are used in therapeutic massage to relieve

common ailments (Chaithavuthi & Muangsiri, 2007). When a person is feeling ill, the supply of the life energy is interfered and insufficient. Stimulating energy lines through massage recovers the flow of life energy naturally (Chaithavuthi & Muangsiri, 2007; Jotisalikor, 2002). Traditional Thai massage (TTM) stimulates ten Sens (Sen Sib), which are considered the most important energy lines. According to Thai energy line theory (Sen Sib), TTM for the back presses on Sen 1 (Itha) and Sen 2 (Pingkla) (Salguero, 2004; Tangtrongchitr, 1992).

### **The characteristics of Sen Sib (ten energy lines)**

Chaithavuthi and Muangsiri (2007) and Tangtrongchitr (1992) reported that there are ten major paths. ‘Sen’ means path or line and ‘Sib’ means ten. All ten Sens originate approximately two thumb widths below the abdominal surface in the area of the navel. Each ‘Sen’ has a different exit point throughout the body (Appendix B). The paths are invisible. They are not blood vessels, nerve fibres, or ligaments. They are invisibly connected to send sensations when pressed at the right pressure point to the responding directions. There is the energy force, running through the path. If the path is blocked, obstruction to the wind can cause illness. The paths have pressure point locations that affect the wind when pressed.

The traditional theory of TTM describes the four elements of life and ‘Sen Sib’ (ten energy lines) as being in correlation (Salguero, 2004). The four elements of life are associated with particular organs, emotional states, and the energy lines (Jotisalikor, 2002; Salguero, 2004) (see Table 3.4).

**Table 3.4: Correlations between the four elements and the Sen Sib (ten energy lines)** (Tangtrongchir, 1992; Salguero, 2004. p.205)

Element	Physical processes	Psychological and spiritual process	Corresponding of Sen Sib
Earth	Skin, muscle, bone, connective tissue, fat	Lethargy, fatigue, obesity, stagnation	Itha (1 <sup>st</sup> line)
Water	Blood, eyes, body fluids, urine, semen	Stagnation, stubbornness, rigidity	Sahudsarangsri (5 <sup>th</sup> line), Tawaree (6 <sup>st</sup> line)
Air	Respiratory system, intestines, sexuality, aging, mobility of joints	Stress, anxiety, nervousness, inability to commit, fear, psychological disorder	Sumuna (3 <sup>rd</sup> line), Kanlataree (4 <sup>th</sup> line), Jantapusunk (7 <sup>th</sup> line), Rusum (8 <sup>th</sup> line), Sukumang (9 <sup>th</sup> line), Sikinee (10 <sup>th</sup> line)
Fire	Body temperature, circulation, metabolism, infection	Aggression, tension, violence, short temper, obsessive, overly sexual	Pingala (2 <sup>nd</sup> line), Kanlataree (4 <sup>th</sup> line)

### 3.3.2 Contraindications of Traditional Thai massage

Traditional Thai massage has the same contraindications as the other massage types outlined in section 3.1.3.

## 3.4 Effects and benefits of ginger (*Zingiber officinale*)

### 3.4.1 Ginger properties

Ginger is a member of the family of plants and contains a very complex mixture of compounds (Altman & Marcussen, 2001). The strong aroma of ginger comes from the pungent ketones (gingerols, shogaols and paradols). As ginger extract and oil has been used in research studies are outlined in Chapter Two, this chapter presents ginger's properties, effectiveness and adverse effects. The effects of ginger will be explained in the mechanism of pharmacological actions as anti-inflammatory and analgesic agents, actions that are relevant to back pain relief.

### **Constituents of ginger**

Ginger extracts are complex and consist of more than 400 components but few have been tested for their pharmacological properties. Currently, evidence suggests that a subtraction containing the structurally related components gingerols, shogaols, and paradols are the main portions of ginger's anti-inflammatory properties (Grzanna et al., 2005). Kiuchi et al. (1982) demonstrated that ginger contains gingerdiones and shogaols, constituents that have pharmacological properties mimicking dual-acting non-steroidal anti-inflammatory drugs (NSAIDs).

### **3.4.2 The effect of ginger on musculoskeletal conditions**

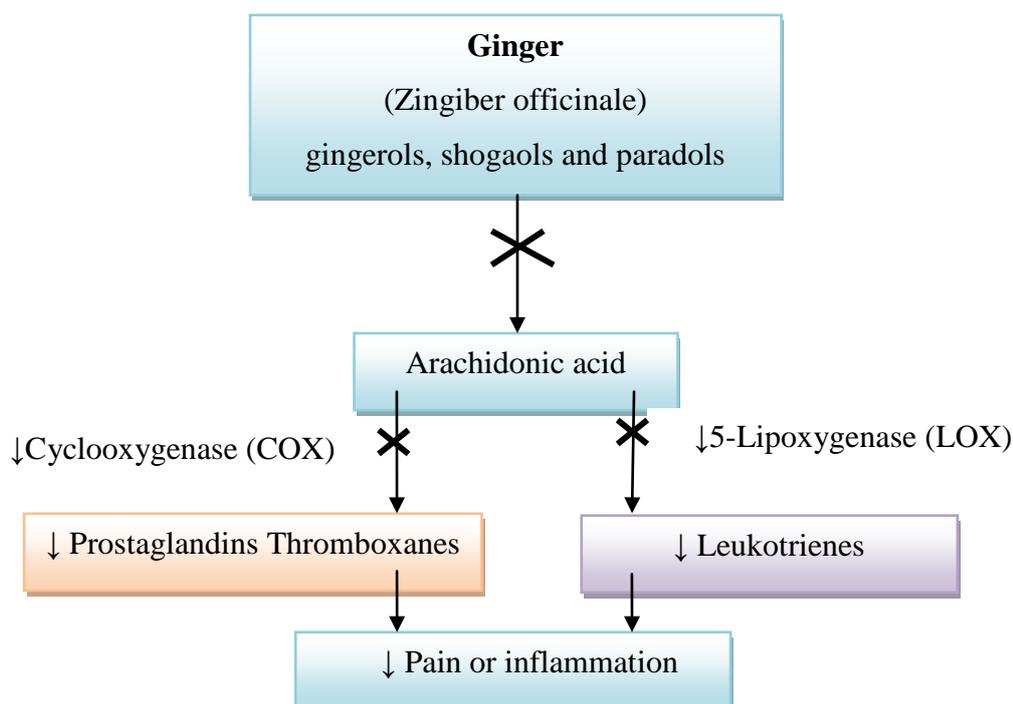
Ginger (*Zingiber officinale*) is one of a number of widely used herbal medicines. It performs as an antipyretic, antiemetic, antitussive, cardiac inotropic, antifungal, sedative and analgesic (Langner et al., 1998). These effects are various and dependent on the herb preparation used. The active elements of ginger (gingerols and gingerdione) are derived from the rhizome and root of the plant. Ginger is used for pain management because the herb is an analgesic and antioxidant, and an inhibitor of inflammatory prostaglandins, thromboxanes and leukotriene synthesis (Haghighi, 2005; Grzanna, 2005).

The analgesic effect of ginger is related to one of its components known as shogaol, which can inhibit the releasing of substance P (Onogi, 1992). The pharmacologically active components of the ginger root are thought to be aromatic ketones known as gingerols, which have been shown in experimental studies to inhibit both the cyclooxygenase and lipoxygenase pathways and the production of prostaglandins, thromboxane and leukotrienes (Kiuchi et al., 1992; Srivastava et al., 1994). In addition, Dedov et al. (2002) reported that gingerols act as agonists at vanilloid receptors. These receptors are activated by capsaicin and are suspected to be present on pain afferents mediating joint pain.

### **3.4.3 Pharmacological action of ginger**

Ginger contains chemical substances with an anti-inflammatory potential, and the effect might be attributed to the actions of gingerols, shogaols, diarylheptanoids, and

dialdehyd diterpens, which may inhibit inflammatory prostaglandins (Kiuchi et al., 1992; Kawasakishi et al., 1994). Ginger's anti-inflammatory actions cause its inhibition of arachidonic acid and the subsequent decreased synthesis of cyclooxygenase and lipoxygenase enzymes of the prostaglandin and leukotriene pathways (Mustafa et al., 1993; Weidner, 1997) (see Figure 3.3). Mascolo et al. (1989) and Sharma & Srivastava (1994) tested ginger effectiveness in rats and reported that ginger compounds affect rheumatoid arthritis, osteoarthritis, and muscle discomfort.



**Figure 3.3: Theoretical model of the possible pharmacological mechanism of ginger in delivering pain relief as anti-inflammatory and analgesic**

(X= inhibition of process) (Mustafa et al., 1993; Weidner, 1997)

### **Ginger inhibits prostaglandin biosynthesis**

When tissues are damaged, white blood cells flood to the site to try to minimize tissue destruction and prostaglandins are produced as a result (Park et al., 2003). Prostaglandin (PG) is the substance which activates the inflammatory response and production of pain. Kiuchi et al. (1982) provided the first direct experimental evidence that ginger

comprises several constituents with anti-inflammatory activities comparable in potency to NSAIDs.

The inhibition of PG synthesis by NSAIDs and ginger is due to an inhibition of arachidonic acid metabolism by cyclooxygenase (COX), an enzyme that plays an important role in many cellular processes (Grzanna et al., 2005). This enzyme is necessary for the synthesis of prostaglandines, which belong to the most important mediators of inflammatory and pain processes (Ali et al., 2008).

### **Ginger inhibits leukotriene synthesis**

The most important event in the characterization of the anti-inflammatory properties of ginger was the discovery that some of its constituents not only inhibit prostaglandin synthesis but also inhibit leukotriene (LT) synthesis (Grzanna et al., 2005). Leukotrienes are involved in asthmatic and allergic reactions and act to sustain inflammatory reactions (Manev & Manev, 2004). Leukotriene syntheses are potent mediators of the inflammatory process and are suspected of playing a key role in the development of gastrointestinal ulcers associated with long-term use of NSAIDs (Asako et al., 1992; Hudson et al., 1993). Therefore, if the patient uses NSAIDs in the long term, these drugs may produce gastrointestinal ulcers as a side effect. Some constituents of ginger such as gingerols, shagols, gingerdiones and dihydroparadol can inhibit prostaglandin and leukotriene production in human neutrophils in the low micromolar range (Flynn et al., 1986; Grzanna et al., 2005). Therefore, ginger appears to be a safer alternative to long-term use of NSAIDs.

### **3.4.4 Side effects of ginger**

Abascal and Yarnell (2009) report there is a theoretical concern that ginger taken by oral ingestion may interact adversely with anti-platelet agents such as NSAIDs activity. They suggest that ginger can be used safely at therapeutic doses along with anti-platelet and anti-coagulant medication, but some individuals may have an adverse reaction, so monitoring is advised. In addition, ginger may increase international normalized ratio (INR) and increase the risk of bleeding in patients who are taking Coumadin anticoagulants.

## **3.5 Aromatic ginger oil**

### **Description**

Aromatherapy is the use of fragrant pure essential and absolute oils extracted from the natural plant as a treatment in order to encourage good health, equilibrium, and psychological and physical well-being (Dunning, 2007; Walters, 1998; Worwood, 1991). Aromatherapy is derived from two words: aroma (meaning fragrance or smell) and therapy (meaning treatment). Aromatherapy is a holistic treatment which can have a profound effect on the body, mind and spirit (Dunning, 2007).

#### **3.5.1 Using essential oil for aromatic massage**

Essential oils are the main tool of aromatherapy. They are pure aromatic substances extracted or distilled from flowers, trees, fruits and herbs (Tisserand, 1990). They contain all the special properties of plants including odour. The properties of the plant are not lost in extraction process but are concentrated and enhanced (Martin, 1992).

Essential oils are very concentrated and should never be used undiluted on the skin, they must be mixed with a carrier oil which can provide lubrication for the massage as well as carrying the therapeutic essential oils being used (Buckle, 2003; Goldberg, 2001). Mineral oils such as baby oil are not suitable as carrier oils because they are not easily absorbed by the skin. Therefore any vegetable oil that is fairly light and does not have a strong smell that would overpower the essential oil is appropriate (Goldberg, 2001). Typical carrier oils used in massage include olive oil, hazelnut oil, sweet almond oil, jojoba oil, and sunflower oil (Goldberg, 2001; Yip & Tam, 2008).

#### **3.5.2 Routes of absorption of essential oil**

There are four methods by which the components within essential oils can be absorbed (Buckle, 2003; Price & Price, 1999):

1. Topical: using external skin via touch, compress, or bath
2. Internal: using internal skin via mouthwashes, douches, pessaries, suppositories
3. Oral: via gelatine capsules or diluted in honey, alcohol
4. Inhaled: direct or indirect inhalation with or without steam.

Goldberg (2001) explained that as well as entering the body through skin in aromatic massage, the volatility of essential oils ensures that odour molecules and the aroma will affect the client immediately by entering the nose. The olfactory nerves carry messages from receptor cells in the upper part of nose to the olfactory bulb which is in direct contact with the limbic system of the brain (Price & Price, 1999). The limbic system is a complex inner area of the brain known to be closely linked with emotions and psychological feelings and instantly affected by smells (Stoddart, 1990). It also controls the autonomic nervous system and some hormones (Goldberg, 2001). The part of the limbic system known as the hippocampus is particularly associated with memory, especially in the conversion of short-term memory into long-term memory (Goldberg, 2001).

### **3.5.3 Aromatherapy in chronic pain management**

Aromatherapy enhances the parasympathetic response through the effect of touch and smell, encouraging relaxation at a deep level. Relaxation has been shown to alter perceptions of pain (Buckle, 2001). Aromatherapy also enables clients to get in touch with feelings of relaxation and pleasure through smell and touch. The analgesic effect of aromatherapy can be traced to several factors: a complex mixture of evaporated chemicals reaching the pleasure memory sites within the brain, certain analgesic components within the essential oil, the interaction of touch with the sensory fibres in the skin, and the friction on the skin (Buckle, 1999). Ginger (*Zingiber officinalis*) can also have an analgesic and deeply warming action. It is comforting to use in a massage oil blend for rheumatic conditions, muscle pains, and stiff joints, and also it helps indigestion and nausea (Buckle, 2003; Goldberg, 2001).

## **3.6 Applying Swedish massage with aromatic ginger oil program for chronic low back pain**

This study examines Swedish massage with ginger oil (SMGO) as a new intervention to relieve CLBP in older people. The study compares the effectiveness of SMGO with TTM (usual massage) as a control group. As SMGO is the treatment of this study, the

conceptual framework presents only Swedish massage and aromatic ginger concepts, not TTM. The conceptual framework for this study is based on the scientific explanations of Swedish massage and aromatic ginger oil outlined previously in this chapter (see Figure 3.4).

Swedish massage with its five basic strokes may involve both physical (biomedical, physiological and neurological) and psychosocial effects through superficial and deep skin by touch and compression. The massage therapist administers mechanical pressure on tissue with different strokes so it may decrease tissue adhesion, increase muscle-tendon compliance and improve lumbar range of motion. Swedish massage may have immediate physiological effects on skin through increased skin circulation and muscle blood flow, and stimulation of parasympathetic activity and changed hormonal levels (serotonin and endorphin). Consequently, it may involve neurological and psychological effects by increasing physical relaxation and pain relief. Aromatic ginger oil with its three main pain-reducing substances may provide back pain relief by its inhibition of prostaglandin leukotriene biosyntheses. In this way, the properties of ginger can reduce pain and give relaxation via an aromatic method. This RCT therefore combines Swedish massage with aromatic ginger as aromatic massage as this intervention may reduce pain, and enhance physical functions and psychological well-being.

## Conceptual framework

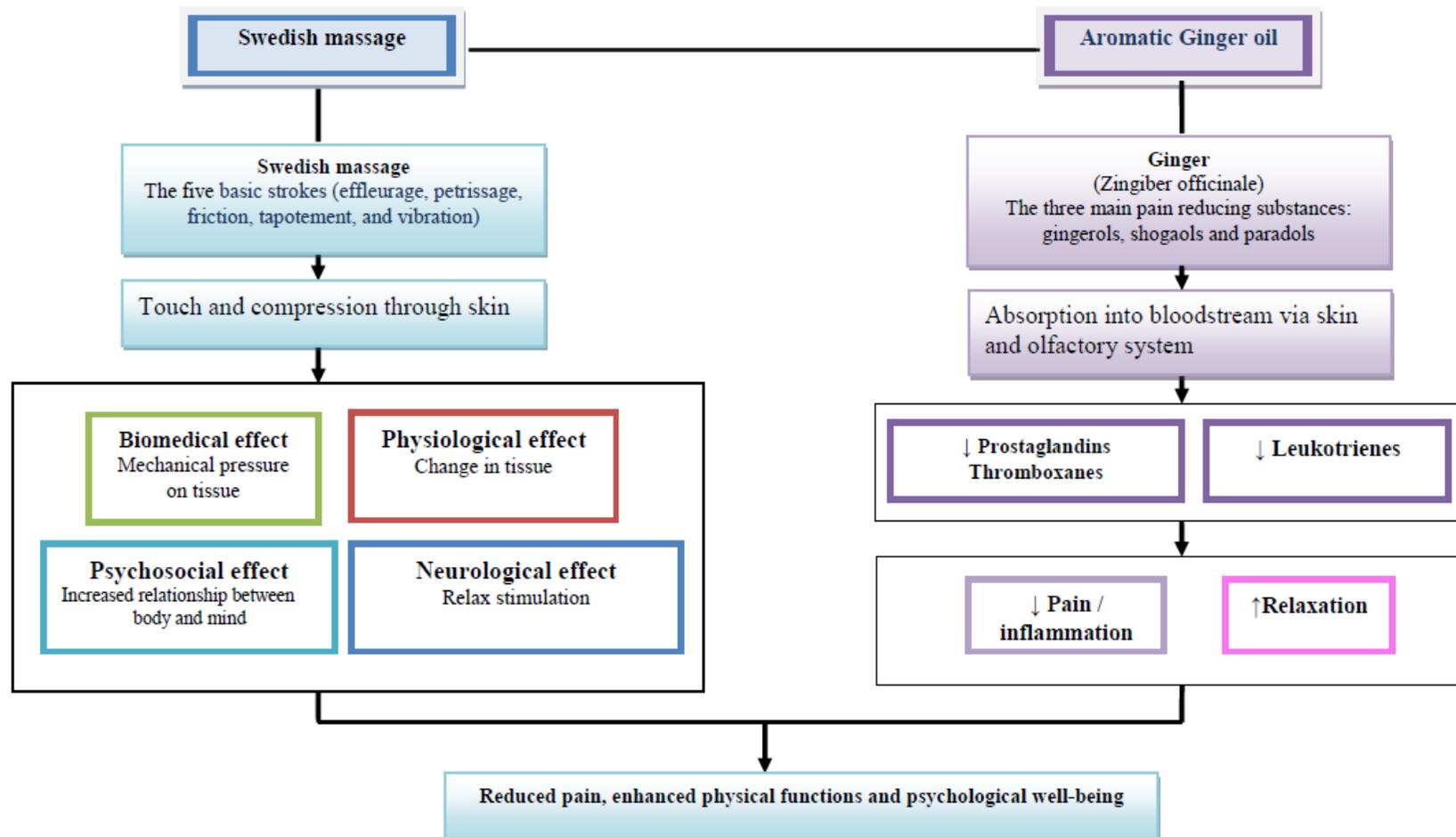


Figure 3.4: Conceptual model of the effect of Swedish massage with aromatic ginger oil on chronic low back pain

# **CHAPTER 4**

## **METHODOLOGY**

### **Introduction**

The review of literature in Chapter 2 has outlined what is currently known about massage and ginger in relation to low back pain and has also identified some methodological limitations of existing studies such as small sample sizes and absence of control groups. Although previous studies of traditional Thai or Swedish massage tested the effects on low back pain, almost all of them explored only the immediate or short-term effectiveness; none examined long-term effects past five weeks. Given that CLBP can last longer than three months, it is important to examine any treatment over this period of time.

Swedish massage is the most commonly offered and best-known type of massage. Swedish massage techniques can be applied to superficial tissue with superficial strokes and friction as well as deep tissue with kneading, percussion, deeper strokes and friction (Braun & Simonson, 2005). Despite the reported benefits of Swedish massage on lower back pain, previous studies have only tested short-term effectiveness. The combination of Swedish massage with aromatic ginger oil, which performs as an analgesic with anti-inflammatory actions, may improve the efficacy of Swedish massage for both the short to longer term relief of lower back pain.

This study was conducted as a randomised control trial with independent (unbiased) group allocation control. The study compared SMGO as a treatment group to TTM (usual massage) as a control group, and controlled a number of limitations of previous studies to provide evidence as to the effectiveness of treatments.

This chapter describes the methodology used in the trial in two parts. The first part reviews the background and fundamental principles of RCT, and reviews the strengths and limitations of RCT as a research methodology. Ethical issues in relation to RCT, quality indicators in RCT, and implementing randomised assignment are also discussed.

The second part of the chapter outlines the particular methodological considerations for the study. The study took place in Thailand and all the instruments applied were standardized Thai versions. The research design, setting, sampling framework, procedure and ethical considerations are described.

## **Principles of RCT**

### **4.1 The RCT design**

A randomised controlled trial (RCT) was the research design used to test most of the massage interventions discussed and critiqued in Chapter 2 (Buttagat et al., 2009; Chatchawan et al., 2005; Cherkin et al., 2011; Field et al., 2007, Franke et al., 2000; Hernandez-Reif et al., 2001; Mackawan et al., 2005; Preyde, 2000). RCTs are quantitative, comparative, controlled experiments that test the efficacy or effectiveness of two or more interventions by administering them to groups of individuals who are randomly allocated to treatment groups (Jadad & Murray, 2007; Stolberg et al., 2004). A RCT design is the most powerful method available to test cause-and-effect relationships between variables where treatment groups are compared with control groups not receiving treatment (Polit & Cheryl, 2008). RCT design is commonly used in studies examining medical technologies and health services (Singh et al., 2011). Smith (2008) reported the main strengths of the RCT design as its power in establishing causality and the use of blinded random allocation method to avoid selection bias as participants are assigned to one of the study groups by chance alone (Altman, 2006). The allocation of study participants into groups is not determined or influenced by the investigators, the clinicians, or the study participants (Jadad & Enkin, 2007).

Stolberg et al. (2004) reported that the randomization procedure gives the randomised controlled trial its strength. The purpose of random allocation of participants is to ensure that the characteristics of the participants are as likely to be as similar as possible across groups at the start of the comparison. If randomization is done properly, it reduces the risk of a serious imbalance in known or unknown factors that could influence the clinical course of the participants. No other study design allows the investigator to balance these factors.

#### **4.1.1 Historical perspectives on RCTs**

The earliest clinical trial was recorded in approximately 600 B.C., conducted by Daniel of Judah (Stolberg et al., 2004). The trial compared the health effects of a vegetarian diet with those of a royal Babylonian diet across a 10-day period. However, it had limitations including allocation bias, ascertainment bias, and confounding by divine intervention (Stolberg et al., 2004). The first paper describing a RCT design was published in the 19<sup>th</sup> century which saw many advances in clinical trials (Stolberg et al., 2004). Credit for the modern randomised controlled trial is given to Sir Austin Bradford Hill who was responsible for many of the methodological initiatives at the UK Medical Research Council during the 1950s and 1960s (Richards & Hamers, 2009). He conducted the first true RCT to test the effectiveness of streptomycin in treating pulmonary tuberculosis; this trial was accepted as a landmark that led a new era of medicine (Richards & Hamers, 2009; Singh et al., 2011; Stolberg et al., 2004). Since Hill's innovative achievement, the methodology of the RCT has been increasingly accepted and the number of RCTs reported has grown exponentially (Stolberg et al., 2004). The RCT gained increasing recognition during the 20<sup>th</sup> century as the best approach for assessment of healthcare and prevention alternatives, and it was recognised as the standard method for rational therapeutics in medicine by the late 20<sup>th</sup> century (Singh et al., 2011). As of 2004, more than 150,000 trials were identified in a search of the Cochrane Library (Stolberg et al., 2004); the RCT has become the heart of 'evidence-based medicine and nursing' (Richards & Hamers, 2009; Stolberg et al., 2004).

#### **4.1.2 Fundamentals of RCT**

RCT design is characterized by three elements: manipulation of the intervention, control and randomization (Polit & Beck, 2012). An RCT is a type of experimental study in which participants are randomly assigned to one of two or more clinical interventions (Akobeng, 2005). The RCT is the most scientifically rigorous method of hypothesis testing (Akobeng, 2005), and is regarded as the gold standard trial for testing the effectiveness of interventions (Akobeng, 2005; Polit & Beck, 2012).

#### **4.1.2.1 Manipulation: the experimental intervention**

Manipulation involves doing something to study participants. Researchers manipulate the independent variable by administering an intervention to some people and withholding it from others, or administering a different intervention (Polit & Beck, 2012). In designing RCTs, researchers make many decisions about what the experimental condition procures, and these decisions can affect the conclusions (Polit & Beck, 2012). To get a fair test, the intervention should be appropriate to the research question, compatible with a theoretical rationale, and have effectual intensity and appropriate duration so that effects can reasonably be expected (Polit & Beck, 2012). The intervention must be analyzed in formal protocols including addressing questions such as the following (Polit & Beck, 2012):

- What is the intervention, and how does it differ from usual methods?
- What specific procedures are to be used with those receiving the intervention?
- What is the dosage or intensity of the intervention?
- How long is the period of intervention? How often is the intervention administered and when will the intervention begin?
- Who will administer the interventions? What are their credentials, and what type of training will they receive?
- Under what conditions will the intervention be withdrawn or altered?

#### **4.1.2.2 The control condition**

RCT measures the effectiveness or efficacy of interventions by comparing two or more groups; experimental groups and a control group are essential (Jadad & Enkin, 2008). The term control group refers to a group of participants whose performance on an outcome is used to evaluate that of the treatment group on the same outcome (Polit & Beck, 2012).

The control condition is a substitution of an ideal counterfactual (the condition or group used as a basis of comparison in the study) (Polit & Beck, 2012). Researchers have choices about what kind of treatment to use in the control group based on theoretical or substantive grounds, but should also consider practical or ethical principles (Polit &

Beck, 2012). The control group can receive an alternative intervention, a placebo, standard method of care, different doses or intensities of treatment, or delayed treatment (wait-list control group) (Polit & Beck, 2012).

#### **4.1.2.3 Randomization: The cornerstone of the RCT**

Randomization is the process of assigning study participants to experimental or control groups at random so that each participant has an equally assigned probability of being in any given group (Lang, 1997). The main purpose of randomization is to eliminate selection bias and balance known and unknown confounding factors in order to create a control group that is as similar as possible to the experiment group (Akobeng, 2005).

Baseline characteristics of the participants should be measured at the stage of initial recruitment into the trial (Kendall, 2003). These include basic demographic characteristics, but more importantly should include any important prognostic factors. It is important at the analysis stage that these potential confounding variables are equally distributed between the two groups; indeed, when reporting an RCT, it is important to demonstrate the integrity of the randomization process by showing that there is no significant difference between baseline variables (Kendall, 2003).

#### **I. Randomized allocation**

Methods for randomly assigning participants to groups, which limits bias, include the use of a table of random numbers and a computer program that generates random numbers (Akobeng, 2005). One appropriate randomization method is for a research support unit not involved in data collection to produce computer-generated sets of random allocations in advance of the start of the study, which are then sealed in consecutively numbered opaque envelopes (Kendall, 2003). After the participants are judged to have met the inclusion criteria and have given consent to be included in the trial, they are then irreversibly randomised by opening the next sealed envelope containing their assignment (Kendall, 2003).

In large sample size trials, simple randomization may lead to a balance between groups in the number of patients allocated to each of the groups, and in patient characteristics

(Akobeng, 2005; Polit & Beck, 2012). However, in small sample size studies, unequal groups may occur. Small to moderate sample size studies (less than 50 per group) may receive advantage from ‘blocked’ and/or ‘stratified’ randomization techniques (Altman & Bland, 1999; Kendall, 2003). Block randomization and stratification are strategies used to achieve balance between groups in size and patient characteristics (Altman & Bland, 1999). ‘Blocked randomization’ is a technique used to ensure that the number of participants assigned to each group is equally distributed (Akobeng, 2005; Kendall, 2003). Randomization is set up in blocks of a pre-determined size. For example, randomization for a block size of 10 would proceed until five assignments had been made to one group, and then the remaining assignments would be to the other group until the block of 10 is complete. ‘Stratified randomization’ is a technique used to ensure that an important baseline variable (potential confounding factors which are known before the study) is more evenly distributed between the two groups than by chance alone. (Akobeng, 2005; Kendall, 2003).

## **II. Bias**

The RCT design is considered the gold standard in evaluating the effectiveness of healthcare interventions, when it has been appropriately designed, conducted and reported (Schulz et al., 2010). However, RCTs can give biased results if they lack methodological rigour (Schulz et al., 2010). There are two main types of bias in RCT: selection bias and ascertainment bias (Jadad & Enkin, 2008). Selection bias can occur if some potentially eligible participants are selectively excluded from the study when the researcher knows that they may not respond to treatments with a good effect (Jadad & Enkin, 2008). However, selection bias can be solved by using allocation concealment (Jadad & Enkin, 2008).

Ascertainment bias occurs when the results of a trial are systematically distorted by knowledge of which intervention each participant receives. Ascertainment bias can be induced by the person administering the interventions, the participants, the investigator assessing or analysing the outcome, and even the people who report the trials. However, ascertainment bias can be reduced by blinding all concerns (Jadad & Enkin, 2008). The best strategy to achieve blinding during data collection is with the use of placebo.

Ascertainment bias after the collection of data can be controlled by keeping the data analysis and coding analysis separate (Jadad & Enkin, 2008). During the time of reporting, withdrawal bias is introduced by inappropriate handling of withdrawals, drop-out, and protocol violations (Jadad & Enkin, 2008). Withdrawal bias can be eliminated by two strategies: intention-to-treat (ITT) analysis and worst-case scenario or sensitivity analysis. ITT analysis entails that all study participants are included in the analysis as part of the groups to which they were randomised whether they complete the study or not (Jadad & Enkin, 2008). Worst-case scenario is performed by assigning the worst possible outcome to the missing participants in the group that shows the best results, and the best possible outcomes to the missing participants in the group with the worst results (Jadad & Enkin, 2008).

Other biases can occur in every phase of an RCT trial: for example, during the planning phase (choice-of-question bias, regulation bias, wrong-design bias), during the course of an RCT (population-choice bias, intervention-choice bias, control-group bias, outcome bias), during the reporting (withdrawal bias and selective bias), and during the dissemination of the trial (publication bias and language bias) (Jadad & Enkin, 2008; Kotaska, 2004).

### **III. Blinding**

Blinding (or masking) is a strategy used to reduce the risk of ascertainment bias. Blinding refers to the practice of preventing study participants, investigators, and those collecting and analyzing data from knowing who is in the experimental group and who is in the control group, in order to avoid them being influenced by such knowledge (Akobeng, 2005). RCTs can be classified as single-blind, double-blind and triple-blind. However, Montori et al. (2002) argue that the various definitions and interpretations of these terms make their use problematic when reporting the blinding status of trials. To provide more clarity to the issue, they argue, it is important to report which groups (for example, participants, care providers, outcome assessors, data collectors, data analysts) are blinded and how.

#### **IV. Intention-to-Treat (ITT)**

To eliminate the effects of withdrawal bias, ITT is a strategy in the conduct and analysis of RCT that ensures all participants allocated to either the treatment or control groups are analysed together as representing the groups, whether or not they received the prescribed treatment or completed the study (Last, 2001). It minimises bias such as type I error (false positive), and effects from omitting dropout and non-compliant participants (Lachin, 2000). The ITT analysis provides the most realistic and unbiased answer to the question of clinical effectiveness. It is also considered unbiased when all randomised patients are included in the analysis of the original design (Lachin, 2000). The adoption of an ITT design is required from the beginning of the trial in which all patients are followed (Lachin, 2000). This not only minimizes the potential for bias in the assessment of treatment effects through efficacy subset selection, but also improves the power of the trial by including all patients in the analysis by increasing the sample size especially in the case of testing an effective treatment over a long-term period (Lachin, 2000).

##### **4.1.2.4 Power and sample size calculation**

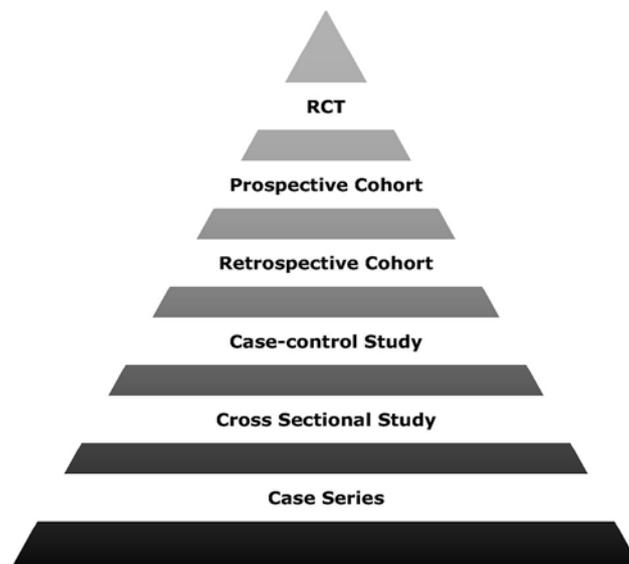
The statistical power of an RCT is the ability of the study to detect a difference between the groups when such a difference exists (Akobeng, 2005). The power of a study is defined by a number of factors, including the frequency of the outcome being studied, the size of the effect, the study design, and the sample size (Last, 2001). A sample size calculation aims to determine the number of participants needed to detect a clinically relevant treatment effect (Noordzij et al., 2010). Commonly, the number of patients in a study is restricted as a result of ethical, cost and time considerations (Noordzij et al., 2010). However, to have a reasonable chance of answering the research question it addresses, the sample size must be large enough so that sufficient participants are available for each group of interventions (Akobeng, 2005; Devane et al., 2004). If the sample size is too small, it may be impossible to detect any true differences in outcome between the groups, while too large samples may waste time, resources and money (Devane et al., 2004; Noordzij et al., 2010). To determine the appropriate sample size for the study, It must prespecify the magnitude of the difference between the Two

groups that it would regard as clinically meaningful and important (Devane et al., 2004). This is known as the ‘effect size’, which is a measure of how ‘wrong’ the null hypothesis is (Devane et al., 2004). The appropriate effect size are vary widely between studies, since it should represent the smallest effect that would be regarded as clinically meaningful and important, and therefore depends on factors such as the convenience of the intervention, the severity of the condition and the outcome being measured (Devane et al., 2004). However, Stanley (2007) suggested that the typical size of a RCT which compares new treatment to the standard therapy or a control or placebo should be 100 to 1000 participants.

### **4.1.3 Strengths and Limitations of RCT**

#### **4.1.3.1 Strengths of RCT**

RCT is considered the gold standard in experimental research, as it reduces the frequency of false-positive conclusions and minimizes unrealistic and therefore exaggerated expectations of therapy (Polit & Beck, 2012). A hierarchical ‘pyramid of evidence’ (see Figure 4.1), with RCT at the apex, has been promulgated as a way of judging study design and quality (Ho et al., 2008).



**Figure 4.1: The pyramid of evidence**

(Ho et al., 2010, p.1679)

RCT is considered the standard for the assessment of the effectiveness of intervention under ideal conditions (Ho et al., 2008). In RCTs, in which participants are randomly allocated to receive an active treatment or a control (placebo, no treatment, or even an active control), each patient has an equal chance of assignment to intervention or control group (Ho et al., 2008). A proper randomization can reduce a serious imbalance in any factors, which could influence the clinical course of participants (Stolberg et al., 2004). Therefore, confounding is not a threat to the internal validity of a properly conducted RCT, and any differences in outcome that occur between groups can be attributed to the intervention (Ho et al., 2008).

#### **4.1.3.2 Limitations of RCT**

Despite these significant strengths, RCTs also have limitations (see Table 4.1). They are typically expensive, time consuming, and designed to answer a single question or several numbers of research questions about treatment efficacy that are usually narrow in scope (Ho et al., 2008). Thus, an RCT design may be impractical or even inappropriate to address questions beyond therapeutic efficacy in a well-circumscribed population (Ho et al., 2008).

#### **I. Limitations of external validity**

RCTs usually have strict inclusion or exclusion criteria that are intended to maximise the internal validity of the study. However, these criteria intrinsically limit the extent to which the findings of an RCT apply to patients seen in clinical practice so the external validity limitations can occur. There are various factors that can affect RCTs' external validity (Rothwell, 2005):

- Research site where the RCT was performed;
- Selection of characteristics of the patients: researchers may include patients whose prognosis is better, or may exclude 'women, children, the elderly, and those with common medical illness;
- Study procedures: patients may receive intensive diagnostic procedures, making follow-up care difficult to achieve in the real world; Outcome measures: researchers may select measures infrequently used in clinical practice;

- Incomplete reporting of adverse effects of interventions.

## II. Cost and time

Some interventions require long-term implementation before an effect can be measured, which may cause practical difficulties in maintaining prospective randomization for prolonged periods across entire populations (Sanson-Fisher et al., 2007). Given the relatively high costs of RCTs in population-based settings, research funding typically determines whether a research project goes ahead or not (Sanson-Fisher et al., 2007). Most research funding is granted in the short term; therefore, longitudinal follow-up depends on the success of complementary applications (Sanson-Fisher et al., 2007). Moreover, the possible decline in differences across experimental and control groups due to contamination over time may offset the benefits of longer-term follow-up (Sanson-Fisher et al., 2007).

**Table 4.1: Strengths and limitations of RCT**

(Ho et al., 2008)

<b>Study Design</b>	<b>Strengths</b>	<b>limitations</b>
RCT	<ul style="list-style-type: none"> <li>• Internal Validity</li> <li>• Control over intervention</li> <li>• Control over end points</li> </ul>	<ul style="list-style-type: none"> <li>• Not feasible in many circumstances</li> <li>• External validity               <ul style="list-style-type: none"> <li>*Restrictive (study procedures, outcome measures, incomplete reporting adverse effects)</li> <li>* Enrolment criteria</li> <li>* Volunteer bias</li> </ul> </li> <li>• Expensive</li> <li>• Time-consuming</li> </ul>

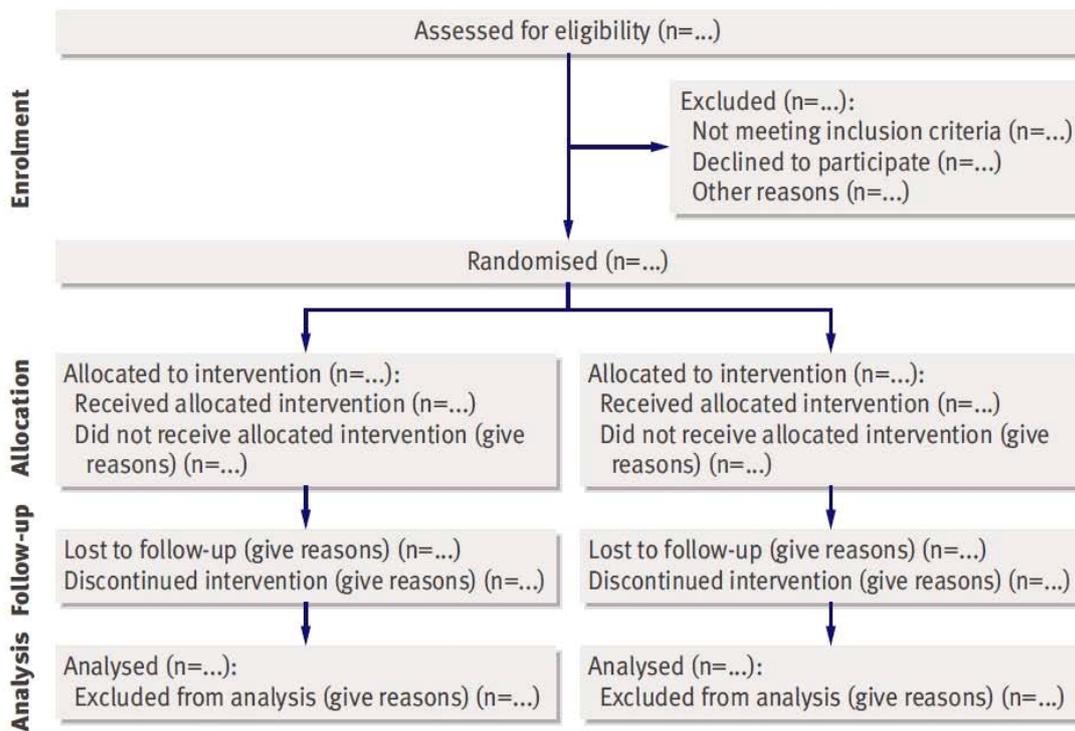
### 4.1.4 Assessing the quality of RCTs

RCT provides the highest level of evidence for medical interventions (Sackett, 2000). The elements inherent in an appropriately designed and conducted RCT will minimize bias, balance confounders, and thus produce the most reliable assessment of treatment effect (Montenegro, 2002). Regardless of whether or not the result of an RCT reaches statistical significance, the design, conduct, and published report should be of high

quality (Moher et al., 1995). High-quality RCTs and their reports should be realistic estimates of treatment effects, accurate and reproducible estimates of treatment efficacy, and hopefully lead to acceptance of the trial's results within the healthcare community (Moher et al., 1995). It is important to distinguish between assessing the quality of an RCT and the quality of its report. RCT quality depends on methodological quality, which can be defined as 'the confidence that the trial design, conduct, and analysis has minimized or avoided biases in its treatment comparisons' (Moher et al., 1995, p.63). High-quality RCT reports perform the role of 'providing information about the design, conduct, and analysis of the trial' (Moher et al., 1995, p.63). An RCT designed with several biases that is well reported can receive a high-quality score, whereas a well-designed and conducted trial that is poorly reported would receive a low-quality score (Moher et al., 1995).

A good quality RCT exhibits both internal and external validity. Internal validity is an essential component of RCT quality (Jadad & Enkin, 2008) and can be influenced by variations in independent variable, the integrity of the instrument and statistical procedures, the choice of statistical methods, and also external validity (Polit & Beck, 2012). A well-controlled (minimize selection and information bias, to control confounding, to attempt to rule out a chance) and well-written research protocol can enhance the internal validity (Brewer, 2000; Victora et al., 2004).

To assess the quality of RCT in publication, scales and checklists are two types of instruments that may be used to assess the quality of reporting of trials (Olivo et al., 2008). Scales and checklists both include items measuring quality; however, with a scale, the responses to the individual items are aggregated to create an overall summary score representing trial quality (Olivo et al., 2008). There are three measurements commonly used to assess the quality of RCT reports (Moher et al, 2001). First, the updated CONSORT 2010 checklist was modified so that multiple items were listed separately, which result in 25 items in the flow diagram and the table (Moher et al., 2010; Schulz et al., 2010) (see Figure 4.2 & Table 4.2). It provides guidance for reporting all RCTs, but focuses on the most common type: individually randomised, two-group, parallel trials (Schulz et al., 2010).

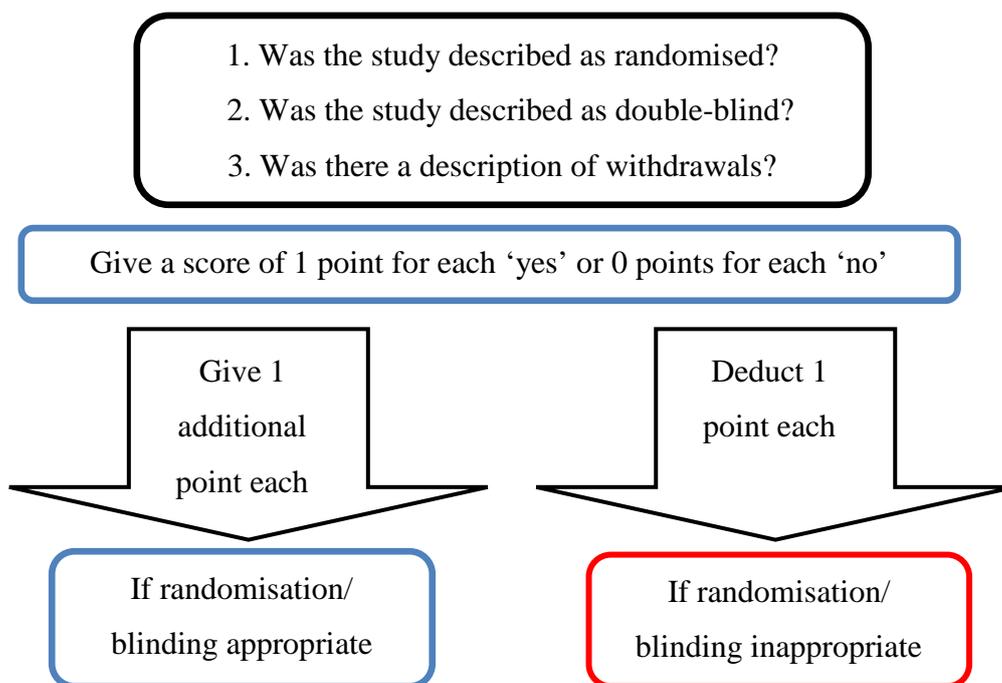


**Figure 4.2: Flow diagram of the progress through the phases of parallel randomised trial of two groups (Moher et al., 2010, p.6; Schulz et al., 2010, p.698)**

**Table 4.2: CONSORT 2010 checklist of information to include when reporting a randomised trial** (Moher et al., 2010, p.6; Schulz et al., 2010, p.698)

Section/Topic	Item No	Checklist item
<b>Title and abstract</b>		
	1a	Identification as a randomised trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts <sup>21,31</sup> )
<b>Introduction</b>		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
<b>Methods</b>		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
<b>Randomisation:</b>		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
<b>Results</b>		
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
	13b	For each group, losses and exclusions after randomisation, together with reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms <sup>26</sup> )
<b>Discussion</b>		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalisability	21	Generalisability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
<b>Other information</b>		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders

Second, the reporting of allocation concealment needs to be assessed as adequate, inadequate, or unclear (Schulz et al., 2010). Third, the Jadad scale is used to assess the quality of the report through two questions for randomization and blinding and one question evaluating withdrawal and drop-out reporting (Jadad, 1996) (see Figure 4.3 & Table 4.3). The Jadad scale is easy and quick to use (about five minutes for scoring), provides consistent measurements, and has construct validity (Jadad & Enkin, 2008). The scale includes three items that are related to bias reduction: randomization, blinding, and description of withdrawals and drop-outs (Jadad & Enkin, 2008). These are demonstrated through questions that elicit ‘yes’ or ‘no’ answers (see Figure 4.3). The scale produces scores from 0 to 5; points are awarded for positive (yes) answers to each question (Jadad & Enkin, 2008).



**Figure 4.3: The Jadad Scale**

(Moher et al., 2010, p.6; Schulz et al., 2010, p.698)

**Table 4.3: Jadad scale for reporting RCTs**

(Halpern &amp; Douglas, 2005)

Item	Maximum points	Description	Examples
Randomization	2	1 point if randomization is mentioned  1 additional point if the method of randomization is appropriate  Deduct 1 point if the method of randomization is inappropriate (minimum 0)	“The patients were randomly assigned into two groups”  The randomization was accomplished using a computer-generated random number list, coin toss or well-shuffled envelopes  The group assignment was accomplished by alternate assignment, by birthday, hospital number or day of the week
Blinding	2	1 point if blinding is mentioned  1 additional point if the method of blinding is appropriate  Deduct 1 point if the method of blinding is inappropriate (minimum 0)	“The trial was conducted in a double-blind fashion”  Use of identical tablets or injectables, identical vials Use of tablets with similar looks but different taste  Incomplete masking
An account of all patients	1	The fate of all patients in the trial is known. If there are no data the reason is stated	“There were 40 patients randomized but the data from 1 patient in the treatment group and 2 in the control were eliminated because of a break in protocol”

#### 4.1.5 Ethics of RCT

RCTs are generally considered to be the best method of evaluating the effectiveness of health treatments. As RCTs involve human subjects, they pose an inherent tension between pursuing socially valuable knowledge and protecting participants (Miller & Veatch, 2007). Moreover, they involve the ethical challenge known as “the RCT dilemma”. This is challenging in that health researchers have to offer competent health care to patients in need of treatment while conducting experiments that select treatments randomly. The common principles of health ethics are autonomy, beneficence, non-maleficence, privacy and justice (National Health and Medical Research Council et al., 2007). The value of ethics in RCT depends on how and why RCTs are used (Jadad & Enkin, 2008). RCTs are not ethical when they are conducted primarily to meet regulatory requirements, to promote commercial or personal interests, or to satisfy the curiosity of the researcher (Jadad & Enkin, 2008).

The main ethical issues in RCT research concern informed consent, equipoise and placebo treatment (Hutton, 2001; Jadad & Enkin, 2008). Every individual has a right to participate in any RCT, with access to the available relevant information, as they should fully understand the research issues before making a decision whether to participate in the research. The ethical requirement for informed consent exists to protect those rights (Jadad & Enkin, 2008). The main purpose of informed consent is protecting the potential participants, not the institutions, the sponsors, the researchers, or the institutional review board (Light, 1998). The World Medical Association (WMA) developed the Declaration of Helsinki in 1964 as a statement of ethical principles for medical research, including human experimentation; it states that participants have to be volunteers and supplied with all relevant information about the research (World Medical Association, 2000, 2008). The written consent forms have become an institutional and legal requirement for research that poses even a minimum degree of risk; informed consent forms need to be written in simple language and contain all essential information (Jadad & Enkin, 2008). Recruitment for participation in clinical research should only be for patients who have previously expressed general willingness to be approached for research purposes (Habiba & Evans, 2002).

The term equipoise (personal and clinical equipoise) refers to the degree of genuine uncertainty about intervention (Chiong, 2006). In term of personal equipoise, clinicians or patients who believe, for whatever reason, that they know the best treatment cannot ethically participate in the trial (Jadad & Enkin, 2008). Randomization would be ethical only if both clinician and the participant are uncertain (Jadad & Enkin, 2008). Clinical equipoise (also called collective or professional equipoise) refers to clinicians as a group not agreeing as to what is the best among the available alternatives (Jadad & Enkin, 2008). Offering trial enrolment when there is professional disagreement within the clinical community is consistent with a clinician's commitment to the patient (Jadad & Enkin, 2008). Equipoise in RCT studies may still present a serious dilemma as most researchers and participants have their own preferences in relation to the treatments on offer; equipoise is not achieved when intervention benefits are conferred by personal's perception (Jadad & Enkin, 2008).

The third main ethical concern in clinical trials is the use of placebo treatment. The World Medical Association has recapitulated that using a placebo treatment is unethical when there is a known effective treatment; however, the use of a placebo is not considered unethical when there is no current proven intervention and no risk of serious or irreversible harm (World Medical Association, 2008). Many drug studies are conducted to meet regulatory standards that advocate use of placebo control in order to determine whether the new intervention is better than nothing and to demonstrate its benefit or risk compared with accepted alternatives (Rothman & Michels, 1994). Placebo-controlled trials are unethical in some circumstances. If an available treatment is known to prevent or delay death or any major harm to long-term health in people with a particular disease or condition, one should not study a new treatment by comparing it to a placebo control, even if it would be informative to do so (Ellenberg, 2003). However, the placebo can ethically be used when adverse outcomes are reversible, and it would be appropriate, and consistent with the principle of patient autonomy, for potential participants to be able to decide for themselves if they wanted to enroll (Ellenberg, 2003).

RCT research is a leading method of testing treatment efficacy and to examine whether a new intervention is safe and effective, rather than to determine efficacy compared with a proven intervention (Miller & Brody, 2002). Without a placebo treatment to ensure validity, there is no difference in findings between experimental and standard treatments, which can be misleading and mean that research findings cannot be easily interpreted (Ellenberg, 2003).

#### **4.1.6 Implementation of RCTs**

The RCT design is considered to be the best method of evaluating the effectiveness of health interventions as using randomised assignment to avoid bias. However, true randomization is difficult because access and feasibility issues limit the ability to have a truly random sample (Winsett et al., 2007). It is possible to gain a fair representation of the target population by careful selection criteria and attention to other variables that might influence the outcomes (Winsett et al., 2007). There are three main concerns

relevant to implementation of RCT: internal and external validity, sampling strategies, and randomization and random assignment (Winsett et al., 2007).

#### **4.6.1.1 Internal and external validity**

Before any RCT gets underway, threats to internal and external validity must be addressed. Internal validity refers to how the study represents the effect of the intervention (Winsett et al., 2007). There are other influences that may involve the outcome, namely historical events, maturation, testing effects, instrumentation, statistical regression, selection bias, mortality, diffusion of treatment, compensatory equalization, and resentful demoralization (Table 4.4); the researcher should evaluate all threats to internal validity before collecting data (Burns & Grove, 2005; LoBiondo-Wood & Haber, 2002; Winsett et al., 2007).

**Table 4.4: Threats to study internal validity**

(Winsett et al., 2007, p. 151)

<b>Threats</b>	<b>Description</b>
Historical events	Events or interactions with life outside of the study environment that may influence subjects responses
Maturation	Effects of learning during the course of the study. Does history or event affect one group over another?
Testing effects	Subjects altering responses based on previous testing or providing socially acceptable responses
Instrumentation	Are the instruments or questionnaires used in a study reliable and valid for the population? Are data collected the same across the entire study period?
Statistical regression	Did the treatment affect the change (type 1 error)? Was there sufficient variability in the data and adequate sample size to detect a change if present (type 2 error)?
Selection bias	Did the sampling plan ensure equal opportunity to participate in the study? If a non-probability sample was used, are there safeguards in place to generalize from the sample?
Mortality	The effect of drop-out in the study (by any means) and how the investigator addresses study mortality
Diffusion of treatment	The controls over the intervention group and how the investigator ensures that the control group and the intervention group are not contaminated
Compensatory equalization	Acts from others or from subjects that alter participation in the assigned group
Resentful demoralization	Subjects perceive that they are receiving less than desirable treatment and opt to withdraw from the study

External validity refers to how the study sample can be generalized to the population at large (Winsett et al., 2007). The ability to generalize from the study sample is in essence the purpose of the research. If the researcher chooses the sample appropriate for the study question and ensures representativeness for the population, then others can use the study outcomes to further their knowledge (Winsett et al., 2007). Table 4.5 presents generally accepted threats to external validity.

**Table 4.5: Threats to study external validity**

(Winsett et al., 2007)

Threats	Description
Interaction of selection and treatment	The impact of entering subjects for whom it is easy to become a subject.
Interaction of setting and treatment	The impact of environmental culture in the study setting such as additional time for personnel, burden to the staff, controversy, and the environment supporting the research.
Interaction of history and treatment	There is an event that influences study results, making the study less generalized or replicable in areas such as changes in health policies.

#### 4.6.1.2 Sampling strategies

One of the challenges for an RCT study is creating the sampling strategy (sampling criteria and representativeness). The researcher needs to consider ways to strengthen the sampling strategy to increase generalization or external validity (Winsett et al., 2007). The sampling strategy is the study's specific plan to determine subject eligibility and the methods by which the sample will be representative of a target population (Winsett et al., 2007). The target population includes all eligible subjects (not just at the study site),

and the goal determines how the sample drawn for the particular study will represent the target population (Winsett et al., 2007). Clinical researchers often do not have the funds to target all eligible subjects, and therefore they will choose subjects from an accessible population in the participating study site. Selecting eligibility criteria carefully will help evaluate the representativeness of the study population to the target population.

Sampling criteria are the characteristics that describe eligibility or ineligibility to participate in the study (Polit & Beck, 2008). Researchers must define inclusion and exclusion criteria and rigorously control the sample criteria to ensure an appropriately representative sample (Winsett et al., 2007). Narrowing the inclusion criteria will limit generalizability, but may help address other threats to validity such a competing hypothesis or alternative explanations for study findings (Winsett et al., 2007).

#### **4.6.1.3 Randomization and random assignment**

There is a difference between the two concepts of randomization and random assignment. Randomization is a process through which all eligible subjects have an equal and independent chance of participating in a study; random assignment, on the other hand, is the method in which subjects are assigned into groups (Winsett et al., 2007). The researchers select inclusion and exclusion criteria, and prepare the study site appropriately to ensure there is access to the population. Random assignment is a way to strengthen the randomization principles in the study; it is a matter of clear articulation about how the sample is chosen (Winsett et al., 2007).

The current study selected the RCT design as this design is the gold standard for evaluating the effectiveness of healthcare interventions. The study examined the effectiveness of SMGO and TTM in treating CLBP in older people. The following presents the method of the study using an RCT design.

## **Study methods**

### **4.2 Study Method**

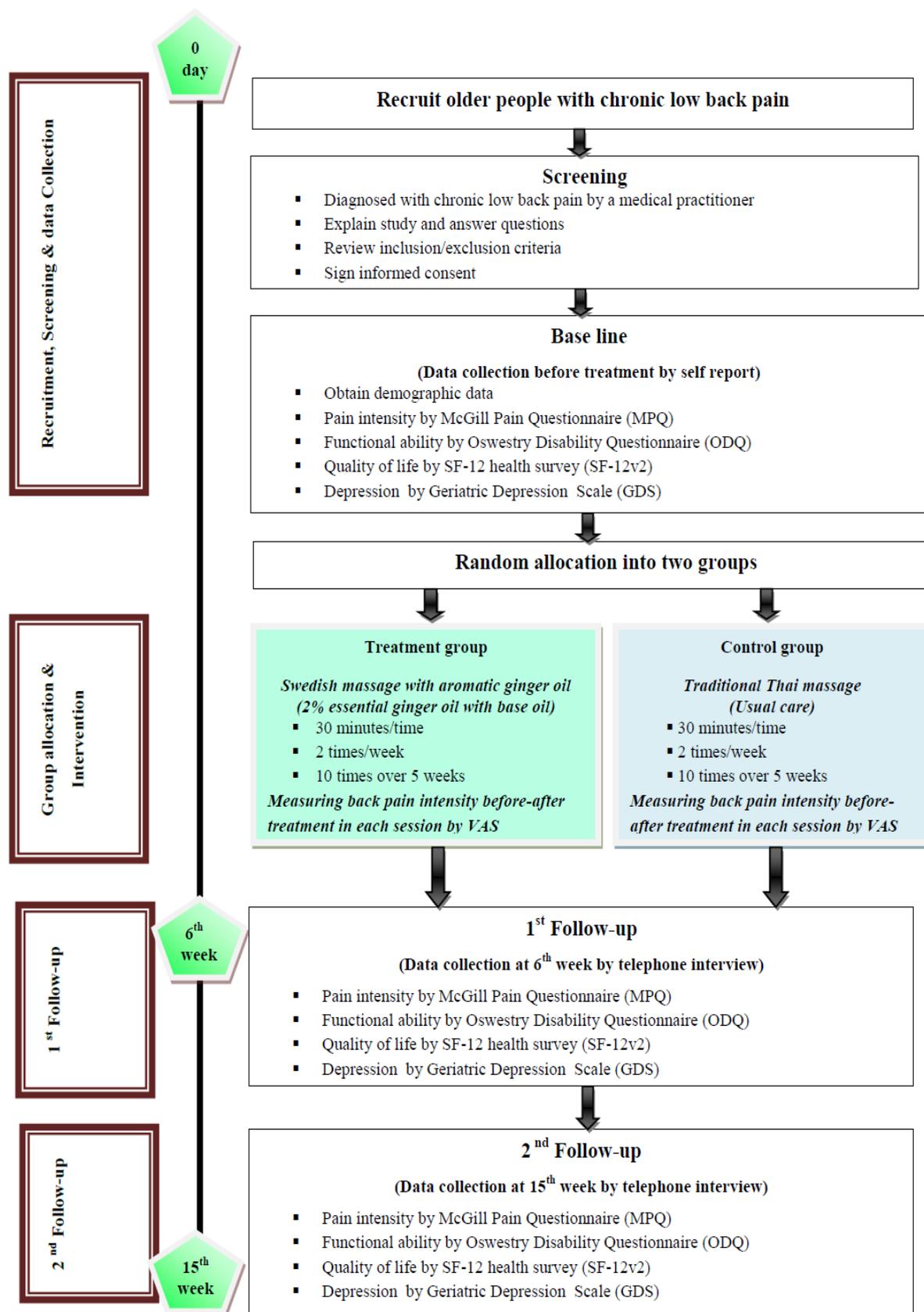
#### **4.2.1 Study design**

A randomised controlled trial was used to investigate the effect of Swedish massage with ginger oil on older people with CLBP. Participants were randomly assigned to one of two groups: Group I (treatment) received Swedish massage with aromatic ginger oil (2% essential ginger oil with Jojoba oil) and Group II (usual massage) received traditional Thai massage delivered through clothing with no oil.

RCTs can be classified according to the aspect of the interventions to be explored, the way participants are exposed to the intervention, the number of participants included in the trial and whether the participants and/or researchers know which intervention is being tested. This study is classified as an explanatory RCT and aimed to test whether or not the interventions works. An explanatory trial is designed to yield a 'clean' evaluation of the intervention. In this type of trial the researcher sets strict participant inclusion criteria so that the study groups are as homogenous as possible. Furthermore, this type of trial uses a placebo group as a control. In addition an intention to treat analysis is used and the trial focuses on hard outcomes (Zwarenstein et.al., 2008). A pragmatic trial in comparison is designed to determine whether the intervention works and to also described all the consequences of its use in the clinical setting. Everitt and Wessely (2004) suggests that an explanatory trial measures the direct effect of the intervention under controlled conditions. Whereas a pragmatic trial measures what happens when the treatment is introduced into routine clinical practice with relatively unselected participants and under flexible conditions (Everitt & Wessely, 2004). Whole of systems research design was considered for this study but seen as being inappropriate because of its complexity which would be beyond the scope of a PhD study. The current explanatory trial tested the effectiveness of Swedish massage with aromatic ginger oil on CLBP.

The study design has a number of strengths. Firstly, this study used a randomised controlled trial, which is the most rigorous way of determining whether a cause-effect

relationship exists between treatment and outcome (Sibbald & Roland, 1998). Secondly, random assignment of participants to treatment by using a probability device allowed the use of statistical methods to make valid statements about the differences between treatments for this set of participants. Thirdly, using standard tools for measuring physical function (pain intensity and functional ability) and psychosocial function (quality of life and depression) improved the reliability and validity of findings. Lastly, the follow-up measurement enabled detection of any sustained effect of the interventions in the longer term. The brief study design is depicted in Figure 4.4



**Figure 4.4: Study design of the effectiveness of SMGO compared to TTM on CLBP**

#### **4.2.2 Setting**

Recruitment took place in Damnoensaduak hospital in Ratchaburi province in Western Thailand, a 300-bed general hospital with 191,558 new clients a year (Damnaensaduak hospital, 2007). The hospital is a part of Thailand's network of provincial government hospitals. Having won the Tourism Authority of Thailand's Award of Excellence for Health Tourism 2010, this hospital provides a variety of traditional Thai treatments. In 2003 it was awarded a 'Certificate for Hospital Quality Assurance' by the Institute of Hospital Quality Improvement and Accreditation, a clear demonstration of the high standards of its management, services offered and academic training program.

Older people with CLBP were recruited from new clients who were admitted for treatments to the massage clinic or the orthopedic clinic at Damnoensaduak hospital. The massage treatments and the base line measurements were attended to at the massage clinic; the outcome data collection was completed by telephone interview for first and second follow-up.

#### **4.2.3 Sampling framework**

##### **4.2.3.1 Participants**

###### **Inclusion criteria**

Inclusion criteria for participation in this study were that participants were:

1. 60 years and older
2. Able to listen, speak, read and write the Thai language
3. Diagnosed with CLBP (lasting more than 12 weeks) by a medical practitioner
4. New clients or clients who had not received any type of massage 12 weeks before testing.

###### **Exclusion criteria**

The exclusion criteria were that clients had:

1. Skin diseases
2. Inflammation or infection on back
3. A history of back fracture or back surgery

4. Temperature of more than 38.5 °C on the examination day
5. Hemi/paraparesis
6. Infectious diseases (e.g. tuberculosis or AIDS)
7. Cancer
8. Prior experience of receiving any type of massage for three months before this study
9. Inability to commit to the full course of treatment and follow-up.

#### **4.2.3.2 Sample size**

The sample size was calculated based on a previous study by Franke et al. (2000) (total n=109), which examined the effectiveness of acupuncture massage (APM) as traditional Thai massage versus Swedish massage in CLBP sufferers using the Visual Analogue Scale for pain (VAS) as the primary outcome measurement. APM showed beneficial effects for both disability and pain compared with SM (group differences: delta FFbH [functional disability] 7.0% [95% confidence interval (CI) 2.5-11.6], p = 0.003; delta VAS 0.8 cm [95% CI: 2-15], p = 0.024). Standardized response means were SRMFFbH = 0.5 and SRMVAS = 0.8 for APM, as opposed to SRMFFbH = -0.01 and SRMVAS = 0.4 for SM.

Based on this research and advice from research methodologist Dr Denise Polit, a total sample size of 128 participants was calculated to provide sufficient power, using G-Power to detect an effect size of 0.5 with 95% probability at an alpha of 0.05. However, to allow for a possible 10% attrition, a minimum of 70 participants was allocated to each group (n=140 in total).

The feasibility of recruiting 140 older people to participate in the study was high. The number of Out-Patient Department (OPD) clients with low back pain is 12,545 per year (Damnaensaduak Hospital, 2007). The approximate total number of clients using the massage services at the data collection site was about 300 per month and nearly 50% of them were older people with low back pain. The number of new older people with back pain attending the massage clinic was approximately 30-40 people per month

(Dumnuansadug hospital note recording by massage-clinic officer, May-June 2010). It was therefore feasible to recruit 140 participants from these potential participants.

#### **4.2.4 Procedure**

##### **4.2.4.1 Recruitment and screening of participant**

Several methods were used to recruit participants to the present study. Firstly, the researcher produced posters of invitation to the study and posters were displayed at the hospital to inform and encourage participation. Flyers describing the nature of the study with the researcher's name and contact information were placed on the information desk at the hospital. Secondly, the staff at the orthopaedic clinic and massage clinic identified from clients' health records potential participants with a medical practitioner diagnosis of chronic low back pain and invited them to participate in the study. If older people with chronic low back pain were interested to participate in the study, after they responded to the clinical staff invitation, an appointment with the researcher was arranged so that there could be further discussion about the study and to provide further research information. Thirdly, the researcher attended the orthopaedic and massages clinics to assist with recruitment. The process of screening and baseline data collection were completed at both clinics.

Older people with CLBP who met the criteria and expressed willingness to participate were given information orally and in writing about the nature of study. The name and contact information of the researcher were provided and the participants were encouraged to contact them for further information. After providing written consent, the participants were asked to complete the Demographic Information Questionnaire, which substantiated eligibility for participation in the study and sought personal background, back pain characteristics and general health behaviours. To ensure confidentiality, participants returned the questionnaire to a researcher who was blinded to treatment and did not provide any massage to any participants as a massage therapist.

#### **4.2.4.2 Randomization**

Participants who met the selection criterion were randomised into two groups: (1) TTM group; (2) SMGO. In order to conceal allocation, a statistician not involved in the study prepared a randomization schedule using a random number generated by computer with permuted block randomization (block of 10) prior to the enrolment of the first participant. Another person not involved in the study placed randomised numbers into opaque envelopes. The assignments were placed in sealed opaque numbered envelopes prior to the onset of the study and treatments determined after the baseline assessments had been completed. Each person who met the eligibility criteria was given the next opaque envelope treatment in sequential order.

At this stage, participants were asked to come to the massage clinic to receive 40 minutes of massage (30 minutes for treatment and 10 minutes for preparation) for 10 sessions (twice per week) over five weeks. The researcher provided contact information to the participants to initiate contact if they wished. The participants were told that they should not take pain medication in the preceding four hours as the effect of the pain medication could interfere with the immediate measurement of the effectiveness of the interventions. Also, the participants were requested not to eat a meal within one hour of coming to the massage clinic to receive the assigned intervention to reduce the incidence of stomach discomfort during the massage session (Chaithavuthi & Muangsiri, 2007).

#### **4.2.4.3 Intervention**

##### **Study protocols** (Appendix C)

The SMGO and TTM interventions used in this study were carried out by trained healthcare professionals (physiotherapists and massage therapists) who hold a certificate in traditional Thai or aromatic oil massage and have been trained in the study training course to ensure they understand the protocols. Both TTM and SM were delivered for 30 minutes. Based on the previous studies (Chatchawan et al., 2005; Field et al., 2007; Hernandez-Reif et al., 2001), a 30-minute session was considered likely to be effective when massage was confined to the back area only. Therefore, each treatment session

was 40 minutes, including 30 minutes treatment and 10 minutes preparation (five minutes before and after the intervention). Participants remained on the same allocation throughout the study period, if they continued in the study. Interventions covered all parts of the back. Details of the two protocols are presented in the following section.

## **I. Experimental group (SMGO)**

As indicated earlier Swedish massage combined with aromatic ginger oil is based on five basic strokes (effleurage, petrissage, friction, tapotement and vibration) which are administered using a lubricant to skin (Goldberg, 2001). Strokes integrate the qualities of intension, touch, pressure, excursion, speed, rhythm, continuity, duration and sequence which vary within the session.

A literature review undertaken for the current study (Sritoomma et al. 2012) reviewed randomised controlled trials that focused on the effectiveness of traditional Thai and Swedish massage in treating chronic low back pain either through a comparison to each other, a usual care group or other therapies such as relaxation therapy or joint mobilisation. A systematic review of the literature was conducted according to the PRISMA 2009 checklist in the review paper. The review paper concluded that TTM, which is usual massage treatment in Thailand and SM appear to be equally effective in relieving chronic low back pain (Sritoomma, et al., 2012).

Goldberg (2001) and Osborn et al. (2001) suggested that the combination of aromatic oil in massage is helpful in prolonging the effect of massage. Furthermore, massage is the most significant and commonly used method of applying oils in aromatherapy because massage combines the therapeutic power of touch with the properties of the oils (Goldberg, 2001). The skin absorbs the oils, which are taken into the bloodstream during the relatively short time of the body massage (Goldberg, 2001). Therefore, to extend current knowledge the present study combined Swedish massage with aromatic ginger oil to test ginger aromatic oil effectiveness in reducing chronic low back pain. The ginger treatment in the present study was aromatic oil, not oral ingestion and the concentration of aromatic ginger oil was 2% which is the lowest and safest way to use for body massage (Yip & Tam, 2008). The study used the lower concentration of ginger essential oil although the recommended percentage varied between 1% to 3% (Schnaubelt, 1998).

Aromatic ginger oil was selected to be the massage oil as it is an analgesic and anti-inflammation agent. The amount of oil needed for massage varied for a full-body massage; generally this was 10 ml for a small person, 14 ml for a medium size and up to

20 ml for a large person (Goldberg, 2001). For body massage, it is recommended that the essential oil is 2% of the blend with the carrier oil (Goldberg, 2001; Yip, 2008). The essential oil is usually measured in drops. For example, 1% of essential oil in 10 ml of carrier oil is 2.5 drops and 2% in 10 ml of carrier oil is 5 drops (Goldberg, 2001).

The study used jojoba oil as the carrier oil because it has anti-microbial and anti-inflammatory properties and the chemical composition of jojoba closely resembles that of the skin's natural sebum (Price et al., 1999). Jojoba (*Simmondsia sinensis*) is produced by heating the seeds of the jojoba plant. It virtually has no odour and readily penetrates the skin. It can be used on all types of skin and is widely used in the cosmetic industry (Dunning, 2007). As a massage carrier oil, jojoba oil has the advantage that essential oils can easily be added (Siegel-Maier, 1999). It is easily absorbed and rarely causes allergic reactions, even in the most sensitive skins (Harry-O'kurua et al., 2005). The study used 10 mls of jojoba oil and 2% of aromatic ginger oil for massaging. In participants who had dry skin, the massage therapist applied only carrier oil, not more aromatic ginger oil. Participants received a 30-minute massage session, two times a week for five weeks (Field et al., 2007; Hernandez-Reif et al., 2001) with massage therapists.

Before each treatment session, all treatment equipment was prepared for SMGO comprising a bottle of aromatic ginger oil, bottle of jojoba oil (in case of dry skin), paper caps (for people with long hair) and pants, face-supported pillow, massage bed, bed sheets, and towels. SMGO was performed on the massage bed with unclothed participants except for pants and towel, with the towel covering opened for massage and replaced when treatment of that body part was concluded (Holey & Cook, 2003). During the waiting period, the massage therapist washed her hands and prepared the materials for the massage (see Appendix C for protocol).

## **II. Control group (traditional Thai massage)**

As traditional Thai massage is based on energy-line theory, the treatment started from the left foot (Salguero, 2004; Tangtrongchir, 1992) following the standardised protocol

(Appendix C). The massage therapist stretched the muscles, applied pressure with the palms, thumbs and elbows, all techniques addressing the energy pathway and points (Gold, 2003; Salguero, 2004). TTM was performed on a mattress with the client fully clothed (Avraham, 2001; Cowen, 2005; Marcati, 1998) (see Appendix C for protocol).

Both protocols (SMGO and TTM) provided 30 minutes of back massage and approximately 40 minutes time overall. SMGO was more complex than TTM as it had more stages and procedures on the back (See Table 4.6) but the time allocated was the same for both groups.

**Table 4.6: Summary of the number of stages, procedures and time taken**

Type of intervention	Total number of stages	Number of procedures on the back	Approximate time taken (minutes)	Intervention time (minutes)
Traditional Thai massage	24	21	40	30
Swedish massage with aromatic ginger oil	43	34	40	30

#### **4.2.4.4 Pilot study**

Prior to starting the actual trial, a pilot study was conducted to assess whether SMGO and TTM protocols were realistic and workable, and to identify practical problems and any adverse effects caused by procedures. The participants in the pilot study were not included in the actual trial.

The first stage of the pilot study assessed both types of massage protocols with expert agreement. The treatment protocols were evaluated for expert agreement by consensus of a panel of two experts, one each in traditional Thai and Swedish massage, one in the United States and another in Thailand. Even though the experts have different backgrounds (massage therapist and physiotherapist), they are both intimately associated with massage and complementary therapy treatments, and both experts are academically qualified as they have doctorates in the area related to massage study. The panel members were asked to evaluate the individual steps of the protocol with regards to their relevance and appropriateness in terms of the sequence, the number of stages and the procedures in each stage. Where panel members raised concerns with any aspect of the protocols, reassessment and revision were undertaken.

Following content validity of the intervention protocols, the researcher applied a snowball technique to recruit four participants using the study sample inclusion and exclusion criteria; and data collection site as basis for the actual trial. Firstly, the researcher informed potential participants both orally and in writing about the nature of the study. Secondly, after participants gave written consent, they were asked to complete the questionnaire including the Demographic Information Questionnaire, McGill Pain scale, ODI and SF-12V2. Participants were instructed to identify any parts of the questionnaire that were difficult to read or understand. Additionally, the first copy of the questionnaire had a page that asked about the time it took them to complete the entire questionnaire. Thirdly, the four participants were randomised into two groups: two in TTM group and two in SM with aromatic ginger oil. All participants were asked to rate the pain intensity with the VAS before receiving the treatments. Each of the participants received 30 minutes of the assigned treatment to identify any adverse effects, discomforts or concerns regarding the intervention. Any adverse effects were

monitored, and participants were referred to their physicians for any adverse effects and massage treatment stopped if recommended.

The pilot study went well. The four participants were generally comfortable answering all questions. There were no negative written or oral comments about the questionnaire. Participants stated that the instructions and items in the questionnaire were clear. All four participants answered the whole questionnaire in an average time of 10.7 minutes. The participants in both the SMGO and TTM groups enjoyed their therapy and did not report any adverse effects throughout the pilot study. The participants in both groups reported that the SMGO and the TTM intervention reduced their back pain intensity immediately after massage.

#### **4.2.4.5 Blinding**

Participants were assigned using computer-generated random assignment in a 1:1 ratio to the SMGO (treatment) group or the TTM (control) group by a statistician. The assignments were placed in a sealed opaque envelope numbered by another person who also was not involved in the study prior to the onset of massage. Thus, both participant and massage therapist could not choose each other. For outcome assessment blinding, the investigator who assessed the outcomes of the interventions did not provide any massage to any participants as a massage therapist but was not blinded to group allocation.

#### **4.2.4.6 Intention-To-Treat**

As an Intention-to-Treat analysis requires data from every randomly allocated participant, regardless of treatments received, study withdrawal, or protocol deviation (Gravel et al., 2007; Polit & Gillespie, 2010), the analysis for this study was based on 70 participants in each treatment group. To manage the missing data, the pattern of missing data in this study was investigated and found to be ‘missing completely at random’ (MCAR), meaning that the missing observations were completely unrelated to either the value of the missing case or the value of any other variables (Polit & Gillespie, 2010). Given the MCAR pattern and the low percentage of missing data,

missing values were imputed using the 'last observation carried forward' (LOCF) method (Polit & Gillespie, 2010).

#### **4.2.4.7 Intervention fidelity**

A number of processes were maintained to ensure intervention fidelity. The massage therapists performed the training course which took three weeks (60 hours) before the pilot study. The massage therapists were assessed by trainers against the protocols when they completed the course. The massage therapists were selected to join the research team according to the following selection criteria: (1) the massage therapists were required to adopt the stages of the study protocols; (2) they had to have a similar pressure and rhythm of massaging; (3) and they also had to willingly join the research team.

To ensure that the massage therapists maintained consistency in their application of study protocols, the study monitored the intervention sessions every three weeks to ensure that massage therapists were complying with the study protocol. The massage therapists were monitored by trainers who had instructed them in the training course. There were two patterns of monitoring. Firstly, trainers observed massage therapists while they performed interventions with participants. The second pattern of monitoring, it involved massage therapists performing both SMGO and TTM on trainers to ensure pressure, rhythm and stages of massaging according to the massage protocol of the study.

#### **4.7.8 Medication and safety monitoring**

Pain medication use and adverse effects were monitored over the course of the study. These data of pain medication and adverse effects monitoring were gathered at the two post-intervention data collection point (6<sup>th</sup> and 15<sup>th</sup> weeks) to allow examination of any changes over time.

During both the pilot study and the actual study, any adverse effects were monitored. If participants had adverse effects, they were to be referred to physicians at the hospital

and the massage treatment stopped if recommended. The following discontinuation criteria were agreed upon before commencement of the study. During the study, no participant had adverse effects or required referral.

**Discontinuation criteria for participants**

1. A symptom of burning on the skin after using aromatic ginger oil
2. Having a severe allergic reaction and a physician recommends discontinuation
3. After treatment by a physician, the adverse effects do not resolve or they become worse
4. Development of a complication which requires the participant to take medication

#### **4.2.4.9 Data collection**

The data for this study was collected pre-treatment and at two post-treatment intervals at the 6<sup>th</sup> and 15<sup>th</sup> weeks. The primary and secondary outcomes were measured at all three time points using the McGill Pain Questionnaire for pain intensity, ODI for functional ability, SF-12v2 for quality of life and Geriatric Depression Scale (GDS) for depression by self-report at pre-treatment and telephone interview at two post-treatment intervals. A research assistant asked the participants to rate their pain using the VAS pre and post each treatment session to measure immediate effectiveness.

Previous studies have measured the outcomes of TTM and SM studies at the 5<sup>th</sup> week or one month post-intervention (Buttagat et al., Chatchawan, et al., 2005; Cowen et al., 2006; Field et al., 2007; Hernandez-Reif et al., 2001; Mackawan et al., 2005; Preyde, 2000) (See Table 4.7), but only one study (Cherkin et al., 2011) has assessed the outcomes at a period longer than 12 weeks and most studies have assessed outcomes at a period no longer than five weeks. As CLBP is defined as lasting for longer than 12 weeks (Airaksinen et al., 2006; Andersson, 1999; Bogduk, 2004; Middleton & Pollard, 2005), the current study assessed pain at period greater than 12 weeks and in this case at week 15<sup>th</sup> post-intervention. During the study, the participants were able to provide feedback about the treatments, including positive and negative comments and side effects of treatments.

**Table 4.7: Summary of intervention sessions identified in the literature**

<b>Author (year)</b>	<b>Time (min)</b>	<b>Frequency (session/week)</b>	<b>Duration of intervention (weeks)</b>	<b>Total massage session</b>	<b>The period of assessment</b>
Buttagat et al. ( 2009)	30 (back)	1	-	1	Immediately following treatment
Chatchawan et al. (2005)	30 (back)	2	3	6	On day 1, 2 <sup>nd</sup> week, 3 <sup>rd</sup> week and 7 <sup>th</sup> week
Cherkin et al. (2009)	60 (whole body)	1	10	10	Baseline, 10 <sup>th</sup> week, 26 <sup>th</sup> week and 52 <sup>nd</sup> week
Cowen et al. (2006)	90 (whole body)	1	-	1	Before treatment, after treatment immediately and 48-hrs after treatment
Field et al. (2007)	30 (back)	2	5	10	On day 1 and last days of 5 <sup>th</sup> week
Franke et al. (2000)	60 (whole body)	1	-	1	Baseline and after treatment
Mackawan et al. (2005)	10 (back)	1	-	1	Before and five minutes after treatment
Preyde (2000)	30-35 (back)	6	1	6	Baseline, after treatment and at one-month follow-up

#### **4.2.5 Variables**

Demographic characteristics and medical pain history were recorded for each participant at baseline (see Appendix D). Outcome measures were patient-rated measurements. Pain intensity as a primary outcome was measured using two measurements: the McGill Pain Questionnaire (MPQ) for musculoskeletal pain, Thai version (Kitisomprayoonkul et al., 2006), and the Visual Analogue Scale for low back pain (VAS) (Carlsson, 1983; Wilkie et al., 1990) (see Appendix E). Three secondary outcomes – functional ability, quality of life and depression – were measured using the Oswestry Disability Questionnaire (ODQ), Thai version 1.0 for back pain (Sae-jung et al., 2002) (see Appendix F); Quality of Life (SF-12v2) in Short-Form Health Survey, Thai version 2.0 (The SF community, 2010) (see Appendix G) and Geriatric Depression Scale (GDS) (see Appendix H). The details of all outcome measures are described below.

##### **4.2.5.1. Demographic variable**

###### **I. Demographic information questionnaire (Appendix D)**

The demographic information questionnaire was developed specifically for this study and sought personal information and details about general health status and back pain characteristics. Self-report data was sought for the personal background and general health section and included participants' age, gender, marital status, educational level, occupation, exercise activities, home address and telephone number.

The back pain characteristic section was comprised of causes of back pain, duration of back pain episode (months), duration of the latest episode of back pain (weeks), the pattern of pain, the position of back pain, the previous treatments for back pain including any type of massage, and the current treatments such as analgesic drugs and/or herbs. For the purpose of monitoring medication and adverse effects, the study included questions on the use of pain medication for the first and second weeks following assessment (see Appendix D).

#### **4.2.5.2 Primary outcome measures: Pain intensity**

##### **I. McGill Pain Questionnaire (MPQ) (Appendix E)**

The McGill Pain Questionnaire (MPQ) was used as the primary outcome measurement. It consists of three main classes of word descriptors – sensory (the quality of pain), affective (description of emotional and anxiety responses to pain) and evaluative (overall intensity) – used by patients to describe their pain (Melzack, 2008). It also comprises an intensity scale and other items to determine properties of the pain experience. The questionnaire was designed to provide quantitative measures of clinical pain. The three major measures are: (1) the pain rating index, based on two types of numerical values that can be assigned to each word descriptor; (2) the number of words chosen; and (3) the present pain intensity based on a 1–5 intensity scale (Herndon, 2006; Melzack, 1987). The McGill Pain Questionnaire provides quantitative information that can be treated statistically, and is sufficiently sensitive to detect differences between different methods of pain relief. Correlation coefficients between rank and scale values for 20 subclasses of the pain questionnaire are high, with most above 0.85 (Herndon, 2006).

A short form of the McGill Pain Questionnaire (SF-MPQ) has been developed by selecting a small representative set of descriptors from the sensory and affective terms of the standard McGill form, along with the Present Pain Intensity scale (PPI) and the Visual Analogue Scale (VAS) (Herndon, 2006; Melzack, 1987; Melzack & Wall, 2008). The major component of the SF-MPQ consists of 15 descriptors (11 sensory; 4 affective) which are rated on an intensity scale as 0 = none, 1 = mild, 2 = moderate or 3 = severe. Three pain scores are derived from the sum of the intensity rank values of the words chosen for sensory, affective and total descriptors (Melzack, 1987). The scale has been validated relative to the standard MPQ and correlation values were consistently high and significant (Herndon, 2006). The SF-MPQ has also been shown to be sufficiently sensitive to demonstrate differences due to treatment at statistical levels comparable to those obtained with the standard form. Administration of the SF-MPQ takes less than five minutes (Herndon, 2006).

The Thai Short-Form McGill Pain Questionnaire has been validated by a study of 60 patients with musculoskeletal (n = 48) or neuropathic pain (n = 12), conducted by Kitisomprayoonkul, et al. (2006). Cronbach's alpha value was 0.7881 and inter-rater validity value of PPI was more than 0.7 (Kitisomprayoonkul, et al., 2006). The correlation coefficient was quite high ( $r > 0.8$ ) for all scales (Kitisomprayoonkul, et al., 2006).

## **II. Visual Analogue Scale (VAS) (Appendix E)**

The VAS consists of a 100-mm horizontal line labelled as 'no pain' at its left end (measured as 0 mm) and as 'worst possible pain' at its right end (measured as 100 mm). This measurement is commonly used to assess changes in pain over time and has been recommended for use in studies of chronic low back pain (Ogon, et al., 1996). It has been shown that data derived from such written scales among patients with chronic low back pain are normally distributed even when the scales are used without verbal instructions (Ogon, et al., 1996).

Before receiving each treatment, patients were asked to rate the average intensity of their back pain over the past 24 hours on a 100-mm line as a scale of relative pain intensity. After each treatment the patient used the same scale to rate their pain at that moment. Reliability and construct validity of data obtained with the VAS for chronic pain have been previously assessed and reported to be high ( $r = 0.99$  for reliability) (Carlsson, 1983; Wilkie et al., 1990) and the reliability of the VAS specifically for chronic low back pain has been reported as good (0.76 to 0.84; Boonstra et al., 2008).

### **4.2.5.3 Secondary outcome measures**

#### **I. Functional ability using the Oswestry Disability Questionnaire (ODQ)**

(Appendix F)

The ODQ (with an outcome score of 0–100) was used to assess the functional ability of each participant. The ODQ contains 10 questions about pain intensity and its effect on sleep, self-care, walking, sitting, standing, lifting, sex life and travelling. In this study, the Thai version of the questionnaire was used to assess functional ability of patients with nonspecific chronic low back pain. This version has been shown to have high

reliability, with the Cronbach's alpha coefficient for every question of the questionnaire exceeding 0.7 and all inter-item correlations exceeding 0.4 (Sae-jung et al., 2002). It usually takes less than five minutes for the client to complete. Higher scores represent increased disability (expressed as a percentage). This questionnaire has been used with acute, sub-acute, and chronic back pain client groups, including various conservative treatments (non-surgical), surgical and behavioural interventions groups (Finch et al., 2002). The range of percentage of disability is 0-20% minimal disability, 20-40% moderate disability, 40-60% severe disability, 60-80% crippled (no longer able to walk or move normally) and 80-100% bed ridden or exaggerated symptoms. A significant change for an individual is 4-6 percentage points (Finch et al., 2002).

## **II. Quality of Life using the 12-item Short-Form Health Survey (SF-12v2)**

(Appendix G)

The SF-12 contains 12 items from the SF-36 Health Survey. It was originally developed in 1994 as a shorter alternative to the SF-36 for studies in which the 36-item form was too long. The SF-36 (Medical Outcomes Trust, Boston, MA) is a multipurpose, short-form health survey; it provides an eight-scale profile of scores as well as physical and mental health summary measures (Ware et al., 1993). The questionnaire consists of 36 items that cover eight aspects of quality of life comprising physical functioning, role limitations due to physical problems, bodily pain, social functioning, general mental health, role limitation due to emotional problems, vitality (energy/fatigue) and general health.

The SF-12 contains one or two items that measure each of the eight concepts included in the SF-36. Like the SF-36, the SF-12 is available in standard (four-week recall) and acute (one-week recall) formats. Version 1.0 of the SF-12 was constructed to reproduce the SF-36 physical and mental health summary measures with at least 90% accuracy and allows for calculation of the physical component summary (PCS) and mental component summary (MCS) scores. An updated Version 2.0 of the SF-12 (SF-12v2™) now allows for calculation of an eight-scale profile in addition to the two summary scores. As a brief, reliable measure of overall health status, the SF-12 has often been used in large population health surveys. However, due to its brevity, the SF-12 is also

frequently embedded in longer, condition-specific surveys that are used in clinical trials and other clinical studies.

The SF-12v2 has been shown to reliably reproduce the same eight scale scores (reliability coefficient range, 0.73-0.87) and the two summary scores (reliability coefficients for PCS=0.89; MCS=0.86 in the general population and reliability coefficient range 0.88-0.97 in cervical and lumbosacral spinal disorders population), and most of the scales ( $r$  range, 0.81-0.99) correlated strongly between the SF-12v2 and SF-36v2 (Lee et al., 2008). Luo et al.'s (2002) study of the validity and responsiveness of Short Form 12-item survey in patients with back pain illustrated that SF-12 was a valid and responsive instrument for measuring health status or health-related quality of life in patients with back pain (Luo et al., 2002). The physical component summary of SF-12 (PSC-12) was significantly correlated with age, back pain, measures of overall well-being and the Oswestry Back Disability Index (Luo et al., 2002). The mental component summary of SF-12 (MCS-12) was significantly correlated with stress, depression, back pain, measures of overall well-being and the Oswestry Back Disability Index (Luo et al., 2002).

### **III. Depression using Geriatric Depression Scale (GDS) (Appendix H)**

The Geriatric Depression Scale (GDS) is used to identify depression in older people in hospital, aged-care homes and community settings. The GDS first created by Yesavage et al. (1983) has been tested and used extensively with older populations (The Royal Australian College of General Practitioners, 2005). It is a brief questionnaire that has 30 questions answered 'yes' or 'no' in reference to how participants feel on the day of administration (Yesavage et al., 1983). Scores of 0-9 are considered normal, 10-19 indicate mild depression and 20-30 indicate severe depression (Yesavage et al., 1983).

The short form 15-item version is most widely used with self report or informant report, and takes 5-10 minutes to complete (The Royal Australian College of General Practitioners, 2005). Sensitivity ranges from 79% to 100% and specificity ranges from 67% to 80%. This version has questionable accuracy when used to detect minor depression (Sheik & Yesavage, 1986). The total score is calculated by adding up the

ticks in bold. Each tick scores one point. For clinical purposes, a score greater than five points is suggestive of depression and should warrant a follow-up interview; scores greater than 10 almost always indicate depression (Sheik & Yesavage, 1986). The 15-item informant version of GDS was found to have sufficient internal consistency reliability ( $\alpha=0.86$ ) and retest reliability ( $r=0.81$ ) to support its use as a clinical instrument (Brown & Schinka, 2005). The reliability coefficient of the Thai Geriatric Depression Scale (TGDS) in Thai older people is 0.93 overall (0.94 in female and 0.91 in male) (Train the brain forum, Thailand, 1994).

**Table 4.8: Summary of the standardized instruments**

Standardized instruments	Number of items	Cronbach's alpha	Sources	Thai version	Estimated time taken
<b>Pain intensity</b>					
Visual Analogue Scale (VAS)	1 scale	0.76-0.84	Ogon, et al. (1996)	Boonstra et al. (2008)	1 minute
Short-Form McGill Pain Questionnaire (SF-MPQ)	3 questions (18 items)	0.7881	Melzack (1987)	Kitisomprayoonkul et al. (2006)	2-5 minutes
<b>Disability</b>					
Oswestry disability questionnaire version 2 (ODQ)	10 questions (10 items)	0.76-0.87	Fisher & Johnson (1997)	Sae-jung, et al. (2002)	<5 minutes
<b>Quality of life</b>					
Quality of Life 12-item short form health survey version 2.0 (SF-12v2)	7 questions (12 items)	0.81-0.99	Ware et al. (1996)	The SF community (2010)	2 minutes
<b>Depression</b>					
Geriatric Depression Scale 15-item short form (GDS)	15 questions (15 items)	0.93	Sheik & Yesavage, (1986)	Nivataphand, Phattharayuttawat & Sangsanguan (1994)	5-10 minutes

#### **4.2.6 Data Analysis**

Data was entered and analysed using the Statistical Package for Social Science (SPSS) version 18.0 personal computer version. Collected data were reviewed for completeness and consistency within a single data form and among data forms. The accuracy of data coding and computer entry was checked by comparing the electronic data set with the original data.

Outcome measures were analysed as continuous variables and presented as means and standard deviations (SD). This study analysed each outcome separately at different points of time over the period of treatment to provide data on the immediate, short-, and long-term therapeutic effectiveness of the massage treatments. All analyses were performed on the basis of intention-to-treat. Repeated measures ANOVA compared outcome variables at baseline (measures taken immediately before the first treatment) with outcome measures both at six weeks and at 15 weeks after baseline treatment. This analysis compared differences in outcome measures between the two intervention groups and estimated the adjusted mean differences and the 95% confidence intervals for each outcome measure at each evaluation time point.

#### **4.2.7 Ethical considerations**

Ethical approval was sought from Griffith University Ethics (Ref. NRS/02/11/HREC) Committee and the Ministry of Public Health in Thailand (Ref. RLC 0041/54) (see Appendix I). The researcher made a request for permission from the hospital (Ref. AF 04-010) where the research was conducted (see Appendix I). The details of the ethical principles related to this study are as follows:

##### **4.2.7.1 The principle of beneficence and non-maleficence**

All participants who met the study inclusion criteria were invited to take part and no individual was coerced to participate. All participants were asked to sign the consent form before taking part in the study. The purpose of the study was communicated both orally and in writing. The intervention was conducted by trained massage therapists to ensure participants' safety. The aromatic oils (Jojoba oil and ginger oil) were also analysed before use in the study (see Appendix J).

If participants experienced any adverse event such as a rash or soreness from the intervention, they were to be referred to see a medical doctor. The doctor would be asked to write a serious adverse event report (see Appendix K) if participants had serious adverse effects; for example, the adverse event causes life threatening, admission in the hospital or prolong hospitalization, and significant disability from interventions. If participants did not want to continue the treatments, or had negative responses during the massage treatment, it would be stopped immediately.

#### **4.2.7.2 The principle of human rights**

All participants were informed that their participation was voluntary and that they were free to withdraw at any time. Provision was made for communicating results in an easily understandable format. A lay summary of the study findings were offered and sent to participants on their request.

#### **4.2.7.3 The principle of dignity**

The researcher and massage therapist gave a Wai (the traditional Thai greeting) to show respect for participants who are older people. Also, the researcher respected the participants' answers and their right to withdraw from the study.

#### **4.2.7.4 The principle of justice**

Participants had the same fair treatment for the whole process of this study regardless of gender or whether they were in the TTM group or the SMGO group; in particular, their healthcare and health services were not influenced by their participation in the study.

#### **4.2.7.5 The right to privacy and confidentiality**

The confidentiality of participants' personal details was protected. All participants were informed that their names and other forms of identification would not appear anywhere in the report or in subsequent publications. The consent form emphasised that participation were voluntary and that individuals could withdraw at any time without any consequence (Appendix L).

Data was entered into a computerized database; the identity of the participant was protected by using a code number, and access to these data was password-protected and available only to the researcher. A copy of these files was stored in a locked filing cabinet accessible only to the researcher.

Upon completion of the study, a short summary of the results was mailed to participants who had requested this. Data was securely locked and stored at Griffith University at the RCCCPI office, with the proviso that the data will be kept for a period of seven years and then destroyed as per the NHMRC research guidelines (National Health and Medical Research Council et al., 2007)

### **4.3 Summary**

A randomised controlled trial (RCT) design was used in the study. One hundred and forty participants were randomly allocated to two groups: experimental group (SMGO) and control group (TTM). The intervention was given in 30-minute sessions twice a week for five weeks (total of 10 sessions). A pilot study was conducted prior to starting the actual trial. A training course and intervention monitoring were provided to ensure intervention fidelity. The primary outcome (back pain intensity) was measured by MPQ and VAS for immediate, short- and long-term assessments. The secondary outcomes (disability, quality of life and depression) were measured by ODQ for disability, SF-12 v2 for quality of life and GDS for depression. Data analysis processes used for descriptive and inferential statistics were outlined. Ethical considerations explained how the research conducted the trial using ethical principles. The next chapter describes the results of this study.

## **CHAPTER 5**

### **RESULTS**

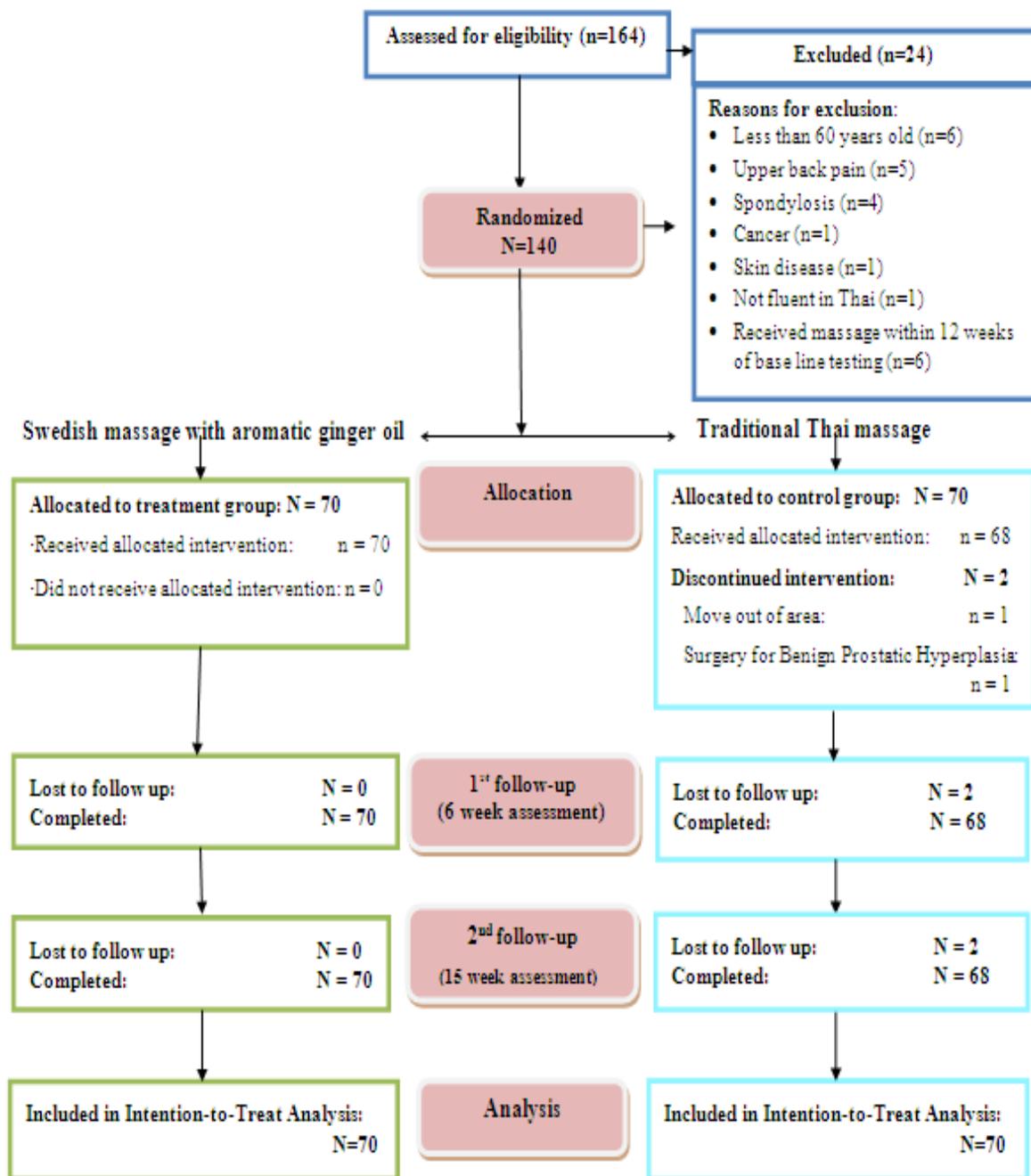
#### **Introduction**

The aim of this study was to compare the effectiveness of Swedish massage using aromatic ginger oil (SMGO) with traditional Thai massage (TTM) in terms of pain intensity, physical functioning and psychosocial well-being in older people with chronic low back pain. The results of this study are presented in two parts. Part One presents participant response rates; the descriptive analysis of the demographic data including health, medication use, and back pain characteristics; and the internal reliability of the measures used in this study. Part Two presents an analysis of the effectiveness of both types of massage for three time periods: immediate (after each massage session), short term (at completion of six weeks of massage) and long term (at 15 weeks post completion of intervention).

#### **Response rate**

One hundred and sixty-four potential participants responded to flyers, community radio, or word-of-mouth through the investigator and associated medical practitioners, physiotherapists, massage therapists and participants. The majority of participants were recruited from a massage clinic (n= 142) and other participants (n=22) were recruited from an orthopaedic clinic. One hundred and sixty-four people expressed interest in the research; 24 were excluded after screening for eligibility. The reasons for exclusion included aged less than 60 years (n = 6), diagnosed with upper back pain (n = 5) or spondylosis (n = 4), a history of cancer (n = 1) or skin disease (n = 1), non-fluency in the Thai language (n = 1), having experienced massage within 12 weeks before participant selection (n = 6). A total of 140 older people with chronic low back pain met the inclusion/exclusion criteria and gave signed consent to take part in the study. Seventy participants were randomly assigned to the experimental group (SMGO) and another 70 to the control group (TTM). Figure 5.1 depicts the enrolment process and the progression of participants through the randomised controlled trial (RCT), according to the CONSORT guidelines (CONSORT-statement, 2010; Moher et al., 2001).

Only two participants withdrew during the period of the study; one moved to another city and the other received surgery for benign prostatic hyperplasia. Both participants were in the control group. These participants withdrew after receiving the eighth and fourth massage sessions in week four and two of the study respectively.



**Figure 5.1: Flow chart of the progression of participants through phases of randomised controlled trial (RCT)**

## **Part I: Characteristics of the sample**

### **5.1.1 Demographic characteristics**

Details of participants' demographic and health status are shown in Table 5.1. Most participants (80%) were women. More than half (57.9%) were married. The majority of participants (91.4%) had only a primary school education. Approximately two-thirds (62.10%) were classified as working class. Most participants in the SMGO group (71.4%) had worked in agriculture (40.0%) or were labourers (31.4%), while a third (31.4%) of participants in the TTM group were unemployed, twice as many as in the SMGO group (14.3%). Most participants (78.6%) undertook regular exercise, although the frequency of exercise per week varied, with approximately 30% taking exercise less than once per week while roughly 40% exercised daily. About 45% of participants in the TTM group undertook daily exercise, with around 35% of participants in the SMGO not exercising at all. There were no significant differences between the experimental and control groups in terms of demographic or health status (see Table 5.1).

**Table 5.1: Participant demographics**

Characteristics	Swedish massage with ginger oil (n=70)		Traditional Thai massage (n=70)		Total sample (n=140)		Group Differences	
	n	%	n	%	N	%	X <sup>2</sup>	p-value
<b>Gender</b>								
Female	54	77.1	58	82.9	112	80.0	0.71	0.26
Male	16	22.9	12	17.1	28	20.0		
<b>Marital status</b>								
Single	11	15.7	12	17.1	23	16.4	0.06	0.97
Married	41	58.6	40	57.1	81	57.9		
Widowed	18	25.7	18	25.7	36	25.7		
<b>Education</b>								
No education	6	8.6	4	5.7	10	7.1	7.47*	0.08*
Primary school	54	77.1	64	91.4	118	84.3		
Secondary school	5	7.1	0	0	5	3.6		
High school	3	4.3	1	1.4	4	2.9		
University	2	2.9	1	1.4	3	2.1		
<b>Occupation</b>								
Agriculture worker	28	40.0	22	31.4	50	35.7	8.61*	0.06*
Labourer	22	31.4	15	21.4	37	26.4		
Business	8	11.4	11	15.8	19	13.6		
Teaching profession	2	2.9	0	0.0	2	1.4		
Jobless	10	14.3	22	31.4	32	22.9		
<b>Frequency of exercise</b>								
None	26	37.1	15	21.4	41	29.3	5.96	0.11
1-2 times/week	9	12.9	14	20.0	23	16.4		
3-4 times/ week	13	18.6	10	14.3	23	16.4		
More than 5 times/ week	22	31.4	31	44.3	53	37.9		

\* A difference at the level of  $p < 0.05$  is considered statistically significant, Chi square with Fisher's Exact Test for count

### 5.1.2 Back pain characteristics

The baseline back pain characteristics of the total sample, and the SMGO and TTM groups, are listed in Table 5.2. There were no significant differences between groups. All participants had suffered with chronic low back pain for three months or more. The majority of participants in both groups reported an average duration of each episode of back pain of 5-8 weeks.

To describe the cause of chronic lower back pain (CLBP) and previous type of treatments, participants were able to select multiple options, so these characteristics are

presented as the total number of participants who selected each cause. Heavy lifting was the most frequently reported by both SMGO and TTM groups (n = 36, n = 30, respectively) followed by working long hours (n = 19 in SMGO and n = 23 in TTM). Both the SMGO and TTM groups reported medicine (n = 37 and n = 18, respectively) as the most frequently used previous treatment for their CLBP (see Table 5.2).

**Table 5.2: Baseline back pain characteristics**

Characteristics	SMGO	TTM
	(n=70)	(n=70)
	n	n
<b>Cause of CLBP</b>		
Heavy lifting	36	30
Working long hours each day	19	23
Ageing	13	17
Sitting for long hours	14	13
Accident	11	9
Wrong posture	5	6
Unknown	9	14
<b>Average duration of each episode of back pain</b>		
Less than 4 weeks	22	21
5-8 weeks	25	28
9-12 weeks	7	6
More than 12 weeks	16	15
<b>Previous type of treatments for CLBP</b>		
Medicine	37	18
Surgery	0	0
Massage	16	17
Acupuncture	3	0
Herbs	0	3
Exercises	3	3
Physiotherapy	18	17
None	14	12

*Note: CLBP= Chronic Low Back Pain, TTM= Traditional Thai massage*

*SMGO= Swedish massage with aromatic ginger oil*

*age*

### 5.1.3 Use of medication and adverse effects

Medication use and adverse effects were monitored over the course of the study (see Table 5.3). For ‘current treatments’ and ‘names of drugs’, participants could select more than one option. At baseline, most participants in the SMGO and TTM groups never used any treatments (n = 43, n = 33, respectively) or medication (n = 59, n = 58). When medications were used, Paracetamol (n = 4, n = 3), Mydocalm (n = 3, n = 4) or Muscol (n = 0, n = 5) were the most common.

At the first follow-up assessment (week 6), the number of medications used was lower than at baseline and at the second follow-up assessment (week 15<sup>th</sup>). Only one participant in the SMGO group reported using medication (Tramol) while seven TTM participants reported medication use (n = 7). At second follow-up, the number of medications used was higher than first follow-up. Diclofenac/Votaren (n = 6) and Paracetamol (n = 5) were the most popular medications used in the TTM group while Diclofenac/Votaren (n = 4) and Tramol (n = 3) were the most popular medications used in the SMGO group. However, the majority of participants in both the SMGO (n=57) and the TTM groups (n=49) did not use any medications.

The number of alternative treatments used at first follow-up was also lower (n = 11 in SMGO and n = 16 in TTM) than at baseline and second follow-up. At second follow-up, the number of participants using alternative treatments was higher (n = 11 in SMGO and n = 16 in TTM) than at first follow-up. Exercise (n = 11, n = 14) and herbs (n = 9, n = 13) were the most popular alternative treatments. Another type of massage (self massage using bottles or coconut shells, n=5 in SMGO and n = 5 in TTM) was used during the study, and also decreased from baseline to first follow-up (n = 1 in SMGO and n = 2 in TTM). However, most participants (n = 37 in SMGO, n = 27 in TTM) never used alternative treatments during the study as shown at second follow-up assessment (see Table 5.3).

Overall, the number of participants using medication for CLBP in both groups was at the lowest point at first follow-up. Although, medication or other treatment use at second follow-up was higher than at first follow-up, it was still lower than at baseline. The study found most participants in both groups of massage (81.43% to 98.57% in

SMGO and 70.00% to 88.57% in TTM) preferred not to use medications for chronic low back pain during the period of the study. However, the number of participants who did not use other treatments or medication in the SMGO group was higher than the TTM group. Similarly, participants in the SMGO group experienced no adverse effects through the period of the study but four of the participants in the TTM group reported soreness after a massage session (see Table 5.3).

**Table 5.3: Use of medicine and adverse effects during period of study at baseline, 1<sup>st</sup> and 2<sup>nd</sup> follow-up assessments**

Characteristics	Pre-intervention		1 <sup>st</sup> post-intervention		2 <sup>nd</sup> post-intervention	
	SMGO	TTM	SMGO	TTM	SMGO	TTM
<b>Current treatments for CLBP</b>						
Another type of massage	5	5	1	2	2	5
Acupuncture	1	0	1	0	1	0
Herbs	3	3	3	2	9	13
Exercises	2	4	5	9	11	14
Physiotherapy	7	9	1	2	3	7
Foot massage	0	1	0	1	0	1
None	43	33	59	52	37	27
<b>Names of drug use for pain relief</b>						
None	59	58	69	62	57	49
Paracetamol	4	3	0	2	2	5
Muscol	1	5	0	1	2	1
Diclofenac/ Voltaren	3	0	0	0	6	6
Mydocalm	3	4	0	2	0	4
Tramol	0	0	1	1	3	3
<b>Any adverse effect of massage</b>						
Yes (Sore)	N/A	N/A	0	3	0	1
No			70	67	70	69

*Note: CLBP= Chronic Low Back Pain, N/A=Not available*

*SMGO= Swedish massage with aromatic ginger oil, TTM= Traditional Thai massage*

#### 5.1.4 Reliability of instruments

The internal reliability of the Short-Form McGill Pain Questionnaire (SF-MPQ), the Oswestry Disability Questionnaire (ODQ), the Quality of Life 12-item Short Form Health Survey Version 2.0 (SF-12v2) and the Geriatric Depression Scale (GDS) at each time-point are shown in Table 5.4. In addition, the reliability of the Visual Analogue Scale (VAS) was calculated for each of ten pre-post massage sessions. Cronbach's alpha values for all instruments at all time points ranged from 0.66 to 0.97, indicating acceptable to good reliability (Altman, 2006; Polit & Beck, 2008) (see Table 5.4).

**Table 5.4: Summary of reliability of instruments**

Instruments	Reliability of instruments (Cronbach's alpha)		
	Pre-intervention	1 <sup>st</sup> post-intervention	2 <sup>nd</sup> post-intervention
SF-MPQ	0.78	0.82	0.87
ODQ	0.67	0.76	0.74
SF-12v2	0.67	0.78	0.79
GDS	0.72	0.66	0.68
VAS		0.97	
(for 10 pre-post session)			

## Part II: Effectiveness of the interventions

This section describes an analysis of the effectiveness of Swedish massage with aromatic ginger oil (experiment group) compared with traditional Thai massage (control group) in relation to pain intensity, disability, quality of life, and depression. Immediate, short-term and long-term outcomes were compared. The primary outcome of the study was pain intensity and other outcomes (disability, quality of life and depression) were secondary outcomes. The data were analysed using the Statistical Package for Social Science (SPSS) version 18.0. Repeated measures ANOVAs were conducted after checking that the data met all the assumptions for these analyses (Field, 2009). Outcome measures were analysed as continuous variables and presented as means and standard deviations (SD). All analyses were performed on the basis of intention-to-treat. The

adjusted mean differences and the 95% confidence intervals were calculated for each outcome measure at each evaluation time point. There were significant changes over time for both groups; there were also significant differences between the groups on all outcomes measures at baseline, first and second follow-up assessment.

## **5.2.1 Primary outcome**

### **5.2.1.1 H1: Pain intensity**

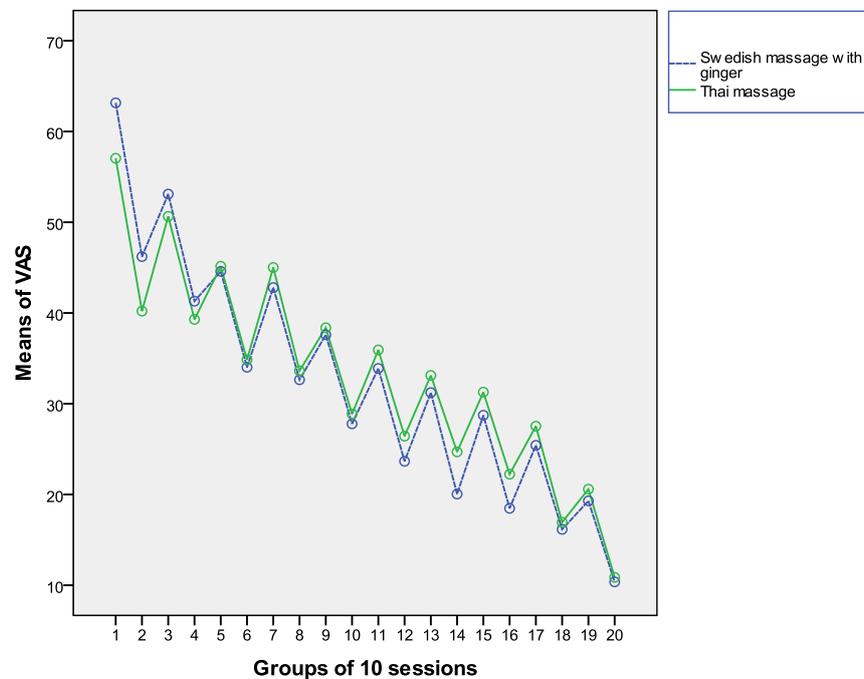
The first hypothesis of the study related to testing the effectiveness of SMGO on pain intensity compared to TTM. Back pain intensity was measured by VAS and MPQ to assess the immediate, short- and long-term effectiveness of interventions. The 0-to-100-mm Visual Analogue Scale (VAS) was used to assess pain immediately before and after each massage session. The Short Form McGill Pain Questionnaire (SF-MPQ) was used to assess pain at baseline, short and long term.

#### **I. Immediate effectiveness of massage**

The 0-100 VAS consists of a 100-mm horizontal line labelled as ‘no pain’ at its left end (measured as 0 mm) and as ‘worst possible pain’ at its right end (measured as 100 mm), higher scores reflecting a greater intensity of pain. Participants responded on this scale before and after each massage (immediate effectiveness).

Figure 5.2 shows the differences in VAS rating before and after each of ten massage sessions in both groups. Table 5.5 shows the average pre-massage and the average post-massage scores in both groups. There were significant reductions in pain intensity immediately after massage in both groups when compared with pre-massage measures ( $37.98 \pm 18.55$  versus  $27.07 \pm 16.51$  in SMGO and  $38.32 \pm 15.09$  versus  $27.73 \pm 13.13$  in TTM;  $P = 0.00$  95%CI =  $-10.75$  [ $-11.64$  to  $-9.86$ ]). However, there was no significant difference between groups in the magnitude of this reduction ( $p = 0.85$ ).

Overall these results indicate that both types of SMGO and TTM can provide immediate reductions in chronic low back pain, with no significant difference in the amount of reduction provided by either massage.



**Figure 5.2: Visual Analogue Scale in each pre-post assessment for 10 sessions of interventions**

**Table 5.5: Average Mean of Visual Analogue Scale pre and post the 10 session of interventions**

Variable	Time of assessment	SMGO	TTM	Total sample	Period Differences		Group differences	
		(n=70)	(n=70)	(n=140)	MD	P-value	MD/ (95%CI)	p-value
		Mean (SD)	Mean (SD)	Mean (SD)	(95%CI)		(95%CI)	
VAS	Pre-intervention	37.98 (18.55)	38.32 (15.09)	38.15 (16.85)	-10.75 [-11.64, -9.86]	<0.01	-0.50 [-5.75, 4.75]	0.85
	Post-intervention (6 weeks)	27.07 (16.51)	27.73 (13.13)	27.40 (14.86)				

**Note:** SMGO= Swedish massage with aromatic ginger oil, TTM= Traditional Thai massage  
A difference at the level of  $P < 0.05$  is considered statistically significant.

## II. Short- and long-term effectiveness

The short form of the McGill Pain Questionnaire (SF-MPQ) was used to measure differences in pain intensity in the short term (first follow-up assessment at week 6) and long term (second follow-up assessment at week 15). The SF-MPQ contains three components: the Pain Rating Intensity (PRI), which is rated on an intensity scale from 0-5; the Visual Analogue Scale (1-100 mm VAS); and the Present Pain Intensity scale (PPI). A repeated measures ANOVA was conducted to assess the impact of the two interventions on participants' McGill pain scores, Visual Analogue Scale and Present Pain Intensity Scale, at each time-point.

There was a statistically significant interaction between intervention type and time with MPQ (Wilks' Lambda = 0.94,  $F(2,137) = 4.06$ ,  $p = 0.02$ , multivariate partial Eta squared = 0.06). A comparison of the McGill Pain Scores between the SMGO and TTM groups was not significant ( $p = 0.09$ ); however, there was significant change in McGill Pain Scores over time (Wilks' Lambda = 0.40,  $F(2,137) = 102.46$ ,  $p = 0.00$ , multivariate partial Eta squared = 0.60) with both groups showing a reduction in MPQ across the three time periods (see Table 5.6).

In relation to the VAS, there was significant interaction between intervention type and time [Wilks' Lambda = 0.94,  $F(2,137) = 4.32$ ,  $p = 0.02$ , multivariate partial Eta squared = 0.06]. There was a significant reduction of pain intensity over the assessment time period from baseline to second follow-up in both groups (Wilks' Lambda = 0.29,  $F(2,137) = 166.24$ ,  $p = 0.00$ , multivariate partial Eta squared = 0.71) (see Table 5.6). There was also a significant difference between the SMGO group and the TTM group; the SMGO group had a greater reduction in back pain intensity than the TTM group (MD-Mean Difference = -6.37 95%CI -12.58 to -0.17,  $p = 0.04$ ) (see Table 5.6 and Figure 5.3).

A comparison of the PPI between the SMGO and TTM groups revealed no significant group difference ( $p = 0.25$ ). However, there was a significant change in the PPI scale over time (Wilks' Lambda = 0.38,  $F(2,137) = 113.94$ ,  $p = 0.00$ , multivariate partial Eta

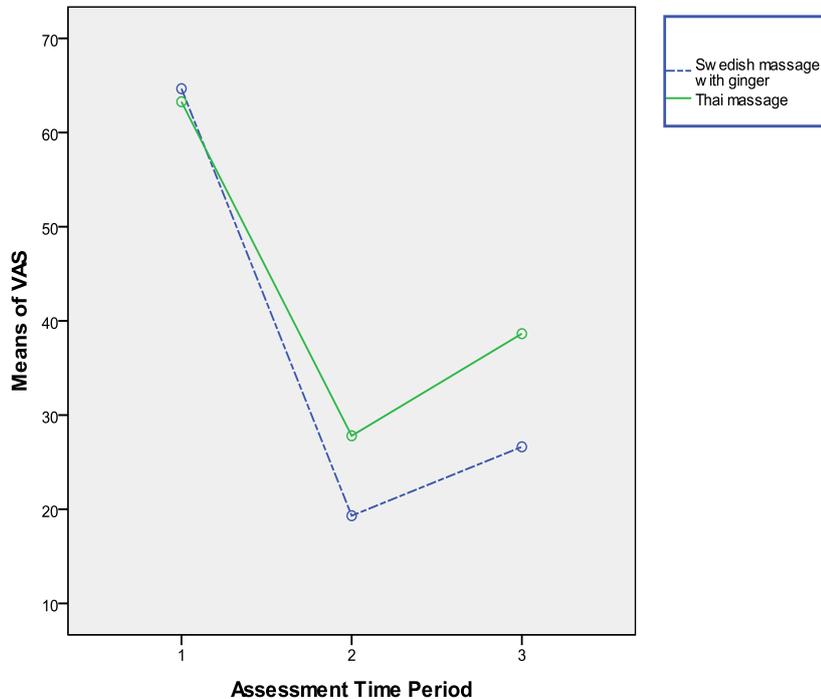
squared=.63) with both groups showing a reduction in PPI across these three time periods. The SMGO group showed progressively reduced back pain using the PPI scale, from a level equivalent to 'distressing pain' ( $M = 2.86 \pm 1.07$ ) at baseline assessment to a level equivalent to 'mild back pain' ( $M = 1.10 \pm 1.01$ ,  $M = 1.29 \pm 1.13$ ) at first and second follow-up. While the TTM group showed progressively reduced back pain from 'distressing pain' ( $M = 2.71 \pm 1.04$ ) at baseline to 'mild pain' ( $M = 1.29 \pm 0.99$ ) at first follow-up and then to 'discomfort pain' at second follow-up ( $M = 1.70 \pm 1.18$ ) (Table 5.6).

In summary, all measurements to assess back pain intensity found that both types of massage significantly reduced back pain intensity across the period of assessments indicating immediate, short- and long-term effectiveness ( $p < 0.05$ ). Overall, pain scores were reduced at first follow-up and increased slightly at second follow-up, though second follow-up scores remained lower than baseline. There were no significant differences between the SMGO and TTM groups in pain immediately after massage. There was, however, a significant difference between the two groups in pain intensity at first and second follow-up. The SMGO group showed the better outcome than the TTM group in the period of short and long term effectiveness. In addition, the characteristics of the type of pain progressively improved from distressing to mild to discomfort in both types of massage. As such, the findings support the hypothesis that participants in the SMGO group had a greater reduction in back pain intensity compared to participants in the TTM group in the short and long term.

**Table 5.6: Comparison of all measurements for pain intensity in pre-intervention, first post-intervention and second post-intervention assessment between the SMGO group and the TTM group**

Outcome	Group	Pre-intervention (Baseline assessment)	1 <sup>st</sup> post-intervention (6 <sup>th</sup> week assessment)	2 <sup>nd</sup> post-intervention (15 <sup>th</sup> week assessment)	Group differences	
Pain intensity		Mean (SD)	Mean(SD)	Mean (SD)	MD / (95%CI)	p-value
SF-MPQ	SMGO (n=70)	14.83 (7.91)	4.31 (5.26)	6.70 (7.27)	-1.67 [-3.59, 0.24]	.087
	TTM (n=70)	14.19 (7.49)	6.99 (6.14)	9.69 (7.61)		
VAS in MPQ	SMGO (n=70)	66.66 (24.17)	19.31(22.83)	26.63 (26.46)	-6.37 [-12.58, -0.17]	.044*
	TTM (n=70)	63.27 (19.15)	27.80 (23.46)	38.64 (25.09)		
PPI	SMGO (n=70)	2.86 (1.07)	1.10 (1.01)	1.29 (1.13)	-0.15 [-0.42, 0.11]	.256
	TTM (n=70)	2.71 (1.04)	1.29 (0.99)	1.70 (1.18)		

\*A difference at the level of  $p < 0.05$  is considered statistically significant



**Figure 5.3: Means of Visual Analogue Scale  
(in McGill Pain Questionnaire)**

## 5.2.2 Secondary outcomes

### 5.2.2.1 H2: Disability

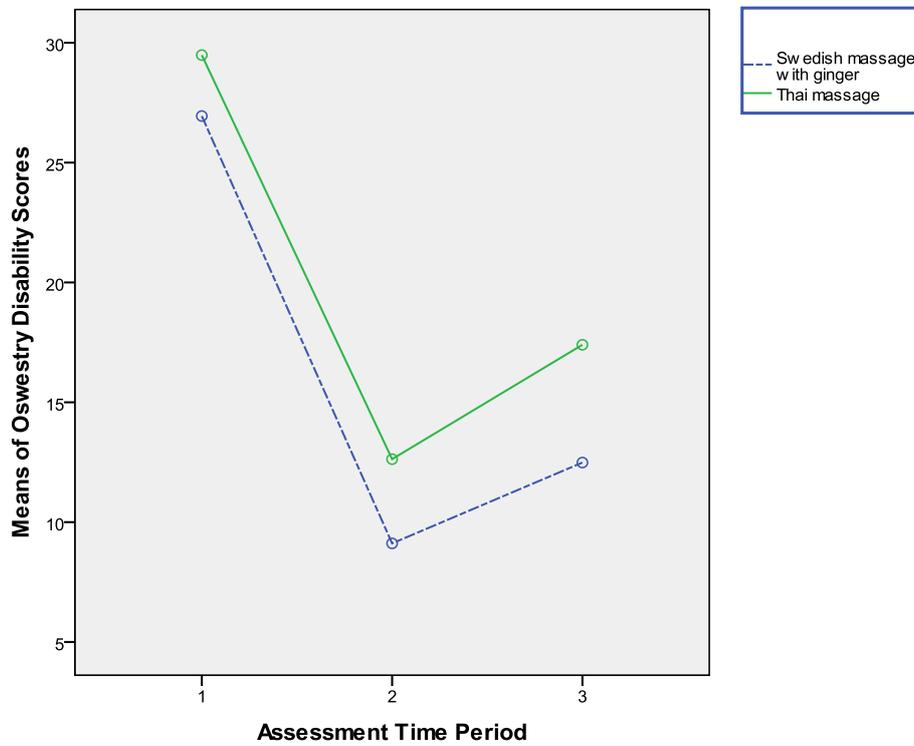
The second hypothesis for the study was that the participants in the SMGO group would have a greater improvement in disability compared to participants in the TTM group. The level of disability was measured by the Oswestry Disability Questionnaire (ODQ).

The ODQ with an outcome score of 0–100 was used to assess the functional ability of each participant. Level of disability is classified as minimal, moderate, severe, crippled (no longer able to walk or move normally), or bed ridden/exaggerated symptoms. A change of 4-6 percentage points is considered to be significant for an individual (Finch et al., 2002).

There was a significant change in the ODQ scale over time (Wilks' Lambda = 0.34,  $F(2,137) = 134.20$ ,  $P = 0.00$ , multivariate partial Eta squared = 0.66) with both groups showing a reduction in ODQ across these three time periods (M = 28.21, 10.87 and 14.94, respectively; see Table 5.7) and (see Figure 5.4). There was a significant difference between the SMGO and TTM groups ( $p < 0.05$ ). The SMGO group had more reduction in disability than the TTM group (MD = - 3.66 95%CI= -7.17 to -0.14,  $p = 0.041$ ) (see Table 5.7). The SMGO group showed progressive reduction of disability from the level of 'moderate disability' ( $26.94 \pm 13.43\%$ ) at baseline assessment to the level of 'minimal disability' ( $9.11 \pm 11.06\%$  and  $12.49 \pm 12.02\%$ ) at first and second follow-up. The TTM group showed reducing disability from 'moderate disability' ( $29.49 \pm 13.91\%$ ) at baseline to 'minimal disability' ( $12.63 \pm 11.82\%$  and  $17.40 \pm 12.61\%$ ) at first and second follow-up (see Table 5.7).

Both types of massage significantly improved participants' disability ratings across the periods of assessments indicating both short- and long-term effectiveness ( $p < 0.05$ ). There was a marked decrease in disability scores from baseline to first follow-up then a gradual increase at second follow-up, although ODQ scores at second follow-up remained lower than the scores at baseline assessment. The SMGO group's disability level improved significantly more than the TTM group. The findings supported the

hypothesis that disability improvement would be greater in the SMGO group than the TTM group.



**Figure 5.4: Means of Oswestry Disability Scores**

**Table 5.7: Comparison of measurements for disability, quality of life and depression across three assessment periods between the SMGO group and the TTM group**

Outcome	Group	Pre-intervention	1 <sup>st</sup> post-intervention	2 <sup>nd</sup> post-intervention	Group differences	
		Mean (SD)	Mean(SD)	Mean (SD)	MD / (95%CI)	p-value
<b>Disability</b> ODQ	SMGO (n=70)	26.94 (13.43)	9.11 (11.06)	12.49 (12.02)	-3.66 [-7.17, -0.14]	.041*
	TTM (n=70)	29.49 (13.91)	12.63 (11.82)	17.40 (12.61)		
<b>Quality of life</b> SF-12-PCS	SMGO (n=70)	44.65 (7.55)	50.49 (9.46)	44.62 (8.17)	2.09 [0.09, 4.10]	.041*
	TTM (n=70)	44.20 (8.48)	47.02 (8.50)	42.26 (8.29)		
SF-12-MCS	SMGO (n=70)	48.77 (9.80)	51.95 (12.40)	58.25 (5.92)	-0.07 [-2.79, 2.65]	.959
	TTM (n=70)	50.35 (11.24)	52.21 (11.40)	56.63 (8.33)		
<b>Depression</b> GDS	SMGO (n=70)	4.39 (2.63)	2.83 (2.05)	2.80 (2.16)	-0.41 (-1.08 to 0.27]	.237
	TTM (n=70)	4.39 (2.68)	3.40 (2.48)	3.44 (2.35)		

\*A difference at the level of  $p < 0.05$  is considered statistically significant

**Table 5.8: Comparison of improvement of disability, quality of life and depression over three assessment periods**

Assessment periods	Disability			Quality of life						Depression		
	ODQ (%)			PCS (%)			MCS (%)			GDS		
	Mean	SE	95%CI	Mean	SE	95%CI	Mean	SE	95%CI	Mean	SE	95%CI
<b>Pre-intervention</b>	28.21	1.16	[25.93, 30.50]	44.42	.69	[43.08, 45.77]	49.56	.89	[47.80, 51.32]	4.39	.22	[3.94, 4.83]
<b>1<sup>st</sup> post intervention</b>	10.87	.97	[8.96, 12.79]	48.76	.76	[47.26, 50.26]	52.08	1.01	[50.09, 54.07]	3.11	.19	[2.73, 3.50]
<b>2<sup>nd</sup> post intervention</b>	14.94	1.04	[12.89, 17.00]	43.44	.70	[42.06, 44.82]	57.44	.61	[56.23, 58.65]	3.12	.19	[2.74, 3.50]

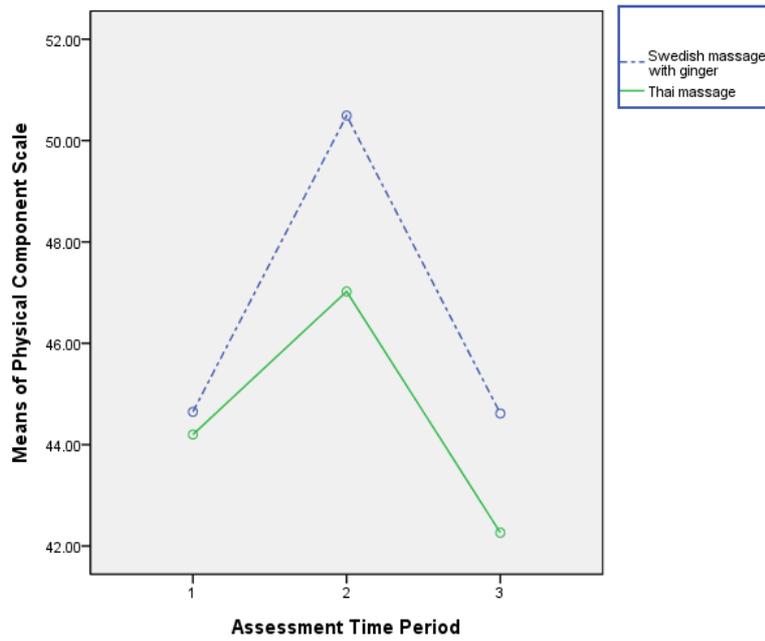
### 5.2.2.2 H3: Quality of life

The study hypothesized that participants in the SMGO would have a greater improvement in quality of life compared to participants in the TTM group. To measure quality of life, the study used the SF-12v2 which contains two items for each of the eight concepts. The SF-12v2 allows for calculation of the physical component summary (PCS) and mental component summary (MCS) scores. Both the PCS and MCS scores for this study were calculated using the US population norm-based scoring for standard four-week recall.

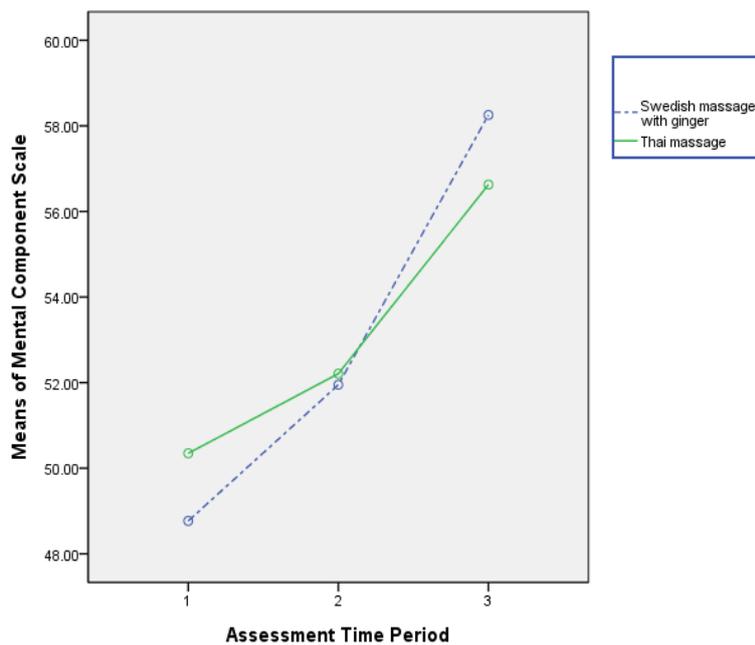
There was a significant improvement in PCS scores in both SMGO and TTM group over the period of assessment (Wilks' Lamda = 0.94,  $F(2, 137) = 22.30, p = 0.00$ ). The PCS score significantly increased in both groups at first follow-up ( $p < 0.05$ ) but there was no significant increase in PCS at the second follow-up compared with baseline ( $p > 0.05$ ) (see Table 5.7) and (see Figure 5.5). However, there was a significant group difference between the SMGO group and the TTM group (MD = 2.09 95%CI 0.09 to 4.10,  $p = 0.41$ ). The SMGO group showed a greater increase in PCS scores than the TTM group.

There was a significant improvement in MCS scores over the assessment period, with both groups showing increased scores across these three time points (see Table 5.8 and Figure 5.6). However, there was no significant difference between the SMGO and TTM groups (MD= - 0.07 95%CI= -2.79 to 2.65,  $p = 0.96$ ) (see Table 5.8).

In conclusion, both SMGO and TTM improved participants' quality of life in both physical and mental components at first follow-up. At second follow-up there was improvement in the mental component only, compared with baseline. The SMGO group had a significantly greater improvement in the physical component at first follow-up than the TTM group.



**Figure 5.5: Means of Physical Component Scale**



**Figure 5.6: Means of Mental Component Scale**

The testing of the hypothesis provided mixed results as participants in both SMGO and TTM groups showed significant improvement in the mental component of quality of life over the period of short- and long-term assessment whereas the physical component

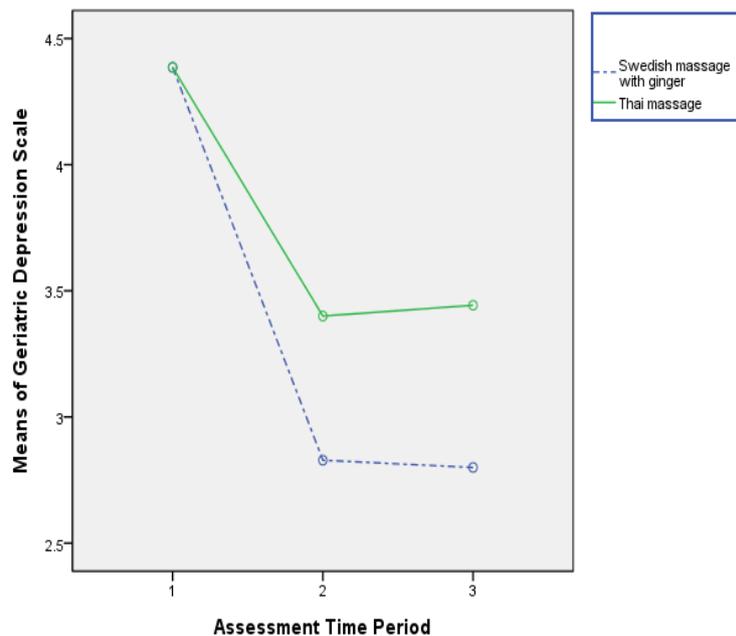
improved only in short term. However, there was a significant difference between groups in the physical component results: the SMGO group demonstrated a greater improvement of quality of life in the physical component compared with the TTM group. These results do not fully support the hypothesis. While it was predicted that participants in the SMGO group would have a greater improvement in quality of life, the benefits of massage were evident only for physical component of quality of life, not the mental component.

#### **5.2.2.3 H4: Depression**

The study hypothesized that participants in the SMGO group would have a greater improvement in depressive symptoms compared to participants in the TTM group. The study used the 15-item Geriatric Depression Scale (GDS) to assess depression in both groups. The range of scores is 0 to 15, with a score greater than 5 points suggestive of depression. The study found an improvement in GDS scores in both massage groups over the three assessment times (Table 5.8). There was a significant improvement in GDS scores at first post intervention compared with baseline assessment (MD = - 1.27 95%CI -1.72 to -8.19,  $p = 0.00$ ) and the improvement was maintained at the second follow-up assessment (MD = 0.01 95%CI -0.40 to 0.41,  $p = 1.00$ ) (Figure 5.7). There were no significant difference in GDS scores between the SMGO group and the TTM group (MD = -0.405 95%CI -1.08 to 0.27,  $p = 0.24$ ).

Overall, the study indicated that both types of massage improved GDS scores significantly in both the short term (first follow-up assessment) and long term (second follow-up assessment) ( $p < 0.05$ ) (see Table 5.7). Additionally, the study found all participants had GDS scores less than 5 points (2.80 to 4.39 points) during the study period.

Although the findings showed both the SMGO and TTM groups had significant improvement in GDS score across the period of time, there was no significant difference in GDS scores between groups: therefore the hypothesis is rejected.



**Figure 5.7: Means of Geriatric Depression Scale**

## Summary

This chapter reported demographic and back pain characteristics, and the effectiveness of both types of massage in older people with chronic low back pain. Most participants were female, married and worked in the agricultural sector. The main reported cause of their back pain was heavy lifting. Medication was the most commonly reported previous treatment for CLBP. Participants' use of medication and other treatments decreased during the study period. Both types of massage (SMGO and TTM) led to significant improvements on measures of pain intensity, disability, quality of life and depression. SMGO was more effective than TTM in reducing back pain intensity at short and long term as measured by VAS, improving disability at short and long term, and improving physical quality of life at short term. There were no significant differences between the SMGO group and the TTM group on back pain intensity as measured by the McGill Pain Score as well as mental quality of life and depression. Two hypotheses (pain intensity and disability) are accepted, one partially (quality of life) and one rejected (depression) in this study. The next chapter discusses these findings, presents implication for nursing practice, recommends future studies, and concludes the current study.

## **CHAPTER 6**

### **Discussion, Recommendation, and Conclusion**

#### **Introduction**

This randomised controlled trial was designed to examine the effectiveness of Swedish massage with aromatic ginger oil (SMGO) in relieving chronic low back pain (CLBP) in older people when compared with traditional Thai massage (TTM). It also examined physical functioning and psychosocial well-being for both massage groups.

The chapter firstly outlines the strengths of the study and then discusses the significant findings according to the conceptual framework and the contemporary literature, before moving on to a discussion of important demographic issues. Challenges in preparing and conducting a RCT are discussed, followed by the implications of the findings for nursing practice. Recommendations for practice, education and research, and limitations of the study are then presented. The last section of this chapter summarizes the study highlights and concludes the study.

#### **6.1 Study strengths**

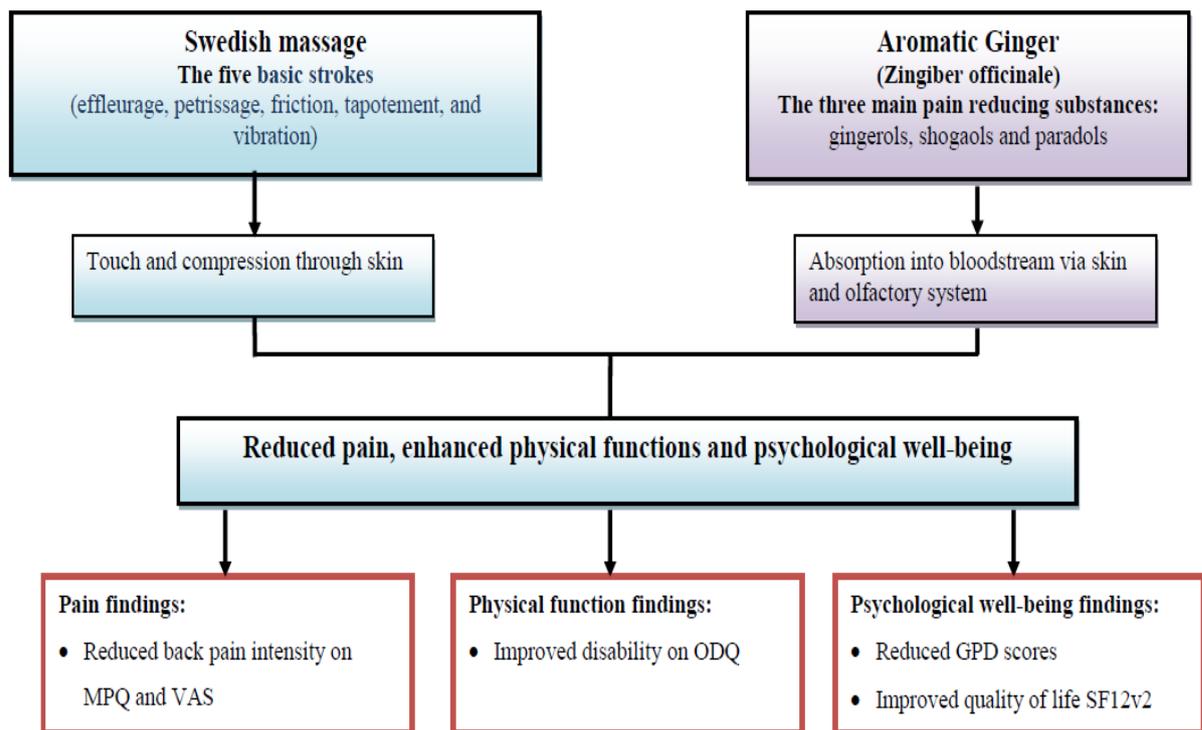
This study incorporated significant methodological strengths:

- It tested a non-pharmacological, and non-invasive intervention that can be used by nurses, physiotherapists and massage therapists who are trained in the technique;
- It employed a comparable placebo control treatment rather than a wait-list control or a no-treatment control to adequately control for all factors that might contribute to the outcome;
- Both massage techniques (TTM and SMGO) were performed using detailed protocols, in the same clinical setting and by the same group of massage therapists to ensure treatment quality and to avoid bias;
- It recruited only participants who had not received massage for at least three months prior to participating in the research project;

- Participants were randomly allocated to treatment groups, ensuring that systematic bias was not introduced (Field, 2011). This randomization was successful, as evidenced by the lack of significant differences between the SMGO and TTM groups on demographic characteristics, MPQ, ODQ and GDS at baseline;
- It used multi-dimensional pain indicators including MPQ and VAS to provide a more complete understanding of the effectiveness of SMGO and TTM on CLBP;
- It is the first known back-pain-massage research to monitor medication use and adverse effects over the course of the study.

## **6.2 Discussion of findings in relation to the conceptual framework**

This study examined SMGO as a new intervention to relieve CLBP in older people. The study compared the effectiveness of TTM (usual massage) as the control group and SMGO as the intervention group. As the SMGO group is the study's treatment group, the conceptual framework of the study focused on how Swedish massage and aromatic ginger oil affects CLBP by reducing pain, enhancing physical functions and promoting relaxation.



**Figure 6.1: Summary of the conceptual framework of the study**

Following the conceptual framework, the study created a new massage protocol based on five basic Swedish massage strokes combined with 10 mls of 2% aromatic ginger oil. Aromatic ginger oil was absorbed into the bloodstream through skin and olfactory systems via touch from the massage. The findings of the study support previous studies that demonstrated the analgesic effects of ginger for pain (Geiger, 2005, Thomson et al., 2002; Yip & Tam, 2008), and also confirms the conceptual framework. For example, Yip and Tam (2008) suggest that ginger may be used as an anti-inflammatory and analgesic agent to relieve pain in older people. Thomson et al. (2002) argue that the soothing action is related to dual inhibition of both the cyclooxygenase and lipooxygenase pathway (prostaglandin synthetase inhibition) in inflammatory processes by active ingredients in ginger (gingerols, shogaols) (Thomson et al., 2002). 6-Shogaol is an analgesic substance which inhibits the release of neuro-peptide and substance P, substances that cause pain (Geiger, 2005). Yip and Tam (2008) identify that the improvement of physical functioning may be related to a reduction in pain by the pharmacological agents in ginger.

The results of the study agree with previous studies (Buttagat et al., 2009; Chatchawan et al., 2005; Cherkin et al., 2011; Field et al., 2007; Franke et al., 2000; Hernandez-Reif et al., 2001; Mackawan et al., 2005 and Preyde et al., 2000) and support the conceptual framework by showing that massage can reduce pain and improve functional ability. Swedish massage has an immediate physiological effect on skin through increased skin circulation and muscle blood flow, stimulation of parasympathetic activity, and changed hormonal levels (serotonin and endorphin). Therefore, it involves neurological and psychological effects through increasing physical relaxation and pain relief. Field et al. (2005) also propose that it leads to increased serotonin and dopamine and ‘closes the gate’ to the pain stimulus. In addition, massage can increase endorphin levels and local blood flow to enhance the clearance of local pain mediators (Ernst, 2004)

When Swedish massage was combined with aromatic ginger as aromatic massage (SMGO), it was hypothesized that it would reduce chronic low pain while providing relaxation. The findings of the study showed that SMGO reduced pain, enhanced physical functions and relaxation, presenting in a reduction of back pain intensity, disability improvement, reduction of depression scores, and enhancement of quality of life.

### **6.3 Effectiveness of the interventions**

The main aim of the research was to assess the effectiveness of Swedish massage with aromatic ginger oil in relieving chronic low back pain (CLBP) in older people compared with traditional Thai massage. It also aimed to assess the effectiveness of the massage for enhancing physical functioning and psychosocial well-being. Data were analysed in order to answer the research questions: (1) What is the effectiveness of Swedish massage with aromatic ginger oil compared to usual massage (traditional Thai massage), for LBP intensity, (2) physical functioning, (3) psychosocial well-being and quality of life, in older people with chronic low back pain? The following section discusses the effectiveness of both Swedish massage and Thai massage in terms of back pain intensity and medication reduction, disability, quality of life and depression.

### **6.3.1 Outcomes of Swedish massage versus traditional Thai massage**

#### **6.3.1.1 Back pain intensity and massage**

Change in chronic low back pain intensity was the primary outcome measured by the study and this was assessed after each massage (immediate effectiveness), after five weeks of the massage intervention (short-term effectiveness), and 15 weeks after completion of the intervention (long-term effectiveness). Both types of massage resulted in change in back pain intensity over time, although there was a significant difference between groups in the extent of that change. Previous studies have found that either Thai massage or Swedish massage can reduce back pain in the immediate and short term (five weeks) (Buttagat et al., 2009; Chatchawan et al., 2005; Field et al., 2007; Franke et al., 2000; Hernandez-Reif et al., 2001; Mackawan et al., 2005 and Preyde, 2000). The current study extended outcome assessment and found that both massage interventions could also reduce chronic low back pain significantly in the longer term (15 weeks after completion of massage intervention). Only one previous massage study compared Swedish and traditional Thai massage (Chatchawan et al., 2005) and concluded that there were no clinically significant differences between SM and TTM in both the immediate and short term.

The current study added aromatic ginger oil to Swedish massage (SMGO) when testing the effectiveness of SMGO and TTM in reducing pain intensity and found that SMGO was more effective than TTM for back pain reduction in the short and long term but that there were no significant differences in the immediate period. It seems that the addition of aromatic ginger oil enhanced the benefit of Swedish massage to make it more effective than TTM in reducing low back pain. Previous studies of the use of aromatic ginger in treating musculoskeletal pain, including knee pain (Altman & Marcussen, 2001; Bliddal et al., 2000; Haghighi et al., 2005; Yip & Tam, 2008) and muscle pain (Black et al., 2010), reported that ginger produced moderate-to-large reductions in pain (Altman & Marcussen, 2001; Black et al., 2010). Ginger was found to be as effective as indomethacin in relieving symptoms of osteoarthritis with insignificant side effects (Haghighi et al., 2005). Comparing ginger with ibuprofen and a placebo in osteoarthritis, there was a statistically significant difference between the placebo, ginger and ibuprofen; the ranking of efficacy of treatments was ibuprofen > ginger > placebo

(Bliddal et al., 2000). These studies support the findings of this study that ginger has an analgesic and anti-inflammatory effect on musculoskeletal pain. However, most previous studies used ginger as an extract rather than aromatic oil; only one study used aromatic ginger oil combined with orange essential oil (Yip & Tam, 2008). That study reported the aroma-massage had potential as an alternative method for short-term knee pain relief. No previous study has tested using aromatic ginger oil for back pain reduction in an RCT.

The findings of the current study agree with those showing the analgesic effects of ginger in musculoskeletal-pain patients. The current study used the lowest concentration of the recommended range of 2-3% for ginger essential oil (Schnaubelt, 1998; Yip & Tam, 2008). The study found that 2% of aromatic ginger oil combined with ten 30-minute sessions of Swedish massage was effective for older people with CLBP. Consequently, a higher concentrate of 3% may be worth testing to assess its short- and long-term effects in any future study. However, the current study lacked a placebo group, so further studies are suggested to test the efficacy of the aromatic ginger dosage and effectiveness for pain compared to a placebo group.

#### **6.3.1.2 Use of previous medications, conventional and unconventional treatments**

The current study is the first known massage study which monitored medication use and adverse effects during the trial. The study found 30-50% of participants in both the SMGO and TTM groups used medication as their main source of treatment for their CLBP before commencing the study. During the study, participants reduced their medication use. Eventually, participants in the SMGO group used less medication or other treatments during the study compared with the TTM group. Several participants also used other treatments such as physiotherapy, exercise and herbs during the period of study. The participants' behaviour shows that older people with chronic disease use both conventional and unconventional treatments for their chronic lower back pain, either because their pain was less or they recognized the adverse effects of long-term use of NSAIDs.

Previous back pain studies found the percentage of participants using CAM was higher in the CLBP group than in other chronic musculoskeletal disorder groups (Foltz et al., 2005; Wolsko et al., 2003), and twice as high as the percentage of use in a chronic arthritis group (Foltz et al., 2005). In Foltz et al.'s study (2005), chiropractic treatment without a medical referral was the most widely used CAM modality in the CLBP group and other chronic disease group, followed by massage. The combination of mainstream medicine and CAM appears to be used by people with CLBP to cope with their symptoms, and CAM use may reflect an active attitude of the patient toward managing their back pain (Foltz et al., 2005; Vincent & Furnham, 1996). The current study supports the assertion that patients with CLBP are keen to use CAM, especially massage and herbs, while taking conventional treatments such as medication, physiotherapy and exercise. Therefore, the study suggests that future research projects could investigate the combination of CAM use with conventional treatments or CAM use in older people with CLBP.

CAM use, including some types of massage, can produce adverse effects. The current study found that four of the 70 participants in the TTM group had soreness after a massage session while there was no adverse effect in the SMGO group. This finding is consistent with Chatchawan et al.'s (2005) finding that between 5 and 10 participants (9%-12%) had a little soreness after each massage session, especially the Thai massage group. In addition, five participants in Chatchawan et al.'s (2005) Swedish massage group reported skin reactions such as rashes and pimples as a result of the massage oil. Another cross-sectional study also reported that 10% of the massage clients experienced some minor discomfort after the massage session; however, 23% experienced unexpected, non-musculoskeletal positive side effects including improvement in mood and emotional well-being (9.9%) (Cambron et al., 2007). While several participants experienced adverse effects (soreness and/or rash) from the massage intervention in the Chatchawan et al. (2005) study and in the current study, no participant dropped out from the trial. As access to massage improves, there is a need to continually monitor the safety of the interventions. Therefore, future massage studies should consider assessing the presence of side effects over a course of several types of massage. It is also recommended that massage research should monitor participants' medication use and adverse effects during the study period.

### **6.3.2 Disability and massage**

In terms of a comparison between TTM and SMGO in improvement of disability, the current study found that both types of massage significantly improved participants' disability ratings from the level of moderate disability to minimal disability across the period of assessment, indicating both short- and long-term effectiveness. However, the SMGO group improved significantly more in the disability level than the TTM group. This result was in contrast to a previous study (Chatchawan et al., 2005), which reported that clients in both massage groups reported improvements in disability measurement, back performance and body flexibility, at all post-treatment assessment times. In Chatchawan et al's (2005) study, TTM improved disability more than SM immediately and at the end of the three-week treatment; however, there were no statistically significant differences on disability, back performance and body flexibility (Chatchawan et.al. 2005).

Previous studies (Hernandez-Reif et al. 2001; Preyde, 2000) that compared Swedish massage with other types of massage or treatments, including acupuncture massage, soft-tissue manipulation, exercise posture, education and sham laser therapy (low-level infrared laser) on low back pain, found that Swedish massage significantly improved functional ability both immediately after the massage session and in the short term (one month). In the current study, when aromatic ginger oil was added to the Swedish-massage treatment, it was more effective than TTM for disability improvement in the short and long term. The therapeutic benefit of aromatic ginger oil may be particularly beneficial for disability; however, further studies should compare the SMGO with SM with base oil as a placebo group to test this assumption.

### **6.3.3 Quality of life and massage**

The current study is the first known trial comparing SMGO and TTM for CLBP in terms of quality of life, as previous studies mostly focussed on physical function. Both types of massage improved participants' quality of life in both the physical and mental domains of the SF12 in the short and long term. The SMGO group was more effective than TTM in the physical component in the short term only (five weeks after completion of intervention) but there was no significant difference in the long term.

There was also no significant difference between both types of massage in terms of the mental health domain. From the results, it would appear that the SMGO intervention was only more effective than TTM in physical aspects as indicated by improvement in disability levels and the physical component of quality of life. So while all massage may be beneficial for general well-being, the addition of aromatic ginger oil seems to be particularly important for physical well-being given that ginger has an analgesic effect. It appears that the analgesic effect of aromatic ginger oil reduced pain, which may have led to improved physical functions both in disability and quality of life. It also seems that SMGO and TTM are equivalent in terms of their impact on the mental component of quality of life.

Although some studies examined quality of life in CLBP, they examined the effect of non-massage therapies such as a back school program (Tavafian et al., 2007) and spa therapy (Constant et al, 1998) as the comparison groups. Both these interventions resulted in significant improvement in quality of life compared with the control group both short term (three weeks after the completion of intervention) and long term (three months after the completion of intervention). These findings, together with those of the current study, suggest that future studies need to consider examining the effectiveness of the massage interventions for both physical and psychological well-being.

Hemmila (2002) reported that the quality of life of patients with CLBP patients was significantly worse than the average person. The current study suggests that massage therapy may be an option for professional healthcare teams seeking to improve quality of life in older people with CLBP. However, future studies are needed to test the cost-effectiveness of massage therapy compared with standard treatment.

#### **6.3.4 Depression and massage**

CLBP and depression are two of the most common health problems that health professionals encounter, and over 20% of older adults with CLBP have symptoms of clinical depression (Currie & Wang, 2004). Currie and Wang (2004) reported that the combination of CLBP and major depression was associated with greater disability than either condition alone; however, back pain severity was found to be the strongest

overall predictor of disability (Currie & Wang, 2004; Ilife et al., 2009). Even though depression in patients with CLBP is a major problem, no previous massage study has examined older people with CLBP and depression. Most of the studies on CLBP were interested in physical rather than psychological factors. The current study is the first known trial comparing SMGO and TTM for older people with CLBP in terms of depressive symptoms. The study found an improvement in geriatric depression scores (GDS) from both types of massage in the short and long term. However, there were no significant differences in GDS between the two types of massage group. Previous massage studies (Field et al., 2007; Field et al., 2009; Hernandez-Reif et al., 2001; Hou et al., 2010) reported that massage therapy was more effective than relaxation therapy in improving mood and reducing CLBP, depression, anxiety and sleep disturbances, and stress hormones (norepinephrine and cortisol) associated with CLBP. The current study also found that massage can reduce depression scores in CLBP and that either type of massage is effective. As no previous study has examined TTM (acupressure massage type) compared to SM (classic-relaxation massage type), however, further investigations are required to confirm the effects of these therapies on depression and anxiety for CLBP sufferers.

The current study found that all Thai older participants with CLBP had a GDS less than 5 and as such not suggestive of depression; even though, the prevalence of depression among Thai older people in Thailand has increased from 24.1% in 1998 (Sukhatunga et al., 1998) to 31.6% in 2008 (Wangtongkum et al., 2008). Ersek et al. (2008) concluded that self-management strategies which incorporate physical and psychosocial pain coping skills are effective in decreasing pain and improving functions and mood in older people with chronic pain. The low GDS scores from Thai older people with CLBP in this study may be a function of their self-efficacy and self-management strategies. The participants actively sought to improve their CLBP by being involved in this study, which may indicate their propensity to be more self-managing and explain their lower scores on the GDS.

Among studies showing the relationship between chronic musculoskeletal pain and depression (Carroll et al., 2004; Seok et al., 2003; Von Korff & Simon, 1996), some studies have concluded that depression was a strong predictor for onset of an episode of intense musculoskeletal pain (Carroll et al., 2004; Von Korff & Simon, 1996), and that

improvement in pain and disability was greater in the non-depressed group. Therefore, the findings of the current study that participants with low GDS scores at baseline and improved post-massage (both types) suggest that the improvement in pain intensity and disability might be even greater for those with higher baseline GDS scores.

#### **6.4 Back pain and personal characteristic issues**

During analysis of the data on personal characteristics, the study identified some interesting issues that were not included as research questions. The results showed the main cause participants identified for their back pain was heavy lifting and working long hours. This finding is consistent with previous reports that identify lifting (Frymoyer et al., 1998), frequent bending and twisting, physically heavy work, static work postures and whole body vibration as associated with low back pain (Carter & Birrell, 2000; Niemisto et al., 2005; Snook, 2004; Vingard & Nachemson, 2000). The risk of low back pain is greatest when lifting from the floor, and lifting bulky objects (Carter & Birrell, 2000; Marras et al., 1999; Snook, 2004; Waddell et al., 2002). Niemisto et al. (2005) also found that safe lifting techniques attracted considerable research attention because of the high risk of injury, but the findings on safer lifting techniques remain inconsistent. Liddle et al. (2007), who conducted a systematic review of CLBP management strategies, found strong evidence that older persons with low back pain should remain active (including specific advice relating to the most appropriate exercise to undertake) and maintain functional activities to promote active self-management. Supervised exercise therapy as a first-line treatment in the management of CLBP and group exercise constitute an attractive option for treating large numbers of patients at low cost (Airaksinen et al., 2006). As a result of this review of the literature, it is recommended that professional healthcare providers should provide a health education program as an alternative treatment option for Thai older people with CLBP (Morone et al., 2009; Tritilanunt & Wajanavisit, 2001). The health education program may be combined with supervised exercise therapy for preventing back pain injuries from heavy lifting.

The current study found that the majority of older people with chronic low back pain (91.4%) had only a primary school level of education. Therefore education and follow-

up advice in relation to safe lifting techniques need to cater for people of all ages and educational backgrounds. Mantyselka et al. (2003), who studied chronic pain and poor self-rated health, found that education level played an important role for older persons compared to individuals aged less than 45 years. This is understandable because a higher proportion of older citizens are less educated than younger ones. Iris et al. (2004) found that socialization and social support are central to health promotion programs for older people with chronic illness, and interpersonal engagement is particularly important. Furthermore, flexibility in choice and structure of programs contributes to older persons' sense of control over their health. Therefore health promotion programs for chronic low back pain should be challenging and tailored to older persons' educational level, needs and expectations. On the basis of the current study that massage significantly reduces CLBP in the older people, health promotion programs should consider including the benefits of massage therapy for treating CLBP.

## **6.5 The challenges and benefits of conducting a RCT**

This study is the first known trial to examine the effects of Swedish massage combined with aromatic ginger oil compared to TTM as usual massage. TTM has played an important role in Thai culture and healthcare. However, the study hypothesized that SMGO could reduce back pain while giving relaxation; therefore, it may be appropriate for older people with CLBP. The researcher found that conducting a RCT study, including gaining ethics approval, was exciting but also challenging. However, positive experiences associated with conducting the RCT included preparation of massage protocols, strong recruitment and screening processes, and an ideal research site and interdisciplinary team.

### **6.5.1 The challenges of conducting a RCT**

#### **6.5.1.1 Ethical issues**

Ethics approval was sought from Griffith University Ethics Committee and the Human Research Ethics Committee from the Institute of Thai Traditional Medicine, Department for Development of Thai Traditional and Alternative Medicine under the Ministry of Public Health of Thailand (Appendix I: Ref.NRS/02/11/HREC). The researcher also

made a request for permission from the hospital in which the research was conducted (Appendix I: Ref.AF 04-010). The process of getting all ethics approvals from two countries as well as hospital permission was challenging for the researcher.

TTM is one component of Thai traditional medicine and has played an important role in treatment for a range of conditions historically and in the present. TTM is recognised and regulated by the government, and is widely considered to be useful for the treatment of a wide variety of ailments (Wikipedia, 2012). As this study modified the SMGO protocol for older people with CLBP in Thailand and as TTM is firmly integrated within Thai culture, concerns were raised by the Ethics Committee of the Thai Ministry of Public Health that a finding that TTM was not effective would be seen as denigrating Thai culture. However, as one of the study purposes was to test the effectiveness of aromatic ginger oil in pain intensity, slow stroking massage combined with aromatic ginger oil was a necessary element in the RCT. TTM does not use aromatic oil as it applies pressure point massage along the energy line and participants are fully clothed (Chatchawan et al., 2005; Mackawan et al., 2005). Therefore, the initial concerns about SM being more effective than TTM were reduced once the Thai Ethics Committee understood the importance of ginger oil and its relationship with SM.

During the trial, no ethical problems in the conduct of the research were raised. However, because of the initial concerns raised about denigration of TTM, the study was strictly reviewed. The researcher had to present the research project to the full Thai Ministry of Public Health Ethics Committee for approval. At week 5 of the trial, five of the 22 members of the Human Research Ethics Committee from the Thai Ministry of Public Health visited the research project as it was being undertaken in the field to review the process. The committee visited the data collection site to review the documents, observe the trial, and interview participants according to the ethical principles.

In relation to the Thai cultural concerns raised by the Thai ethics committee, future studies should consider further developing the TTM style, for example by combining it with a herbal compress such as a ginger compress for analgesic effectiveness (Therkleson, 2010). For clinical practice, back pain sufferers could choose which type of massage style they prefer, with SMGO as an option for them.

## **6.5.2 The benefits of conducting the RCT**

### **6.5.2.1 Preparation of massage protocols**

Although Swedish and Thai massages have been used worldwide to treat pain, there was no published standard protocol for CLBP available when the RCT was conducted. Therefore, this study developed two massage protocols (SMGO and TTM) for older people with CLBP. Both protocols were assessed for consensus agreement by a panel of two experts in the area of traditional Thai and Swedish massage, one from the United States and one from Thailand. Although the experts had different backgrounds – one was a massage therapist and one a physiotherapist – they were both intimately associated with massage and complementary therapy treatments and possessed doctoral qualifications. The panel members were asked to evaluate the individual steps of the protocol with regards to their relevance and appropriateness in terms of the sequence, the number of stages and the procedure at each stage. Where panel members raised concerns with any aspect of the protocols, revision was undertaken until consensus agreement was achieved.

Both assessors gave good scores for both protocols (see Appendix C). One assessor suggested both types of massage should use the same bodily position and the protocol should contain picture of procedures, so the protocol was revised to accommodate these suggestions.

### **6.5.2.2 Recruitment and Screening**

After the pilot study, the actual study started with the process of recruitment and screening. Weeks after the study was announced, many older people with CLBP in Rachaburi province and nearby expressed their interest in this project as we had 20-30 participants each screening time. Advertising and communication from posted flyers, community radio, or word-of-mouth by physiotherapists, massage therapists and patients were effective so the recruitment process was quick. The study screened 164 potential subjects in a month.

### **6.5.2.3 An ideal research site**

The clinic provided an ideal site for massage research as it had a dedicated massage space that was ideal for the therapeutic trial conducted in this study. This is in contrast to general clinics that provide for multipurpose therapies. The setting had individual massage bed spaces that were screened, and provided comfortable seating for waiting participants.

### **6.5.2.4 Interdisciplinary team**

Lyons (2010) concluded that interventions for CLBP including massage therapy used by an interdisciplinary healthcare team may offer pain relief and lead to improved physical function. The current study used an interdisciplinary healthcare team approach that included a medical doctor, nurses, physiotherapists and massage therapists. The interventions were delivered by this team with positive results for all outcomes of the study (pain relief, improvement of disability, quality of life and depression) in both groups (SMGO and TTM). Further studies of massage should consider including an interdisciplinary healthcare team for their research projects.

## **6.6 Implications for Nursing**

### **6.6.1 Implication for nursing practice**

The research study results found that both types of Thai and Swedish massage improve chronic low back, quality of life, disability and depression. As massage is a popular therapy and helps in reducing pain, there is potential for nurses to integrate massage into

nursing practice. Furthermore, massage may be used to enhance care in a holistic direction (Redfern & Ross 2005). Back massage using a specific protocol does not require a licence for practice and can be applied by nurses once they have the appropriate level of knowledge and skill. A member of a multi-professional clinical team experienced in the therapy can educate and train nurses to adhere to the protocols developed in a particular clinical area (Royal College of Nursing 2003). These nurses will not be qualified as massage therapists, but will be nurses who have extended their practice by incorporating complementary therapy techniques in order to enhance patient care (Royal College of Nursing, 2003).

Patients who want to make better healthcare choices often approach nurses when they want advice regarding complementary therapies such as massage (Melancon & Miller, 2005). Nurses viewing healthcare holistically should consider massage therapy when helping patients make healthcare choices for their CLBP because massage is a non-invasive treatment and has many advantages. Melancon and Miller (2005) recommended massage therapy for CLBP relief because: (1) it allows patients an alternative to traditional medical therapy; (2) it is attractive to patients who see holistic healing as a strategy that avoids non-natural compounds (medications) or for those who cannot use analgesics; (3) it is non-addictive compared to some pharmaceutical treatments taken for pain; and (4) it is low in cost compared to many prescription medications.

Melancon and Miller (2005) concluded that both massage and traditional therapies can be incorporated into a unified holistic nursing practice as an alternative option for patients with CLBP. Arcy (2009) also recommended the combination of medication and CAM treatments to provide the best outcome for CLBP. In practice, nurses in hospitals, healthcare centres or aged-care settings can incorporate the application of back massage into care to relieve chronic low back pain and potentially reduce overreliance on medication once they are trained in the appropriate techniques. The results of this study showed that both SMGO and TTM were effective in treating CLBP; therefore, nurses may choose to apply a suitable type of massage to their patients based on culture or personal preference.

### **6.6.2 Implication for nursing education**

Sohn and Loveland-Cook (2002) reported that 83% of nurse practitioners (NPs) in the United States of America (USA) recommended complementary and alternative medicine (CAM) to their patients, with massage being the most frequently recommended therapy (50.3%). However, only 24% of NPs reported that formal education was a source of knowledge about these treatments, and over 60% relied on their personal experiences for this knowledge, as well as lay and professional journals. More than half of the NPs (54.0%) received training in complementary and alternative treatments outside of their educational program and 36.2 % were interested in massage therapy (Sohn & Loveland-Cook, 2002). The majority of NPs' comments from the study (64%) support the use of CAM in healthcare, frequently linking its use with nursing's position on holism. Margaret O'Brien et al. (1999) also found that nurses had positive opinions about CAM, but a low level of knowledge. Sohn and Loveland-Cook (2002) suggested that if NPs deem CAM to be an appropriate amplification of their scope of practice, it is essential that their work with CAM modalities be based on up-to-date scientific knowledge. Unfortunately, only 24% of the participants cited formal education as a source of information about CAM modalities, despite recommendations from professional and governmental organizations that schools of nursing adequately prepare advanced practice nurses for the changing healthcare environment (Sohn & Loveland-Cook, 2002).

Concentration on advancing knowledge about the use of CAM in healthcare will strengthen the practice of nursing and broaden the scope of practice (Sohn & Loveland-Cook, 2002). As massage therapy involves manipulation, trained nurses would need to practise their massage skills so inclusion of formal education about CAM modalities in curricula may promote decisions about whether to use these modalities based upon scientific foundations rather than personal experience. A supportive scholarly environment in turn may stimulate further scientific inquiry into the safety and efficacy of massage therapy and other CAM treatments. Given continued academic and professional support, future nurse researchers and clinicians of CAM modalities could make worthwhile contributions to nursing practice, and improvements in patients'

quality of life. A massage course could also be an option for further education development.

## **6.7 Recommendations for future direction**

The study identified key issues surrounding the outcomes of SMGO compared to TTM for older people with CLBP. It also provides a foundation for further work in relation to back pain. Recommendations for future research, practice and education are outlined in Table 6.1 and subsequently detailed.

**Table 6.1: Recommendations for future research, practice and nursing education**

<b>Research</b>	<b>Practice</b>	<b>Nursing Education</b>
<ul style="list-style-type: none"> <li>• Further studies to test the effectiveness of massage on pain relief</li> <li>• Emphasise psychosocial outcomes in CLBP research</li> <li>• Conduct a cost-benefit evaluation of back massage therapy</li> </ul>	<ul style="list-style-type: none"> <li>• Integrate massage with standard treatment</li> <li>• Utilise a standard massage protocol or guideline for CLBP among older adults</li> </ul>	<ul style="list-style-type: none"> <li>• Include massage therapy in nursing curriculum or in a short course as an optional subject</li> </ul>

### **6.7.1 Recommendations for research**

In planning further research in the field of CLBP in older people, the following issues/areas should be considered.

#### **Methodology**

##### **6.7.1.1 Further studies to test the effectiveness of massage on pain relief**

With the limitation of funding and time for this current PhD study, the study examined two groups of interventions: treatment (SMGO) and usual massage in Thailand (TTM) as one previous study (Chatchawan et al., 2005) concluded that there was no significant difference between SM and TTM in delivering back pain relief. However, to enhance the strength of the findings, future studies should consider including a control alongside the placebo and treatment groups. For example, SMGO group (treatment) compared to TTM group (usual massage) and SM with base oil (placebo). Future studies could also test the effectiveness of both types of SM and TTM on back pain relief by comparing each type of massage therapy with control and/or placebo groups (e.g. SMGO and SM or SM with base oil, TTM with ginger compress and TTM).

Previous studies have tested ginger's effectiveness in reducing pain, knee pain, hip pain and osteoarthritis pain (Altman & Marcussen, 2001; Bliddal et al., 1999; Haghghi et al., 2005; Yip et al., 2008). The current study is the first known trial to test aromatic ginger oil to reduce back pain and the results support that aromatic ginger has an analgesic effect on back pain relief for older adults. However, the current study lacked a placebo group so future studies could consider examining the effectiveness of aromatic ginger compared to a placebo group. Varying dosages of aromatic ginger oil could also be examined to see whether larger doses lead to greater effects. It is also recommended that prospective studies should consider aromatic ginger research for other types of pain and different age groups. Researchers could use ginger in its different forms such as an extract, aromatic oil or herbal drink.

#### **6.7.1.2 Emphasise psychosocial outcome in CLBP research**

The literature review of the effectiveness of massage therapy for CLBP showed that only a few studies were interested in psychosocial outcomes. The current study is the first known trial to examine the effectiveness of SM and TTM in relation to quality of life and depression and significant positive effects were seen. Future studies of massage therapy for CLBP should emphasize both the physical and psychological outcomes as this will prove a strong evidence base for holistic nursing care.

#### **6.7.1.3 Conduct cost-benefit evaluation of back massage therapy**

The current study monitored medication and alternative treatment use throughout the study. It showed several participants were keen to use other CAM treatments with massage such as herbs and exercise as they tried to reduce their medication given the side effects of NSAIDs. Therefore, it would be useful to evaluate the relative costs and benefits of using massage or CAM compared with a standard pharmaceutical treatment for CLBP. The results may give practitioners, healthcare providers and patients who use CAM an alternative treatment and recommendation for CLBP management.

#### **6.7.1.4 Investigate complex interventions in nursing**

The current study was an RCT study, which adds to the complexity of the research design. The Medical Research Council (2008) suggests that RCT design is best research practice to develop and test interventions through a phased program of pilot studies. In reality nursing /CAM interventions can arise from 'past practice, existing evidence or theory. The strength of nursing research can be the combination of different types of (qualitative and quantitative) research, and in the duplication of research findings (Richards & Hamers, 2009).

## **6.7.2 Recommendations for practice**

### **6.7.2.1 Integrate massage with standard treatment**

The significant results showing the effectiveness of both types of massage (SMGO, TTM) for reducing pain, enhancing quality of life and improving disability and depression in older people with CLBP, suggest that massage can be an appropriate optional treatment for patients with CLBP. Practitioners can softly integrate SMGO or TTM into their standard treatment. For example, nurses in hospitals or aged-care facilities can incorporate back massage into their nursing care to relieve CLBP and reduce overreliance on medication.

### **6.7.2.2 Utilise a standard massage protocol or guideline for CLBP**

This recommendation arises from the finding that the SMGO intervention was effective in treating older adults with CLBP. The SMGO protocol was assessed by two experts before the study commenced and proved to be a good massage protocol for older adults with CLBP. Only one guideline for the management of CLBP (Airaksinen et al., 2006) that includes comments on massage has been published. No standard massage guideline, however, for back pain has been published. The current massage protocol was 30 minutes in duration and includes 10 sessions for five weeks, which may be an appropriate treatment duration given the success of this trial. A standardized massage protocol and guideline may help nurses or massage therapists in providing holistic evidence-based care for their patients. Nurses or therapists may integrate the massage protocol into the guidelines for management of CLBP in hospitals or aged-care facilities once they are trained.

## **6.7.3 Recommendations for nursing education**

### **6.7.3.1 Include massage therapy in nursing curricula or as a short course**

With the increasing use of CAM by the general public in the US and worldwide (Sohn & Loveland-Cook, 2002), it is important that nurses and/or nurse practitioners have up-to-date information about the use and safety of CAM modalities. A strong knowledge foundation is important in delivering competent and culturally sensitive care; unfortunately, the level and source of nurse/NP knowledge in the CAM area is largely

unknown (Sohn & Loveland-Cook, 2002). In Sohn and Loveland-Cook's (2002) study, about half of NPs reported receiving training in complementary and alternative therapies outside their program; consequently, these researchers recommended better integration of this content into NP curricula.

However, although CAM short courses including massage therapy are of interest to nurses, many hospitals are understaffed and nurses overworked (Labrique-Walusis et al., 2010). Finding the time to provide an hour-long Swedish massage may not be time-efficient for the already overwhelmed nurse. Therefore, the shorter 30-minute back pain massage protocol used for this study may be useful for nurses who have busy patient workload schedules.

Nursing students should be also educated on CLBP management in older people and its treatment, and the safety and efficacy of CAM including back massage (SMGO & TTM), as part of their standard undergraduate training. It is important to integrate content and skills into the nursing curricula to ensure nursing students are able to competently care for older people with CLBP when they graduate and work as nurses.

## **6.8 Research limitations**

Limitations of the study are acknowledged and predominantly relate to the study design. Placebo interventions substantially improve patient-reported and observer-reported outcomes in many clinical conditions, but most reports on effects of placebos are based on studies that have not randomised patients to placebo or no treatment (Hróbjartsson & Gøtzsche, 2010). A review (Hróbjartsson 2004) found that placebo interventions in general did not have clinically important effects, but that there were possible beneficial effects on patient-reported outcomes, especially pain. With the limitation of funding and time for this PhD study, the research team made a decision to have two groups (treatment and control groups) to enable a bigger sample size in each group rather than adding a third placebo group. Although, the study lacked a placebo group, it still compared the treatment intervention with a relevant control group and as such has a low risk of bias. Future studies should consider the addition of a placebo group.

The literature review of TTM and SM concluded that both type of massage have equal effectiveness on low back pain. To ensure the effectiveness of aromatic ginger oil, any further study should compare SMGO and SM.

Another potential limitation of the intervention relates to the jojoba oil base. As jojoba has an anti-inflammatory effect, there is the potential that this could interfere with the effect of SMGO. However, this risk is low as the jojoba oil base was diluted and therefore in a low concentration level.

Secondly, the investigator who assessed the outcomes of the interventions could not be blinded to group allocation. As this was a PhD project, it was not possible to provide outcome assessors blinded to group allocation.

Finally the use of self massage whereby participants lay on bottles or coconut shells and moved around may have potentially interfered with the effect of the massage. However, only 5 participants in each group used self massage after receiving 10 sessions of massage (during the first follow-up). Future studies should ask participants not to use any type of massage during the study.

## **6.9 Study highlights**

The high rate of CLBP in older people highlights the importance of this study, which ultimately aimed to reduce the side effects of this condition and improve quality of life for older people. This study has important findings that further our understanding of how massage and aromatherapy, such as SMGO, can influence pain, physical functioning and psychological well-being of older people with CLBP. Such an understanding can improve the evidence-based for care of aging populations.

The study highlights that both SMGO and TTM can reduce back pain and improve disability, quality of life and depression. SMGO was more effective than TTM in reducing pain intensity, disability and quality of life both short and long term. However, SMGO and TTM were not significantly different in improving depression. However,

the Thai older people with CLBP had a geriatric depression score less than 5, which indicates they did not have depression across the study measurement time points.

The study also highlights the effectiveness of aromatic ginger oil for CLBP as it is the first known trial to test its use for back pain. Also, the study developed an appropriate protocol for SMGO assessed by expert agreement. The study recommends that future trials should consider investigating the effectiveness of aromatic ginger oil in pain intensity. The integration of massage therapy in nursing practice for patients with CLBP in hospitals or aged-care facilities may be used as an optional treatment. A standardized massage protocol and guideline may help nurses or massage therapists in providing holistic care for their patients. The usefulness of massage therapy for CLBP management should be integrated within curricula and short courses for nurses or nursing students.

## **6.10 Conclusion**

This study examined the effectiveness of SMGO compared to TTM for older people with CLBP. It is the first RCT to test the effect of aromatic ginger oil for back pain relief. The findings support the conceptual framework of the study that Swedish massage with five basic strokes can result in physical, psychosocial and neurological effects through the skin by touch and compression. The combination of Swedish massage and aromatic ginger oil has been shown to reduce back pain and improve disability, quality of life and depression. Ginger properties can reduce pain and give relaxation via the aromatic absorption through the skin. The study concludes that both SMGO and TTM are effective in reducing pain, enhancing quality of life, improving disability and depression across the period of immediate, short and long term. SMGO is more effective than TTM in reducing pain intensity, disability and quality of life in the short and long term. However, they were both equally effective for depressive symptoms across the three time periods and pain intensity in the immediate period. The fact that the TTM intervention was delivered as per current standard approach used throughout Thailand supports the generalizability of the results. Recommendations from this study may be helpful in informing the direction and focus of future studies and practice.

## **APPENDICES**

## **APPENDIX A: SWEDISH MASSAGE TECHNIQUE**

### **Swedish massage techniques**

#### **I. Effleurage (Gliding strokes)**

Effleurage is an elongated, slow stroke that slides across the surface of the skin with unbroken gliding movement (Braun & Simonson, 2005). It is used to introduce touch and apply lubricant. Effleurage is administered at the beginning and end of a treatment session because it is so proficient at moving blood and lymph. This stroke may be applied with hands (palm, knuckles, and fingertips), or forearm; the pressure can be either superficial (gentle) or deep (Salvo, 2003). Many times, it is the only stroke needed to eliminate discomfort in a painful area. Effleurage can be used on virtually every type of body surface, making it the preferred transition stroke to use between other strokes (Salvo, 2003). Light compression reduces muscle tone and induces a state of relaxation that relieves muscle spasm and prepares the clients for more vigorous procedures. Rapid strokes have the opposite effect. These may increase muscle tone and may be useful during the final preparation (Goats, 1994).

#### **Benefits of effleurage**

Effleurage has benefits and uses such as warming body tissue and making it more extensible, relaxation and preparation of an area for deeper strokes, soothing an area after deep work, calming the nervous system with slow stroke and stimulating with quick stroke, rising blood and lymph circulation, and reducing exhausted and muscle spasm (Goldberg, 2001; Salvo, 2003).

#### **II. Petrissage (Kneading strokes)**

Petrissage movements are those in which soft tissue is compressed against underlying bone or squeezed in some way. The term kneading is used to describe all petrissage movements: kneading, picking up, wringing, and rolling (Goats, 1994; Goldberg, 2001;

Salvo, 2003). In Swedish massage routine, petrissage typically follows effleurage strokes.

Salvo (2003) explained that these squeezing, compressing movements of petrissage have a pumping effect on the blood and lymphatic vessels in the soft tissues and stimulate the drainage of blood, oxygen and lymph petrissage. Many of the petrissage movements also stretch and broaden the tissue so it is important to repeat the effleurage stroke after petrissage to flush the stirred-up waste from area and back into the circulatory system.

### **Benefits of petrissage**

#### 1. Kneading

Kneading is a circular movement where the hand moves the skin onto the deeper tissues (Goldberg, 2001). The hands do not move over the skin except to move to the next part to be treated. This technique stimulates lymphatic drainage and supply of arterial blood into the muscles and other tissues. Additionally, it produces vasodilatation and mobilizes subcutaneous tissue (Goldberg, 2001).

#### 2. Picking up

Picking up is an action whereby tissue is lifted a way from the deeper tissue or bone, squeezed and released on muscle (Goldberg, 2001). The technique is used to stimulate venous, lymphatic and arterial flow, and also to loosen tight subcutaneous tissue.

#### 3. Wringing

Wringing is similar to picking up. The tissue is compressed and picked up from the bone as in the picking-up technique, but instead of being released they are passed from hand to another hand in a wringing movement (Goldberg, 2001). It is used to improve elasticity by stretching along the length of muscle.

#### 4. Rolling

The most common type of rolling is skin rolling where the skin and subcutaneous tissue is rolled between fingers and thumb; muscle rolling is performed as a deeper rolling

across muscle fibres (Goldberg, 2001). Skin rolling benefits are stimulation of circulation in the skin, making softer hard subcutaneous tissue such as fat or scars, and giving relaxation and elasticity of skin. Muscle rolling is used to relieve tension and adhesion in the muscle, and also to improve blood circulation in the muscle.

### **III. Friction**

The term friction comes from the Latin word meaning to rub. Friction typically follows petrissage in the sequential order of massage strokes. Friction movement is performed by compressing tissue in several directions (Salvo, 2003). It can be applied superficially or deep with completely different methods and effects (Braun & Simonson, 2005). Friction movements can increase circulation, so it is used for areas that have little or no blood supply, such as ligament and tendons. Varieties of friction range from general techniques such as superficial warming, rolling, and wringing to deep, but specific techniques such as cross-fibre, chucking, and circular. General friction is used to address large areas (the back or the arm) while deep friction is suitable for areas that lack muscle bulk (ankle, the side of head, the suboccipital region) (Salvo, 2003).

#### **Benefits of friction**

Friction movements can benefit muscle by increasing circulation, loosening joint stiffness, breaking down and freeing adhesions, softening hyperplasia, broadening and stretching muscle, and reducing trigger point formation and activity (Salvo, 2003).

### **IV. Tapotement (Percussion strokes)**

The terms tapotement and percussion are interchangeable and describe a group of movements where the parts are struck repeatedly with soft blows of the hands (Goldberg, 2001). The movements must be light and bouncy, not heavy and solid. All the movements are stimulating and are usually left out from a relaxing style of massage. Tapotement has four movements: hacking, pounding, clapping, and beating.

## **Benefits of tapotement**

### **1. Hacking**

Hacking is performed with the ulnar edge of one hand or both hands alternately, striking the surface of the client's skin (Salvo, 2003). The hands should be held loosely with fingers slightly spread. This produces a slight vibratory action coupled with the percussive action. Hacking with fingers parallel along muscle fibres produces relaxation in the muscle. Hacking is applied across large muscles with the finger perpendicular, to stimulate muscle spindle activity. Commonly, hacking is used to stimulate superficial muscle by producing a reflex contraction.

### **2. Pounding**

Pounding is a heavier percussion movement than hacking and should be used over well-covered areas such as the back or the gluteal region (Goldberg, 2001). The movement made is similar to hacking, but the hand should be loosely clenched so that a soft fist is made. This movement helps to increase local circulation and soften fatty tissue.

### **3. Clapping**

Clapping or slapping is performed with the palm surface of the hands and fingers, striking the skin with alternate strokes (Salvo, 2003). The hands should be cupped so that the centre of the palm does not touch the part. Also, the fingers are held together with a loud smacking sound. Clapping is used to stimulate skin circulation and also shake and stimulate circulation in deeper tissue (Goldberg, 2001).

### **4. Beating**

Beating is performed as in clapping but with the hand held in loose fists. This movement can soften hard fatty tissue (Goldberg, 2001).

In summary, tapotement can stimulate nerve endings initially, tone atrophied muscles, increase local blood flow, relieve pain (perhaps due to the gate theory), and desensitize a hypersensitive area after a few minutes of tapotement stimulation (Salvo, 2003).

## **V. Vibration**

Vibration is rapid shaking, quivering, trembling, or rocking movements applied with the fingertips, full hand, or an appliance (Salvo, 2003). Done properly, the tissues are moved near the area of contact. As in tapotement, the client should feel the onset and removal of pressure. In contrast, the hands with vibration do not break contact with the client's skin.

### **Benefits of vibration**

Vibration gives benefits to muscle such as stimulating muscle spindle and creating minute muscle contraction, pain relief, reducing trigger and tender point activity, and increasing circulation and general relaxation (Salvo, 2003).

## APPENDIX B: THAI MASSAGE ENERGY LINES

### The ten-energy-line (Sen Sib) pathways

The name of lines (Sens)	Pathway
Sen 1: Itha: exits left nostril	On the left side of body: it starts one thumb width to the left side of the navel and passes through pubic area to the inside of the left thigh toward the back. Then it runs upwards to the left buttock and proceeds along left side of spine, continuing over the head and curving downwards to the left side of the face and exits via left nostril.
Sen 2: Pingkla: exits right nostril	It follows the same pathway as Sen 1(Itha) but on the right side of the body and exits via the right nostril.
Sen 3: Summana: exits tongue	At the centre of the body, it starts two thumb widths above the navel, runs deeply inside the chest and passes through the throat exiting at the tongue.
Sen 4: Kanlataree: exits ten fingers and toes	It starts a thumb width above the navel and separates into four branches. The two upper branches run along both sides of the body, winding their way up through the scapular blades to the shoulders, then over the head. Then the wind goes back and forth, continuing on the posterior arms to the wrists where they exit all fingers. The two lower branches run through both thighs along the tibia bone

	to the ankles and all ten toes.
<b>The name of lines (Sens)</b>	<b>Pathway</b>
Sen 5: Hadsarangsri: exits left eye	On the left side of body: It starts three thumb widths on the left side of the navel. It runs down the medial side of the left thigh and leg to the left foot passing along the base of all five toes. It continues to the lateral side of the left foot moving upwards along the lateral side but closer to the tibia bone of left leg to the left thigh. Then it continues to the left side of the ribcage passing the left nipple and upwards to below the left side of the chin to the left eye.
Sen 6: Tawaree: exits right eye	It run the same pathway as Sen 5 (Hadsarangsri) but it runs on the right side of the body and exits at the right eye.
Sen 7: Jantapusank: exits left ear	On the left side of body: it starts four thumb widths on the left side of the navel, runs upwards through the left breast to the left side of the neck and exits at the left ear.
Sen 8: Rusum: exits right ear	It run the same pathway as Sen 6 (Tawaree) but it runs on the right side of the body and exits at the right ear.
Sen 9: Sukumand: exits anus	It starts two thumb widths under the navel a little to the left and proceeds downwards exiting at the anus.
Sen 10: Sikhinee: exits anus	It starts two thumb widths under the navel a little to the right and runs downwards to exit at the sex organ and the urethra.

## APPENDIX C: THE INTERVENTION PROTOCOLS

**Table1: Swedish massage with aromatic ginger oil protocol**

Stage	procedure	Position of masseuse	Procedures	Time taken	conductors	Equipment required
Before the intervention						
1.	Introducing and Explanation	-	<ul style="list-style-type: none"> <li>The researcher introduces herself to a participant.</li> <li>Explain to the participant that the treatment session will last 30 minutes for each intervention, approximately 40 minutes for the whole process of each session and encourage the participant to inform a masseuse his/her pain tolerance threshold during the treatment session.</li> </ul>	5 minute	Researcher	Researcher's name card
2.	Assessment of the outcomes	-	The participant is asked to complete all of the questionnaires in Thai version; Short-Form McGill pain questionnaire, Oswestry Low Back Pain Disability Questionnaire, SF-12V2 and GDS at baseline, 6 <sup>th</sup> week (2 <sup>nd</sup> follow up) and 15 <sup>th</sup> week (3 <sup>rd</sup> follow up). The VAS will be assessed by a participant in each session before treatment.	10-15 minute	Researcher	All of the questionnaire papers & a pen
During the intervention						
1.	Preparation	-	<ul style="list-style-type: none"> <li>Preparation of materials</li> <li>Set up a quiet and private environment</li> <li>Masseuse keeps her finger nails trimmed and removes rings, watches and any other jewellery that may retard the treatment session</li> <li>Masseuse washes and dries hands</li> <li>The VAS will be assessed by a participant in each session before treatment.</li> <li>The participant changes his/her clothes to be more comfortable</li> </ul>	5 minutes	Masseuse  Research assistant (for VAS)	<ul style="list-style-type: none"> <li>a bottle of aromatic ginger oil</li> <li>bottle of jojoba oil (base oil)</li> <li>paper caps and pants</li> <li>face-supported pillow</li> <li>oil massage bed</li> <li>bed sheets and towels</li> </ul>
2.	Masseuse introduce	Stand at left side	Introduce to participants and ask them to lay down in prone position	0.5 minute	Masseuse	

**Table1 (Cont.): Swedish massage with aromatic ginger oil protocol**

Stage	procedure	Position of masseuse	Procedures	Time taken	conductors	Equipment required
I. Prone position						
3.	Swedish massage and aromatic ginger oil sequences	Stand at left side	<ul style="list-style-type: none"> <li>• Rocking vibration and palm compressions on the back of body through towel draping.</li> <li>• As a compression, the right palm of masseuse presses on the client's back into the 6 points of zigzag direction from the left side to the right side while the left palm of masseuse presses on trapezes muscle (beside the scapular spine) as a supporting.</li> </ul>	0.5 minute	Masseuse	
4.		Stand at left side	Undrape back	0.5 minute		
5.		Stand at left side	Apply aromatic ginger oil about 2 ml (approximately 2 pumps) on the masseur's hands	0.5 minute	Masseuse	
6.		Stand at left side	Rowing strokes (Effleurage) from sacrum to neck, upward and downward for 2 times until oil is absorbed.	0.5 minute	Masseuse	
7.		Stand at left side	Thumbs slide on the right back along latissimus dorsi muscle (beside the spinal cord) from sacrum to the neck, thumbs circle around the scapular then going to elbow. Doing it upward and downward for 2 times	1 minutes	Masseuse	
8.		Stand at left side	Reinforced stroking with crossing hands as X shape by thumbs and palm slide on right side from the waist to the neck, upward and downward for 2 times	1 minute	Masseuse	
9.		Stand facing back	Side pulls (transition stroke) on the right back for 2 times	1 minute	Masseuse	

**Table1 (Cont.): Swedish massage with aromatic ginger oil protocol**

Stage	procedure	Position of masseuse	Procedures	Time taken	conductors	Equipment required
Change to another side						
10.	Swedish massage and aromatic ginger oil sequences (Cont.)	Stand at right side	Apply aromatic ginger oil about 2 ml (approximately 2 pumps) on the masseur's hands	0.5 minute	Masseuse	
11.		Stand at right side	Rowing strokes (Effleurage) from sacrum to neck, upward and downward for 2 times until oil is absorbed.	0.5 minute	Masseuse	
12-14		Stand at right side	Repeat stage 7-9 but doing on the opposite side that it did	3 minutes	Masseuse	
15.		Stand at right side	Apply aromatic ginger oil about 2 ml (approximately 2 pumps) on the masseur's hands	0.5 minute	Masseuse	
16.		Stand at right side	Rowing strokes (Effleurage) from sacrum to neck, upward and downward for 2 times until oil is absorbed.	0.5 minute	Masseuse	
17.		Stand at right side	Reinforced circular finger kneading along right latissimus dorsi muscle and paraspinal muscles	1 minute	Masseuse	
18.		Stand at right side	Alternating circular thumbs kneading along right latissimus dorsi muscles and paraspinal muscles	1 minute	Masseuse	
19.		Stand facing back	Figure of 8 (integration stroke) on the right back	1 minute	Masseuse	
20.		Stand facing back	C-scoop kneading over opposite side of back (left side)	1 minute	Masseuse	
21.		Stand facing buttocks	Broad forearm compression on the right portion of buttock	1 minute	Masseuse	
22.		Stand facing back	Reinforced circular fingertips friction to the opposite latissimus dorsi muscle and paraspinal muscles (left side)	1 minute	Masseuse	
23.		Stand facing back	Wringing up from the right lower back to shoulder (transitional stroke)	1 minute	Masseuse	
24.		Stand facing back	Skin rolling upward on the right back	1 minute	Masseuse	

**Table1 (Cont.): Swedish massage with aromatic ginger oil protocol**

Stage	procedure	Position of masseuse	Procedures	Time taken	conductors	Equipment required	
Change to another side							
25.	Swedish massage and aromatic ginger oil sequences (Cont.)	Stand at left side	Apply aromatic ginger oil about 2 ml (approximately 2 pumps) on the masseur's hands	0.5 minute	Masseuse		
26.		Stand at left side	Rowing strokes (Effleurage) from sacrum to neck, upward and downward for 2 times until oil is absorbed.	0.5 minute	Masseuse		
27-34		Stand at left side & facing on back	Repeat stage 17-24 but doing on the opposite side that it did	8 minutes	Masseuse		
35.		Stand facing back	Hacking over the back for 2 round	0.5 minute	Masseuse		
36.		Stand facing back	Beating over the back for 2 round	0.5 minute	Masseuse		
37.		Stand facing back	Cupping over the back for 2 round	0.5 minute	Masseuse		
38.		Stand at left side	Apply aromatic ginger oil about 2 ml (approximately 2 pumps) on the masseur's hands	0.5 minute	Masseuse		
39.		Stand at left side	Rowing strokes (Effleurage) from sacrum to neck, upward and downward for 2 times until oil is absorbed.	0.5 minute	Masseuse		
40.		Stand facing back	Forearm press on both sides of the back for 2 times	0.5 minute	Masseuse		
41.		Stand at left side	Rowing stroke (integration stroke) for 2 times	0.5 minute	Masseuse		
42.		Stand at left side	Redrape the back and press the towel over the back to remove excess oil	1 minute	Masseuse		
0.		Assessment the pain intensity	-	Client is asked to rate the average intensity of his/her back pain intensity by VAS	2 minute	Researcher	The VAS questionnaire & a pen

**Table2: Traditional Thai massage protocol**

Stage	procedure	Position of masseuse	Procedures	Time taken	conductors	Equipment required
Before the intervention						
1.	Introduce and Explanation	-	<ul style="list-style-type: none"> <li>The researcher introduces herself to a participant.</li> <li>Explain to the participant that the treatment session will last 30 minutes for each intervention, approximately 40 minutes for the whole process of each session and encourage the participant to inform a masseuse his/her pain tolerance threshold during the treatment session.</li> </ul>	5 minute	Researcher	Researcher's name card
2.	Assessment the outcomes	-	The participant is asked to complete all of the questionnaires in Thai version: Short-Form McGill pain questionnaire, Oswestry Low Back Pain Disability Questionnaire, SF-12V2 and GDS in the baseline before treatment, 6 <sup>th</sup> week (2 <sup>nd</sup> follow up) and 15 <sup>th</sup> week (3 <sup>rd</sup> follow up). The VAS will be assessed by a participant in each session before treatment.	10-15 minute	Researcher	All of the questionnaire papers & a pen
During the intervention						
1.	Preparation	-	<ul style="list-style-type: none"> <li>Preparation of materials</li> <li>Set up a quiet and private environment</li> <li>Masseuse keeps her finger nails trimmed and removes rings, watches and any other jewellery that may retard the treatment session</li> <li>Masseuse washes and dries hands</li> <li>The VAS will be assessed by a participant in each session before treatment.</li> <li>The participant changes his/her clothes to be more comfortable</li> </ul>	5 minutes	Masseuse	<ul style="list-style-type: none"> <li>a mattress</li> <li>a pillow</li> <li>bed sheets</li> <li>comfortable clothes</li> </ul>
2.	Masseuse introducing	Stand at left side	Introduction to participant and then ask them to lay down on the left side position	0.5 minute	Masseuse	

**Table2 (Cont.): Traditional Thai massage protocol**

Stage	procedure	Position of masseuse	Procedures	Time taken	conductors	Equipment required
<b>I. Left lateral position</b>						
3.	Traditional Thai massage sequences	Sit at right side	<b>The left leg</b> Starting on the left leg, fore arm presses and knead on the sole of the right foot	1 minute	Masseuse	
4.		Sit at right side	Thumbs press along two lines of the inside of the left leg  <ul style="list-style-type: none"> <li>• 1<sup>st</sup> line (Sen 1: Itha) is along the inner edge of the left tibia bone</li> <li>• 2<sup>nd</sup> line (Sen 2: Pingkla) is along the left Achilles' tendon</li> </ul>	2 minutes	Masseuse	
5.		Sit at right side	Palm presses along the inside of the left leg	1 minute	Masseuse	
6.		Sit at right side	<b>The right leg</b> Switch to the right leg, thumbs press on the outer edge of the right foot	0.5 minute	Masseuse	
7.		Sit at right side	Thumbs press along two lines of the inside of the right leg  <ul style="list-style-type: none"> <li>• 1<sup>st</sup> line (Sen 1: Itha) is along the upper edge of the right ankle bone</li> <li>• 2<sup>nd</sup> line (Sen 2: Pingkla) is along the lower edge of the right ankle bone</li> </ul>	2 minutes	Masseuse	
8.		Sit at right side	Palm presses along the outside of the flexed leg	1 minute	Masseuse	
9.		Sit at right side	Thumbs press around the hip, follow the lines of the outside of the right leg	1 minute	Masseuse	
10.		Sit beside the back	<u>The back</u> Forearm presses and knead on the hip	0.5 minute	Masseuse	

**Table2 (Cont.): Traditional Thai massage protocol**

Stage	procedure	Position of masseuse	Procedures	Time taken	conductors	Equipment required
11.	Traditional Thai massage sequences (Cont.)	Sit beside the back	Thumbs press on two lines of the back for 2 times each line <ul style="list-style-type: none"> <li>• 1<sup>st</sup> line is along the edge of the spinal cord</li> <li>• 2<sup>nd</sup> line is one finger based apart from the 1<sup>st</sup> line</li> </ul>	5 minute	Masseuse	
12.		Sit beside the back	Thumbs knead on three lines of the scapula and upper shoulder (Supraspinatus and Infraspinatus muscles) <ul style="list-style-type: none"> <li>• 1<sup>st</sup> line is around the scapula border</li> <li>• 2<sup>nd</sup> line is upper shoulder, start from the angle of scapula going down to the inferior angle of the scapula</li> <li>• 3<sup>rd</sup> line is one finger based apart from the 2<sup>nd</sup> line- starting from Acromion process going down to armpit</li> </ul>	2 minutes	Masseuse	
13.		Sit beside the back	Stretch the upper body and arm (2 times)	0.5 minute	Masseuse	
<b>II. Prone position</b>						
14.		Sit beside the left leg	<b>The left leg</b> Starting on the left leg, parallel thumbs press on the sole from the distal of sole to the heel.	0.5 minute	Masseuse	
15.		Sit beside the left leg	Thumbs press along the 2 <sup>nd</sup> line (Sen 2: Pingkla) of the inside of leg, along the left Achilles' tendon, start from the left ankle to the buttock	1 minute	Masseuse	
16.		Sit beside the left leg	Palm presses along the back of the left leg from the ankle to the buttock	1 minute	Masseuse	

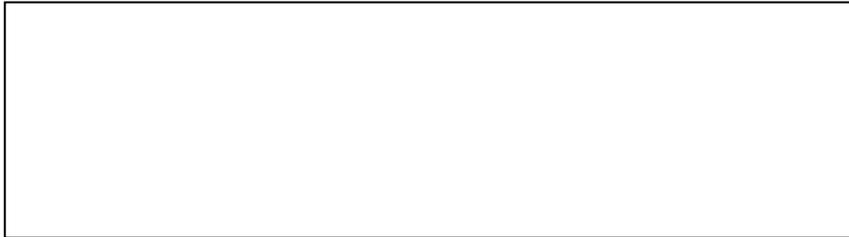
**Table2 (Cont.): Traditional Thai massage protocol**

Stage	procedure	Position of masseuse	Procedures	Time taken	conductors	Equipment required
17.	Traditional Thai massage sequences (Cont.)	Sit beside the left leg	<b>The right leg</b> Switch to the right leg, parallel thumbs press on the sole	0.5 minute	Masseuse	
18.		Sit beside the left leg	Thumbs press along the 2 <sup>nd</sup> line (Sen 2: Pingkla) of the inside of leg, along the right Achilles' tendon, start from the right ankle to the buttock	1 minute	Masseuse	
19.		Sit beside the left leg	Palm presses along the back of the right leg from the ankle to the buttock	1 minute	Masseuse	
20.		Sit facing back	<b>The back</b> Double palms press on the lower back at the waist and the hip in the rhythm of 1-2-1	0.5 minute	Masseuse	
21.		Sit facing back	Thumbs press along two lines of the back for 2 times each line <ul style="list-style-type: none"> <li>• 1<sup>st</sup> line is along the edge of the spinal cord</li> <li>• 2<sup>nd</sup> line is one finger based apart from the 1<sup>st</sup> line</li> </ul>	5 minutes	Masseuse	
22.		Sit facing back	Double palms press along the back, the shoulder and the top of the arms	1 minute	Masseuse	
23.		Sit facing buttocks	Bend the left leg upward and palm presses on the lower in the rhythm of 1-2-1	1 minute	Masseuse	
24.		Sit facing buttocks	Bend the right leg upward and palm presses on the lower back in the rhythm of 1-2-1	1 minute	Masseuse	
0.	Assessment the pain intensity	-	Client is asked to rate the average intensity of his/her back pain intensity by VAS	2 minute	Researcher	The VAS questionnaire & a pen

## THE SMGO PROTOCOL (THAI VERSION)

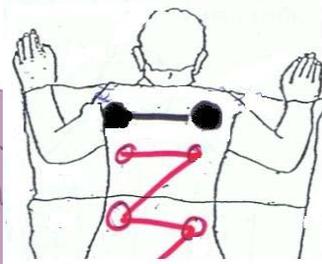
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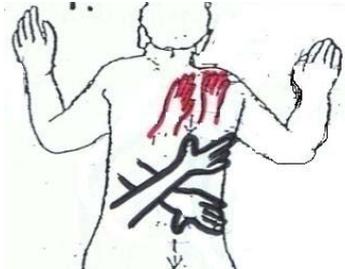
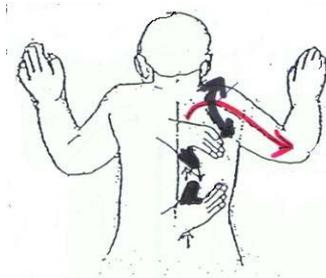
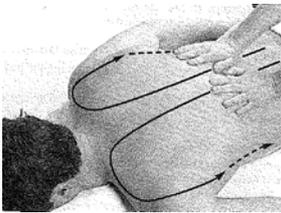
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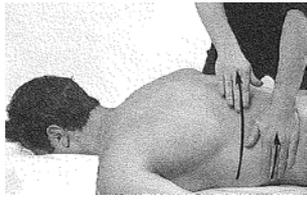
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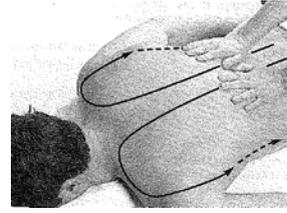
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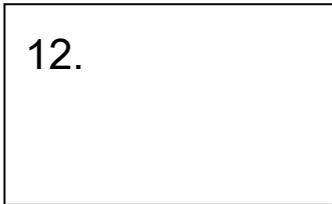
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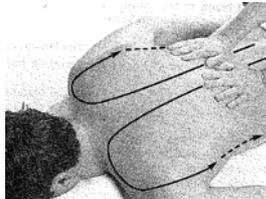


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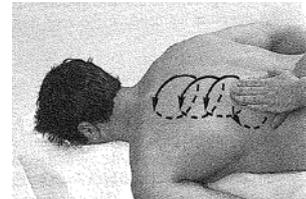
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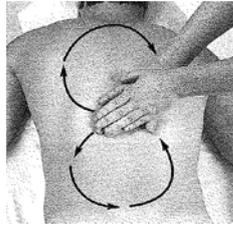


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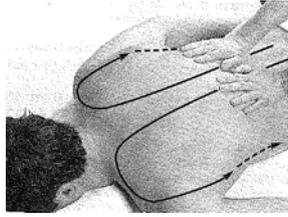
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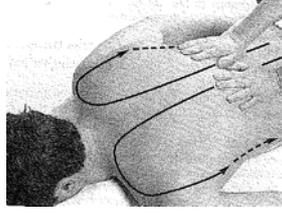


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Cupping)

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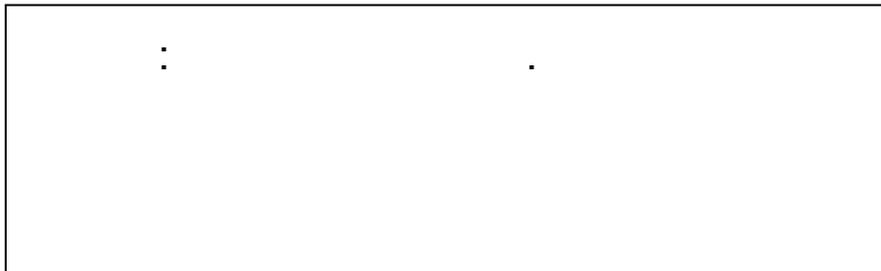
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Goldberg, L. (2001). *Massage and aromatherapy*.(2nd ed.). United Kingdom:

# THE TTM PROTOCOL (THAI VERSION)

(Tangtrongchir, 1992)

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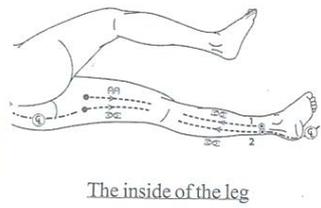
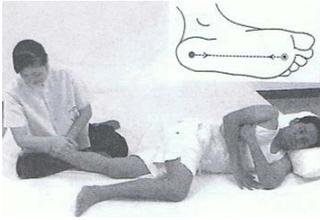


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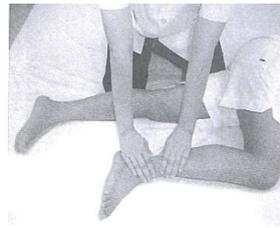
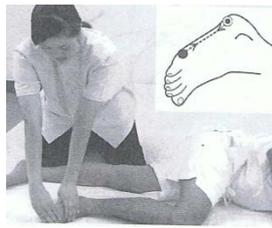
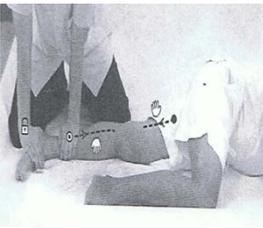


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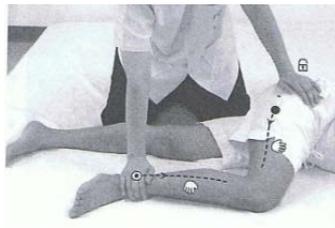
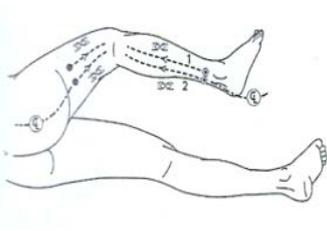


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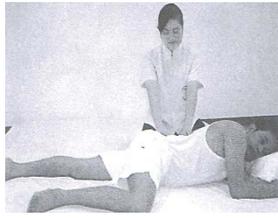
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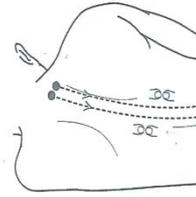
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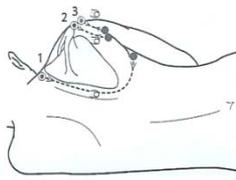


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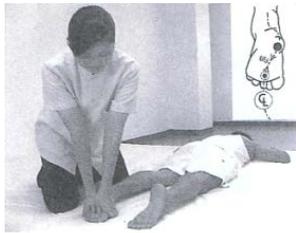
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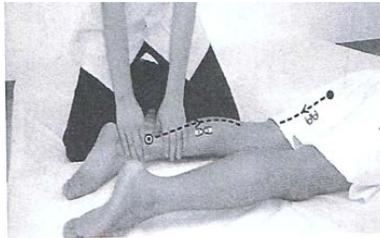
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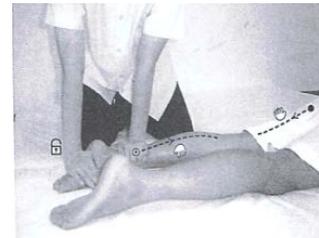
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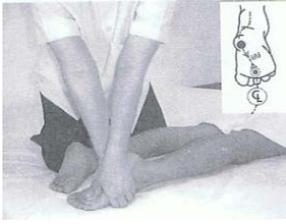
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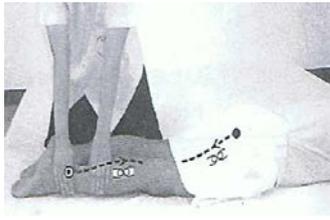
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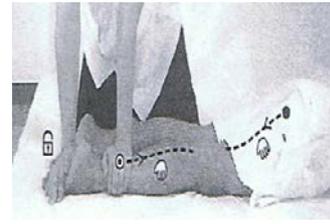
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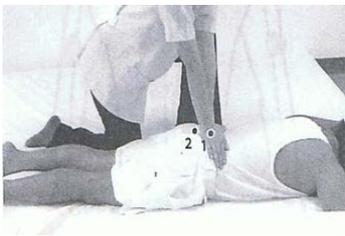
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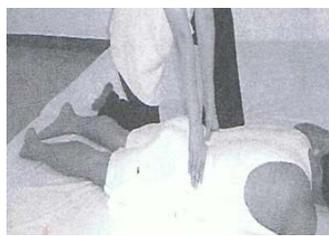
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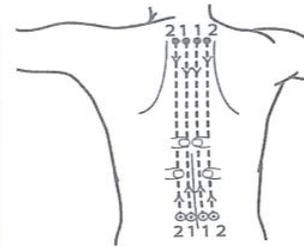
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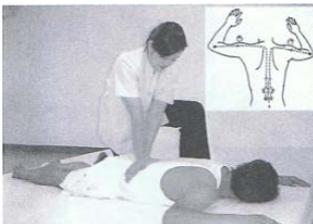
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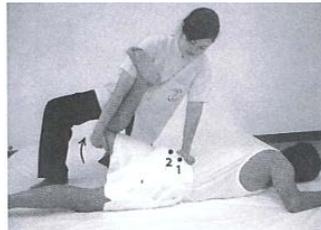
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**Assessment of massage protocols**

Swedish massage with aromatic ginger oil protocol (The treatment group)						Reasons of rating score
Items of assessment	1 Poor	2 Fair	3 Average	4 good	5 Excellent	
The procedure is clear and practical						
The stages are appropriate						
The sequences is suitable						
Traditional Thai massage protocol (The control group)						Reasons of rating score
Items of assessment	1 Poor	2 Fair	3 Average	4 good	5 Excellent	
The procedure is clear and practical						
The stages are appropriate						
The sequences are suitable						

Other Comments.....

Thank you for your assessment

Netchanok Sritoomma (Nok)

Expert Signature & Name

.....

## Assessment of massage protocols

### The assessment of massage protocols

Swedish massage with aromatic ginger oil protocol (The treatment group)						Reasons of rating score
Items of assessment	1 Poor	2 Fair	3 Average	4 Good	5 Excellent	
The procedure is clear and practical					X	<i>Very detailed protocol. Timing and number of strokes and rhythm of massage may be challenging for the masseuse. But, it is essential to have the detail to answer the research question.</i>
The stages is appropriate					X	<i>The series of techniques follows standard "five-stroke" Swedish massage sequencing.</i>
The sequences is suitable					X	<i>Sequence is logical and follows standard Swedish massage order of strokes.</i>
Traditional Thai massage protocol (The control group)						Reasons of rating score
Items of assessment	1 Poor	2 Fair	3 Average	4 Good	5 Excellent	
The procedure is clear and practical					X	<i>Good detail. Including the lines of the legs and back is important to be true to Traditional Thai massage style.</i>
The stages is appropriate					X	<i>The progression from the legs to the back follows a rational order. Points, sen lines, and major muscles of the back, hip, and legs are addressed in the massage.</i>
The sequences is suitable					X	<i>The sequence is practical, sensible, and could be easily replicated.</i>

Other Comments: *Well done. Good attention to detail in the protocol and the measurements. Both protocols follow typical sequences and address the important superficial muscles of the back. Since many studies have found no difference between aromatherapy massage and "regular" massage, there are citations available to support the selection of an aromatic oil. If ginger root essential oil is used, part of the effects of the Swedish massage could be attributed to aromatherapy rather than the massage. However, the researcher should be prepared to evaluate a possible confounder due to the ginger oil. Both sequences contain protocols that are logical and could be replicated in professional practice.*

Thank you for your assessment

Netchanok Sritoomma (Nok)

Expert Signature & Name

  
 Virginia S. Cowen, PhD, LMT  
 Associate Professor, Massage Therapy Program  
 Queensborough Community College  
 The City University of New York



### Demographic Information Questionnaire

**All information will remain strictly confidential**

(Please “√” the appropriate response and/or fill the blank.

**Part I. Personal background and health status**

1.	Gender	<input type="checkbox"/> <input type="checkbox"/>	(1) Female (2) Male
2.	Marital status	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	(1) Single (2) Married (3) Separated (4) Divorced (5) Widowed (6) Other (Specify.....)
3.	Educational level (State the highest level you achieved)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	(1) No education (2) Primary school (3) Secondary school (4) High school (5) University (6) Other (Specify.....)
4.	Occupation	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	(1) Agriculture (2) Labourer (3) Officer (4) Business (5) Teaching profession (6) Health profession (7) Other (Specify.....)
5.	Exercise (Do you undertake regular exercise?)	<input type="checkbox"/> <input type="checkbox"/>	(1) Yes How many times per week (Specify .....) (2) No
6.	Home address & Phone number		..... ..... ..... Phone No. ....

## Part II. Back pain characteristics

1.	Cause of chronic low back pain (Tick one or more boxes)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	(1) Heavy lifting (2) Wrong posture (3) Sitting for long hours (4) Working long hours per day (5) Type of job (specify.....) (6) Aging (7) Diseases (specify.....) (8) Other (Specify.....)
2.	Duration of current back pain episode (months)	<input type="checkbox"/> <input type="checkbox"/>	(1) Less than 3 months (2) 3 months or more
3.	Average duration of each episode of back pain (weeks)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	(1) Less than 1week (2) 1-4 weeks (3) 5-8 weeks (4) 9-12 weeks (5) More than 12 weeks
4.	Position of back pain	<input type="checkbox"/> <input type="checkbox"/>	(1) Upper back (the bottom of neck to the top of lumbar spine-the waist) (2) Lower back (lumbar spine-the waist to the sacral area)
7.	Previous type of treatments for low back pain (After you were sick with lower back pain)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	(1) Western Medicine by a medical practitioner (2) Surgery (3) Buying medicines from a pharmacy (4) Buying medicines from a non-pharmacy (6) Massage (Specify.....) (7) Acupuncture (8) Herbs (9) Exercises (10) Other (Specify.....)
8.	Current treatments (Are you currently on any treatment? Tick all that apply.)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	(1) Western Medicines by a medical practitioner (2) Buying medicines from a pharmacy (3) Buying medicines from a non-pharmacy (4) Another type of Massage (Specify.....) (5) Acupuncture (6) Herbs (7) Exercises (8) Other (Specify.....)

## MEDICATION AND ADVERSE EFFECTS MONITORING

For 1<sup>st</sup> & 2<sup>nd</sup> follow-up assessment only

### Use of medications

1.	<p>Current treatments (Are you currently on any treatment? Tick all that apply.)</p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<p>(1) Western Medicines by a medical practitioner (2) Buying medicines from a pharmacy (3) Buying medicines from a non-pharmacy (4) Another type of Massage (Specify.....) (5) Acupuncture (6) Herbs (7) Exercises (8) Other (Specify.....)</p>
2.	<p>During the last months how often have you taken any type of pain medication to relieve your back pain</p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<p>(1) Never (2) 1-2 times a week (3) 3-4 times a week (4) 5-6 times a week (5) Daily</p>
3.	<p>If you have taken pain medications, please write the names of drugs and dose of each drug in the left side</p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<p>(1) ..... (2) ..... (3) ..... (4) .....</p>
4.	<p>Do you have any side effect while massaging or after massaging</p>	<input type="checkbox"/> <input type="checkbox"/>	<p>(1) Yes (Specify.....) (2) No</p>

## แบบสอบถาม

เรื่อง ประสิทธิภาพของการวัดในการลดอาการปวดหลังในผู้สูงอายุที่มีอาการปวดหลังช่วงล่างเรื้อรัง: การทดลองแบบสุ่ม

คำชี้แจง แบบสอบถามชุดนี้ประกอบด้วย 5 ส่วน

ส่วนที่ 1 แบบบันทึกข้อมูลทั่วไป

ส่วนที่ 2 แบบประเมินความปวด

ส่วนที่ 3 แบบประเมินผลกระทบต่ออาการปวดหลังในชีวิตประจำวัน

ส่วนที่ 4 แบบประเมินสุขภาพและความผาสุก

ส่วนที่ 5 แบบประเมินความเครียดในผู้สูงอายุไทย

## ส่วนที่ 1.1 แบบบันทึกข้อมูลทั่วไป

โปรด กาเครื่องหมาย “√” ลงใน  หรือเติมข้อความในช่องว่างที่เว้นไว้ให้ตรงกับความเป็นจริง  
ข้อมูลของท่านในการวิจัยครั้งนี้จะเก็บเป็นความลับ

1.	เพศ	<input type="checkbox"/>	(1) หญิง
		<input type="checkbox"/>	(2) ชาย
2.	สถานภาพสมรส	<input type="checkbox"/>	(1) โสด
		<input type="checkbox"/>	(2) สมรส
		<input type="checkbox"/>	(3) แยกกันอยู่
		<input type="checkbox"/>	(4) หย่า
		<input type="checkbox"/>	(5) หม้าย
		<input type="checkbox"/>	(6) อื่นๆ (ระบุ.....)
3.	ระดับการศึกษาสูงสุดของท่าน	<input type="checkbox"/>	(1) ไม่ได้รับการศึกษา
		<input type="checkbox"/>	(2) ประถมศึกษา
		<input type="checkbox"/>	(3) มัธยมศึกษาตอนต้น
		<input type="checkbox"/>	(4) มัธยมศึกษาตอนปลาย
		<input type="checkbox"/>	(5) ปริญญาตรี
		<input type="checkbox"/>	(6) สูงกว่าปริญญาตรี
4.	อาชีพ	<input type="checkbox"/>	(1) เกษตรกรรม (ระบุ.....)
		<input type="checkbox"/>	(2) รับจ้าง (ระบุ.....)
		<input type="checkbox"/>	(3) เจ้าหน้าที่สำนักงาน
		<input type="checkbox"/>	(4) ธุรกิจส่วนตัว
		<input type="checkbox"/>	(5) ครู อาจารย์
		<input type="checkbox"/>	(6) บุคลากรทางการแพทย์
		<input type="checkbox"/>	(7) อื่นๆ (ระบุ.....)

5	ท่านออกกำลังกายสม่ำเสมอหรือไม่	<input type="checkbox"/> <input type="checkbox"/>	(1) ใช่ ออกกำลังกายก็ครั้งต่อสัปดาห์ (ระบุ.....) (2) ไม่ใช่
6.	ที่อยู่ปัจจุบัน และ เบอร์โทรศัพท์ของท่าน		..... ..... เบอร์โทรศัพท์ .....

### ส่วนที่ 1.2 ข้อมูลเกี่ยวกับลักษณะอาการปวดหลัง

1.	ท่านคิดว่าข้อใดคือ สาเหตุของอาการปวดหลังของท่าน (ตอบได้มากกว่า 1 ข้อ)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	(1) ยกของหนัก (2) ผิดท่า (3) นั่งทำเดียนานๆ (4) ทำงานหนัก (5) ลักษณะของงานที่ทำ (ระบุ.....) (6) ความชรา (7) โรค/ความเจ็บป่วย (ระบุ.....) (8) อื่นๆ (ระบุ .....
2.	ท่านเริ่มมีอาการปวดหลังเมื่อไร (เดือน)	<input type="checkbox"/> <input type="checkbox"/>	(1) น้อยกว่า 3 เดือน (2) มากกว่า 3 เดือน
3.	ระยะเวลาโดยเฉลี่ยที่ท่านมีอาการปวดหลังในแต่ละครั้ง (สัปดาห์)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	(1) น้อยกว่า 1 สัปดาห์ (2) 1-4 สัปดาห์ (3) 5-8 สัปดาห์ (4) 9-12 สัปดาห์ (5) มากกว่า 12 สัปดาห์
4.	ตำแหน่งที่ปวด	<input type="checkbox"/> <input type="checkbox"/>	(1) หลังส่วนบน (ต้นคอไปถึงเอว) (2) หลังส่วนล่าง (เอวไปถึงกระดูกกระเบนเหน็บ)
5.	ก่อนหน้าที่ท่านจะเข้ารับบริการการนัดบำบัดครั้งนี้ ท่านได้ใช้วิธีการรักษาแบบใดมาก่อน (ตอบได้มากกว่า 1 ข้อ)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	(1) การรักษาด้วยยาโดยแพทย์แผนปัจจุบัน (2) การผ่าตัด (3) ซั้อยารับประทานเองจากร้านขายยา (4) ซั้อยารับประทานเองจากร้านทั่วไป (5) นวด (ระบุชนิดการนวด .....) ) (6) การฝังเข็ม (7) สมุนไพร (8) การออกกำลังกาย (9) อื่นๆ (ระบุ .....

6.	<p>ขณะนี้ท่านได้ใช้การรักษาอื่นร่วมกับการ การนวดบำบัดหรือไม่ หากใช้วิธีอื่นร่วม ด้วย ท่านใช้วิธีใดบ้าง (ตอบได้มากกว่า 1 ข้อ)</p>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<p>(1) การรักษาด้วยยาโดยแพทย์แผนปัจจุบัน  (2) ซื้อยารับประทานเองจากร้านขายยา  (3) ซื้อยารับประทานเองจากร้านทั่วไป  (4) นวด (ระบุชนิดการนวด .....)  (5) การฝังเข็ม  (6) สมุนไพร  (7) การออกกำลังกาย  (8) อื่นๆ (ระบุ .....)</p>
7	<p>หากท่านใช้ยาตลอดปอดในการรักษา ร่วมกับกับการนวด โปรดระบุชื่อและ จำนวนยาที่ใช้ต่อวัน ในช่องซ้ายมือ</p>		<p>(1) .....  (2) .....  (3) .....  (4) .....  (5) .....</p>

## APPENDIX E: BACK PAIN INTENSITY QUESTIONNAIRES

Questionnaire No. 2

### Short-Form McGill Pain Questionnaire

**Instructions:** Since you have reported that one of your problems is **physical pain**, the purpose of this checklist is for you to give us an idea about what your **physical pain feels like**. Each of the words in the left column describes a **quality or characteristic** that pain can have. Therefore, for **each pain quality** in the left column, check the **number** in that row that tells how much of that specific quality your pain has. *Rate every pain quality.*

Pain Quality	None (0)	Mild (1)	Moderate (2)	Severe (3)
Throbbing				
Shooting				
Stabbing				
Sharp				
Cramping				
Gnawing				
Hot-burning				
Aching				
Heavy				
Tender				
Splitting				
Tiring-exhausting				
Sickening				
Fearful				
Punishing-cruel				

A. Please make an "X" on the line below to show how bad your pain is right now.  
 No pain (0) \_\_\_\_\_ (100) Worst possible pain

B. Please check the one descriptor below that best describes your present pain.

- 0 No pain
- 1 Mild
- 2 Discomforting
- 3 Distressing
- 4 Horrible
- 5 Excruciating

## Visual Analog Scale (VAS)

Date...../...../.....

Code.....

Session..... Week of massaging .....

### Pre-treatment

A. Please make an "X" on the line below to show how bad your pain is right now.

No pain (0) \_\_\_\_\_ (100) Worst possible pain

### Post-treatment

A. Please make an "X" on the line below to show how bad your pain is right now.

No pain (0) \_\_\_\_\_ (100) Worst possible pain

## ส่วนที่ 2 แบบประเมินความปวด

คำชี้แจง: แบบประเมินความปวด แบ่งเป็น 3 ส่วน

1. ประเมินลักษณะความปวด ให้ท่านลงคะแนนลักษณะความปวดที่ตรงกับความรู้สึกของท่านมากที่สุด (ตารางลักษณะความปวด)
2. กากบาท "x" บนแบบวัดระดับความปวดของท่าน ตั้งแต่ไม่ปวด (0 คะแนน) จนถึง ปวดมากจนทนไม่ได้ (100 คะแนน)
3. กากบาท "x" บอกระดับอาการปวดของท่านในขณะนี้

### 1. ตารางลักษณะความปวด

ลักษณะของความปวด	ไม่ปวด/ไม่รู้สึก (0)	ปวด/รู้สึกน้อย ไม่รบกวน ชีวิตประจำวัน (1)	ปวด/รู้สึกปานกลาง รบกวนชีวิตประจำวัน (2)	ปวด/รู้สึกมาก จนทนไม่ได้ (3)
ปวดตื้อๆ				
ปวดจี๊ด				
ปวดเหมือนถูกแทง				
ปวดแปลบ				
ปวดเกร็ง				
ปวดเหมือนถูกแตะ				
ปวดแสบปวดร้อน				
ปวดตื้อๆ				
ปวดหนักๆ				
กดเจ็บ				
ปวดเหมือนแตกเป็นเสี่ยง				
รู้สึกเหนียวล้า				
รู้สึกไม่สบาย				
รู้สึกหวาดกลัวความ เจ็บปวด				
รู้สึกทรมาน				

### 2. แบบวัดระดับความปวด

ให้ "x" บนเส้นลงคะแนนระดับความปวดของท่าน ตั้งแต่ไม่ปวด (0 คะแนน) จนถึง ปวดมากจนทนไม่ได้ (100 คะแนน)

ไม่ปวดเลย \_\_\_\_\_ ปวดมากจนทนไม่ได้  
(0 คะแนน) (100 คะแนน)

### 3. ระดับอาการปวดในขณะนี้

- 0 ไม่ปวด
- 1 ปวดเล็กน้อย
- 2 ปวดพอรำคาญ
- 3 ปวดจนรู้สึกรบกวนการดำเนินชีวิต
- 4 ปวดจนทุกข์ทรมาน

## แบบวัดความปวดหลัง

วันที่...../...../.....

Code.....

ขนาดครั้งที่..... สัปดาห์ที่.....

### ก่อนการวัด

ให้ "x" บนเส้นลงคะแนนระดับความปวดของท่าน ตั้งแต่ไม่ปวด (0 คะแนน) จนถึง ปวดมากจนทนไม่ได้ (100 คะแนน)

ไม่ปวดเลย (0) (0 คะแนน) | (100) ปวดมากจนทนไม่ได้ (100 คะแนน)

### หลังการวัด

ให้ "x" บนเส้นลงคะแนนระดับความปวดของท่าน ตั้งแต่ไม่ปวด (0 คะแนน) จนถึง ปวดมากจนทนไม่ได้ (100 คะแนน)

ไม่ปวดเลย (0) (0 คะแนน) | (100) ปวดมากจนทนไม่ได้ (100 คะแนน)

# APPENDIX F: OSWESTRY LOW BACK PAIN QUESTIONNAIRE

Questionnaire No. 3

## Oswestry Low Back Pain Questionnaire

Please read and "✓" the appropriate response and/or fill the blank.

This questionnaire has been designed to Tell us information as to how your back pain has affected your ability to manage in everyday life – please answer every section, & mark in each one

Only tick the *one box* which applies to you. We realise you may consider that 2 statements in any 1 section relate to you, but please *just mark the box which most closely describes your problem*

### Section 1 - pain intensity

- I can tolerate the pain I have without having to use pain killers
- the pain is bad but I manage without taking pain killers
- pain killers give complete relief from pain
- pain killers give moderate relief from pain
- pain killers give very little relief from pain
- pain killers have no effect on the pain and I do not use them

### Section 2 - personal care (washing, dressing, etc)

- I can look after myself normally without causing extra pain
- I can look after myself normally but it causes extra pain
- it is painful to look after myself and I am slow and careful
- I need some help but manage most of my personal care
- I need help every day in most aspects of self care
- I do not get dressed, wash with difficulty and stay in bed

### Section 3 - lifting

- I can lift heavy weights without extra pain
- I can lift heavy weights but it gives extra pain
- pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, eg on a table
- pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
- I can lift only very light weights
- I cannot lift or carry anything at all

### Section 4 - walking

- pain does not prevent me walking any distance
- pain prevents me walking more than 1 mile
- pain prevents me walking more than 1/2 mile
- pain prevents me walking more than 1/4 mile
- I can only walk using a stick or crutches
- I am in bed most of the time and have to crawl to the toilet

### Section 5 - sitting

- I can sit in any chair as long as i like
- I can only sit in my favourite chair as long as i like
- pain prevents me from sitting more than 1 hour
- pain prevents me from sitting more than 1/2 hour
- pain prevents me from sitting more than 10 minutes
- pain prevents me from sitting at all

### Section 6 - standing

- I can stand as long as I want without extra pain
- I can stand as long as I want but it gives me extra pain
- pain prevents me from standing for more than 1 hour
- pain prevents me from standing for more than 1/2 hour
- pain prevents me from standing for more than 10 minutes
- pain prevents me from standing at all

### Section 7 - sleeping

- pain does not prevent me from sleeping well
- I can sleep well only by using tablets
- even when I take tablets I have less than six hours sleep
- even when I take tablets I have less than four hours sleep
- even when I take tablets I have less than two hours sleep
- pain prevents me from sleeping at all

### Section 8 - sex life

- my sex life is normal and causes no extra pain
- my sex life is normal but causes some extra pain
- my sex life is nearly normal but is very painful
- my sex life is severely restricted by pain
- my sex life is nearly absent because of pain
- pain prevents any sex life at all

### Section 9 - social life

- my social life is normal and gives me no extra pain
- my social life is normal but increases the degree of pain
- pain has no significant effect on my social life apart from limiting my more energetic interests, eg dancing etc
- pain has restricted social life and I do not go out as often
- pain has restricted my social life to my home
- I have no social life because of pain

### Section 10 - travelling

- I can travel anywhere without extra pain
- I can travel anywhere but it gives me extra pain
- pain is bad but I manage journeys over two hours
- pain restricts me to journeys of less than one hour
- pain restricts me to short necessary journeys of less than 1/2 hour
- pain prevents me from travelling except to the doctor or hospital

Comments.....  
.....

## Oswestry Low Back Pain Disability Questionnaire

Sources: Fairbank JCT & Pynsent, PB (2000) The Oswestry Disability Index. *Spine*, 25(22):2940-2953.

Davidson M & Keating J (2001) A comparison of five low back disability questionnaires: reliability and responsiveness. *Physical Therapy* 2002;82:8-24.

*The Oswestry Disability Index (also known as the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability. The test is considered the 'gold standard' of low back functional outcome tools*

### Scoring instructions

For each section the total possible score is 5: if the first statement is marked the section score = 0; if the last statement is marked, it = 5. If all 10 sections are completed the score is calculated as follows:

**Example: 16 (total scored)**

50 (total possible score) x 100 = 32%

**If one section is missed or not applicable the score is calculated:**

16 (total scored)

45 (total possible score) x 100 = 35.5%

**Minimum detectable change (90% confidence): 10% points (change of less than this may be attributable to error in the measurement)**

<b>Interpretation of scores</b> 0% to 20%: minimal disability:	The patient can cope with most living activities. Usually no treatment is indicated apart from advice on lifting sitting and exercise.
21%-40%: moderate disability:	The patient experiences more pain and difficulty with sitting, lifting and standing. Travel and social life are more difficult and they may be disabled from work. Personal care, sexual activity and sleeping are not grossly affected and the patient can usually be managed by conservative means.
41%-60%: severe disability:	Pain remains the main problem in this group but activities of daily living are affected. These patients require a detailed investigation.
61%-80%: crippled:	Back pain impinges on all aspects of the patient's life. Positive intervention is required.
81%-100%:	These patients are either bed-bound or exaggerating their symptoms.

### ส่วนที่ 3 แบบประเมินผลกระทบบทอาการปวดหลังในชีวิตประจำวัน

**คำชี้แจง** กรุณาตอบแบบสอบถามทุกข้อโดยทำเครื่องหมาย “√” ลงใน  เพียงช่องเดียวที่สามารถอธิบายอาการได้ใกล้เคียงกับอาการของท่านมากที่สุด

#### 1. ความรุนแรงของอาการปวด

- อาการปวดของฉันพอทนได้โดยไม่ต้องใช้ยา
- อาการปวดของฉันแย่มาก แต่ฉันก็จัดการได้โดยไม่ต้องใช้ยา
- ยาแก้ปวดช่วยลดอาการปวดได้ทั้งหมด
- ยาแก้ปวดช่วยลดอาการปวดได้บางส่วน (ประมาณครึ่งหนึ่ง)
- ยาแก้ปวดช่วยลดอาการปวดได้เล็กน้อย
- ยาแก้ปวดไม่ช่วยลดอาการปวดและฉันไม่ได้ใช้ยาแก้ปวดนั้น

#### 2. การดูแลตัวเองในชีวิตประจำวัน (อาบน้ำ, แต่งตัว เป็นต้น)

- ฉันสามารถอาบน้ำ, แต่งตัว ได้เหมือนปกติโดยไม่ต้องทำให้อาการปวดมากขึ้น
- ฉันสามารถอาบน้ำ, แต่งตัว ได้เหมือนปกติแต่ทำให้มีอาการปวดเกิดขึ้น
- ฉันสามารถอาบน้ำ, แต่งตัว ได้แต่ต้องเป็นไปอย่างช้า ๆ และระมัดระวัง เพราะ ทำให้มีอาการปวด
- ฉันสามารถอาบน้ำ, แต่งตัว ได้แต่ต้องมีผู้ช่วยเหลือบ้างบางส่วน
- ฉันสามารถอาบน้ำ, แต่งตัว ได้แต่ต้องมีผู้ช่วยเหลือเกือบทั้งหมด
- ฉันไม่สามารถอาบน้ำ, แต่งตัว ได้เอง และต้องอยู่แต่บนเตียง

#### 3. การยกของ

- ฉันสามารถยกของหนักได้โดยไม่ต้องมีอาการปวดมากขึ้น
- ฉันสามารถยกของหนักได้แต่ทำให้เกิดอาการปวดมากขึ้น
- ฉันไม่สามารถยกของหนักจากพื้นได้ แต่ถ้าของหนักอยู่สูงระดับโต๊ะฉันจะสามารถยกของหนักนั้นได้
- ฉันไม่สามารถยกของหนักจากพื้นได้ แต่ถ้าของหนักอยู่สูงระดับโต๊ะ ฉันจะสามารถยกของได้ แต่น้ำหนักของต้องไม่มากนัก
- ฉันสามารถยกได้แต่ของน้ำหนักเบา ๆ
- ฉันไม่สามารถยกของได้เลย

#### 4. การเดิน

- ฉันสามารถเดินได้ระยะทางเหมือนปกติโดยไม่ต้องมีอาการปวด
- อาการปวดทำให้ฉันสามารถเดินได้ระยะทางไม่เกิน 1.6 กิโลเมตร (ประมาณ 5 ป้ายรถเมล์)
- อาการปวดทำให้ฉันสามารถเดินได้ระยะทางไม่เกิน 800 เมตร (ประมาณ 2 ป้ายรถเมล์)
- อาการปวดทำให้ฉันสามารถเดินได้ระยะทางไม่เกิน 400 เมตร (ประมาณ 1 ป้ายรถเมล์)
- ฉันสามารถเดินได้แต่ต้องใช้เครื่องช่วยเดิน เช่น ไม้เท้า, ไม้ค้ำพุง
- ฉันต้องอยู่แต่บนเตียง แต่ต้องคลานเวลาจะไปห้องน้ำ

## 5. การนั่ง

- ฉันสามารถนั่งได้นานเหมือนปกติโดยไม่มีอาการปวด
- ฉันสามารถนั่งได้นานเหมือนปกติโดยไม่มีอาการปวดเฉพาะเก้าอี้ที่ฉันนั่งเป็นประจำและสบายเท่านั้น
- อาการปวดทำให้ฉันสามารถนั่งได้ไม่เกิน 1 ชั่วโมง
- อาการปวดทำให้ฉันสามารถนั่งได้ไม่เกิน 30 นาที
- อาการปวดทำให้ฉันสามารถนั่งได้ไม่เกิน 10 นาที
- อาการปวดทำให้ฉันไม่สามารถนั่งได้เลย

## 6. การยืน

- ฉันสามารถยืนได้นานเหมือนปกติ โดยไม่มีอาการปวดมากขึ้น
- ฉันสามารถยืนได้นานเหมือนปกติแต่จะทำให้ฉันปวดมากขึ้น
- อาการปวดทำให้ฉันสามารถยืนได้ไม่เกิน 1 ชั่วโมง
- อาการปวดทำให้ฉันสามารถยืนได้ไม่เกิน 30 นาที
- อาการปวดทำให้ฉันสามารถยืนได้ไม่เกิน 10 นาที
- อาการปวดทำให้ฉันไม่สามารถยืนได้เลย

## 7. การนอน

- ฉันสามารถหลับได้เหมือนปกติ โดยไม่มีอาการปวด
- ฉันสามารถหลับได้เหมือนปกติแต่ต้องใช้ยา
- ถึงแม้จะใช้ยาแล้วก็ตามฉันสามารถหลับได้น้อยกว่า 6 ชั่วโมง
- ถึงแม้จะใช้ยาแล้วก็ตามฉันสามารถหลับได้น้อยกว่า 4 ชั่วโมง
- ถึงแม้จะใช้ยาแล้วก็ตามฉันสามารถหลับได้น้อยกว่า 2 ชั่วโมง
- อาการปวดทำให้ฉันไม่สามารถหลับได้เลย

## 8. การมีเพศสัมพันธ์

- ฉันสามารถมีเพศสัมพันธ์ได้เหมือนปกติโดยไม่มีอาการปวดมากขึ้น
- ฉันสามารถมีเพศสัมพันธ์ได้เหมือนปกติแต่จะทำให้ฉันปวดมากขึ้น
- ฉันสามารถมีเพศสัมพันธ์ได้เกือบเหมือนปกติ แต่มีอาการปวดมาก
- ฉันมีเพศสัมพันธ์ได้น้อยมากเพราะอาการปวด
- ฉันปวดมากจนแทบจะไม่สามารถมีเพศสัมพันธ์ได้
- ฉันปวดมากจนไม่สามารถมีเพศสัมพันธ์ได้เลย

### 9. การเข้าสังคม เช่น การไปตลาด ดูหนัง ไปห้างสรรพสินค้า

- ฉันสามารถเข้าสังคมได้เหมือนปกติโดยไม่มีอาการปวดมากขึ้น
- ฉันสามารถเข้าสังคมได้เหมือนปกติโดยมีอาการปวดมากขึ้น
- อาการปวดไม่ได้มีผลต่อการเข้าสังคมของฉันมากนักยกเว้นมีกิจกรรมที่ต้องเคลื่อนไหวมาก เช่น การเดินรำ เล่นกีฬา เป็นต้น
- อาการปวดทำให้ฉันไม่สามารถเข้าสังคมนอกบ้านได้บ่อย ๆ
- อาการปวดทำให้ฉันไม่สามารถเข้าสังคมนอกบ้านได้แต่สามารถมีการเข้าสังคมที่จัดในบ้านได้
- อาการปวดทำให้ฉันไม่สามารถเข้าสังคมได้เลย

### 10. การเดินทาง

- ฉันสามารถเดินทางไป ที่ต่าง ๆ ได้โดยไม่มีอาการปวดมากขึ้น
- ฉันสามารถเดินทางไปที่ต่าง ๆ ได้แต่มีอาการปวดมากขึ้น
- อาการปวดของฉันแย่มาก แต่ฉันก็สามารถจัดการได้ และเดินทางได้มากกว่า 1 ชั่วโมง
- อาการปวดทำให้ฉันสามารถเดินทางไปที่ต่าง ๆ ได้น้อยกว่า 1 ชั่วโมง
- อาการปวดทำให้ฉันสามารถเดินทางไปใกล้ ๆ ได้ที่ใช้เวลาน้อยกว่า 30 นาที
- ฉันไม่สามารถเดินทางไปที่ต่าง ๆ ได้ ยกเว้นไปพบแพทย์ หรือ ไปโรงพยาบาล

# APPENDIX G: QUALITY OF LIFE QUESTIONNAIRE

## (SF-12V2 HEALTH SURVEY)

Questionnaire No. 4

### SF-12v2 Health Survey

Instructions: Please tick “√” the answer in the answer choice that best describes how do you feel

1. In general, would you say your health is :
- Excellent  
 Very good  
 Good  
 Fair  
 Poor
2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?
- |  | Yes,<br>limited<br>a lot | Yes,<br>limited<br>a little | No, not<br>limited<br>at all |
|--|--------------------------|-----------------------------|------------------------------|
| a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | <input type="checkbox"/> | <input type="checkbox"/>    | <input type="checkbox"/>     |
| b. Climbing several flights of stairs  | <input type="checkbox"/> | <input type="checkbox"/>    | <input type="checkbox"/>     |
3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?
- |   | All<br>of the<br>time    | Most<br>of the<br>time   | Some<br>of the<br>time   | A little<br>of the<br>time | None<br>of the<br>time   |
|---|--------------------------|--------------------------|--------------------------|----------------------------|--------------------------|
| a. Accomplished less than you would like                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> |
| b. Were limited in the kind of work or other activities | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> |
4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depression or anxious)?
- |   | All<br>of the<br>time    | Most<br>of the<br>time   | Some<br>of the<br>time   | A little<br>of the<br>time | None<br>of the<br>time   |
|---|--------------------------|--------------------------|--------------------------|----------------------------|--------------------------|
| a. Accomplished less than you would like            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> |
| b. Did work or activities less carefully than usual | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>   | <input type="checkbox"/> |

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- Not at all
- A little bit
- Moderate
- Quite a bit
- Extremely

6. These questions are about you how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like	<input type="checkbox"/>				
b. Did you have a lot of energy?	<input type="checkbox"/>				
c. Have you felt downhearted and depressed?	<input type="checkbox"/>				

7. During the past 4 weeks, how much of time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

- All of the time
- Most of the time
- Some of the time
- A little of the time
- None of the time

#### ส่วนที่ 4 แบบประเมินสุขภาพและความผาสุก

คำชี้แจง กรุณาตอบแบบสอบถามทุกข้อโดยทำเครื่องหมาย “√” ลงใน  เพียงช่องเดียวที่ตรงกับความรู้สึกของท่านมากที่สุด

##### 1. โดยทั่วไป คุณจะบอกว่าสุขภาพของคุณ

ดีที่สุด	ดีมาก	ดี	พอใช้	แย่
<input type="checkbox"/>				

##### 2. คำถามต่อไปนี้เป็นคำถามเกี่ยวกับ กิจกรรมที่อาจจะทำในช่วงวันหยุดทั่วๆไป สุขภาพของคุณในตอนนี้ทำให้คุณถูกจำกัดในการทำกิจกรรมเหล่านี้หรือไม่ ถ้าใช่ ถูกจำกัดมากน้อยแค่ไหน

	ใช่ ถูกจำกัดมาก	ใช่ ถูกจำกัดเล็กน้อย	ไม่ใช่ ไม่ถูกจำกัดมาก
a. <u>กิจกรรมที่ใช้แรงปานกลาง</u> เช่น การย้ายโต๊ะ การกวาดพื้น การทำสวน การปั่นจักรยาน หรือการว่ายน้ำ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. การเดินขึ้นบันไดขึ้นตึก 2-3 ชั้น	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. ในช่วง 4 สัปดาห์ที่ผ่านมา บ่อยแค่ไหน ที่คุณมีปัญหาต่างๆ ต่อไปนี้ ในการทำงาน หรือทำกิจกรรมประจำวันอื่นๆ อันเนื่องมาจากสุขภาพทางกายของคุณ
- |   | ตลอดเวลา                 | เป็นส่วนใหญ่             | เป็นบางครั้ง             | นานๆครั้ง                | ไม่เคยเลย                |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a. ทำงานหรือกิจกรรมประจำวันอื่นๆ สำเร็จได้น้อยกว่าเท่าที่คุณต้องการ | <input type="checkbox"/> |
| b. ถูกจำกัดชนิดของงานหรือกิจกรรมที่คุณสามารถทำได้                   | <input type="checkbox"/> |

4. ในช่วง 4 สัปดาห์ที่ผ่านมา บ่อยแค่ไหน ที่คุณมีปัญหาต่างๆ ต่อไปนี้ ในการทำงาน หรือทำกิจกรรมประจำวันอื่นๆ อันเนื่องมาจากปัญหาด้านอารมณ์ (เช่น รู้สึกซึมเศร้า หรือวิตกกังวล)
- |   | ตลอดเวลา                 | เป็นส่วนใหญ่             | เป็นบางครั้ง             | นานๆครั้ง                | ไม่เคยเลย                |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a. ทำงานหรือกิจกรรมประจำวันอื่นๆ สำเร็จได้น้อยกว่าเท่าที่คุณต้องการ | <input type="checkbox"/> |
| b. ทำงานหรือกิจกรรมอื่นๆ ด้วยความระมัดระวังน้อยกว่าปกติ             | <input type="checkbox"/> |

5. ในช่วง 4 สัปดาห์ที่ผ่านมา ความเจ็บปวดมีผลรบกวนการทำงานตามปกติของคุณ (ทั้งงานนอกบ้านและงานบ้าน) มากน้อยแค่ไหน

ไม่เคย	เล็กน้อย	ปานกลาง	ค่อนข้างมาก	มากที่สุด
<input type="checkbox"/>				

6. คำถามต่อไปนี้จะถามเกี่ยวกับว่าคุณรู้สึกอย่างไร และคุณเป็นอย่างไร ในช่วง 4 สัปดาห์ที่ผ่านมา แต่ละคำถามต่อไปนี้ โปรดเลือกเพียงคำตอบเดียว ที่ใกล้เคียงกับความรู้สึกของคุณมากที่สุด
- ในช่วง 4 สัปดาห์ที่ผ่านมา บ่อยแค่ไหน ที่...

- |                               | ตลอดเวลา                 | เป็นส่วนใหญ่             | เป็นบางครั้ง             | นานๆครั้ง                | ไม่เคยเลย                |
|-------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| a. คุณรู้สึกใจเย็นและสงบ      | <input type="checkbox"/> |
| b. คุณรู้สึกเต็มไปด้วยพลัง    | <input type="checkbox"/> |
| c. คุณรู้สึกท้อแท้และซึมเศร้า | <input type="checkbox"/> |

7. ในช่วง 4 สัปดาห์ที่ผ่านมา บ่อยแค่ไหน ที่สุขภาพทางกายหรือปัญหาด้านอารมณ์ของคุณ มีผลรบกวนกิจกรรมทางสังคมของคุณ (เช่น การไปเยี่ยมเพื่อน หรือญาติมิตร เป็นต้น)

ไม่เคย	เล็กน้อย	ปานกลาง	ค่อนข้างมาก	มากที่สุด
<input type="checkbox"/>				

## APPENDIX H: GERIATRIC DEPRESSION QUESTIONNAIRE

Questionnaire No. 5

### Geriatric Depression Scale (Short form)

Instructions: Please circle “○” the answer in the answer choice that best describes how do you feel

- |   |     |    |
|---|-----|----|
| 1. Are you basically satisfied with your life                             | YES | NO |
| 2. Have you dropped many of your activities and interests?                | YES | NO |
| 3. Do you feel that your life is empty?                                   | YES | NO |
| 4. Do you often get bored?  | YES | NO |
| 5. Are you in good spirits most of the time?                              | YES | NO |
| 6. Are you afraid that something bad is going to happen to you?           | YES | NO |
| 7. Do you feel happy most of the time?                                    | YES | NO |
| 8. Do you often feel helpless?  | YES | NO |
| 9. Do you prefer to stay at home, rather than going out and doing things? | YES | NO |
| 10. Do you feel that you have more problems with memory than most?        | YES | NO |
| 11. Do you think it is wonderful to be alive now?                         | YES | NO |
| 12. Do you feel worthless the way you are now?                            | YES | NO |
| 13. Do you feel full of energy?   | YES | NO |
| 14. Do you feel that your situation is hopeless?                          | YES | NO |
| 15. Do you think that most people are better off than you are?            | YES | NO |

Total Score.....

ส่วนที่ 5 แบบวัดความเศร้าในผู้สูงอายุไทย

**คำชี้แจง** โปรดอ่านข้อความในแต่ละข้ออย่างละเอียด และประเมินความรู้สึกของท่านในช่วงเวลาหนึ่งสัปดาห์ที่ผ่านมา  
 ทำเครื่องหมาย “○” ลงในช่องที่ตรงกับ “ใช่” ถ้าข้อความในข้อนั้นตรงกับความรู้สึกของท่าน  
 ทำเครื่องหมาย “○” ลงในช่องที่ตรงกับ “ไม่ใช่” ถ้าข้อความในข้อนั้นไม่ตรงกับความรู้สึกของท่าน

- |  |     |        |
|--|-----|--------|
| 1. คุณพอใจกับชีวิตความเป็นอยู่ตอนนี้                             | ใช่ | ไม่ใช่ |
| 2. คุณไม่อยากทำในสิ่งที่เคยสนใจหรือเคยทำเป็นประจำ                | ใช่ | ไม่ใช่ |
| 3. คุณรู้สึกชีวิตของคุณช่วงนี้ว่างเปล่าไม่รู้จะทำอะไร            | ใช่ | ไม่ใช่ |
| 4. คุณรู้สึกเบื่อหน่ายบ่อยๆ                                      | ใช่ | ไม่ใช่ |
| 5. ส่วนใหญ่แล้วคุณรู้สึกอารมณ์ดี                                 | ใช่ | ไม่ใช่ |
| 6. คุณรู้สึกกลัวว่าจะมีเรื่องไม่ดีเกิดขึ้นกับคุณ                 | ใช่ | ไม่ใช่ |
| 7. ส่วนใหญ่คุณรู้สึกมีความสุข                                    | ใช่ | ไม่ใช่ |
| 8. บ่อยครั้งที่คุณรู้สึกไม่มีที่พึ่ง                             | ใช่ | ไม่ใช่ |
| 9. คุณชอบอยู่กับบ้านมากกว่าที่จะออกนอกบ้าน                       | ใช่ | ไม่ใช่ |
| 10. คุณคิดว่าความจำของคุณไม่ดีเท่าคนอื่น                         | ใช่ | ไม่ใช่ |
| 11. การที่มีชีวิตอยู่ถึงปัจจุบันนี้ เป็นเรื่องที่น่ายินดีหรือไม่ | ใช่ | ไม่ใช่ |
| 12. คุณรู้สึกว่าชีวิตค่อนข้างไม่มีคุณค่า                         | ใช่ | ไม่ใช่ |
| 13. คุณรู้สึกกระตือรือร้น  | ใช่ | ไม่ใช่ |
| 14. คุณรู้สึกสิ้นหวัง  | ใช่ | ไม่ใช่ |
| 15. คุณคิดว่าคนอื่นดีกว่าคุณ                                     | ใช่ | ไม่ใช่ |

## APPENDIX I: ETHICS APPROVAL

### I. Griffith University Ethical Approval



#### Office For Research

Gold Coast Campus  
Griffith University  
Queensland 4222  
Australia

Telephone +61 (0)7 5552 7226  
Facsimile +61 (0)7 5552 9058

21 March 2011

TO WHOM IT MAY CONCERN

#### Griffith University Human Research Ethics Application – NRS/02/11/HREC

This is to confirm that Human Research Ethics Application NRS/02/11/HREC titled "The effectiveness of Swedish massage with aromatic ginger oil in treating chronic low back pain in older adults: A randomised controlled trial" conducted by Wendy Moyle, Marie Cooke and Netchanok Sritoomma, was approved by the Griffith University Human Research Ethics Committee (HREC) on 14 February 2011. The authorisation for this research was issued from 01 March 2011 to 31 December 2011.

The HREC is constituted and operates in accordance with the *National Statement on Ethical Conduct in Human Research (2007)*.

Please do not hesitate to contact me if you have any further queries about this matter.

Regards



Gary Allen  
Senior Manager, Research Ethics and Integrity  
Office for Research

## II. Thai Ethical Approval



RLC00A1/5A

สำนักงานเลขาธิการคณะกรรมการ  
พิจารณาการศึกษาวิจัยในคน ฯ  
กรมพัฒนาการแพทย์แผนไทยและ  
การแพทย์ทางเลือก ถนนพหลโยธิน 11000

1 กรกฎาคม 2554

เรื่อง อนุมัติให้ดำเนินการศึกษาวิจัย

เรียน คณะคณาจารย์ภาควิชาการศึกษาศาสตร์ มหาวิทยาลัยศรีนครินทรวิโรฒ

สิ่งที่ส่งมาด้วย 1. ผลการพิจารณาโครงการวิจัย (AF 02-008) วันที่ 30 มิ.ย. 2554 - 30 มิ.ย. 2555

2. แบบรายงานความก้าวหน้าของการวิจัย (AF 08-010)
3. แบบรายงานเหตุการณ์ไม่พึงประสงค์ชนิดร้ายแรง (AF 02-018)
4. แบบรายงานส่วนแก้ไขเพิ่มเติมโครงการวิจัย (AF 02-007)
5. แบบรายงานการยุติโครงการวิจัยก่อนกำหนด (AF 01-017)
6. แบบรายงานการวิจัยฉบับสมบูรณ์ (AF 01-014)

ตามที่ ท่าน ได้ส่งโครงการวิจัยเรื่อง “ ประสิทธิภาพของการนวดน้ำมันจึงหอมระเหยในการลด  
อาการปวดหลัง ในผู้สูงอายุที่มีอาการปวดหลังช่วงล่างเรื้อรัง : การทดลองแบบสุ่มเปรียบเทียบกลุ่มข้างคลินิก ”  
ให้คณะกรรมการพิจารณาการศึกษาวิจัยในคนด้านการแพทย์แผนไทยและการแพทย์ทางเลือก พิจารณาความ  
เป็นไปได้และความเหมาะสมในการศึกษาวิจัยในคน นั้น

ในการนี้ คณะกรรมการฯ ได้พิจารณาโครงการวิจัยดังกล่าวแล้ว และมีมติ “ อนุมัติ ”

จึงเรียนมาเพื่อทราบ

ขอแสดงความนับถือ



( นายแพทย์วิรัช โชคดีวัฒน์ )

ประธานกรรมการพิจารณาการศึกษาวิจัยในคน  
ด้านการแพทย์แผนไทยและการแพทย์ทางเลือก

สำนักงานเลขาธิการฯ

โทร / โทรสาร 02-591-6061

### III. The Hospital Permission

AF 04-010

#### หนังสืออนุญาตให้เก็บข้อมูลวิจัยของสถาบันที่ทำการศึกษาวิจัย

ด้วยดิฉัน นางเนตรชนก ศรีทุมมา อาจารย์ประจำคณะพยาบาลศาสตร์ มหาวิทยาลัยคริสเตียน ซึ่งขณะนี้กำลังศึกษาในระดับปริญญาเอก สาขาพยาบาลศาสตร์ ณ มหาวิทยาลัยกรีฟิฟท์ (PhD in Nursing, School of Nursing and Midwifery, Griffith University) เมืองบริสเบน ประเทศออสเตรเลีย ในหัวข้อ วิทยานิพนธ์ (โครงการวิจัย) เรื่อง ประสิทธิภาพของการนวดน้ำมันจึงหอมระเหยในการบำบัดผู้สูงอายุที่มีอาการปวดหลัง: การทดลองเปรียบเทียบกลุ่มทางคลินิก (The effectiveness of Swedish massage with aromatic ginger oil in treating chronic low back pain in older adults: A randomised controlled clinical trial) เพื่อให้ การศึกษาดังกล่าวสำเร็จตามวัตถุประสงค์ จึงใคร่ขออนุญาตเก็บข้อมูลวิจัยในกลุ่มผู้สูงอายุ (60 ปีขึ้นไป) ที่มี อาการปวดหลังตั้งแต่ 3 เดือนขึ้นไป และไม่ได้รับการนวด ภายใน 3 เดือนนับจากวันที่เริ่มเข้าร่วมการวิจัย จำนวน 140 ราย ณ ศูนย์ส่งเสริมสุขภาพแผนไทยและสปา ระหว่างเดือน พฤษภาคม - พฤศจิกายน 2554 ซึ่ง โครงการวิจัยครั้งนี้ได้รับการสนับสนุนจากศูนย์วิจัยปฏิบัติการทางคลินิกและนวัตกรรม มหาวิทยาลัยกรีฟิฟท์ ประเทศออสเตรเลีย (Research Centre for Clinical and Community Practice Innovation, Griffith University) ดังนั้นค่าตอบแทนนักนวดบำบัด ค่าสนับสนุนการดำเนินงาน และ ค่าใช้สถานที่ ณ ศูนย์ส่งเสริมสุขภาพ แพทย์แผนไทยและสปา ตามอัตราที่ท่านเห็นสมควร

หากท่านอนุญาตให้เก็บข้อมูลวิจัยในโรงพยาบาลดำเนินสะดวก จังหวัดราชบุรี โปรดลงนาม ในหนังสือฉบับนี้ ทั้งนี้เพื่อประกอบการพิจารณาการศึกษาวิจัยในคนด้านการแพทย์แผนไทยและการแพทย์ ทางเลือก กรมพัฒนาการแพทย์แผนไทยและการแพทย์ทางเลือก กระทรวงสาธารณสุข

อนุมัติ  
30 ต.พ. 2554

(นายแพทย์สุรติ เล็กอุทัย)

ผู้อำนวยการ โรงพยาบาลดำเนินสะดวก จังหวัดราชบุรี

## APPENDIX J: CERTIFICATE OF ANALYSIS OF AROMATIC OILS

**T. Tangsiamhong Co.,Ltd.**

TEL : +0066-82-098-1677,+0066-2-944-8594  
14 Srimuang-Anusom, Suthisan, Dindaeng,  
Bangkok, 10400, THAILAND

Revision Date: June 14, 2011

<h3 style="margin: 0;">SPECIFICATION</h3> <p style="margin: 0;">Product: Jojoba Oil</p>
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<b>Date</b>	June 14, 2011
<b>Product name</b>	Jojoba Oil
<b>Product type</b>	Pure carrier base oil
<b>INCI name</b>	Simmondsia Chinensis (Jojoba) Seed Oil
<b>CAS No.</b>	61789-91-1
<b>Application</b>	Raw material for the product of cosmetics and household products.
<b>Colour and appearance</b>	Colorless to pale yellow liquid
<b>Odour</b>	Conform
<b>Specific gravity @ 25 °C</b>	0.8622
<b>Refractive Index</b>	1.461
<b>Storage</b>	Keep in cool, preferably at about 20-25 °C dry place and protected from light. Keep containers tightly sealed.
<b>Shelf life</b>	12 months quality should be checked visually & olfactory before each use and fully checked after the shelf life period.

**Note:**

This report pertains only to the sample taken by the lot. This is indicative and may be vary according to the raw material and climate variation.

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Revision Date: **June 14, 2011****Certificate of Analysis**  
**Product: Jojoba Oil**

<b>Common Name</b>	Clear Jojoba Oil
<b>Botanical Name</b>	Simmondsia Chinensis

<b>Characterization</b>	<b>Observed</b>
<b>Melting Point</b>	7 °C
<b>Boiling Point</b>	398 °C
<b>Moisture Contents</b>	< 0.3%
<b>Unsaponifiable Mater</b>	49-53%
<b>Specific Gravity @ 25 °C</b>	0.8622
<b>Refractive Index</b>	1.461
<b>Acid Value</b>	0.35
<b>Iodine Value g/100g</b>	83.51
<b>Peroxide Value mg/kg</b>	0.28
<b>Saponification Value</b>	100.81
<b>Coliform Count (g Negative Bacteria)</b>	Absent/ml

**Note:**

This report pertains only to the sample taken by the lot. This is indicative and may be vary according to the raw material and climate variation.

**CERTIFICATE OF ANALYSIS**

Our order reference : 00417416

Your order reference : 01/09 PC.09216

Date : 21/01/2010

**HH - GINGER OIL**

YOUR PRODUCT CODE : 020076

LOT NUMBER : 0009294009

MANUFACTURING DATE : 2009/02/16

BEST BEFORE : 2011/02/16

PARAMETERS	VALUES	SPECIFICATIONS		METHOD
		Low	High	
SPECIFIC GRAVITY (20/20)	0,8757	0,873	0,884	IDTA.CQ/001
REFRACTIVE INDEX (20)	1,4894	1,485	1,495	IDTA.CQ/002
FLASH POINT (CLOSED CUP)	78 °C			IDTA.CQ/005
COLOR	CONFORM			IDTA.CQ/012
ODOUR	CONFORM			IDTA.CQ/012

Signed : Mara JANOTTIN  
QC Manager

*This is an electronic document and therefore not signed  
Charabot certifies that the quality of this product conforms to our specifications*



# APPENDIX K: SERIOUS ADVERSE EVENT REPORT FORM

AF 02-018

55

## แบบรายงานเหตุการณ์ไม่พึงประสงค์ชนิดร้ายแรง Serious Adverse Event Report Form

รหัสโครงการวิจัย.....  
ชื่อโครงการวิจัย.....  
.....  
.....  
ผู้วิจัย.....  
เบอร์โทรศัพท์..... แหล่งทุน.....  
รหัสผู้เข้าร่วมวิจัย..... เพศ ชาย หญิง อายุ.....

รายละเอียดเหตุการณ์ไม่พึงประสงค์ชนิดร้ายแรง (อาการ/อาการแสดง/การวินิจฉัย/การรักษา/ผลการรักษา)

### ความรุนแรง

- ( ) ตาย (Death)
- ( ) รุนแรงและอาจทำให้เสียชีวิต (Life threatening)
- ( ) ต้องรักษาในโรงพยาบาล (Hospitalization / prolonged hospitalization)
- ( ) พิการหรือทุพพลภาพ (Persistent or significant disability / incapacity)
- ( ) ทารกพิการแต่กำเนิด (Congenital anomaly / birth defect)
- ( ) อื่นๆ (ระบุ).....

### ความเกี่ยวข้องกับอาการ

- ( ) ไม่เกี่ยวข้อง (Not related)       ( ) อาจเกี่ยวข้อง (Possibly related)
- ( ) น่าจะเกี่ยวข้อง (Probable related)       ( ) เกี่ยวข้องแน่นอน (Definitely related)       ( ) ไม่รู้ (Unknown)

การเปลี่ยนแปลงโครงการวิจัย     ( ) ไม่มี     ( ) มี (ระบุรายละเอียด)

การเปลี่ยนแปลงเอกสารเพื่อขอการยินยอม     ( ) ไม่มี     ( ) มี (ระบุรายละเอียด)

ลงชื่อผู้วิจัย..... วันที่รายงาน.....

# APPENDIX L: INFORMATION AND CONSENT FORMS

## Griffith University Letterhead

### INFORMATION SHEET

**Study title: The effectiveness of massage in treating chronic low back pain in older adults: A randomised controlled trial**

**Student investigator:** Netchanok Sritoomma

PhD candidate, School of Nursing and Midwifery/ Research Centre for Clinical & Community Practice Innovation, Griffith Health Institution, Griffith University. Ph. 07-37355253; Email: [n.sritoomma@griffith.edu.au](mailto:n.sritoomma@griffith.edu.au)

**Chief Investigators:** Professor Wendy Moyle

School of Nursing and Midwifery/ Research Centre for Clinical & Community Practice Innovation, Griffith Health Institution, Griffith University. Ph. 07-3735526; Email: [w.moyle@griffith.edu.au](mailto:w.moyle@griffith.edu.au)

Professor Marie Cooke

School of Nursing and Midwifery/ Research Centre for Clinical & Community Practice Innovation, Griffith Health Institution, Griffith University. Ph. 07-37357985; Email: [m.cooke@griffith.edu.au](mailto:m.cooke@griffith.edu.au)

#### Background

Chronic low back pain is both common and a major health problem for up to 70% of older adults. This pain has an impact on functioning, health-related quality of life and the cost of health-care. Complementary and alternative therapies are most commonly used to manage pain, and massage is the most popular. Aromatic massage is safe and non-invasive therapy that may help to reduce back pain, improving functional ability and psychosocial well-being. The study aims to examine the effectiveness of massage in relieving chronic low back pain in older people. The study is being undertaken for a PhD degree at Griffith University by Netchanok Sritoomma.

#### What participation in this study involves

You will be randomly allocated to one of three groups involving different massage therapies. You will be provided with one type of back massage twice a week for 5 weeks. I will also ask you to rate your pain on a pain rating scale before and immediately after each session of massage. Each treatment session will last about 40 minutes. You will not have to pay for the massage treatment.

You will be asked to fill out a survey at time of admission to the study. We are interested in the lasting effect of the massage and therefore I will ask you at the 6<sup>th</sup> week and 15<sup>th</sup> week of the study to complete two further surveys by telephone interview.

#### The basis by which participants will be selected

To participate in this study you must be:

1. Aged 60 years and older
2. Able to listen, speak, read and write Thai language
3. Diagnosed with chronic low back pain by a medical practitioner (lasting for over 12 weeks)
4. A new client or not contaminated with any type of massage within 12 weeks before testing

You are unable to participate in this study if you have:

1. Skin diseases
2. Inflammation or infection on back
3. A history of back fracture or back surgery
4. Temperature of more than 38.5 °C on the examination day

5. Hemi/paraparesis
6. Infectious diseases (e.g. tuberculosis or AIDS)
7. Cancer
8. Prior experience of receiving any type of massage for three months before this study
9. Being unable to commit to the full course of treatment and follow-up.

### **Consent to participate**

Participation in this research is voluntary and you are not under any obligation to participate in this research. Non-participation will not involve any penalty; affect any current or future care given from the hospital. You may choose to discontinue participation at any time without penalty or without providing an explanation. We hope that you will consider participation in this study which may help to reduce your chronic low back pain and may have to potential to improve your functional ability, quality of life, and reducing your anxiety.

### **Risk**

Back massages are not harmful; however, it may aggravate minimal pain and discomforts i.e. Skin rash. Any adverse effects will be monitored and you will be referred to the physician for any concerning adverse effects and massage treatment stopped if recommended. The massage treatment will be carried out by trained health care professionals who have received a certificate in traditional Thai or aromatic oil massage, and all of the massage therapists are trained to ensure they understand the treatment protocols. Massage therapists will encourage you to inform them of your pain tolerance threshold during each treatment session. They will adjust massage pressure within your pain tolerance.

### **Confidentiality**

All information will be treated in the strictest confidence. You will be asked to provide contact information which includes your first name, phone number, and home address but you will be given a code number for the study. Only group data, from which no individual could be identified, will be published. These measures are to ensure your privacy is protected. The questionnaires and the personal details sheet will be kept in a locked and secure place at Griffith University for a period of 5 years before being destroyed. On completion of the study, a report of the general finding from the study will be made available to participants.

### **Complaints Mechanism**

Griffith University conducts research in accordance with the National Statement on Ethical Conduct in Research Involving Humans.

You may contact Associate Professor Luckana Inklab, Dean of college of Nursing, Christian Univerisity of Thailand, Nakhonphatom, telephone (034) 229480-7 Ext. 2204, 2210 or [lucksanai@hotmail.com](mailto:lucksanai@hotmail.com) if you have any complaints about the conduct of the research or wish to raise any concerns. Alternately, if you have any concerns or complaints about the ethical conduct of the research project you should contact the Manager, research Ethics on +61 (07) 3875 5585 or [research-ethics@griffith.edu.au](mailto:research-ethics@griffith.edu.au).

### **Privacy statment**

The conduct of this research involves the collection, access and/ or use of your identified personal information. The information collected is confidential and will not be disclosed to third parties. A deidentified copy of this data may be used for other research purposes. However, your anonymity will at all times be safeguarded.

**Griffith University thanks you for your consent (assent) and participation in this research.**

**Griffith University Letterhead**

**CONSENT FORM**

**Study title: The effectiveness of massage in treating chronic low back pain in older adults: A randomised controlled trial**

**Student investigator:** Netchanok Sritoomma

PhD candidate, School of Nursing and Midwifery/ Research Centre for Clinical & Community Practice Innovation, Griffith Health Institution, Griffith University. Ph. 07-37355253; Email: [n.sritoomma@griffith.edu.au](mailto:n.sritoomma@griffith.edu.au)

**Chief Investigators:** Professor Wendy Moyle

School of Nursing and Midwifery/ Research Centre for Clinical & Community Practice Innovation, Griffith Health Institution, Griffith University. Ph. 07-37355526; Email: [w.moyle@griffith.edu.au](mailto:w.moyle@griffith.edu.au)

Professor Marie Cooke

School of Nursing and Midwifery/ Research Centre for Clinical & Community Practice Innovation, Griffith Health Institution, Griffith University. Ph. 07-37357985; Email: [m.cooke@griffith.edu.au](mailto:m.cooke@griffith.edu.au)

I have read the information form and understand that:

- This research is to test the effectiveness of massage with aromatic oil in treating chronic low back pain in older adults
- I will receive one type of back massage twice a week for 5 weeks, will be asked to rate my pain on a pain rating scale before and immediately after each massage session, and will be asked to fill out five questionnaires and a pain rating scale immediately participate in the study, repeat four of the questionnaires and a pain rating scale in 6<sup>th</sup> week and 15<sup>th</sup> week of the study by telephone interview
- Each treatment session will last about 40 minutes, the questionnaires will take approximately 20-25 minutes to complete each time
- My participation is voluntary and I may discontinue my participation at anytime without penalty or explanation
- Any reports or publications from this study will be reported in general terms and will not involve any identifying features
- The data will be kept confidential at all times and in a locked filing cabinet in the chief investigator's office for a period of 5 years before being destroyed
- A report about the study findings will be made available to me.

I have read the information sheet and the consent form. I agree to participate in this study and give my consent freely. I understand that the study will be carried out as described in the information statement, a copy of which I have retained. I realise that whether or not I decide to participate is my decision and will not affect any my current or future care given from the hospital. I also realize that I can withdraw from the study at any time and that I do not have to give any reasons from withdrawing. I have had all questions answered to my satisfaction.

.....  
Name and Signature/Date

Please provide contact information

First name	
Home Phone and/or Mobile:	
Do you wish to receive a lay summary of the study?	<input type="checkbox"/> No <input type="checkbox"/> Yes (If yes, Mailing address: )

## **APPENDIX M: PUBLICATION PAPER OF THE STUDY**

Sritoomma, N., Moyle, W. Cooke, M. & O'Dwyer, S. (2012). The effectiveness of Swedish massage and traditional Thai massage in treating chronic low back pain: A review of the literature. *Complementary Therapies in Clinical Practice*, 18, 227-234.

## REFERENCES

- Abascal, K. & Yarnell, E. (2009). Clinical uses of *Zingiber officinale* (ginger). *Alternative and Complementary Therapies*, 15(5), 231-237.
- Airaksinen, O., Brox, J.I., Cedraschi, C., Hildebrandt, J., Klüber-Moffett, J., Kovacs, F., Mannion, A.F., Reis, S., Staal, J.B., Ursin, H., & Cost b13 Working Group on Guidelines for Chronic Low Back Pain. (2006). Chapter 4. European guidelines for the management of chronic nonspecific low back pain. *European Spine Journal*, 15(Suppl.2), S192-S300.
- Akobeng, A. (2005). Understanding randomised controlled trials. *Archives of Disease in Childhood*, 90(8): 840–844.
- Ali, H.B., Blunden G., Tanira, O.M. & Nemmaar, A. (2008). Some phytochemical, pharmacological and toxicological properties of ginger (*Zingiber officinale* Roscoe): A review of recent research. *Food and Chemical Toxicology*, 46, 409-420.
- Altman, D.G., & Bland, J.M. (1999). Treatment allocation in controlled trials: why randomise? *British Medical Journal*, 318, 1209.
- Altman, D.G. (2006). *Practical statistics for medical research* (2nd ed.). London: Chapman & Hall.
- Altman, R.D. & Marcussen, K.C . (2001). Effect of a ginger extract on knee pain in patients with osteoarthritis. *Arthritis and Rheumatism*, 44, 2531-2538.
- Andersson, G.B. (1999). Epidemiological features of chronic low-back pain. *Lancet*, 354, 581-585.
- Anichini, M., Ceseratti, S., Lepori, M., Maddali, B.S., Maresca, M., & Zoppi, M. (1997). Substance P in the serum of patients with rheumatoid arthritis. *Revue du Rhumatisme (English ed.)*, 64, 18-21.
- Appelgren, A., Appelgren, B., Kopp, S., Lundeberg, T. & Theodorsson, E. (1998). Substance P-associated increase of intraarticular temperature and pain threshold in the arthritic temporomandibular joint. *Journal of Orofacial Pain*, 12(2), 101-107.
- Arcy, D.Y. (2009). Is low back pain getting on your nerves? *The Nurse Practitioner*, 34(5), 10-17.

- Asako, H., Kubes, P., Wallace, J., Wolf, R.E. & Granger, D.N. (1992). Indomethacin-induced leukocyte adhesion in mesenteric venules: Role of lipoxygenase products. *American Journal of Physiology*, 262, 903-908.
- Avraham, B. (2001). *Thai massage*. Hod Hosharon, Israel: Astrolog Publishing house.
- Balaskas, K. (2002). *Thai yoga massage*. London, England: Thorsons.
- Beck, M.F. (2010). *Theory and practice of therapeutic massage* (5th ed.). Albany, NY: Milady Publishing Company.
- Black, C., Vickerson, B. & McCully, K. (2003). Noninvasive assessment of vascular function in the posterior tibial artery of healthy humans. *Dynamic Medicine*, 2(1), 1-7.
- Black, C.D., Herring, M.P., Hurley, D.J., & O'Connory, P.J. (2010). Ginger (*Zingiber officinale*) reduces muscle pain caused by eccentric exercise. *The Journal of Pain*, 11(9), 894-903.
- Blackwood, B. (2006). Methodological issues in evaluating complex healthcare interventions. *Journal of Advanced Nursing*, 54, 612–622.
- Bliddal, H., Rosetzky, A., Schlichting, P., Weidner, M. S., Andersen, L. A., Ibfelt, H., et al. (2000). A randomised, placebo-controlled, cross-over study of ginger extracts and Ibuprofen in osteoarthritis. *Osteoarthritis and Cartilage*, 8(1), 9-12.
- Bogduk, N. & McGuirk, B. (2002). *Medical management of acute and chronic low back pain: An evidence-based approach*. Amsterdam, Netherlands: Elsevier.
- Bogduk, N. (2004). Management of chronic low back pain. *Medical Journal of Australia*, 180(2), 79-83.
- Boonstra, A. M., Preuper, H. R. S., Reneman, M. F., Posthumus, J. B., & Stewart, R. E. (2008). Reliability and validity of the visual analogue scale for disability in patients with chronic musculoskeletal pain. *International Journal of Rehabilitation Research*, 31(2), 165–169.
- Borglin, G., & Richards, D. A. (2010). Bias in experimental nursing research: Strategies to improve the quality and explanatory power of nursing science. *International Journal of Nursing Studies*, 47(1), 123-128.
- Braun, B., & Simonson, S. (2005). *Introduction to massage therapy*. Philadelphia, PA: Lippincott Williams and Wilkins.

- Brewer, M. (2000). Research design and issues of validity in H.Reis & C.Judd (Eds.), *Handbook of Research Methods in Social and Personality Psychology*. New York, NY: Cambridge University Press.
- Brown, L.M. & Schinka, J.A. (2005). Development and initial validation of a 15-item informant version of the Geriatric Depression Scale. *International Journal of Geriatric Psychiatry*, 20, 911-918.
- Buckle, J. (2001). The ethic of plant v petrochemical medicine. *International Journal of Aromatherapy*. 11(1), 8-17.
- Buckle, J. (2003). *Clinical Aromatherapy: Essential oils in practice* (2nd ed.). Philadelphia, PA: Churchill Livingstone.
- Burn, N., & Grove, S. (2005). *The practice of nursing research: conduct, critique, and utilisation* (5th ed.). St.Louis, MO: Elsevier Saunders.
- Buttagat, V., Eungpinichpong, W., Chatchawan, U. & Kharmwan, S. (2009). The immediate effects of traditional Thai massage on heart rate variability and stress-related parameters in patients with back pain associated with myofascial trigger points. *Journal of Bodywork and Movement Therapies*, 6, 1-9.
- Campbell, N.C., Murray, E., Darbyshire, J., Emery, J., Farmer, A., Griffiths, F., et al. (2007). Designing and evaluating complex interventions to improve health care. *British Medical Journal*, 334, 455–459.
- Cambron, J.A., Dexhelmer, J., Coe, P., & Swenson, R., (2007) Side effects of massage therapy: A cross-sectional study of 100 clients. *The Journal of Alternative and Complementary Medicine*, 13, 793-796.
- Carlsson, A.M. (1983). Assessment of chronic pain I: Aspects of the reliability and validity of the visual analogue scale. *Pain*, 16, 87–101.
- Carroll, L.J., Cassidy, J.D. & Cote, P. (2004). Depression as a risk factor for onset of an episode of troublesome neck and low back pain. *Pain*, 107, 134-139.
- Carter, J.T., & Birrell, L.N. (2000). *Occupational health guidelines for the management of low back pain at work: Principal recommendations*, London: Faculty of Occupational Medicine.
- Casanelia, L. & Stelfox, D. (2010). *Foundations of Massage*, (2nd ed.). Australia: Churchill Livingstone.

- Cathy, W. (2011). *Which massage oil is best? Five massage oils to try*. Retrieved 30 September, 2011 from [http://altmedicine.about.com/od/massage/a/massage\\_oil.htm](http://altmedicine.about.com/od/massage/a/massage_oil.htm)
- Cayea, D., Perera, S., & Weiner, D. K. (2006). Chronic Low Back Pain in Older Adults: What Physicians Know, What They Think They Know, and What They Should Be Taught. *Journal of the American Geriatrics Society*, 54(11), 1772-1777.
- Celotti, F. & Laufer, S. (2001). Anti-inflammatory drugs: New multi target compounds to face an old problem. The dual inhibition concept. *Pharmacological Research*, 43, 429–436.
- Chaithavuthi, J. & Muangsiri, K. (2007). *Thai massage the Thai way: Healing body and mind*. Chiang Mai, Thailand: Thai Massage Book Press.
- Charoenchai, L., Chaikoolvatana, A., & Chaiyakul, P. (2006). The relationship between health behavior and pain scale in patients with low back pain in thailand. *Southeast Asian Journal of Tropical Medicine and Public Health*, 37(5), 1040-1047.
- Chatchawan, U., Thinkhamrop, B., Kharmwan, S., Knowles, J. & Eungpinichpong, W. (2005). Effectiveness of traditional Thai massage versus Swedish massage among patients with back pain associated with myofascial trigger points. *Journal of Bodywork and Movement Therapies*, 9, 298-309.
- Cherkin, D.C., Eisenberg, D., Sherman, K.J., Barlow, W., Kaptchuk, T.J., Street, J., et al. (2001). Randomized trial comparing Traditional Chinese Medical acupuncture, therapeutic massage, and selfcare education for chronic low back pain. *Archives of Internal Medicine*, 161, 1081–8.
- Cherkin, D.C., Sherman, K.J., Kahn, J., Wellman, R., Cook, A.J., Johnson, E., et al. (2011). A comparison of effect of two types of massage and usual massage on chronic low back pain. *Annals of Internal Medicine*, 155, 1-9.
- Cheung, C.K. & Halcon, L.L. (2007). Use of complementary and alternative therapies in community-dwelling older adults. *Journal of Alternative and Complementary Medicine*, 13, 997-1006.
- Chiong, W. (2006). The real problem with equipoise. *The American Journal of Bioethics*, 6(4), 37-47.

- Chou R. & Huffman, L. (2007). Non pharmacologic therapies for acute and chronic low back pain: A review of the evidence for an American Pain Society /American college of Physicians clinical practice guideline. *Annals of Internal Medicine*, 147(7), 492-504.
- Constant, S., Guillemine, F., Collin, J.F., & Boulange, M., (1998). Use of spa therapy to improve the quality of life of chronic low back pain patients. *Medical Care*, 36(9), 1309-14.
- Corley, M., Ferriter, J. & Zeh, J. (1995). Physiological and psychological effects of back rubs. *Applied Nursing Research*, 8(1), 39-43.
- Cowen, V. S. (2005). *A comparative study of Thai massage and Swedish massage*. (Doctoral dissertation). Available from *ProQuest Dissertations and Theses*.
- Cowen, V. S., Burkett, L., Bredimus, J., Evans, D. R., Lamey, S., Neuhauser, T., et al. (2006). A comparative study of Thai massage and Swedish massage relative to physiological and psychological measures. *Journal of Bodywork and Movement Therapies*, 10(4), 266-275.
- Currie, S.R., & Wang, J.L. (2004). Chronic back pain and major depression in the general Canadian population. *Pain*, 107, 54-60.
- Damkot, D.K., Pope M.H. & Lord, J. (1984). The relationship between work history, work environment and low back pain in men. *Spine*, 9, 395-359.
- Deardorff, W.W. (2010). *Depression is common for those with chronic back pain*. Retrieved 22 December, 2010 from <http://www.spine-health.com/conditions/depression/depression-and-chronic-back-pain>.
- Dedov, V.N., Tran, V.H., Duke, C.C., Connor M., Christic, M.J., Mandadi, S., et al. (2002). Gingerols: A novel class of vanilloid receptor (VR1) agonists. *British Journal of Pharmacology*, 137, 793-7998.
- Delaney, J.P.A., Leong, K.S., Watkins, A. & Brodie, D. (2002). The short-term effects of myofascial trigger point massage therapy on cardiac autonomic tone in healthy subjects. *Journal of Advanced Nursing*, 37, 364-371.
- Delitto, A., George, S.Z., Van Dillen, L., Whitman, J.M., Sowa, G., Shekelle, P., et al. (2012). Low Back Pain: Clinical Practice Guidelines Linked to the International Classification of Functioning; Disability, and Health from the Orthopaedic Section of the American Physical Therapy Association. *Journal of Orthopaedic and Sports Physical Therapy*, 42(4): A1-A57.

- Devane, D., Begley, C. M., & Clark, M. (2004). How many do I need? Basic principles of sample size estimation. *Journal of Advanced Nursing*, 47(3), 297-302.
- Deyo, R.A., Mirza, S.K., & Martin, B.I. (2006). Back pain prevalence and visit rates: Estimates for US national survey. *Spine*, 31(23), 2724-2727.
- Diego, M. & Field, T. (2009). Moderate pressure massage elicits a parasympathetic nervous system response. *International Journal of Neuroscience*, 119(5), 630-638.
- Domenico, I. G., & Wood, E.C. (1997). *Beard's Massage* (4th ed.). Philadelphia, PA: W.B.Saunders.
- Dougherty, P., Salsbury, S.A., Everett, C., & Weiner, D. (2010). Chronic lower back pain with stenosis in an older adult male. *Topics in Integrative Health Care*, 1(2), 1-9.
- Dunning, T. (2007). *Essential Oils in Therapeutic Care*. Melbourne, Australia: Australian Scholarly Publishing.
- Dumnaensaduak hospital (2007). *The information of Dumnaensaduak hospital: the statistics of patients with back pain in 2007(Thai ed.)*. Retrieved 12 August, 2010 from <http://www.dnhospital.com/index1.php#>
- Ellenberg, S. S. (2003). Scientific and Ethical Issues in the Use of Placebo and Active Controls in Clinical Trials. *Journal of Bone and Mineral Research*, 18, 1121–1124.
- Ernst, E. (2001, September). Massage therapy for low back pain: an update. *Alternative Therapies in Woman's Health*, 69-71.
- Ernst, E. (2004). Manual therapies for pain control: Chiropractic and massage. *The Clinical Journal of Pain*, 20(1), 8-12.
- Ersek, M., Turner, J.A., Cain, K.C., & Kemp, C.A. (2008). Results of randomised controlled trial to examine the efficacy of chronic pain self-management group for older adults. *Pain*, 138, 29-40.
- Everitt, B.S. & Wessely, S. (2004). *Clinical Trials in Psychiatry*. Oxford: Oxford University Press.
- Fakata, K.L. (2004). Anti-inflammatory agents for the treatment of musculoskeletal pain and arthritis. *Current Pain and Headache Reports*, 8, 173–177.
- Field, A. (2011). *Discovering statistics using SPSS* (3rd.ed.). London, England: SAGE Publications Ltd.

- Field, T., Deed, O., Diego, M., Gualer, A., Sullivan, S., Wilson, D., et al (2009). Benefits of combining massage therapy with group interpersonal psychotherapy in prenatally depressed woman. *Journal of Bodywork and Movement Therapies*, 13(4), 297-303.
- Field, T., Diego, A., Hernandez-Reif, M., Schanberg, S. & Kuhn, C. (2004). Massage therapy effects on depressed pregnant women. *Journal of Psychosomatic Obstetrics and Gynecology*, 25(2), 115-22.
- Field, T., Diego, M. & Hernandez-Reif, M. (2007). Massage therapy research. *Developmental Review*, 27, 75-89.
- Field, T., Hernandez-Reif, M., Diego, M. & Fraser, M. (2004). Lower back pain and sleep disturbance are reduced following massage therapy. *Journal of Bodywork and Movement Therapies*, 11, 141-145.
- Field, T., Hernandez-Reif, M., Diego, M., & Fraser, M. (2007). Lower back pain and sleep disturbance are reduced following massage therapy. *Journal of Bodywork and Movement Therapies*, 11(2), 141-145.
- Field, T.M., Sunshine, W., Hernandez-Reif, M., Quintino, O., Schanberg, S. & Kuhn, C. (1997). Chronic fatigue syndrome: Massage therapy effects on depression and somatic symptoms in chronic fatigue syndrome. *Journal of Chronic Fatigue Syndrome*, 3, 43-51.
- Finch, E., Brooks, D., Stratford, P.W. & Mayo, E.N. (2002). Oswestry Low Back Pain disability Questionnaire. In E. Finch (Ed.), *Physical rehabilitation outcome measures* (2nd ed.), (pp.186-187). Hamilton, Ontario: Lippincott, Williams & Wilkins.
- Fiorucci, S., Meli, R., Bucci, M. & Cirino, G. (2001). Dual inhibitors of cyclooxygenase and 5-lipoxygenase: A new avenue to anti-inflammatory therapy. *Biochemical Pharmacology*, 62, 1433-1438.
- Flynn, D.L. & Rafferty, M.F. (1986). Inhibition of human neurotrophil 5-lipoxygenase activity by gingerdione, shagaol, capsaicin and related pungent compounds. *Prostaglandins Leukot Med*, 24, 195-198.
- Foltz, V., Pierre, Y.S., Rozenberg, S., trossignol, M., Bourgeois, P., Joseph, L., Adam, V., Penrod, J.R., Clarke, A.E. & Fautrel, B. (2005) Use of complementary and alternative therapies by patients with self-reported chronic back pain: A nationwide survey in Canada. *Joint Bone Spine*, 72, 571-577.

- Franke A., Gebauer, S., Franke, K. & Brockow, T. (2000). Acupuncture massage versus Swedish massage and individual exercise versus group exercise in low back pain sufferers: A randomised controlled clinical trial in a 2x2 factorial design. *Forsch Komplementarmed Klass Naturheilkd*, 7(6), 286-293.
- Fritz, S. (2000). *Mosby's fundamentals of therapeutic massage*. (2nd ed.). St. Louis, MO: Mosby Inc.
- Frymoyer, J.W., Pope M.H., Clements, J. H., Wilder, D.G., MacPherson, B., Ashikaga, T. & Vermont, B. (1983). Risk factors in low back pain: An epidemiological survey. *The Journal of Bone & Joint Surgery*, 65(2), 213-218.
- Furlan, A.D., Imamura, M. Dryden, T. & Irvin, E. (2009). Massage for low back pain: an updated systematic review within the framework of the Cochrane Back Review Group. *Spine (Phila Pa 1976)*, 34(16), 1669–1684.
- Gao, W., Ma, S., Dong, X., Qin, T., Qiao, X., & Fang, Q. Massage can facilitate soft tissue expansion. *Medical Hypotheses*, 76(1), 148-149.
- Geiger J.L. (2005). The essential oil of ginger, *Zingiber officinale*, and anaesthesia. *The International Journal of Aromatherapy*, 15, 7-14.
- Goats, G .C. (1994). Massage--the scientific basis of an ancient art: Part 1 The techniques. *British Journal of Sports Medicine*, 28, 149-152.
- Goats, G .C. (1994). Massage--the scientific basis of an ancient art: Part 2. Physiological and therapeutic effects. *Journal of Sports Medicine*, 28, 153-156.
- Gold, R. (2003). *Thai massage: A traditional medical technique*. London, England: Churchill Livingstone.
- Goldberg, J., Sullivan, J. & Seaborne, E. (1992). The effect of two intensities of massage on H-reflex amplitude. *Physical Therapy*, 72(6), 449-457.
- Goldberg, L. (2001). *Massage and aromatherapy: A practical approach* (2nd ed.). Cheltenham, England: Nelson Thornes Ltd.
- Goldstein, S. & Casanelia, L. (2010). *The techniques of Swedish massage in foundations of massage* (3rd ed.). London, England: Churchill Livingstone.
- Gravel, J., Opatrny, L., & Shapiro, S. (2007). The intention-to-treat approach in randomized controlled trials: Are authors saying what they do and doing what they say? *Clinical Trials*, 4(4), 350-356.

- Grzanna, R., Lindmark, L. & Frondoza, G.C. (2005). Ginger: An herbal medicinal product with broad anti-inflammatory actions. *Journal of Medical Food*, 8(2), 125-132.
- Gunn, C.C. (1996). *The Gunn approach to the treatment of chronic pain*. New York, NY: Churchill Livingstone.
- Guyton, A. & Hall, J. (2000). *Textbook of medical physiology*(10th ed.). Philadelphia, PA: W.B. Saunders Company.
- Habiba, M., & Evans, M. (2002). The inter-role confidentiality conflict in recruitment for clinical research. *Journal of Medicine and Philosophy*, 27, 565-587.
- Haghighi, M., Khalvat, A., Toliat, T. & Jallaei, S. (2005). Comparing the effects of Ginger (*Zingiber officinale*) extract and ibuprofen on patients with osteoarthritis. *Archives of Iranian Medicine*, 8, 267-271.
- Halpern, S.H., & Douglas, J. (2005). *Evidence-based obstetric anaesthesia*. Malden, Mass: Blackwell Publishing/BMJ Books.
- Harris, M. & Richards, K.C. (2010). The physiological and psychological effects of slow-stroke back massage and hand massage on relaxation in older people. *Journal of Clinical Nursing*, 19, 917-926.
- Harry-O'kuru, R.E., Mohamedb, A. & Abbott, T.P. (2005). Synthesis and characterization of tetrahydroxyjojoba wax and ferulates of jojoba oil. *Industrial Crops and Products*, 22, 125-133.
- Hartvigsen, J., Christensen, K. & Frederiksen H. (2003). Back pain remains a common symptom in old age, a population-based study of 4486 Danish twins aged 70-102. *European Spine Journal* 12(5), 528-34.
- Helme, R. & Gibson, S. (1999). Pain in older people. In I. Crombie, P. Croft & S. Linton (Eds.), *Epidemiology of pain* (pp.103-112). Seattle, WA: IASP Press.
- Hemmila, H.M. (2002). Quality of life and cost of care of back pain patients in Finnish general practice. *Spine*, 27(6), 647-653.
- Herndon R.M. (2006). *Handbook of neurologic rating scales* (2nd ed). New York, NY: Demos Medical Publishing Inc.
- Hernandez, R., Field, T., Krasnegor, J. & Theakston, H. (2001). Lower back pain is reduced and range of motion increased after massage therapy. *International Journal of Neuroscience*, 106, 131-145.

- Herman, P.M., Szczurko, O., Cooley, K. & Mills, E.J. (2008). Cost-effectiveness of naturopathic care for chronic low back pain. *Alternative Therapies in Health and Medicine*, 14(2), 32-39.
- Ho, P. M., Peterson, P.N., & Masoudi, F. A. (2008). Evaluating the evidence: is there a rigid hierarchy? *Circulation*, 118(16), 1675–1684.
- Holey, E. & Cook, E. (2003). *Evidence-based therapeutic massage: A practical guide for therapists* (2nd ed.). London, England: Churchill Livingstone.
- Hou, W.H., Chiang, P.T., Chiu, S.Y. & Yen, Y.C. (2010). Treatment effects of massage therapy in depressed people: a meta-analysis. *Journal of Clinical Psychiatry*, 71(7), 894-901.
- Hróbjartsson, A. & Gøtzsche, P.C. (2004). Is the placebo powerless? Update of systematic review with 52 new randomised trials comparing placebo with no treatment. *Journal of Internal Medicine*, 256, 91-100.
- Hróbjartsson, A. & Gøtzsche, P.C. (2010). Placebo interventions for all clinical conditions. *Cochrane Database of Systematic Reviews*, Issue 1. Art. No.: CD003974. DOI: 10.1002/14651858.CD003974.pub3.
- Hudson, N., Balsitis, M., Everitt, S. & Hawkey, C.J. (1993). Enhanced gastric mucosal Leukotriene B<sub>4</sub> synthesis in patients taking non-steroidal anti-inflammatory drugs. *Gut*, 34(30), 742-747.
- Hutton, J. L. (2001). Are distinctive ethical principles required for cluster randomised controlled trials? *Statistics in Medicine*, 20(3), 473–488.
- Iiffe, S., Kharicha, K., Carmaciu, C., Harari, D., Swift, C., Gillman, G. & Struck, A.E. (2009). The relationship between pain intensity and severity and depression in older people: Exploratory study. *BMC Family Practice*, 10 (54), 1-7.
- Imamura, M., Furlan, A.D., Dryden T. & Irvin E. (2008). Evidence-informed management of chronic low back pain with massage. *The Spine Journal*, 8, 121-133.
- Institute for Small and Medium Enterprises Development. (2002). *Thai massage business*. Bangkok: P2 Design & Print Co.Ltd.
- Ireland, M. & Olson, M. (2000). Massage therapy and therapeutic touch in children: State of the science. *Alternative Therapies in Health and Medicine*, 6(5), 54-63.

- Irnich, D., Behrens, N., Molzen, H., Konig, A., Gleditsch, J., & Krauss, M. (2001). Randomised trial of acupuncture compared with conventional massage and “sham” laser acupuncture for treatment of chronic low neck pain. *British Medical Journal*, *322*, 1574-1578.
- Jadad, A. R., Moore, R. A., Carroll, D., Jenkinson, C., Reynolds, D. J. M., Gavaghan, D. J., et al. (1996). Assessing the quality of reports of randomised clinical trials: Is blinding necessary? *Controlled Clinical Trials*, *17*(1), 1-12.
- Jadad, A.R. & Enkin, M.W. (2008). *Randomised controlled trials: Questions, answers and musings* (2nd ed.). Malden, Mass: Blackwell Publishing/BMJ Books.
- Jolad, S.D., Lantz, R.C. & Solyom, A.M. (2004). Fresh organically grown ginger (*Zingiber officinale*): Composition and effect on LPS-induced PGE2 production. *Phytochemistry*, *65*, 1937-1954.
- Jotisalikor, C. (2002). *Thai spa book*. Paterson Hill, Singapore: Periplus editions (HK) Ltd.
- Kawakishi, S., Morimitsu, Y. & Osawa, T. (1994). Chemistry of ginger compounds and inhibitory of arachidonic acid cascade. *American Chemical Society Symposium Series*, *547*, 244-250.
- Kendall, J. (2003). Designing a research project: Randomised controlled trials and their principles. *Emergency Medicine Journal*, *20*(2), 164–168.
- Khadlikar, A., Odebiyi, D.O., Brosseau, L. & Wells, G.A. (2008). Transcutaneous electrical nerve stimulation (TENS) versus placebo for chronic low back pain. *Cochrane Database of Systematic Reviews*, Issue 4. Art.No.:CD003008. DOI:10.1002/4651858.CD003008.pub3.
- Kira, B. (2002). *Thai yoga massage*. London, England: Thorsons.
- Kitisomprayoonkul, W., Klaphajone, J. & Kovindha, A. (2006). Thai short-form McGill Pain Questionnaire (Th-SFMPQ). *Journal of The Medical Association of Thailand*, *89*, 846-53 (Thai version).
- Kiuchi, F., Shibuya, M. & Sankawa, U. (1982). Inhibitors of prostaglandin biosynthesis from ginger. *Chemical and Pharmaceutical Bulletin (Tokyo)*, *30*, 754-757.
- Kiuchi, F., Iwakami, S., Shibury, M., Hanaoka, F. & Sankawa, U. (1992). Inhibitors of prostaglandin and leukotriene biosynthesis by gingerols and diaryl heptanoids. *Chemical and Pharmaceutical Bulletin (Tokyo)*, *40*, 387-391.

- Kotaska, A. (2004). Inappropriate use of randomised trials to evaluate complex phenomena: Case study of vaginal breech delivery. *British Medical Journal*, 329, 1039-1042.
- Kulsomboon, S., Attasit, R. (2007). Situation of the traditional medicine researches in Thailand. *Journal of Thai Traditional & Alternative Medicine*, 5, 50-61. (in Thai)
- Labrique-Walusis, F., Keister, K.J. & Russell, A.C. (2010). Massage Therapy for Stress Management: Implications for Nursing Practice. *Orthopaedic Nursing*, 29(4), 254-257.
- Lachin, J.M. (2000). Statistical considerations in the intention-to-treat principle. *Controlled Clinical Trials*, 21, 167-189.
- Laine, L. (2001). Approaches to nonsteroidal anti-inflammatory drug use in the high-risk patient. *Gastroenterology*, 120, 594-606.
- Landeros, C.R. (n.d.). *Depression in later life: A review of assessment and treatment*. University of Texas at Austin. Retrieved from [http://socialwork.nyam.org/nsw/students/journals/Depression\\_in\\_Later\\_Life.pdf](http://socialwork.nyam.org/nsw/students/journals/Depression_in_Later_Life.pdf)
- Langlitz, G. (n.d.). *Joint Health and Massage Therapy*. Retrieved 19 August, 2010 from <http://www.spineuniverse.com/conditions/neck-pain/joint-health-massage-therapy>
- Langner, E., Greifengberg, S. & Gruenwald, J. (1998). Ginger: History and use. *Advances in Therapy*, 5(1), 25-44.
- Larson, J. (2001, April 06). *Massage*. [Press release]. Retrieved 15 July, 2010 from <http://findarticles.com/health care industry/Encyclopedia of medicine/Massage.htm>
- Last, J.M. (2001). *A dictionary of epidemiology*. New York, NY: Oxford University Press.
- Laufer, S. (2003). Role of eicosanoids in structural degradation in osteoarthritis. *Current Opinion in Rheumatology*, 15, 623-627.
- Lawton, G. (2003, July 02). *Toward a Neurophysiological Understanding of Manual Therapy Neuro-Manual Therapy*. [Press release]. Retrieved 2 June, 2010 from <http://www.americanmanualmedicine.com/education/a14z2.html>

- Lee, C.E., Browel, L.M. & Jones, D.L. (2008). Measuring health in patients with cervical and lumbosacral spinal disorders: Is the 12-Item Short-Form Health Survey a valid alternative for the 36-Item Short-Form Health Survey? *Archives of Physical Medicine and Rehabilitation*, 89, 829-833.
- Lee, M.H.M, Itoh, K. & Yang, G-F.W. (1990). Physical therapy and rehabilitation medicine: massage. In J.J. Bonica (Ed), *The management of pain* (pp.1777-1778). Philadelphia, PA: Lea & Febiger.
- Levine, J. D., Clark, R., Devor, M., Helms, C., Moskowitz, M. A. & Basbaum, A. I. (1984). Intraneural substance P contributes to the severity of experimental arthritis. *Science*, 226, 547-549.
- Liddle, S.D., Gracey, J.H. & Baxter, G.D. (2007) Advice for the management of low back pain: A systematic review of randomised controlled trials. *Manual therapy*, 12(4), 310-27.
- Light, I.J. (1998). The consent form: A time for reassessment. *Journal of Paediatrics*, 132, 567-568.
- LoBiondo-Wood, G., & Haber, J. (2002). *Nursing research: Methods, critical appraisal, and utilisation*. (5th ed.). St.Louis, MO: Mosby, Inc.
- Loving, E. J. (1999). *Massage therapy*. Stamford, Conn: A Simon & Schuster company.
- Lundeberg, T.C. (1983). Vibratory stimulation for the alleviation of chronic pain. *Acta physiologica Scandinavica Supplement*, 523,1-51.
- Luo, X., George, M., Richardson, W. & Hey, L. (2002). Validity and responsiveness of Shor Form 12-item survey in patients with back pain. *Proceedings of the NASS 17<sup>th</sup> Annual Meeting, The Spine Journal*, 2, 47S-128S.
- Lyons, S.S. (2010). Discussant 4: Nursing. In Dougherty, P., Lyons, S.S., Everett, C. & Weiner, D. (Grand Rounds, 2010), Chronic Lower Back Pain with Stenosis in an Older Adult Male. *Topics in Integrative Health Care*, 1(2), 1-9.
- Mackawan, S., Eungpinichpong, W., Pantumethakul, R., Chatchawan U., Hunsawong, T. & Arayawichanon, P. (2005). Effects of traditional Thai massage versus joint mobilization on substance P and pain perception in patients with non-specific low back pain. *Journal of Bodywork and Movement Therapies*, 10, 1-7.
- Magnusson, S. (1998). Passive properties of human skeletal muscle during stretch manoeuvres. *Medicine and Science in Sports and Exercise*, 8, 65-77.

- Manev, R. & Manev, H. (2004). 5-Lipoxygenase as a putative link between cardiovascular and psychiatric disorders. *Critical Reviews in Neurobiology*, 16(1-2), 181-186.
- Mäntyselkä, P.T., Turunen, J.H.O., Ahonen, R.S. & Kumpusalo, E.A. (2003). Chronic pain and poor self-rated health. *The Journal of the American Medical Association*, 290(18), 2435-2442.
- Marcati, M. (1998). *Thai massage manual*. New York, NY: Sterling Publishing Co., Inc.
- Margaret O'Brien, K., Pettigrew, A. C., & Fay Carol, R. (1999). Complementary, alternative, integrative: Have nurses kept pace with their clients? *Medsurg Nursing*, 8(4), 249-256.
- Marras, W.S., Granata, K.P., Davis, K.G., Allread, W.G. & Jorgensen, M.J. (1999). Effects of box features on spine loading during warehouse order selecting, *Ergonomics*. 42(7), 980-996.
- Martel-Pelletier, J., Lajeunesse, D., Reboul, P. & Pelletier, J.P. (2003). Therapeutic role of dual inhibitors of 5-LOX and COX, selective and non-selective non-steroidal anti-inflammatory drugs. *Annals of the Rheumatic Diseases*, 62, 501-509.
- Martin G. (1992). *Alternative health aromatherapy*. London, England: Optima.
- Marukawa, H., Shimomura, T. & Takashashi, K. (1996). Salivary substance P, 5-hydroxytryptamine, and gamma-aminobutyric acid levels in migraine and tension-type headache. *Headache*, 36, 100-104.
- Mascolo, N., Jain, R., Jain, S. & Capasso, F. (1989). Ethnopharmacologic investigation of ginger (*Zingiber officinale*). *Journal of Ethnopharmacology*, 27, 129-140.
- Medical Research Council (2008). *Developing and evaluating complex interventions: new guidance*. London, England: Medical Research Council.
- Melancon, B. & Miller, L.H. (2005). Massage Therapy versus traditional therapy for low back pain relief: Implications for holistic nursing practice. *Holistic Nursing Practice*, May/June, 116-121.
- Melzack, R. (1987). The short-form McGill Pain Questionnaire. *Pain*, 30, 191-197.
- Melzack, R. & Wall, P.D. (1996). *The challenge of pain* (2nd ed.). London, England: Penguin Books.

- Melzack, R. & Wall, P.D. (2008). *The challenge of pain* (Updated 2nd ed.). London, England: Penguin Books.
- Middleton, P. & Pollard, H. (2005). Are chronic low back pain outcomes improved with co-management of concurrent depression? *Chiropractice & Osteopathy*, 13(8), 1-7.
- Miller, F.G., & Brody, H. (2002). What makes placebo-controlled trials unethical? *The American Journal of Bioethics*, 2(2), 3-9.
- Miller, F.G., & Veatch, R.M. (2007). Symposium on equipoise and the ethics of clinical trials. *Journal of Medicine and Philosophy*, 32 (2), 77-78.
- Miu, D.K.Y., Chan, T.Y. & Chan, M.H. (2004). Pain and disability in a group of Chinese elderly out-patients in Hong Kong. *Hong Kong Medical Journal*, 10(3), 160-165.
- Moher, D., Jadad, A. R., Nichol, G., Penman, M., Tugwell, P., & Walsh, S. (1995). Assessing the quality of randomised controlled trials: An annotated bibliography of scales and checklists. *Controlled Clinical Trials*, 16(1), 62–73.
- Moher, D., Jones, A., Lepage, L., & for the CONSORT Group (2001). Use of the CONSORT statement and quality of reports of randomised trials: A comparative before-and-after evaluation. *Journal of the American Medical Association*, 285(15), 1992–1995.
- Moher, D., Hopewell, S., Schulz, K. F., Montori, V., Gøtzsche, P. C., Devereaux, P.J., et al. (2010). CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. *Journal of Clinical Epidemiology*, 63(8), e1-e37.
- Moldofsky, H. (1982). Rheumatic pain modulation syndrome: The interrelationships between sleep, central nervous system, serotonin, and pain. *Advances in Neurology*, 33(33), 51-57.
- Montenegro, R., Needleman, I., Moles, D., & Tonetti, M. (2002). Quality of RCTs in periodontology - a systematic review. *Journal of Dental Research*, 81(12), 866-870.
- Morelli, M., Seaborne, D. & Sullivan, S. (1990). Changes in H-reflex amplitude during massage of triceps surae in healthy subjects. *Journal of Orthopaedic and Sports Physical Therapy*, 12(2), 55-59.

- Morelli, M., Seaborne, D. & Sullivan, S. (1991). H-reflex modulation during manual muscle massage of human triceps surae. *Archives of Physical Medicine and Rehabilitation*, 72, 915-919.
- Morelli, M., Chapman, C. & Sullivan, S. (1999). Do cutaneous receptors contribute to the changes in the amplitude of the H-reflex during massage? *Electromyography and clinical neurophysiology*, 39, 441-417.
- Morone, N.E., Rollman, B.L., Moore, C.G., Qin, L. & Weiner, A.K. (2009). A Mind-Body Program for Older Adults with Chronic Low Back pain: Result of a Pilot Study. *American Academy of Pain Medicine*, 10, 1395-1407.
- Moyer, C., Rounds, J. & Hannum, J.W. (2004). A meta-analysis of massage therapy research. *Psychological Bulletin*, 130, 3-18.
- Mustafa, T., Srivastava, K.C. & Jeusen, K.B. (1993). Drug development reports. Pharmacology of ginger (*Zingiber officinale*). *Journal of Drug Development*, 6, 25-39.
- National Centre for Complementary and Alternative Medicine. (2007). *What is complementary and alternative medicine?* Retrieved 12 March, 2012 from <http://nccam.nih.gov/health/whatiscom/>
- National Health and Medical Research Council, Australian Research Council & Australian Vice-Chancellors' Committee (2007). *National statement on ethical conduct in human research*. Canberra, Australia: Attorney General's Department.
- National Institute for Health and Clinical Excellence. *Low back pain. Early management of persistent non-specific low back pain*. NICE Clinical Guideline 88. <[www.nice.org.uk/CG88fullguideline](http://www.nice.org.uk/CG88fullguideline)>.
- National Statistic Office, Ministry of Information and Technology. (2003). A survey report of elderly in Thailand in 2002, Bangkok : Chan Chom Pub.
- Niemistö, L., Rissanen, P., Sarna, S., Lahtinen-Suopanki, T., Lindgren, K.A. & Hurri, H. (2005). Cost-effectiveness of combined manipulation, stabilizing exercises, and physician consultation compared to physician consultation alone for chronic low back pain: a prospective randomised trial with two-year follow-up. *Spine*, 30(10), 1109–1115.

- Noordzij, M., Tripepi, G., Dekker, F. W., Zoccali, C., Tanck, M. W., & Jager, K. J. (2010). Sample size calculations: Basic principles and common pitfalls. *Nephrology Dialysis Transplantation*, 25(5), 1388-1393.
- Ogon, M., Krismer, M., Sollner, W., Kantner-Rumplmair, W., & Lampe, A. (1996). Chronic low back pain measurement with visual analogue scales in different settings. *Pain*, 64(3), 425-428.
- Ojala, R.S. (n.d.). *An introduction to the benefits of massage therapy: massage: Swedish massage*. Retrieved 10 September, 2010 from <http://www.lovinghandsinstitute.com/htm/massage.htm>
- Olivo, S. A., Macedo, L. G., Gadotti, I. C., Fuentes, J., Stanton, T., & Magee, D. J. (2008). Scales to assess the quality of randomised controlled trials: A systematic review. *Physical Therapy*, 88(2), 156–175.
- Onogi, T. (1992). Capsaicin-like effect of shogaool on substance P-containing primary afferents rat: A possible mechanism of analgesic action. *Neuropharmacology*, 31, 1165-1169.
- Osborn, C. E., Barlas, P., Baxter, G. D., & Barlow, J. H. (2001). Aromatherapy: a survey of current practice in the management of rheumatic disease symptoms. *Complementary Therapies in Medicine*, 9(2), 62-67.
- Park, S., Choue, R., Cho, Y. & Ziboh, V. (2003). Regional biosynthesis of prostaglandins and hydroxyeicosatetraenoic acids from arachidonic acid in the rat stomach tissue. *Prostaglandins, Leukotrienes and Essential Fatty Acids*, 68, 35-42.
- Parris, W.C.V., Kambam, J.R. & Naukam, R.J. (1990). Immunoreactive substance P is decreased in saliva of patients with chronic back pain syndromes. *Anesthesia and Analgesia*, 70, 63–67.
- Phillips, J.A. & Brown, K.C. (1996). Low Back Pain: Prevention and Management. *Journal of the American Association of Occupational Health Nurses*, 44(1), 40-54.
- Polit, D.F. & Hungler, B.P. (1999). *Nursing research: Principles and methods* (6th ed.). Philadelphia, PA: J.B. Lippincott.
- Polit, D.F. & Beck, C.T. (2012). *Nursing research: Generating and assessing evidence for nursing practice* (9th ed.). Philadelphia, PA: Lippincott Williams & Wilkins.

- Polit, D.F. & Gillespie, B.M. (2010). Intention-to-treat in randomised controlled trials: Recommendations for a total trial strategy. *Research in Nursing & Health*, 33, 355-368.
- Prateepavanich, P., Kupniratsaikul, V. & Charoensak, T. (1999). The relationship between myofascial trigger points of gastrocnemius muscle and nocturnal calf cramps. *Journal of the Medical Association of Thailand*, 82, 451-459.
- Prescott, R.J., Counsell, C.E., Gillespie, W.J., Grant, A.M., Russell, I.T., Kiauka, S., et.al., (1999). Factors that limit the quality, number and progress of randomised controlled trials. *Health Technology Assessment* 3 (20).
- Preyde, M. (2000). Effectiveness of massage therapy for subacute low-back pain: A randomised controlled trial. *Canadian Medical Association Journal*, 162(13), 1815-1820.
- Price, L., Smith, I. & Price, S. (1999). *Carrier oil for aromatherapy and massage* (3rd ed.). New York, NY: Riverhead Publishing.
- Price S. & Price L. (1999). *Aromatherapy for health professionals* (2nd ed.). London, England: Churchill Livingstone.
- Purves, D. (2004). *Neuroscience* (3rd ed.). Sunderland, Mass: Sinauer Associates, Inc.
- Rachlin, I. (1994). Therapeutic massage in the treatment of myofascial pain syndromes and fibromyalgia. In E.S. Rachlin (Ed.), *Myofascial pain and fibromyalgia: Trigger point management* (pp. 455-474). St. Louis, MO: Mosby.
- Redfern, S.J. & Ross, F.M. (2005). *Nursing older people* (3rd ed.). London, England: Churchill Livingstone.
- Reese, N.B. & Bandy, W.D. (2002). Measurement of range of motion of the thoracic and lumbar spine. In N.B. Reese (Ed.), *Joint range of motion and muscle length testing* (pp.169-208). Philadelphia, PA: W.B. Saunders Company.
- Remington, R. (2002). Calming music and hand massage with agitated elderly. *Nursing Research*, 51, 317-323.
- Richards, D. A., & Hamers, J. P. H. (2009). RCTs in complex nursing interventions and laboratory experimental studies. *International Journal of Nursing Studies*, 46(4), 588-592.
- Ritzwoller, D. P., Crouse, L., Shetterly, S. & Rublee, D. (2006). The association of comorbidities, utilization and costs for patients identified with low back pain. *BMC Musculoskeletal Disorders*, 7:72.

- Rolfe, G. (2002). Faking a difference: evidence-based nursing and the illusion of diversity. *Nurse Education Today*, 22 (1), 3–12.
- Rothman, K.L., & Michels, K.B. (1994). The continuing unethical use of placebo controls. *New England Journal of Medicine*, 331(6), 394-398.
- Rothwell, P.M. (2005). External validity of randomised controlled trials: To whom do the results of this trial apply? *Lancet*, 365, 82-93.
- Royal College of Nursing (2003, October) *Complementary therapies in nursing, midwifery and health visiting practice* [Press release]. Retrieved 10 March, 2011 from [http://www.rcn.org.uk/data/assets/pdf\\_file/0008/78596/002204.pdf](http://www.rcn.org.uk/data/assets/pdf_file/0008/78596/002204.pdf)
- Rudy, T.E., Weiner, D.K., Lieber, S.J., Slaboda, J. & Boston, J.R. (2007). The impact of chronic low back pain on older adults: A comparative study of patients and controls. *Pain*, 131(3), 293-301.
- Rush, A. J., Polatin, P. & Gatchel, R. J. (2000). Depression and Chronic Low Back Pain: Establishing Priorities in Treatment. *Spine*. 25(20), 2566-2571.
- Saastamoinen, P., Leino-Arjas, P., Laaksonen, M., Martikainen, P. & Lahelma, E. (2006). Pain and health related functioning among employees. *The Journal of Epidemiology and Community Health*, 60, 793–798.
- Sackett, D. L. (2000). The fall of clinical research and the rise of clinical-practice research. *Clinical and Investigative Medicine*, 23(6), 331-381.
- Sae-jung, S., Hunzavong, T. & Jirattanapochai, K. (2002). Reliability of Thai version of Oswestry Questionnaire for the evaluation of low back pain patients. *Srinagarind Medical Journal*, 17, 247-253.
- Sagar, S., Dryden, T. & Wong, K. (2007). Massage therapy for cancer patients: A reciprocal relationship between body and mind. *Current Oncology*, 14, 45-56.
- Salguero, C. (2004). *Encyclopedia of Thai massage*. Findhorn, Finland: Findhorn Press.
- Salvo, G.S. (2003). *Massage therapy: Principles and practice* (2nd ed.). St. Louis, Mo: Saunders.
- Sanson-Fisher, R.W., Bonevski, B., Green, L.W., & D'Este, C. (2007). Limitations of the randomised controlled trial in evaluating population based health interventions. *American Journal of Preventive Medicine*, 33, 155–161.
- Schnaubelt, K. (1998). *Advanced aromatherapy: The science of essential oil therapy*. Rochester: Vermont.

- Schulz, K.F. (2000). Assessing allocation concealment and blinding in randomised controlled trials: why bother? *Evidence-Based Nursing*, 5, 36–37.
- Schulz, K.F., Altman, D.G., Moher, D. & for the CONSORT Group (2010). CONSORT2010 statement: Updated guidelines for reporting parallel group randomised trials. *British Medical Journal*, 340, c332.
- Schulz, K. F., & Grimes, D. A. (2002). Allocation concealment in randomised trials: defending against deciphering. *The Lancet*, 359(9306), 614-618.
- Seok, H., Son, B.K., Ha, Y.R., Ryu, H.H. & Moon, J.H. (2003). Clinical influence of emotional depression on chronic low back pain. *Journal of Korean Academy of Rehabilitation Medicine*, 27(40), 568-574.
- Sharma, J.N. & Srivastava, K.C. (1994). Suppressive effects of eugenol and ginger oil on arthritic rats. *Pharmacology*, 49, 314-318.
- Sheikh, R.L. & Yesavage, J.A. (1986). Geriatric Depression Scale (GDS): Recent evidence and development of a shorter version. *Clinical Gerontologist*, 5, 165-173.
- Sherman, K.J., Cherkin, D.C., Connelly, M.T., Erro, J., Savetsky, J.B., Davis, R.B. & Eisenberg, D.M. (2004). Complementary and alternative medical therapies for chronic low back pain: What treatments are patients willing to try? *BMC Complementary and Alternative Medicine*, 4(9), 1-8.
- Sibbald, B., & Martin, R. (1998). Why are randomised controlled trials important? *British Medical Journal*, 316(7126), 201.
- Siegel-Maier, K. (1999). Aromatherapy & massage: Healing that makes scents. *Better Nutrition*, 61(10), 72-76.
- Simons, D.G., Travell, J.G. & Simons, L.S. (1999). Apropos of all muscles: Trigger point release. In D.G. Simon (Ed.), *Myofascial pain and dysfunction: The trigger point manual – upper half of body* (pp.140–150). Baltimore, MD: Williams & Wilkins.
- Singh, N.P., & Sarkar, T. (2011). Randomised controlled trials. *Indian Journal of Medical Specialities*, 2(2), 194-199.
- Smith, B. A., Lee, H.-J., Lee, J. H., Choi, M., Jones, D. E., Bausell, R. B., et al. (2008). Quality of reporting Randomised Controlled Trials (RCTs) in the nursing literature: Application of the Consolidated Standards of Reporting Trials (CONSORT). *Nursing Outlook*, 56(1), 31-37.e33.

- Snook, S.H. (2004). Work-related low back pain: Secondary intervention. *Journal of Electromyography and Kinesiology*, 14, 153-160.
- Sohn, P.M. & Loveland Cook, C.A. (2002). Nurse practitioner knowledge of complementary alternative health care: Foundation for practice. *Journal of Advanced Nursing*, 39(1), 9-16.
- Sritoomma, N., Moyle, W., Cooke, M. & O'Dwyer, S. (2012). The effectiveness of Swedish massage and traditional Thai massage in treating chronic low back pain: A review of the literature. *Complementary Therapies in Clinical Practice*, 18(4), 227-234.
- Srivastava, K.C. & Mustafa, T. (1989). Ginger (zingiber officinale) and rheumatic disorders. *Medical Hypotheses*, 29, 25-28.
- Srivastava, K.C. & Mustafa, T. (1992). Ginger (zingiber officinale) in rheumatism and musculoskeletal disorders. *Medical Hypotheses*, 39, 342-348.
- Stanley, K. (2007). Design of randomised controlled trials. *Circulation*, 115(9), 1164–1169.
- Stoddart, D. (1990). *The scented ape*. Cambridge: Cambridge University Press.
- Stolberg, H.O., Norman, G. & Trop, I. (2004). Fundamentals of clinical research for radiologists: Randomised controlled trials. *American Journal of Roentgenology*, 183, 1539-1544.
- Sugiura, M., Hayakawa, R., Kato, Y., Sugiura, K. & Hashimoto, R. (2000). Result of patch testing with lavender oil in Japan. *Contact Dermatitis*, 43, 157-160.
- Sukhatunga, K., Phattarayuttawat, S., Chantra, J., Luckom, M., Chaiyasit, W. & Bunnagulrote, K. (1998). Depression and dementia in the Thai elderly in urban and rural communities. *Siriraj Hospital Gaz*, 50, 232-43.
- Sullivan, S., Williams, L., Seaborne, D. & Morell, M. (1991). Effects of massage on alpha motoneuron excitability. *Physical Therapy*, 71 (8), 555-60.
- Tangtrongchir, P. (1992). *Traditional Thai massage*, Bangkok, Thailand: Chetawan Traditional Massage School.
- Tapanya, S. (1990). *Traditional Thai massage*, Bangkok, Thailand: Duang Kamol.
- Tavafian, S.S., Jamshidi, A., Mohammad, K. & Montazeri, A. (2007). Low back pain education and short-term quality of life: A randomised trial. *BioMed Central Musculoskeletal Disorders*. 8(21), 1-6.

- The Royal Australian college of General Practitioners. (2005). *Medical care of older persons in residential aged care facilities: Geriatric Depression Scale*. Retrieved 20 December, 2010 from <http://www.racgp.org.au/silverbookonline/4-4.asp>
- The SF Community. (n.d.). *The SF-12®: An even shorter health survey*. Retrieved 15 December, 2010 from <http://www.sf-36.org/tools/sf12.shtml>
- Therkleson, T. (2010). Ginger compress therapy for adults with osteoarthritis. *Journal of Advanced Nursing*, 66(10), 2225–2233.
- Thomas, K.J., MacPherson, H., Thorpe, L., Brazier, J., Fitter, M., Campbell, M.J. et al. (2006). Randomised controlled trial of a short course of traditional acupuncture compared with usual massage for persistent non-specific low back pain. *BMJ*, 333, 623.
- Thomson, M., Al-Qattan, K.K. & Al-Sawan, S.M. (2002). The use of ginger (*Zingiber officinale* Roscoe) as a potential anti-inflammatory and antithrombotic agent. *Prostaglandins, Leukotrienes and essential fatty acids*, 67, 475-478.
- Thongtang, O., Sukhatunga, K., Ngamthipwatthana, T., Chulakadabba, S., Vuthiganond, S., Pooviboonsuk, P., Kooptiwoot, S. & Phattharayuttawat, S. (2002). Prevalence and incidence of depression in the Thai elderly. *Journal of The Medical Association of Thailand*, 85(5), 540-544.
- Tisserand, R. (1990). *Aromatherapy for everyone*. Ringwood, England: Arkana.
- Tjendraputra, E., Tran, V.H., Liu-Brennan, D., Roufogalis, B.D. & Duke, C.C. (2001). Effect of ginger constituents and synthetic analogues on cyclooxygenase-2 enzyme in intact cell. *Bioorganic Chemistry*, 29, 156-163.
- Tonino, P., De Bruyne, B., Pijls, N., Siebert, U., Ikeno, F., Van 't, Veer, M., et al. (2009). Fractional Flow Reserve versus Angiography for Guiding Percutaneous Coronary Intervention. *The New England Journal of Medicine*, 360(3), 213-24.
- Train the brain forum committee (Thailand). (1994). *Thai Geriatric Depression Scale: Thai Version of the Geriatric Depression scale*. Retrieved 20 December, 2010 from <http://www.stanford.edu/~yesavage/Thai.html>
- Travell, J.G. & Simons, D.G. (1992). *Myofascial pain and dysfunction: The trigger point manual: The lower extremities* (Vol 2.). Baltimore, MD: Williams and Wilkins.

- Tritilanunt, T. & Wajannavisit, W. (2001). The efficacy of an aerobic exercise and health education program for treatment of chronic low back pain. *Journal of The Medical Association of Thailand*, 84 (Suppl2), S528-S532.
- Tuchtan, C., Tuchtan, V. & Stelfox, D. (2004). *Foundation of massage*. (2nd ed.). Marrickville, Australia: Elsevier Australia.
- Vane, J.R., Bakhele, Y.S. & Botting, R.M. (1998). Cyclooxygenases I and 2. *Annual Review of Pharmacology Toxicology*, 38, 97-120.
- Victora, C.G., Habicht, J-P., & Bryce, J. (2004). Evidence-based public health: moving beyond randomised trials. *American Journal of Public Health*, 94(3), 400–405.
- Vincent, C. & Furnham, A. (1996). Why do patients turn to complementary medicine? An empirical study. *British Journal of Clinical Psychology*, 35, 37–48.
- Vingard, E. & Nachemson, A. (2000). Work-related influences on neck and low back Pain. In A. Nachemson & E. Jonsson (Eds.), *Neck and back pain. The scientific evidence of causes, diagnoses and treatment* (pp. 97-126). Philadelphia: Lippincott Williams & Wilkins.
- Von, Korff M. & Simon, G. (1996). The relationship between pain and depression. *The British Journal of Psychiatry*, 30 (supplement), 101-108.
- Waddell, G. & Burton, A.K. (2000). *Occupational health guidelines for the management of low back pain at work-evidence review*. London: Faculty of Occupational Medicine.
- Waddell, G., Aylward, M. & Sawney, P. (2002). *Back pain, incapacity for work and social security benefits: An international literature review and analysis*. London: The Royal Society of Medicine Press Ltd.
- Walker, J., Holloway, I. & Sofaer, B. (1999). In the system: the lived experience of chronic back pain from the perspectives of those seeking help from pain clinics. *Pain*, 80, 621-628.
- Walker, B. F, Muller, R. & Grant, W.D. (2004). Low Back Pain in Australia Adults, Health Provider Utilization and Care Seeking. *Journal of manipulative and physiological therapeutics*, 27 (5), 327 – 335.
- Walters, C. (1998). *Aromatherapy: An illustrated guide*. Boston: Element books Inc.

- Wangtongkum, S., Sucharitakul, P., Wongjaroen, S. & Maneechompoo, S. (2008). Prevalence of Depression among a population Aged over 45 Years in Chiang Mai, Thailand, *Journal of The Medical Association of Thailand*, 91(12), 1812-1817.
- Ware, J.E., Kosinski, M. & Keller, S.D. (1996). A 12-Item Short-Form Health Survey: Construction of scales and preliminary test of reliability and validity. *Medical care*, 34(3), 220-233.
- Ware, J. E., Snow, K. K., Kosinski, M., Gandek, B., & Institute, N. E. M. C. H. H. (1993). *SF-36 health survey: manual and interpretation guide*: The Health Institute, New England Medical Center.
- Watson J. (1981). Pain mechanisms: a review. 1. Characteristics of the peripheral receptors. *Australian Journal of Physiotherapy*, 27, 135-143.
- Watson J. (1982). Pain mechanisms: a review. 3. Endogenous pain mechanisms. *Australian Journal of Physiotherapy*, 27, 135-143.
- Warner, T.D. & Mitchell, J.A. (2004). Cyclooxygenases: New forms, new inhibitors, and lessons from the clinic. *The FASEB Journal*, 18, 790-804.
- Weerapong, P., Hume, P.A. & Kolt, G.S. (2005). The mechanisms of massage and effects on performance, muscle recovery and injury prevention. *Sports Med*, 35(3), 235-256.
- Weidner, M.S. (1997). HMP-33 ginger extract-a new anti-inflammatory compound. *Osteoarthritis Cartilage*. 5 (suppl A), 42.
- Weiner, D. K., Haggerty, C. L., Kritchevsky, S. B., Harris, T., Simonsick, E. M., Nevitt, M., et al. (2003). How Does Low Back Pain Impact Physical Function in Independent, Well-Functioning Older Adults? Evidence from the Health ABC Cohort and Implications for the Future. *Pain Medicine*, 4(4), 311-320.
- Weiner, D.K., Sakamoto, S., Perera, S. & Breuer, P. (2006). Chronic low back pain in older adults: prevalence, reliability, and validity of physical examination finding. *Journal of the American Geriatrics Society*, 54(1), 11-20.
- Weiner, S. S. & Nordin, M. (2010). Prevention and management of chronic back pain. *Best Practice & Research Clinical Rheumatology*. 24, 267-279.
- Wheeler, A.H. (2010). *Low back pain and sciatica*. Retrieved 04 January, 2011 from <http://emedicine.medscape.com/article/1144130-overview>

- Wieting, M.J. & Cugalj, A.D. (2008, October 02). *Massage, traction, and manipulation* [Press release]. Retrieved 20 September, 2010 from <http://emedicine.medscape.com/article/324694-overview>
- Wikipedia. ( 2012). Thai massage. Retrieved from [http://en.wikipedia.org/wiki/Thai\\_massage](http://en.wikipedia.org/wiki/Thai_massage)
- Wilkie, D., Lovejoy, N., Dodd, M. & Tesler, M., (1990). Cancer pain intensity measurement: concurrent validity of three tools: finger dynamometer, pain intensity number scale, visual analogue scale. *Hospice Journal*, 6, 1-13.
- Willison, K.D & Andrews, G.J. (2004). Complementary medicine and older people: Past research and future directions. *Complementary Therapies in Nursing and Midwifery*, 10, 80-91.
- Winsett, R. P., Thompson, D. A., Gower, G., Leimig, R., & et al. (2007). Implementing randomised assignment in a nursing clinical randomised control trial. *Progress in Transplantation*, 17(2), 150-156.
- Wolsko, P.M., Eisenberg, D.M., Davis, R.B, Kessler, R. & Phillips, R.S. (2003). Patterns and perceptions of care for treatment of back and neck pain: Results of a national survey, *Spine*, 28, 292-297.
- Wood, L. (2002). Physiology of pain. In S. Kitchen (Ed.), *Electrotherapy: Evidence-based practice* (pp. 75-83). London, England: Churchill Livingstone.
- World Medical Association (2000). Declaration of Helsinki: ethical principles for medical research involving human subjects. *Journal of American Medical Association*, 284(23), 3043-3045.
- World Medical Association (2008). *WMA Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects*. Retrieved from <http://dl.med.or.jp/dl-med/wma/helsinki2008e.pdf>
- Worwood, V. (1991). *The fragrant pharmacy: A complete guide to aromatherapy and essential oils*. London, England: Random House.
- Wright, A. & Sluka, K.A. (2001). Nonpharmacological treatments for musculoskeletal pain. *The Clinical Journal of Pain*, 17(1), 33-46.
- Yesavage, J.A., Brink, T.L., Rose, T.L., Lum, O., Huang, V., Adey, M.B. & Leirer, V.O. (1983). Development and Validation of Geriatric Depression Screening Scale: A Preliminary Report. *Journal of Psychiatric Research*, 17, 37-49.

- Yip, Y.B. & Tam, A.C.Y. (2008). An experimental study on the effectiveness of Massage with aromatic ginger and orange essential oil for moderate-to-severe knee pain among the elderly in Hong Kong. *Complementary Therapies in Medicine, 16*, 131-138.
- Zehr, E. (2002). Consideration for the use of the Hoffmann reflex in exercise studies. *European Journal of Applied Physiology, 86*, 455-468.
- Zepinic, V. (2009). Post injury chronic low back pain and depression: comparative study between early and late post-injury sufferers shows significant difference. *International Journal of Health Science, 2*, 244.
- Zwarenstein, M., Treweek, S., Gagnier, J.J., Altman, D.G., Tunis, S., Haynes, B.(2008). Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *British Medical Journal, 337*, 1223-1226.