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MANAGEMENT OF BEHAVIOURAL AND
PSYCHOLOGICAL SYMPTOMS OF
DEMENTIA (BPSD) BY COMPLEMENTARY
AND ALTERNATIVE MEDICINE (CAM)
APPROACHES

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Management of Behavioural and Psychological
Symptoms of Dementia (BPSD) by
Complementary and Alternative Medicine (CAM)
Approaches

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A thesis submitted in partial fulfilment of the
requirements for the degree of Master of
Philosophy

February 2016

CERTIFICATE OF ORIGINALITY

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ABSTRACT

Background: The behavioural and psychological symptoms of dementia (BPSD) remain a major health problem and cause tremendous stress among older adults and caregivers, thereby impeding the healthcare system and increasing the cost burden on the community.

Literature review: Aromatherapy, therapeutic massage, and acupressure have received independent support in the literature; however, the quality of evidence is not high. Moreover, the synergistic effects of these three treatment modalities when combined are unknown.

Development of an intervention protocol: A complementary and alternative medicine protocol (i.e., the aroma-massage with acupressure protocol) was developed, which combined these three treatments based on the opinions of selected experts and information provided in the literature. The feasibility and safety of this protocol were assessed in a feasibility study with a small group of older adults with dementia. The results show that the protocol is safe and easy to administer.

The pilot RCT: A pilot randomized control trial (RCT) with adequate concealment in subject allocation, valid outcome assessments, a sample size based on an effect size calculation, and an intention-to-treat analysis was conducted to evaluate the immediate clinical effectiveness of this new intervention protocol in the management of BPSD and its effect six months after treatment completion. We also investigated the enhancing effect of the protocol on cognitive training, which is regarded as the active control. The results indicated positive effects in reducing the severity and distress of BPSD as assessed at the 3-month follow-up, and the positive effects remained unchanged at the 6-month follow-up. A continual improvement in the MMSE scores was noted. No adverse side effects were observed. The findings supported the safety, clinical efficacy

and effectiveness of the aroma-massage with acupressure protocol as an adjunct intervention for BPSD.

PUBLICATIONS ARISING FROM THE THESIS

Fung, J. K. K. M. & Tsang, H. W. H (2017). Management of behavioral and psychological symptoms of dementia (BPSD) by an aroma-massage with acupuncture treatment protocol: a randomized clinical trial. *Journal of Clinical Nursing*. doi: 10.1111/jocn.14101

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CHAPTER 1

BEHAVIOURAL AND PSYCHOLOGICAL SYMPTOMS OF DEMENTIA

1.1 Behavioural and Psychological Symptoms of Dementia: Definition, Prevalence & Impact

The increasing ageing population has become a global trend. The rate of dementia, an age-related condition, is rapidly increasing with increased longevity. Unfortunately, dementia has a profound impact on the community in various ways; it not only causes suffering for patients and poses a burden on their relatives but also hampers the healthcare system (Burns, 2000).

Dementia presents as a combination of symptoms, including memory loss and a decline in multiple cognitive functions (Cerejeira, Lagarto, & Mukaetova-Ladinska, 2012). For most individuals with dementia, behavioural disturbances further impede their quality of life (Robinson *et al.*, 2006). These behavioural disturbances are often regarded as the Behavioural and Psychological Symptoms of Dementia (BPSD).

They are defined as “signs and symptoms of disturbed perception, thought content, mood, or behaviour that frequently occur in patients with dementia” (Finkel, Costa E Silva, Cohen, Miller, & Sartorius, 1997; p. 1060). BPSD refer to neuropsychiatric symptoms manifested by behaviours such as repetitive questioning, wandering, and

hitting, as well as psychological signs, including delusion, agitation, and anxiety.

BPSD may also be considered the subjective experiences of individuals with dementia as these symptoms include depressive mood, anxiety, hallucination, and delusions, which may be assessed by interviewing the patients and their caregivers.

Some BPSD are behaviours observed by clinicians, including agitation, wandering, sexual disinhibition, restlessness, aggression, cursing, shadowing, and other culturally inappropriate behaviours. BPSD are very common in older adults with dementia who live within the community and account for between 56% and 98% of dementia sufferers or individuals residing in short- or long-term care facilities (Cerejeira *et al.*, 2012). Despite its high prevalence during the natural course of dementia, BPSD have not been included in the diagnostic criteria of dementia. They affect the emotions, perceptions, and functioning of older adults with patterns that vary over time (Harwood, Barker Ownby, & Duara, 2000). Eventually, individuals with dementia may progressively deteriorate into a state of total dependence in terms of daily living activities (Shin, Carter, Masterman, Fairbanks, & Cummings, 2005).

These symptoms are not typically manifested alone and co-occur with other symptoms, such as apathy, irritability, and sleep problems, as indicated in the Medical Research Council Cognitive Function and Ageing Study (Savva *et al.*, 2009). Depression and anxiety are also symptoms that frequently co-occur in

individuals in the early stages of dementia (Payne *et al.*, 2002). In contrast, wandering and agitation, which are related to the neuropathology of Alzheimer's disease, more commonly co-occur in the later stages of dementia (Steinberg *et al.*, 2006). Sleep disturbance is common in all stages of dementia (Aalten, de Vugt, Jaspers, Jolles, & Verhey, 2005).

BPSD are the fundamental cause of the poor quality of life of both older adults and their caregivers (Ryu, Ha, Park, Yu, & Livingston, 2011). When caring for individuals with dementia, caregivers may be consigned to a long period of caregiving, which ranges from three to 15 years (Vitaliano, Wayne, & Katon, 2006). These behavioural disturbances (i.e., agitation, restlessness, and others) cause tremendous stress among caregivers (Haupt & Kurz, 1993), which is a genuine reason for them to send individuals with dementia to care facilities, such as old age homes (Chan, Kasper, Black, & Rabins, 2003). BPSD may also be a reason for admission to an acute care hospital, and providing care in this environment is highly challenging for hospital staff (Sampson *et al.*, 2014). As a result, the costs associated with hospitalization and institutionalization have remarkably increased (Schneider Beerl, Werner, Davidson, & Noy, 2002; Herrmann *et al.*, 2006).

1.2 Limitations of Mainstream Treatment

The maintenance of the cognitive function of individuals with dementia has previously received the most attention. Currently, the focus has shifted to the management of BPSD. The mainstream treatment of BPSD involves pharmacotherapy and non-pharmacological treatments. Both treatments are subject to rigorous investigation, and some forms of treatment have been shown to be effective for the management of BPSD.

For non-pharmacological interventions, research efforts include sensory interventions, purposeful activities, person-centred care, communication skills, dementia care mapping, and training of family caregivers in behavioural management therapies (BMT) and/or cognitive-behavioural therapy (CBT) (Livingston *et al.*, 2014). Sensory interventions (Van Weert, van Dulmen, Spreeuwenberg, Ribbe, & Bensing, 2005; Remington, 2002) are compatible with purposeful activities (Buettner & Ferrario, 1998; Kovach, Taneli, Dohearty, Schlidt, Cashin, & Silva-Smith, 2004; Cohen-Mansfield, Parpura-Gill, & Golander, 2006) in reducing agitation. Some sensory interventions are theory-based activities, such as neurodevelopment and Montessori techniques, and some interventions are pleasure-based activities, such as listening to music and receiving a hand massage (Lin *et al.*, 2009), which have been shown to have beneficial effects. However, their

effects are only short-term, and they do not appear to be sustainable after withdrawal.

Person-centred care, communication skill training, and dementia care mapping are reported to be effective in reducing agitation by up to 30% (Chenoweth *et al.*, 2009). This is based on the theory that changes to the physical/human environment will compensate for the ineffective attempts of patients to cope with their environment and stress factors. These treatments involve communication tactics, understanding the needs of individuals with dementia, and techniques to fulfil their unmet wishes that the care staff must learn. Compelling evidence on the long-lasting effects has been identified three to six months after the implementation of these techniques. The major drawback is the long training hours caregivers must undergo, which may not be affordable for many care facilities. More importantly, significant results have only been obtained when the care procedures are conducted under the close supervision of professional staff.

BMT and CBT are often implemented to reduce BPSD; however, they have been shown to be ineffective in several studies, as stated in the systematic review by Livingston *et al.* (2014). As the cognitive function of patients decline, BPSD become more unpredictable. As a result, BMT and CBT interventions are less likely to be applicable.

Apart from the non-pharmacological interventions, pharmacotherapies are also a mainstream treatment for BPSD. They are particularly crucial when severe aggression or other severe psychotic symptoms are present (Lawlor, 2004). The routine use of antipsychotics to handle severe behavioural disturbances is the foremost mainstream treatment of physicians (Schneider *et al.*, 2006).

Conventional antipsychotic drugs, such as haloperidol and thioridazine, are often used as the first line of medication; however, as a result of their intolerable, severe adverse side effects, they are currently being substituted by newer, atypical antipsychotic drugs, such as risperidone, olanzapine, quetiapine, and aripiprazole (Schneider, Dagerman, & Insel, 2005). These second generation antipsychotic drugs are preferred because of emerging clinical evidence regarding their effectiveness and efficacy in minimizing BPSD with acceptable side effects (Katz *et al.*, 1999; Brodaty *et al.*, 2003).

Apart from antipsychotic drugs, antidepressants and anticonvulsant mood stabilizers are also used to manage mood disorders and nonpsychotic agitation, respectively (Beier, 2007). However, they may increase the risk of confusion, which is the underlying cause of agitation (Scarmeas *et al.*, 2005).

Patients are more likely to discontinue medication as a result of severe adverse side effects (Beier, 2007). Adverse side effects include not only frequent falls and

drowsiness but also major cognitive decline (Bierman *et al.*, 2007) and cerebrovascular adverse events (Layton, Harris, Wilton, & Shakir, 2005), which may lead to higher mortality rates than dementia alone (Liperoti *et al.*, 2009; Opie, Doyle, & O'Connor, 2002).

As a result of the limitations of mainstream treatments, the development of novel non-pharmacological and alternative approaches for the management of behavioural disturbances is urgently needed (Burns *et al.*, 2011; Fung, Tsang, & Chung, 2012).

1.3 Paradigm Shift in the Management of BPSD

In the past, the treatment of individuals with dementia mainly focused on the maintenance of cognitive function. As understanding of disease progression increases, it is clear that the deterioration of independence and functioning is inevitable; therefore, in adjunct to the continuation of the search for a cure, the exploration of plausible methods for the management of BPSD has become an increasingly important research field.

Although the manifestation of BPSD is thought to be unpredictable, these non-cognitive symptoms and behaviours are signs of further decline of cognitive functioning and are common during the course of dementia. To date, there are no

diagnostic criteria for these symptoms. Similar symptoms are difficult to accurately distinguish from one another. BPSD are well established to be a substantial challenge in treatment and management. For example, depression and apathy are very similar symptoms; however, the treatments are completely different.

To date, the pathogenesis of BPSD is poorly understood. There are different theories regarding environmental factors (both psychosocial and physical), which are reported to lead to the occurrence of BPSD. Studies relate verbal/vocal behaviours with the pain, discomfort, or loneliness experienced by individuals with dementia, whereas physically non-aggressive behaviours result from low engagement with any activity (Cohen-Mansfield & Werner, 1995; Cohen-Mansfield, 2000; Cohen-Mansfield, Dakheel-Ali, Marx, Thein, & Regier, 2015; Sloane *et al.*, 1997). Wetzels, Zuidema, de Jonghe, Verhey, and Koopmans (2010) reported that sensory overstimulation by the surrounding environment, crowded living spaces, and poor attitudes of care staff may be the cause of the high prevalence of BPSD.

Similarly, complicated care procedures and the restraint of patients may lead to more severe symptoms (Kunik *et al.*, 2010). Apart from environmental factors, internal factors, such as an impairment in verbal expression that results from the inability to express mood and need, are highly correlated with the psychotic symptoms of individuals with dementia (Tsai, Wang, Zheng, & Fuh, 2010).

As patients encounter difficulties in coping with their environment, as well as physiological stress factors, studies focused on modifying their environment, reducing stress factors, and improving mood have become the focus of research. Instead of aiming to identify a cure for dementia, clinical trials of various novel non-pharmacological interventions aimed at reducing the occurrence of BPSD have been placed under the spotlight in the field of geriatric rehabilitation.

CHAPTER 2
AROMATHERAPY, ACUPRESSURE, AND THERAPEUTIC MASSAGE AS
COMPLEMENTARY AND ALTERNATIVE APPROACHES FOR THE
MANAGEMENT OF BEHAVIOURAL AND PSYCHOLOGICAL SYMPTOMS
OF DEMENTIA

2.1 Definition and Utilization of Complementary and Alternative Medicine

Approaches

The definition of Complementary and Alternative Medicine (CAM) by the National Center for Complementary and Alternative Medicine (NCCAM, 2011) is “a group of diverse medical and healthcare systems, practices, and products that are not presently considered to be part of conventional medicine”. This centre is currently referred to as the National Center for Complementary and Integrative Health (NCCIH). Examples of CAM include hypnotherapy, acupuncture, and herbal medicine. In contrast to standard treatments in conventional medicine, fewer systematic and well-planned research studies have been conducted to determine the safety and effectiveness of most types of CAM.

In December 2014, the NCCIH claimed complementary therapies are “non-mainstream practice used *together with* conventional medicine”, and when complementary health approaches are used alongside conventional approaches in a

systematically coordinated fashion, this combination should be referred to as integrative health approaches. Alternative therapies were defined as “non-mainstream practice used *in place of* conventional medicine”. As most individuals use non-mainstream approaches together with conventional treatments, true “alternative” medicine is scarce.

According to the NCCIH, most complementary health approaches may be differentiated into two subgroups: natural products and mind and body practices. Natural products, such as botanicals, probiotics, vitamins, and minerals, are well known as dietary supplements and are well accepted by the general public. The utilization of these natural products constituted the most popular complementary health approach among adults in the United States in 2012 (Clarke, Black, Stussman, Barnes, & Nahin, 2015).

Mind and body practices include massage therapy, relaxation techniques, and meditation. Other well-known clinical practices, such as yoga, chiropractic, and osteopathic manipulation, also belong to this category. Some approaches are less commonly practised in Western countries; however, they are very common in Asia. These approaches include Tai Chi and Qi-gong.

The utilization of CAM or integrative health approaches is universal and comprehensive, particularly for medical conditions in which the effect of

conventional treatments is not satisfactory. CAM approaches are often used for different conditions. Pain and symptom management are mediated through various types of CAM in cancer patients (Bardia, Barton, Prokop, Bauer, & Moynihan, 2006). Various types of CAM are implemented to treat many different types of chronic pain in all age groups (McEachrane-Gross, Liebschutz, & Berlowitz, 2006). Hypnotherapy is used for smoke cessation (Rigotti, 2002). Dietary supplements are used for weight control (Pittler & Ernst, 2004), stabilizing and harmonizing mood for depression (Ernst, Rand, & Stevinson, 1998), and strengthening the immune system (Morris, Johnson, Homer & Walts, 2000).

2.2 Aromatherapy

2.2.1 Definition, History & Utility in Mood Conditions

Aromatherapy involves the use of essential oils (EOs), also referred to as volatile oils, extracted from different parts of plants, including flowers, stem, leaves, root, bark, peel, and resin, by distillation, compression, and, in some cases, chemical procedures, such as CO₂ or solvent extraction but with the natural chemical compositions of EOs preserved. Aromatherapy is administered via different approaches, including direct and indirect inhalation, massage, and topical

application; however, it is rarely administered through oral intake. As EOs are very concentrated, they are always diluted prior to application.

Aroma refers to the scent, which is the signature of EO. However, the treatment effect is not only mediated through the olfactory system. The treatment effect of aromatherapy is based on the theory that the utilization of energy from the sun and elements from the soil, air, and water stored in plant extracts may achieve harmony in the mind, body, and spirit.

The healing effect of fragrant plants was recognized in many ancient civilizations, such as China, Egypt, and India. The modern age of aromatherapy began in the early 20th century, when the father of aromatherapy, French chemist Rene Gattefosse, first studied the treatment effect of EOs on different types of illnesses. His pioneer work coincided with an increasing interest in the therapeutic effects of EO.

The calming effect of EOs is attained when they enter the circulation system and react with enzymes and hormones, thereby causing the desired physiological response. Previous studies have shown that the application of lavender EO increased the level of blood serotonin, which is essential for achieving better sleep quality (Zeilmann *et al.*, 2003; Louis & Kowalski, 2002; Gyllenhaal, Merritt, Peterson, Block, & Gochenour, 2000).

To examine the anxiolytic effects of lavender EO, an experiment was conducted in rodents by Tsang *et al.* (2013), who reported that the inhalation of 2.5% lavender EO significantly up-regulated brain serotonin levels in the prefrontal cortex and produced anxiolytic effects similar to tranquilizing drugs.

Aromatherapy is a non-pharmacological approach that has been widely used to manage insomnia (Hardy, Kirk-Smith, & Stretch, 1995; Wolfe & Herzberg, 1996), reduce behavioural disturbances (Brooker, Snape, Johnson, & Ward, 1997; Fujii *et al.*, 2008; Mitchell, 1993), and improve social engagement (Ballard, O'Brien, Reichelt, & Perry, 2002) in individuals with dementia.

2.2.2 Clinical Studies of Aromatherapy on BPSD

To identify the clinical benefits and efficacy of aromatherapy in reducing the occurrence of BPSD in older adults with dementia and address the gap in the literature, a systematic review was performed based on randomized control trials (RCT) by Fung *et al.* (2012).

Studies written in English were extracted from electronic databases (CINAHL, Medline, PubMed, Cochrane Library, PsycINFO, Social Sciences Citation Index, SCOPUS, and the International Journal of Aromatherapy) from 1995 to 2011. The

keywords used included “dementia” or “Alzheimer’s disease” or “behavioural and psychological symptoms of dementia” and “essential oil” or “aromatherapy”.

Eleven prospective RCT published from 1997 to 2011 were identified. Data, including study design, treatment method and regime, and outcomes, were extracted using a data extraction form (refer to Appendix I for the description of the 11 RCT reviewed). The studies were also assessed using the Jadad score (Jadad *et al.*, 1996) to determine whether they have an appropriate randomization procedure; blinding of subjects, treatment providers, and outcome assessors; and dropouts or withdrawals.

A meta-analysis was performed for the same outcome measures grouped from different studies using the Cochrane Collaboration’s software (Review Manager [RevMan] version 5 for Windows, the Nordic Cochrane Centre, Copenhagen, Denmark).

Six of the 11 studies were conducted in Hong Kong (Lin, Chan, Ng, & Lam, 2007), the USA (Gray & Clair, 2002), Iran (Akhondzadeh *et al.*, 2003), Japan (Jimbo, Kimura, Taniguchi, Inoue, & Urakami, 2010), Australia (Kilstoff & Chenoweth, 1998), and a non-specific place (Snow, Hovanec, & Brandt, 2004), whereas the other studies were conducted in the UK (Ballard, O’Brien, Reichelt, & Perry, 2002; Burleigh & Armstrong, 1997; Burns *et al.*, 2011; Holmes *et al.*, 2002; Smallwood, Brown, Coulter, Irvine, & Copland, 2001). The clinical settings

included 13 long-term care homes, three clinical centres, one day care unit, one psychogeriatric and one general ward, and three centres of an unknown nature; one study did not specify its nature.

There were 405 participants in total with sample sizes that ranged from 11 to 114. Participants had different severities of dementia. Five studies had 20 participants or less. Most participants were diagnosed according to the diagnostic criteria of the International Classification of Diseases (ICD-10), the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV), and the National Institutes of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorder Association (NINCDS-ADRDA). In Smallwood *et al.*'s (2001) study, participants were diagnosed by a consultant psychiatrist with no criteria reported. One study (Ballard *et al.*, 2002) recruited their subjects based on the presence of BPSD assessed by the Neuropsychiatric Inventory (NPI), the Clinical Dementia Rating Scale (CDRS), and the Cohen-Mansfield Agitation Inventory (CMAI). Snow *et al.* (2004), Burleigh and Armstrong (1997), and Kilstoff and Chenoweth (1998) recruited their participants according to the BPSD reported by caregivers or caregiving staff. Apart from the CMAI and NPI (Ballard *et al.*, 2002; Lin *et al.*, 2007; Snow *et al.*, 2004), the Pittsburgh Agitation Scale (PAS) (Burleigh & Armstrong, 1997; Holmes *et al.*, 2002) and the Behavior

Assessment Scale of Later Life (BASOLL) (Burleigh & Armstrong, 1997) were also used for the assessment of BPSD. Cognitive functions were assessed by the CDRS (Akhondzadeh *et al.*, 2003; Ballard *et al.*, 2002), the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog) (Akhondzadeh *et al.*, 2003; Burns *et al.*, 2011), the Mini-Mental State Examination (MMSE) (Snow *et al.*, 2004), the Gottfries, Brane, Steen Scale (GBSS-J) (Jimbo *et al.*, 2009), the revised version of Hasegawa's Dementia Scale (HDS) (Jimbo *et al.*, 2009), and the Touch Panel-type Dementia Assessment Scale (Jimbo *et al.*, 2009).

Four studies had one treatment and one placebo group (Akhondzadeh *et al.*, 2003; Ballard *et al.*, 2002; Holmes *et al.*, 2002; Lin *et al.*, 2007), four studies were within-subject designs (Burleigh & Armstrong, 1997; Gray & Clair, 2002; Jimbo *et al.*, 2009; Kilstoff & Chenoweth, 1998), and the remaining studies had three treatment or placebo groups (Burns *et al.*, 2011; Smallwood *et al.*, 2001; Snow *et al.*, 2004). Sunflower oil (Ballard *et al.*, 2002; Lin *et al.*, 2007) and water (Holmes *et al.*, 2002) were used as controls. For the treatment group, lavender EO (Holmes *et al.*, 2002; Lin *et al.*, 2007; Smallwood *et al.*, 2001; Snow *et al.*, 2004) and lavender EO mixed with other EOs, such as lemon, sweet orange, and rosemary (Jimbo *et al.*, 2009), sweet orange and tea tree (Gray & Clair, 2002), marjoram, chamomile, and

rosemary (Burleigh & Armstrong, 1997), and mandarin and geranium (Kilstoff & Chenoweth, 1998), were used.

Snow *et al.* (2004) used lavender EO and thyme EO separately. Three studies used melissa leaf EO alone (Akhondzadeh *et al.*, 2003; Ballard *et al.*, 2002; Burns *et al.*, 2011). Most EOs were administered via inhalation (Gray & Clair, 2002; Holmes *et al.*, 2002; Jimbo *et al.*, 2009; Lin *et al.*, 2007; Snow *et al.*, 2004;) and massage (Ballard *et al.*, 2002; Burns *et al.*, 2011; Kilstoff & Chenoweth, 1998), one was administered by massage and inhalation (Smallwood *et al.*, 2001), one combined hot bath with massage and inhalation (Burleigh & Armstrong, 1997), and one was administered by oral intake. For the study that involved oral intake (Akhondzadeh *et al.*, 2003), concentrated EOs were used. Four studies (Ballard *et al.*, 2002; Burns *et al.*, 2011; Holmes *et al.*, 2002; Kilstoff & Chenoweth, 1998) reported the use of EOs diluted to concentrations of 10% or less, whereas the other studies did not report the concentration.

The functioning of the activities of daily living (ADL) was also assessed by the Barthel Index (BI) (Ballard *et al.*, 2002; Burns *et al.*, 2011) and the Functional Assessment Staging Test (FAST) (Jimbo *et al.*, 2009). Quality of life was assessed by the Blau Quality of Life Scale (Jimbo *et al.*, 2009).

Five RCT reported significant differences in the scores of the outcome assessment between the treatment group and the control group, which confirmed the positive treatment effects of aromatherapy on behavioural disturbances (Akhondzadeh *et al.*, 2003; Ballard *et al.*, 2002; Burns *et al.*, 2011; Jimbo *et al.*, 2010; Lin *et al.*, 2007).

Among the five studies, three studies reported that the behavioural disturbances of participants in the treatment groups were significantly reduced (Akhondzadeh *et al.*, 2003; Ballard *et al.*, 2002; Lin *et al.*, 2007). Two studies resulted in an increase in engagement in constructive conversation and social activities (Akhondzadeh *et al.*, 2003; Jimbo *et al.*, 2010), whereas Burns *et al.* (2011) identified a significant improvement in quality of life ratings in participants in the treatment group.

Three of the six remaining studies of this review reported positive effects of aromatherapy on relationships and conversations between patients and their caregivers (Burleigh & Armstrong, 1997; Kilstoff & Chenoweth, 1998; Smallwood *et al.*, 2001).

A meta-analysis was performed on the CMAI variables used as outcome measures in three papers (Ballard *et al.*, 2002; Lin *et al.*, 2007; Snow *et al.*, 2004) and showed significant results that favoured the treatment effect of the treatment groups. The side effects were minimal when applied topically or via inhalation.

These findings are encouraging; however, as a result of the small number of publications reviewed (among them, six studies had a Jadad score of two or less, which implies a rather low quality) and the different choices of EOs and implementation protocols, a more standardized protocol must be developed and tested before we can reach a final conclusion regarding the clinical effects of aromatherapy.

Although the researchers in three studies (Ballard *et al.*, 2002; Burns *et al.*, 2011; Holmes *et al.*, 2002) claimed that concomitant drug use may be a confounding factor that should be taken into account, all of the previously described findings have led to the conclusion that aromatherapy using certain types of EO, such as lavender EO and melissa EO, is likely to constitute an alternative intervention for managing behavioural disturbances.

Additional studies were conducted from 2012 onwards. Sakamoto, Ebihara, and Ebihara (2012) conducted a randomized placebo-controlled trial to investigate the effects of lavender olfactory stimulation on the fall incidence in elderly home residents; there were fewer fallers in the treatment group than in the placebo group. One reason for the reduction in falls was believed to be the reduction in agitation by lavender olfactory stimulation.

O'Connor, Eppingstall, Taffe, and van der Ploeg (2013) conducted a randomized trial that compared dermally applied lavender EO with control EO. No significant difference was identified in the counts of agitated behaviour between the two groups. Similarly, another RCT conducted in the same year that compared the treatment effects of aromatherapy, a combination of aromatherapy and hand massage, and a placebo control showed no significant reduction of disruptive behaviour (Fu, Moyle, & Cooke, 2013).

In contrast, a study by Yang *et al.* (2015) reported that aromatherapy combined with acupuncture was effective in the treatment of dementia-associated agitation. This finding provides further evidence regarding the efficacy of aromatherapy for the treatment of BPSD, particularly when combined with other complementary interventions.

Two studies were conducted in 2017 in Japan (Takeda, Watanuki & Koyama, 2017) and Turkey (Kaymaz & Ozdemir, 2017). The former study reported that the inhalation of lavender EO and sweet orange EO effectively improved sleep quality and elongated sleep duration, whereas the latter study provided evidence that massage and inhalation of lavender and lemongrass effectively reduced BPSD and thus minimized carer stress.

This literature provides evidence to support the effective use of aromatherapy with certain types of EOs, particularly the use of lavender, for the management of BPSD, including agitation and restlessness.

2.2.3 Aromatherapy and Therapeutic Massage

Therapeutic massage works on the integumentary system to improve circulation, the musculo-skeletal system to reduce muscle fatigue, the circulatory system to supply fresh, oxygenated blood to remove waste, and the lymphatic system to stimulate the flow of lymph. Therapeutic massage by nature promotes relaxation and the reduction of stress. Therapeutic massage techniques, such as effleurage, petrissage, light friction, and ischaemic compression, work on the previously described systems to calm down agitated older adults and reduce their restlessness to achieve a sedative effect.

Six studies that investigated the clinical effects of aromatherapy massage on depression or depressive symptoms were reviewed by Yim, Ng, Tsang, and Leung (2009). The review suggested that the combination of aromatherapy and massage has an alleviation effect on the depressive mood of patients, and additional clinical trials should be conducted to further investigate this effect.

Thirty-four articles, in which massage or touch therapy were compared to other forms of treatment or no treatment, were reviewed. The results indicated that for patients who have a disability in verbal communication, physical touch may be the only way for them to connect with other individuals (Viggo, Jorgensen, & Ortenblad, 2004).

2.3 Acupressure

2.3.1 Definition, History & Grounding in Traditional Chinese Medicine

Acupressure refers to the manipulation of acupuncture points (acu-points) on the body by pressure using various types of massage techniques. It is an alternative to acupuncture, which also aims to stimulate the acu-points; however, it uses needles. Thus, acupressure is safer than acupuncture as it is non-invasive. Both approaches are practices used in Traditional Chinese Medicine (TCM), which originated in ancient China, and similar to other practices within this medical system, they share the same theory.

Meridians theory suggests that energy (Qi) flows in the human body along a special transportation and communication system. Qi flows along different routes referred to as the channel (Jing [經]) and the Collateral (Luo [絡]), which are branches of the channels. The two routes constitute the Meridians system, which has

numerous acu-points located in it that connect the interior and superficial, as well as superior and inferior parts of the body.

The acu-points lie along 12 principal meridians and eight extra meridians. They are very sensitive and may indicate abnormalities in the organs. If Qi flows smoothly along the meridians, pressing the acu-points results in no pain and vice versa. Acupressure may help clear barriers in the meridians and make energy flow more smoothly along them. Moreover, it stimulates nerves and tissues and simultaneously facilitates the flow of Qi, thus resulting in a healing effect. Risks are minimal if applied with caution.

In TCM theory, mind and body are closely interrelated, and neuropsychiatric symptoms may be explained by the blockage of Qi in the meridians, such as the Heart Meridian and Pericardium Meridian, which are located in the forearm and govern the heart.

2.3.2 Clinical Studies on Acupressure in BPSD and Mood Conditions

Studies on the effectiveness of acupressure in reducing agitation remain limited.

Yang, Wu, Lin, and Lin (2007) investigated acupressure on five acu-points,

including Fengchi [風池] (GB20), Baihui [百會] (GV20), Shenmen [神門] (HT7), Niguan [內關] (PC6), and Sanyinjiao [三陰交] (SP6), in 31 patients with dementia and identified a significant reduction in verbal and physical attacks. Lin *et al.* (2009) assessed the treatment effect of acupressure on the same five acu-points combined with Montessori-based activities on agitation among patients with dementia. This study was a large-scale RCT with 133 subjects, and significant reductions in aggressive behaviour and physical nonaggressive behaviour were identified. Moreover, affect was significantly increased.

Apart from agitation, acupressure was assessed in several studies for its effectiveness on mood and insomnia. In a review of 29 CAM studies by Meeks, Wetherell, Irwin, Redwine, and Jeste (2007), acupressure appeared to be effective in reducing depression and promoting sleep. Sun, Sung, Huang, Cheng, and Lin (2010) concluded from their RCT that acupressure on the Shenmen [神門] (HT7) is effective in improving insomnia among long-term care facility residents not only during the intervention period but also for an extended period after the intervention. Another study on the effect of acupressure on Shenmen [神門] (HT7), Niguan [內關] (PC6), and Yangchuan [湧泉] (KI1) showed a significant improvement in subjective sleep quality among psychogeriatric inpatients compared to the control group (Lu, Lin, Chen, Tsang, & Su, 2013).

Studies on acupressure are no longer limited to Asia. Anxiety and depression in individuals with dementia were significantly reduced after ear acupressure on Ear Chenmen [神門點] (MA-TF1), Myorelaxant [肌肉放鬆點] (159.C), and Xin [心點], administered in a study conducted in Spain (Rodriguez-Mansilla *et al.*, 2014).

Other studies have also reported the effectiveness of acupressure. In 2014, to investigate the effect of acupressure on agitation among individuals with dementia, Kwan, Leung, and Lai (2014) started an RCT to compare acupressure on Fengchi [風池] (GB20), Baihui [百會] (GV20), Shenmen [神門] (HT7), Niguan [內關] (PC6) and Yingtang [印堂] (EX-HN3) with sham acupressure.

2.4 Cognitive Training and Exercise for BPSD

Cognitive training is often implemented with the aim to overcome age-related cognitive decline and has been extensively investigated in individuals with dementia (Clare *et al.* 2010; Tarraga *et al.* 2006). It is “an intervention providing structured practice on tasks relevant to aspects of cognitive functioning, using standardized tasks” and aims to “address cognitive function and/or cognitive impairment directly” as quoted from Martin *et al.* (2011). It is a commonly used intervention to treat older adults with BPSD and has a mild to moderate effect on behaviours based on a systematic review (Azermai, 2015). Several review studies have also summarized

the positive evidence for cognitive training (Alves, Magalhaes, Thomas, Goncalves, Petrossyan, & Sampaio, 2013; Bahar-Fuchs, Clare, & Woods, 2013; Mayer, Bishop, & Murray, 2012). Research suggests that cognitive training has a better effect in conjunction with physical activity, and findings support this idea (Kraft, 2012; Schneider & Yvon, 2013). Exercise on its own has also been extensively investigated, and evidence is in favour of its effect on cognitive functioning and the promotion of functional mobility in healthy ageing (Colcombe & Kramer, 2003; Forte *et al.*, 2013).

2.5 Aims and Objectives

Based on the previous review of the literature, there is evidence for aromatherapy, therapeutic massage, and acupressure as effective interventions in managing BPSD or mood conditions. However, limited evidence is available regarding the synergistic effects of all three components when applied together at the same time. Therefore, there is an urgent need to determine whether these three modalities may be combined to provide another novel effective intervention for the management of BPSD.

The aims of this study are as follows:

- 1) To develop a complementary and alternative treatment protocol that combines aromatherapy, acupressure, and therapeutic massage (the aroma-massage with acupressure protocol) for the management of BPSD.
- 2) To conduct a pilot RCT to evaluate the clinical effectiveness of this new protocol.

The research questions are listed as follows:

- i) How should the protocol be adapted so that
 - it would be easily administered by non-professional caring staff,
 - it does not harm individuals with dementia, and
 - it has potential to minimize BPSD as judged by concerned caring staff.
- ii) Does this new protocol have a real effect in reducing the occurrence of BPSD after implementation, and does its effect last in the long term, i.e., 6 months after the completion of the treatment period?
- iii) Does this new protocol enhance the effect of cognitive intervention by improving mood or agitation?

2.6 Overview of the Study

This project was conducted in two phases. Phase I includes the formulation of the aroma-massage with acupressure protocol and a feasibility study.

Standardized training was conducted to equip the caring staff, and a checklist was used to ensure safety prior to introducing the protocol in the subsequent experiment.

Phase II includes a pilot RCT to investigate the effectiveness of this protocol in the management of BPSD. A three-arm parallel group design was adopted in this phase.

CHAPTER 3

THE APPLICABILITY & SAFETY OF THE AROMA-MASSAGE WITH ACUPRESSURE PROTOCOL FOR INDIVIDUALS WITH BPSD

3.1 Introduction

As discussed in Chapter 2, aromatherapy, acupressure, and therapeutic massage have been shown to be effective in the management of BPSD (Fung *et al.*, 2012; Yang *et al.*, 2007; Viggo *et al.*, 2004) when used alone or in conjunction with each other (Lin *et al.*, 2015). The potential benefits of the combination of these three treatment approaches have not been previously tested. Therefore, we developed the aroma-massage with acupressure protocol, which consists of the three treatment approaches.

Session 3.2 reports the procedures in the development of the aroma-massage with acupressure protocol (specified as “the protocol” in the following text), the training procedures to equip clinicians with adequate skills, safety and quality assurance measures, and the feedback obtained from participants and clinicians.

Session 3.3 reports the results of a feasibility study that investigated the primary effect, applicability and safety of the protocol by assessing cognitive function and rating the occurrence of BPSD among the participants using

standardized outcome measures. We also obtained reflections from the clinicians on the training sessions and treatment implementation process.

3.2 Formulation of the Aroma-Massage with Acupressure Protocol

3.2.1. Participants

The MPhil student, who is an occupational therapist and a certified aromatherapist, and one certified TCM practitioner were the main contributors in the development of the protocol. They both had more than 5 years of clinical experience in practising aromatherapy and TCM. The MPhil student had been working with elderly individuals with dementia for eight years. In the four settings she had worked or has been working in, 30% of the elderly individuals were diagnosed with dementia, and more than half of them manifested different types and extents of BPSD. Experience in the management of BPSD was obtained from working in these settings, as well as from working as mentors in a geriatric day care centre.

3.2.2. The Aroma-Massage with Acupressure Protocol

The selection of acu-points for this study was performed by a certified TCM practitioner based on meridians theory, which was described in Chapter 2.3.1. The selections were also made according to common practices reported in the literature

(Lin *et al.*, 2009; Sun *et al.*, 2010; Yang *et al.*, 2007). We did not involve family members of the elderly individuals because many of them are not well educated and their literacy in rehabilitation is extremely limited. Moreover, they may have problems with motivation and expression. However, their safety concerns regarding the protocol and the body parts on which the acupuncture should be performed were assessed.

The selected acupuncture points were located in different parts of the body. To facilitate implementation of the protocol, we selected acupuncture points that were located in areas in which elderly individuals were less reluctant to be touched. The locations were easy to reach and exposed for acupuncture. For example, if an elderly individual refused to expose his/her legs, acupuncture could be performed on their forearms and head. For patients who were contra-indicated in any one of the chosen parts, such as the presence of a skin rash on the forearm or a musculoskeletal condition in the lower leg, other acupuncture points could be used to serve a similar purpose.

There are more than 300 acupuncture points in 12 pairs of principal meridians. They represent different body parts and functions of the mind and body. In this study, our acupuncture point selections were mainly from the Heart Meridian [手少陰心經], the Pericardium Meridian [手厥陰心包經], and the Governor Vessel [督脈].

For the forearm, we selected the Heart Meridian [手少陰心經], which lied along the arm starting from the axilla to the distal part of the little finger. It consisted of nine acu-points, seven of which were located at the elbow or below. In TCM theory, the heart is the leader of the other organs; it also refers to the mind and thus cognitive function. The acu-points located in the forearm and hand in this meridian have a calming effect and may reduce restlessness and symptoms of hysteria. We included three acu-points in the protocol as follows: Lingdao [靈道] (HT4), Tong Li [通里] (HT5), and Shenmen [神門] (HT7).

Moreover, we included the Pericardium Meridian [手厥陰心包經], which lied laterally to the Heart Meridian [手少陰心經] starting from the chest at the fifth rib cage near the nipple to the distal part of the middle finger via the axilla. It consisted of nine acu-points, seven of which were located at the elbow or below. Stimulation of these acu-points could protect the heart and the mind. The acu-points located in the forearm and hand were employed to reduce stress and had calming effects in supplementary to the Heart Meridian. As a result of the similar effects with the Heart Meridian [手少陰心經], we only selected one acu-point that was easier to locate and more commonly used based on the literature: Neiguan [內關] (PC6).

For the head, several acu-points along the Governor Vessel (督脈) were selected. Among them, Baihui [百會] (GV20) was the conjunctive of several

meridians and vessels, which was effective in calming and reducing blood pressure.

We also included Shenting [神庭] (GV24), which was employed for calming and relieving headache. Other acu-points from the head included Taiyang [太陽] (Ex-HN5) and Yintang [印堂] (Ex-HN3), which had a calming effect, and GB20 Fengchi [風池], located at the back of the head, which was used to improve memory.

Apart from the forearm and the head, we also selected an acu-point located above the medial side of the ankle on the lower leg, the Sanyinjiao [三陰交] (SP6), which was effective for nervous breakdown. The anatomical positions of the selected acu-points on the body are shown in Figure 3.1.

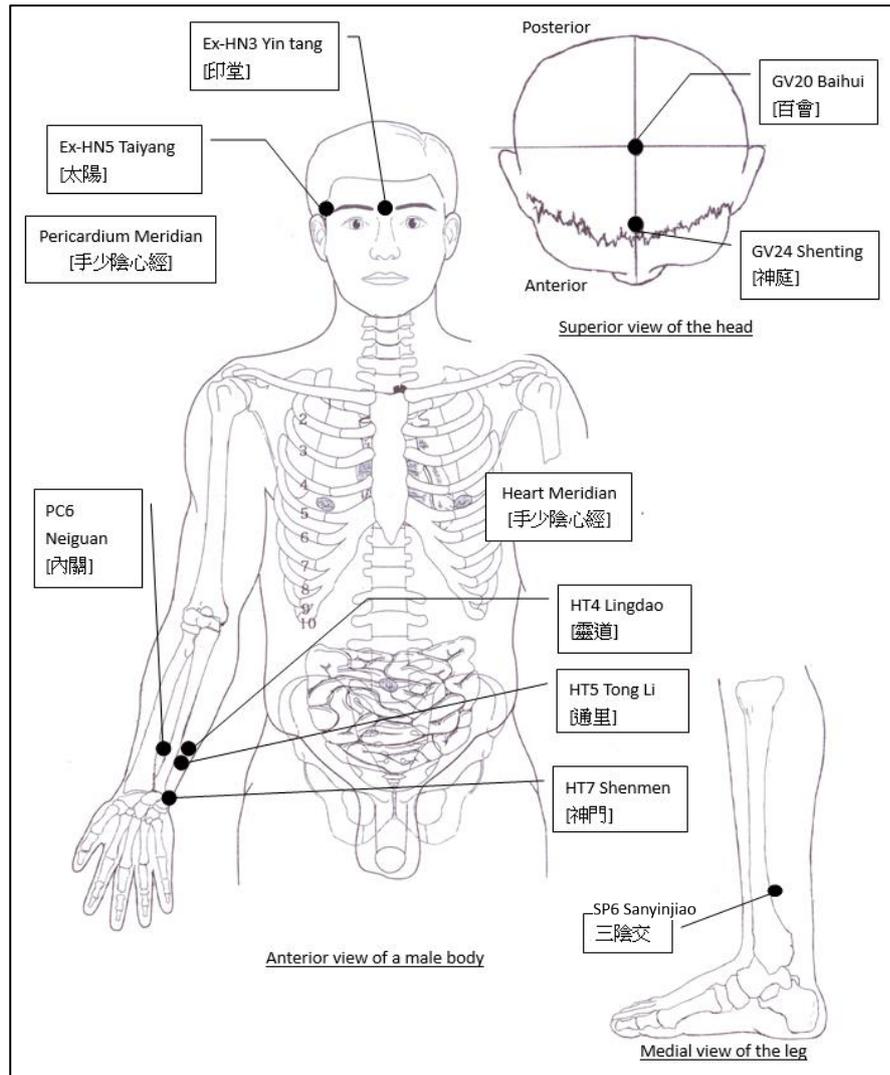


Figure 3.1 Locations of the Acu-points Selected for the Protocol

The protocol combines acupressure and therapeutic massage with the use of lavender EO. We purchased lavender EO that originated from France (botanical name: *Lavandula officinalis*) from a well-recognized company in Hong Kong and blended it with sunflower oil (botanical name: *Helianthus annuus*) with a concentration of 2%. We did not verify the quality and concentration in the lab; we assumed that this brand is of high quality. Blending of the massage oil was performed by the aromatherapist, i.e., the MPhil student. Blended massage oil was

stored under supervision of the aromatherapist and distributed to the occupational therapist in each setting using plastic bottles created for EO storage with proper labelling. The blended massage oil was discarded three months after blending to ensure over-oxidized blended oil was not in use. Therapeutic massage techniques, including effleurage and friction, were adopted. These techniques are mainly used for warming up and stimulating the body along the meridians. The protocol lasted no longer than 20 minutes, which was a similar duration as other studies (Gray & Clair, 2002; Kilstoff & Chenoweth, 1998).

After the protocol was developed, a manual was written, and a video that demonstrated the protocol was created. The protocol manual is enclosed as Appendix II.

3.2.3. Training of Clinicians

Two training sessions in two weeks were provided by the MPhil student to train three occupational therapists from three care facilities, including two long-term care residential homes and one community care service team for elderly individuals. The therapists were male and had worked with elderly clients for more than three years.

None of them had experience in performing or receiving aromatherapy, acupuncture, or therapeutic massage. They were not allergic or reluctant to use EOs and did not have a medical condition that contraindicated the three treatment approaches. The two training sessions were conducted in one geriatric day care centre.

As we planned to adopt cognitive training and an exercise programme as controls for the RCT, we also included these two interventions in the training sessions.

In part I of session 1, the occupational therapists were introduced to the protocol with respect to the basic techniques of measuring “Chinese inch”, therapeutic massage techniques on “effleurage” and “friction”, and a brief introduction to the acu-points used in the protocol. The MPhil student subsequently demonstrated how to implement the protocol by performing it according to the manual on an occupational therapist who was not involved in the study. Afterwards, the occupational therapists in the training were required to practice the protocol on each other. The MPhil student checked their accuracy in locating the acu-points and performing the massage techniques.

The occupational therapists were asked to perform the protocol on one adult and one elderly individual, who were not their service users, after the training session as a homework assignment. They had to record the difficulties they faced (if

any) in the homework assignment record sheet (Appendix III). Moreover, they had to complete the Safety Practice Checklist with criteria adopted according to safe practices suggested by the American College of Sports Medicine (2005) and Niemeyer (1980) (Appendix IV) to record adverse effects caused by the protocol.

In part II of session 1, the occupational therapists were introduced to the exercise programme (refer to Appendix V for details of the exercise programme) and the cognitive training programme (10-piece puzzle and work sheets on attention, short-term memory, and simple calculations).

At the end of this session, the occupational therapists were given one bottle of massage oil for the homework assignment and a DVD that included a demonstration video in case they forgot the procedures.

After one week, in part I of training session 2, the occupational therapists were asked to share their homework assignment in which they recorded the difficulties they encountered, and the MPhil student clarified their queries. They subsequently had the opportunity to practice with two older adults who were service users and who had volunteered for the session with consent obtained. During this practical session, the occupational therapists were observed by the MPhil student to identify mistakes and were immediately corrected.

In part II of this session, practical tests were completed on each therapist to ensure they could accurately perform the protocol. The tests were conducted using a checklist shown in Appendix VI, which required the therapists to correctly use the EO and massage techniques to perform acupressure on the exact location of the acu-points.

The two training sessions were conducted according to the following schedule, and a detailed training protocol is shown in Appendix VII.

Table 3.1 Outline of Two Training Sessions

Session	Topic/duration	Content
1	Part I: 90 mins	<ol style="list-style-type: none"> 1. Brief introduction to research goals, interventions, regime 2. Demonstration of the protocol 3. practice on partners
	Part II: 60 mins	<ol style="list-style-type: none"> 1. Demonstration of the exercise program 2. Introduction to the cognitive training program
2	Part I: 90 mins	<ol style="list-style-type: none"> 1. Revision of aroma-massage with acupressure protocol 2. Practice on older adults
	Part II: 60 mins	<ol style="list-style-type: none"> 1. Practical test on the protocol

3.2.4. Safety and Quality Assurance

As previously discussed, a Safe Practice Checklist was adopted to identify adverse events during the treatment process. There were seven items: 1) abnormalities such as chest pain or dizziness, 2) signs of insufficient blood circulation, such as paleness or confusion, 3) low blood oxygen saturation level, 4) irregular pulse, 5) abnormal increase in heart rate, 6) hypertension or hypotension during or immediately after the treatment, and 7) inability to return to normal blood pressure within 2 minutes after treatment ceases. No adverse events occurred during the training sessions or homework assignment practice.

Practical tests were performed to ensure accurate implementation of the aroma-massage with acupressure protocol, and all three occupational therapists passed the practical tests.

3.2.5. Results: Comments from Participants and Clinicians

The two older adults who joined the second training session were interviewed. They strongly appraised the pleasant smell of EO, the comfort they experienced and the soothing effect on their mood. They were also surprised by the relaxing effect of the combination of acupressure and therapeutic massage.

The occupational therapists also reported the same feeling as the older adults. In regards to the training and their experience in administering the protocol, they

agreed that it was clear and easy to perform, and the duration was suitable. In short, the occupational therapists believed that the protocol would be well received by elderly individuals, and they were confident that the protocol would be clinically effective in the management of BPSD.

3.3 Phase II: Feasibility Study on Safety and Applicability Issues

Despite claims for the safety of the three treatment approaches (aromatherapy, therapeutic massage, and acupressure) in the literature, studies have reported adverse side effects, such as dizziness and nausea, particularly when an EO was orally administered (Akhondzadeh *et al.*, 2003). Thus, the development of a more structured and standardized treatment protocol is necessary. According to Good Clinical Practice (GCP), it is essential to ensure the safety of the intervention protocol and estimate the potential efficacy in patients before a randomized controlled trial (RCT) is conducted (Dixon, 1999).

Therefore, we first performed a feasibility study to determine the feasibility and safety of the protocol following the method adopted when a novel qigong protocol was developed (Ng & Tsang, 2009). The purpose was to ensure that the protocol we developed is safe and feasible for the management of behavioural disturbances among elderly individuals.

3.3.1. Participants

Eight older adults were recruited from three nursing homes and one day care centre for elderly individuals. The participants were aged 77–90 and had at least one type of behavioural disturbance as assessed by the 29-item Chinese Version of the Cohen-Mansfield Agitation Inventory (CCMAI-29 items) (Choy, Lam, Chan, Li, & Chiu, 2001) and the Neuropsychiatric Inventory (NPI) (Cummings *et al.*, 1994), which caused distress to the caregivers. Not all participants in this study had received a proper diagnosis of dementia. However, BPSD do not only occur in individuals with dementia; they may also occur in other conditions, such as vascular cognitive impairment (Gupta *et al.*, 2013). BPSD refer to neuropsychiatric symptoms that include agitation, apathy, hallucination, and other symptoms. These symptoms may also occur in elderly individuals without dementia.

We recruited our participants using standardized cognitive assessment procedures and only included individuals with obviously impaired cognitive function. The participants may not necessarily have a dementia diagnosis. This approach was evident in previous and similar studies that included elderly individuals as participants (Cooke, Moyle, Shum, Harrison, & Murfield, 2010). Furthermore, it is common in Chinese culture that individuals with a diagnosis of

dementia are stigmatized. As a result, many family members are reluctant to take elderly individuals with cognitive impairments to medical doctors for proper diagnosis and treatment (Dong, Chen Fulmer, & Simon, 2014). This may also account for the fact that some participants in this study did not have a diagnosis of dementia.

3.3.2. Procedures

Written consent was obtained from each participant prior to data collection (Appendix VIII). A data book (Appendix IX) was provided to the three previously trained occupational therapists for the documentation of each patient included in this study. Baseline information, such as gender, age, medication use, and medical history, and data pre- and post-treatment were recorded in the data book. The outcome measures included the following instruments:

To determine whether the aroma-massage with acupressure protocol could effectively reduce BPSD, the 29-item Chinese Version of the Cohen-Mansfield Agitation Inventory (CCMAI- 29 items) (Choy *et al.*, 2001) was adopted as the primary outcome measure to rate the frequency of occurrences of BPSD. It is a caregiver-rated inventory to assess agitation in elderly individuals and records the frequency of occurrence of BPSD at different periods of time; thus, it may be used

for comparison. It is a 29-item caregiver rating questionnaire for the assessment of agitation in elderly individuals. It includes descriptions of 29 agitated behaviours, each rated on a seven-point scale of frequency. The internal consistency for the CCMAI as shown by the Cronbach's alpha was 0.75, and the inter-rater reliability was excellent with an intraclass correlation of 0.98. A high test-retest reliability was also reported ($r = 0.85, p < 0.01$). In this study, domain scores were used for comparison.

Apart from the CCMAI, we used the Neuropsychiatric Inventory (NPI) (Cummings *et al.*, 1994) to assess abnormalities of mood and psychotic phenomena. It assesses both the severity and frequency of 12 behavioural disturbances that are common in dementia, such as delusions, hallucinations, agitation, anxiety, and appetite changes. The test-retest reliabilities were 0.79 and 0.86 ($p < 0.01$) for the frequency and sensitivity, respectively. For the internal consistency, a Cronbach's alpha score of 0.88 was reported for the total score and ranged from 0.87 to 0.88 for the individual subscales (Cummings *et al.*, 1994). In this study, we adopted this as one of the primary outcome measures to understand the extent of distress caused by the BPSD to the caregivers.

As the secondary aim was to evaluate whether the aroma-massage with acupressure protocol could enhance the effect of a cognitive training programme by

improving mood or agitation, cognitive and functional assessments were also adopted. Cognitive function was assessed by the Cantonese Version of the Mini-mental State Examination (CMMSE). It is a brief 30-point questionnaire used to screen for cognitive impairment. It was used in this study as a screening test for cognitive impairment and dementia. The internal consistency was adequate with a Cronbach's alpha score of 0.86, and the inter-rater reliability was excellent with an intraclass correlation of 0.99. A high test-re-test reliability was identified ($r = 0.78, p < 0.001$) (Chiu, Lee, Chung, & Kwong, 1994), which has been determined to be a significant predictor for the development of functional dependence at a 3-year follow up interval (Folstein, Folstein, & McHugh, 1975; McDowell, Kristjansson, Hill, & Hebert, 1997; Agüero-Torres *et al.*, 1998).

Functional performance was assessed by the Barthel Index-20 (BI-20). It is a measure of performance in basic daily living activities and is sensitive to declines or improvements in the functional level of elder individuals. A higher score is associated with greater independence and a greater likelihood of being able to live at home. The validity of the Barthel Index used for assessing patients with stroke was shown to be high. The reliability and validity of the BI-20 were highly rated as the test-retest reliability was 0.989, the inter-rater reliability was 0.994, and the Cronbach's alpha score was 0.935 (Collin, Wade, Davies, & Horne, 1988).

The data books that contained the demographic data collection form, CMMSE, BI-20, CCMAI, and NPI were completed by the case therapists. Pre-tests were conducted, and after two weeks of intervention, a post-test was completed using the previously stated outcome measures.

3.3.3. Data Analysis

IBM Statistical Package for the Social Sciences (SPSS) version 21 was used to analyse the data. Descriptive and frequency statistics were used to summarize the demographic data of the participants.

3.3.4. Results: Short-term Effects, Safety & Application Issues

The demographic data of the eight participants were recorded as follows:

Table 3.2 Demographic Data of Participants in the Feasibility Study (n = 8)

	Frequency	Percentage
Gender		
Male	2	25.0
Female	6	75.0
Living with		
Spouse	3	37.5
Daughter/ Son	2	25
Maid	3	37.5
Others	2	25
Marital Status		
Married	3	37.5
Widowed	5	62.5
Diagnosis		

Dementia	5	62.5
Hypertension	4	50
Parkinsonism	2	25
Diabetes Mellitus	2	25
Bilateral cataract	3	37.5
Cerebral vascular accident	1	12.5
Skeletal disorder	4	50
Others	7	87.5
Activity Level		
Bed-chair bound	3	37.5
Homebound	4	50
Outdoor	1	12.5
Education Level		
Illiterate	6	75
1-2 years	2	25
Alertness		
Alert	7	87.5
Sleepy	1	12.5
Communication		
Follow verbal command	8	100
Attention Level		
> 5 mins	4	50
2-5 mins	2	25
< 2 mins	2	25
	<i>Mean</i>	<i>Standard Deviation</i>
Age	83.13	3.919

There were no significant differences in the mean scores of the pre-test and post-test scores of the CMMSE with $p = 0.763$. For the sub scores on orientation, registration, attention and calculation, recall, language, and praxis, there were also no significant differences between the pre- and post-tests with p -values of 0.351, 0.451, 0.227, 0.451, 0.170, and 1, respectively.

For the CCMAI and NPI, there were no significant differences with $p = 1$ for all components.

Table 3.3 Results of Outcome Measures of Pre-test and Post-test and Comparison by

Paired *t*-test

Outcome Assessments	Pre- (mean)	Post- (mean)	<i>p</i> -value
BI-20	10.38	10.38	1.000
CMMSE total score	12.38	12.25	.763
CMMSE sub scores			
1. Orientation	3.00	2.75	.351
2. Registration	1.88	2.13	.451
3. Attention and calculation	0.75	0.25	.227
4. Recall	0.63	0.88	.451
5. Language	5.88	6.13	.170
6. Praxis	0.00	0.00	1.000

The occupational therapists were asked to submit self-reflections on the implementation of the protocol, which included: 1) comments on the training sessions, 2) difficulty in administration, 3) duration of the protocol, 4) experience of implementing acupuncture, 5) experience of using EO, 6) experience of therapeutic massage, and 7) other comments.

All the therapists reported that the EO had a pleasant smell and a soothing effect on the mood of the participants in the feasibility study. They all reported an immediate calming effect on the elderly individual and a decrease in restlessness.

Apart from the pleasant odour of the EO, they also identified positive effects of the

therapeutic massage. They reported that massage helped the participants to gain a sense of comfort, and the sense of touch was pleasant. Moreover, they all agreed that therapeutic massage was good for agitated elderly individuals as they became more relaxed during the treatment session. In addition, the massage oil was nourishing and very effective in moisturizing the dry skin of the elderly individuals.

3.4 Discussion

Aromatherapy and therapeutic massage have been shown to be effective in promoting sleep (Buchbauer Jirovetz, Jager, Plank, & Dietrich, 1993; Yang *et al.*, 2007; Zeilmann *et al.*, 2003), alleviating anxiety and depression (Yim *et al.*, 2009), and reducing the occurrence of BPSD (Burns *et al.*, 2011; Ballard *et al.*, 2002; Holmes *et al.*, 2002; Lin *et al.*, 2007) in many studies. An increasing number of studies have been conducted to assess the clinical effectiveness of EO, and most results have been positive.

Although the therapeutic effects of the aroma-massage with acupressure protocol had no statistical significance in the feasibility test, the potential benefits on individuals with BPSD, such as calming and relaxing, were generally supported by the occupational therapists who administered treatment to the participants. We believe that the non-significant result was a result of the small sample size ($n = 8$)

and the short treatment period (two weeks). The reflections of the therapists suggested the therapeutic effects of this CAM intervention. This is also consistent with a recent report that the combination of treatment modules used in our protocol is effective in the management of BPSD (Yang *et al.*, 2015; Kaymaz, & Ozdemir, 2017).

The healing capacity of an EO is derived from the energy of the plants, which is subsequently transformed to the chemical constituent of the EO that contributes to the healing effect (Izhaki, 2002). This is similar to the herbal medicine used in TCM practice. Moreover, one major principle of aromatherapy is the equilibrium of mind and body, which is also consistent with TCM theory. As a result of these characteristics, we suggest that the two treatment approaches, used together with therapeutic massage, may have a synergistic effect on each other.

Based on the feedback of the therapists and the elderly individuals, a better designed RCT with an adequate sample size should be conducted to assess the effects of the aroma-massage with acupressure treatment protocol, which is a promising adjunct therapy that is safe and manageable for caregivers in the treatment of BPSD.

3.5 Conclusion

The feasibility study suggests that the protocol was feasible and safe to administer. The positive results provided support for proceeding to the second phase, which was a pilot RCT. Apart from the sample size calculation and the determination of the treatment period, all relevant training materials of the training sessions were translated to Chinese for further training of the frontline caring staff to ensure unity of skills.

CHAPTER 4

THE EFFECTIVENESS OF THE AROMA-MASSAGE WITH ACUPRESSURE PROTOCOL FOR THE MANAGEMENT OF BPSD – A PILOT RCT

4.1 Introduction

Aromatherapy, therapeutic massage, and acupressure were independently shown to be effective in reducing BPSD in different research studies (Ballard & Howard, 2006). However, the combined effects of these three components have not been clearly documented despite the fact that clinical experience suggests that when used together, client satisfaction is higher (Yang *et al.* 2015). However, there is a lack of high quality experiments to provide support for their effectiveness (Lee, Choi, Posadzki, & Ernst, 2012). Moreover, the long-term benefits are not known (Kverno, Black, Nolan, & Rabins, 2009).

Based on the results of the field test described in Chapter 3, we formulated a structured protocol with standardized procedures, techniques, and equipment. The innovative aspect of this study was that we attempted to combine the three treatment modules in our aroma-massage with acupressure protocol and explored clinical outcomes with respect to the reduction of BPSD. In the feasibility study previously

reported, the protocol was shown to have a calming effect on agitated mood and promoted a sense of security among older adults with dementia. It remains unclear whether the treatment protocol is effective in reducing the severity of and/or distress caused by BPSD.

In this phase, we aimed to investigate the effects of the protocol in reducing BPSD for individuals with dementia, as well as its effect over an extended period of time. The literature indicates that many studies using non-pharmacological therapies regarded a period that ranges from 20 weeks to 10 months as “long-term follow up” (Deudon *et al*, 2009; Luttenberger, Hofner, & Graessel, 2012). Based on the time constraints on this MPhil study, we adopted a period of 6 months as the long-term follow-up interval. In addition to the protocol, we also examined the synergistic effect of the protocol with cognitive training. In this thesis, it is hypothesized that the aroma-massage with acupressure protocol, in adjunct to cognitive training, would reduce the occurrence and severity of BPSD and thus caregiver distress.

4.2 Methods

4.2.1. *Design of the Experiment*

Three occupational therapists trained for the implementation of the protocol in the feasibility study and 24 caring staff were recruited from three clinical settings, including two day care centres for elderly individuals and one nursing home. The

personal care workers were trained by the MPhil student following the same format as reported in Chapter 3 (Section 3.2.3) using the Chinese version of the protocol manual (Appendix X), exercise programme (Appendix XI) and homework sheets (Appendix XII) translated by a qualified translator. All occupational therapists and caring staff attended two training sessions with hands-on practice on elderly individuals and passed the practical test prior to providing treatment to the study participants.

To ensure the quality of the treatment, occupational therapists in each setting who were initially trained in the feasibility study performed one quality assurance review for each caring staff. They reviewed one treatment session of each participant and recorded the performance of the caring staff using the quality control checklist (Appendix XIII). If the caring staff encountered difficulties, the occupational therapists provided immediate support and onsite supervision. The MPhil student also performed one onsite inspection for each caring staff when he/she was conducting the protocol on participants. The results of the onsite inspection were also recorded on the quality control checklist.

This study comprised a pilot RCT with a 3-arm design. After individual written consents were obtained from their guardians, eligible participants were randomly allocated to the three different treatment groups according to the time of inclusion by

a randomization table (Appendix XIV). The guardians and participants were not aware of the differences between the three treatment groups. This pilot RCT consisted of three treatment groups as follows: Group 1: aroma-massage with acupressure + exercise; Group 2: cognitive training + exercise; and Group 3: aroma-massage with acupressure + cognitive training. The event flowchart is shown in Figure 4.1, and details regarding each treatment will be introduced in the next section:

Group 1: Aroma-massage with acupressure + Exercise

Group 2: Cognitive training + Exercise

Group 3: Aroma-massage with acupressure + Cognitive training

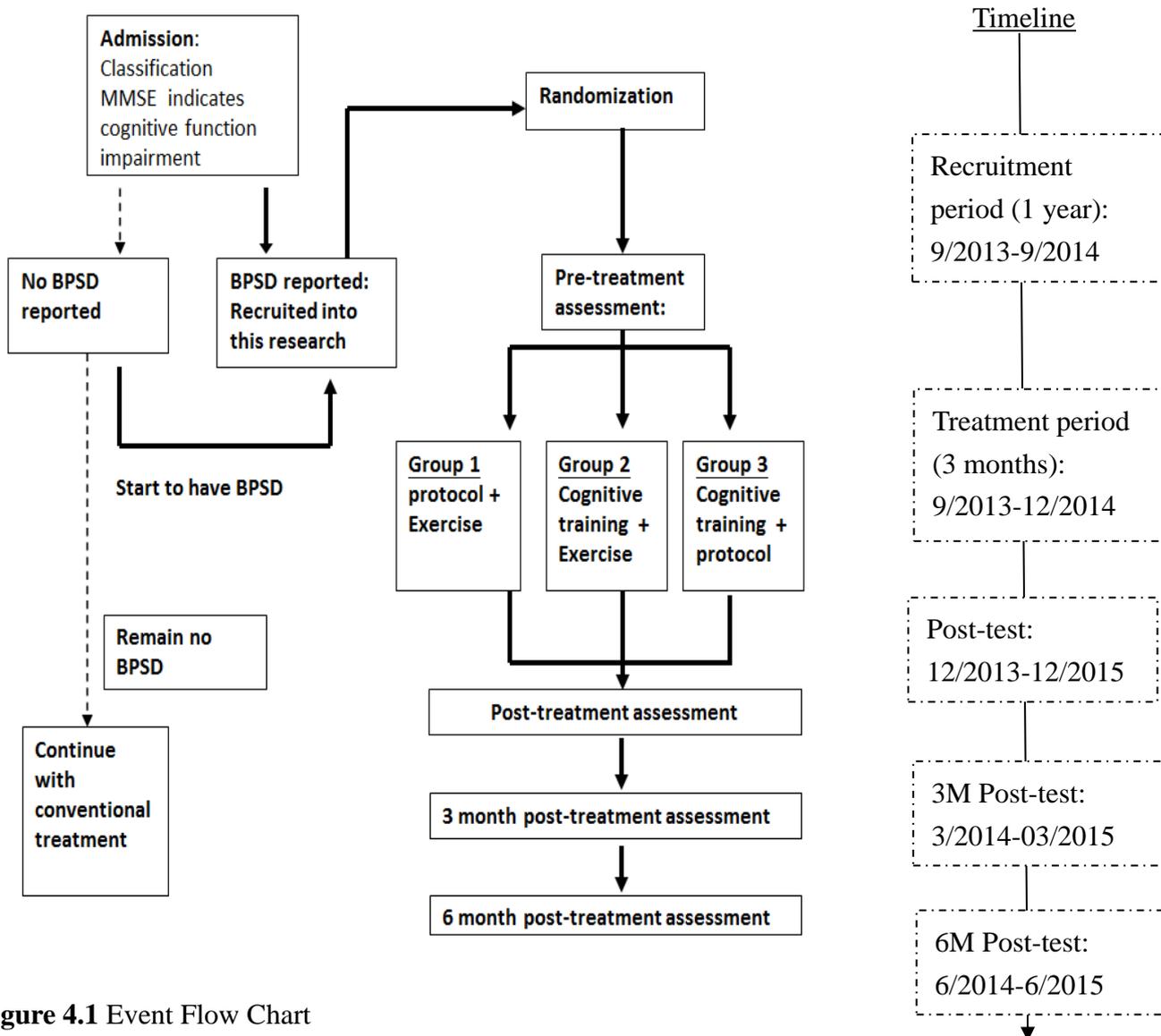


Figure 4.1 Event Flow Chart

4.2.2. Intervention Protocols

Each group received a three-month twice-per-week intervention by the time of inclusion. The treatment duration was based on our literature review, which indicated that more than half of similar studies had an intervention period that ranged from nine to 16 weeks (Akhondzadeh *et al.*, 2003; Burleigh & Armstrong, 1997; Snow *et al.*, 2004).

Each participant received two of the following interventions or controls according to the allocated group. The following interventions were introduced to the care staff with training provided by an occupational therapist in each setting. The training consisted of two sessions with tutorial, practices, and practical tests with details described in Chapter 3 (Section 3.2.3.). Adverse side effects were recorded if present. The participants continued their psychotropic medication throughout the trial period as per many other studies (Ballard, O'Brien, Reichelt, & Perry, 2002; Burns *et al.*, 2011; Holmes *et al.*, 2002; Lin, Chan, Ng, & Lam, 2007; Smallwood, Brown, Coulter, Irvine, & Copland, 2001).

4.2.2.1. Aroma-massage with Acupressure Protocol

This new treatment protocol was described in detail in Chapter 3 (Section 3.2.2.). It was developed in collaboration with a TCM practitioner. The points were selected based on the literature (Lin *et al.*, 2009), TCM theory, and location of the body part, ensuring it was easy to reach. For patients who were contra-indicated in any one of the selected parts, such as the Sanyinjiao [三陰交] on the leg, other acu-points, such as Shenmen [神門] on the forearm or Shenting [神庭] on the head, were used to serve a similar purpose. The trained caring staff or occupational therapists provided no longer than 20 minutes of aromatherapy that combined

therapeutic massage with blended 2% lavender EO in sunflower base oil.

Acupressure performed on the selected acu-points was integrated into the protocol.

The quality assurance of the intervention was performed by the occupational therapists on each of the care staff.

4.2.2.2. Cognitive Training (Served as “active control”)

“Cognitive training” was regarded as an “active control” in this pilot RCT to enable comparisons with the newly developed intervention protocol. The rationale was that “cognitive training is a commonly used intervention to treat older adults with BPSD” and has a mild to moderate effect on behaviours based on a systematic review (Azermai, 2015); moreover, one goal was to determine whether the protocol could enhance their mood or reduce agitation and ultimately enhance the effect of cognitive training. The trained caring staff administered no longer than 20 minutes of cognitive training that targeted attention, short-term memory, calculation, and orientation. In the first 15 minutes, work sheets were administered to the participants that required answers on the orientation of time and place. They were also instructed to complete 10 tasks of simple calculation (plus or minus) and short-term memory on 10 sets of words or pictures. In the last 5 minutes, they were given a 10-piece

puzzle. The caring staff learned techniques for providing cognitive training in their everyday duties, which were reinforced in the first training session.

4.2.2.3. Exercise (Served as “passive control”)

“Exercise” was considered “activity as usual” or “passive control” as it is well recognized to be a part of routine treatment for older individuals in institutional settings. The use of “exercise” as a control group has been reported in many studies (Hsu, Moyle, Cooke, *et al.* 2016). Moreover, this approach helped to ensure that participants would not be deprived of basic interventions and could receive a comparable level of care if they enrolled in this study. Trained personal workers instructed the participants to perform no longer than 20 minutes of an upper limb stretching exercise programme developed by a physiotherapist. If the participants were not able to follow the instructions, assistance was given where appropriate.

4.2.3. Participants & Settings

The pilot RCT was conducted from September 2013 to June 2016 after ethical approval was obtained from The Hong Kong Polytechnic University. Sixty-eight older adults with BPSD were recruited from three long-term care facilities located in Hong Kong and operated by an NGO. One facility was a nursing home, and the

other two facilities were day care centres. The participants from the nursing home stayed there day and night, and the participants from the day care centres received day care service daily or every alternate day.

Assessments were conducted by case occupational therapists to confirm their eligibility. When the participant was considered suitable for inclusion, his/her name was given to the investigator and subsequently assigned to one of the three groups using systematic random sampling. This method was adopted in another similar study (Moeini, Khadibi, Bekhradi, Bekhradi, Mahmoudian, & Nazari, 2011; Kamioka, Okuizumi, Okada, *et al.*, 2011).

As previously discussed, not all patients had a diagnosis of dementia because some patients did not seek medical follow up and did not want to know their diagnosis, which is a very common situation in Hong Kong. However, they definitely had BPSD as determined by our screening tool, which included the MMSE and observations by our case occupational therapists.

The inclusion criteria for participants were older adults who: 1) were aged 60 or above, had a MMSE score less than 18 if illiterate, 19 if they had 1–2 years of education, and 20 if they had more than 2 years of education; 2) were reported to have BPSD at the time of inclusion; and 3) were willing to participate in the research study with informed consent provided by their guardian or caregiver.

The exclusion criteria were older adults who: 1) were allergic to EO; 2) refused to provide consent; 3) suffered from musculoskeletal conditions that are contra-indicated to acupressure at the selected points; or 4) were over-reactive to tactile stimulation.

Eight of the guardians refused to join the pilot RCT; thus, 60 patients were included in this pilot RCT with an acceptance rate of 88.2%.

4.2.4 Ethical Considerations

This trial was not registered with the clinical trial registry at the time of commencement as Hong Kong has only recently stipulated that researchers must register clinical trials. When this pilot RCT was initiated in 2013, registration was not required. However, ethical approval was obtained from The Hong Kong Polytechnic University and the organization from which the participants were recruited. Written consents (Appendix VIII) were obtained from the guardians or carers of the participants.

4.2.5. Sample Size & Power Calculation

The Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield *et al.*, 1989), which is used worldwide as an outcome measurement of the occurrence of BPSD, was used to estimate the power and sample size. Assuming an effect size of f

= 0.52737,

45 subjects in three groups were required to obtain a 95% power with α equal to 0.05 for analysis using repeated measure ANOVA. We ultimately recruited more subjects (60 in total and 20 per group). The effect size of our study was considered to be medium, and many studies have adopted a medium effect size (Ballard, O'Brien, Reichelt, & Perry, 2002; Fu, Moyle, & Cooke, 2013; Holmes *et al.*, 2002; Wells, Dawson, Sidani, Craig, & Pringle, 2000).

4.2.6. Randomization & Allocation Concealment

After individual written consent was obtained from the guardians, the participants who met the previously described criteria were referred for enrolment in the study by the case therapist and were then randomly assigned (using blocked randomization, block size 3) to the three treatment groups at a 20:20:20 ratio using a randomization list by the time of inclusion. This procedure was performed by the MPhil student, and the case therapist did not know the group the participants would be assigned to before the randomization was completed. The allocation results were only disclosed to the case therapists for the arrangement of the intervention. The guardians and participants were not aware of the differences between the three treatment groups.

4.2.7. Outcome Measures

The outcome measures included the four standardized assessments described in Chapter 3 (Part 3.3.2.). The primary outcome measures included the 29-item Chinese Version of the Cohen-Mansfield Agitation Inventory (CCMAI). It was used for the assessment of BPSD in the elderly individuals to assess the agitation of the participants and record the frequency of the occurrence of BPSD at different periods of time for comparison purposes. The items included wandering, screaming, hurting self or others, and repetitive actions. In this study, domain scores were used for comparison.

Another primary outcome measure was the Neuropsychiatric Inventory (NPI) (Cummings *et al.*, 1994). It was used to assess the behavioural and neuropsychological disturbances (including abnormalities of mood and psychotic phenomena) of clients with dementia. It assessed both the severity and level of distress of 12 neuropsychological disturbances that are common in dementia, such as delusions, agitation, anxiety, and appetite changes.

The 30-point questionnaire Mini-Mental State Examination (MMSE) (Folstein *et al.*, 1975) was used as a secondary outcome measure to assess cognitive function.

It included orientation, registration, attention and calculation, recall, language, and praxis tasks.

The Barthel Index-20 (BI20) (Collin *et al.*, 1988) was used to measure the functional performance of the participants in ADL. It assessed 10 ADL tasks, including dressing, feeding, mobility, and bathing. A higher score was associated with greater independence and a greater likelihood of being able to live at home.

We did not conduct proper reliability testing among the practitioners. However, the investigator paid visits to different facilities to observe each caring staff who implemented the protocol at least once during the treatment period following a Quality Control Checklist.

4.2.8. Data Collection and Data Analysis

Data books that contained the demographic data collection forms, BI-20, CMMSE, CCMAI, and NPI were completed by the case therapists. Pre-tests were conducted, and after the 3-month intervention period, a post-test was conducted. Three months and six months after the intervention period, follow-up assessments with the previously described outcome measures were performed. The participants and the case therapists were not blinded.

SPSS version 22 was used for data analysis. We performed One Way ANOVA to identify differences in the baseline scores, and the BI20 scores of Group 2 and Group 3 were significantly different. Descriptive statistics and Chi's Square test were used to analyse the demographic data, and the "attention span" of Group 3 was significantly different from the other groups.

Multiple comparison procedures by repeated measures and parametric data were analysed by repeated measures analysis of covariance (ANCOVA) adjusted for attention and the BI20 (pre-test) as a post hoc decision to detect between-group differences (group consisting of three levels) and within-subject differences (time consisting of three endpoints: pre-, post-, and 3-months), as well as the interaction effect between group and time. When a significant interaction was identified, a post hoc analysis was adopted to identify which time point contributed to it.

Two 3-month and eight 6-month follow up datasets in Group 1, three 6-month follow up datasets in Group 2, and nine 6-month follow up datasets in Group 3 were unable to be collected as a result of subject drop out. A last observation carried forward (LOCF) approach was used to treat these missing datasets that was completely at random. Data from all sixty participants were analysed.

4.2.9. Compliance

A treatment log was used to monitor participant compliance. Regarding quality control and assurance, the MPhil student paid regular visits to different facilities and observed the performance of each caring staff to ensure compliance with the treatment protocol. Each time, the “Quality Control Checklist” was used to rate the care worker’s ability to correctly administer the protocol. As adequate training sessions and practical sessions were conducted, all care workers were able to correctly adhere to the protocol. The percentage of correct procedures ranged from 90.6% to 100%, in which 83.3% of the care workers correctly followed procedures 100% of the time.

4.3 Results

The pilot RCT was conducted from September 2013 to June 2015 after ethical approval was obtained from The Hong Kong Polytechnic University. Sixty-eight older adults with BPSD were recruited from three long-term care facilities located in Hong Kong, which were operated by an NGO. The guardians of eight of the older adults refused to consent to the study. In total, 60 participants were included in the pilot RCT (18 males and 42 females) with an age range from 63 to 100 (*mean* = 84.02, *SD* = 7.62). The demographic data were not significantly different among the three groups with the exception of attention span with $p < 0.05$ (Table 4.1

summarizes the demographic data of the participants). The participants were then randomly assigned to the three groups as illustrated in the Consort Flow Diagram in Figure 4.2.

Table 4.2 shows the results at different time points among the three groups: the mean pre-test scores of the BI-20 for the three groups were 15.56 ± 4.76 , 13.32 ± 6.51 , and 10.84 ± 4.43 , respectively. A one Way ANOVA test indicated an overall significant difference between the groups ($p = 0.03$, $df = 2$). The post hoc multiple comparison (LSD) showed a significant difference between Group 3 and Group 2 with $p < 0.05$, $f = 3.932$ as shown in Figure 2(a).

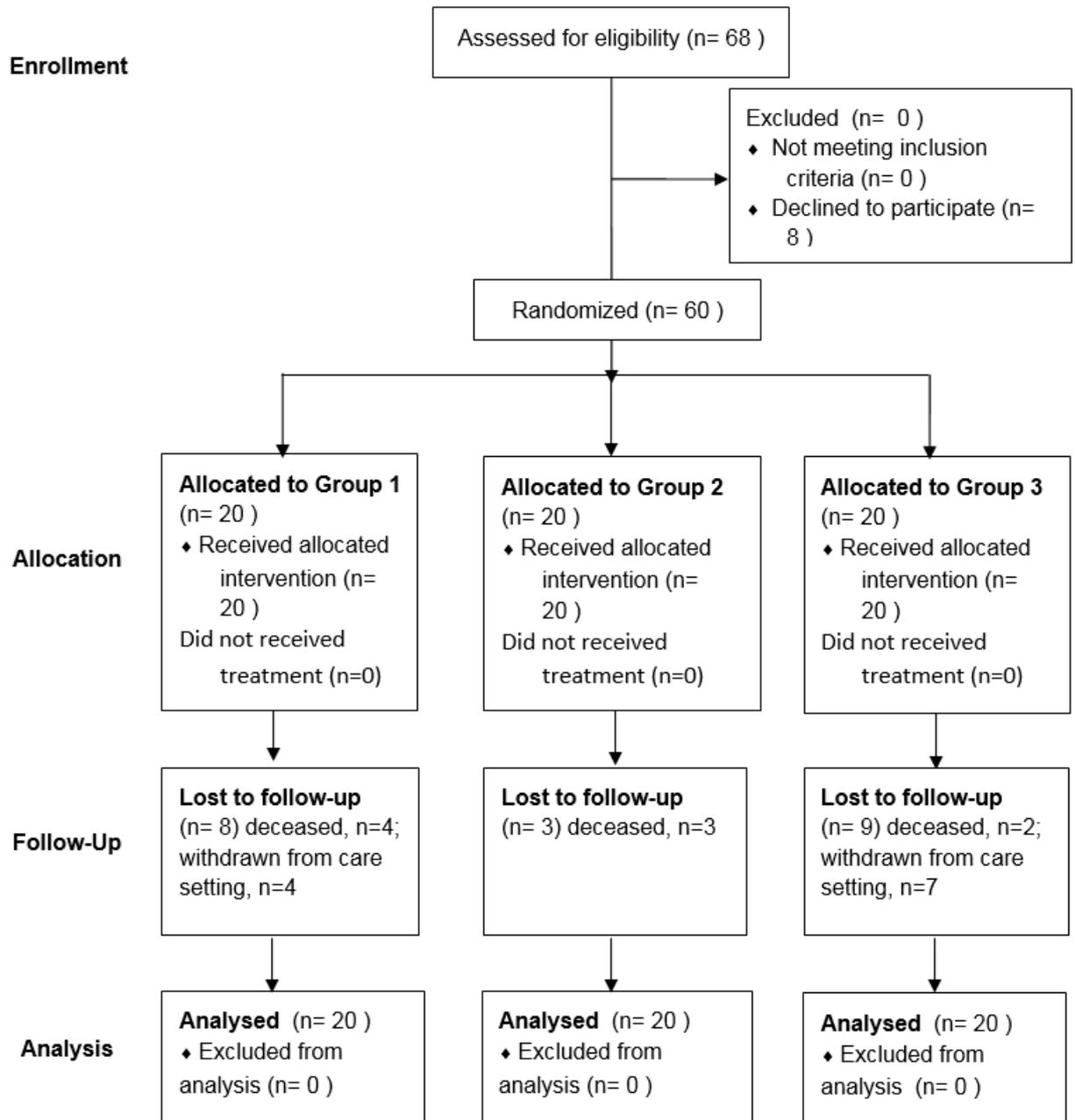


Figure 4.2 CONSORT Flow Diagram

Table 4.1 Demographic Data of Subjects in the Three Groups

	Group 1 Aroma-massage with acupressure + Exercise (<i>n</i> = 20)	Group 2 Cognitive training + Exercise (<i>n</i> = 20)	Group 3 Cognitive training + Aroma-massage with acupressure (<i>n</i> = 20)	<i>P</i> -value [†]
Gender				0.50
Male	4 (20%)	7 (35%)	7 (35%)	
Female	16 (80%)	13 (65%)	13 (65%)	
Age (range, <i>mean</i> ± <i>SD</i>)	66-92 (82.13 ± 7.69)	78-100 (84.33 ± 7.85)	65-97 (84.11 ± 7.33)	0.33
Marital Status				0.22
Single	7 (35%)	1 (5%)	0 (%)	
Married	13 (65%)	9 (45%)	5 (25%)	
Widowed	0	10 (50%)	15 (75%)	
Diagnosis				0.60
Dementia	13 (65%)	15 (75%)	12 (60%)	
Hypertension	14 (70%)	12 (60%)	14 (70%)	0.75
Parkinsonism	3 (15%)	2 (10%)	1 (5%)	0.58
Diabetes Mellitus	8 (40%)	4 (20%)	5 (25%)	0.35
Bilateral cataract	7 (35%)	11 (55%)	6 (30%)	0.24
Cerebral vascular accident	5 (25%)	7 (35%)	7 (35%)	0.74
Skeletal disorder	2 (10%)	3 (15%)	5 (25%)	0.43
Others	9 (45%)	4 (20%)	9 (45%)	0.52
Activity Level				0.10
Bed-chair bound	1 (5%)	3 (15%)	4 (20%)	
Homebound	11 (55%)	12 (60%)	15 (75%)	
Outdoor	7 (35%)	5 (25%)	1 (5%)	
Education Level				0.97
Illiterate	11 (55%)	10 (50%)	11 (55%)	
1-2 years	2 (10%)	3 (15%)	2 (10%)	
>2 years	7 (35%)	7 (35%)	7 (35%)	
Alertness				1.00
Alert	19 (95%)	19 (95%)	19 (95%)	
Sleepy	0	0	1 (5%)	
Drowsy	1 (5%)	1 (5%)	0	
Communication				0.35
Follow verbal command	20 (100%)	18 (90%)	18 (90%)	
Gesture	0	2 (10%)	2 (10%)	
Attention Level				0.04*
> 5 mins	15 (75%)	8 (40%)	8 (40%)	
2-5 mins	4 (20%)	9 (45%)	8 (40%)	
< 2 mins	1 (5%)	3 (15%)	4 (20%)	

* *P* < 0.05 Values are counts of subjects and percentages (except age). [†]Chi's Square test was performed between groups for count data, and One-way ANOVA test was performed for continuous data.

The effects of the covariates (attention and BI-20 pre-test score) were controlled for the following analysis. Comparisons of the various outcome measures of the post-test, 3-month and 6-month follow-up assessments among the three groups are shown in Table 4.3.

In a comparison of the sub-scores of the NPI, significant time \times group effects were identified in the “severity score” as shown in Figure 2(b) ($p < 0.05$, $f = 2.889$, $df = 2$, observed power = 0.69) after controlling for the effect of attention and the BI-20 score. To determine which time point contributed to this finding, a post hoc comparison was performed, and the results are shown in Table 4.4.

Regarding the mean “severity score” of the NPI, it significantly decreased from the pre-test (3.70 ± 3.30) to 3-month post-test (1.85 ± 1.46) in group 1 ($p < 0.01$). There was also a significant reduction in the pre-test score (3.60 ± 3.05) to the 3-month follow-up (2.35 ± 2.26) of Group 3 ($p < 0.01$). These two differences contributed to the overall significance ($p = 0.04$, $f = 2.889$, $df = 2$, observed power = 0.69).

In terms of the “distress score”, there was a significant overall difference ($p < 0.05$, $f = 3.022$, $df = 2$, observed power = 0.68) as shown in Figure 2(c).

In Group 1, the mean “distress score” significantly decreased from the pre-test (5.80 ± 5.09) ($p < 0.01$) to the post-test (4.25 ± 3.78) ($p < 0.05$) and then the

3-month post-test (2.75 ± 2.66). Similar changes were identified in Group 3 from the pre-test (5.40 ± 4.53) ($p < 0.01$) and post-test (4.50 ± 3.50) ($p < 0.05$) to the 3-month follow-up (2.95 ± 3.02). These differences contributed to the overall significance.

In comparing the outcome measures among the three groups at the four time points, the statistical analysis indicated there were no significant differences. The effects of the covariates (attention and BI-20 pre-test score) were controlled for in the previous analysis.

Concomitant drug use was allowed, and prescribed medications remained unchanged throughout the intervention period. No adverse side effects were identified in the participants during the entire research period.

Table 4.2 Comparison of Various Outcome Measures at Baseline Assessments among the Three Groups

	Group 1: aroma-massage with acupressure + exercise (<i>n</i> = 20) Mean (SD)	Group 2: cognitive training + exercise (<i>n</i> = 20) Mean (SD)	Group 3: aroma-massage with acupressure + cognitive training (<i>n</i> = 20) Mean (SD)	One Way ANOVA		LSD
				<i>P</i> -value	<i>F</i> -value	<i>P</i> -value
CCMAI Domain Score:						
Aggressive behaviour	14.60 (1.90)	15.35 (4.36)	13.85 (1.93)	0.29	1.283	
Physically nonaggressive behaviour	12.75 (5.74)	13.00 (5.53)	13.90 (6.88)	0.82	0.198	
Verbally agitated behaviour	12.40 (4.80)	12.75 (7.07)	13.30 (6.78)	0.90	0.103	
NPI Sub-scores:						
Severity score	3.70 (3.30)	2.65 (2.98)	3.60 (3.05)	0.50	0.694	
Distress score	5.80 (5.09)	3.70 (4.57)	5.40 (4.53)	0.34	1.111	
BI-20	15.56 (4.76)	13.32 (6.51)	10.84 (4.34)	0.03	3.932	0.01 [§]
MMSE	10.30 (6.64)	9.30 (6.53)	6.48 (0.41)	0.41	0.904	

Post hoc test was performed when significant between group differences were identified: [§]LSD (Group 2 vs. Group 3).

Table 4.3 Comparison of Various Outcome Measures of Post-test and 3-month Follow-up Assessments among the Three Groups

		Group 1:	Group 2:	Group 3:	3 Time-point x 3 group		Observed
		aroma-massage with acupressure + exercise (<i>n</i> = 20)	cognitive training + exercise (<i>n</i> = 20)	aroma-massage with acupressure + cognitive training (<i>n</i> = 20)	Interaction measured by repeated measure ANCOVA		Power
		Mean (SD)	Mean (SD)	Mean (SD)	<i>P</i> -value	<i>F</i> -value	
MMSE	Post-	10.00 (6.67)	8.55 (6.55)	10.80 (6.74)	0.33	1.172	0.36
	3M FU	10.25 (6.60)	8.95 (6.50)	11.25 (7.13)			
CCMAI Domain Score:							
Aggressive behaviour	Post-	13.35 (0.93)	14.95 (3.52)	14.95 (3.56)	0.06	2.397	0.67
	3M FU	13.50 (1.00)	13.80 (1.99)	14.10 (2.77)			
Physically nonaggressive behaviour	Post-	12.80 (7.18)	13.65 (5.84)	13.15 (6.71)	0.16	1.722	0.47
	3M FU	13.30 (7.75)	13.75 (6.04)	12.90 (7.77)			
Verbally agitated behaviour	Post-	11.20 (4.56)	12.70 (7.41)	12.60 (5.93)	0.63	0.595	0.17
	3M FU	11.80 (4.79)	12.85 (7.01)	12.80 (6.00)			
NPI Sub-scores:							
Severity score	Post-	2.55 (2.48)	2.00 (2.70)	2.75 (2.17)	0.04	2.889	0.69

	3M FU	1.85 (1.46)	2.35 (2.64)	2.35 (2.26)			
Distress score	Post-	4.25 (3.78)	3.00 (3.33)	4.50 (3.50)	0.04	3.022	0.68
	3M FU	2.75 (2.66)	3.05 (2.80)	2.95 (3.02)			

Repeated measures ANCOVA adjusted for attention and BI-20 pre-test.

3M FU, 3-month follow-up; CMMSE, Mini-mental Status Examination; BI-20, Barthel Index; CCMAI, Chinese Cohen-Mansfield Agitation Inventory; NPI, Neuropsychiatric Inventory.

Table 4.4 Significant differences in NPI sub-scores at post-test and 3-month follow-up in Group 1 and Group 3

aroma-massage with acupressure + exercise							
Group 1	NPI sub-scores:	Pre-test	Post-test	3M FU			
(n = 20)		Mean (SD)	Mean (SD)	Mean (SD)	<i>t</i>	<i>p</i> -value	95% CI
	Severity score	3.70 (3.30)	2.55 (2.48)		2.93	0.01	[0.33, .197]
		3.70 (3.30)		1.85 (1.46)	3.00	0.01	[0.56, 3.14]
	Distress score	5.80 (5.09)	4.25 (3.78)		2.58	0.02	[0.29, 2.81]
		5.80 (5.09)		2.75 (2.66)	3.27	0.00	[1.10, 5.00]
			4.25 (3.78)	2.75 (2.66)	2.64	0.02	[0.31, 2.69]
Group 3	Severity score	3.60 (3.05)		2.35 (2.26)	2.80	0.01	[0.32, 2.18]
(n = 20)	Distress score	5.40 (4.53)		2.95 (3.02)	2.92	0.01	[0.70, 1.91]
			4.50 (3.50)	2.95 (3.02)	2.68	0.02	[0.34, 2.76]

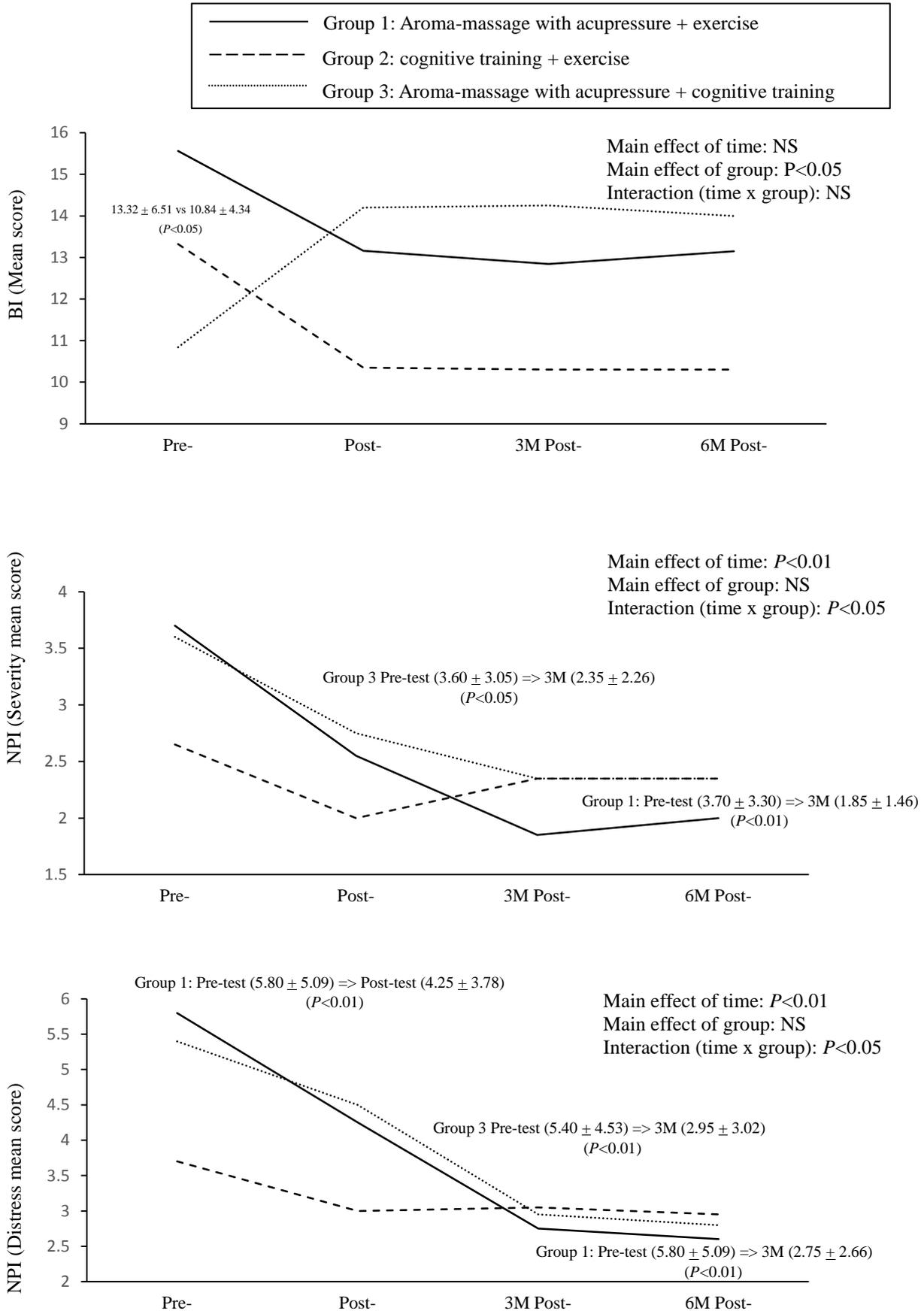


Figure 4.3 Mean Scores of Measure Outcomes with Significant Results

4.4 Discussion

Aroma-massage with acupressure combined with cognitive training or treatment as usual significantly reduces the severity and distress caused by BPSD, whereas cognitive training + exercise does not have similar effects.

Several interesting observations were made. First, significant results were not obtained at the post-test; however, they were obtained during the follow-up period, which indicates that positive outcomes only appeared after 3 months. Second, the protocol was implemented by non-professionals during the treatment period and caregivers during the follow-up period. Occupational therapists were only involved in the training of individuals who implemented the programme. This indicates that the intervention was easy to learn and may be implemented by non-professionals. Caregivers involved in the intervention programme could obtain additional value as their involvement may have improved their relationship with the older adults as observed by the researchers. Third, no significant effects were reported in the cognitive training + exercise group, which implies that the aroma-massage with acupressure protocol was more effective compared to cognitive training and the control. When the participants received aroma-massage with acupressure, they were relaxed and calm. In contrast, cognitive intervention

may irritate them and was not effective in improving their cognitive function or addressing behavioural problems.

Finally, the CMMSE scores showed an upward trend in the aroma-massage with acupressure + cognitive training group, but not in the other groups. Although this change was not significant, it suggests that the aroma-massage with acupressure protocol may enhance the effect of cognitive training in this group. We suggest that the pleasant experience of the aroma-massage with acupressure protocol may calm participants from their agitated state during cognitive training, which enables them to function better when asked to perform table tasks for a duration of twenty minutes. In short, aroma-massage with acupressure further enhances the effect of cognitive training, and future research should be conducted to confirm this finding.

4.5 Conclusion

Aromatherapy, therapeutic massage, and acupressure were independently shown to be effective in reducing BPSD (Ballard & Howard, 2006). However, the combined effects of these three components have not been clearly documented despite the fact that clinical experience suggests that when used together, client satisfaction is higher (Yang *et al.*, 2015). Thus, the innovative aspect of this study

is that we combined three interventions in the aroma-massage with acupressure protocol and explored clinical outcomes with regard to the effects on BPSD.

This pilot RCT contributed to the existing literature by providing evidence of the effectiveness of the combination of three interventions in the management of BPSD. Our results provide preliminary evidence that the aroma-massage with acupressure protocol may reduce the severity and level of distress of neuropsychiatric symptoms in older adults with dementia. This finding also indicates that the protocol is safe, well tolerated and easy to administer by non-professionals with minimal training from professional staff, such as occupational therapists. Further large-scale studies are required to investigate its mechanism and the differential effects compared with the three interventions used alone. With more evidence, this protocol may be recommended as an adjunct therapy to psychotic medication and an alternative to cognitive interventions in the treatment of BPSD in individuals with late-stage dementia.

CHAPTER 5

DISCUSSION AND CONCLUSION

5.1 Summary of Original Contribution

5.1.1 The Aroma-massage with Acupressure Protocol as an Adjunct Intervention for BPSD

BPSD remains a marked health issue that imposes profound stress on caregivers of older adults with dementia and is also a substantial burden on the community. Antipsychotics are believed to be effective in reducing BPSD; however, evidence indicates only modest efficacy for specific symptoms (Sultzer *et al.*, 2008; Yury & Fisher, 2007). More importantly, the US Food and Drug Administration (FDA) has issued warnings regarding their usage and adverse effects (US Food and Drug Administration Public Health Advisory, 2008). Thus, the prolonged use of antipsychotics is not recommended. These issues suggest the need for nonpharmacological interventions despite the limited consensus on their efficacy (Azermai, 2015).

Nonpharmacological intervention studies that included music therapy, physical activity, cognitive training, the education of professional/formal/informal caregivers (Livingston *et al.*, 2014), and massage (Moyle, Murfield, O'Dwyer, &

Van Wyk, 2012) have reported positive results; however, the quality of supporting evidence remains low. New innovative approaches, such as the utilization of interactive therapeutic robotic animals, are under investigation (Moyle *et al.*, 2015) and may shed light on the issue.

Apart from the use of new technologies, the National Institute for Health and Clinical Excellence (NICE) Guidelines (National Institute for Health and Clinical Excellence, 2012) currently recommend the use of aromatherapy, therapeutic massage, and several other nonpharmacological approaches for the management of BPSD. In regards to aromatherapy, there is no clear rationale and widely accepted administration protocol for its implementation (Nguyen & Paton, 2007; Turner, 2005). This results in the general belief among the public that aromatherapy is not an evidence-based clinical practice (Johannessen, 2013). The situation is more or less the same with acupressure and therapeutic massage.

As a result of the limitations of existing studies, we intend to develop a structured protocol, the aroma-massage with acupressure protocol, which combines different complementary and alternative approaches for the management of BPSD with a standardized selection of acu-points, massage techniques, and choice of EOs in standard concentrations. Based on the positive findings of our clinical trial, we conclude that the aroma-massage with

acupressure protocol is a promising approach that may be well-received by older adults and their caregivers. From the findings reported in this thesis, as discussed in Chapter 4, the application of the aroma-massage with acupressure protocol significantly reduced the neuropsychiatric symptoms of older adults with dementia and provided support for our postulation on the clinical efficacy of the protocol in BPSD treatment. First, the aroma-massage with acupressure protocol was shown to be safe as indicated in the feasibility study, as well as the finding that no adverse effects were identified in both the feasibility study and the pilot RCT. Second, it may easily be administered by frontline care workers and caregivers under minimal supervision by occupational therapists or other allied health professionals. Third, a marked reduction in the severity of neuropsychiatric symptoms and the distress caused was noted among participants in the 3-month follow-up. Finally, the continual improvement in the CMMSE scores indicates that aroma-massage with acupressure may enhance the positive effects of cognitive training.

5.1.2 Augmenting the Effect of Cognitive training

In the pilot RCT, we identified an increasing trend in cognitive function after the participants received the aroma-massage with acupressure protocol and

cognitive training compared with the participants who received cognitive training alone. This finding suggests that aroma-massage with acupressure may enhance the effect of cognitive training. This may be a result of the anxiolytic effect of aromatherapy (Lee, Wu, Tsang, Leung, & Cheung, 2011). As anxiety and related symptoms in the cognitively impaired are both direct and indirect factors in further cognitive deterioration (Rozzini *et al.*, 2009), quelling anxiety may mitigate cognitive decline in older adults with dementia (McClive-Reed & Gellis, 2011). The physiological mechanism of aromatherapy is believed to start with EO absorption into the circulatory system, which then stimulates the olfactory bulb and eventually works on the limbic system of the brain (as shown in Figure 5.1), in which the amygdala and the hippocampus process aromas and govern the retrieval of important memories and emotional responses (Buckle, 1998; Nagai, Nijjima, Horii, Shen, & Tanida, 2014). As a result, the stimulation of the limbic system may evoke powerful memories; thus, EOs may improve cognitive and emotional functioning (Cook & Lynch, 2008). The use of lavender EO, as per the current trial, has been the most commonly used EO in controlled trials as it may serve as an anxiolytic agent to manage agitation (Abuhamdah & Chazot, 2008) and simultaneously enhance cognitive function.

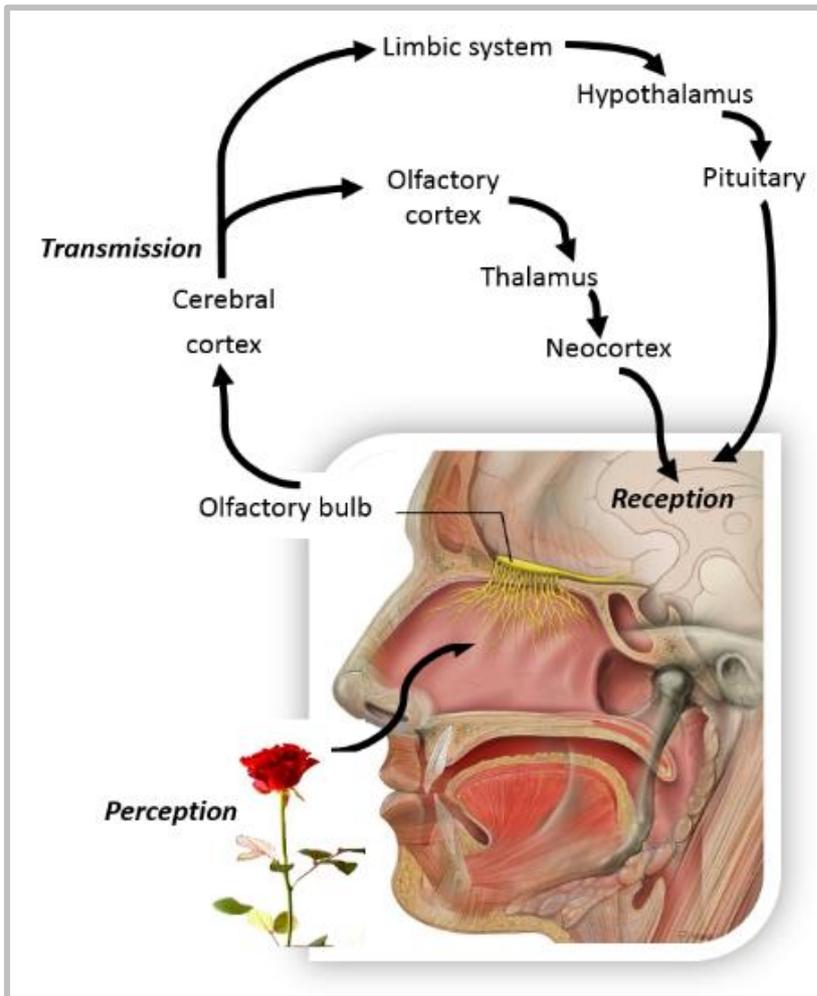


Figure 5.1 The Olfactory System

Aromatherapy administered in combination with a form of physical contact may have an overall better therapeutic effect and minimize distress that results from confusion (Behrman, Chouliaras, & Ebmeier, 2014). Aromatherapy together with therapeutic massage has an effect in down-regulating the parasympathetic nervous system, resulting in a sense of calmness and relaxation (Ferguson, Kleinman, & Browning, 2013) and stimulating endorphin release (Maddocks-Jennings & Wilkinson, 2004). Moreover, acupressure contributes to

the aroma-massage with acupressure protocol based on enhanced experienced (Lin *et al.*, 2015; Yang *et al.*, 2007). In short, massage and acupressure may reinforce the effects of EOs to improve cognitive function.

Current studies on aromatherapy, acupressure, and therapeutic massage in relation to dementia mainly focus on agitation, stress, anxiety, and other mood disorders. Limited evidence is available regarding its effects on cognitive function. In this view, further investigations into this issue are essential, which include RCT with higher quality biomedical studies to understand the physiological mechanisms that underlie its therapeutic effects.

5.2 Implications for Clinical Practice

BPSD represent a major cause of institutionalization of older adults with dementia and constitute a major financial burden on the healthcare sector. Our study has provided empirical evidence that supports the clinical benefits of the aroma-massage with acupressure protocol in the management of BPSD. Using this protocol, we hope the impact of BPSD on older adults and their families may be mitigated to some degree.

The aroma-massage with acupressure protocol may be regarded as an adjunct therapy complementary to other treatment modalities to achieve optimal results. It

may be used together with cognitive training, music therapy, or pharmacological interventions. Given its low cost and potential benefits, the protocol may be adopted in most long-term care settings, as well as the homes of older adults. It is also suggested that the protocol be administered regularly in these settings. As previously discussed, extra manpower is not typically needed. However, the education and training of informal caregivers and volunteers to provide the protocol are necessary.

5.3 Limitations and Future Studies

Although there are many positive results, this pilot RCT has a number of limitations that deserve attention. The main limitation stems from the small sample size and the pilot nature of this study. As this was a new treatment protocol, some guardians of the older adults and healthcare professions were not willing to provide consent.

Second, in this study, only functional abilities, the occurrence of BPSD and their severity and level of distress among caregivers were recorded for analyses. The use of the CCMAI and NPI as the primary outcome measures could only assess behavioural disturbances, and there were no outcome measures on desirable behaviours, such as increases in social engagement and interaction with

other individuals. We should have employed other assessments, such as video analysis of engagement (Jones, Sung, & Moyle, 2015) and quality of life (Moyle & Murfield, 2013), which are crucial to determine the effectiveness of interventions. Third, there was no blinding of the treatment of the participants or assessors, which may lead to bias in assessing the effect of the treatment. Missing data may introduce further bias. Fourth, anti-psychotic and concomitant drugs taken by the participants were not controlled. Fifth, as a result of its pilot nature and the fact that it was an MPhil study, we mainly focused on testing the effectiveness of this new programme that combined three intervention elements compared to conventional interventions. We did not compare it with the effects of separate interventions of these three therapeutic components. Finally, we may further use a combination of EOs, for example, lavender and melissa leaf (which has an additional benefit of maintaining attention as reported by Abuhamdah and Chazot, 2008), to provide additional scientific-based evidence on the synergistic effects of EO. We fully understand this would be the next step in future research that may be undertaken by nurses and allied health professionals. Our hypothesis that aroma-massage with acupressure would be more effective than conventional interventions in reducing BPSD was preliminarily supported by this pilot RCT.

5.4 Conclusion

In conclusion, the aroma-massage with acupressure protocol is a safe and effective therapy for a reduction in the severity and distress of BPSD, as supported by preliminary evidence. Moreover, it may promote a sense of comfort and improve the relationship between older adults and the caregivers who administer the intervention. The aroma-massage with acupressure protocol should be used in adjunct with other treatment modalities to achieve optimal results. In addition, precise training in the administration of the protocol should be performed to ascertain the accuracy and adherence of frontline care workers.

As a result of the small sample size of this pilot RCT, its generalizability must be further investigated to ensure that the aroma-massage with acupressure protocol is effective in managing BPSD in older individuals. Moreover, we may further ascertain its effect on individuals with dementia by recruiting subjects with a proper diagnosis of dementia.

We may also investigate the effect of variations in the protocol, for example, the use of different EOs or a combination of EOs, as well as adjustments in the duration to assist health care providers in incorporating it into daily practice.

APPENDIX I

Description of the Eleven Reviewed Randomized Controlled Trials on
Aromatherapy

Study (1st author, year)	Study design	Subject details	Treatment group	Control group	Outcome measures	Results	Comments
Akhondzadeh, 2003	<ul style="list-style-type: none"> • N=42 • 18 F, 24 M • Age: 65-80 • Randomized, placebo controlled • 3 centres in Tehran, Iran • Intervention period: 4 months 	<p>History of cognitive decline for six months</p> <p>Diagnosis of AD, ADAS\geq2, CDR\leq2</p> <p>satisfied the NINCDS/ADRDA criteria for possible AD concomitant disease + other drugs treating dementia were stopped</p>	<ul style="list-style-type: none"> • Direct intake of 60 drops Melissa officinalis extract daily for 4 months - n=21 - 12M, 9F - Mean age:73.0 - 1 dropout 	<ul style="list-style-type: none"> • Direct intake of 60 drops of Placebo (unknown) daily for 4 months - n=21 - 12M, 9F - Mean age:73.3 - 6 dropouts 	<ul style="list-style-type: none"> • Alzheimer's disease assessment scale-cognitive subscale (ADAS-cog) • Clinical dementia rating-sum of the boxes (CDR-SB) (Assessed at baseline and every 2 weeks by a neurologist in a clinic) 	<ul style="list-style-type: none"> • Significant difference between scores of outcome measures between the two groups • No. of subjects with agitation was significantly less in the treatment group 	<ul style="list-style-type: none"> • Side effect: vomiting (3), dizziness (1), wheezing (2), abdominal pain (2) and nausea (1) were occurred in 9 subjects <p>JADAD score: 5</p>
Ballard, 2002	<ul style="list-style-type: none"> • N=72 • 43F, 29M • Mean Age 78.5 • Randomized, double-blind, placebo-controlled • 8 nursing home in UK 	<ul style="list-style-type: none"> • Agitation as defined on the NPI and CMAI. Dementia was confirmed as severe by CDR • 92%(33) in each group were 	<ul style="list-style-type: none"> • 10% blended Melissa oil in lotion and topical application on face or arm twice per day for 4 weeks by caregiving staff 	<ul style="list-style-type: none"> • 10% blended placebo (sunflower) oil in lotion and topical application on face or arm twice per day 	<ul style="list-style-type: none"> • Cohen-Mansfield Agitation Inventory (CMAI) • Neuropsychiatric Inventory (NPI) • Barthel Index (BI) • Dementia Care Mapping (DCM) 	<ul style="list-style-type: none"> • 60% of treatment group and 14% of placebo group attained 30% improvement in CMAI score • Significant improvements in 	<ul style="list-style-type: none"> • 8% of the placebo group and 6% of the treatment group were prescribed additional psychotropic medication

	<ul style="list-style-type: none"> Intervention period: 4 weeks 	<p>taking at least 1 psychotropic agent and were not discontinued during study period</p>	<ul style="list-style-type: none"> - n=36 - Mean age:77.2 - 24F, 12M - 1 dropout 	<p>for 4 weeks by caregiving staff</p> <ul style="list-style-type: none"> - n=36 - Mean age: 79.6 - 19F,17M 	<ul style="list-style-type: none"> CDR (Assessed at baseline and at 4th week by examined and certificated raters in the care facilities) 	<p>domains of motor restlessness, physical aggression, and verbal nonaggression.</p> <ul style="list-style-type: none"> Increase in time engaged in constructive activities in treatment group 	<p>because of increasing agitation</p> <ul style="list-style-type: none"> 1 subject in treatment group experienced 2 days of diarrhea <p>JADAD score: 5</p>
Burleigh, 1997	<ul style="list-style-type: none"> N=7 2M, 5F Age: 61-96 Within subject design A continuing care home for people with severe dementia in London Intervention period: 9 weeks 	<ul style="list-style-type: none"> With agitation and restlessness Wandering to the point that patients' feet were sometimes swollen and bleeding With challenging behaviors, and sleep disturbances 	<ul style="list-style-type: none"> Every subject received own blend of oils including the following Combination: lavender, roman chamomile, rosemary, marjoram in carrier oil Choice of EOs were by a qualified aromatherapist on analyzed BASOLL score result. Treatments were performed by trained caregiving staff Week 1-3: foot bath/bath, and oils applied to pillows at night five times per week Week 4-6: stop treatment 	<ul style="list-style-type: none"> Behavior Assessment Scale of Later Life (BASOLL) (Assessed at 3rd week and 12th week by trained nursing staff) 	<ul style="list-style-type: none"> 5 subjects with reduction in challenging behaviours 6 subjects required less assistance with ADL tasks 	<ul style="list-style-type: none"> Some allergic reactions occurred despite skin tests before treatment 1 subject was reported with drowsiness which was discontinued when treatment stopped No statistical analysis 	

			<ul style="list-style-type: none"> • Week 7-9: bath/footbath/basin, applied to pillow, and massaged with the oils on hands, neck, face, and shoulders five times per week • Week 10-12: Treatment stopped 			<ul style="list-style-type: none"> • No description on concomitant drug use • No blinding of treatment to staff or carers
						JADAD score: 0
Burns, 2011	<ul style="list-style-type: none"> • N=114 • Double-blind parallel-group placebo-controlled randomized trial • 3 clinical centres Manchester, London, and Southampton • Intervention period: 12 weeks 	<ul style="list-style-type: none"> • Had agitation for 4 weeks minimally, CMAI>39, satisfied the NINCDS/ADRD A criteria for possible AD, CDR score:3, age >60 • Free of antipsychotics and/or anticholinesterase for at least 2 weeks 	<ul style="list-style-type: none"> • Group 1: placebo medication and active aromatherapy: 1 ml of 10% Melissa oil in base lotion massage into the hands and upper arms 1-2 minutes twice daily by carer of participants - n=38 - 11M, 21F - Mean age:85.6 - 8 dropouts • Group 2: active medication (Donepezil) and placebo aromatherapy: 5mg Donepezil daily intake for the first month and increased to 10mg afterwards, plus 10% of placebo oil (sunflower) massage - n=37 - 11M, 20F 	<ul style="list-style-type: none"> • Pittsburgh Agitation Scale (PAS), • NPI, • BI, • Blau QOL scale (QOL) <p>(Assessed at 4th week and 12th week by blinded research nurse)</p>	<ul style="list-style-type: none"> • Significant difference of QOL score between groups with the aromatherapy group experiencing the best result • No other significant difference between or within groups for agitation and functioning in ADL • 18% and 37% improvement in PAS and NPI respectively in 	<ul style="list-style-type: none"> • 8 serious adverse events: donepezil (4), Melissa oil (2), placebo (2); 27 adverse events with 9 subjects withdrew the study because of breakthrough agitation • 6 dropouts at point of admission to the study and further 26 dropouts at the endpoint • 50% compliance

JADAD score: 0

[Each subject were exposed to all 3 EOs and placebo repeatedly for 4 times (in total 16 times); n=13]

<p>Holmes, 2002</p> <ul style="list-style-type: none"> • N= 15 • 7F, 8M • Mean age: 79 • Placebo-controlled • A long-stay psychiatric ward in UK • Intervention period: 2weeks 	<ul style="list-style-type: none"> • Meeting ICD-10 diagnostic criteria for severe dementia and suffering from agitated behaviour defined as a minimum score of 3 points on the PAS • Satisfied the NINCDS/ADRD A criteria for possible AD 	<ul style="list-style-type: none"> • Diffusion of 2% lavender oil on alternate days, using three aroma-streams for a period of 2 hours (4pm-6pm) followed by placebo (water) for another 2 hours. 	<ul style="list-style-type: none"> • Diffusion of placebo (water) on alternate days, using three aroma-streams for a period of 2 hours followed by 2% lavender oil for another 2 hours. 	<ul style="list-style-type: none"> • PAS • (Assessed by blinded rater at the end of treatment period and the end of placebo period) 	<ul style="list-style-type: none"> • 60% showed modest improvement in agitated behaviour, 33% showed no change, 7% became worse 	<ul style="list-style-type: none"> • Concomitant drug was allowed throughout the trial but not change of medication regime <p>JADAD: 2</p>
<p>Jimbo, 2009</p> <ul style="list-style-type: none"> • N=28 • 2M, 26F • Mean age:86.1 • Placebo-controlled, within subject 	<ul style="list-style-type: none"> • Diagnosed with AD or vascular dementia by DSM-IV and NINCDS-ADRD 	<ul style="list-style-type: none"> • 28 days of control period and then 28 days of treatment period followed by 28 days of washout period • Control period: no treatment • Treatment period: 	<ul style="list-style-type: none"> • Gottfries, Brane, Steen scale (GBSS-J), • Functional Assessment 	<ul style="list-style-type: none"> • Significant improvement in cognitive function was observed after aromatherapy 	<ul style="list-style-type: none"> • Outcome measures mainly on cognitive function but not on BPSD 	

design	A	0.08mL of Rosemary and 0.04 mL Lemon EO in the morning from 0900-1100, and 0.08mL of Lavender and 0.04mL of Orange EO in the evening from 1930-2100 by means of dropping on a gauze in diffusers with an electric fan	Staging of Alzheimer's disease (FAST), • Revised version of Hasegawa's Dementia Scale (HDS-R), • Touch Panel-type Dementia Assessment Scale (TDAS) (Assessed at baseline, after 28 days of control period, after 28 days of treatment period, and after 28 days of washout period. Each assessment lasts for 1 week by trained evaluator)	(GBSSJ-A-13 score) • Significant improvement in cognitive function after aromatherapy (TDAS score) • Patients with AD showed significant improvement in ideational praxis function (TDAS understanding score)	• Not clear whether concomitant drug was allowed JADAD score: 0	
Kilstoff, 1998	• N=16 • Within subject design	• Subjects: moderate to moderately	• Using 0.5ml of lavender, mandarin, and geranium • EOs blended in 5ml of sweet almond	• Post treatment focus group, memos, field notes,	• Indicated "a positive strengthening of	• No statistical analysis performed

	<ul style="list-style-type: none"> • 1 multicultural dementia day-care centre in Sydney of Australia • Treatment period: unknown 	severe symptoms of dementia	oil, provide gentle strokes, pressure and other circular movements in a rhythmic pattern on fingers, hand and wrist for 10-15 mins by trained carers N=16	in-depth focused interview	<ul style="list-style-type: none"> • Observation logbooks • The Revised Elderly Persons' Disability Scale (REPDS) (Rated post treatment by carers and staff) 	the relationship between the person with dementia and their family carers, and an improvement in feelings of health and well-being for both". (P.....)	<ul style="list-style-type: none"> • No clear treatment regime reported • No blinding of treatment to subjects, carers and staff <p>JADAD score: 0</p>
Lin, 2007	<ul style="list-style-type: none"> • N=70 • 41F, 29M • Mean age: 78.29 • Placebo-controlled crossover randomized study • Care and attention home in Hong Kong • Intervention period: 10 weeks 	<ul style="list-style-type: none"> • Subjects: dementia diagnosed with DSM-IV, with clinically significant agitation identified using CCMAI • Concurrent psychotropic drugs were allowed 	<ul style="list-style-type: none"> • Inhalation of lavender EO in cosmetic cotton diffused by aroma diffuser. Two diffusers were placed at each side of the pillow during sleep at night for at least 1 hour - n=35 - 21F, 14M - Mean age: 78.2 	<ul style="list-style-type: none"> • Inhalation of placebo (sunflower) oil in cosmetic cotton diffused by aroma diffuser. Two diffusers were placed at each side of the pillow during sleep at night for at least 1 hour - n=35 	<ul style="list-style-type: none"> • Chinese version of CMAI (CCMAI), • Chinese version of NPI (CNPI) • Mini-Mental State Examination (CMMSE) (at baseline only) (Assessed done by research team psychiatrist at baseline, after treatment by oil , before and after 	<ul style="list-style-type: none"> • Change of total scores in CNPI and CCMAI after treatment of lavender was significantly larger than after the placebo control • Significant reduction in sub score of CNPA including agitation, dysphoria, irritability, aberrant 	<ul style="list-style-type: none"> • Rater not blinded to treatment • Pharmacological and non-pharmacological interventions like medication and rehabilitation programs existed in adjunct to the treatment <p>JADAD score: 3</p>

			- 20F, 15M - Mean age: 78.4	placebo period	motor behaviour, and night-time behaviour	
Smallwood, 2001	<ul style="list-style-type: none"> • N=21 • 12F, 9M • Mean age: 66.8 • Single-blinded randomized controlled • District general hospital ward in UK • Intervention period: 1 day 	<ul style="list-style-type: none"> • Diagnosed as dementia by a consultant psychiatrist 	<ul style="list-style-type: none"> • Group 1: Lavender oil massage; n=7 • Group 2: plain oil massage; n=7 • Group 3: conversation and lavender oil diffusion; n=7 • (All 3 groups received treatment twice in a specific period of the day and twice a week) 	<ul style="list-style-type: none"> • 2 Video-tapes recording behaviour for 15 minutes in each specified 4 periods (1000-1100, 1100-1200, 1400-1500, 1500-1600) during the day at baseline and after treatment. Video records were sampled once every 30 seconds and behaviour recorded was rated by 2 blinded raters 	<ul style="list-style-type: none"> • Between the period of 3pm-4pm, a more consistent reduction is observed in the lavender oil massage group than in the conversation and aroma diffusion group 	<ul style="list-style-type: none"> • Rater rated frequencies of behaviour but not severity • Concomitant drug was allowed throughout the trial <p>JADAD score: 3</p>
Snow, 2004	<ul style="list-style-type: none"> • N=7 • Placebo-controlled, within subject design • A long-term care 	<ul style="list-style-type: none"> • Probable AD who displayed “marked agitation” using CMAI by nursing 	<ul style="list-style-type: none"> • 2 drops of undiluted oil was placed every 3 hours on an absorbent fabric sachet pinned near the collarbone of each subject’s shirt. Three application per day 	<ul style="list-style-type: none"> • CMAI (rated every 2 days) • Severe Impairment Rating Scale (SIRS), 	<ul style="list-style-type: none"> • No evidence of reduction of agitation in treatment groups • No evidence 	<ul style="list-style-type: none"> • Unknown blinding of subjects and rater • Analysis just as

<p>facility specifically for persons with dementia (unknown location)</p> <ul style="list-style-type: none"> • Intervention period: 10 weeks 	<p>staff</p>	<ul style="list-style-type: none"> - Lavender (A), - Thyme (B), - Unscented grape-seed oil (C) <p>Each oil treatment for two weeks following the order of A>B>C>B>A</p>	<ul style="list-style-type: none"> • Mini Mental State Exam (MMSE) (Assessed on baseline, after each treatment session, and 2 weeks after all treatment sessions.) 	<p>demonstrated non specific pleasant smelling substances</p> <ul style="list-style-type: none"> • No indication of a global placebo effect • One significant difference found in before and after the first lavender treatment in CMAI score but nil finding in the second lavender treatment in the same subject which shows no consistency of treatment effect 	<p>a series of single case evaluation as only within subject data is analysed</p> <ul style="list-style-type: none"> • Sample size too small <p>JADAD score: 0</p>
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The Eleven Reviewed Randomized Controlled Trials on Aromatherapy

1. Akhondzadeh, S., Noroozian, M., Mohammadi, M., Ohadinia, S., Jamshidi, A. H., & Khani, M. (2003). Melissa officinalis extract in the treatment of patients with mild to moderate Alzheimer's disease: a double blind, randomised, placebo controlled trial. *Journal of Neurology, Neurosurgery & Psychiatry*, 74(7), 863-866.
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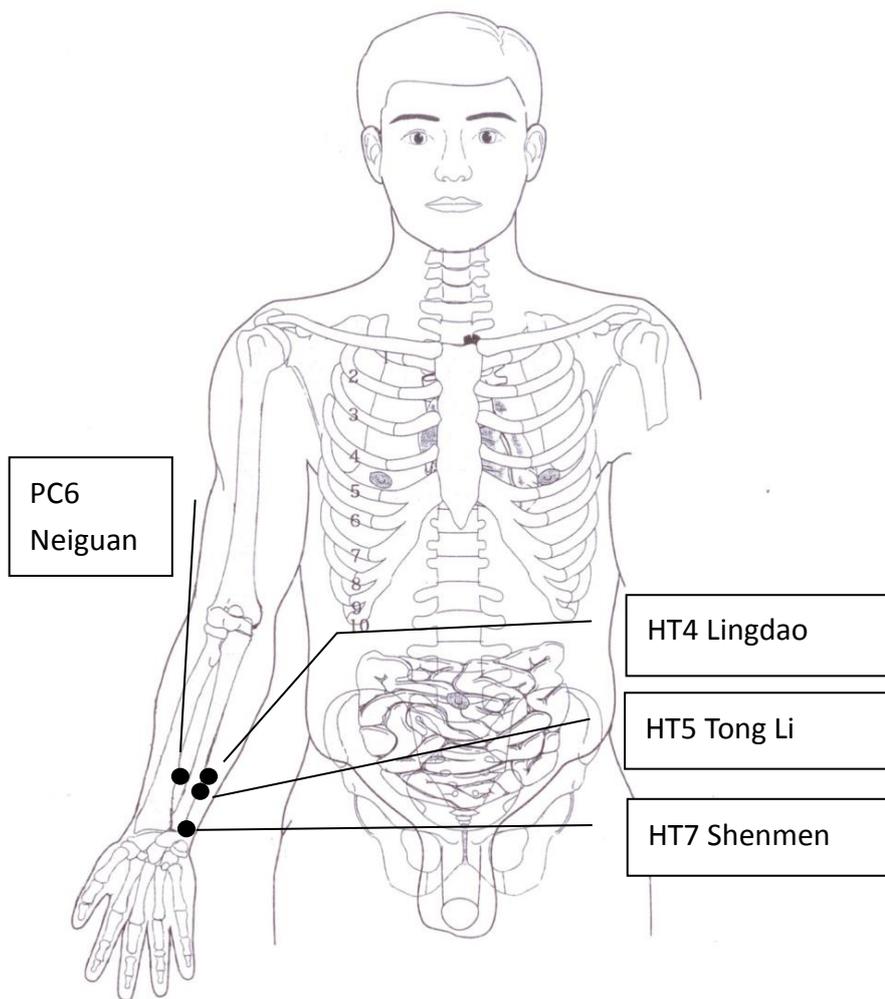
APPENDIX II

The Aroma-massage with Acupressure Protocol Manual

Important notes	
Duration	No longer than 20 minutes
Positioning and environment	Prepare the participant in a comfortable chair/wheelchair. Sit face to face to the elderly person. Room temperature should be warm with a range of 23 to 26 degree. Environmental and distraction, such as noises of a radio, should be kept to minimal.
Procedures and sequencing	3 parts: forearm, head, and lower leg. With the sequence: forearm→head→lower leg. Areas not massaged and the underlying reasons should be clearly recorded e.g., hypersensitivity and aggressiveness.
Acupressure techniques used	Use pressing and kneading techniques with the thumb. Press downward vertically with the tip of the thumb, knead with clockwise direction for 20 strokes, and then 20 strokes in anti-clockwise direction. Note: the finger nails of worker should be kept short.
Measurement of “Chinese inch”: (mentioned as “inch” in this table)	
Getting started	
Material and equipment	Massage oil (blended lavender essential oil in base oil with concentration of 2%) in glass container; Alcohol wrap tissue × 5 packs; and

	Tissue paper × 1 box.
Explain treatment procedures	<p>“Today I will perform no longer than 20 minutes of acupressure and aromatherapy massage on your forearm, head, and leg. The purpose is to help you relax and have a peaceful mind. You may feel tenderness or numbness during acupressure. Please let me know if you are feeling uncomfortable or want me to press with more or less strength. Let’s get started.”</p> <p>We must explain the procedures to every elderly person even they may not understand or have no response.</p>
Sterilization	Use a large alcohol wrapping tissue to clean your own hands. Then, use another one for cleaning each forearm and another one for each leg of the elderly person.
Prepare your hands	Use some massage oil to rub and warm your hands before you start to perform the procedures for the participant.

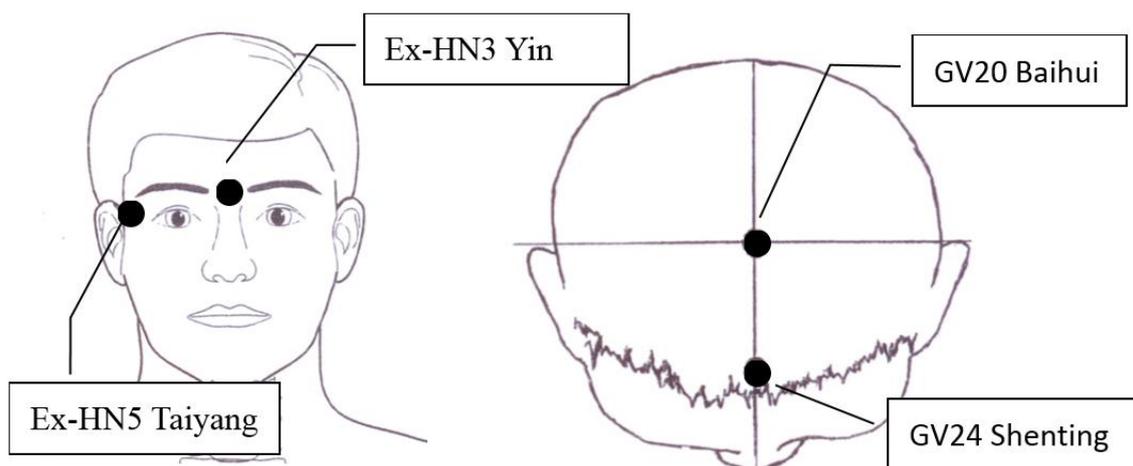
Forearm



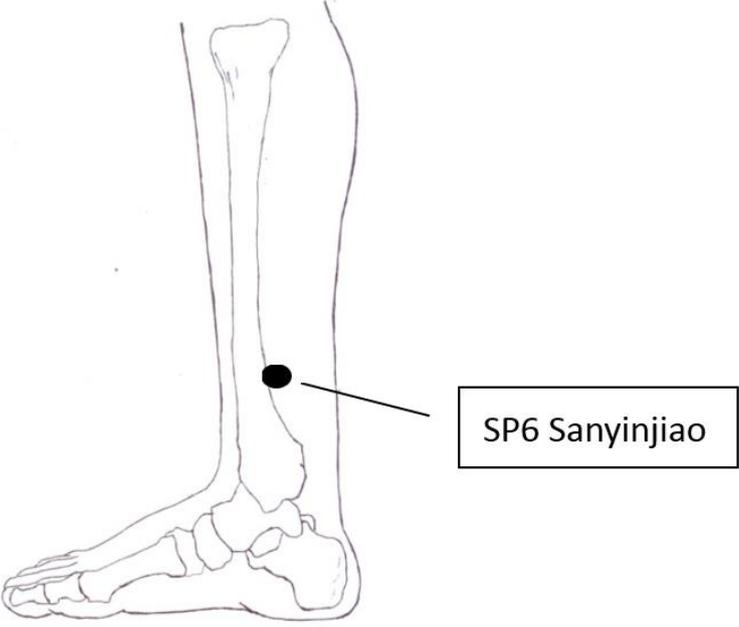
Warm up	<p>Use some oil on the elderly person's hand and forearm with palm facing upward. Hold his/her hand with your hands. Use your thumbs to massage the palm from the middle of the palm to both sides for 5 times. Massage the forearm with the same technique until the forearm is covered with massage oil. Check for the elderly person's facial expression and their responses. If the elderly person seems not warmed up yet, extend the period up to not more than 2 minutes.</p> <p>Use your non-dominant hand to hold the forearm and then use your dominant hand to perform acupressure. You can start with less force and ask how they feel for every acu-points. If the elderly person suffers from dysphasia, observe for any adverse facial expression or reaction.</p>
HT7 Shenmen	At the wrist cease of the palmer side of the wrist, proximal to the carpal bone, next to the tendon above the head of ulnar bone (lateral side).
HT5 Tong Li	One inch above the above acu-point.
HT4 Lingdao	Half inch above the above acu-point.
Heart meridian	Extend your thumb, friction along the meridian with hard surface of the distal joint for 10 times.
PC6 Neiguan	Ask the elderly person to make a fist, two tendons will be slightly protruded and the acu-point is located between the two tendons at the point 2 inches proximal to the wrist cease.

Having finished the acu-points of the left side, repeat the above procedures on the right side.

Head



Ex-HN5 Taiyang	1 inch behind the conjunction of the end of the eye brow and edge of the eye, there is a concave area. Another side of the head should be supported during this step.
Ex-HN3	Stand behind the elderly person, help to extend his/her neck to 40 degrees. The

Yin- tang	acu-point is located at the mid-point of the two eye brows. Then, friction along the midline towards the hair line and to the next acu-points. The back of the head should be well supported during this step. Perform acupressure on the right side after the left side is done.
GV24 Shenting	Upward along the vertical midline of the face and 0.5 inch behind the hair line. Back of the head should be well supported during this step.
GV20 Baihui	Neck in neutral position, this acu-point is located at the conjunction of a line collecting tips of two ears and the midline of the head. When acupressure is applied on this point, the head should be supported by holding the chin.
GB20 Fengchi	At the end of the curve at the back of the skull, there are two major muscles at both sides of the mid line. Across the muscle to the lateral side, there is a depression point at the conjunction of the muscle and the curve of the head. Chin should be supported during acupressure at this acu-point. Perform the right side after the left side is completed.
<u>Leg</u>	
Warm up	Elderly person in supine position or sitting with lower leg resting on a stool or a chair. Use some massage oil to massage the lower leg.
SP6 Sanyinjiao	3 inches above the medial malleolus and along the edge of the tibia.
Spleen meridian	Extend your thumb, friction along the meridian with hard surface of the distal joint for 10 times.
When the acu-points of the left side are completed, repeat the above procedures on the right side.	

APPENDIX III

Homework Assignment for Practicing the Aroma-massage with Acupressure Protocol

Management of Behavioural and Psychological Symptoms of Dementia (BPSD)
by Complementary and Alternative Medicine (CAM) Approaches
Homework Assignment

Staff name: _____ Date of treatment: _____

Please perform Aroma-massage with Acupressure Protocol on one subject and rate yourself (one form for one treatment only):

Item	Criteria	Easy	Difficult (why?)
1.	Prepare the environment properly		
2.	Position the subject properly		
3.	Know clearly the subject's characteristics (e.g. affected side of stroke, etc)		
4.	Prepare required materials (tissue, alcohol pad, massage oil, etc)		
5.	Clearly explain procedures to subject		
6.	Take correct measurements of BP, HR and SaO ₂		
7.	Properly sanitize own hands and forearms of the participant		
8.	Warm up own hands		
9.	Warm up subject's forearm (proper use of massage technique: effleurage)		
10.	Locate 1 st acu-point: Shenmen with explanation		
11.	Locate 2 nd acu-point: Tong Li with explanation		
12.	Locate 3 rd acu-point: Lingdao with explanation		
13.	Locate the heart meridian and friction correctly for 10 times		
14.	Locate 4 th acu-point: Neiguan with explanation		

15.	Perform acupressure on the other forearm		
16.	Locate 5 th acu-point: Taiyang with explanation		
17.	Perform acupressure on the other side of head		
18.	Locate 6 th acu-point: Yintang with explanation		
19.	Locate 7 th acu-point: Shenting with explanation		
20.	Locate 8 th acu-point: Baihui with explanation		
21.	Locate 9 th acu-point: Fengchi with explanation		
22.	Perform acupressure on the other side of head		
23.	Position the subject properly for lower leg session		
24.	Locate 10 th acu-point: Sanyinjiao with explanation		
25.	Locate the spleen meridian and friction correctly for 10 times		
26.	Measurements of BP, HR and SaO2		
27.	Fill in the “safe practice checklist”		
28.	Apply correct acupressure techniques: flex IPJ of thumb to 90°, press with tip of thumb, clockwise stroke x 20 followed by anti-clockwise stroke x 20 for all acu-points		
29.	Press with sufficient power on the acu-points		
30.	Observe the subject’s response during the treatment		
31.	Manage to finish the treatment in no longer than 20 minutes		

32.	Notice and respond to any adverse events		
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Adverse event (please specify if any):

APPENDIX IV

Safety Practice Checklist

Management of Behavioural and Psychological Symptoms of Dementia (BPSD) by
Complementary and Alternative Medicine (CAM) Approaches
Safe Practice checklist

Subject no: _____ Date of treatment: _____

Staff name: _____

Item	Descriptions	Yes	No
1	No chest pain or dizziness during or after the practice		
2	No observable signs of insufficient blood circulation such as paleness and/or confusion during or after the practice		
3	SaO2 maintained a 90% or above during or after the practice		
4	No palpitation together with irregular pulse pattern during or after the practice		
5	Maximum rise in heart rate (HR) be with 70% of heart rate reserve during or after the practice		
6	Blood pressure (BP) showing no hypertensive nor hypo adaptive responses during or after the practice		
7	Rise in BP normalized within 2 minutes or rest		

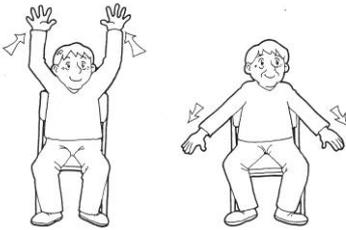
The Seven Criteria for judging “safe practice” of the Aroma-massage with acupressure protocol, adapted from the American College of Sports Medicine, (2005) and Niemeyer (1980)

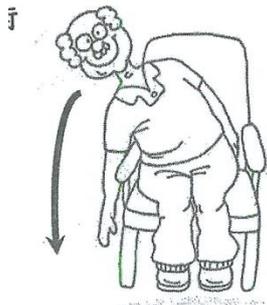
APPENDIX V

Exercise Program

**Management of Behavioural and Psychological Symptoms of Dementia (BPSD) by
Complementary and Alternative Medicine (CAM) Approaches**

Exercise program

<p><u>Neck (1)</u></p> <ol style="list-style-type: none"> 1. Sit up straight, look at your front 2. Turn head to look at left side, stop for 5s 3. Turn head to look front, stop for 2s 4. Turn head to look at right side, stop for 5s <p>Repeat steps 2 to 4 five times</p>	
<p><u>Neck (2)</u></p> <ol style="list-style-type: none"> 1. Sit up straight, look at your front 2. Bend neck to left side, stop for 5s 3. Return to upright position, stop for 2s 4. Bend neck to right side, stop for 5s <p>Repeat steps 2 to 4 five times</p>	
<p><u>Shoulder</u></p> <ol style="list-style-type: none"> 1. Sit up straight, look at your front 2. Raise your arms as shown in the picture, stop for 5s 3. Lowers your arms <p>Repeat steps 2 to 3 ten times</p>	
<p><u>Waist (1)</u></p> <ol style="list-style-type: none"> 1. Sit up straight, look at your front 2. Fold your arms in front of your chest 3. Turn to your left side, stop for 5s 4. Turn to your right side, stop for 5s <p>Repeat steps 3 to 4 ten times</p>	

<p><u>Waist (2)</u></p> <ol style="list-style-type: none"> 1. Sit up straight. Look at your front 2. Bend waist to left side, try to touch the ground, stop 5s 3. Bend waist to right side, try to touch the ground, stop 5s <p>Repeat step 2 and 3 ten times</p>	
<p><u>Thigh</u></p> <ol style="list-style-type: none"> 1. Sit up straight. Look at your front 2. Raise your left leg, stop for 5s and then lower it 3. Raise your right leg, stop for 5s and then lower it <p>Repeat steps 2 and 3 ten times</p>	
<p><u>Ankle</u></p> <ol style="list-style-type: none"> 1. Sit up straight. Look at your front 2. Move left foot up and down for twenty times 3. Move right foot up and down for twenty times <p>Repeat step 2 and 3 five times</p>	
<p><u>Upper extremity (1)</u></p> <ol style="list-style-type: none"> 1. Sit up straight. Look at your front 2. Swing left arm backward and forward for twenty times 3. Swing right arm backward and forward for twenty times <p>Repeat step 2 and 3 five times</p>	
<p><u>Upper extremity (2)</u></p> <ol style="list-style-type: none"> 1. Sit up straight. Look at your front 2. Touch left knee with right hand for twenty times 3. Touch right knee with left hand for twenty times <p>Repeat step 2 and 3 five times</p>	

Standing

1. Sit up straight. Look at your front
2. Stand up, stop 5s, sit down, repeat ten times



APPENDIX VI

Practical Test on the Aroma-massage with Acupressure Protocol

Management of Behavioural and Psychological Symptoms of Dementia (BPSD) by
Complementary and Alternative Medicine (CAM) Approaches
Aroma-massage with Acupressure Protocol Practical Test

Staff name: _____ Assessment Date: _____

Item	Criteria	Able	Unable
1.	Prepare the environment properly		
2.	Position the subject properly		
3.	Know clearly the subject's characteristics (e.g. affected side of stroke,etc)		
4.	Prepare required materials (tissue, alcohol pad, massage oil, etc)		
5.	Clearly explain procedures to subject		
6.	Take correct measurements of BP, HR and SaO2		
7.	Properly sanitize own hands and forearms of the participant		
8.	Warm up own hands		
9.	Warm up subject's forearm (proper use of massage technique: effleurage)		
10.	Locate 1 st acu-point: Shenmen with explanation		
11.	Locate 2 nd acu-point: Tong Li with explanation		
12.	Locate 3 rd acu-point: Lingdao with explanation		
13.	Locate the heart meridian and friction correctly for 10 times		
14.	Locate 4 th acu-point: Neiguan with explanation		
15.	Perform acupressure on the other forearm		
16.	Locate 5 th acu-point: Taiyang with explanation		
17.	Perform acupressure on the other side of head		
18.	Locate 6 th acu-point: Yintang with explanation		
19.	Locate 7 th acu-point: Shenting with explanation		
20.	Locate 8 th acu-point: Baihui with explanation		
21.	Locate 9 th acu-point: Fengchi with explanation		
22.	Perform acupressure on the other side of head		
23.	Position the subject properly for lower leg session		
24.	Locate 10 th acu-point: Sanyinjiao with explanation		
25.	Locate the spleen meridian and friction correctly for 10 times		

26.	Measurements of BP, HR and SaO2		
27.	Fill in the “safe practice checklist”		
28.	Apply correct acupressure techniques: flex IPJ of thumb to 90°, press with tip of thumb, clockwise stroke x 20 followed by anti-clockwise stroke x 20 for all acu-points		
29.	Press with sufficient power on the acu-points		
30.	Observe the subject’s response during the treatment		
31.	Manage to finish the treatment in no longer than 20 minutes		
32.	Notice and respond to any adverse events		

All of the above items should be rated as “Able” to pass the assessment

APPENDIX VII

Training Protocol

Management of Behavioural and Psychological Symptoms of Dementia (BPSD) by
Complementary and Alternative Medicine (CAM) Approaches
Training protocol

Session 1 Part I: Aroma-massage with Acupressure Protocol

Duration: 90 mins

Duration	Details	Materials
5 mins	Introduction to research goal, treatments and treatment regime	PowerPoint file
10 mins	Introduction to the Aroma-massage with Acupressure Protocol	
20 mins	Demonstration of the Aroma-massage with Acupressure Protocol	Protocol manual, DVD
30 mins	Practice on partner	
10 mins	Management of complicated situations	Safe practice checklist
15 mins	Briefing on homework assignment	Homework assignment

Other materials: Alcohol pad, tissue paper, massage oil, paper towel, tables and chairs, bed/ stool or leg stand, BP monitor, stop watch, oximeter.

Session 1 Part II: Exercise program and cognitive intervention

Duration: 60 mins

Duration	Details	Materials
15 mins	Introduction to exercise program	Exercise program sheet
10 mins	Practice with partners	
15 mins	Introduction to cognitive intervention	Cognitive training games (puzzles or table tasks)
10 mins	Practice with partners	
10 mins	Discussion on common mistakes and solution for adverse events	

Other materials: tables and chairs, bed/ stool or leg stand, BP monitor, stop watch, oximeter.

Session 2 Part I: Aroma-massage with Acupressure Protocol

Duration: 90 mins

Duration	Details	Materials
15 mins	Discussion on homework assignment and questions from the floor	Protocol manual
	Revision of the Aroma-massage with Acupressure Protocol	
60 mins	Practice on older adults (3 groups of 2, no longer than 20 minutes on each elderly person) with coaching.	2 subjects
	Practice on partners when subjects occupied	
15 mins	Discussion on common mistakes and solution for adverse events	

Other materials: Alcohol pad, tissue paper, massage oil, paper towel, tables and chairs, bed/ stool or leg stand, BP monitor, stop watch, oximeter..

Session 2 Part II: Practical test for Aroma-massage with Acupressure Protocol

Duration: 60 mins

Duration	Details	Materials
60 mins	20 mins for each staff	Practical test form
	Arrange for re-test if needed	

Other materials: Alcohol pad, tissue paper, massage oil, paper towel, tables and chairs, bed/ stool or leg stand, BP monitor, stop watch, oximeter.

APPENDIX VIII

Consent Form

香港理工大學康復治療科學系科研同意書

科研題目：以輔助醫療草案處理老年癡呆症患者的行為問題

科研負責人：

香港理工大學康復治療科學系曾永康教授

科研內容：

是項研究是為了發展一種以香薰治療、穴位按摩及治療性按摩結合而成的輔助醫療草案，用以幫助處理患有老年癡呆症患者的行為問題。閣下的參與包括於訪問中提供個人資料，及准許研究員從閣下的檔案中得到有關資料。閣下將會參與一個為期三個月的治療草案及十二個月的跟進服務。由開始參與治療至完成草案後的十二個月期間，閣下需要定期接受已安排的自理能力、認知及行為問題評估。如閣下對計劃有任何查詢，可聯絡研究員馮嘉雯女士（電話：2398 ）。有關的評估及治療應不會引起任何不適的感覺。凡有關閣下的資料均會保密，而編碼亦只有研究人員知道。

謝謝閣下有興趣參與是項研究。

同意書：

本人_____已瞭解此次研究的具體情況。本人願意參加此次研究，本人有權在任何時候，無任何原因放棄參與此次研究，而此舉不會導致我受到任何懲罰或不公平對待，亦不會對本人在中心／院舍接受的治療有任何影響。本人明白參加此研究課題的潛在危險性及本人的資料將不會洩露給與此研究無關的人員，我的名字或相片亦不會出現在任何出版物上。

本人可以致電 2766 6750 聯絡是次研究課題負責人曾永康教授。若本人對此研究人員有任何投訴，可以聯絡梁女士（部門科研委員會秘書），電話：2766 5398。本人亦會得到一份已簽署的同意書副本。

簽名（參與者）：_____ 日期：_____

簽名（保證人）：_____ 日期：_____

簽名（證人）：_____ 日期：_____

APPENDIX IX

Data Book

Management of Behavioral and
Psychological Symptoms of Dementia
(BPSD) by Complementary and Alternative
Medicine (CAM) Approaches

Data Book

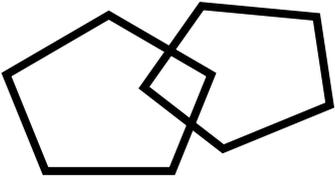
Case No: _____

Confidential

評估及治療記錄表				
項目	日期	特別事項	負責員工姓名 及簽署	治療師姓名 及簽署
治療前評估				
治療 ¹	1.			
	2.			
	3.			
	4.			
	5.			
	6.			
	7.			
	8.			
	9.			
	10.			
	11.			
	12.			
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	20.			
	21.			
	22.			
	23.			
	24.			
治療後評估 ²				
治療後 3 個月評估				
治療後 6 個月評估				
治療後 12 個月評估				

¹治療需每星期兩次

²治療後評估請於完成最後一次治療後兩星期內完成

Cantonese Version of Mini-mental State Examination (CMMSE)				
	Pre-	Post-	3M	6M
<i>Date:</i>				
ORIENTATION				
依家係咩日子〔年份〕〔季節〕〔月份〕〔日期〕〔星期幾〕？ (5)				
我地依家係邊度？〔九龍／新界／香港〕〔九龍／新界／香港既邊度〔醫院／老人院／老人中心／街道〕〔院舍／大廈名稱〕〔樓層〕 (5)				
REGISTRATION				
依家我會講三樣野既名，講完之後，請你重覆講一次。請記住呢幾個名，因為幾分鐘後，我會叫你再講番俾我聽，【蘋果】、【報紙】、【火車】，依家請你講番呢三樣野俾我聽。〔以第一次講既計分，一個一分〕 (3)				
ATTENTION & CALCULATION				
請你用一百減七，然後再減七，一路減落去，直至我叫你停為止。〔減五次便停〕或依家我讀幾個數目俾你聽，請你倒轉頭講番出來。 4 2 7 3 1 (5)				
RECALL				
我頭先叫你記住既三樣野係咩呀？ (3)				
呢樣係咩？〔伸出【鉛筆】、【手錶】〕 (2)				
請你跟我講句說話【姨丈買魚腸】 (1)				
依家檯上面有一張紙。用你既右手拎起張紙，用雙手一齊將張紙摺成一半，然後放番張紙係檯上面。 (3)				
請你讀出呢張紙上面既字，然後跟住去做。 (1) 〔拍手〕				
請你講任何一句完整既句子俾我聽。〔例如：今日天氣好好〕 (1)				
PRAXIA				
呢度有幅圖，請你照住來畫啦。 (1)				
				
Total:				
Signature:				

Barthel Index-20 (BI-20)					
		Pre-	Post-	3M	6M
		<i>Date:</i>			
Bowel	0 Incontinent or need to be given enema 1 Occasional accident (once per week) 2 Continent				
Bladder	0 Incontinent or catheterized and unable to manage 1 Occasional accident (max. once per 24 hr) 2 Continent				
Grooming	0 Needs help with personal care 1 Independent (implements provide)				
Toileting	0 Dependent 1 Needs some help but can do something alone 2 Independent (on and off, wiping, dressing)				
Feeding	0 Unable 1 Self feed but messy 2 Independent (food provided)				
Dressing	0 Dependent 1 Needs help but can do about half unaided 2 Independent (including buttons, zips, laces)				
Bathing	0 Dependent 1 Independent				
Transfer	0 Unable –no sitting balance 1 Major help (physical, one or two people), can sit 2 Minor help (verbal or physical) 3 Independent				
Mobility	0 Immobile 1 Wheelchair independent or walk with 2 assistants 2 Walk with help of 1 person (verbal or physical) 3 Independent				
<i>Wheelchair*</i>	0 <i>Dependent</i> 1 <i>Wheelchair independent</i>				
Stairs	0 Unable 1 Need help (verbal or physical, carrying aid) 2 Independent up and down				
Total:					
Signature:					

** This item is used if the patient is rated “0” for ambulation & if he has been trained in w/c management*

Chinese Version of Cohen-Mansfield Agitation Inventory – 29 items (CCMAI-29)

在以下每個所列的行為當中，請選出在過去兩星期，該行為在長者身上平均出現的次數。並填上以下代號。

沒有	每週少於一次	每週一至兩次	每週幾次	每天一至兩次	每天幾次	每小時幾次
1	2	3	4	5	6	7

		Pre-	Post-	3M	6M
<i>Date:</i>					
1	打人(包括自己)/ 東西				
2	踢人/東西				
3	緊捉他人				
4	推人/東西				
5	拋物品				
6	咬人/東西				
7	抓人				
8	吐痰/唾沫				
9	傷害自己或他人				
10	撕破東西或毀壞物品				
11	作行動性騷擾				
12	漫無目的踱步/遊走				
13	不適當地穿/脫衣服				
14	嘗試到不同的地方				
15	故意跌倒				
16	吃喝不合適的物品				
17	不適當地處理物品				
18	收藏東西				
19	收集東西				
20	作重覆的動作				
21	煩躁不安				
22	尖叫				
23	作言語性騷擾				
24	咒罵或言語性騷擾				
25	重覆語句/問題				
26	發出奇怪聲音(怪誕的笑聲或哭聲)				
27	投訴				
28	唱反調				
29	經常無理要求關注或幫助				
Signature:					

參考資料：Choy N.P.; Lam C.W.; Chan W.C.; et al. (Sept. 2001)

Neuropsychiatric Inventory (NPI) Pre-test Date: _____

Informant: Spouse/ Child/ Other: _____

Please answer the following questions based on changes that have occurred since the patient began to experience memory problems. Circle “yes” only if the symptoms have been present in the past month, circle “no” otherwise.

For each item marked “yes”

Rate the severity of the symptom (how it affects the patient):

1 = Mild (noticeable, but not a significant change)

2 = Moderate (significant, but not a dramatic change)

3 = Severe (very marked or prominent, a dramatic change)

Rate the distress you experience because of the symptom (how it affects you):

0 = Not distressing at all

1 = Minimal (slightly distressing, not a problem to cope with)

2 = Mild (not very distressing, generally easy to cope with)

3 = Moderate (fairly distressing, not always easy to cope with)

4 = Severe (very distressing, difficult to cope with)

5 = Extreme or very severe (extremely distressing, unable to cope with)

Please answer each question honestly and carefully. Ask for assistant if you are not sure how to answer any question.

Delusion	Does the patient believe that others are stealing from him or her, or planning to harm him or her in some way?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Hallucinations	Does the patient act as if he or she hears voices? Does he or she talk to people who are not there?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Agitation or aggression	Is the patient stubborn and resistive to help from others?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Depression or dysphoria	Does the patient act as if he or she is sad or in low spirits? Does he or she cry?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Anxiety	Does the patient become upset when separated from you? Does he or she have any other signs of nervousness, such as shortness of breath, sighing, being unable to relax, or feeling excessively tense?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Elation or euphoria	Does the patient appear to feel too good or act excessively happy?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Apathy or indifference	Does the patient seem less interested in his or her usual activities and in the activities and plans of others?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Disinhibition	Does the patient seem to act impulsively? For example, does the patient talk to strangers as if he or she knows them, or does the patient say things that may hurt people’s feelings?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Irritability or lability	Is the patient impatient and cranky? Does he or she have difficulty coping with delays or waiting for planned activities?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Motor disturbance	Does the patient engage in repetitive activities, such as pacing around the house, handling buttons, wrapping string, or doing other things repeatedly?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Nightmare behaviours	Does the patient awaken you during the night, rise too early in the morning, or take excessive naps during the day?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Appetite and eating	Has the patient lost or gained weight, or had a change in the food he or she likes?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5

Adopted from: <http://www.aafp.org/afp/2002/0601/p2263.html>

Neuropsychiatric Inventory (NPI) Post-test Date: _____

Informant: Spouse/ Child/ Other: _____

Please answer the following questions based on changes that have occurred since the patient began to experience memory problems. Circle “yes” only if the symptoms have been present in the past month, circle “no” otherwise.

For each item marked “yes”

Rate the severity of the symptom (how it affects the patient):

1 = Mild (noticeable, but not a significant change)

2 = Moderate (significant, but not a dramatic change)

3 = Severe (very marked or prominent, a dramatic change)

Rate the distress you experience because of the symptom (how it affects you):

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4 = Severe (very distressing, difficult to cope with)

5 = Extreme or very severe (extremely distressing, unable to cope with)

Please answer each question honestly and carefully. Ask for assistance if you are not sure how to answer any question.

Delusion	Does the patient believe that others are stealing from him or her, or planning to harm him or her in some way?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Hallucinations	Does the patient act as if he or she hears voices? Does he or she talk to people who are not there?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Agitation or aggression	Is the patient stubborn and resistive to help from others?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Depression or dysphoria	Does the patient act as if he or she is sad or in low spirits? Does he or she cry?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Anxiety	Does the patient become upset when separated from you? Does he or she have any other signs of nervousness, such as shortness of breath, sighing, being unable to relax, or feeling excessively tense?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
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Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Apathy or indifference	Does the patient seem less interested in his or her usual activities and in the activities and plans of others?	
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Disinhibition	Does the patient seem to act impulsively? For example, does the patient talk to strangers as if he or she knows them, or does the patient say things that may hurt people’s feelings?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Irritability or lability	Is the patient impatient and cranky? Does he or she have difficulty coping with delays or waiting for planned activities?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Motor disturbance	Does the patient engage in repetitive activities, such as pacing around the house, handling buttons, wrapping string, or doing other things repeatedly?	
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Nightmare behaviours	Does the patient awaken you during the night, rise too early in the morning, or take excessive naps during the day?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5
Appetite and eating	Has the patient lost or gained weight, or had a change in the food he or she likes?	
Yes No	Severity: 1 2 3	Distress: 0 1 2 3 4 5

Adopted from: <http://www.aafp.org/afp/2002/0601/p2263.html>

Neuropsychiatric Inventory (NPI) 3M Post-test Date: _____

Informant: Spouse/ Child/ Other: _____

Please answer the following questions based on changes that have occurred since the patient began to experience memory problems. Circle “yes” only if the symptoms have been present in the past month, circle “no” otherwise.

For each item marked “yes”

Rate the severity of the symptom (how it affects the patient):

1 = Mild (noticeable, but not a significant change)

2 = Moderate (significant, but not a dramatic change)

3 = Severe (very marked or prominent, a dramatic change)

Rate the distress you experience because of the symptom (how it affects you):

0 = Not distressing at all

1 = Minimal (slightly distressing, not a problem to cope with)

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3 = Moderate (fairly distressing, not always easy to cope with)

4 = Severe (very distressing, difficult to cope with)

5 = Extreme or very severe (extremely distressing, unable to cope with)

Please answer each question honestly and carefully. Ask for assistant if you are not sure how to answer any question.

Delusion	Does the patient believe that others are stealing from him or her, or planning to harm him or her in some way?
Yes No	Severity: 1 2 3 Distress: 0 1 2 3 4 5
Hallucinations	Does the patient act as if he or she hears voices? Does he or she talk to people who are not there?
Yes No	Severity: 1 2 3 Distress: 0 1 2 3 4 5
Agitation or aggression	Is the patient stubborn and resistive to help from others?
Yes No	Severity: 1 2 3 Distress: 0 1 2 3 4 5
Depression or dysphoria	Does the patient act as if he or she is sad or in low spirits? Does he or she cry?
Yes No	Severity: 1 2 3 Distress: 0 1 2 3 4 5
Anxiety	Does the patient become upset when separated from you? Does he or she have any other signs of nervousness, such as shortness of breath, sighing, being unable to relax, or feeling excessively tense?
Yes No	Severity: 1 2 3 Distress: 0 1 2 3 4 5
Elation or euphoria	Does the patient appear to feel too good or act excessively happy?
Yes No	Severity: 1 2 3 Distress: 0 1 2 3 4 5
Apathy or indifference	Does the patient seem less interested in his or her usual activities and in the activities and plans of others?
Yes No	Severity: 1 2 3 Distress: 0 1 2 3 4 5
Disinhibition	Does the patient seem to act impulsively? For example, does the patient talk to strangers as if he or she knows them, or does the patient say things that may hurt people’s feelings?
Yes No	Severity: 1 2 3 Distress: 0 1 2 3 4 5
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Nightmare behaviours	Does the patient awaken you during the night, rise too early in the morning, or take excessive naps during the day?
Yes No	Severity: 1 2 3 Distress: 0 1 2 3 4 5
Appetite and eating	Has the patient lost or gained weight, or had a change in the food he or she likes?
Yes No	Severity: 1 2 3 Distress: 0 1 2 3 4 5

Adopted from: <http://www.aafp.org/afp/2002/0601/p2263.html>

Neuropsychiatric Inventory (NPI) 6M Post-test Date: _____

Informant: Spouse/ Child/ Other: _____

Please answer the following questions based on changes that have occurred since the patient began to experience memory problems. Circle “yes” only if the symptoms have been present in the past month, circle “no” otherwise.

For each item marked “yes”

Rate the severity of the symptom (how it affects the patient):

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5 = Extreme or very severe (extremely distressing, unable to cope with)

Please answer each question honestly and carefully. Ask for assistance if you are not sure how to answer any question.

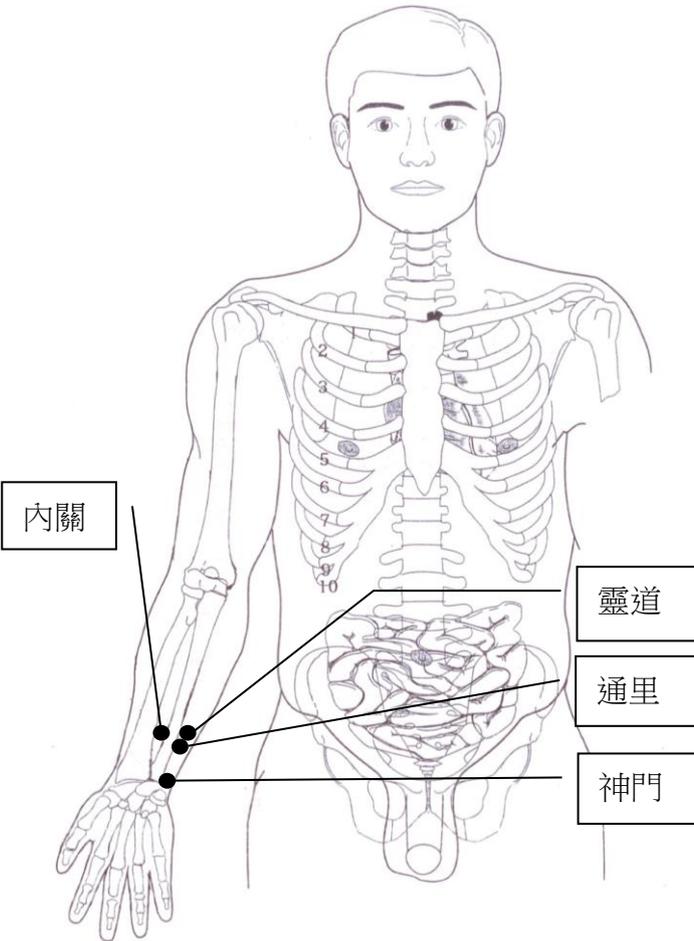
Delusion	Does the patient believe that others are stealing from him or her, or planning to harm him or her in some way?
Yes No	Severity: 1 2 3 Distress: 0 1 2 3 4 5
Hallucinations	Does the patient act as if he or she hears voices? Does he or she talk to people who are not there?
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Yes No	Severity: 1 2 3 Distress: 0 1 2 3 4 5

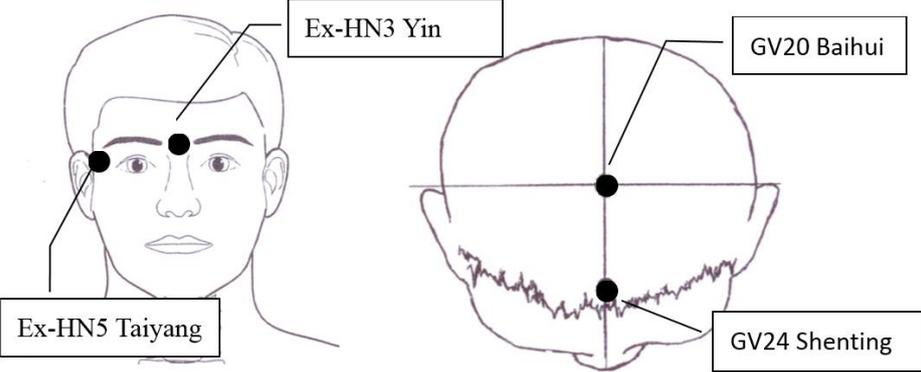
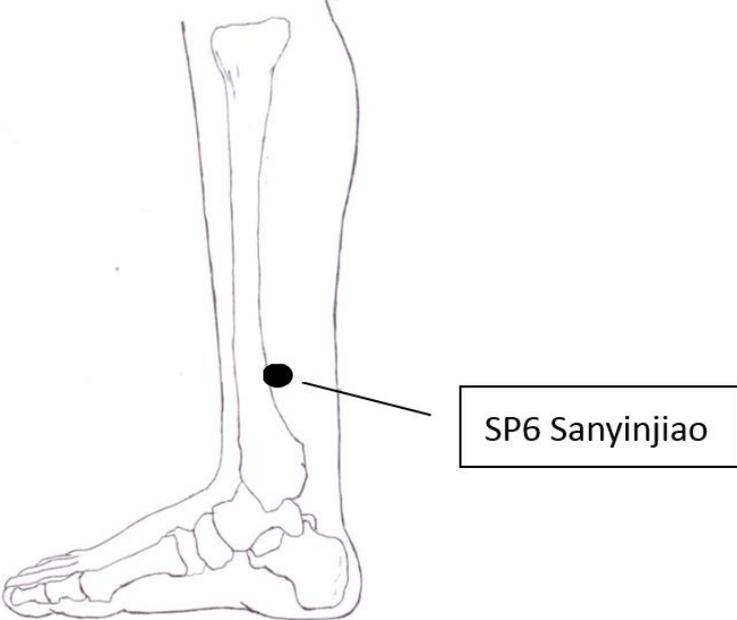
Adopted from: <http://www.aafp.org/afp/2002/0601/p2263.html>

APPENDIX X

The Aroma-massage with Acupressure Protocol Manual (in Chinese)

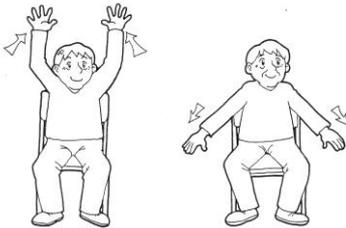
按摩須知	
時間	二十分鐘
位置及環境	請長者安坐於舒適的坐椅／輪椅上，和職員面對面坐。 室內溫度需要適中，並且減少其他滋擾（如收音機聲音）。
內容及次序	分成三部份前臂、頭、小腿。可由前臂→頭→小腿，亦可因應長者當時情況決定。 每部份完成左邊後亦需按摩右邊。 事前應了解不能按摩的部份及原因並紀錄，例如長者左邊身中風並有觸感過敏，便不應按摩該處。
按壓手法	「揉」—屈曲拇指第一節，垂直向下按壓穴位，同時以順時鐘方向微微揉動 20 下，再逆時針方向微微揉動 20 下。（請剪短指甲）
距離度法： 同身寸	<p>The diagrams show four methods for measuring body parts using the hand as a ruler:</p> <ul style="list-style-type: none"> 一夫法: A horizontal line across the four fingers (index, middle, ring, little) is labeled as 3 cun. 3指同身寸: A horizontal line across the three middle fingers (middle, ring, little) is labeled as 2 cun. 中指同身寸: A horizontal line across the middle finger and thumb is labeled as 1 cun. 拇指同身寸: A horizontal line across the thumb is labeled as 1 cun.
準備開始按摩	
準備用具	以玻璃容器盛放的按摩油（已混合底油及薰衣草精華油） 消毒濕紙巾 5 包 紙巾一盒
向長者講解是次治療的過程及原因	「今日同你以香薰油按摩穴位，大約 20 分鐘，會按手臂、頭同埋腳，幫助你舒緩同放鬆。按穴位可能會有脹痛或麻痺既感覺，如果按既途中有咩唔舒服可以同姑娘講，如果想大力或輕力都可以同我講。我地而家開始啦。」即使長者或未能理解或沒有反應，我方仍有責任解釋清楚。
進行消毒	以消毒濕紙巾消毒自己雙手，並另開一張為長者消毒雙手前臂，再用另一張清潔雙腳。

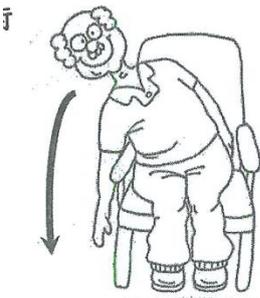
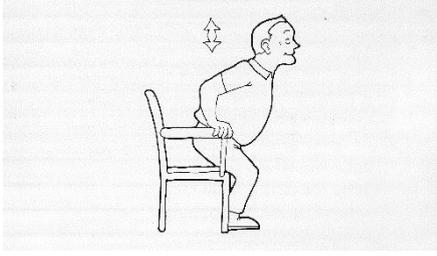
雙手準備	為長者進行按摩前，員工須以已混合好的按摩油磨暖雙手。
前臂	
熱身	<p>取少量按摩油，塗於長者前臂，掌心向上。雙手握長者掌心，由中心位開始，以拇指來回按壓 5 次，以同樣方式按摩前臂直至吸收足夠按摩油。期間留意長者面部表情及反應，如長者仍未能適應，則延長熱身時間不多於 2 分鐘。</p>
	<p>以「非重心手」從下托住長者手前臂，以「重心手」進行揉穴。最初按時可由輕力開始，嘗試長者可接受的力度，每按壓一個穴位亦應問長者有沒有感覺。如長者不能說話，按穴時便需要留意長者的面部表情是否有異，或有其他反應。</p>
神門	<p>掌心方向手腕上有一關節紋，波子骨上緣，尺骨肌腱側（靠近外側）</p>
通里	<p>神門以上一寸</p>
靈道	<p>通里以上半寸</p>
手少陰心經	<p>伸直拇指，以關指位置直線由下向上重覆推此經脈 10 下完成長者左手之按摩後便進行右手，重覆以上步驟。</p>
內關	<p>手握拳頭，關節紋向上方二寸，前臂正中出現兩筋之凹陷位置。</p>

<p>頭部</p>	
<p>太陽</p>	<p>眉毛外端與外眼角中央後一寸交界凹陷處，按此穴時需用扶著另一側頭部。按完左邊按右邊。</p>
<p>印堂</p>	<p>站於長者後面，請長者抬頭約 40 度，按壓眉心與鼻交界隆起位置。揉完此穴後沿直線向後推至神庭，全時間需托著後腦位置。</p>
<p>神庭</p>	<p>印堂直線向後至髮線後半寸，全時間需托著後腦位置。</p>
<p>百會</p>	<p>長者前望，兩耳尖向上與頭顱中線交界處。揉時需托著下巴。</p>
<p>風池</p>	<p>後腦弧型盡頭與後頸兩邊肌肉中間有一凹位，從該處向旁繞過肌肉凹陷位置。揉時需托著下巴，完成左邊後揉右邊。</p>
<p>小腿</p>	
<p>熱身</p>	<p>長者可仰臥或以椅托高小腿</p>
<p></p>	<p>可取少量按摩油為長者按摩小腿</p>
<p>三陰交</p>	<p>內踝上方三寸</p>
<p>足太陰脾經</p>	<p>伸直拇指，以關指位置直線由下向上重覆推此經脈 10 下完成長者左腳之按摩後便進行右腳，重覆以上步驟。</p>

APPENDIX XI

Exercise Program (in Chinese)

<p>頸部運動(1) 坐位 頭緩慢轉向左肩，維持 5 秒， 停一會，再向轉右肩，維持 5 秒 左右各 <u>5</u> 次</p>	
<p>頸部運動(2) 坐位 頭緩慢側向左肩，維持 5 秒， 停一會，再向側右肩，維持 5 秒 左右各 <u>5</u> 次</p>	
<p>肩部運動 坐位，如圖提起雙手，停 5 秒， 重覆 <u>10</u> 次</p>	
<p>腰部運動(1) 雙手環抱胸前，慢慢將身體向 右轉，停 5 秒，再向左轉，重 覆 <u>10</u> 次。</p>	
<p>坐位踢腿 伸直膝關節，停 5 秒，左右重 覆 <u>10</u> 次</p>	
<p>腳踝運動 坐位 把腳踝向上下擺動，左右重覆 <u>20</u> 次</p>	

<p>上肢運動 坐位 上肢向前後擺動，重覆 <u>20</u> 次</p>	
<p>腰部運動(2) 坐位 慢慢將身體側向一邊，停 5 秒， 左右重覆 <u>10</u> 次</p>	
<p>上肢運動 坐位 用手拍打對側膝部，重覆 <u>20</u> 次</p>	
<p>站立訓練 坐位 用手扶椅柄站立，停 5 秒，重 覆 <u>10</u> 次</p>	

APPENDIX XII

Homework Assignment for Practicing the Aroma-massage with Acupressure Protocol
(in Chinese)

香薰穴位按摩 功課紀錄表

員工姓名: _____ 日期: _____

請為一位治療對象進行香薰穴位按摩及自我評估(每份紀錄表只紀錄一次治療):

項目	準則	容易	困難 (請記錄原因)
1.	準備環境：室內溫度需要適中，並且減少其他滋擾（如收音機聲音）。		
2.	請對象安坐於舒適的坐椅／輪椅上，和職員面對面坐。		
3.	事前應了解不能按摩的部份及原因並紀錄。		
4.	準備用具(紙巾、消毒液、按摩油)		
5.	向對象講解是次治療的過程及原因		
6.	需要時為長者量度血壓、血氧、心跳等。		
7.	以消毒濕紙巾消毒自己雙手，並另開一張為長者消毒雙手前臂，再用另一張清潔雙腳。		
8.	為對象進行按摩前，員工須以已混合好的按摩油磨暖雙手。		
9.	取少量按摩油，塗於長者前臂，掌心向上。雙手握長者掌心，由中心位開始，以拇指來回按壓 5 次，以同樣方式按摩前臂直至吸收足夠按摩油。期間留意長者面部表情及反應，如長者仍未能適應，則延長熱身時間不多於 2 分鐘。		
10.	找到第一個穴位「神門穴」		
11.	找到第二個穴位「通里穴」		
12.	找到第三個穴位「靈道穴」		
13.	找到「手少陰心經」，以關指位置直線由下向上重覆推此經脈 10 下		
14.	找到第四個穴位「內關穴」		
15.	於另一隻手完成穴位按摩		
16.	找到第五個穴位「太陽穴」		
17.	於頭另一邊完成按摩「太陽穴」		
18.	找到第六個穴位「印堂穴」		
19.	找到第七個穴位「神庭穴」		
20.	找到第八個穴位「百會穴」		
21.	找到第九個穴位「風池穴」		
22.	於頭另一邊完成按摩「風池穴」		
23.	為對象擺放好小腿		

24.	找到第十個穴位「三陰交穴」		
25.	找到「足太陰脾經」，以關指位置直線由下向上重覆推此經脈 10 下		
26.	以正確的方法進行按摩：「揉」— 屈曲拇指第一節，垂直向下按壓穴位，同時以順時鐘方向微微揉動 20 下，再逆時針方向微微揉動 20 下。		
27.	以足夠的指力進行按摩		
28.	進行治療時觀察對象的反應		
29.	能夠於二十分鐘內完成治療		
30.	觀察及需要時對不良反應作出行動		

不良反應 (如有，請註明):

APPENDIX XIII

Quality Control Checklist

Management of Behavioural and Psychological Symptoms of Dementia (BPSD) by
Complementary and Alternative Medicine (CAM) Approaches
Quality Control Checklist

Staff name: _____ Assessment Date: _____

Assessor Name: _____

Please rate the staff on the following criteria:

Item	Criteria	1(Able)	0 (Unable)
1.	Prepare the environment properly		
2.	Position the subject properly		
3.	Know clearly the subject's characteristics (e.g. affected side of stroke,etc)		
4.	Prepare required materials (tissue, alcohol pad, massage oil, etc)		
5.	Clearly explain procedures to subject		
6.	Take correct measurements of BP, HR and SaO2		
7.	Properly sanitize own hands and forearms of the participant		
8.	Warm up own hands		
9.	Warm up subject's forearm (proper use of massage technique: effleurage)		
10.	Locate 1 st acu-point: Shenmen with explanation		
11.	Locate 2 nd acu-point: Tong Li with explanation		
12.	Locate 3 rd acu-point: Lingdao with explanation		
13.	Locate the heart meridian and friction correctly for 10 times		
14.	Locate 4 th acu-point: Neiguan with explanation		
15.	Perform acupressure on the other forearm		
16.	Locate 5 th acu-point: Taiyang with explanation		
17.	Perform acupressure on the other side of head		
18.	Locate 6 th acu-point: Yintang with explanation		
19.	Locate 7 th acu-point: Shenting with explanation		
20.	Locate 8 th acu-point: Baihui with explanation		
21.	Locate 9 th acu-point: Fengchi with explanation		
22.	Perform acupressure on the other side of head		
23.	Position the subject properly for lower leg session		
24.	Locate 10 th acu-point: Sanyinjiao with explanation		
25.	Locate the spleen meridian and friction correctly for 10 times		
26.	Measurements of BP, HR and SaO2		
27.	Fill in the safe practice checklist		
28.	Apply correct acupressure techniques: flex IPJ of thumb to 90°, press with tip of thumb, clockwise stroke x 20 followed by anti-clockwise stroke x 20 for all acu-points		
29.	Press with sufficient power on the acu-points		
30.	Observe the subject's response during the treatment		
31.	Manage to finish the treatment in no longer than 20 minutes		

32.	Notice and respond to any adverse events		
	Total score:		/32
	Percentage of correct procedures:		%

APPENDIX XIV

Randomization Table

Management of Behavioural and Psychological Symptoms of Dementia (BPSD) by
Complementary and Alternative Medicine (CAM) Approaches

Randomization Table

Group 1: aroma-massage with acupressure + exercise		Group 2: cognitive training + exercise		Group 3: cognitive training + aroma-massage with acupressure	
01		02		03	
04		05		06	
07		08		09	
10		11		12	
13		14		15	
16		17		18	
19		20		21	
22		23		24	
25		26		27	
28		29		30	
31		32		33	
34		35		36	
37		38		39	
40		41		42	
43		44		45	
46		47		48	
49		50		51	
52		51		54	
55		56		57	
58		59		60	

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