# An Investigation of Aromatherapy and Hand Massage on Disruptive Behaviour in People with Dementia

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Submitted in fulfilment of the requirements of the degree of

Doctor of Philosophy

**December 2009**

# Statement of originality

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

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# Abstract

Agitation and aggression are some of the most difficult behaviour symptoms to manage in older people living with dementia. These disruptive behaviours can lead to staff injury and burnout, decreased job satisfaction, as well as recruitment and retention challenges. Disruptive behaviours can also influence the quality of care received by residents. Therefore management of such behaviours is paramount to staff satisfaction and quality of care. Complementary and Alternative Medicine (CAM) therapies such as aromatherapy and massage have been applied to a range of health problems including dementia. Such therapies have become popular in residential care and in some cases additional cost for these therapies are invoiced to residents. While both aromatherapy and hand massage therapies have been reported to have some benefit in people with dementia, there are a number of limitations in the research design of reported studies.

This study aimed to overcome some of the design problems of previous studies to investigate the effect of Aromatherapy (3% lavender angustifolia mist) with or without hand massage (five minutes with aqua cream) on disruptive behaviour in people with dementia living in residential aged care facilities (RACF). Sixty-one residents with a diagnosis of dementia and a history of disruptive behaviour from three RACF were randomized into three groups: (1) Combination (aromatherapy and hand massage), (2) Aromatherapy, (3) Control (placebo). The intervention was given twice a day, at two time periods, 9am to 11am and 2pm to 4pm, seven days a week for six weeks. Data (resident behaviour and cognition) were collected using three instruments: MMSE (pre and post intervention), Cohen-Mansfield Agitation Inventory (CMAI) and Revised Memory and Behaviour Problems Checklist (RMBPC) at 5 time periods: pre-intervention, week 2 and week 4, at the end of the intervention period (week 6), and 6 weeks post-intervention.

The mean for verbal agitation 2.33 (SD = 1.09) and memory loss 2.31 (SD = 1.27) were the highest scores in CMAI and RMBPC measurements. However, none of the interventions significantly reduced disruptive behaviour and in fact in one control group (age group 60-84 years) there was a significant effect for the control intervention at four weeks ($p<.05$) and six weeks ($p<.02$). On the other hand,

aromatherapy combined with hand massage treatment seemed to increase disruptive behaviours in the 60-84 year old group. In participants older than 84 years, there were non-significant effects, which could be interpreted to mean that water is as effective as aromatherapy, or aromatherapy and massage (*p>.05*). Although the water mist used for the control group had a better effect in decreasing disruptive behaviours, two participant case studies demonstrate the positive effects of aromatherapy and hand massage treatments.

There were a number of challenges in undertaking this study that may have influenced the findings. The initial mean scores of the CMAI and RMBPC were low which may be related to several factors: the lack of a formal diagnosis, participants' level of cognitive impairment, limited level of mobility, organizational and environmental issues, nursing staff attitudes and knowledge, social desirability bias (SDB), and measurement challenges.

A number of conclusions can be drawn from this study with the main conclusion being the need for further research that takes into consideration formal dementia diagnosis, dementia subtypes, dementia educational programmes for nursing staff, pain and psychotropic medication use.

# Acknowledgements

By the end of my PhD, I have realised that I could not have succeeded without the support of other people, self-control and strong will. Therefore, there are many people who have given me a great support; it is my pleasure to thank those who made this thesis possible.

First, my thanks go to my principal supervisor, Professor Wendy Moyle, and associate supervisor, Professor Marie Cooke. You are the two people most responsible for successfully guiding me through the PhD journey. Thank you for always being available and helping to solve my ongoing questions and concerns. Without your extensive knowledge and encouragement, my goal would not be accomplished.

I am very pleased to give warm thanks to all participants, relatives, staff members and the aged care facility managers for their enormous contribution to this research; without their participation, I could not have started or finished this thesis.

I would also like to acknowledge and thank the Queensland Nursing Council for the research grant and financial support for this study. The funding enabled me to employ RAs to assist with data collection.

Special thanks go to Dr. Peter Grimbeek and Dr. Jesus Lopez who provided statistical expertise and advice to this study.

I would like to extend appreciation to my parents and Tim Huang, for inspiring me with nursing, for sending me to Australia, for unconditional support and encouragement to pursue my interests, and belief in me.

Last, but not least, a special thanks to all my PhD colleagues, Cathy Wu, Sarah Huang, Juli Yeh, Andy Chia, Susan Chang, Zoe Wei, Jane Yeh, Xiao-Feng Luo and Aggie Wu for valuable emotional support, for sharing their experiences of the dissertation writing endeavour with me, for listening to my complaints and frustrations, and for offering delicious meals when I had no time to cook, thank you.

# Dissemination of Study Results

**Conference Presentations**

Fu, C. Y., Moyle, W. & Cooke, M. (2007). "An Investigation of Complementary Therapy on Disruptive Behaviour in People with Dementia: An RCT", oral presentation at the 2007 Alzheimer's Australia Conference, Perth, WA., Australia, May 30th.

Fu, C. Y., Moyle, W. & Cooke, M. (2008). "An Investigation of Complementary Therapy on Disruptive Behaviour in People with Dementia: A Randomized Controlled Trial (RCT)" – "失智症破壞行為輔助療法之研究: 隨機受控制性實驗", oral presentation at the 11th Asia-Pacific Regional Conference of Alzheimer's Disease International, Taipei, Taiwan, June, 15th.

**Poster Presentations**

Fu, C. Y., Moyle, W. & Cooke, M. (2008). "An Investigation of Complementary Therapy on Disruptive Behaviour in People with Dementia: A Randomized Controlled Trial (RCT)" poster presented at the Asia Pacific Research Symposium, Gold Coast, QLD, Australia, July, 1st-2nd.

Fu, C. Y., Moyle, W. & Cooke, M. (2009). "An Investigation of Aromatherapy and Hand Massage on Disruptive Behaviour in People with Dementia" poster presented at the Quality of Care and Quality of Life: An Ageing Research Symposium, Brisbane, QLD, Australia, November, 19th.

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# Glossary of Abbreviations

| | |
|---|---|
| AAMA | Australian Aromatic Medicine Association |
| AAMT | Australian Association of Massage Therapists |
| ABC | A- Antecedent and activating event |
| | B- Behaviour |
| | C- Consequence |
| ABRS | A Modified Agitated Behaviour Rating Scale |
| ACE | Angiotensin converting enzyme |
| ACFI | Aged Care Funding Instrument |
| AChE | Acetylcholinesterase |
| ACTH | Adrenocorticotrophic hormone |
| AD | Alzheimer's disease |
| ADAS-Cog | Alzheimer's Disease Assessment Scale-Cognition |
| A.D. | Anno Domini |
| ADD | Assessment of Discomfort in Dementia |
| ADL | Activities of Daily Living |
| AIDS | Acquired Immunodeficiency Syndrome |
| AMA | Australiasian Massage Association |
| AMRF | Australian Massage Research Foundation |
| AN(s) | Assistant Nurse(s) |
| ANS | Autonomic Nervous System |
| AIN(s) | Assistant(s) in Nursing |
| APA | Australian Physiotherapy Association |
| ATAS | Attitude Towards Aggression Scale |
| ARTG | Australian Register of Therapeutic Goods |
| B.C. | Before Christ |
| BEAM-D | Behavioural and Emotional Activities Manifested in Dementia |
| BEHAVE-AD | Behavioral Pathology in Alzheimer's Disease Rating Scale |
| BP | British Pharmacopoeia |
| BPSD | Behavioural and Psychological Symptoms of Dementia |
| CADE | Confused and Disturbed Elderly |
| CAM | Complementary and Alternative Medicine |
| CCMAI | Chinese version of Cohen-Mansfield Agitation Inventory |
| CDR | Clinical Dementia Rating Scale |
| CDR-SB | Clinical Dementia Rating-Sum of the Boxes Scale |
| CI | Cholinesterase inhibitor |
| CM | Calming Music |
| CMAI | Cohen-Mansfield Agitation Inventory |
| CNS | Certified Nursing Assistant |
| CNPI | Chinese version of  Neuropsychiatric Inventory |
| CN(s) | Clinical Nurse(s) |
| CNPI | Checklist of Nonverbal Pain Indicators |
| Combination group | Aromatherapy and hand massage group |
| CONSORT | Consolidated Standards of Reporting Trials |
| COX-2 | Cyclooxygenase-2 |
| DBDS | Dementia Behaviour Disturbance Scale |
| DCM | Dementia Care Mapping |
| DLB | Dementia with Lewy Bodies |

| | |
|---|---|
| DP | Decline Perspective |
| DSM-IV-TR | Diagnostic and Statistical Manual of Mental Disorders 4th Edition (Text Revision) |
| DS-DAT | Discomfort Scale in Dementia of the Alzheimer's Type |
| DTSC | Dementia Training and Study Centres |
| E-BEHAVE-AD | Empirical Behavioural Pathology in Alzheimer's Disease Rating Scale |
| EN(s) | Enrolled Nurse(s) |
| EM | Expectation Maximization |
| FTD | Frontotemporal Dementia |
| GP(s) | General Practitioner(s) |
| HM | Hand Massage |
| HP | Healthful Perspective |
| IFA | The international Federation of Aromatherapists |
| ITT | Intention-to-treat |
| $LD_{50}$ | Lethal dose 50% |
| LOCF | Last Observation Carried Forward |
| LTCF | Long Term Care Facility |
| MCI | Mild Cognitive Impairment |
| MCAR | Missing Completely at Random |
| MDS | Minimum Data Set |
| MMSE | Mini Mental Status Examination |
| NHBPS | Nursing Home Behavior Problem Scale |
| NHMRC | Natinal Health and Medical Research Council |
| NOSGER | Nurses' Observation Scale for Geriatric Patients |
| NPI | Neuropsychiatric Inventory |
| NRS | Neurobehavioral Rating Scale |
| NSAIDs | Non-Steroid Anti-Inflammatory Drugs |
| PAINAD | Pain Assessment in Advaned Dementia |
| PADE | Pain Assessment for the Dementing Elderly |
| PAS | Pittsburgh Agitation Scale |
| PCC | Person-Centred Care |
| PEDro | Physiotherapy Evidence Database Scale |
| POAS | Perception of Aggression Scale |
| P.R.N. | As required |
| PQ | Proxy Pain Questionnaire |
| PSA | Pittsburgh Agitation Scale |
| RACF | Residential Aged Care Facilities |
| RAGE | Rating Scale for Aggressive Behavior in the Elderly |
| RCS | Resident Classification Scale |
| RCT(s) | Randomized Controlled Trial(s) |
| RMBPC | Revised Memory and Behaviour Problem Checklist |
| REPDS | Revised Elderly Persons' Disability |
| RN(s) | Registered Nurse(s) |
| SCU | Special Care Unit |
| SDB | Social Desirability Bias |
| SDS | Sundown Syndrome |
| SIRS | Severe Impairment rating Scale |
| SPSS | Statistical Package for Social Sciences |
| SRI | Stochastic Regression Imputation |

| | |
|---|---|
| SUSDP | Standard for the Uniform Scheduling of Drugs and Poisons |
| TSI | Test for Severe Impairment |
| TGA | Therapeutic Goods Administration |
| VaD | Vascular Dementia |
| VP | Vulnerable Perspective |
| USA | United States of America |
| UK | United Kingdom |
| WA | West Australia |
| WBFS | Wong-Baker Faces Rating Scale |
| WMA | World Medical Association |
| WWI (II) | World War I (II) |

# CHAPTER 1
# INTRODUCTION

## Chapter Overview

Dementia is a term used to describe a set of symptoms that is caused by many different diseases. Symptoms usually include some or all of the following: memory loss; language impairment; difficulties with orientation, comprehension, reasoning, planning and judgement, calculating ability and learning capacity; and changes in personality, emotions and behaviour (Alzheimer's Australia, 2005; American Psychiatric Association, 2000, p. 57). Dementia usually affects people over 65 years of age and increases rapidly in the over 85 year-old population. In Australia, there were 2.82 million people or 13.3% of the total population over the age of 65 years in the year 2008 (Australian Bureau of Statistics, 2008). Dementia affects approximately 6.5% of the population, those 65 years and older and between 25–30% of people aged over 80 years (Australian Institute of Health and Welfare, 2004). Dementia has been found to be the largest cause of disability burden, second only to depression (Access Economics, 2003; Alzheimer's Disease, 2008). Despite the best efforts by family caregivers, as a result of increasing frailty, most people with dementia will be placed into long-term care in the mid to late stages of dementia.

Alzheimer's disease is the most common form of dementia in most countries throughout the world, followed by vascular dementia (Australian Institute of Health and Welfare, 2007). Dementia brings with it a number of behavioural challenges. Over 50% of people who suffer from dementia often experience psychiatric symptoms and behavioural disturbances, such as agitation and aggression, which are difficult for nurses to manage (Griffiths, 2002; Hay, Klein, Hay, Grossberg, & Kennedy, 2003). Physical and chemical restraints are frequently used to manage disruptive behaviours displayed by people living with dementia in a nursing home (Hamers, Gulpers, & Strik, 2004; Moore & Haralambous, 2007; Nakahira, Moyle, Creedy, & Hitomi, 2009).

Furthermore, disruptive behaviours have the potential to create staff recruitment and retention problems as caring for people who are agitated and/or aggressive is

demanding and constant threats of violence are recognised as one of the causes of staff resignation (Jackson, Mannix, & Daly, 2003). Behaviour problems may lead to a number of physical, psychological and behavioural consequences that impact on nursing staff, such as staff injury, frustration, burnout, decreased job satisfaction and high staff turnover (Ito, Eisen, Sederer, Yamada, & Tachimori, 2001; Mayhew & Chappell, 2003; McMinn & Hinton, 2000). Therefore, it is important that nursing staff who work in units which provide care for people with dementia have the appropriate knowledge and skills to care for this population.

Complementary and Alternative Medicine (CAM) therapies, such as aromatherapy and massage treatments, have been applied to a range of health problems including dementia. These therapies are used in aged care settings as a means to reduce the use of restraints and disruptive behaviours. While both of these therapies have been reported in a number of papers to have some benefits in reducing disruptive behaviours in people with dementia, there are a number of limitations in the research designs of these studies. The purpose of this research is to investigate the effects of aromatherapy (Lavender Oil Spray) treatment with or without hand massage treatment on disruptive behaviour in people with dementia. In this research, disruptive behaviour is defined as agitation and aggression. These terms are defined in the next chapter. The findings of the current study have potential for reducing the use of chemical and physical restraint, and to provide evidence for better behaviour management and improved quality of care. Such changes may reduce the impact of behaviourial challenges for staff, increase job satisfaction as well as improve recruitment and retention of aged care nurses.

## 1.1    The Economic Impact of Dementia on Health Care Systems in Australia

Dementia has been a major public health problem in many countries for several decades. In 2008, there were approximately 29.8 million people with dementia in the world and this is expected to rise to 81.1 million by 2050 (Alzheimer's Disease, 2008). A Delphi consensus study by Ferri et al. (2005), estimated that a new case of dementia is diagnosed every seven seconds and that there will be 4.6 million new cases of dementia every year. In Australia, almost 190,000 people or 1% of the

population had dementia during 2006, and this number is predicted to increase to 465,000 people by 2030 (Access Economics, 2009; Australian Institute of Health and Welfare, 2007). Moreover, Queensland is one of the fastest growth regions for dementia prevalence (Access Economics, 2007). In Queensland, there were approximately 30,000 people with dementia in 2000 and approaching to 40,000 by 2007, about one in six people with dementia (Access Economics, 2007). By 2050, there are projected to be more than 41,000 new cases of dementia diagnosed every year in Australia (Access Economics, 2007).

The prevalence rate for dementia nearly doubles with every five year age increase. Longer life expectancy for women means that women suffer from dementia at greater rates than men (Australian Institute of Health and Welfare, 2004, 2007). Dementia is also the fourth largest cause of death for those over 65 years of age (Alzheimer's Disease, 2008). Approximately twice as many women as men die with an underlying diagnosis of dementia each year; about 2500 females died from dementia-related complications compared with 1100 males in Australia during 2001 (Australian Institute of Health and Welfare, 2004).

Dementia is the most costly disease burden upon the Australian health system (Access Economics, 2003; Australian Institute of Health and Welfare, 2004, 2007). The total health and welfare system expenditure for dementia was estimated at $1.4 billion in 2003, including hospitalised patient expenditure of $149.3 million, pharmaceutical expenditure of $72.8 million, and out-of-hospital service expenditure of $20 million (Australian Institute of Health and Welfare, 2007). In terms of hospital services, the average length of stay with a principal diagnosis of dementia or Alzheimer's disease, was 26 days where the average cost per bed day was $282 (Australian Institute of Health and Welfare, 2007). Moreover, the $20 million for out-of-hospital services, includes $10 million for general practitioners (GPs) services, $5.4 million for specialist services and $2.7 million for pathology (Australian Institute of Health and Welfare, 2007). More than 66% of this expenditure was for females and more than three-quarters was allocated for people aged 75 or older (Australian Institute of Health and Welfare, 2007).

Dementia is generally a progressive cerebral failure which can be classified into three stages of mild, moderate and severe. In Australia during 2003, about 96,000 people (55%) were classified with mild, 52,000 people (30%) with moderate and 26,000 people (15%) with severe dementia (Australian Institute of Health and Welfare, 2007; Burns, O'Brien, & Ames, 2005). People with dementia experience a gradual deterioration that is usually not reversible, and in the later stages, they require on-going high levels of care (Agronin, 2004; Jacques & Jackson, 2000). Dementia is one of the reasons for people needing placement in residential aged care facilities (RACF). People in the mild stage of dementia usually live in a household as part of the community; however, those at moderate and severe stages normally require high levels of care and are therefore usually placed into RACF (Australian Institute of Health and Welfare, 2007). More than 204,000 aged care beds currently operate in Australia (Australian Government Department of Health and Ageing, 2006). Approximately 90,200 older people with dementia live in RACF and more than 52,000 live in the community (Access Economics, 2009). The majority of government funding of nearly $993 million is to care for people with dementia including Alzheimer's disease. In RACF, over 90% of the expenditure was dedicated to high level aged care (Access Economics, 2009; Australian Institute of Health and Welfare, 2007). In addition, the majority (78%) of the funding was used to care for females and 59% was for people aged 85 and over (Australian Institute of Health and Welfare, 2007).

Home and community care services estimated that in 2002 a total of $175 million was spent on care for people with dementia, which included 84,394 people with dementia receiving $2071 per person at home (Access Economics, 2003). The total expenditure for dementia is projected to increase by 225% by the year 2031 (Australian Institute of Health and Welfare, 2007). In addition, approximately $225 million was provided from 2006 to 2009 to create 2,000 new dementia-specific Extended Aged Care at Home (EACH) places, which allow people with dementia and complex care needs to stay at home in familiar surroundings rather than entering RACF (Australian Government Department of Health and Ageing, 2005). The dementia initiative, an Australian government initiative, also provides $25 million over four years for dementia training for up to 9,000 residential aged care employees and up to 7,000 people in the community, such as police, emergency services and transport staff

(Australian Government Department of Health and Ageing, 2005). Therefore, early prevention can reduce the high cost of dementia. It has been predicted that delaying the onset of dementia and reducing the age-specific population rates would lead to significant reductions in the number of people with dementia and associated health care costs (Access Economics, 2004; Jorm, Dear, & Burgess, 2005). In addition, delaying the progression of dementia would decrease late-stage prevalence but increase overall prevalence of the disease as victims would remain alive longer.

## 1.2    Management Strategies in Residental Care Facilities in Australia

Alongside the increase in people with dementia there has been an increase in people with behavioural and psychological symptoms of dementia (BPSD). As a result the management of people with dementia and other mental disorders have diversified in Australia. For example, psychogeriatric extended care units and nursing homes have been developed in Western Australia and Victoria to manage BPSD. Confused and Disturbed Elderly (CADE) units have been set up in New South Wales. These units have collaborated with Commonwealth funded RACF and restructured into short term transitional facilities for residents before placement into long-term care institutions (Department of Health and Ageing, 2008). However, Brodaty et al. (2003a) argued that these facilities did not have adequate resources to manage the different stages of dementia including complications of severe BPSD. In addition, behavioural advisory services are in place in each state as a result of the 2005 Australian government dementia initiative, *Helping Australians with Dementia, and their carers – Making dementia a National Health Priority*. Furthermore, RACF staff have been able to receive education and training on dementia care through the Dementia Training and Study Centres (DTSC), also as a result of the Australian government dementia initiative.

In early 2000, a seven-tiered model of service delivery was designed to outline management strategies for different levels of dementia care and other mental disorders (Brodaty, et al., 2003a; Department of Health and Ageing, 2008; Draper, Brodaty, & Low, 2006). Table 1.1 indicates the seven-tiered model of service delivery with a range from no dementia or mental disorder though to the top tier of severe

BPSD with dementia or mental disorder. This table assists in both understanding the

prevalence of BPSD and management.

**Table 1.1 Seven-tiered model of service delivery for older people with dementia and other mental disorders in Australia**
**(Brodaty, et al., 2003a; Department of Health and Ageing, 2008; Draper, et al., 2006)**

| The level of tiers | Management Strategies | Prevalence In ≥ 65 years |
|---|---|---|
| **Tier 7** Dementia with extreme BPSD (Physical violence) | • Require intensive specialist psychogeriatric care units | Rare, it happens in men with non-Alzheimer type dementia < 70 years old |
| **Tier 6** Dementia with very severe BPSD (Severe psychosis/depression with high suicide risk) | • Require treatment or care in institutions | < 1% |
| **Tier 5** Dementia with severe BPSD (Agitation or aggression with care stress, chronic depression/schizophrenia) | • A case management model<br>Provided individual care services from the multidisciplinary psychogeriatic team<br>• Care in institutions | 0.6% BPSD < 1% affective disorder in late life psychosis |
| **Tier 4** Dementia with moderate BPSD (Depression/schizophrenia/bipolar disorder, BPSD including verbal abuse, agitation and sexual disinhibition) | • Continue psychotherapy and pharmacotherapy<br>• Require a specialist consultation<br>• Behavioural programs<br>• Plan for psychiatric transfer if necessary | 1.2% BPSD, 0.4-4.6% major depression and 1.7% late life psychosis |
| **Tier 3** Dementia with mild BPSD (apathy, wandering, anxiety disorders and night time disturbance) | • Continue Tier 1 and Tier 2<br>• Psychogeriatric services involves training of GP, nursing staff and caregivers<br>• Environmental modification<br>• Psychotherapy and pharmacotherapy<br>• Psychoeducation and BPSD training programs in caregivers | 1.8% mild BPSD, 10% depression and 5-10% anxiety |
| **Tier 2** Dementia with no BPSD (People live in RACF, have a risk of depression because of stroke and macular degeneration) | Selective prevention:<br>• Continue Tier 1<br>• Primary care involves primary care workers, non-mental health specialist, hospital services and carer/consumer organisations<br>• Caregivers training programs | 2% dementia no BPSD. |
| **Tier 1** No dementia | Universal prevention:<br>• Attend educational seminars<br>• Increase social, mental and physical activities<br>• Prophylactic therapies including low cholesterol, antioxidant, anti-inflammatories, hormone replacement therapy and anti-hypertensive. | Tier1+Tier 2: 73% low psychological distress, 92.8% no BPSD lasts up to 6 months |

Pharmacological and non-pharmacological management such as CAM are generally focused on Tier 1 to Tier 5 (Bowles, 2006). In this study, complementary therapies such as aromatherapy and hand massage target the populations in RACF between Tier 3 and Tier 5.

## 1.3    Issues in Care of People with Dementia

Caring for people with dementia and associated behavioural symptoms can be challenging for caregivers. Severe behavioural problems lead to an increase of burden and impact on the personal health of caregivers; it may be also associated with extra indirect costs (Evers & Brouwers, 2002). As dementia is a universal problem, there are seveal issues that need to be considered in long-term care settings. The following sections report on issues such as dementia diagnosis, restraint and falls, staff attitude and knowledge and pain. These sections demonstrate the challenge and complexity of care of people with dementia.

### 1.3.1    Diagnosis from General Practitioners

Dementia is a complex condition and it may take time to diagnose (Hansen, Hughes, Routley, & Robinson, 2008). An Australia single sub-study investigated the prevalence of Alzheimer's disease and other dementias in 2,194 adult general practice patients, aged 18 and over with data collected from 88 GPs during August 2001 (Australian Institute of Health and Welfare, 2002, 2004, 2007). This study found the prevalence of diagnosed Alzheimer's disease and other dementias 1.6% (95% CI: 0.0-4.4) and 2.4% (95% CI: 0.0-5.4) respectively. However, of the remaining adult patients not diagnosed with dementia, 4.2% of patients displayed cognitive impairment, 4.9% of patients had difficulties with daily living, and 5.6% of the patients experienced behavioural changes (Australian Institute of Health and Welfare, 2002, 2004, 2007). Furthermore, all three symptoms were displayed by 1.4% of the patients, 2.7% of the patients had two symptoms, and 5% had at least one symptom of early dementia. GPs indicated that 2.9% (n = 59) of patients might have an undiagnosed dementia and 3.1% (n = 63) were likely to have early Alzheimer's disease and other types of dementia not yet diagnosed (Australian Institute of Health and Welfare, 2002, 2004, 2007).

Also, it is reported that the GPs of more than 40% of patients with dementia were unaware of the potential for dementia in their patients (Chodosh, et al., 2004). This statistic is even worse in low-income older adults. An American study (Wilkins, et al., 2007) examined risk factors for poor recognition of cognitive impairment in poor urban older people, which revealed that 56% (n = 232) of low-income older people with dementia were not diagnosed by their GPs. These people with dementia were more likely to be older and live alone than people diagnosed by GPs. The failure of GPs to diagnose people with dementia may be related to an expected cognitive decline in older adults; therefore, GPs may not report cognitive changes amongst at risk older people with dementia (Wilkins, et al., 2007).

This trend is in spite of results from Wilkinson et al. (2004) that found the majority of people consult GPs after noticing early signs of cognitive decline. Even if the person was screened and diagnosed, Valcour et al. (2000) reported that up to 91% of patients do not have their level of dementia severity identified. Wilkins et al. (2007) suggested that there are a limited number of people diagnosed with dementia and this is related to GPs' limited knowledge and ability to recognise dementia.

Delays in the early diagnosis of dementia can also relate to GPs' attitudes. GPs may not have confidence or be limited by time to observe patients in making a formal diagnosis of dementia (IIiffe, Manthorpe, & Eden, 2003; Wood, et al., 2003). Moreover, GPs have been reported as feeling there are no effective options for the treatment of dementia, being skeptical about the usefulness of dementia medicine, and having limited awareness of the benefits of diagnosis for people with dementia and their respective families; therefore, an early diagnosis of dementia is not necessarily seen as important by GPs (Hansen, et al., 2008; Vernooij-Dassen, et al., 2005). In addition, GPs may feel uncomfortable to disclose a diagnosis of dementia to patients and decide instead to inform patients that they are having 'memory problems' or 'getting older' (Bamford, et al., 2004). In an Australian study, Hansen et al. (2008) found GPs seemed to view dementia as a disease which is a natural process of normal ageing in older people. Therefore, GPs may delay the diagnosis of dementia until they see benefits for their patients. It is important to enhance an early detection, diagnosis and care management for people newly diagnosed with cognitive impairment and dementia in order to reduce the high cost in health systems and slow the progress of

dementia in older people. The limited number of older people being diagnosed with dementia has the potential to influence care provision. For example, where undiagnosed people in RACF exhibit challenging behaviours, care staff may blame the person for their behaviour rather than accept the person is distressed as a result of an illness or the environment of care. Furthermore, in such situations staff may encourage the use of sedatives rather than to investigate the cause of the behaviour.

### 1.3.2 Restraints and Falls

Falls are prevalent occurring in older people in RACF, especially in people with dementia (Doorn, et al., 2003; Eccles, Clarke, Livingston, Freemantle, & Mason, 1998). People with dementia are more likely to repeat the incidents of falls due to behaviours such as wandering, confusion and medication (Eccles, et al., 1998). In aged care settings, physical and pharmacological restraints are commonly used for managing older people with disruptive behaviours (Poole & Moot, 2003). However, inappropriate use of restraint is considered to be aggravated negligence and therefore elder abuse (Kurrle, 2004).

In spite of the high use of bed rails, physical restraints have not been found to reduce residents' recurrent falls or serious injuries when controlling for cognition/functional and behavioural status in nursing homes (Capezuti, Maislin, Strumpf, & Evans, 2002). It has been argued that this method may increase disruptive behaviours and create a negative impact on older people with dementia (Evans, Wood, & Lambert, 2003).

Chemical restraints, such as antipsychotic drugs are frequently used to treat behavioural disturbances as first-line intervention (Boyle, 2008; Poole & Moot, 2003). An American study of national nursing homes found that nearly a quarter of nursing home residents received antipsychotics. In addition, these medications were targeted to 70% of older residents with dementia (Kamble, Chen, Sherer, & Aparasu, 2008). Chemical restraints can also increase the risk of falls and other side-effects in people with dementia. Medical literature suggests medical officers need to be aware of the adverse events in using neuroleptic medication in different types of dementia. For example, Haloperidol should be avoided in administration to people with Lewy body dementia, as this increases morbidity and mortality (Eccles, et al., 1998). Moreover, nursing staff should not administer pharmacological medication influenced by

patients' behaviours for their own convenience and as the favoured treatment (Banerjee, 2009; Poole & Moot, 2003). Poor mobility, high care categories and the risk of falling have been found to be highly correlated with the judgments made by nursing staff in restraint usage (Hamers, et al., 2004). However, non-pharmacological interventions should be considered for use before restraints. More details on non-pharmacological interventions are discussed in Chapter 2.

### 1.3.3   Nursing Staff Attitudes and Knowledge

Nursing literature demonstrates that teamwork, administrative support, and staff attitude and knowledge are three key factors in promoting quality dementia care (Kovach & Krejci, 1998). However, several studies have found that residential aged care staff tend to perceive older people in negative ways (Brodaty, Draper, & Low, 2003b; Hsu, Moyle, Creedy, & Venturato, 2005; Jones, Matias, et al., 2007; McCarthy, 2003a, 2003b; Nakahira, et al., 2009; Poole & Moot, 2003). Nursing staff with negative attitudes were more likely to supply chemical and apply physical restraints to older people with aggressive behaviours. Brodaty et al. (2003b) investigated 253 nursing home staff in Sydney regarding their attitudes and stress towards people with dementia, the results revealed that anxiety, difficulty in controlling their behaviour, unpredictability, loneliness and fear were the top five stereotyped perceptions. Furthermore, these negative perceptions are highly related to nurses' difficulty in caring for older people with BPSD (Brodaty, et al., 2003b). A relationship between staff attitudes towards older residents and job satisfaction has also been identified (Brodaty, et al., 2003b). Low work satisfaction, a deficiency in knowledge of residents' diseases and insufficient education and training created negative staff attitudes towards older people with mental illness (Brodaty, et al., 2003b; Hsu, et al., 2005; Jones, Matias, et al., 2007).

Kovach and Krejcl (1998) surveyed 181 long-term care employees, where they revealed staff attitude and knowledge was the third most important factor for adopting positive changes in dementia care. In a large study undertaken in Japan (n = 675), where nursing staff had more clinical experiences, a higher education and were in a higher clinical position, they were reported to have more positive attitudes towards aggression in older people (Nakahira, et al., 2009). Therefore, this study supports education as an important factor in improving nursing staff's negative perception.

### 1.3.4 Pain in Older Residents in the RACF

A number of studies have found that pain is also a major cause of disruptive behaviours in people with dementia (Allen, Burgio, Fisher, Hardin, & Shuster, 2005; Kunik, et al., 2003; Kyomen & Whitfield, 2008; Won, et al., 2004b). Pain is defined as an internal, complex, multidimensional, unpleasant, subjective and emotional experience that is influenced by social, cultural and individual differences (Mobily & Herr, 2001). It has been estimated that 45% to 80% of older people in nursing homes experience pain; however, 25% of older people with persistent pain do not receive analgesia (American Geriatrics Society Panel, 2002; Won, et al., 2004b). Persistent pain or chronic pain is pain lasting for a prolonged period of time and may be or may not be related with a disease process (American Geriatrics Society Panel, 2002, 2010). Poor pain management can result in sleep and appetite disturbance, depression, anxiety, agitation, falls and a decreased quality of life (Hutt, Pepper, Vojir, Fink, & Jones, 2006; Smalbrugge, Jongenelis, Pot, Beekman, & Eefsting, 2007). Therefore, it is important to assess pain as one of the primary vital signs and pain should have proper management and reporting (The American Pain Society, 2010).

### 1.3.4.1 Pain medication management

Musculoskeletal disorders including arthritis, osteoporosis and degenerative problems, and vascular disease can result in persistent pain in older people including those with dementia (Higgins, 2005; Tomas & Javier, 2010). Pharmacologic intervention is often used for pain management in older people; these include acetaminophen, non-steroid anti-inflammatory drugs (NSAIDs), opioid analgesics, corticosteroids and muscle relaxants (American Geriatrics Society Panel, 2002, 2010). Other adjuvant drugs include antidepressants, anticonvulsants that may also be co-administered with non-opiod or opioid analgesics in persistent pain, especially neuropathic pain. Although pharmacological treatment can decrease persistent pain, serious side effects from inappropriate taking of medication can also cause adverse reactions in older people such as drowsiness and visual, urinary and gastrointestinal problems.

Acetaminophen and NSAIDs usually treat musculoskeletal pain (American Geriatrics Society Panel, 2010). Acetaminophen, such as paracetamol, is generally the first choice in pain relief for osteoarthritis and low back pain in older people (American Geriatrics Society Panel, 2010; Wegman, van der Windt, van Tulder, Stalman, & de

Vries, 2004). NSAIDs are effective for chronic inflammatory pain such as rheumatoid arthritis; however, aspirin can create gastrointestinal and bleeding problems in older people (American Geriatrics Society Panel, 2010). Such problems may be difficult to monitor in people with dementia as they may lack the ability to communicate their discomfort. Opioid analgesics have a great effect in decreasing moderate to severe persistent pain; however, the serious side effect of respiratory depression is found to be associated with long term opioid therapy (American Geriatrics Society Panel, 2010; Tomas & Javier, 2010). Respiration depression can affect respiratory rate, volume and oxygen saturation; therefore, older people with opioid analgesics should be regularly assessed by clinicians for responsible opioid usage. Other anti-inflammatory drugs include corticosteroids, which have a strong effect on rheumatoid arthritis and asthma (American Geriatrics Society Panel, 2010; Joseph, 1994). Common side effects include nausea and headache and people that use corticosteroids long-term may develop osteoporosis (Joseph, 1994). Muscle relaxant and anticonvulsant drugs including baclofen and gabapentin are used to treat muscle spasm and trigeminal neuralgia; however, these drugs increase the risk of falls in older people (Tomas & Javier, 2010). Adjuvant drugs such as tricyclic antidepressants are found to have beneficial effects in neuropathic pain conditions; however, anticholinergic and cardiovascular effects can occur with an inadequate usage (American Geriatrics Society Panel, 2002, 2010). People with dementia may be admitted to a RACF on any number of the above pain medications. Where the resident is unable to communicate their pain such medication may be withdrawn by staff and as a consequence may lead to the resident displaying disruptive behaviour.

**1.3.4.2 Nurses' perception of pain in people with dementia**

People with dementia are less likely to receive analgesics; in addition, cognitive impairment can also be exacerbated by the presence of pain (Nygaard & Jarland, 2005; Parke, 1998). Discomfort is also a term used interchangeably with pain in nonverbal people with advanced dementia (Smith, 2005). The definition of discomfort is 'a negative emotional and/or physical state subject to variation in magnitude in response to internal or environmental conditions' (Hurley, Volicer, Hanrahan, Houde, & Volicer, 1992, p. 369).

Older people with dementia are often under-treated for pain for two main reasons.

First, people commonly have a misconception that pain is a natural part of ageing and cannot be avoided; in addition, older people may not always experience pain due to their decline in sensitivity (Delac, 2002; Ferrell, 1991; Smith, 2005). Secondly, staff may not be able to detect pain or discomfort in people with advanced dementia because of the loss of language ability (Delac, 2002; Jones, Vojir, Hutt, & Fink, 2007). Furthermore, it has been argued that nurses lack the ability to assess pain and this therefore may account for why nurses are not recognising pain in older people (Hughes, 2008). Nursing staff education may influence their beliefs and knowledge about pain in older people (Zwakhalen, Hamers, Peijnenburg, & Berger, 2007). In an Australian study, Neville et al. (2006) investigated 197 RACF staff in terms of their knowledge and educational needs in relation to pain management in older people with dementia in Queensland. Although the majority of nursing staff ranked 'average' in their current knowledge of pain management, more than 50% still believed that it was necessary for residents to experience high level of pain before they received the next dose of pain relief (Neville, et al., 2006). Furthermore, Buffum and Haberfelde (2007) conducted a pilot study survey with 34 family caregivers. They discovered 67% of family caregivers doubted nursing staff capability in detecting pain in their relatives with dementia. In addition, 50% of family caregivers complained that their relatives' pain was not discussed during administration of medication or upon admission to the RACF.

Although older people with advanced dementia may be unable to report pain to nursing staff, their pain can be detected through observation of their behaviours. There is a correlation between aggression and pain/discomfort (Kovach, Griffie, Matson, & Muchka, 1999). Tense body language, sad facial expression, fidgeting, perseverant verbalisations and verbal outburst were the most frequent behavioural symptoms associated with discomfort in people having advanced dementia (Kovach, et al., 1999; Kovach, Griffie, Mucbka, Noonan, & Weissman, 2000). Nonverbal behavioural pain includes facial expression such as grimacing, furrowing of brows, squinting and wrinkling (Kovach, et al., 1999; Kovach, et al., 2000). Other agitated physical behaviours associated with pain include restlessness, withdrawal, guarding, bracing, resistance to movement, rigidity and combative behaviours (Kovach, et al., 1999; Kovach, et al., 2000). Older people who suffer from pain daily were more likely to have severe ADL impairment, less frequently involved in activities and showed

more depressive signs and symptoms (Won, et al., 1999). Lack of knowledge in the assessment of pain in older people with dementia may lead to inadequate treatment. Furthermore, there is the potential for nursing staff to focus on treating disruptive behaviours rather than on pain relief.

## 1.4    Current Status of Complementary and Alternative Medicine Use

Complementary and Alternative Medicine (CAM) is used in conjunction with orthodox medical treatment or in place of standard medical care (National Centre for Complementary and Alternative Medicine, 2004). It is defined by the Therapeutic Goods Act 1989 as therapeutic goods which consist of one or more active ingredients, where each of them has a clearly established identity and either a traditional use or any other use prescribed in the regulations (Commonwealth of Australia, 1990). CAM comprises five areas: (1) Alternative medical system (e.g. traditional Chinese medicine); (2) Body-mind interventions (e.g. music and prayer); (3) Biologically based therapies (e.g. herbs, vitamins and foods); (4) Manipulative and body-based interventions (e.g. massage); and (5) Energy-based therapies (e.g. therapeutic touch and Reiki) (National Centre for Complementary and Alternative Medicine, 2004).

CAM can include all forms of health care and has been used by a number of researchers and in different clinical situations (Saks, 2003). CAM is popular in the community and approximately one-third of the population uses CAM in the United States of America (USA) and the United Kingdom (UK) (Andrews, Peters, & Hammond, 2003; Willison & Andrews, 2004). In the UK, one-third of the population has used CAM at some point in their life (Andrews, et al., 2003). There were approximately 12 million adult CAM consumers in the UK in 2009; in addition, the complementary medicines market has grown in value by 18% with a total of £213 million from 2007 to 2009 (Mintel, 2009). In Canada, 3.8 million people (about 12% of the total population) reported the use of an alternative practitioner during the previous 12 months for illnesses and certain conditions (Verhoef & Findlay, 2003). Many older people have reported an increased use of CAM (Andrews, 2002; Sleath, Rubin, Campbell, Gwyther, & Clark, 2001). The greatest users among the older population are the Japanese, with 74% of older users followed by 61% older North Americans (Flaherty, et al., 2001). The most commonly used CAM modalities in the

USA were herbal therapy (18.6%), relaxation techniques (14.2%) and chiropractic therapy (7.4%) (Tindle, Davis, Phillips, & Eisenberg, 2005). Similarly, Andrews (2002) found the most common modalities used in the UK were reflexology (43.7%), massage (35.4%), acupuncture (34.7%), chiropractic (21.5%) and aromatherapy (20.8%).

A national Australian study (Cohen, Penman, Pirotta, & da Costa, 2005) surveyed over six hundred GPs for their attitudes toward use of CAM. This research found that more than half of the GPs felt the demand for CAM was increasing. In addition, a majority of GPs believed CAM was effective and safe in CAM and they would like to refer their patients for CAM therapies (Cohen, et al., 2005). MacLennan et al. (2006) reported that the main purpose in using CAM was for general health. They estimated that over 50% of the South Australia population used CAM. In addition, more than one quarter of people surveyed had used at least one CAM therapist in the previous year. Women aged 25-34 years were the primary consumers and in fact, women tended to spend more money ($23.24) on CAM per month compared with men ($18.50). Also, another Australian national survey found that adults spent $1.73 billion to visit CAM practitioners each year and also estimated the total annual expenditure on CAM was $4.13 billion in 2005 (Xue, Zhang, Lin, Da Costa, & Story, 2007).

## 1.5 Aromatherapy and Massage in Australia

Aromatherapy and massage are an alternative means to promote optimum health and vitality. Both therapies are believed to be able to balance the body's equilibrium and improve mental and physical health (Battaglia, 2002; Worwood, 1991). The following section introduces the history of aromatherapy and hand massage, regulation and standards and clinical practice in older people.

### 1.5.1 Aromatherapy

The word "aromatherapy" was first introduced in the 1930s; however, aromatherapy was used in ancient times (Battaglia, 2002). Aromatherapy is defined as the use of natural aromatic substances from the extraction of certain plants, and has been classified for physical therapeutic modalities (Bell & Sikora, 1996; Brett, 2002;

Pietroni, 1992). Essential oils are the fundamental elements in performing aromatherapy. Essential oils are described as a concentrated, volatile material extracted from botanical and species (Weiss, 1997). The methods of extraction involve extraction with volatile solvents, expression and distillation processes (Battaglia, 2002). Essential oils were used for food, embalming, perfume and cosmetics in Egypt, Greece, Rome, China and India (Battaglia, 2002; Stevensen, 1998; Wheeler Robins, 1999).

In the 1980's, aromatherapy was introduced to Australia and was focused on both beauty and medical therapy (Pénoël & Pénoël, 1998; Sheen, 2006). Overtime aromatherapy became commercialised and "Perfect Potion" stores opened, promoting both pharmaceutical and cosmetic products (Sheen, 2006). With the increasing popularity of aromatherapy practice in the Australian market, the International Federation of Aromatherapists (IFA) and Australian Aromatic Medicine Association (AAMA) were also established to train professional aromatherapists (Sheen, 2006; The Australian Aromatic Medicine Association, 2005).

Shorofi and Arbon (2010) reported that most Australian nurses were positive about CAM; however, more than 60% of nurses have very little or no knowledge of CAM. Aromatherapy is considered to have a therapeutic effect and it has been widespread in its application in many areas including nurses using CAM in a variety of care settings (Maddocks-Jennings & Wilkinson, 2004). In a qualitative study, Sheen (2006) found nursing staff believed aromatherapy practice should not be undervalued as a professional component of the Australian health system. However, Sheen (2006) argued that it is difficult for nurses to maintain aromatherapy practice when there are no policies and protocols to assist professional practice. Furthermore, authors argue for nursing staff to train in aromatherapy similar to their training in wound care, and to maintain their independence of work (Mackereth, 1995; Sheen, 2006). Currently, not many nursing staff are formally trained to use aromatherapy and the level of competence for aromatherapy usage is debatable (Rawlings & Meerabeau, 2003). As there is likely to be an increase in Australian nurses using CAM in workplaces, it is important that they understand the fundamentals of CAM in order to implement CAM safely.

### 1.5.1.1 Regulation and standards of aromatherapy

Aromatherapy products such as essential oils are regulated by the Australian Commonwealth Government through the Therapeutic Goods Administration (TGA) (Therapeutic Goods Administration, 2005). The TGA is designed for assessing and monitoring the therapeutic goods that meet an acceptable standard in Australia (Commonwealth of Australia, 2003; Therapeutic Goods Administration, 2005). Advertisements for therapeutic goods must go through the requirements set by the Therapeutic Goods Act and Regulations which ensure their quality, safety, efficacy and timely availability. These products are intended for therapeutic use, which must be listed or registered in the Australian Register of Therapeutic Goods (ARTG) with either 'Aust L' or 'Aust R' appearing on the label. It also requires them to comply with standards from the British Pharmacopoeia (BP), the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) (Therapeutic Goods Administration, 2005). The statements 'Keep out of reach of children' and 'Not to be taken' should also be labelled with these warnings on containers of $\leq 25$ ml (Therapeutic Goods Administration, 2005). Over 500 essential oils including lavender oil are listed on the ARTG (Dunning, 2005).

### 1.5.1.2 Essential oil administration and toxicity

Aromatherapy has been used as a complementary therapy for various conditions such as mental, spiritual, physical healing and beauty purposes in the twentieth century (Battaglia, 2002; Stevensen, 1998). People may receive the effects of essential oils commonly via three methods; skin absorption, inhalation and oral administration (Tisserand & Balacs, 1995). Although rectal and vaginal application can also administer essential oils into the body, these methods are rarely used in RACF.

The skin can absorb essential oils via massage and commercial aromatherapy lotion and cosmetic products. An Austrian study investigated the bioavailability of essential oils and reported on the amount of essential oils reaching the systemic circulation of the body after massage (Jäger, Buchbauer, Jirovetz, & Fritzer, 1992). The researchers discovered the peak plasma concentrations were detected in the blood after 20 minutes and this lasted for 90 minutes after applying 1.5 g of massage oil containing 2% lavender oils (Jäger, et al., 1992). In addition, the warm temperature of the skin and hot water would also increase the proportion of blood circulation in the dermis

and enhance the absorption of essential oils (Tisserand & Balacs, 1995). The inhalation of essential oils results in odour molecules being breathed into the lungs and through the bloodstream affecting the brain's limbic area and central nervous system (CNS). A variety of inhalation techniques can be selected such as burners, nebulisers, vaporizers and baths (Snyder & Lindquist, 2006). Inhalation of aromatherapy oils is a safe application, unless people are exposed to a high concentration for more than one hour or directly sniffing undiluted oils from a bottle (Tisserand & Balacs, 1995). For example, in high air concentrations of essential oils, people can absorb up to 70% of the dosage into the bloodstream during a two-hour period, and it may take three days to eliminate the high dosage from the body. Essential oils can be taken orally; however, the effects of oral administration are 8 to 10 times greater than via massage (Tisserand & Balacs, 1995). The drawbacks of oral ingestion include irritation of the gastrointestinal mucosa.

Most Australian people consider CAM including aromatherapy products are safe, effective and of good quality (Commonwealth of Australia, 2003; Myers & Cheras, 2004). However, a lack of knowledge when using essential oils may cause skin irritation, allergic reaction, and acute and chronic toxicity (Standen, 2006). Acute toxicity is associated with the lethal dose 50% ($LD_{50}$) that indicates 50% of the group can be killed by the dose (cited in Tisserand & Balacs, 1995). The $LD_{50}$ test is generally used in oral administration. Acute toxicity results in double vision, nausea, convulsions, severe hepatic failure and acidosis or even death (Tisserand & Balacs, 1995). Photosensitivity of the skin can also occur. This results in the skin being sensitive to sunlight and therefore placing the skin at risk of sunburn, erythema, oedema and dermatitis (Tisserand & Balacs, 1995). Chronic toxicity is a toxic reaction caused by prolonged or repeated low-level doses and has toxic effects on organ tissues (Buckle, 1997). In Australia, the lower dose usage of essential oils is common, applying essential oils to children and frail older people should comply with aromatherapy guidelines, that is 1-3% essential oil in a blend (Battaglia, 2002; Price & Price, 1999). Symptoms of chronic toxicity are likely to be present through headaches, loss of appetite, minor skin eruption, nausea, and lethargy (Tisserand & Balacs, 1995). Although chronic toxicity is unlikely to occur at the low dose used in aromatherapy and particularly with topical application, a patch-test is required before using essential oils in the clinical setting (Bowles, 2006; Buckle, 1997).

**1.5.1.3 The effects of essential oils**

Essential oils have been reported to have an effect on different body functions, such as the nervous and immune systems (Battaglia, 2002). A telephone-interview study by Standen et al. (2006; 2004) surveyed 11 Australian aromatherapy educators to select the most effective essential oils on the immune system and anti-inflammatory effects. The study found tea tree was the first preference, followed by *Eucalyptus globulus*, frankincense, West Australia (WA) sandalwood and thyme. In the anti-inflammatory category, German chamomile was reported at the top of the list, WA sandalwood, Everlasting and Roman chamomile were also the second popular choices of the aromatherapy educators. Lavender has a long history as an anti-inflammatory oil, and was also chosen by aromatherapy educators for its immune and anti-imflamatory properties (Cavanagh & Wilkinson, 2005a; Standen, 2006; Standen & Myers, 2004).

Aromatherapy is the most widely used CAM in people with dementia in RACF and oils that have a sedative effect are popular (Ballard, O'Brien, Reichelt, & Perry, 2002; Bowles, Griffiths, Quirk, Brownrigg, & Croot, 2002; Brooker, Snape, Johnson, Ward, & Payne, 1997; Holmes, et al., 2002; Lin, Chan, Ng, & Lam, 2007; Nguyen & Paton, 2008; Smallwood, Brown, Coulter, Irvine, & Copland, 2001; Snow, Hovanec, & Brandt, 2004; Webber, 2003). Presented below (Table 1.2) are a number of essential oils that are reported to be used to alleviate stress, anxiety, restlessness and depression, and which are listed to have a sedative effect (Battaglia, 2002).

**Table 1.2 The actions of essential oils on the nervous system**

| Types of essential oils | Actions on Nervous System |
| --- | --- |
| **Bergamot** | sedative, uplifting, antidepressant |
| **Basil** | relaxing, sedative |
| **Cajeput** | alleviating restlessness |
| **Cardamom** | antidepressant |
| **Cedarwood** | reducing stress, anxiety and tension |
| **Chamomile** | sedative, soothing, calming, antidepressant |
| **Clary sage** | relaxing, sedative, reducing anxiety, tension and depression |
| **Fir** | alleviating anxiety and stress |
| **Frankincense** | alleviating anxiety and nervous tension, sedative |
| **Geranium** | sedative, uplifting, antidepressant, relieving stress and anxiety |
| **Grapefruit** | antidepressant, reducing stress and depression |
| **Jasmine** | antidepressant, sedative, reducing anxiety, restlessness and depression |
| **Lemongrass** | sedative, uplifting, antidepressant |
| **Lavender** | sedative, antidepressant, relieving stress-related symptoms such as pain, spasms, cramps, nervous tension, irritability, mental distraction and insomnia, decreasing agitation and unrest, alleviating fears, uplifting |
| **Lime** | antidepressant, uplifting, reducing stress |
| **Mandarin** | sedative |
| **May chang** | alleviating stress and anxiety |
| **Melissa (lemon balm)** | sedative, uplifting, antidepressant, reducing anger, anxiety, stress, insomnia |
| **Manuka** | sedative |
| **Marjoram** | sedative, relaxing nerves, stress-related conditions, anxiety and insomnia |
| **Neroli** | sedative, antidepressant, insomnia |
| **Orange** | sedative, antidepressant, reducing anxiety, nervousness and insomnia |
| **Palmarosa** | alleviating stress, restlessness and anxiety |
| **Patchouli** | antidepressant, alleviating anxiety and stress-related conditions |
| **Petitgrain** | antidepressant, sedative, alleviating stress-related conditions |
| **Pine** | reducing severe psychological stress |
| **Rose** | antidepressant, sedative, releasing anger, despair, frustration and psychological pain |
| **Rock Rose** | sedative |
| **Rosemary** | antidepressant |
| **Rosewood** | antidepressant, alleviating anxiety and stress |
| **Sandalwood** | sedative, reducing agitated emotional states, nervous tension and insomnia |
| **Spearmint** | uplifting, reducing mental strain, stress and depression |
| **Tangerine** | sedative |
| **Thyme** | relieving nervous depression and stress-related complaints |
| **Vetiver** | sedative, relaxing, decreasing anxiety, stress, depression and insomnia |
| **Ylang ylang** | antidepressant, reducing anxiety, anger and frustration |

### 1.5.2 Massage

The earliest history of massage therapy is believed to have emanated from China and Egypt, and this therapy has been developed and refined over 5000 years (Tuchtan, Tuchtan, & Stelfox, 2004). Foot and hand massage was first recorded around 2330 B.C. in Egypt, the techniques were similar to reflexology and used thumb and finger pressure. In China, the earliest history of massage was documented in the 14 medical manuscripts that spanned three dynasties from 1122 B.C. to 220 A.D. (cited in Casanelia & Stelfox, 2010).

Australian historical records state that massage therapies were originally introduced from the United Kingdom (UK) (Chipchase, et al., 2006). Massage therapists were trained by other therapists who had credible reputations during the 1870s. Moreover, massage therapists worked under the direction of medical practitioners in public hospitals where massage was a third branch of medical practice and was considered to be of equal importance to surgery and medicine in Australia (Australian Physiotherapy Association, 2008; cited in Casanelia & Stelfox, 2010). In 1906, the national Australiasian Massage Association (AMA) was established, which developed a two-year educational program for training therapists and resulted in a diploma of massage. Many staff members of the AMA provided service during World War I (WWI) and World War II (WWII) (Australian Physiotherapy Association, 2008; Chipchase, et al., 2006). However, after the AMA changed its name to the Australian Physiotherapy Association (APA) in 1939, the field of physiotherapy began to work independently. Physiotherapists focused on rehabilitation from injury and used appliances in assisting the traditional human touch (Casanelia & Stelfox, 2010). Massage courses became less available and the quality of training was not able to be controlled.

In 2000, a national training system from the Vocational Education and Training (VET) sector established the level of qualification for maintaining qualified massage therapists in Australia. Massage therapists acquired knowledge and skills with a certificate IV in massage therapy practice in order to maintain a consistent standard of service for people (Casanelia & Stelfox, 2010; Department of Education Employment and Workplace Relations, 2010). Subsequently, the Australian Association of Massage Therapists (AAMT) was formed in 2003 and linked with the Australian Massage

Research Foundation (AMRF) for massage related research across Australia and New Zealand (Australian Association of Massage Therapists, 2003). This contributes to the health benefits of massage in clinical practice. Although massage therapy is still self-regulatory in Australia, qualified massage therapists can join these associations and practice skills under their scope of practice (Casanelia & Stelfox, 2010).

**1.5.2.1 The effects and adverse events of massage on the body**

Massage is defined as the use of a systematic and scientific method of hand manipulation to the body's soft tissues for obtaining or maintaining health and well-being (Salvo, 2003; Tuchtan, et al., 2004). Soft tissues include ligaments, tendons, muscles, nerves, bloodvessels and other membranes of the body (Salvo, 2003). Massage can be divided into direct contact and indirect contact; direct contact involves joint movements and pressures that affect surrounding tissues. Indirect contact does not include physical touch as it involves the sensitivity and manipulation of energy into the body (Salvo, 2003). Massage therapy creates two body responses that can have miscellaneous effects on the body's system (see Table 1.3). There are both a mechanical response and reflexive response (Salvo, 2003). The mechanical response can reduce swelling and increase blood circulation; in addition, a reflexive response can decrease the sympathetic nervous system and reduce blood pressure (Salvo, 2003). Massage therapy has been shown to be effective in many ways including reducing pain and anxiety, decreasing muscle tension and heart rate, increasing skin temperature and blood flow. It also improves sleep and reduces fatigue, nausea and depression (Bauer, et al., 2010).

**Table 1.3 The actions of massage on the body system**

| Effects of massage on the body system | Actions |
|---|---|
| Cardiovascular system | • Improves blood circulation<br>• Decreases blood pressure and dilates blood vessels<br>• Increases oxygen saturation in blood and blood flow |
| Lymphatic/immune ststems | • Promotes lymph circulation<br>• Increases lymphocyte count |
| Skin | • Increases skin temperature<br>• Stimulates sebaceous and sudoriferous glands |
| Nervous and endocrine systems | • Promotes relaxation<br>• Increases dopamine and serotonlin levels<br>• Decreases pain<br>• Reduces stress and anxiety<br>• Increases vagal activity |
| Muscles | • Relieves muscular tension<br>• Increases range of motion and flexibility<br>• Reduces trigger point formation |
| Respiratory system | • Reduces respiration rate<br>• Improves pulmonary functions |
| Digestive system | • Promotes evacuation of the colon and relieves constipation<br>• Stimulates digestion |

There are numerous types of massage therapy that can be applied to the body. The most frequently applied massage therapies are listed below (see Table 1.4). Swedish massage or therapeutic massage generally has both mechanical and reflexive responses (Salvo, 2003). Trigger point massage, reflexology and shiatsu are similar methods that use finger pressure for pain relief. Therapeutic touch and reiki focusses on healing energy by the touch of the hands (National Centre for Complementary and Alternative Medicine, 2004).

**Table 1.4 Types of massage**

| Types of massage | Techniques |
|---|---|
| Swedish massage | Five basic strokes:<br>Effleurage, petrissage, friction, tapotement and vibration |
| Deep tissure massage | Focuses on deeper layers of muscles and connective tissue |
| Trigger point massage | Trigger points are located in tense muscles, ligaments, and tendons with palpable nodules. Therapists use fingers to compress small contraction knots for relief of pain |
| Therapeutic touch | A natural healing modality whereby mind and emotions form a dynamic energy field to heal the body |
| Reflexology | Pressure is applied to the feet and hands by thumb, finger and hand techniques without the use of oil, cream or lotion. The feet and hands reflect an image of the body, the massage is based on a zone therapy and reflex areas |
| Shiatsu | The word shiatsu means "finger pressure", it is a Japanese form of bodywork |
| Reiki | Reiki is also a Japanese technique for stress reduction and relaxation. It is based on the idea of "universal life energy" |

Although massage is ranked as having a moderate or high potential effectiveness adverse effects of massage can also harm the body (Cohen, et al., 2005). Literature reports the adverse effects of massage from mild to severe including, bruising, increased discomfort, thrombosis, embolism, ulceration, haematoma, nerve damage and displacement of organs (Cambrone, Dexheimer, Coe, & Swenson, 2007; Ernst, 2003). There are two contraindications where people are not allowed or caution is needed for them to receive massage therapy. In terms of absolute contraindictions, massage therapy can not be safely applied to people due to their health conditions, which include untreated arterial or venous thrombus, congestive cardiac failure, toxaemia, systemic infection, undiagnosed oedema, untreated aortic aneurysm and alcohol and recreational drug use (Casanelia & Stelfox, 2010; Salvo, 2003). Local or relative contraindications refers to people with complex medical histories and they should provide medical clearance before receiving massage (Casanelia & Stelfox, 2010; Salvo, 2003). Precautions also need to be considered when administering massage to people taking pharmacologic medication. For example, NSAIDs and Opiods increase the pain threshold of the body; therefore, people taking these medications should receive a less intense massage in order to avoid tissue injury (Casanelia & Stelfox, 2010). Angiotensin converting enzyme (ACE) inhibitors, β-

adrenoceptor and calcium channel blockers may cause a risk of fainting, so people should stand up slowly and with support of assistance after completing massage (Casanelia & Stelfox, 2010).

### 1.5.3 Aromatherapy and Massage in Older People

Several studies have found CAM is frequently used in the treatment of age-related health  conditions such as anxiety or depression, arthritis, back pain and cancer; furthermore, women tend to use more CAM than men (Cheung, Wyman, & Halcon, 2007; Grzywacz, et al., 2006; Yim, Ng, Tsang, & Leung, 2009). Aromatherapy and massage were also found to have benefits in older people with health conditions such as treating symptoms of mental illness related behaviour and chronic pain (Grzywacz, et al., 2006; Yuan, et al., 2006).

Bowles et al. (2006; 2005) conducted a survey of aromatherapy use in 28 RACF in Northern NSW. Data was obtained from care directors and aromatherapy care planners about their practices and perceptions of aromatherapy for dementia. A majority of care directors perceived aromatherapy was moderately useful in reducing medication such as sedatives and analgesics (Bowles, 2006; Bowles, et al., 2005). Aromatherapy seemed to have an effect on physical discomfort, behavioural and psychological symptoms in older residents. The survey found nearly 60% of the older residents receiving aromatherapy and over 40% of people with dementia received treatments daily. Footbaths, foot massage, neck-and-shoulder and hand massage were commonly applied to the older residents. Bowles et al. (2006; 2005) found that touch, one-to-one contact were more important than mental stimulation and reminiscence when the residents smelt the essential oils. Although aromatherapy spray was only used by half of the facilities, it was positively correlated with "perception of efficacy" for dementia symptoms (Bowles, 2006; Bowles, et al., 2005). The survey also reported that assistants-in-nursing (AINs) were the primary staff used to administer the CAM treatments (Bowles, 2006; Bowles, et al., 2005). Unsurprisingly, use of lavender oil (Lavandula angustifolia) was popular in the RACF, followed by tea tree (Melaleuca alternifolia) and geranium (Pelargonium graveolens). In addition, the cost of essential oils ranged between $0.42AUD to $21.05 AUD per resident per month with the average being $4.50AUD.

CAM is also used by older people living in the community. An American cross-sectional survey (Cheung, et al., 2007) assessed knowledge and factors of CAM use in 1200 older people who lived in a community-dwelling. Arthritis and chronic pain were the most common health problems for older people using CAM (Cheung, et al., 2007). More than a quarter of the older people used massage therapy including healing, therapeutic touch and reflexology. Grzywacz et al. (2006) investigated approximately 6000 people aged 60 and over and compared the CAM use in two groups with and without self-reported anxiety or depression. Massage was positively chosen to treat any health condition in over 50% of each group. Although older people are a high risk for decline in cognition, sensation and physical functions, their sense of touch could be extended into later life.

Alongside an increase in CAM amongst the general population, various CAM programs to treat disruptive behaviours in people with dementia have arisen. These include aromatherapy (Ballard, et al., 2002; Beshara & Giddings, 2002; Bowles, et al., 2002; Brooker, et al., 1997; Gray & Clair, 2002; Holmes, et al., 2002; Kilstoff & Chenoweth, 1998; Lin, et al., 2007; MacMahon & Kermode, 1998; Smallwood, et al., 2001; Snow, et al., 2004), music (Götell, Brown, & Ekman, 2009; Suzuki, Kanamori, et al., 2004; Tuet & Lam, 2006), massage (Kim & Buschmann, 1999; Remington, 2002a; Remington, 2002b; Sansone & Schmitt, 2000; Snyder, Egan, & Burns, 1995a, 1995b; Woods, Craven, & Whitney, 2005), light therapy (Burns, Allen, Tomenson, Duignan, & Byrne, 2009; Forbes, et al., 2004; Skjerve, Bjorvatn, & Holsten, 2004; Sutherland, Woodward, Byrne, Allen, & Burns, 2004), behaviour therapy (Herrmann, 2005), activity programs (Anderson, 2008; Connell, Sanford, & Lewis, 2007; Heyn, 2003; Jarrott & Bruno, 2003) and environmental changes (Chapman, Hazen, & Noell-Waggoner, 2007; Goodall, 2006). In South Australia, a survey found aromatherapy (88.9%), music (80.2%) and massage (79%) were the most common CAM used in RACF (Webber, 2003). In this thesis, the CAM investigated is aromatherapy and hand massage treatments and their effect in reducing disruptive behaviours in people with dementia in RACF.

## 1.6 Overview of the Thesis

This thesis consists of eight chapters. Chapter one outlines an overview of dementia including demographic data, and the economic impact of dementia on the health care system in Australia. Current issues, such as diagnosis, nursing staff attitudes and knowledge, pain management, and a relationship between restraints and falls in relation to the people with dementia are discussed. Finally, a brief Australian history of aromatherapy and massage and its application in the dementia field are outlined.

Chapter two presents an outline of dementia, including the symptoms and different types of dementia. This chapter also discusses disruptive behaviours associated with dementia such as agitation and aggression, the causes of these disruptive behaviours, and how physical and pharmacological approaches are used to prevent or decrease disruptive behaviours in people with dementia.

Chapter three illustrates the thesis theoretical basis of aromatherapy and hand massage, how odours affect the olfactory and limbic system and influence physical and emotional changes. Moreover, olfactory dysfunction in people with dementia and using aromatherapy for cognitive improvement are presented. The chapter also presents a review of aromatherapy and massage research and its effect on reducing disruptive behaviours in people with dementia living in RACF, and discusses the limitations of these studies.

Chapter four reviews the background and evaluation of the randomized controlled trial (RCT) design. Ethical issues in relation to RCT are also discussed. The theoretical framework of aromatherapy and hand massage is also presented by using the modified Dungan's Model of Dynamic Integration (1997). The thesis justification for the choice of RCT in research is emphasized followed by the research hypotheses and objectives. Finally, the rigor of this RCT study is discussed in relation to guiding the study intervention protocol and the Consolidated Standards of Reporting Trials (CONSORT) Statement.

Chapter five details the research method used in this study. A single blind randomized controlled trial (RCT) design is used with five times of data collection. This chapter

outlines the research design, intervention, settings, and recruitment of participants. The instruments for measuring participant behaviour including the Cohen-Mansfield Agitation Inventory (CMAI), Revised Memory and Behaviour Problem Checklist (RMBPC) and Mini Mental Status Examination (MMSE) are addressed. Lastly, statistical analysis and ethical considerations are described.

Chapter six presents the findings of the study. Data analysis is guided by the intention-to-treat (ITT) protocol; a demographic profile of a sixty-one participant sample is described. The data was analysed using descriptive and inferential statistics. Findings of the study are demonstrated using tables and figures. Descriptive statistics are reported for the measurements of CMAI and RMBPC. Inferential statistics are reported that test the hypotheses of interest. Finally, five case studies are presented to provide some examples of individual residents' experiences.

Chapter seven discusses the results of the study and compares these findings to the research literature. Findings relate to the level of cognitive impairment, mobility restrictions, impact of physical restraint and antipsychotic medication used, and the relationship between pain/discomfort and disruptive behaviours are presented. The challenge of data collection including participant diagnosis, organizational/environmental issues, and nursing staff attitudes and knowledge are explored. The implications for health professionals, clinical practice, nursing staff attitude and knowledge, and residential aged care facilities (RACF) are also discussed in this chapter. These implications included in this study explain the needs for enhancing formal diagnosis, increasing community awareness of screening potential residents with dementia and improving health systems in early diagnosis of dementia. It is argued that nursing staff knowledge and education need to be assessed regularly and educational programs offered in order to maintain a high quality of care to people with dementia. Provision of government funding and the way it is allocated may affect the relationship between RACF and nursing staff and may increase staff workload, especially in relation to documentation. It may also influence the number of nursing staff available to provide quality of care for people with dementia. Lastly, the limitations of the Cohen Mansfield Agitation Inventory (CMAI) and Revised Memory and Behaviour Problem Checklist (RMBPC) and the limitations of the research are also discussed.

The final Chapter eight concludes the study. This chapter outlines such issues as the need for a formal dementia diagnosis and documented history of disruptive behaviours, treatment outcomes associated with the level of cognitive impairment, and the potential influence of negative attitudes and insufficient knowledge of dementia care among nursing staff. Further research is recommended including recommendations for further research using RCT methodology and education programs for improving nursing staff attitudes in caring for people with dementia.

## 1.7    Summary

Dementia is a world wide challenge for public health, particularly in countries where populations are ageing as dementia usually affects older people. There were 2.82 million people over the age of 65 in Australia in 2008. This number is expected to increase and as a consequence, there will be a rise in the incidence of dementia. Dementia affects approximately 6.5% of the population whose age is 65 years and older and 25–30% of people aged over 80. It is also a costly burden on the Australian health system. Since 2003, the total health and welfare system expenditure for dementia was over $1 billion, which includes hospitalisation, pharmaceutical expenditure and out of hospital service. In RACF, over 90% of the expenditure was for high-level aged care. People who suffer from dementia often experience psychiatric symptoms and behaviour disturbances including agitation and aggression. However, current issues such as unclear diagnosis of dementia types, staff negative attitudes and insufficient knowledge and issues related to medication for older people, not only influence the quality of life in people with dementia, but also challenge caregivers' ability and increase stress. Therefore, it is important to seek a solution that might improve the current situation. A number of CAM are reported to be of benefit in reducing behaviour disturbance and have been used by a number of researchers and in different clinical situations. Aromatherapy and massage have been used with people with dementia in RACF as a means of reducing restraint use and disruptive behaviours. The following chapter discusses the literature related to aromatherapy and hand massage.

# CHAPTER 2
# BACKGROUND TO DEMENTIA

## Chapter Overview

Dementia is not just a problem of memory; it also influences daily routine such as a decrease in the ability of a person to cope with daily living and an increase in mental conditions such as depression and disruptive behaviours. These issues may influence quality of life for the person living with dementia; increase the risk of caregiver burden, and the need for institutionalization. The literature in this chapter is used to outline types of dementia including Alzheimer's disease (AD), vascular dementia (VaD), mixed dementia, dementia with Lewy Bodies (DLB) and fronto-temporal dementia. Moreover, the chapter presents dementia associated with the category of disruptive behaviours, verbal and physical agitation/aggression, sundown syndrome and also examines the causes of disruptive behaviours. The contradictions of using both physical and pharmological treatments with disruptive behaviours are also discussed.

## 2.1    Dementia

Dementia is the term used to describe the symptoms of a large group of diseases which cause a progressive decline in a person's functioning (Alzheimer's Australia, 2005). Those symptoms include a loss of memory, intellect, rationality, social skills and normal emotional reactions (Alzheimer's Australia, 2005). Dementia generally occurs late in life and affects approximately 6.5% of the population 65 years and older and between 25– 30% of people aged over 80 years (Australian Institute of Health and Welfare, 2004).

The most common form of dementia is Alzheimer's disease (AD); approximately 50% to 70% of people with dementia have AD (Australian Institute of Health and Welfare, 2007). The second form is vascular dementia (VaD), accounting for between 10% and 20% of pathological cases (Leifer, 2003; Low, Gomes, & Brodaty, 2008). Mixed dementia, which combines vascular dementia and Alzheimer's disease, is the third most common type of dementia. Dementia with Lewy Bodies (DLB) is the

fourth most common group (10–20%) of people with dementia followed by fronto-temporal dementia case (2%) (Low, et al., 2008).

### 2.1.1 Types of Dementia

According to DSM-IV-TR diagnostic criteria, dementia includes (American Psychiatric Association, 2000, p. 276):

A.      Memory impairment, one or more cognitive disturbances such as aphasia, apraxia, agnosia, disturbance in executive functioning

B.      A significant impairment in social and occupational functioning decline caused by memory impairment or cognitive disturbances

C.      Gradual onset and continuing cognitive deterioration

D.      The deficits do not occur exclusively during the course of a delirium

E.      The disruptive behaviours are not accounted by Axis I disorder such as a major depressive episode and schizophrenia.

Alzheimer's disease (AD) was first identified by a German physician, Alois Alzheimer in 1906 (Ganzer, 2007; Graeber, Kosel, & Grasbon-Frodl, 1998; Kidd, 2008). AD is a chronic neurodegenerative disorder that usually develops after 65 years of age; in addition, AD is more common among women (Desai & Grossberg, 2005; Ganzer, 2007; O'Connor, 2005). AD includes loss of memory and other cognitive functions such as difficulty in remembering recent events or things, naming, word finding and calculation (Desai & Grossberg, 2005; Ganzer, 2007; Leifer, 2003). Memory loss was found to be associated with a lack of choline and a decrease in the activity of choline acetyltransferase (Kidd, 2008). AD is a long progressive disorder that consists of three stages, mild, moderate and severe with a range of three to twenty years (Desai & Grossberg, 2005; Leifer, 2003). Cognitive deterioration is the first symptom in early stage AD which is often accompanied by anxiety and depression (Kempler, 2005). Mild cognitive impairment (MCI) is a common precursor to AD (Desai & Grossberg, 2005; Leifer, 2003). Older people with the diagnosis of MCI have memory impairments; however, MCI does not interfere significantly with their daily activities. Although older people with MCI do not meet the criteria for dementia, MCI contributes a transitional stage between the cognitive changes in normal aging and the earliest sign of dementia (Flashman, Malamut, & Saykin, 2008). In addition, depression is highly correlated to MCI (Dash & Villemarette-Pittman, 2005;

Gabryelewicz, et al., 2007; Gabryelewicz, et al., 2004). In Poland, researchers found that older people with depressive symptoms were more likely to develop dementia (Gabryelewicz, et al., 2007; Gabryelewicz, et al., 2004). People with AD also experience personality and behaviour changes which involve irritability, agitation and aggression; other behaviours such as delusion and hallucinations can also be part of the syndrome in the moderate stage (Desai & Grossberg, 2005; Leifer, 2003). By the moderate stages, people with AD have difficulty in sentence comprehension due to memory deficits (Kempler, 2005). People with moderate to severe AD are usually living in residential care because of a decline in ability to carry out activities of daily living (ADL) (Desai & Grossberg, 2005).

Vascular dementia (VaD) is the second most common type of dementia (Craig & Birks, 2006; Rockwood, et al., 2000). VaD includes all cases in which dementia is associated with cerebrovascular disease, such as small strokes (multi-infarct) or transient ischaemic attacks (TIA) because of a lowered supply of blood to areas of the brain (Alzheimer's Australia, 2005). The most common form of vascular dementia involves cortical stroke damage to the grey matter (Paul, Cohen, Ott, & Salloway, 2005). Binswanger's encephalopathy or subcortical vascular dementia involves ischemic changes that take place in the deep white matter of the cerebral hemispheres and diffuse demyelination of the white matter (Paul, et al., 2005). It is caused by high blood pressure, thickening of the arteries and inadequate blood flow (Alzheimer's Australia, 2005). Therefore, people with vascular dementia are more likely to have a history of stroke or hypertension, neurological symptoms and signs (Leifer, 2003). People with VaD usually have more neurodegenerative signs when compared with people with AD (Paul, et al., 2005). Depression and mood disturbances are common in Binswanger's disease (Paul, et al., 2005). People with VaD have depression rates of 20–50% compared with 3–30% of people with AD (Hebert, et al., 2000). Executive dysfunctions, such as with activities of daily living (ADL), are the first signs leading to a diagnosis of dementia in VaD (Bruandet, et al., 2009). VaD is commonly associated with disruptive behaviours that impair overall functioning and often require active intervention (Paul, et al., 2005).

Mixed dementia is due to multiple medical conditions which includes both Alzheimer's type and vascular pathology occurring in tandem (Rockwood, 2003).

Other combinations include AD and hypothyroidism or vitamin B-12 deficiency (Rockwood, 2003). However, it is difficult to identify the type of dementia which has caused the failure of brain function. Mixed dementia could present clinically as AD with evidence of cerebrovascular lesions in the brain or features of both AD and VaD (Rockwood, 2003).

Dementia with Lewy bodies (DLB), (found in the pigmented nuclei of the brain stem) is a recently described dementia accounting for 10–20% of cases (Leifer, 2003; Low, et al., 2008). Lewy body dementia is common in people with Parkinson's disease (Buracchio, Arvanitakis, & Gorbien, 2005; Leifer, 2003). DLB has the pathological features of Alzheimer's disease and Parkinson's disease in both the cortical and subcortical regions (Ince & Perry, 2005). Hypometabolism and lack of perfusion in the occipital lobe in DLB are common findings (Buracchio, et al., 2005). This type of dementia involves various movement disorders (extrapyramidal symptoms) such as restlessness, tremor and bradykinesia. People with DLB may experience problems with attention and alertness and often have spatial disorientation. Fluctuation in cognitive function, visual hallucinations, sleep disorder and repeated falls are the most common signs and symptoms in dementia with Lewy bodies (Alzheimer's Australia, 2005; McKeith, 2005).

Frontotemporal dementia (FTD) is a relatively common form of early-onset dementia, which is also the second most prevalent type of dementia developed in people less than 65 years of age (Hodges, Davies, Xuereb, Kril, & Halliday, 2003; Neary, 2005). FTD is a progressive degenerative disorder of the frontal and anterior temporal lobes, which affects personality and social conduct and impaired frontal executive functions (Neary, 2005). People with FTD progress to death faster than those with AD (Roberson, et al., 2005). Approxmiately 30% to 40% of people with FTD have other family members with a neurodegenerative condition or dementia (Farmer & Grossman, 2005). FTD is also associated with Pick's disease which progresses as a non-fluent aphasia and semantic dementia (Agronin, 2004; Bird, et al., 2003). Pick's disease is a progressive dementia which usually begins at 50–60 years of age (Access Economics, 2003; Hardin & Schooley, 2002). In the early stages of FTD the person is likely to exhibit symptoms that resemble psychiatric disorders with personality changes, repetitive, deterioration of social skills and emotional blunting (Agronin,

2004; Neary, 2005).

Beyond these types of dementia, other causes of dementia in older persons are Acquired Immunodeficiency Syndrome (AIDS), Huntington's disease, Spongiform encephalopathies and Wernicke-Korsakoff's syndrome (Agronin, 2004; Alzheimer's Australia, 2005; Australian Institute of Health and Welfare, 2007). Huntington's disease usually appears between the age 30 and 50 and causes intellectual decline and irregular, involuntary movement of the limbs or facial muscles (Alzheimer's Australia, 2005). Wernicke-Korsakoff's syndrome is associated with a diet deficient in thiamine (vitamin B1) and particularly with excess alcohol consumption (Alzheimer's Australia, 2005; Australian Institute of Health and Welfare, 2007). Toxic dementia can result from excessive use of a poisonous substance (Anderson, Novak, & Elliot, 2002). Other types of dementia are due to metabolic disorders, caused by older people's livers and kidneys being less efficient as well as metabolic conditions that can occur with thyroid disease and diabetes (Van den Berg, Biessels, De Craen, Gussekloo, & Westendorp, 2007; Yaffe, Kanaya, & Lindquist, 2004).

## 2.2    Disruptive Behaviours

Over 60% of people who suffer from dementia experience psychiatric symptoms and behaviour disturbances such as agitation and aggression (Griffiths, 2002; Hay, et al., 2003; Sink, Holden, & Yaffe, 2005).  An American study reported that approximately 90% of people with advanced dementia display agitated behviours (Tariot, 2003). These disruptive behaviours have been found to be highly associated with Frontotemporal dementia (FTD) (Agronin, 2004; Jacques & Jackson, 2000). People in younger age with dementia were more likely to have these behavioural disturbances; moreover, male patients exhibit more aggressive behaviours than female patients (Brodaty, et al., 2001; Orengo, Kunik, Molinari, Wristers, & Yudofsky, 2002).

### 2.2.1   Agitation and Aggression

In this research disruptive behaviour associated with dementia is defined as agitation and aggression. Agitation is operationally defined by Cohen-Mansfield and Billing (Cohen-Mansfield & Billing, 1986, p. 712) as "inappropriate verbal, vocal, or motor activity that is not judged by an outside observer to result directly from the needs or

confusion of an agitated individual". The Collins Cobuild English dictionary (1999, p. 35) defines aggression as a quality of anger and determination which makes a person attack other people. It is behaviour that can be damaging both physically and mentally. In the community, 23.7% of older people with dementia were reported to display aggression (Lyketsos, et al., 2000). Moreover, Orengo et al. (2008) found 19.5% of a total of 365 veterans with a newly diagnosed dementia had aggressive behaviours including of these 31% verbal, 12% physical, 32% verbal and physical and 25% with unspecified aggression.

Cohen-Mansfield et al. (1995) defined four types of disruptive behaviours: verbally nonaggressive, verbally aggressive, physically nonaggressive and physically aggressive. The characteristics of these four types are displayed in Figure 2.1.

Verbal/Vocal

**Verbally nonaggressive**

Complaining
Negativism
Repetitive sentences or questions
Constant, unwarranted requests
for attention or help

**Verbally aggressive**

Cursing and verbal aggression
Making strange noise
Verbal sexual advances
Screaming

Nonaggressive — — — — — — Aggressive

**Physically nonaggressive**

Performing repetitious mannerisms
Inappropriate robing and disrobing
Eating inappropriate substances
Handling things inappropriately
Trying to get to a different place
Pacing, aimless wandering
Intentional falling
General restlessness
Hoarding things
Hiding things

**Physically aggressive**

Physical sexual advances
Hurting self or others
Throwing things
Tearing things
Scratching
Grabbing
Pushing
Spitting
Kicking
Biting
Hitting

Physical

**Figure 2.1 Behaviours defined in the Cohen-Mansfield Agitation Inventory (CMAI)**
**(Cohen-Mansfield, 2000, p. 11; 2003, p. 5)**

Because the subtypes are not independent and each subtype tends to co-occur, Cohen-Mansfield et al. (1989) identified the original four factors into three subtypes of agitation: physically nonaggressive behaviour, aggressive behaviour and verbal agitated behaviour. These subtypes were developed into an inventory called the Cohen-Mansfield Agitation Inventory (CMAI) that nurses and other health professionals can use to measure behavioural disturbance and to identify the precursors for behaviour disturbance as a means of managing these behaviours.

### 2.2.2 Verbal Agitation and Aggression

According to the CMAI, certain behaviours distinguish whether the aggression displayed is for example verbal agitation (nonaggression) or verbal aggression (Cohen-Mansfield, 2000, 2003). Verbal agitation includes complaining, constant requests for attention, repetition of sentences or questions; these are the most disruptive behaviours for staff in nursing homes (Cohen-Mansfield, 2000, 2003; Cohen-Mansfield & Libin, 2005; Cohen-Mansfield, et al., 1989). Verbally agitated behaviours tend to correlate with females who have cognitive decline, poor performance of ADL, impaired social functioning and depression (Cohen-Mansfield & Libin, 2005).

Verbal aggression includes screaming, cursing, verbal sexual advances and making strange noises (Cohen-Mansfield, 2000, 2003). Older people with dementia may use verbal abuse to control, gain power, or take revenge in a situation in which they perceive their self-esteem to be demeaned so that they feel powerless, anxious, frustrated or fearful (Anderson & Clarke, 1996). Verbal aggression is an indication of the fight response; the autonomic nervous system is activated in warning and the entire body responds (Anderson & Clarke, 1996). A qualitative study found screaming or yelling were the most commonly mentioned verbal aggressive behaviours in nursing homes (Rosen, et al., 2008). In addition, when older people displayed verbal aggression they received less care and less time in verbal interaction from nursing staff (Allen, et al., 2005; Landreville, Dicaire, Verreault, & Lévesque, 2005).

### 2.2.3  Physical Agitation and Aggression

The common physically nonaggressive behaviours include pacing, trying to get to a different place, general restlessness, inappropriate dressing or disrobing, and performing repetitious mannerisms (Cohen-Mansfield, 2003). Physically nonaggressive behaviours tend to be correlated with cognitive impairment and with concurrent medical diagnoses (Cohen-Mansfield & Libin, 2005). Some people with advanced AD or FTD may become more resistive to daily care activities such as changing clothes or bathing (Smith, 2004). People with dementia who exhibit behavioural symptoms were less likely to have high mobility limitations than those who did not, and wandering may account for this relationship (William, et al., 2005). Wandering is the most dangerous behaviour among older people with dementia as it can lead to serious injury or death (Smith, 2004). The Alzheimer's Association estimates approximately 70% of people with AD or a related dementia wander and get lost during the progress of the disease (Silverstelin, Flaherty, & Tobin, 2002). Moreover, older residents wandering into the private rooms of other residents can trigger aggressive behaviours between residents (Rosen, et al., 2008).

Physical aggression includes hitting, spitting, pinching, thumping, scratching and kicking (Cohen-Mansfield, 2003). Male patients seem to display more physically aggressive behaviours (Cohen-Mansfield, 1996). Pushing, punching or fighting were most commonly discussed as problem behaviours in nursing homes (Rosen, et al., 2008). These behaviours are dangerous to older residents or other people. Physical aggression is the most difficult to tolerate for nursing staff in RACF followed by resistance to care provision (Manderson & Schofield, 2005; Schonfeld, 2003).

### 2.2.4  Sundown Syndrome

Sundown syndrome (SDS) occurs in the early evening and as the light decreases and after sunset, and is considered to be a common and recognisable phenomenon for agitation in dementia (Dewing, 2003; Volicer, Harper, Manning, Goldstein, & Satlin, 2001; Volicer & Hurley, 2003). It is also associated with delirium and occurs in mid-stage dementia (Dewing, 2003; Nowak & Davis, 2007). Sundowning is estimated to occur in 10–25% of older people living with dementia in nursing homes (Martin, Marler, Shochat, & Ncoli-Israel, 2000). SDS has been related to environmental

influences such as shift changes in nursing staff and a biological basis related to delaying circadian cycle of body temperature (Harper, et al., 2007; Volicer, et al., 2001; Volicer & Hurley, 2003). People with SDS may have eating change, delusions, night-time disturbances, daytime sleepiness, aberrant motor behaviour, physical aggression, resistiveness, disconcerted verbalising and wandering (Dechamps, Jutand, Onifade, Richard-Harston, & Bourdel-Marchasson, 2008; Nowak & Davis, 2007). SDS not only increases patients' verbal and physical agitation but also aggravates resistance to nursing care. Therefore, life history/patterns, health status, stress threshold, history of delirium/acute confusion, medicines and sleep pattern are essential for nursing assessment and care management (Dewing, 2003).

## 2.3    Causes of Agitation and Aggression

There are a number of causes that explain the genesis of agitation and aggression, including factors related to individuals with dementia, caregivers and environment (Kunik, et al., 2003). Dementia and related disease characteristics, personality, socioeconomic status, gender and patient preferences, physiological and psychological needs, pain and medical conditions and medication are all associated with individuals expressing agitation and aggression (Kunik, et al., 2003; Kyomen & Whitfield, 2008). Agitation often occurs when older people with dementia feel frustrated by a loss of capacity or control in performing daily activities and forgetfulness (Jeste, Sable, & Salzman, 2004; Kunik, et al., 2003). Pain is also a major cause of disruptive behaviour; older females are more likely to report pain than older males (Allen, et al., 2003; Varela-Burstein & Miller, 2003; Won, et al., 2004a). However, around 25% of nursing home residents with daily pain received no analgesic medicine or were given inadequate treatment either in prescription drugs or load dose (Allen, et al., 2003; Won, et al., 2004a).

Factors influencing the quality of care in RACF include gender, quality of past relationship with family caregiver, education and quality of current relationship and caregiver skills (Kunik, et al., 2003). Egan et al. (2007) found nursing home staff had limited understanding of the history of older residents with dementia. However, knowledge of an older resident's life history may assist nursing staff to approach the resident individually and help minimise the resident's aggression (Egan, et al., 2007).

Staffing issues, the setting, physical aspects of facility, social interaction and stimulation and the use of restraints are related to environmental factors (Kunik, et al., 2003). Cohen-Mansfield et al.'s study (1995) evaluated causes of disruptive behaviours in relation to the environmental conditions. Twenty-four nursing home residents with cognitive impairment were observed for disruptive behaviours over a nine-month period. The observations were classified into physical and social environment, activities and stimulation, timing and location with regard to environmental factors. The authors found staff members were more likely to trigger residents' behaviours. On the other hand, agitated behaviours decreased when staffing levels increased or residents had visitors; moreover, residents engaged with social activities which could also decrease their agitated behaviours rather than being alone (Cohen-Mansfield & Werner, 1995). In physical environmental attributes, older residents perceived variations in air temperature, which also increased residents' disruptive behaviours. For example, older residents tended to pace frequently when they perceived lower temperatures; on the other hand, hot weather was likely to increase older residents seeking for attention. The study suggested that a monotonous place without active stimulation may create noxious stimuli in people with dementia (Cohen-Mansfield & Werner, 1995).

As described earlier the term sundowning has been given to the symptoms and patterns of behaviours observed during the period of late afternoon and early evening as the sun goes down and there is an associated increase in agitation and worsening of disorientation in patients with dementia (Brown & Hillam, 2004). Patients are highly affected by noisy environments and light changes (Dewing, 2003). Therefore, bright light therapies and environmental changes have been found to have some effectiveness in decreasing agitation in people with dementia (Forbes, et al., 2004; Goodall, 2006; Skjerve, et al., 2004; Sutherland, et al., 2004).

## 2.4   Physical and Pharmacological Interventions

Agitation and aggression are highly correlated with injuries and in particular falls in people with dementia (Doorn, et al., 2003; Hamers, et al., 2004). In RACF, caregivers often use physical and chemical restraints to manage agitation and aggression (Nakahira, et al., 2009). Older people who received physical restraints were more

dependent on nursing staff to meet their needs; furthermore, those people who received more psychotropic medication had reduced mobility (Gallinagh, et al., 2002). However, such restrictions can challenge older residents' tolerance, which may lead to residents becoming more aggressive. Thus, understanding how to use physical and chemical restraints appropriately is important for all caregivers.

### 2.4.1   Physical Approach

Physical restraint is defined as any mechanical or manual device that is used to limit the physical mobility of people (Anderson, et al., 2002, p. 1339). Lee et. al (2003) surveyed 269 nurses' perceptions for using physical restraints in regional secure and psychiatric intensive care units. They found the common reasons for applying physical restraints were to separate violent patients, manage violent situations, protect patients from self-harm, discontinue behavioural disturbance and the administration of medication. Also, an Israeli study surveyed 200 nursing staff members for using physical restraints on patients with dementia in internal medicine wards of three general hospitals and psychogeriatric wards of three nursing homes (Weiner, Tabak, & Bergman, 2003). The study found nurses working in internal medicine wards of hospitals had less knowledge about the guidelines on restraints and tended to agree strongly with the use of restraints; physical restraints were frequently used to treat people with dementia in hospitals rather than nursing homes (Weiner, et al., 2003).

The most common type of restraint used with older adults were bed rails followed by waist belts, recliner chairs and barriers to prevent movement, such as a table placed in front of the person (Hamers, et al., 2004; Moore & Haralambous, 2007). Older people who experience verbal agitation or aggression are more likely to be restrained in bed (Allen, et al., 2005). The reasons for applying physical restraints are to minimise disruption to care therapies, reduce confusion, fall prevention, to reduce wandering, and for behaviour management (Forrester, McCabe-Bender, Walsh, & Bell-Bowe, 2000; Hamers, et al., 2004; Sweeney-Calciano, Solimene, & Forrester, 2003).

Physical restraints are usually applied to manage disruptive behaviours in aged care settings in order to prevent wandering or aggressive older residents from falls (Flicker, 2005). Prevention of falls was the most common reason given for using restraints in nursing homes (Hamers, et al., 2004). However, in spite of high use of restraints

people with dementia had double the fall rate compared to people without dementia living in nursing homes (Doorn, et al., 2003). Additionally, inappropriate application of restraints can produce negative consequences, which include physical and psychological harm. Physical restraints create a physical problem such as incontinence, constipation, pressure ulcers, loss of strength and the ability to walk and dependence in activities in daily living (Evans, et al., 2003). In addition, confusion, distress, anger, fear, disassociation and poor image are related to emotional impacts; both problems can affect quality of life in people with dementia (Flicker, 2005; Lee, et al., 2003; Weiner, et al., 2003)

A Dutch study found that 49% of residents in RACF were restrained and about 90% of restrained residents had been restrained as a routine measure for longer than three months (Hamers, et al., 2004). On the other hand, Noy and Koch (2006) found that reducing restraints required normalising the risk, and for the changing of the organisational culture to be supportive of restraint-free care and better collaboration between nurses, family, and other healthcare professionals and institutions. Although the purpose of utilising physical restraints is for older residents' safety, there is no strong evidence that physical restraints can prevent resident injuries (Wang & Moyle, 2005). Many studies concluded that nursing staff need more education about physical restraints and alternative interventions to be used in the care of older people with dementia (Nay & Koch, 2006; Wang & Moyle, 2005).

**2.4.1.1 The ethics and strategies of using physical restraints**

Although safety is a primary factor for using restraints in people with dementia, applying physical restraints to these people can be a dilemma in acute settings and RACF (Moyle, Borbasi, Wallis, Olorenshaw, & Gracia, 2010). Organizational issues, such as the shortage of staffing levels, poor environment and the stress from relatives also indicate the purpose of restraint use (Lee, et al., 2003; Weiner, et al., 2003). In acute hospital settings, the one–on-one care environment is predominately concerned with preventing falls and managing agitation of confused older patients (Moyle, et al., 2010). Professional caregivers often have a limited understanding of strategies they can use in place of restraint use and rather than trying to understand the patient's perceptive they may limit their social interaction with a patient as a means to manage disruptive behaviours (Flicker, 2005; Gastmans & Milisen, 2006; Moyle, et al., 2010).

Staff may experience conflict between patients' autonomy and the obligation to provide a safe environment. However, as previously indicated there is no strong evidence to support the use of physical restraints for safety (Flicker, 2005). Although restraint use often focuses on preventing physical harm to older people, older people and those also with dementia also have the right to make their own decision in regard to restraint. In addition, professional caregivers need to respect the dignity of older people and this should always be considered before using physical restraints (Flicker, 2005; Gastmans & Milisen, 2006; Moyle, et al., 2010).

Before making a decision for the use of restraints, a review from medical officers and nursing staff is necessary (Flicker, 2005; Gastmans & Milisen, 2006). Older people for whom restraint is used need to have a documented rationale, intended duration and alternative interventions already offered (Flicker, 2005). A full explanation for older people involved is also required. During the period of restraint use, nursing staff should check the person every 30 to 60 minutes; furthermore, restraints must be removed at least once hourly. Physical condition and adverse effects such as pressure ulcers, hydration, elimination and social interaction need to be monitored regularly (Flicker, 2005; Gastmans & Milisen, 2006). Clear guidelines for restraint use, regular training and education programs can also assist nursing staff to eliminate restraint use (Flicker, 2005; Weiner, et al., 2003).

### 2.4.2 Pharmacological Approach

Chemical restraint is an intentional use of medication to sedate a person's behaviour (NSW Health Department, 2000). Antipsychotics are generally applied in treating people with schizophrenia or bipolar disorder. These people are unable to distinguish their imagination from reality (Banerjee, 2009). People with dementia may experience similar symptoms in some stages of the dementia syndrome; therefore, medical practitioners may prescribe antipsychotics to treat behavioural and psychological symptoms of dementia (BPSD) for people with dementia. A survey by Greve and O'Connor in Australia (2005) reported that psychiatrists preferred atypical antipsychotics to treat BPSD including psychosis, verbal abusiveness, physical aggression, sexual disinhibition, sundowning and persistent yelling.

The principal drugs used in the treatment of aggressive behaviour in older people are

antipsychotics, sedatives, lithium, beta blockers and oestrogen (Kyomen & Whitfield, 2008; Schneider, Dagerman, & Insel, 2006). In Sydney, an exploration of neuroleptic drug use in nursing homes found that although olanzapine, risperidone and haloperidol were the most common neuroleptic drugs administered to people with dementia, 80% (n = 463) of the nursing home residents did not have a diagnosis of schizophrenia (Snowdon, Day, & Baker, 2005). Unnecessary use of neuroleptics is of concern as older people are more sensitive to the side effects of antipsychotics compared with younger people (Banerjee, 2009).

Haloperidol is significantly effective against prominent aggression; however, there is no evidence that the drug is also effective in relation to agitation (Lonergan, Luxenberg, Colford, & Birks, 2002). Moreover, people having long-term therapy with haloperidol of more than six weeks or a higher dose of more than 2mg a day are more likely to have side effects than when they have short-term therapy (Lonergan, et al., 2002). Haloperidol and chlorpromazine are typical antipsychotics found to be associated with increased death rates (Hollis, et al., 2007). Because of marked extrapyramidal side effects, such as akathisia, rigidity and tardive dyskinesia, people with Lewy body dementia and Parkinson's disease should not be treated with haloperidol (Maher, 2006).

Due to a decrease in extrapyramidal symptoms, atypical antipsychotics are recommended. Risperidone has been found to significantly improve disruptive behaviours in people with dementia (Frank, Kleinman, Ciesla, Rupnow, & Brodaty, 2004; Kurz, Schwalen, & Schmitt, 2005; Rabinowitz, Katz, Deyn, Greenspan, & Brodaty, 2007). However, studies have reported that atypical antipsychotics, such as risperidone and olanzapine could have an increased risk of a cerebrovascular adverse event and metabolic syndrome (Schneider, et al., 2006). Orthostatic hypotension and weight gain are associated with the side effects of quetiapine (Maher, 2004).

Sedatives include benzodiazepines, barbiturates and related drugs, such as chloral hydrate. Benzodiazepines are useful to treat anxiety in patients with alcohol or drug withdrawal; however, it may also increase risk of aggravated confusion and over-sedation (Maher, 2006). Prolonged use of high doses of benzodiazepines may result in confusion, dependency or exacerbation of concomitant depression. In addition,

research has shown that benzodiazepines may increase the risk of hip fracture in older people by up to 24% (Wagner, et al., 2004). A low risk of side effects such as short-acting lorazepam and oxazepam are suggested to treat behavioural disturbances in people with dementia (Maher, 2004). Lithium and beta blockers have little evidence in efficacy for treating behavioural and psychological symptoms of dementia (BPSD) and have significant adverse effects (Kyomen & Whitfield, 2008). Therefore, these medications are not often prescribed and then usually only if other treatments have failed.

Pharmacological treatment is often used by professional caregivers to prevent agitation and aggression in older people with dementia. A UK study found nursing staff who received training and support, were lesser users of neuroleptic drugs (23%) compared to other nursing staff (42%) (Fossey, Ballard, & Juszczak, 2006). The findings also indicated that reducing neuroleptic drug use did not increase aggression in people with dementia (Fossey, et al., 2006). The authors concluded that chemical restraints should not be a routine treatment of behavioural symptoms and nursing staff could consider psychological and social interventions before administering pharmacological treatment to people with dementia (Fossey, et al., 2006).

Given the poor evidence for the benefits of pharmacological treatment of restraint and their side effects, CAM modalities have received more attention in recent years in the management of disruptive behaviours in people with dementia (Andrews, 2002; Ballard, et al., 2002; Bowles, et al., 2002; Holmes, et al., 2002; Kilstoff & Chenoweth, 1998; Lin, et al., 2007; Nguyen & Paton, 2008; Remington, 2002a; Smallwood, et al., 2001; Snyder, et al., 1995a; Tindle, et al., 2005; Webber, 2003; Woods, et al., 2005). CAM modalities such as aromatherapy and massage are commonly used in the management of disruptive behaviours in people with dementia (Ballard, et al., 2002; Beshara & Giddings, 2002; Bowles, et al., 2002; Brooker, et al., 1997; Gray & Clair, 2002; Holmes, et al., 2002; Kilstoff & Chenoweth, 1998; Kim & Buschmann, 1999; Lin, et al., 2007; MacMahon & Kermode, 1998; Remington, 2002a; Remington, 2002b; Sansone & Schmitt, 2000; Smallwood, et al., 2001; Snow, et al., 2004; Snyder, et al., 1995a, 1995b; Woods, et al., 2005). The following chapter will discuss CAM and its use in further detail.

## 2.5    Summary

The chapter background presented an overview of the different types of dementia, described disruptive behaviours associated with dementia, and their physical and chemical management in the clinical field. The most common form of dementia is Alzheimer's disease (AD) and memory loss is the first symptom. Over 60% of people with dementia experience behaviour disturbances at some stage such as agitation and aggression. Verbal agitation is the most commonly reported disruptive behaviour in people living in nursing homes; in addition, physical aggression is the most difficult behaviour for nursing staff to tolerate. Nursing staff often use bed rails, waist belts and antipsychotic medication to restrain older people with dementia. However, these treatments may increase the risk of falls and agitation. CAM such as aromatherapy and massage have been shown to decrease disruptive behaviours in people with dementia. The following chapter presents the theoretical framework of the current study and discusses the CAM literature related to aromatherapy and hand massage and their role in the management of disruptive behaviours.

# CHAPTER 3
# LITERATURE REVIEW

## Chapter Overview

This review focuses on two main areas. First, the theoretical basis of aromatherapy and hand massage is used to structure the current study. The chapter explains how essential oils affect the olfactory and limbic system, and the relevant behavioural and cognitive changes in people with dementia as a result of exposure to lavender oil. Hand massage is presented in terms of its effect on relieving stress through the hypothalamus and improving physical and psychological status. Second, research literature reporting the effectiveness of aromatherapy and hand massage in the management of disruptive behaviours is critiqued. The literature reviewed in this chapter was identified via databases including Medline, Cinahl, ProQuest, Pubmed and Cochrane. The gaps identified in the review of the literature is also presented at the end of the chapter. This section also emphasises the important elements of the current study as a means to overcome the gaps in the literature.

## 3.1    Theoretical Basis for Aromatherapy and Hand Massage

### 3.1.1   The Olfactory System

The rhinencephalon is the important olfactory region of the brain and consists of the following structures: olfactory nerve rootlets, olfactory bulb, olfactory tract, olfactory striae, and primary olfactory cortex (Crossman & Neary, 2005). The olfactory system detects odorants that are inhaled through the nose and then contact the main olfactory epithelium of the nasal cavity, which contains various olfactory receptors (Crossman & Neary, 2005). The receptor axons assemble into numerous small fascicles and enter the cranial cavity through the foramina of the cribriform plate of the ethmoid bone; after that, these fascicles attach to the olfactory bulb on the inferior surface of the frontal lobe (Crossman & Neary, 2005).

Olfactory information is preliminary processed in the olfactory bulb which contains interneurones and large mitral cells. First, olfactory nerve fibres terminate in the olfactory bulb, then second-order fibres travel in the olfactory tract and terminate in

the primary olfactory cortex of the uncus in the temporal lobe (Crossman & Neary, 2005).

The olfactory information is conveyed to the frontal association areas involved in planned behaviour and also to the inferior temporal association areas, where information can reach supramodal status and meaning (Crossman & Neary, 2005). The limbic system is located on the medial rim of the brain (Crossman & Neary, 2005). When the information enters the limbic system, amygdala and hippocampal formation receive the information via the entorhinal area. The amygdala appears to provide an affective connotation to experience, when the information flows into the hippocampal formation which links to previous experience and then to remembering and learning (Crossman & Neary, 2005). The hippocampus plays a role in declarative or associative memory, attention and alertness, and behavioural endocrine and visceral functions (Afifi & Bergman, 2005).

The limbic system functions in five areas including emotional behaviour, memory, homeostatic responses, sexual behaviour and motivation (Afifi & Bergman, 2005). Moreover, the limbic system is strongly connected to the hypothalamus, which is essential for adaptive behaviour such as the ability to learn new responses based on previous experience from memory (Crossman & Neary, 2005). However, the nervous system is affected by aging; after age 50, the number of brain cells undergoes degenerative changes, which decrease by about 1% per year. As a result the hypothalamus is less effective at regulating body temperature, and furthermore, the cerebral cortex undergoes a 20% neuron loss (Lippincott Williams & Wilkins, 2009).

### 3.1.2 Behavioural and Emotional Changes

Odours have been found to have an effect on behavioural and cognitive changes in people. Studies have suggested that essential oils can affect the modulation of the central neurotransmitter system (Heuberger, Hongratanaworakit, Böhm, Weber, & Buchbauer, 2001; Komoria, Fujiwarab, Tanidac, Nomuraa, & Yokoyamad, 1995). For example, common smells affect the human autonomic nervous system (ANS), people can have immediate physiological changes to their blood pressure, muscle tension, pupil dilation, heart rate and skin temperature while the olfactory system is stimulated by odours (Heuberger, et al., 2001). Heart rate is associated with the pleasantness

factor; unpleasant odours can increase the human heart rate and skin conductance (Bensafi, Rouby, Farget, Vigouroux, & Holley, 2002). Furthermore, odours significantly influence human mood (Heuberger, et al., 2001). Unpleasant odour often results in negative mood state and pleasant odour induces positive mood (Robin, Alaoui-Ismaili, Dittmar, & Vernet-Maury, 1999). Pleasant scents can improve self efficacy and working performance (Baron, 1990; Baron & Bronfen, 1994). Essential oils such as lavender and melissa have been used to treat depression, anxiety, and some forms of cognitive disorders, as well as insomnia and stress-induced ailments (Battaglia, 2002; Komoria, et al., 1995). The effects of essential oils may help patients to reduce dose and the side effects of consumed antipsychotic medication.

Odours affect both physical and emotional conditions, such as the subjective experiences of people (Heuberger, et al., 2001). Odours also elicit memories that induce a general hedonic tone of subjective experience that can bias the retrieval of happy and unhappy memories (Ehrlichman & Halpern, 1988). People who experience a positive mood are more likely to recall positive memories than people who experience a negative mood (Ehrlichman & Halpern, 1988). Therefore, odours such as essential oils play an important role in people's lives.

### 3.1.3  Olfactory Function in People with Dementia

A decline of the olfactory function is associated with normal ageing, medication, surgical treatments environmental exposure and diseases, such as AD and Parkinson disease (Lang, et al., 2006; Schiffman, 1997). Older people have difficulty in identifying familiar odours which may result from neuropathological changes (Gilbert & Murphy, 2004; Wilson, Arnold, Schneider, Tang, & Bennett, 2007). In the olfactory system the pyriform cortex is important for connecting odours to the hypothalamus. If the pyriform cortex is damaged, this leads to an impairment in odour identification at the sensory or perceptual level (Luzzi, et al., 2007).

Olfactory dysfunction is commonly associated with AD and has been well described as an early sign in dementia with Lewy bodies (DLB) (Gilbert, Barr, & Murphy, 2004; Luzzi, et al., 2007; Olichney, et al., 2005; Royet, et al., 2001; Suzuki, Tamamoto, et al., 2004). In some studies, older people with AD showed a decrease in odour familiarity and identification scores and these were often lower than other older

people and younger groups (Royet, et al., 2001; Suzuki, Tamamoto, et al., 2004). Furthermore, Gilbert et al. (2004) discovered that people with Lewy Bodies Dementia showed poorer odour detection ($p<.05$) than people with AD. In a study of 89 participants with AD and 17 participants with Lewy Bodies Dementia, the researchers found that participants with Lewy Bodies Dementia had a 65% increased prevalence of anosmia as compared with participants with AD (Olichney, et al., 2005). A longitudinal cohort study in USA with 589 community-dwelling older people revealed that odour identification scores predicted the development of mild cognitive impairment (MCI) risk (Wilson, Schneider, et al., 2007).

However, there are also studies such as Rentowl and Hanning (2004) that reported no significant relationship between odour identification deficit and dementia. A pilot study of 53 participants aged 62 to 86 years investigated the relationship between odour identification and postoperative cognitive dysfunction (Rentowl & Hanning, 2004). The researchers found there was no association between odour identification ability and postoperative cognitive dysfunction ($p = 0.1444$). The small sample size is a limitation of this study and may have influenced the lack of significant results. Although the relationship between olfactory dysfunction and dementia is uncertain in some studies, olfactory tests have been suggested to be applicable as one of the measurements in early diagnosis of demenita.

### 3.1.4   Aromatherapy for Improvement of Cognitive Function

Pharmacological treatment of dementia focusses on improving cognitive function. Cholinesterase inhibitor (CI) drugs, such as donepezil, galantamine and rivastigmine are commonly used in the treatment of people with AD; however, with side effects occurring from an increase of dose, a regular review of these medications is required (Bowles, 2006; Kidd, 2008). The aromatherapy literature showed some essential oils have an effect on cognitive functions. Lemon balm or melissa (*Melissa officinalis*), rosemary (*Rosmarinus officinalis*), sage (*Salvia officinalis*) and lavender sage (*Salvia lavandulaefolial officinalis*) seem to enhance cognition with acetylcholinesterase (AChE) inhibition (Akhondzadeh, et al., 2003a, 2003b; Kennedy & Scholey, 2006; Perry, Bollen, Perry, & Ballard, 2003; Scholey, et al., 2008).

A double-blind, placebo-controlled, and five-period crossover design by Scholey et al.

(2008) examined twenty healthy older volunteers with cognitive function using different dosages of sage capsules (167, 333, 666 and 1332mg). Cognitive outcome was measured by the Cognitive Drug Research computerised assessment battery which covered tasks such as memory, recognition, and reaction time. After the first visit on practice day, older volunteers subsequently attended the laboratory five times for five testing sessions including a pre-dose test 1, 2.5, 4 and 6 hours following the treatments. A seven day wash-out period occurred between each visit. The results showed a significant improvement in secondary memory performance with a low dose of 167mg at 2.5 and 4 hours post-dose and 333mg at all post-dose time points. Additionally, older people receiving 333mg of sage showed an improvement in tasks of attention. This may indicate a therapeutic effect did not require a high dosage of essential oil. Besides the learning and Hawthorne effects, the flaws of this study were that level of IQ and education have the potential to affect the volunteers' performance. Although these drawbacks may indirectly influence the results, the findings suggest further research and in particular in people with dementia is required.

Perry et al. (2003) investigated the tolerability of increasing the oral dosage of combined 50µl lavender sage and 50µl sunflower oil for six weeks. Eleven residents with mild to moderate AD aged between 76 and 95, had a Mini-Mental State Examination (MMSE) score of between 10 and 26, and Neuropsychiatric Inventory (NPI) scores of 0 in agitation and irritability. Older residents received one capsule per day in the first week, two capsules per day in the second week then three capsules per day between week 3 and week 6. Primary outcome was measured by vital signs, blood samples and neurological test at baseline and after six weeks of treatment. At the end of week 6, the mean score of the MMSE had an increase of +0.46; moreover, NPI scores decreased by three points. Although a drawback of the clinical trial was in having no placebo group, the results indicated that essential oils had an effect on behavioural management.

Akhondzadeh et al. (2003a, 2003b) assessed the cognitive effects of melissa and sage oils in older residents with mild to moderate AD. Although melissa and sage were reported in two different studies, the study design, setting and recuitment were the same. Forty-two older residents aged between 65 and 80 with at least 6 months cognition decline had their cognitive test fitting criteria, such as Alzheimer's Disease

Assessment Scale-Cognition (ADAS-cog) $\geq$12 and Clinical Dementia Rating Scale (CDR) $\leq$ 2. Medication for dementia treatment was discontinued during the study period. During a four-month melissa randomized trial, an experimental group (n= 20) received 60 drops of melissa oil per day compared with the placebo group (n= 15) (Akhondzadeh, et al., 2003a). In the experimental group, older residents had a significant cognitive improvement after receiving 16 weeks of melissia oil. The initial score of the ADAS-cog decreased from approximately 27 to 21 (mean= -6.40, Sd= 1.66, $p<$ 0.0001) as compared to the older residents in the placebo group (mean= 5.60, Sd= 1.40). The clinical dementia rating-sum of the boxes scale (CDR-SB) also indicated a significant effect on older residents in the melissa group (mean= -1.92, Sd= 1.48) when compared with older residents who received the placebo treatment (mean= 1.03, Sd= 0.54).

Similiarly, an impressive result was achieved on the sage study (Akhondzadeh, et al., 2003b). Over the same four month period, older residents (n= 15) who received sage treatment improved cognitive function more than older residents in the placebo treatment (n= 15). At the end of the 16 week treatment, the sage treatment had enhanced the cognitive function of older residents on the ADAS-cog ($p=$ 0.03) and CDR-SB ($p<$ 0.003). Although there were some side effects of the essential oils in both studies, melissa and sage may have an additional benefit in managing agitation.

These two studies reported a significant notable outcome in the improvement of cognition; however, some drawbacks are of concern. First, as the ADAS-cog was measured by a neurologist every two weeks, older residents may possibly develop a learning effect (Bowles, 2006; Le Bars, et al., 1997). Second, an ethical issue of whether to discontinue other drugs for dementia treatment needs to be considered. Third, the method of administering 60 drops of essential oils was not discussed. The extract of essential oils from 1:1 alcohol: dried leaf tincture did not provide a dose of known concentration. It assumed the high dose of essential oils was taken by older residents who were unable to tolerate the treatment and therefore side effects occured. In addition, the content of the placebo was not reported. Finally, a double-blind trial of ginkgo consisted of 236 older people with mild to severe AD; the mean score of ADAS-cog had only a 1.7 point difference between the treatment and placebo groups after 52 weeks of intervention (Le Bars, et al., 1997). In Akhondzadeh's study, a great

decline in the ADAS-cog scores was unusual in a clinical trial of 16 weeks with a small sample size of 30 to 35 (Kennedy & Scholey, 2006).

Although the above studies presented a cognitive improvement as a result of aromatherapy, another study showed no significant difference between cognition and aromatherapy. Bowles (2006) tested the cognitive effects of aromatherapy on 72 people with mild to moderate dementia from ten RACF in a double-blind, controlled study for 18 weeks. The study consisted of two treatment groups and one control group. Eucalyptus oil, cypress oil and lime oil were administered to the active group (Treatment A) to inhibit AChE, mandarin oil, lemongrass oil and ginger oil were administered to the inactive group (Treatment B). These essential oils were mixed with 1.6 ml of aqueous lotion and the control group only used plain lotion. Data were collected from a four-week baseline washout phase, twelve weeks of intervention and two weeks of post-treatment washout. Primary outcome was measured by MMSE and the secondary outcome was obtained from the Nurses' Observation Scale for Geriatric Patients (NOSGER), which measures mood, memory, ADL and disruptive behaviours. There was no significant difference reported between the three groups in the MMSE and NOSGER scores during the study period. However, post intervention a small number of residents (10/72) increased by 3 points their MMSE score from a mean score of 15.8 (Sd= 4.09) to 19.5 (Sd= 4.03).

### 3.1.5  The Basis of Aromatherapy

The theoretical basis of aromatherapy spray treatment as an intervention relates to the influence of odours on emotions and cognition. It is theorised that components of essential oils, entering the body through the nose and skin pass though two pathways, the mucous membranes and electrochemical signals. First, the mucous membranes absorb these components and circulate in the body then excrete them via organs such as the lungs, liver and kidneys (Price & Price, 1999). Furthermore, there is a direct link between odour and the psyche (Battaglia, 2002; Davis, 1999). The stimulation of smell as an electrochemical signal is transmitted to the limbic area of the brain by the olfactory nerve and may have an effect on mental states via the hypothalamus on the central nervous or endocrine systems (Jellinek, 1999). Emotions such as pain, anger and other feelings are associated with the primary function of the limbic system. Moreover, some memories are associated with smells; stimulation of these smells may

trigger receptors and evoke memories from the olfactory bulb in the process of memory storage in the hippocampus (see Figure 3.1) (Battaglia, 2002; Brett, 2002; Davis, 1999; Price & Price, 1999). Therefore, it is assumed that essential oils can affect the emotions of people with dementia and may decrease agitation and aggressive behaviours.

Lavender (*Lavandula angustifolia*) and melissa (*Melissa officinalis*) essential oils have been reported to have a sedative effect (Ballard, et al., 2002; Bowles, et al., 2002; Cavanagh & Wilkinson, 2005b; Holmes, et al., 2002; Lin, et al., 2007; Smallwood, et al., 2001; Standen, 2006; Standen & Myers, 2004). A recent study also reported lavender oil has additional effects such as anti-inflammatory, immune stimulation and antioxidant (Standen, 2006; Standen & Myers, 2004). Lavender oil is a popular complementary therapy and a compatible addition to many other complementary therapies and cosmetic products (Battaglia, 2002; Cavanagh & Wilkinson, 2005b). Lavender has been shown to be a safe essential oil for use on babies and pregnant women with no record of adverse reaction (Blackwell, 1991; Buckle, 1993; Tisserand, 1990). Therefore, lavender oil is asserted to be safe for use on older people with dementia. On the other hand, Melissa is a very expensive essential oil that is often blended with various other essential oils (Purchon, 2002; The International School of Aromatherapy, 1993). Furthermore, blended oil is not suitable for the purpose of this research, which seeks to investigate the effect of one essential oil. Additionally, lavender oil has been ranked as having the most sedative effect of 42 essential oils and is widely used in RACF (Buchbauer, Jirovetz, Jager, Plank, & Dietrich, 1993). Moreover, 6mls of lavender oil costs between $3.30 and $10.89, compared with the same amount of pure melissa oil which costs $77.00 (New Direction Australia, 2010). Therefore, lavender oil is significantly cheaper than melissa oil and a price that is more affordable for families and long term care facilities (Battaglia, 2002).
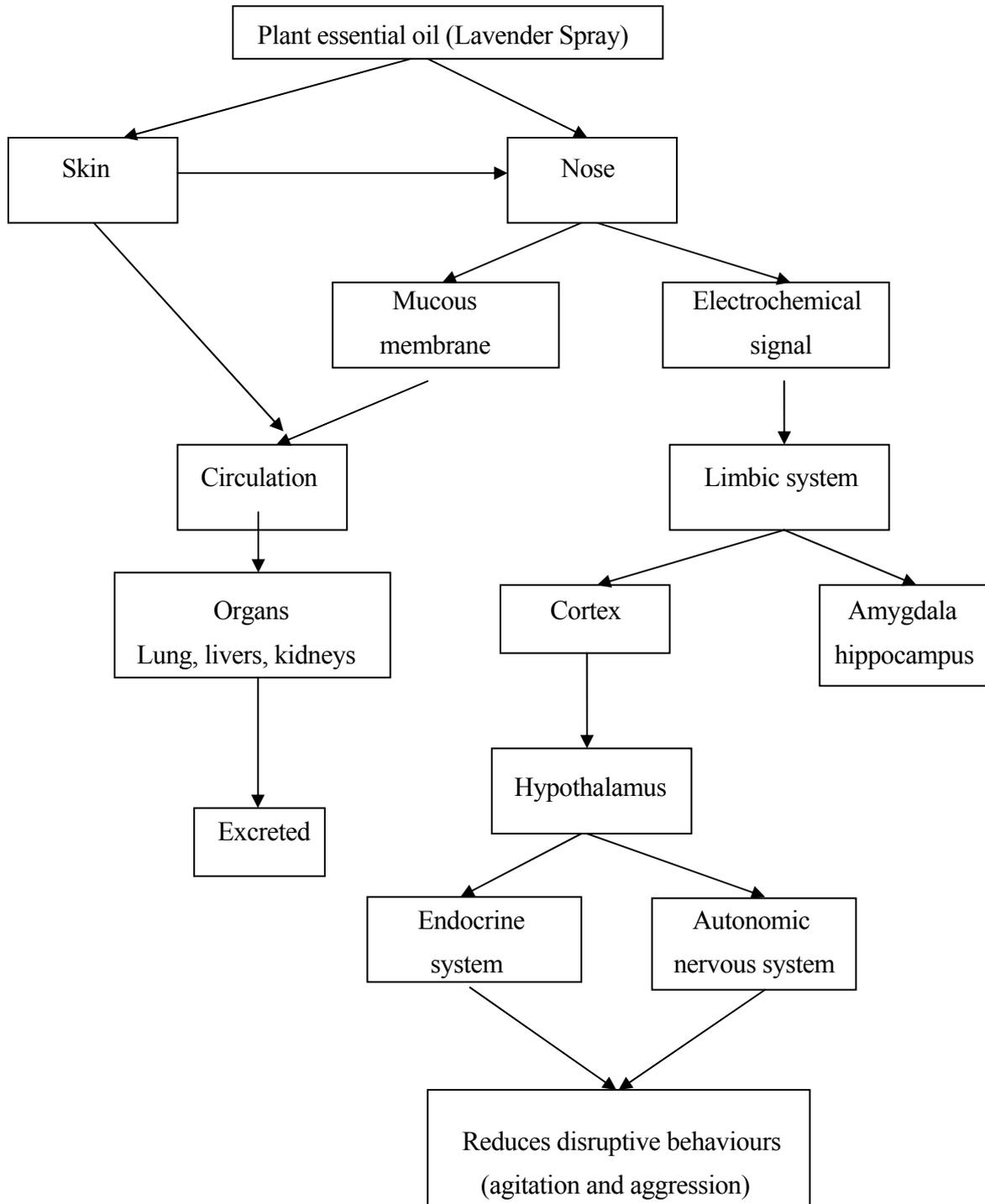
**Figure 3.1: A modified diagram of the pathways of effects for lavender spray in a clinical aromatherapy context (Battaglia, 2002, p. 87; Price & Price, 1999, p. 92)**

### 3.1.6  The Basis of Hand Massage

Massage is usually applied to the skin, fascia, muscles, tendons and ligaments of the body and includes touching, soft pressing, squeezing, rubbing, handling or kneading with the hands (Tuchtan, et al., 2004). Massage has a positive effect in the individual; the action is therapeutic. Therefore, the term therapeutic massage has been applied to all methods and forms of massage (Tuchtan, et al., 2004).

When a person experiences pain, anxiety, stress or has a strong emotional reaction, the hypothalamus is stimulated to transmit impulses to the spinal cord and results in the alarm response (Holey & Cook, 2003). Pain produces in relfex muscle contraction, tense and spasm, which restricts the amount of oxygen in blood circulation and creates more pain into a repeated pain cycle (Salvo, 2003). Older people can suffer from chronic pain and this may also turn into stress. Stress acts to arouse the sympathetic branch of the autonomic nervous system (ANS); the changes in the body include an increase in blood levels of glucose, cortisol and adrenaline. As a result of blood pressure, blood flow to skeletal muscles, muscle tone and heart rate also increase.

Massage achieves the opposite effect, which reduces the physiological response to stress and decreases the output of adrenocorticotrophic hormone (ACTH) (see Figure 3.2). Massage provokes a decrease of activity in the sympathetic branch and an increase of activity in the parasympathetic branch of the ANS in order to return the body to a normal baseline state of homoeostasis (Braun & Simonson, 2005; Holey & Cook, 2003). Hand massage treatment as an intervention is acceptable as a common physical contact for older people with dementia (Kolcaba, Schirm, & Steiner, 2006; Kyle, 1999). After massage therapy, people with dementia are expected to have lower anxiety and less pain, and their disruptive behaviour decreases compared with baseline measures. Therapeutic hand massage treatment has numerous psychological and physical benefits for nursing home residents and it is assumed that hand massage treatment may provide comfort and reduce agitation and aggression in older residents with cognitive impairment.

Massage

Act through the
brain (hypothalamus)
reduces stress stimulation

in
sympathetic centres

in
anterior pituitary to
decrease secretion of ACTH

lower stimulate adrenal
medulla to decrease
secretion of adrenaline

lower ACTH in blood

lower hypertrophy
of adrenal cortex and
decrease secretion of
glucocorticoids

Reduces disruptive behaviours

(agitation and aggression)
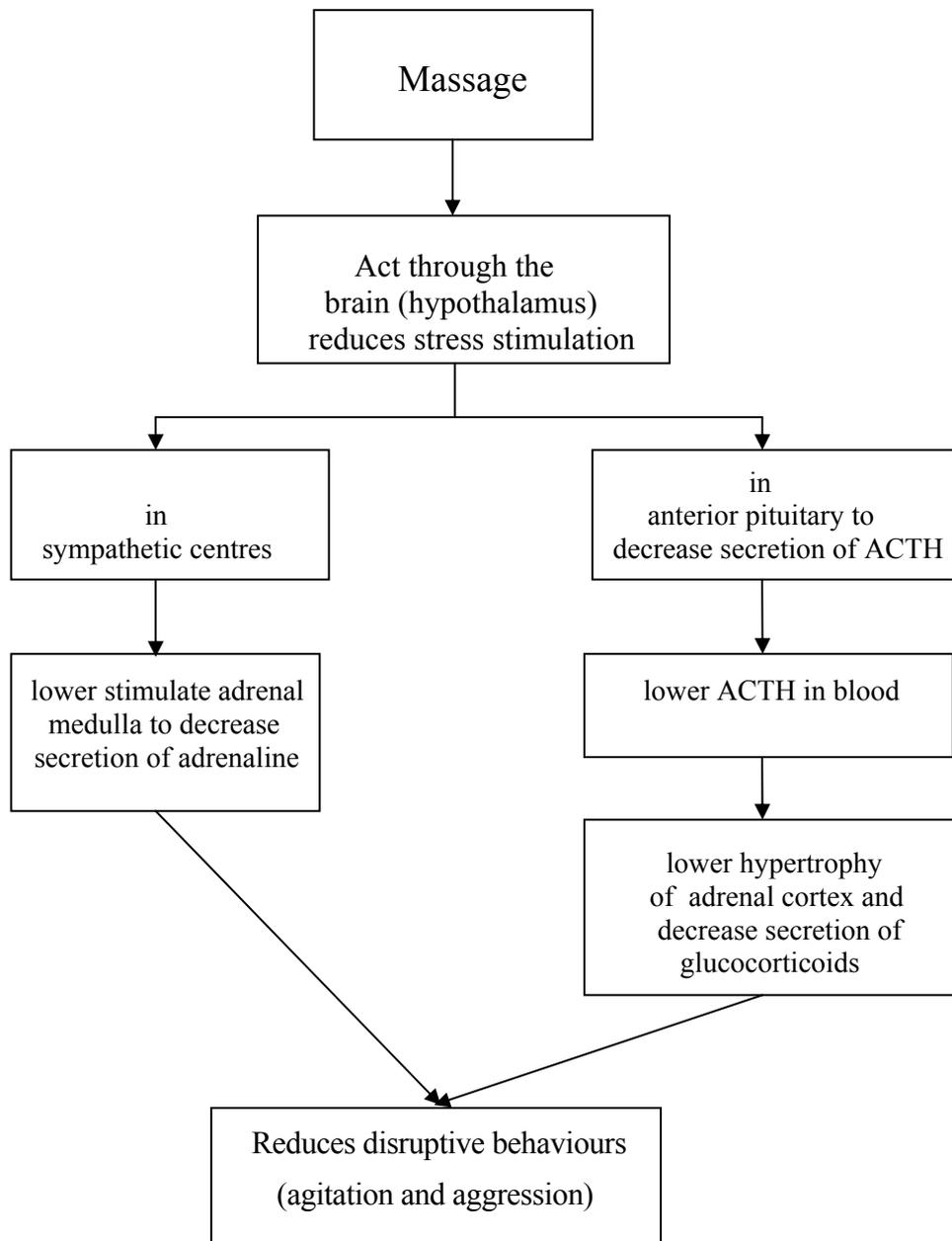
**Figure 3.2: A modified diagram of the pathways of effects for hand massage in older people (Holey & Cook, 2003, p. 255)**

## 3.2 Aromatherapy and Touch Massage Research

In recent years aromatherapy has been introduced as a sensory stimulation approach to modify behaviour disturbances in people with dementia. Aromatherapy is often used in combination with touch massage. A computerised search of the databases ProQuest Nursing and Allied Health Source, Cinahl, Medline, Pubmed and the Cochrane Library was conducted using the keywords *agitation*, *aggression*, *dementia*, *aged care*, *nursing home*, *CAM*, *aromatherapy* and *hand massage*. Study inclusion criteria for paper selection include:

1. dementia or cognitive impairment
2. disruptive behaviours such as agitation and aggression
3. aged 65 and over
4. English publications
5. clinical trials
6. methods of aromatherapy, excluding oral application
7. methods of massage or therapeutic touch
8. quantitative outcome measures of behavioural and psychological symptoms.

A review of the literature was intended to critique previous studies and identify how aromatherapy and massage was applied in the dementia field. Therefore, all relevant studies in this area were reviewed. Nineteen studies were identified from 1995 to 2009, including eleven aromatherapy studies and seven touch massage studies. The design, treatment used, measurement, outcomes and limitations of these studies are shown in Table 3.1 and Table 3.2.

**Table 3.1 Aromatherapy studies exploring disruptive behaviours in people with dementia**

| Author/Country | Study design / Setting | Treatment | Measurement | Outcomes | Limitations |
|---|---|---|---|---|---|
| Lin et al., 2007 Hong Kong | A cross-over randomized trial<br><br>70 Chinese older adults from care and attention homes. (moderate to severe dementia)<br><br>2 treatment groups -<br>A: activity group- lavender oil<br>B: placebo group- sunflower oil | Essential oil was applied to cotton and placed in an aroma diffuser. 2 aroma diffusers were placed either side of the subjects's pillow at night-time sleep for at least 1 hour each night<br><br>3 weeks treatment/placebo then 2 weeks washout, then swap over for 3 weeks | Chinese version of the Mini-Mental State Examination (MMSE)<br><br>Chinese version of Cohen-Mansfield Agitation Inventory (CCMAI)<br>Chinese version of Neuropsychiatric Inventory (CNPI) at assessed; week 0, weeks 3, 5, 8 weeks | A decrease of CCMAI mean score from 24.68 to 17.77, and mean CNPI scores decreased from 63.17 to 58.77 | 1. Staff collecting data were not blinded to the treatments offered<br>2. Did not include all types of dementia |
| Snow et al., 2004 USA | Intervention study<br><br>7 participants in LTCF (Severe dementia)<br><br>3 treatment groups -<br>A. lavender oil<br>B. thyme oil<br>C. unscented grapeseed oil | Baseline/4 weeks<br>Treatment time/10 weeks, (ABCBA- 2 weeks for each of the oil), Pos-test/2 weeks<br><br>Oil placed on an absorbent sachet + pinned on participants' shirts near the collarbone every 3 hours | Olfactory function test<br><br>Severe Impairment Rating Scale (SIRS), MMSE, CMAI were collected every 2 days and qualitative behavioural observation | Neither lavender or thyme decreased participants' agitation<br><br>There was no difference between participants with less intact olfactory function | 1. Small sample size<br>2. Unclear whether blinding of participants' or data collectors occurred<br>3. No mention of whether concomitant medication was used |

**(Continued)**

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**Table 3.1 (Continued)**

| Author/Country | Study design / Setting | Treatment | Measurement | Outcomes | Limitations |
|---|---|---|---|---|---|
| Ballard et al., 2002 UK | Double blind Placebo controlled trial<br><br>71 participants in LTCF (severe dementia)<br><br>2 groups -<br>A. activity group-<br>  lemon Balm (Melissa)<br>B. placebo group-<br>  sunflower oil | Aroma oil/placebo combined with a base lotion, applied to face + arms twice/daily/4 weeks | Physical examination, Barthel scale, Clinical Dementia Rating Scale (CDR) and Neuropsychiatric Inventory (NPI)<br><br>Agitated behaviours were recorded by CMAI and an additional Dementia Care Mapping (DCM)<br><br>Activities recorded every 5 mins/6hrs period/weekly/4 weeks | 60% of active and 14% of placebo groups had a 30% reduction in CMAI score<br><br>Overall improvement was 35% in active and 11% in placebo group | Residents' behaviour may have been influenced by external factors (eg. social contact) |
| Beshara et al., 2002 USA | Intervention: baseline and post report study<br><br>10 older people in LTCF<br><br>Blended oils | Two blends of essential oils were diffused via fans in residents' rooms from 9am to 5pm, six days a week/six months | Standardized Minimum Data Set assessment tool (MDS) recorded $1^{st}$, $3^{rd}$ and $6^{th}$ months | A decrease of > 50% in disruptive behaviour | 1. A wide range of essential oils<br>2. The lack of a standardised formula concentration<br>3. Small sample size<br>4. No participants' levels of cognitive impairment |

**(Continued)**

**Table 3.1 (Continued)**

| Author/Country | Study design / Setting | Treatment | Measurement | Outcomes | Limitations |
|---|---|---|---|---|---|
| Bowles et al., 2002 Australia | Cross-over design<br><br>56 participants LTCF (most severe dementia)<br><br>Blended oils<br><br>2 groups -<br>A. touch + oils<br>B. touch + no oils | Essential oils blended into a cream and massaged onto the neck, shoulders, back and arms of each subject for 5 minutes/5 times/day<br><br>Wash out 1 week, Touch/ no oils on both groups in week 1-2. Group A touch + oils and Group B touch + no oils in weeks 3-6, then groups swap over in weeks 7-10 | MMSE collected at baseline and after treatment<br><br>Resistance to nursing care: frequency and severity of occurrence were recorded for each trial period | 7 subjects showed an improvement of MMSE<br><br>A significant decrease between the frequency and severity scores in both groups | 1. Data collectors were not blinded to the treatment groups<br>2. Large missing data set (36%)<br>3. No established baseline<br>4.No formal inter-rater reliability testing |
| Gray et al., 2002 USA | Intervention study<br><br>13 participants from 2 care facilities<br><br>4 interventions -<br>A. lavender<br>B. sweet orange<br>C. tea tree<br>D. control group (no aroma oil) | Aroma oil soaked in cotton ball and attached to clothing | Clients were videotaped to determine whether resistive behaviours occurred in each 10 second interval | No statistically significant outcomes across all groups | 1. Unclear if data collectors were blinded<br>2. Duration of study unclear<br>3. Participants' levels of cognitive impairment not documented |

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**Table 3.1 (Continued)**

| Author/Country | Study design / Setting | Treatment | Measurement | Outcomes | Limitations |
|---|---|---|---|---|---|
| Holmes, et al., 2002 UK | A placebo controlled trial with blinded observer<br><br>15 participants from a long- stay psychogeriatric ward (severe dementia)<br><br>2% lavender oil water (placebo) | 2% of lavender oil or water was diffused for 2 hours (4-6pm), 5 treatments each of placebo and lavender oil were given over a period of 2 weeks period | Pittsburgh Agitation Scale (PAS) was collected in the second hour of each treatment | 60% showed modest improvement , 33% showed no improvement and 7% showed worsening of agitated behaviour compared with placebo | Small sample |
| Smallwood et al., 2001 UK | A single blind randomized study<br><br>21 participants from a hospital ward (most severe dementia)<br><br>3 groups (lavender oil)<br>A. aroma oil + massage<br>B. plain oil + massage<br>C. aroma diffuser + Conversation | Treatments were given twice/weekly | A baseline of behaviours was video recorded over a two-week period<br><br>Behaviours were videoed for 2 x 15 minutes/10-11am, 11-12noon, 2-3pm, 3-4 pm/day | Aromatherapy massage and lavender oil decreased behaviour problems between 3pm + 4pm | 1. Unclear length of intervention phase<br>2. No explanation which part of body the treatment was applied to<br>3. No concentration of lavender oils reported<br>4. Staff interaction/attitudes might be influenced by video recording<br>5. Small sample size |

**(Continued)**

**Table 3.1 (Continued)**

| Author/Country | Study design / Setting | Treatment | Measurement | Outcomes | Limitations |
|---|---|---|---|---|---|
| MacMahon et al., 1998 Australia | A case study reported<br><br>A single female from a LTCF<br><br>Blended oils | Oil Burner commenced 7am | 2 months baseline Motivational behaviour recorded from 7am-12noon | Increase of motivation from 6.25 (SD = 1.946) to 7.473 (SD = 2.15) | 1. Type of aroma oils used not identified<br>2. No time given when the intervention was performed<br>3. Single participant and no control group<br>4. Level of cognitive impairment not reported |
| Kilstoff et al., 1998 Australia | An action research: pre-post intervention<br><br>16 participants in a dementia day-care center (moderate to severe dementia)<br><br>Blended oils | Blended oils applied to hands for 10-15 minutes/for 18 months | Revised Elderly Person's Disability Scale (REPDs), focus group discussion, memos, filed notes, observation logbooks and In-depth interview pre & post treatment | Positive feedback on relationship between older people with dementia and their family carer, also improved feelings of health and well-being | 1. Complex environmental factors in each client's house<br>2. No statistical test applied<br>3. No control group |
| Brooker et al., 1997 UK | A single-case research design<br><br>4 Participants in a LTCF (severe dementia)<br><br>Lavender oil/ Hand massage/ combination/ No treatment | An aromatherapy fan 30 minutes & lower arm/ hand massage 30 minutes/ over 3 month period including 10 sessions of "no treatment" | Participants were observed for the hour following the treatment session<br><br>Individual observation of agitation | Only 1 participant benefited from the treatment, 2 participants continued with high levels of disturbance | 1. No report of administering time of intervention<br>2. Small sample size<br>3. No dosage of lavender oil reported |

### 3.2.1 Aromatherapy Research for Agitation and Aggression in Dementia

Researchers have reported that aromatherapy has had a significant effect on disruptive behaviour in older people with dementia. MacMahon and Kermode (1998) reported a statistically significant improvement in motivational behaviour by using an oil burner in the room of a 77-year-old woman with a diagnosis of dementia and depression during a four-month single case study. Nursing staff collected the baseline data between 7am and 12 midday based on the following rating: *remains in bed*, *out of bed but refused to cooperate*, *cooperated with encouragement* and *self-initiated activity*. After two months of baseline recording, staff vaporized a blend of essential oils at 7am in the resident's room. They found her activity levels were higher and she was more cooperative with nursing care (MacMahon & Kermode, 1998). The study, however, did not describe the type of essential oils used nor the proportion of essential oils in a blended aromatherapy. Participant's behavioural changes were unclear affected by one or a variety of essential oils. Moreover, the authors did not provide sufficient information, such as how many hours the intervention was performed each day. In addition, there was no standard instrument to measure outcomes. Furthermore, as nursing staff were not blinded, a personal bias could have influenced the results. Moreover, the level of cognitive function and the type of dementia were not reported. A single case design also limits the generalisability of the findings.

Beshara and Giddings (2002) examined ten older people with behaviour disturbance in a long-term care facility (LTCF). They diffused two blends of essential oils; Blend A included tangerine, orange, ylang ylang, patchouli and blue tansy, and Blend B contained basil, cardamom, rosemary, cineol, peppermint, rosewood, geranium, lemon, palmarosa, ylang ylang, bergamot, roman chamomile and jasmine. These essential oil blends were diffused via fans in resident rooms, the nurses' station and the ward lobby from 9am to 5pm six days a week for a six-month trial period (Beshara & Giddings, 2002). The frequency of disturbed behaviour by participants decreased by 50% as recorded in the first, third and sixth months by using the standardized Minimum Data Set assessment tool (MDS). However, the study design was flawed as the intervention (aromatherapy) was not standardised. For example, participants could request to have only one essential oil or not to have fan diffusers in their room (Beshara & Giddings, 2002). In addition the wide range of essential oils and the lack of a standardised formula concentration made the efficacy of specific oils difficult to identify. Participants' levels of cognitive impairment were not

reported; the correlation between cognitive function and effect of aromatherapy was unable to be identied. Also, there was no information about participants' current antipsychotic medication used, which may create difficulty in determining the effects of aromatherapy. Furthermore, the nonrandomized sample and small sample size (n = 10) also limited the results of the study.

In a cross-over randomized trial in Hong Kong (Lin, et al., 2007), seventy Chinese older people with moderate to severe dementia were recruited by blocked randomization with a two-week washout for six-week lavender and sunflower inhalations. Two aroma diffusers were placed at either side of the participants' pillows for at least an hour during sleep time each night (Lin, et al., 2007). Participants were evaluated with the Chinese version of the Mini-Mental State Examination (MMSE), Chinese versions of both the Cohen-Mansfield Agitation Inventory (CCMAI), and the Neuropsychiatric Inventory (CNPI) at baseline. The CCMAI and CNPI measured the participants' agitated behaviours at Week 3, Week 5 and Week 8. After receiving three weeks of lavender inhalation, the total mean scores of CCMAI showed a decrease from 24.68 to 17.77 ($p<.001$); moreover, CNPI mean scores decreased from 63.17 (SD = 17.81) to 58.77 (SD = 16.74). There was no statistical significance in the group having sunflower inhalations (Lin, et al., 2007). The study had difficulty recruiting all sub-types of dementia. In addition, staff were not blinded; the same staff who implemented the intervention evaluated participants' behaviours, and this may have led to bias of results (Lin, et al., 2007). Furthermore, the trial was unable to control variables such as medication use and rehabilition, as aromatherapy was used for adjunct therapy only. Participants continued receiving regular pharmacological treatments or exercise programs. Therefore, the results of participants' improvement may have been affected by these variables, which makes demonstrating the effect of aromatherapy on behaviour difficult.

A number of researchers have found aromatherapy effective when essential oils are combined with massage (Ballard, et al., 2002; Bowles, et al., 2002; Kilstoff & Chenoweth, 1998; Meyer, 1996; Opie, Rosewarne, & O'Connor, 1999; Smallwood, et al., 2001; Thorgrimsen, Spector, Wiles, & Orrell, 2003). In Australia, most aromatherapy educators have chosen massage as the most effective route for administering essential oils to the human body (Standen, 2006; Standen & Myers, 2004). Essential oils appear to promote positive emotional balance and specific physical actions and massage has been shown to

have an effect on improving circulation, joint mobility, and relieving muscle pain and tension (Dunning & James, 2001).

In a single-blind randomized controlled trial, researchers (Smallwood, et al., 2001) allocated twenty-one older people with severe dementia into three groups: aromatherapy and massage, plain oil massage, and conversation and aromatherapy. Participants received the treatment twice weekly. Participants' behaviours were measured using the behavioural categories of Bowie and Mountain (1993). Each participant's behaviours were recorded twice, using a video camera for 15 minutes during the periods 10 - 11am, 11 - 12am, 2 - 3pm and 3 - 4pm, giving a total of two hours of video recordings per day. The researchers found that aromatherapy massage with lavender oil decreased behaviour problems in the 3 - 4pm period (Smallwood, et al., 2001). However, this study was limited by four factors: (1) a small sample size (n = 21); (2) participants' dementia types were not reported; and (3) the investigators did not define the concentration of the lavender oils, the length of the treatment or how it was administered to participants; (4) behaviours were only recorded using a video camera in specific time periods. In addition, a Hawthorne effect may have arisen as the video recording may have also influenced staff interaction with residents and residents' behaviours (Jones, 1992; Polit & Beck, 2008).

In an Australian study, Bowles et al. (2002) tested an aqueous cream that consisted of four essential oils: lavender, sweet marjoram, patchouli and vetiver. The cream was massaged into the bodies and limbs of 56 residents with dementia (group A and group B) five times a day in a cross-over design. Eighteen participants in group A received touch with plain aqueous cream and the other participants in group B received touch with essential oil cream. Nursing staff recorded the frequency and severity of occurrence of resistance to nursing care procedures and other dementia-related behaviours at the end of each shift. The Cohen-Mansfield Agitation Inventory (CMAI) identified a significant decrease in the average frequency and severity of disruptive behaviours. Most of the residents had severe dementia (MMSE score 0) and only 36 respondents had full data sets at the end of the study. Seven respondents had an improvement in their Mini Mental State Examination (MMSE) score, which ranged from one to eight points (Bowles, et al., 2002). However, only eight out of thirty-six could complete pre and post MMSE, seven showed significant improvement in cognitive function. The small number of participants (n = 7) reduce the reliability and generalisability of the findings. Although the study found aromatherapy not

only decreased disruptive behaviours but contributed to an improvement of cognition, this study also reported essential oils may actually cause an increase in the resistance to nursing care for some older residents with dementia. The authors argued that due to essential oils, residents were more alert and aware of possible indignity during some nursing care. The large missing data set (36%), and lack of baseline measurements and formal inter-rater reliability testing were limitations in this study.

A double-blind controlled trial design was conducted with 72 people with severe dementia from eight UK nursing homes with residents randomly assigned to a 10% melissa (lemon balm) essential oil group and placebo-sunflower oil group (Ballard, et al., 2002). Both essential oils were combined with lotion and applied to residents' faces and arms twice a day for a four-week period of treatment. A standard evaluation was collected which included the Cohen-Mansfield Agitation Inventory (CMAI), Neuropsychiatric Inventory (NPI), Barthel Scale, a physical examination, the Clinical Dementia Rating Scale (CDR) and an additional Dementia Care Mapping (DCM) assessment. The study results found that aromatherapy was associated with a significant decrease as assessed by staff of 35% in disruptive behaviours of residents treated with melissa (Lemon balm) and 11% in those receiving the placebo (Ballard, et al., 2002). All CMAI sub-scales showed a decrease in agitation, physical nonaggression ($p<.0001$), physical aggression ($p<.01$) and verbal nonaggression ($p<.001$) and demonstrated a statistically significant effect. Although the result showed a significant effect of melissa oil, the study had several flaws. First, this study randomized eight facilities into treatment groups rather than the participants. Participants received their treatment according to the facility in which they resided and this may have influenced the ability to generalise the results. Second, a safe concentration of essential oil for older people should not be over 5% in order to avoid adverse events such as skin irritation (Tisserand & Balacs, 1995). Surprisingly, there were no adverse effects from participants receiving a high dosage of 10% essential oils. In addition, although staff were blind to the study groups, the strong odor of sunflower oil could have led staff to influence the reported effects of the placebo group thus introducing potential bias. Furthermore, residents' behaviours might have been influenced by external factors. For example, the reduction in disruptive behaviour may have been a result of an increase in social contact between residents and nursing staff occasioned by the intervention and data collection. In addition, the aromatherapy fragrance may also have influenced the mood of nursing staff and their subsequent ranking of residents' behaviour. Moreover, the

melissa essential oil group had a higher baseline compared to the placebo-sunflower oil group, which could create a bias to report a decrease of agitation in melissa group.

Kilstoff and Chenoweth (1998) investigated sixteen residents with moderate to severe dementia from six different nationalities, as well as sixteen family caregivers and seven nursing workers in a dementia day-care centre in Sydney. An application of 5ml of sweet almond cream consisting of 0.5ml of a combination of lavender, mandarin and geranium, was applied to the clients' fingers, back of the hand and wrist for 10-15 minutes. The Revised Elderly Persons' Disability (REPDS) instrument and observation logbooks were used to assess clients' ability to self-care and their behaviours. During the period of the 18-month study, specific improvements for clients included reduced levels of agitation, withdrawal and wandering; also family caregivers reported less distress, greater feelings of calm and improved sleeping patterns. The benefits of the treatment for nursing workers were less stressful care and the development of an enjoyable relationship with clients (Kilstoff & Chenoweth, 1998). However, the REPDS did not report on the reliability of the intervention for use with multicultural residents. Although the investigators used ethnic translators to overcome the potential problem of culture and language barriers, the effect on accuracy of data was unknown. In addition, even though the investigators trained staff and family carers on standard hand treatment, observation and data recording, a limitation of the study was the complex environmental factors in each participant's home which may have influenced data collection.

Although these studies provided evidence that aromatherapy can decrease dementia-related behaviours, some researchers also argue that aromatherapy does not work for all disruptive behaviours. Snow et al. (2004) conducted a controlled trial study consisting of seven participants with severe dementia in a long-term care facility. Participants' levels of cognitive function (SD = 5.25, range 8-18) were assessed with the Severe Impairment Rating Scale (SIRS) (Rabins & Steele, 1996). The study design involved particpants being treated consecutively (ABCBA) with three essential oils, (A) lavender, (B) thyme or (C) unscented grapeseed oil. Each oil was placed on an absorbent sachet and pinned on each participant's shirt near the collarbone every three hours, three times a day for two weeks each followed by two weeks of lavender treatment, then two weeks of thyme treatment, totalling ten weeks. Participants' agitation was measured every two days for 16 weeks using the CMAI and qualitative behavioural observation. Olfactory function was assessed

with olfactory identification and discriminiation tasks. The small sample size (n = 7) of the study could have influenced the result, thus affecting the findings which showed lavender and thyme oil did not decrease participants' agitated behaviours. Moreover, there was no difference between participants with more or less intact olfactory abilities (Snow, et al., 2004).

Holmes et al. (2002) investigated 15 patients (mean age = 79 years, SD = 6.3) with severe dementia in a long-stay psychogeriatric ward. The types of dementia included Alzheimer's disease (AD) (n = 4), Vascular dementia (VaD) (n = 7), Dementia with Lewy bodies (DLB) (n = 3), and Frontotemporal dementia (FTD) (n = 1). Five treatments of 2% lavender oil or five placebos of water stream were administered on the ward in the 4pm–6pm period for over two weeks. The Pittsburgh Agitation Scale (PAS) was used to assess patients' agitation. However, as lavender oil and water stream were administered on alternative days, the effect of lavender oil may have carried over into the placebo days when essential oils remained in the bloodstream. The results showed that nine patients (60%) decreased their agitated behaviour. On the other hand, there were five patients (33%) that showed no change and one patient (7%) showed a worsening of agitation during aromatherapy compared with placebo (Holmes, et al., 2002). Only nine participants showed a decrease in disruptive behaviours, which was also difficult to provide a strong evidence for effect of aromatherapy.

Gray and Clair (2002) used four aroma interventions, lavender vera, sweet orange, tea tree and no aroma with thirteen participants in two residential care facilities. Each of the conditions was repeated four times for a total of 16 administrations. All participants' shirts had cotton balls with essential oils taped on them for twenty minutes before medication administration. Participants' behaviours were videotaped and rated by two observers. However, a short observation of behaviours might not notice participants' behavioural changes. Also, variation between two facilities could affect the analyses. The results indicated that aromatherapy did not decrease combative, resistive care in people with dementia (Gray & Clair, 2002).

In addition, another study investigated hand massage or vaporized lavender oils for 30-minute treatments for three months (Brooker, et al., 1997). Four participants with severe dementia were recruited to the study; moreover, each participant received 8 to 12

treatment sessions of aromatherapy, a combination of aromatherapy and massage, massage alone and no treatment. Outcomes of agitation were measured by a 6 point individual observational scale. The results showed there was no effect from the combination of aromatherapy and hand massage. Two participants maintained high levels of disturbance when they received these treatments (Brooker, et al., 1997). Although there appears to be some benefit in using aromatherapy, the dosage of lavender oil used and the range of effect on disruptive behaviours needs further investigation to provide evidence for practice.

**Table 3.2 Touch massage studies in disruptive behaviours in people with dementia**

| Author/Country | Study design / Setting | Treatment | Measurement | Outcomes | Limitations |
|---|---|---|---|---|---|
| Holliday-Welsh et al., 2009 USA | A prospective study/ repeated measure design<br><br>52 participants with cognitive impairment from 2 nursing homes<br><br>(moderate to severe cognitive impairment) | Western massage technique/Swedish massage<br><br>Lotion applied & massage area includes head, shoulders and hands<br><br>Massage was provided 10~15 minutes on 6 separated days during 2-week intervention period | Minimum Data Set (MDS)<br><br>Data was collected during baseline 3 days, intervention 6 days, and follow-up<br><br>Agitation was assessed during the hour, five one-minute observation during 1 hour, a total of up to 5 observations /day | Participants' agitation was lower during massage intervention and remained lower at follow-up.<br><br>4 out of 5 agitated behaviours were decreased, including wandering, verbally agitated/abusive, physically agitated/abusive and resists care | 1. No control group<br>2. No type of dementia reported<br>3. No report of the number of caregivers administering massage to participants<br>4. Unclear time given when massage was performed |
| Wood et al., 2005 USA | Randomized/ double-blind study<br><br>57 participants from 3 special care units (SCU) (severe dementia)<br><br>3 groups -<br>A: therapeutic touch<br>B: placebo therapeutic touch<br>C: control (usual care) | The therapeutic touch (neck & shoulders) & placeo groups (mimic treatment) received the intervention for 5-7 minutes at 10am ~ 11:30am & 3pm ~ 4:30pm twice a day / three days | The Mini Mental State Exam (MMSE), the Revised Memory and Behaviour Checklist (RMBPC), A modified agitated behaviour rating scale (ABRS)<br><br>Participants' behaviours were recorded every 20 mins between 8am and 6pm daily pre- and post the intervention for a total of 6 days | Therapeutic touch decreased disruptive behaviour ($F =$ 3.331, $p$ = .033); however, no significant difference between the activity group and placebo group | A short-term period of intervention (only 3 days). The length of intervention for determining dose-response was not able to be identified |

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**Table 3.2 (Continued)**

| Author/Country | Study design / Setting | Treatment | Measurement | Outcomes | Limitations |
|---|---|---|---|---|---|
| Remington, 2002 USA | A control group study<br><br>68 participants in 4 nursing homes<br><br>4 groups -<br>A: calming music (CM)<br>B: hand massage (HM)<br>C: combination (CM-HM)<br>D: no treatment (control) | CM, HM & CM-HM groups all received 10 minutes treatment for 1 day only | A modified version of the Cohen-Mansfield Agitation Inventory (CMAI) / collected 4 times | CM, HM & CM-HM all reduced agitation; however no treatment significantly reduced physical/ aggression/nonaggression. CM-HM did not have an added benefit in decreasing disruptive behaviour | 1. Unclear periods of interventions |
| Sansone, 2000 USA | A convenience sample/ demonstration project<br><br>71 participants from a nursing home<br><br>2 groups -<br>A: chronic pain<br>B: people with dementia | Tender touch to the forehead, neck, shoulders, back and hands 15 minutes/ twice weekly for 3 months | Numerical Pain Scale & The Institutional Comprehensive Assessment and Referral Evaluation<br><br>Follow-up classes/ Qualitative data | 71% of the nursing attendants reported their communication with residents had improved | 1. No baseline data<br>2. Lack of consistency in staff giving treatment<br>3. No standard length of time & frequency of massage<br>4. No participants' levels of cognitive impairment reported |
| Kim et al., 1999 South Korea | A repeated measures design<br><br>30 participants (moderate to severe dementia) | Expressive physical touch (hand massage) and verbalisation / 5.5 minutes/ 2 times a day/10 days | The Mini-Mental State Examination (Korean version), a physical assessment, The Empirical Behavioural Pathology in Alzheimer's Disease Rating Scale (EBEHAVE -AD) /collected every 5 days | A significantly decreased level of dysfunctional behaviours in the 5 days washout period ($F = 6.42$, $p = .034$) | 1. Convenience sample<br>2. No control group |

**Table 3.2 (Continued)**

| Author/Country | Study design / Setting | Treatment | Measurement | Outcomes | Limitations |
|---|---|---|---|---|---|
| Sydner et al., 1995 (a) 1995 (b) USA | (a) A cross-over design<br><br>26 participants from 3 dementia care units (most severe dementia)<br><br>5 minutes hand massage | 5 days baseline→10 days hand massage, each hand being massaged for 2.5 minutes in morning & afternoon→ 5 days baseline→10 days presence→5 days postest | Videotapes/agitation behaviours & agitation behaviour checklist | A decrease in the frequency (*p*<.05) & intensity (*p*<.025) of agitated behaviours only in the morning<br><br>Females had a better result than males | 1. Small sample 2. Participants' level of anxiety may be increased by videotape. |
| | (b) A cross-over design<br><br>17 participants from 3 dementia care units (most severe dementia)<br><br>A: hand massage<br>B: therapeutic touch | 5 days observe→ 10 days hand massage/10 minutes in the afternoon→ 5 days observe→ 10 days therapeutic touch/ 10 minutes in the afternoon→5 days nurses' presence→ 5 days observe | The Haycox rating scale, the relaxation checklist, pulse rate and self-developed anxious behaviour records, Videotapes/agitation behaviours & agitation behaviour checklist | Both treatments had a significant effect on reducing agitated behaviours; hand massage (*p*<.001) was more effective than therapeutic touch (*p*<.027) | |

### 3.2.2    Massage Research for Agitation and Aggression in Dementia

Several studies in the literature have suggested using physical touch to reduce agitated behaviours in older people with dementia (Buckle, 1993; Holliday-Welsh, Gessert, & Renier, 2009; Kunstler, Greenblatt, & Moreno, 2004; Remington, 2002a; Sansone & Schmitt, 2000; Snyder, et al., 1995a, 1995b; Woods, et al., 2005). There are two forms of touch, therapeutic touch and massage (Snyder, et al., 1995b). Therapeutic touch is a non-contact procedure when the therapist transmits energy to another ill or anxious person for the purpose of a potential healing process (Egan, 1992). Therapeutic massage refers to "the manipulation of soft tissue of the body though stroking, rubbing, kneading or tapping, to increase circulation, to improve muscle tone and to relax the patient" (Anderson, et al., 2002, p. 1054). Both interventions provide non-verbal communication to comfort and provide warmth and security to older people (Gleeson & Timmins, 2004). The studies referred to in this review can be found in Table 3.2.

Holliday-Welsh, Charles and Gessert (2009) investigated fifty-two older residents with moderate to severe cognitive impairment from two nursing homes in the USA. Older residents were placed in one group and a repeated measures design was used. Swedish massage was used to apply lotion on each resident's head, shoulders and hands for 10 to 15 minutes. Massage was provided on six separate days during a two-week intervention period. Caregivers were trained in one or two lessons before administering massage to older residents. Minimum Data Set (MDS) was used to measure residents' behavioural symptoms including *wandering*, *verbally abusive*, *physically abusive*, *social inappropriate* and *resists care*. Data collection included three days of baseline, five days of intervention and post-test. Older residents' agitation was assessed during a one-minute period before the beginning of massage, then followed at five-minute intervals after the onset of the massage intervention. At the end of the intervention, a final one-minute observation was made. The result found incidence of residents' negative behaviour was lower during the intervention and remained lower post test. An intention to treat analysis (ITT) showed four out of five agitated behavours were decreased such as *wandering* ($p < .001$)*, verbally abusive* ($p = .002$), *physically abusive* ($p < .001$) and *resists care* ($p = .022$). This study was limited by the absence of a contol group and failure to specify type of dementia.  Moreover, some participants continued to receive antipsychotics during the

intervention periods. These participants may have presented low level or no agitated behaviours; the results were difficult to attribute to the effect of massage. Furthermore, the study did not report the number of caregivers that administered massage and was unclear about the administering time of the intervention. Such variations could influence the analysis and create a false result.

A double-blind experimental study in the USA (Woods, et al., 2005) randomized 57 older residents (mean age = 81 years, SD = 5.50) with severe dementia from three special care units (SCU) into three groups: therapeutic touch (neck and shoulders), placebo (mimic treatment) and control (usual routine) groups. The therapeutic touch and placebo groups received the intervention from 10am to 11:30am and from 3pm to 4:30pm twice a day for three days. Research assistants observed and recorded residents' behaviours every 20 minutes between 8am and 6pm daily pre and post the intervention. This study used the Mini Mental State Exam (MMSE) (Folstein, Folstein, & McHugh, 1975) and the Revised Memory and Behaviour Checklist (RMBPC) (Teri, et al., 1992) to screen older residents' cognitive impairment and behavioural problems. A modified agitated behaviour rating scale (ABRS) measured frequency and intensity of behavioural symptoms in people with dementia. The study found therapeutic touch decreased behavioural problems ($F = 3.331$, $p = .033$) such as manual manipulation and vocalisation, when the experimental group was compared with the other two groups. The placebo group received one-to-one social interaction with a positive effect on decreasing behavioural symptoms. However, there was no significant difference between the experimental group and the placebo group. These results may be influenced by the experimental group and the control group, which had a higher percentage of participants taking antipsychotics and antianxiety medication compared with the placebo group. The study limitations include the intervention being administered for only three days, and the length of treatment for determining dose-response not being clearly identified.

Remington (2002a) assigned a total of 68 nursing home residents (mean age = 82.4 years) with dementia and agitated behaviours into four groups: 10 minutes calming music (CM), 10 minutes hand massage (HM), 10 minutes calming music with hand massage simultaneously (CM-HM), and a control group. Seventeen subjects were randomized into each group and received the different interventions four times for one

day only. A pilot study of 24 agitated older residents was conducted before commencing this research. Agitated behaviours were collected before intervention, at intervention, following the intervention, and again at one hour post intervention using a modified 29-item Cohen-Mansfield Agitation Inventory (CMAI). The study found physically nonaggressive behaviours decreased in CM, HM and CM-HM groups. However, calming music combined with hand massage did not contribute an added benefit in decreasing agitated scores. The study was limited by unclear periods of intervention for only one day. Moreover, due to a low score of initial level of physical aggression, no significant difference was found between the three interventions. Although the author excluded participants receiving medication for agitation within the four hours preceding the intervention, the type of medication was not identified and the effect of some medication may have lasted longer than the expected time. For example, olanzapine (Zyprexa) reaches the peak plasma levels in 5 to 8 hours and has a half- life of 35 hours (Labbate, Fava, Rosenbaum, & Arana, 2009). Therefore, the duration of effect of these types of medication may remain throughout the intervention and affect the results.

A study by Sansone and Schmitt (2000) in the USA examined the influence of tender touch massage on seventy-one older nursing home residents who were divided into two groups: older people with chronic pain and people with dementia with agitated behaviours. Each resident received tender touch in certain areas of their body, which included the forehead, neck, shoulders, back and hands, for approximately 15 minutes at least twice a week. Findings showed mean scores of the numerical pain scale (0-10) and anxiety levels (anxiety/agitation assessment form scale 0-4) declined; moreover, 71% of the nursing attendants reported their communication with residents had improved and most residents enjoyed tender touch (Sansone & Schmitt, 2000). However, the study lacked rigor in that many caregivers used a different approach to tender touch massage and the length of time and frequency of massage was not standardised. Furthermore, it appears that there was no baseline data collection and no piloting of the pain scale tool or the modified Institutional Comprehensive Assessment and Referral Evaluation Instrument.

In Korea, Kim and Buschmann (1999) used a one-group repeated measures design to investigate the effect of expressive physical touch with verbalization on thirty older

residents (mean age = 76.58 years, SD = 9.98) with moderate to severe dementia and anxiety. Expressive touch was defined as hand massage for five minutes and 30 seconds twice a day (Snyder, et al., 1995a). Cognitive impairment was measured by the Mini-Mental State Examination (Korean version); anxiety was assessed by measuring the resident's pulse rate four times a day during the 10 days of the intervention period. The Empirical Behavioural Pathology in Alzheimer's Disease Rating Scale (E-BEHAVE-AD) recorded the dysfunctional behaviours of older residents (Auer, Monteiro, & Reisberg, 1996). The findings revealed lower anxiety levels as indicated by the resident's pulse rate. Furthermore, E-BEHAVE-AD indicated a significantly decreased level of dysfunctional behaviours in the five-day washout period ($F = 6.42$, $p = .034$). Although the study provided evidence of hand massage decreasing anxiety levels, no control group was used in this study. In addition, participants' regular medication treatments were not mentioned in the study. These treatments may influence the results between two interventions.

In an American study, Snyder, Egan and Burns (1995b) recruited 17 older residents (mean age = 77.7 years) with a high incidence of agitated behaviours, most with severe dementia. Older residents were placed in a study that used an experimental crossover design. Each resident received three interventions: hand massage for 10 days, therapeutic touch for 10 days and nurses' presence for five days for 10 minutes in the late afternoon. Five days of observation were collected before and after the administration of each intervention. The Haycox rating scale (Haycox, 1984), relaxation checklist (Luiselli, Steinman, Marholin, & Steinman, 1982), pulse rate and self-developed anxiety behaviour records were used for data collection. The study found both therapeutic touch ($p = .027$) and hand massage ($p = .001$) had a significant effect on reducing residents' agitated behaviours when compared with the intervention of nursing staff being present with residents. Furthermore, hand massage was more effective than therapeutic touch. In a subsequent study, Snyder et al. (1995a) reiterated a similar method with 26 subjects (mean age = 78.7 years); the length of time for administering hand massage was reduced from ten to five minutes, each hand being massaged for 2.5 minutes in two time periods, morning and afternoon. The findings showed that the frequency ($p<.05$) and intensity ($p<.025$) of aggressive behaviours were decreased in the morning. In addition, hand massage decreased agitated behaviours in female residents, whereas agitated behaviours increased in men. Both

studies reduced agitated behaviours through the use of hand massage; however, there were some flaws in the studies. First, although the authors mentioned that the interventions were administered to participants in two time periods (morning and afternoon); they did not specify the details of the timeframe. Secondly, agency staff assisted with data collection from 6am to 9pm; however, it was unclear whether these staff were blinded during the intervention. This may create bias in relation to results being influenced by staff judgement. Moreover, videotaping of participants' behaviours not only limited recording of behavioural changes, but also increased participants' level of anxiety, as participants' behaviours could only be recorded in a certain area and it was difficult to keep participants in the room all the time. Furthermore, a larger sample size is needed to validate this approach and studies exploring gender difference are also needed.

### 3.2.3   Summary

This literature review of aromatherapy and hand massage research outlined the evidence for the effectiveness of these therapies in decreasing disruptive behaviours in people with dementia. However, these studies were limited in their findings in that many aspects of the research design include:

1. no formal diagnosis of dementia (Holliday-Welsh, et al., 2009; Kim & Buschmann, 1999; MacMahon & Kermode, 1998; Smallwood, et al., 2001),

2. lack of standardised aromatherapy oil concentration (Beshara & Giddings, 2002; Bowles, et al., 2002; MacMahon & Kermode, 1998; Smallwood, et al., 2001)

3. unclear explanation of the essential oils used (Beshara & Giddings, 2002; Brooker, et al., 1997; MacMahon & Kermode, 1998),

4. no explanation of the length of treatment (Holliday-Welsh, et al., 2009; MacMahon & Kermode, 1998; Sansone & Schmitt, 2000; Smallwood, et al., 2001; Woods, et al., 2005),

5. lack of standard outcome measurements (Kilstoff & Chenoweth, 1998; MacMahon & Kermode, 1998),

6. no cognitive impairment level description (Beshara & Giddings, 2002; MacMahon & Kermode, 1998; Smallwood, et al., 2001),

7. no indication of current antipsychotic medication used (Beshara & Giddings,

2002; Bowles, et al., 2002; Kim & Buschmann, 1999; MacMahon & Kermode, 1998; Smallwood, et al., 2001)

8. no control group (Holliday-Welsh, et al., 2009; Kim & Buschmann, 1999; MacMahon & Kermode, 1998) and,

9. insufficient sample size (Beshara & Giddings, 2002; MacMahon & Kermode, 1998; Smallwood, et al., 2001; Snow, et al., 2004; Snyder, et al., 1995a, 1995b).

Even though previous studies of aromatherapy and massage effectiveness were weak in methodology, aromatherapy and massage seemed to have an ambiguous benefit in decreasing disruptive behaviours in people with dementia. In addition, the literature was unclear about whether the effect of the aromatherapy intervention was the result of smelling the aroma stimulating the endocrine and autonomic nervous system or cutaneous absorption of the oils. Moreover, the potential effect of essential oils on the cognitive function of people with dementia is needed to be retested in large samples and compared to previous studies.

A critique of studies exploring the effect of aromatherapy and hand massage on agitation and aggression in people with dementia identified the strengths and weaknesses in the current understanding of the effect of these CAM modalities so as to direct aspects and approaches of this current study. The quality of future research relies on a rigorous approach to overcome the research limitations outlined above. A research protocol, placebo treatment, an adequate length of treatment and reliable instruments are important elements for the quality of research. Therefore the current study attempted to overcome the research limitations of previous research by administering a specific essential oil in a single blind randomized controlled trial (RCT) design. While many studies have showen potential effects of aromatherapy via massage and inhalation, the spray method was selected for this study due to efficiency and control of the dose response and convenience for nursing staff (Bowles, 2006; Bowles, et al., 2005). The purpose of this RCT study is to investigate the effects of aromatherapy - lavender oil spray or lavender oil spray combined with hand massage in decreasing agitation and aggression in people with dementia.

## 3.3    Conclusions

This chapter presented the way in which odours influence the olfactory system and have physical and emotional changes as a result of their affect on the limbic system. Moreover, the amygdala plays an important role in evoking previous experience and memory and therefore potential happy moments through smell. Although aging influences the decline in the olfactory function, olfactory dysfunction has also been indicated as an early warning sign of dementia. Essential oils such as melissa, rosemary, sage and lavender sage have been found to be potentially useful for enhancing cognitive impairment. Furthermore, essential oils may also have a positive effect on anxiety, depression and disruptive behaviours.

In conclusion, essential oils have shown some positive effects on physical and emotional status that may potentially benefit older people with dementia. The basis of aromatherapy and hand massage treatments are considered to calm emotions and thereby decrease disruptive behaviours. The next chapter outlines the methdology used in this study.

# CHAPTER 4
# METHODOLOGY

## Chapter Overview

Randomized controlled trials (RCTs) are a highly valued research design, which contain, manipulation, a control group and randomization (Polit & Beck, 2008). Good RCT research consists of an appropriate design, management and reporting that represent the gold standard in evaluating health care interventions (Schulz, Altman, & Moher, 2010). On the other hand, lack of methodological rigour can affect RCT results; therefore, comprehension and adherence to the fundamentals of RCT is essential. This chapter presents a background to RCT, the fundamentals of RCT, assessment of trial quality, and the importance of RCT ethics. This provides the background for the application of the design that is used for this research project. In addition, the application of RCT in dementia research and an outline of justification for the use of RCT are also discussed and in relation to the complementary therapy protocol used in this study.

## 4.1    Background to Randomized Controlled Trial (RCT)

A randomized controlled trial (RCT) is a scientific comparative experiment and commonly used in health care and health technologies research. It has been claimed that RCT is the most powerful quantitative research design as people are allocated at random to receive one of several clinical treatments (Jadad & Enkin, 2008). RCT has been used as a standard research design in medicine. The earliest clinical trial was recorded in approximately 600 B.C. (cited in Stolberg, Norman, & Trop, 2004). The first paper describing a RCT design was published in 1948 by Austin Bradford Hills, and concerned the Medical Research Council Trials on streptomycin for pulmonary tuberculosis (cited in Stolberg, et al., 2004). Since the publication of this paper, more than 150,000 RCT articles were identified in a search of the Cochrane Library (Stolberg, et al., 2004). The Consolidated Standards of Reporting Trials (CONSORT) Statement was published in 1996 by a group of clinical epidemiologists, biostatisticians and journal editors, and has been regularly revised in order to improve the quality of reporting of RCT in the literature (Begg, et al., 1996; Hopewell, Dutton, Yu, Chan, & Altman, 2010).

## 4.2    Fundamentals of Randomized Controlled Trial (RCT)

RCT design is based on three elements, manipulation, control and randomization (Polit & Beck, 2008, p. 250). RCT is an experimental design because participants are randomly allocated to receive different treatments, which test the effectiveness of one treatment compared with one or other alternative treatments under study. RCT provides the strongest evidence of cause and effect (Jadad & Enkin, 2008; Schneider, Elliott, LoBiondo-Wood, & Haber, 2003).

### 4.2.1    Manipulation

### 4.2.1.1 Design

Hopewell and colleagues (2010) used the Cochrane highly sensitive strategy to identify the RCT studies that were indexed in PubMed 22 March 2007. They screened 1735 RCT papers for reporting characteristics and methodological details to assess whether the quality of reporting had been improved after publication of the CONSORT statement in 2001. A total of 616 RCT studies were examined between 2000 and 2006, the major categories of RCT design were parallel groups (78%), crossover (16%), factorial (2%), cluster (2%) and others (2%). Parallel group is the most frequently used design, whereby each participant is randomized to a group that receives a treatment or a placebo. When participants receive a treatment in a random sequence and change treatments after a wash out period this is called a crossover design. In a factorial design, each participant is randomized to a group that receives a particular combination of treatment or placebo. Researchers compare two or more experimental interventions in combination. The factorial design can have two independent variables and refers to the number of levels; therefore, it is sometimes more complex than a 2×2 design (Polit & Beck, 2008). This design allows researchers to compare the experimental interventions with each other and with a placebo, it can also examine interactions between the interventions (Jadad & Enkin, 2008). In a cluster RCT design a pre-existing group of participants is randomized to receive or not receive a treatment (Jadad & Enkin, 2008).

### 4.2.1.2 Participant Size

RCT can be applied to one or thousands of people. RCT with one participant is called an *n*-of-one trial; it is easily adapted to the randomized, double-blind, placebo-

controlled clinical trial (Avins, Bent, & Neuhaus, 2005). An *n*-of-one trail is usually used for chronic, stable conditions and for which the proposed treatment does not have good effect in an open trail. In an *n*-of-one trial a patient will undergo pairs of treatment periods, such as one period of each pair with an active drug and one with matched placebo at random.  In this case both the patient and the clinician are blinded to allocated treatment.  On the other hand, RCT can involve thousands of people and where there is limited data collection in a simple design this is called a mega-trial (Woods, 1995). A sequential trial is used when the number of participants is not specified before commencing treatments. In a sequential trial investigators can continue recruiting participants until outcomes show whether there is significance or no difference between the treatments (Stolberg, et al., 2004). In a fixed trial, the sample size can be decided by investigators or calculated using statistical methods (Stolberg, et al., 2004).

### 4.2.2   Control

RCT measures efficacy or the effectiveness by comparing two or more interventions; a control group and experimental (treatment) groups are essential (Jadad & Enkin, 2008). The control group is usually a basis of comparison to compare to experimental groups in a study. In RCT, researchers can decide what kind of  treatment to use in the control group based on theoretical or substantive grounds (Polit & Beck, 2008). The control group can receive an alternative intervention, placebo, standard care, different doses or intensities of treatment or even receive the same treatment as experimental groups but the treatment is deferred (Polit & Beck, 2008).

### 4.2.3   Randomization

All participants are equally assigned to each study group though a randomiation process. The purpose of the randomization procedure is to eliminate selection bias and balance prognostic factors in the treatments (Moher, et al., 2010). The investigators have to define the rules for randomization and consistently follow the rules during the study (Jadad, 1998). Therefore, allocation concealment is important to prevent researchers and participants from knowing the upcoming interventions (Polit & Beck, 2008). Simple methods of random allocation of participants include using appliances such as coins, dies and computers. The investigators can also use random number tables that have more rigour with restricted or stratified randomization to maximise

similarities of the number of participants or characteristics of the participants in the study groups (Jadad & Enkin, 2008).

### 4.2.3.1 Bias

Although RCT is a most rigorous design, some common biases still exist. There are two main types of bias in RCT; selection bias and ascertainment bias (Jadad & Enkin, 2008). Selection bias occurs when investigators selectively exclude potential eligible participants who may not respond to treatments with a good effect (Jadad & Enkin, 2008; Schneider, et al., 2003). Selection bias can be reduced by using allocation concealment (Jadad & Enkin, 2008). Ascertainment bias occurs when people distort the results or conclusions of a trial; these people include the person administering the intervention, the participants, the investigators or even the people who report the trial (Jadad & Enkin, 2008). In the recruitment of participants for a RCT, population choice bias occurs when researchers overly restrict participants by their gender or age (Jadad & Enkin, 2008). During the course of analysing the data, withdrawal bias arises in the situation when the researchers inappropriately manage drop-outs. Numbers of participants withdrawing from the analysis can lead to false results or another cause of ascertainment bias. This bias can be eliminated by intention-to-treat (ITT) analysis and a worse-case scenario or sensitivity analysis. Publication bias can occur during the dissemination of the study. Positive results are more likely to be published than negative results. Other important biases can occur during the course of a RCT including regulation bias, population choice bias, comparison choice bias, outcome choice bias, withdrawal bias, selective reporting bias, fraud bias and so on (Jadad & Enkin, 2008; Kotaska, 2004; Lilford, Braunholtz, Greenhalgh, & Edwards, 2000).

### 4.2.3.2 Blinding

Blinding (masking) can prevent biases such as researchers in charge of enrolment assigning participants to a favourable treatment or prevent participants being aware of their treatment condition and therefore distorting the results (Polit & Beck, 2008). Blinding can reduce the risk of ascertainment bias when the assessment of outcomes of an intervention is influenced by knowledge of which intervention a participant is receiving (Jadad & Enkin, 2008). Participants and researchers can be blinded during a trial. The RCT is classified as single-blind, double-blind, triple-blind, quadruple-blind

and so on; the double-blind RCT is often argued as presenting the most valid results in a study design (Jadad & Enkin, 2008). However, the number of people who are blinded in the research project is not important. The role of the participant, clinician and researchers in the research determines whether they are blinded since their knowledge of the intervention may affect the results (Jadad & Enkin, 2008).

### 4.2.3.3 Intention-to-Treat (ITT)

To avoid the effects of withdrawal bias, intention-to-treat (ITT) is a commonly used method to eliminate this bias. ITT is a strategy for the analysis of randomized controlled trials that includes all randomized participants to the group they were randomized, regardless of what subsequently occurs (Hollis & Campbell, 1999). The principle of the ITT approach includes analysis of available outcome data for all randomized participants, it minimizes bias such as type I error (false positive) and avoids problems created by omiting drop outs and non compliant patients (Hollis & Campbell, 1999; Kruse, et al., 2002; Lachin, 2000). Although participants are free to refuse treatments in the trial at anytime, their data should be included in the trial when possible (Lachin, 2000). Participants should be considered as 'temporarily inactive', either because of participants' insistence or due to external factors such as relocation (Lachin, 2000). Researchers need to continue to follow participant outcome evaluations unless the patient dies or withdraws consent from the study (Gross & Fogg, 2004; Lachin, 2000). ITT has a great strength equal to efficacy analysis and without the risk of bias due to subset selection. ITT analysis provides the most realistic and considered unbiased analysis when all randomized participants are included in the analysis of the original design (Lachin, 2000).

This study adheres to the Lachin (2000) ITT protocol.

### 4.2.4   Strengths and Limitations of RCT

RCT is considered the gold standard in experimental research; manipulation, control, and especially randomization procedures provide its strength (Polit & Beck, 2008; Stolberg, et al., 2004). A proper randomization can reduce a serious imbalance in any factors which could influence the clinical course of the participants (Stolberg, et al., 2004). A successful randomization procedure needs to be defined by rules and

followed throughout the entire study. Researchers should not modify the procedure at any point of the study in order to maintain the highest quality.

Besides the benefits of RCT, it also has limitations. First, RCT is criticised for artificiality (Polit & Beck, 2008). In reality, the randomization makes RCT impractical. For example, nursing staff may modify their behaviour and address different aspects of patient care in clinical settings, which are not randomized (Polit & Beck, 2008). Secondly, if RCT is undertaken without a guiding theoretical framework it is criticised for not providing any explanation to connect independent and dependent variables (Polit & Beck, 2008).

Another potential problem is the Hawthorne effect; this was derived from an experimental study carried out in the Hawthorne works of the Western Electric Company between 1927 and 1933 (cited in Jones, 1992). Researchers examined environmental conditions such as the effects of light and working hours on workers' productivity; they found that regardless of whether the light was made better or worse, workers' productivity still increased. The study concluded that workers were aware of being involved in the study which affected their behavior (Jones, 1992; Polit & Beck, 2008). Nursing staff and patients may be aware of their participation and may change their behavior in order to conform to the customs of society. These limitations may make RCT difficult to apply in clinical settings.

## 4.3    Quality Indicators Randomized Controlled Trial (RCT)

RCT is widely used and promotes evidenced-based research (Polit & Beck, 2008). The quality of a RCT needs to be evaluated and controlled. A good quality RCT needs to rely on internal and external validities. Internal validity is an essential component of RCT quality (Jadad & Enkin, 2008). Internal validity can be influenced by variations in the independent variable, the integrity of the instruments and statistical procedures and the choice of statistical methods (Brewer, 2000; Polit & Beck, 2008). Internal validity is also influenced by external validity (Brewer, 2000). From the perspective of internal validity, highly controlled true experimental designs such as random selection and control or experimental groups, the very strategies employed to control these factors, may also limit the generalizability of the findings (Brewer,

2000). A well-written research protocol can enhance these validities. A research protocol provides the detailed plan and a basic guide of the study, it maintains the validities and minimises the bias to affect the results. Once the protocol has been developed and the study has progressed, researchers should adhere to the protocol and should not change it under any circumstance in order to carry out the study with good quality control.

In order to assess the quality of RCT in publications, a number of assessment tools have been developed. These are also particularly useful in designing RCT to ensure all quality elements are appropriated considered and incorporated. RCT quality can be measured using a number of tools including the Jadad scale, the Physiotherapy Evidence Database (PEDro) scale, Delphi-based tools and Downs and Black checklist. The Jadad scale is easy and quick to use scoring a trial report in about five minutes (Jadad, 1994). It provides consistent measurement and has construct validity (Jadad & Enkin, 2008). The scale includes three items to assess bias reduction, randomization, blinding, and description of withdrawals and drop-outs (see Figure 4.1). These are presented as "yes" or "no" questions; a score is from 0 to 5 produced for a positive answer (Jadad, 1994). For the first two items, if the methods of generating the randomization sequence or creating blinded conditions are described and are appropriate, an additional point would be obtained for each item. On the contrary, both items would be deducted one point respectively, if the methods described were inappropriate. Although there were more than 300 reviews of trials using the Jadad scale in health care, a low rate of inter-rater agreement (overall kappa 0.48) of the assessment has been reported as a concern (Bhandari, Richards, Sprague, & Schemitsch, 2001; Clark, et al., 1999).
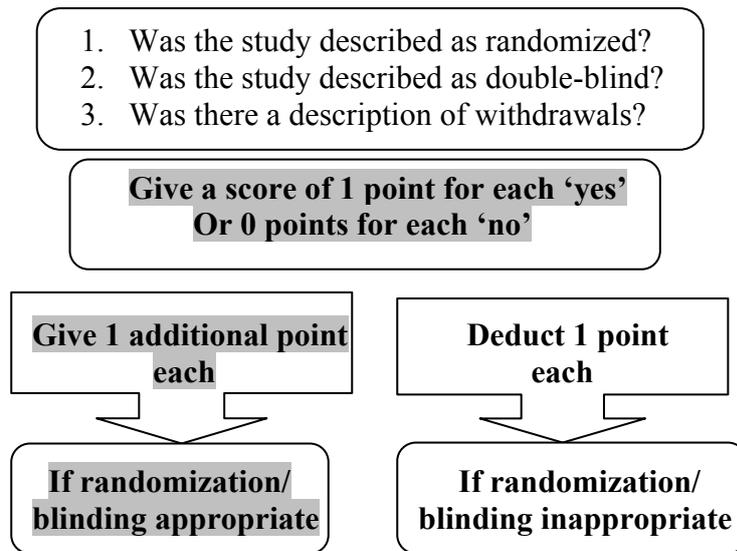
**Figure 4.1 The Jadad Scale (Jadad & Enkin, 2008, p. 54)**

The Physiotherapy Evidence Database (PEDro) scale was developed to assess the quality of trials in physiotherapy (Maher, Sherrington, Herbert, Moseley, & Elkins, 2003). The PEDro scale includes 11 items; when an answer is positive in the article, one point is contributed to each item except the first item (see Table 4.1). This tool has been shown to provide more reliability (ICC= .68, 95% CI= .57, .76) and consistent results when compared to the Jadad scale during the assessment of trials on physical therapy (ICC= .59, 95% CI= .46, .74) (Bhogal, Teasell, Foley, & Speechley, 2005; Maher, et al., 2003).

**Table 4.1 PEDro Scale Items**

| 1. | Eligibility criteria were specified |
|---|---|
| 2. | Participants were randomly allocated to groups (In a crossover study, participants were randomly allocated an order in which treatments were received) |
| 3. | Allocation was concealed |
| 4. | The groups were similar at baseline regarding the most important prognostic indicators |
| 5. | There was blinding of all participants |
| 6. | There was blinding of all therapist who administered the therapy |
| 7. | There was blinding of all assessors who measured at least one key outcome |
| 8. | Measurements of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups |
| 9. | All participants for whom outcome measurements were available received the treatment or control condition as allocated, or where this was not the case, data for at least one key outcome were analysed by "intention to treat" |
| 10. | The results of between-group statistical comparisons are reported for at least one key outcome |
| 11. | The study provides both point measurements and measurements of variability for at least one key outcome |

Delphi-based tools were developed following a Delphi consensus building process (Sindhu, Carpenter, & Seers, 1997; Verhagen, et al., 1998). In Sindhu et al. (1997) a Delphi technique includes 53 items in 15 different dimensions while the other tool, the Delphi list only consists of 9 items (Verhagen, et al., 1998). The Downs and Black checklist is designed for assessing both randomized and non-randomized trials (Downs & Black, 1998). There are 26 items including reporting (9 items), external validity (3 items), bias (7 items), confounding (6 items) and power (1 item). However, both Delphi-based tools and the Downs and Black checklist are not used worldwide to assess RCT (Jadad & Enkin, 2008).

In addition to the above measurements, the Consolidated Standards of Reporting Trials (CONSORT) Statement has been used worldwide in the past decade. In the 1990s, a group of scientists and editors developed the CONSORT statement to improve the quality of reporting of RCTs (Begg, et al., 1996). The purpose of CONSORT was to help readers to comprehend the results of a RCT and understand design, conduct, analysis and interpretation in order to improve the reporting of RCT (Moher, et al., 2010; Moher, Schulz, & Altman, 2003; Schulz, et al., 2010; Tandon, Mahajan, Sharma, & Gupta, 2007). The CONSORT is primarily intended for use in

writing, reviewing, or assessing reports of simple two-group parallel RCTs (Moher, et al., 2003). However, its detail and guidelines provide a useful guide when designing a RCT. It consists of a checklist and flow diagram for reporting a trial. The latest version of the flow diagram provides a detailed description of the progress of participants through the randomized trial (see Figure 4.2), and the current version of CONSORT 2010 has been updated from 22 items to 25 items in the checklist (see Table 4.2).
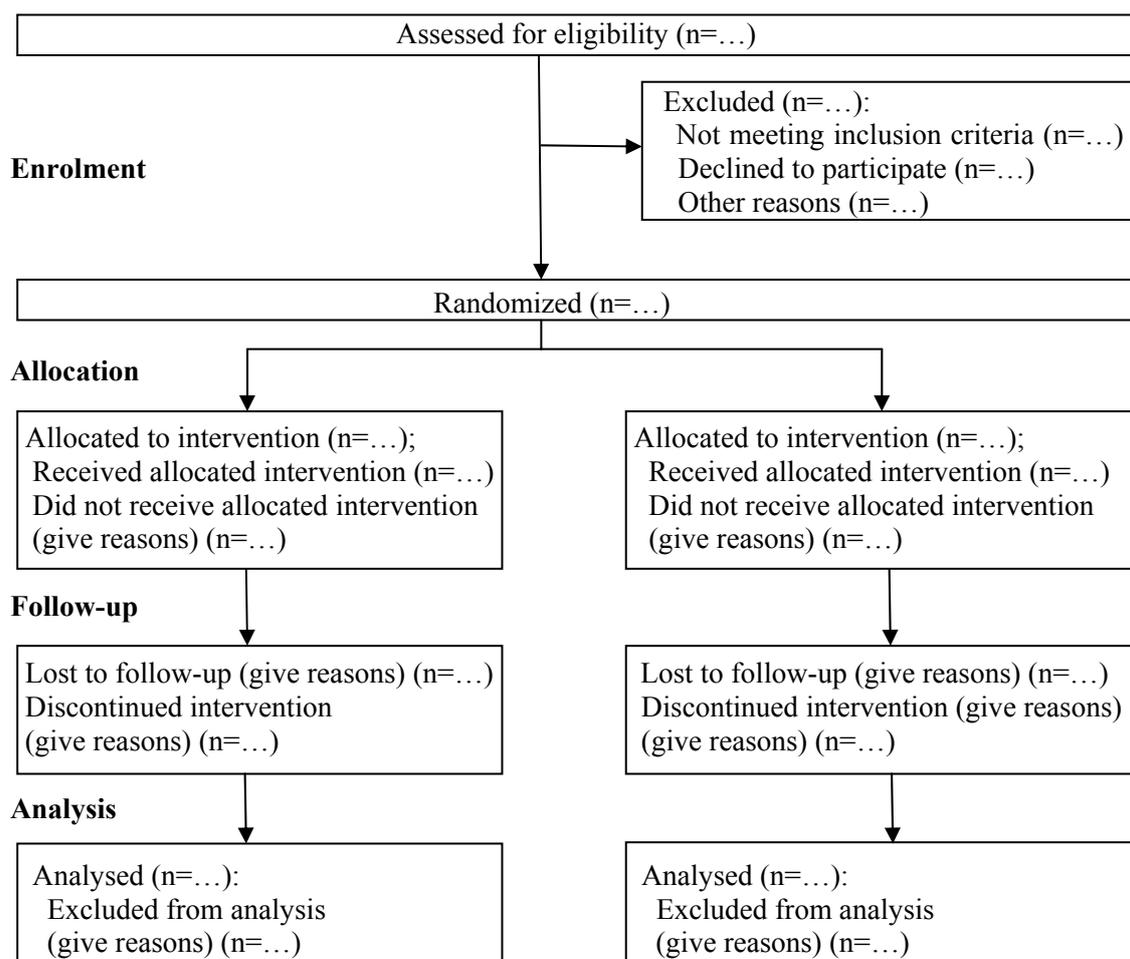
**Figure 4.2 Flow diagram of the progress through the phase of a parallel-randomized trial of two groups (Reprinted from Moher, Jones, & Lepage, 2001; Moher, et al., 2003, p. 5)**

**Table 4.2 CONSORT 2010 Checklist**

| Section/Topic | Item No | Checklist item |
|---|---|---|
| Title & abstract | 1a | Identification as a randomized trial in the title |
| | 1b | Structured summary of trial design, methods, results, and conclusions |
| **Introduction** | | |
| Background & | 2a | Scientific background and explanation of rationale |
| objectives | 2b | Specific objectives or hypotheses |
| **Methods** | | |
| Trial design | 3a | Description of trial design including allocation ratio |
| | 3b | Important changes to methods after trial commencement, with reasons |
| Participants | 4a | Eligibility criteria for participants |
| | 4b | Settings and locations where the data were collected |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons |
| Sample size | 7a | How sample size was determined |
| | 7b | When applicable, explanation any interim analysis and stopping guidelines |
| **Randomization** | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence |
| | 8b | Type of randomization; details of any restriction |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence, describing any steps taken to conceal the sequence until interventions were assigned |
| Implementation | 10 | Who generated random allocation sequence, who enrolled participants, and who assigned participants to interventions |
| Blinding | 11a | If done, who was blinded after assignment to interventions and how |
| | 11b | If relevant, description of the similarity of interventions |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes |
| | 12b | Methods for additional analysis, such as subgroup analyses and adjusted analysis |

**(Continued)**

**Table 4.2 (Continued)**

| Section/Topic | Item No | Checklist item |
|---|---|---|
| **Results** | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the number of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome |
| | 13b | For each group, losses and exclusions after randomization, together with reasons |
| Recruitment | 14a | Dates defining the periods of recruitment |
| | 14b | Why the trial ended or was stopped |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision |
| | | For binary outcomes, presentation of both absolute and relative effect sizes is recommended |
| | 17b | |
| Ancillary analysis | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory |
| Harms | 19 | All important harms or unintended effects in each group |
| | | |
| **Discussion** | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and if relevant multiplicity of analyses |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |
| | | |
| **Other information** | | |
| Registration | 23 | Registration number and name of trial registry |
| Protocol | 24 | Where the full trial protocol can be accessed, if available |
| Funding | 25 | Sources of funding and other support, role of funders |

## 4.4    Ethics of Randomized Controlled Trial (RCT)

Beauchamp and Childress (2001) stated that the common principles of medical ethics are autonomy, beneficence, non-maleficence and justice. To apply these principles in research, researchers must ensure that participants have the right to decide what they want to happen to them (autonomy and respect for human dignity); researchers must try to do good (beneficence) to the participants and without harm (non-maleficence) and treat participants fairly and equally (justice). However, it has been argued that human experimentation and RCT studies in humans may not be commensurate to ethical principles such as the Australian guidelines concerning ethical conduct (National Health and Medical Research Council, Australian Research Council, & Australian Vice-Chancellors' Committee, 2007).

The key ethical issues in RCT research concern informed consent, equipoise and placebo treatment (Edwards, Lilford, & Hewison, 1998; Hutton, 2001; Jadad & Enkin, 2008). Since 1964, the World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research including human experimentation, and this is widely regarded as the cornerstone document of human research ethics (World Medical Association, 2000, 2008). The provision clearly indicates participants have to be volunteers and supplied with all relevant information in the research project. The primary purpose of informed consent is to protect potential participants; therefore, participants have the right to access any relevant information to help them in making a decision of whether to participate in the research. Furthermore, it is necessary for the researcher to provide adequate information as a legal document to participants. While participants give consent to participate in the study, they may not have fully understood what was being asked of them or realize the implications (Edwards, et al., 1998; Jadad & Enkin, 2008). Ferguson (2002) identified that although most participants (94%) think that they have received enough information, only 50% of them actually understood it. A lack of understanding can be caused by educational, psychological, linguistic and social states (Jadad & Enkin, 2008). Therefore, the contents of informed consent need to be written in simple language and contain all essential information (Jadad & Enkin, 2008). Furthermore, studies have reported that three major clinical barriers to participation in RCT included time constraints, lack of staff and training, and impact on the doctor-

patient relationship (Edwards, et al., 1998; Ross, et al., 1999). Lack of time in the consent process could influence participants in fully understanding procedures before participating in a RCT (Ross, et al., 1999).

The term equipoise (personal and clinical equipoise) refers to the degree of genuine uncertainty about interventions and that there is no reason for believing one intervention to be more effective than the other (Ashcroft, 1999; Chiong, 2006; Evans & Evans, 1996). Equipoise is applied to individual practitioners, the clinicians, the researchers and communities of patients (personal equipoise) (Scullion, 2000). Clinical equipoise is also called collective or professional equipoise (Johnson, Lilford, & Brazier, 1991; Liford & Jackson, 1995). Ethically, clinicians and participants do not know which one of a number of interventions may be effective and therefore participants receive equivalent treatments. However, equipoise in RCT studies presents a serious dilemma as most researchers and participants already have their preferences in relation to the treatments on offer (Jadad & Enkin, 2008). Therefore, equipoise does not apply when intervention benefits are conferred by people's perception. It is argued that if researchers insist on equipoise in RCT studies, the validity of the results are doubtful (Jadad & Enkin, 2008; Olsen, 2000).

Another related major area of ethical concern in clinical trials is the use of placebo treatment. The first placebo treatment was applied in 1931; a clinical trial of pulmonary tuberculosis assigned participants by a flip of the coin into an experimental group treated with sanocrysin and a control group treated with distilled water (cited in Emanuel & Miller, 2001). Ever since then, placebo controlled trials have been controversial for RCT research. The World Medical Association (WMA) (2000) has reiterated that using a placebo treatment is unethical to participants when there is a known effective treatment. However, there is an exception when there is no current proven intervention, compelling and scientifically methodological reasons and no risk of serious or irreversible harm (World Medical Association, 2008). Rothman and Michels (1994) supported the view that placebos can ethically be used when any adverse outcomes are reversible; moreover, if participants are fully informed about the risks of a trial and still agree to participate then a placebo controlled trail should be ethical. Also, Temple and Ellenberg (2000a, 2000b) claimed that if participants who receive a placebo are neither harmed or they do not experience permanent adverse

effects, or only experience a temporary discomfort then the use of placebo treatment is ethical. Consequently, RCT research is a leading method of testing treatment efficacy; such a design is used to determine whether a new intervention is safe and effective, rather than to determine how efficacy compares with already proven interventions (Miller & Brody, 2002; Temple & Ellenberg, 2000a, 2000b). Therefore, without a placebo treatment to ensure validity, the finding that there is no difference between the investigational and standard treatments can be misleading or uninterpretable (Temple & Ellenberg, 2000a, 2000b).

## 4.5 Randomized Controlled Trial (RCT) in Dementia Research

Nursing research involves both quantitative and qualitative methodologies to generate evidence for clinical practice (Avis & Robinson, 1996). Because RCT design is considered to be the gold standard quantitative design, RCT is now in widespread use in nursing research including dementia research (Polit & Beck, 2008). These studies often focus on the problems in people with dementia such as falls (Neyens, et al., 2009), poor nutritional intake (Sampson, Candy, & Jones, 2009), the effects of antipsychotic medication, depression, psychiatric care and behavioural problems (Van Iersel, Zuidema, Koopmans, Verhey, & Olde Rikkert, 2005). Although the RCT design is recognised as a gold standard, the quality of reporting RCT continues to be problematic.

Mills and Chow (2003) evaluated the quality of reporting RCT studies in dementia research using the Jadad scale and 22 items of the CONSORT statement checklist. Fifteen articles for pharmacological intervention such as risperidone and haloperidol in long-term care residents with dementia were assessed between 1977 and 2003. In total, five studies did not report an institutional ethical review while two studies lacked informed consent from participants and next of kin; seven studies inadequately described blinding and ten studies did not report prior sample size calculations (Mills & Chow, 2003). In addition, Van Iersel et al. (2005) reported a systematic review of pharmacological adverse events in people with dementia from 1980 to 2005, they also found no RCT studies achieved all CONSORT statement requirements for the reporting of harm.

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## 4.6     Theoretical Framework Integrating Aromatherapy and Hand Massage

The purpose of this study was to compare the effects of two interventions - lavender oil spray and lavender oil spray combined with hand massage. Figure 4.3 outlines the theoretical framework used in this study, linking both aromatherapy and hand massage through the modified Dungan's Model of Dynamic Integration. Dungan (1997) claimed that humans have multi-dimensions; the dimensions of body, mind, and spirit are continuous, open and indivisible. Health relies on these three dimensions being integrated together and to allow for optimum functioning. The body embraces mind and spirit as an internal environment to allow functional interaction between the internal and external environment. The mind consists of cognition and psychology, which produces emotional and behavioural responses of humans. Spirit provides energy as an important part of the integrating influence of the whole. Such views are supported by Sheen (2006) in her study that interviewed 12 aromatherapists about the professionalisation of CAM in the Australian health system; the author found most aromatherapists agreed that aromatherapy was holistic and linked with body, spirit and mind.
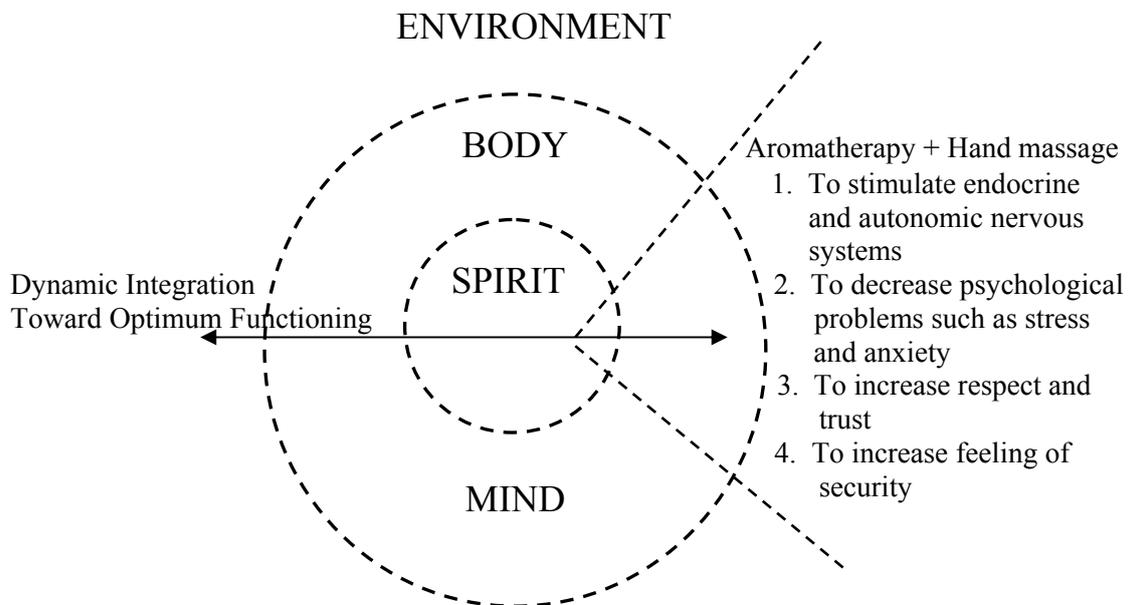


**Figure 4.3: Theoretical framework - The combination of aromatherapy and hand massage based on Dungan's Model of Dynamic integration (Lamm, Dungan, & Hiromoto, 1991, p. 183)**

This theoretical framework presents a successful integration and balance of three dimensions – body, spirit and mind (Lamm, et al., 1991). A combination of aromatherapy and hand massage provides an optimum function with a physical mechanism and psychospiritual comfort in the nursing home environment. Physical comfort refers to bodily sensations and the maintenance of homeostasis, which relates to the disease process or medical problems (Kolcaba, 2003). Psychospiritual comfort involves mental, emotional and spiritual elements of self, such as self-estem, self-concept and one's relationship to a higher order or being (Kolcaba, 2003).

Maslow's (1970) hierarchy of needs suggests that the basic physiological and safety needs are primary in human lives. Tender physical touch and pleasant smells may address a person's feeling of security and may fulfil higher-order needs. Lavender oil spray can stimulate the endocrine and autonomic nervous systems and have a psychological effect. Hand massage can be benefical for pain and discomfort because of its ability to decrease tension and stress, affect the pain cycle, and bring comfort through an increase in trust and respect (Greene & Goodrich-Dunn, 2004; Holey & Cook, 2003; Rose, 2010). Therefore, it is hypothesised that the combination of massage and lavender oil spray leads to decreased disruptive behaviour in older people when compared to people who receive lavender oil spray only.

## 4.7    Justification for using Randomized Controlled Trial (RCT)

The purpose of this study was to investigate the effects of two types of aromatherapy treatment; lavender oil spray and lavender oil spray combined with hand massage in decreasing agitation and aggression in older people with dementia. A single blind randomized controlled clinical trial (RCT) design was used with 61 participants allocated into three groups including a control (placebo) group. Nursing staff received an educational program on how to record agitation on the outcome measures (CMAI and RMBPC) before recording data from residents. In this study, a RCT was chosen as it represents a robust trial design to test complementary therapies which may be effective in decreasing disruptive behaviour in people with dementia. The RCT design would help to establish if the intervention was a reliable method to reduce the problem of behavioural disturbances and therefore offer the opportunity to lead to a reduction in the use of chemical and physical restraints in the long term care setting.

Due to the nature of aromatic substances in lavender oil, it was difficult to blind with any degree of certainty due to the fragrance; therefore, the double-blind placebo RCT was unable to be used in this study (Standen, 2006). In addition due to limited funds the investigator undertook some of the treatments. The RCT design helped to overcome the limitations of previous studies such as a single case study, no baseline data and no control group in order to avoid selection bias. The RCT design enabled a rigorous study of the effectiveness of aromatherapy, with or without hand massage, to be compared to a control group (Bowles, et al., 2002; Holliday-Welsh, et al., 2009; Kim & Buschmann, 1999; MacMahon & Kermode, 1998; Sansone & Schmitt, 2000).

### 4.7.1 Research Hypotheses

The research sought to answer the following question: what is the effect of aromatherapy with or without hand massage on disruptive behaviours in people with dementia? The research sought to address three hypotheses:

H1: Participants with dementia who receive aromatherapy (lavender oil spray) and hand massage for six weeks will display less agitation and aggression following the intervention than participants who receive aromatherapy only.

H2: Participants with dementia who receive aromatherapy (lavender oil spray) and hand massage for six weeks will display less agitation and aggression following the intervention than participants who receive water mist only.

H3: Participants with dementia who receive aromatherapy (lavender oil spray) for six weeks will display less agitation and aggression following the intervention than participants who receive water mist only.

### 4.7.2 Research Objectives

Primary objective:

- To investigate the efficacy of aromatherapy on disruptive behaviour in the management of people with dementia, as measured by CMAI and RMBPC
- To investigate the efficacy of aromatherapy and hand massage on disruptive behaviour in the management of people with dementia, as measured by CMAI and RMBPC.

Secondary objective:

- To evaluate the level of cognitive impairment in people with dementia, as measured by MMSE
- To evaluate staff reaction on disruptive behaviour in people with dementia, as measured by RMBPC-reaction.

### 4.7.3   Complementary Therapy Intervention Protocol

This study was guided by the protocol outlined below:

### 4.7.3.1 Before the intervention

1.      The investigator and research assistants (RAs) check that the participant's condition is unchanged since last intervention session, such as not being acutely ill with no behavioural symptom escalations.

2.      The investigator and RAs keep fingernails trimmed and remove rings, watches and jewellery, and do not wear any perfume that might interfere with the treatment session.

3.      Resources required: The investigator and RAs prepare liquid hand washing soap, paper towel, aqua lotion, lavender spray, water mist, participant's bed or a chair, a stopwatch for timing and the participants' list.

4.      Preparing environment: The investigator and RAs ensure all complementary therapies are undertaken in a quiet and private treatment environment such as the participant's room, a corner of the recreation room or garden.

### 4.7.3.2 Aromatherapy spray

Aromatherapy spray was used in this study because it was a simple and convenient way to convey a controlled treatment (lavender oil) to participants rather than using inhalation or a vaporizer, in which the treatment dose were considered to be less able to be controlled.  The use of inhalation or a vaporizer to administer essential oils is challenged by the size of the room, and the treatment may also accidentally be given to participants for example if they are walking through the environment, and in particular potentially influence the control group or residents not participating in the study if they are in proximity of the vaporization. Furthermore, standardized treatment is difficult with vaporization as participants may move from the room where the

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vaporizer is set up and therefore there is the potential that they will not receive a complete treatment during the intervention period. In addition vaporization would mean that the nursing staff would easily be made aware of the types of treatment that participants receive and therefore they may be biased when reporting their observations of disruptive behaviour. Therefore, lavender oil was administered by direct and individualised spray and in a private area, therefore ensuring an accurate recording of treatment dose without potentially influencing the control group or influencing nurses reporting of their observations.

Due to this population's frailty and to limited research funds, a dosage regimen trial was unable to be conducted to establish an effective dosage and frequency of application. Therefore, appropriate studies (Ballard 2002, Bowles 2006, Sydner 1995a, 1995b) were consulted for an appropriate dosage regimen and frequency of application. The aromatherapy used in this study was "Lavandula Angustifolia" by "Perfect Potion", which was listed in the Australian Register of Therapeutic Goods (ARTG) and each bottle was labeled with 'Aust L'. The oil supplied was 20 drops being equal to 1 ml (Svoboda, Ruzickova, Allan, & Hampson, 2001). The complementary therapy literature reported that a solution of between 2% to 5% of lavender oil is considered to be generally acceptable for spray application (Bowles, 2006; Buckle, 1997, p. 65). To reduce the risk of dermal irrtation in participants, the investigator followed the aromatherapy guidelines that suggest a safe dosage for dermal use is a maximum of 3% essential oil (Battaglia, 2002; Price & Price, 1999).

Before commencing the initial intervention during the first week, an allergic skin test was applied to participants' inner arm. If participants showed an allergic reaction over 24 hours such as redness and swelling, these participants are excluded from the study.

Lavender oil

The aromatherapy used in this study was "Lavandula angustifolia" by "Perfect Potion", a 3% lavender mist was made by the investigator. The product Lavender Essential Oil is described as follows (Battaglia, 2002, p. 218):

Essential oil: Lavender *(Lavandula angustifolia)*

Synonyms: L. officinalis Chaix; L. vera, Ture lavender

Origin: Bulgaria

Method of Extraction: Steam distillation

Chemical Composition: α-pinene (0.02-0.67%), limonene (0.02-0.68%), 1,8-cineole (0.01-0.21%), cis-ocimene (1.35-2.87%), trans-ocimene (0.86-1.36%), 3-octanone (1.75-3.04%), camphor (0.54-0.89%), linalool (29.35-41.62%), linalyl acetate (46.71-53.80%), caryophyllene (2.64-5.05%), terpinen-4-o1 (0.03-4.16%), lavendulyl acetate (0.27-4.24%).

Safety: non-toxic, non-irritating and non-sensitising.

Storage Conditions: Store below 30°C and protect from light.

The aromatherapy treatment protocol used in this study is described below (see Table 4.3).

**Table 4.3 The Aromatherapy Protocol**

| Procedure | Explanation | Time | Equipment |
|---|---|---|---|
| **Entry** | 1. The investigator/ research assistant enters the environment where the participant is identified and checked against the participants' list, ensuring correct participant.<br><br>2. Greet the participant, introduce self, explain the purpose of visiting and gain consent. For example, *"How are you, _____ my name is _____ and I am here to give you a complementary therapy, would you like to have it?"*<br><br>3. Check the environment if it is not private, seek the participant's consent to move to another place where the staff are not aware of the details of the type of the intervention. | 1~5 minutes (depending on environment) | • Private environment<br>• Participant list |
| **Position** | 1. Assist the participant to lie/sit on the bed or sit on the chair.<br><br>2. Allow the participant to adjust to the environment. | 2 minutes | • A bed or a chair |
| **Assessment** | The investigator/research assistant assesses any uncovered wounds on the participant's chest and face where the sprays may directly irritate the skin. | 0.1 minute | |
| **Information** | 1. The investigator/research assistant gives instruction about how the complementary therapy is given and avoids spraying into both eyes. For example, *"I am going to give you some mist sprays. Would you close* | 0.5 minute | |

| | | | |
|---|---|---|---|
| | *your eyes?*<br><br>2. The investigator/research assistant should limit conversation with the participant.<br><br>3. If at this point, or at any point before, during and after the intervention has begun, the participant becomes agitated, upset, distressed, or is attempting to get up, then the investigator/research assistant should leave the participant alone, and return at least 30 minutes later to attempt the procedure from the beginning.<br><br>4. Participants' agitated behaviour can be observed by their facial expression including tight facial muscles, eyebrows draw together, teeth clench, lines across forehead, rapid breathing, mouth turned down at corners and so on.<br><br>5. If the participant refuses treatment twice during each intervention period (9am-11am & 2pm-4pm), the participant is left alone, and participation is sought again at the next treatment period.<br><br>6. Inform staff of any agitated patients or other problems. | | |
| **Aromatherapy sequences** | 1. The investigator/research assistant keeps a 30 cm horizontal distance between the treatment spray and the participant's chest.<br><br>2. Administer three sprays of 3% Lavandula angustifolia mist to participant's chest<br><br>3. If the participant becomes agitated during the intervention, the intervention is stopped, the details of agitation are recorded in the log sheets and the participant is left alone.<br><br>4. During the intervention no deliberate communication is made with the participant. | 0.1~5 minutes (depending on the participant's mood) | • Lavender spray<br>• Participants' log sheets |
| **Completion** | 1. The participant's name checked on log sheets.<br><br>2. Assist participant to leave the private area or ensure the environment is safe to leave the participant alone. | 1~5 minutes | • Participant log sheets |

When combined therapy (aromatherapy spray and hand massage) is given, hand massage is adminstered first followed by aromatherapy spray. This process helps to reduce the chance of the research assistants inhaling the aromatherapy during administeration of hand massage.

### 4.7.3.4 Hand Massage

An expert masseuse trained the investigator before she trained the assistants to ensure the same method of administering hand massage was undertaken. The Snyder et al. procedure (1995a, p. 61) of hand massage guided the protocol, with each hand being massaged for two and half minutes using approximately 5 ml or four pumps of aqua lotion for both hands. Photographs of each step the protocol assistants applied can be viewed in Appendix I.

The lotion used for hand massage was Aqua Lotion. Product information is as follows:

<u>Aqua Lotion</u>

Skin Basics Aqueous Lotion (Soap Free)

- Made to a dermatological standard and is both a soap substitute and moisturiser.
- Hypoallergenic and pH balanced – suitable for sensitive skin.
- Non-greasy, fast absorbing
- Free of colour, perfume, lanolin and propylene glycol.
- Can be used on face, hands and body.

Ingredients: purified water, paraffin soft white, paraffin liquid, emulsifying wax-anionic, phenoxyethanol.

Entry, position and completion are the same as aromatherapy spray. The hand massage treatment protocol is below (see Table 4.4)

**Table 4.4 The Hand Massage Protocol**

| Procedure | Explanation | Time | Equipment |
|---|---|---|---|
| **Hand washing** | The investigator/research assistant washes hands with water and liquid hand washing soap and then dry hands. | 1 minute | <ul><li>Liquid hand washing soap</li><li>Paper towel</li></ul> |

| | | | |
|---|---|---|---|
| **Assessment** | The investigator/research assistant assesses any wounds on the participant's hands such as skin tears, laceration, bruises, red and swollen. | 0.1 minute | |
| **Information** | 1. The investigator/research assistant explains how the hand massage is given. For example, *"I will apply some lotion to your hands first, then I will gently massage your hands.*<br><br>2. The investigator/research assistant limits conversation with the participant.<br><br>3. If at this point, or at any point before, during and after the intervention has begun, the participant becomes agitated, upset, distressed, or attempts to get up, then the investigator/research assistant should leave the participant alone, and return at least 30 minutes later to attempt the procedure from the beginning.<br><br>4. Participants' agitated behaviour can be observed by their facial expression including tight facial muscles, eyebrows draw together, teeth clench, lines across forehead, rapid breathing, mouth turned down at corners and so on.<br><br>5. If the participant refuses treatment twice during each intervention period (9am-11am & 2pm-4pm), the participant is left alone, and participation is sought again at the next treatment period.<br><br>6. Inform staff of any agitation or other problems. | 0.5 minute | |
| **Hand massage sequences** | <u>Right hand</u><br>&bull; Apply aqua lotion (2.5 ml) to hands and rub hands together, then start the participant's treatment<br>1. Back of the hand massage:<br>A. Short/medium length straight strokes from wrist to fingertips using moderate pressure (effleurage).<br>B. Large half-circular stretching strokes from centre to side of hand using moderate pressure.<br>C. Small circular strokes over entire back of hand using light pressure (making little O's with thumb).<br>D. Featherlike straight strokes from | 5 minutes (Each hand massaged for two and half minutes) | &bull; Aqua Lotion (using 5 mls of four pumps of aqua lotion for both hands.)<br>&bull; Participants' log sheets |

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| | wrist to fingertips using very light pressure.<br>2. Palm of hand massage:<br>A. Short/medium length straight strokes from wrist to fingertips using moderate pressure (effleurage).<br>B. Gentle milking/lifting of tissue of entire palm of hand using moderate pressure.<br>C. Small circular strokes over entire palm of hand using light pressure (making little O's with thumb).<br>D. Large half-circular stretching strokes from centre of palm to side using moderate pressure.<br><br>3. Finger massage:<br>A. Gentle squeezing of fingers from base to tips on sides and top/bottom using light pressure.<br>B. Gentle circular range of motion of each finger followed by a gentle squeeze of the nail bed.<br><br>4. Completion of hand massage: Lay participant's hand on yours and cover it with your other hand. Gently draw your top hand toward you several times. Turn participant's hand over and gently draw the other hand toward you several times.<br><br><u>Left hand</u><br>Repeated above instructions for left hand.<br><br>5. If the participant becomes agitated during the intervention, the intervention is stopped, details of agitation are recorded in the log sheets and the participant is left alone.<br><br>6. During the intervention no deliberate communication is made with the participant. | | |
|---|---|---|---|
| **Hand washing** | The investigator/research assistant washes hands with water and liquid hand washing soap and dries hands. | 1 minute | • Liquid hand washing soap<br>• Paper towel |

Total 10.6~19.6 minutes (includes entry and completion time)

<u>Water Mist/Placebo</u>

Entry to information and completion were the same as the aromatherapy spray protocol. The water mist protocol is below (see Table 4.5)

**Table 4.5 The Control (Water Mist) Protocol**

| Procedure | Explanation | Time | Equipment |
|---|---|---|---|
| **Water mist sequences** | 1.  The investigator/research assistant keeps a 30 cm horizontal distance between water mist and the participant's chest.<br><br>2. Administer three sprays of water mist to the participant's chest.<br><br>3.  If the participant becomes agitated during the intervention, the intervention is stopped, the details of agitation are recorded in the log sheets and the participant is left alone.<br><br>4. During the intervention no deliberate communication is to be made with the participant. | 0.1~5 minutes (depending on the participant's mood) | • Water mist<br>• Participants' log sheets |

Total 4.7~18.6 minutes (includes entry and completion time)

## 4.8    Summary

This chapter outlined the fundamentals of RCT and presented two main types of bias that may occur in RCT studies, such as selection bias and ascertainment bias. Blinding helps to prevent these biases. Participants received the treatments in private areas without the nursing staff being aware of the treatment group in order to reduce bias. The three key principles of ethical conduct in RCT research revealed the dilemma between clinical efficacy and the code of ethics. Although RCT design has been used in long-term care settings and with people with dementia, the quality of reporting of such studies is a concern. Lavender oil is the most highly ranked sedative-effective essential oil and it is widely used in RACF. Hand massage therapy may address a person's feeling of security and may fulfil higher-order needs and provide a soothing effect under conditions of stress. As a therapy it is considered to be an acceptable physical treatment for older people with dementia and it has the potential to reduce disruptive behaviours. The research hypotheses and objectives clearly state the purpose of this study. In addition, a research protocol presents the details of the intervention process. Lastly, the Jadad scale, the Physiotherapy Evidence Database

(PEDro) scale, Delphi-based tools, Downs and Black checklist and the Consolidated Standards of Reporting Trials (CONSORT) Statement are discussed as a means of evaluating the importance of RCT quality. CONSORT is demonstrated to be a good guideline to report RCT and also a good basis for establishing a trial protocol. This study followed the CONSORT statement to guide the trials quality and the trials methods are discussed in Chapter 5.

# CHAPTER 5
# METHODS

## Chapter Overview

The aim of aromatherapy when used with people with dementia is to calm their mood in order to decrease agitation and aggression. Although studies have shown that aromatherapy may have positive influences on the behaviours of older residents who are in dementia care units or aged care settings, the range of effects of aromatherapy on disruptive behaviours is still largely unknown. In addition, the effect of massage therapy when combined with blended essential oils has not been clearly defined (Ballard, et al., 2002; Bowles, et al., 2002; Brooker, et al., 1997; Kilstoff & Chenoweth, 1998). There are a number of limitations of the previous aromatherapy research including small numbers of participants or a single case study and inaccurate recording of behaviour observations. This has resulted in limited generalisability of results (Beshara & Giddings, 2002; MacMahon & Kermode, 1998; Opie, et al., 1999). No control group and a short period of washout have also limited the validity of some results (Bowles, et al., 2002; Kim & Buschmann, 1999). Future research therefore needs to have a strong research design to overcome these problems. This study attempted to overcome the weaknesses of previous studies. This chapter provides a description of the research design, sample, and instruments that were used in this study.

## 5.1    Study Design

A single blind randomized controlled trial (RCT) design was used, with pre, during, and post intervention measures. This consisted of a control group and two experimental groups: (1) Combination (aromatherapy and hand massage), (2) Aromatherapy, (3) Control (placebo). A total of six trained assistants administered aromatherapy and hand massage using the protocol outlined in Chapter 4 in three RACF for a total of six weeks. As discussed previously in Chapter 2, agitation and aggressive behaviours are more likely to occur in the late afternoon or evening (Volicer, et al., 2001; Volicer & Hurley, 2003). Therefore, in an attempt to reduce agitation and aggressive behaviours before they occur, the intervention was given twice a day, at two time periods, 9 am to 11 am and 2 pm to 4 pm, seven days a week

for six weeks.

The six week intervention period was a modification of Ballard (2002) and Bowles' study (2002) with the intervention period being increased from four to six weeks treatment. Previous studies applied massage with essential oils onto participants, as the literature showed essential oils are well absorbed; the peak plasma concentrations were detected in the blood after 20 minutes by applying 2% lavender oils/1.5g of massage oil (Jäger, et al., 1992). However, as one group of participants was to be exposed just to lavender oil aroma a decision was made to use a direct spray to the upper chest of the person. This decision was based as outlined in Chapter 4, on residents being actively mobile around the facility and therefore challenging the restriction of the lavender oil aroma just to the treatment group. In addition given that the participants level of olfactory dysfunction may be compromised a direct spray to individuals was considered to be a more effective treatment.  This study is the first known study to apply essential oil spray to people with dementia, and therefore there is no literature to determine the dosage of essential oil spray and the effective period. Therefore, a decision was made to extend the treatment period of Ballard (2002) and Bowles' study by a further two-week treatment period with several data collection points as outlined later.

The length of hand massage followed Snyder et al.'s (1995a) study, where the results presented an effect on people with dementia when administering a five minute hand massage, each hand being massaged for 2.5 minutes in two equal time periods, morning and afternoon.

Agitated and aggressive resident behaviours were recorded on the 14 short-item Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield, et al., 1989) and the Revised Memory and Behaviour Problems Checklist (RMBPC) (Teri, et al., 1992). Justification for using these instruments is provided later in the chapter (see section 5.5.2). Data (resident behaviour) were collected five times in the study; prior to the intervention, at the end of the second and fourth weeks of intervention, at the completion of intervention, and six weeks following the completion of the intervention. A Mini Mental Status Examination (MMSE) (Folstein, et al., 1975) was also recorded at two time intervals (see Table 5.1).

**Table 5.1 Data collection**

| Measures | Pre-test/ Baseline | Week 2 | Week 4 | Week 6/ Completion Intervention | Post-test/ 6 weeks |
|----------|--------------------|--------|--------|--------------------------------|--------------------|
| CMAI | ✓ | ✓ | ✓ | ✓ | ✓ |
| RMBPC | ✓ | ✓ | ✓ | ✓ | ✓ |
| MMSE | ✓ | | | ✓ | |

## 5.2    The Intervention

The investigator trained six assistants to assist with administration of the treatments in Facility 1 and 2. The investigator administered treatments in Facility 2 and 3. To ensure assistants had the same method of administering treatments, each assistant received a total of three hours of training. First, assistants attended one hour of hand massage training from the investigator, and all assistants were required to demonstrate the hand massage protocol procedure to the investigator individually. In the following week of one hour training, the investigator explained how to administer the lavender spray and placebo (water mist) and the assistants practised the skills of aromatherapy and hand massage on each other. Lastly, the investigator undertook an audit of all assistants two or three days before administering treatments in the facilities. In addition, a protocol booklet of the aromatherapy and hand massage procedure, including pictures of each step, was provided to all assistants, to remind assistants and increase accuracy of treatments.

Nursing staff were blinded in this study, the investigator and research assistants followed the protocol to administer treatments to participants in private areas. The purpose of blinding was to ensure nursing staff (who were collecting data) did not know the types of intervention given to participants in order to provide behavioural data without personal bias. Treatments were undertaken in a quiet and private treatment environment such as the participant's room, a corner of the recreation room

or a garden. Curtains and folding screens were used if necessary to screen participants from the view of the nursing staff.

### 5.2.1  Aromatherapy

In this study the investigator used a 3% lavender mist, consisting of 75 drops of pure 100% lavender oil mixed with 4 ml essential oil solubiliser and 125 cc purified water. This mix was made by the investigator in order to ensure a standard was maintained in the dilution of the lavender oil. An allergic skin test was carried out before commencing the initial intervention at week one and was applied to participants' inner arm. The aromatherapy intervention consisted of lavender mist sprayed onto participants' chest, avoiding the face and eyes, the control group received three placebo sprays of water mist sprayed in the same way.

### 5.2.2  Hand Massage

The investigator and assistants administered hand massage to participants by using the Snyder et al. procedure (1995a, p. 61), with each hand being massaged approxmately for two and half minutes. The three groups received their assigned intervention twice a day, from 9am to 11am and 2pm to 4pm. Experimental Group 1 received three sprays of  3% lavender angustifolia mist and five minutes hand massage with 5ml of aqua lotion. Experimental Group 2 received three sprays of 3% lavandula angustifolia mist without hand massage. The Control Group received three sprays of water mist (placebo) (see Table 5.2).

**Table 5.2 Research design**

| | Intervention / Six weeks | |
|---|---|---|
| **Groups** | **Intervention** | **Method** |
| Experimental Group 1 | Combination (aromatherapy + hand massage) | Three sprays of 3% lavandula angustifolia mist twice /a-day, from 9am to 11am and 2pm to 4pm seven days a week. |
| | | 5 minutes hand massage with 5ml of aqua lotion twice /a day, from 9am to 11am and 2pm to 4pm seven days a week. |
| Experimental Group 2 | Aromatherapy | Three sprays of 3% lavandula angustifolia mist twice /a-day, from 9am to 11am and 2pm to 4pm seven days a week. |
| Control Group | Placebo | Three sprays of water mist (placebo) twice /a day from 9am to 11am and 2pm to 4pm seven days a week. |

## 5.3    The Settings

The research was conducted in three residential aged care facilities owned and operated by a not-for-profit aged care provider. The three facilities were located in the metropolitan area north of Brisbane. All facilities were selected as suitable facilities as the population, management and care systems, as well as staffing levels, were relatively the same, ensuring similar conditions. The facilities encompassed a total of 284 beds. Facility 1 contained 100 beds including low care, high care and a special care unit, Facility 2 was 88 beds with high care and Facility 3 included a 43-bed low care, 31-bed high care and 22-bed special care unit. As a result of the challenge of gaining relatives' consent for residents to participate in the research in an expedient manner, data were collected in two of the three facilities (Facility 1 and Facility 2) in the period 05/03/2006 to 02/07/2006 and data were collected from the third facility between 15/08/2006 and 7/12/2006.

## 5.4    The Sample

Participants were recruited from a combined total of 284 beds in the three facilities. The care managers selected 165 residents who appeared to fit the research selection criteria and then sent informed consent information to their next of kin. If there was

no response, a second posting of information was sent as a reminder three weeks later. A total of 67 residents with a diagnosis of dementia or cognitive impairment were recruited from the three facilities. Participants were recruited from Facility 1 (29 residents), Facility 2 (16 residents) and twenty-two residents were from Facility 3.

To reduce selection bias, a person not involved in the study randomized participants by a random number table (restricted randomization) in each residential care facility into three groups. As there are more females (70.9%) than males (29.1%) in nursing home populations it was likely that more females would be recruited, but that this would be a representative sample of the population (Australian Bureau of Statistics, 2003). Participants were randomly allocated into three groups: 22 participants into experimental group 1 and 23 participants into experimental group 2. The remaining 22 residents were allocated into the control group.

### 5.4.1 Selection Criteria

Residents in the designated aged care facilities were eligible for inclusion/exclusion if he or she met the following inclusion criteria:

1. Was aged 60 and over

2. Had lived in one of the three participating nursing homes for at least three months

3. Had cognitive function impairment indicative of a dementing condition, for example MMSE was 24 out of 30 or below 24 and has the features of Alzheimer's disease according to DSM-IV (American Psychiatric Association, 1991)

4. Had a two-week documented behavioural history of agitation and aggression in past three months

5. Received current physical or chemical restraint for agitation and aggression including P.R.N. (as required) medication

6. Consent had been given by family or a health-attorney for the resident's participation

7. Had no allergy to lavender oils

8. Had no recent wound on hands that would interfere with hand massage such as skin tears, laceration, and bruises, red and swollen.

The following exclusion criteria applied:

1.  Had a diagnosis of schizophrenia or mental retardation
2.  Had no documented behavioural history in the previous three months
3.  Was currently hospitalized
4.  Was going to be transferred to another residential facility in 3 months
5.  MMSE was higher than 24 out of 30.

Participants' age, frailty and diagnosis created participation challenges. One male resident died in the first week of the study and as per Lachin (2000) ITT protocol his data was excluded from the study. Five participants or their relatives withdrew their consent for participation in the six weeks of the study and as such the data for these cases were also excluded (Gross & Fogg, 2004) (see Figure 5.1).

### 5.4.2 Power Calculation

A power calculation was undertaken to identify group participation size. The sample size calculation was based on a previous study by Ballard et al. (2002), which explored the effectiveness of aromatherapy on agitated behaviour in 72 older adults with dementia using the CMAI as a primary outcome measurement. The results of the Ballard study showed that, post-intervention, the mean score of the CMAI was 23.1 (SD = 12.85) for the intervention group and 7.3 (SD = 17.1) for the control group and the effect size was $f = 0.52737$. Using this previously reported effect size, G-Power *a priori* calculations showed that, for this study, n=45 (n= 15 in each group) was required to obtain a power = 0.95, with an α of .05, using a repeated measures ANOVA analysis framework.
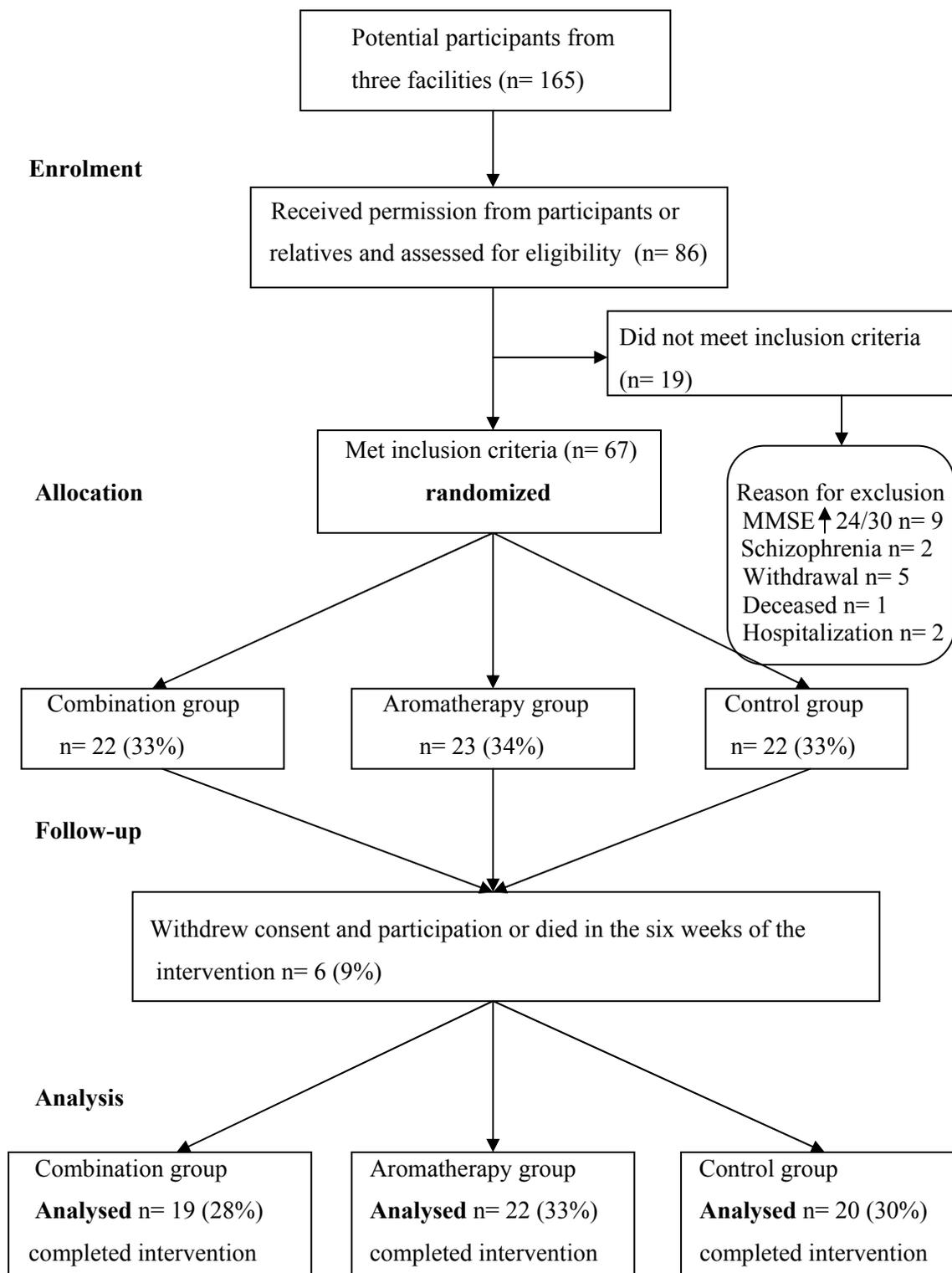
Figure 5.1 Flow chart of participants' progress through randomized trial

## 5.5 Measures

Qualified staff from each of the three facilities, such as clinical nurses (CNs), registered nurses (RNs), enrolled nurses (ENs), assistants in nursing (AINs) and activity therapists were involved in the data collection. As the majority of employees in long-term care settings are unqualified care staff, for example AINs and personal care workers (PCWs) and as they perform 80~90% of the direct care to nursing home residents (Edwards & Forster, 1998; Meyer, 1996), they were asked to be involved in the observation and recording of residents' agitated behaviour. Fifteen nursing and care staff were asked to rate disruptive behaviours at five intervals: during the pre-intervention period, the end of second week intervention, the end of fourth week intervention, at completion of the intervention, and six weeks post-intervention. To assist in the reliability of this data collection and to guide and assist staff to undertake the recording of behavioural data before data collection, the investigator conducted three educational programs on observation of agitation and aggression in the three facilities. Moreover, the investigator guided each nursing staff member who participated in rating residents' disruptive behaviours. The investigator encouraged all nursing staff to record residents' behaviour in each resident's progress notes to avoid losing potential data. Staff were blinded to the intervention type given to participants. During the data collection, the investigator or assistants attended the facilities seven days a week to implement the intervention and they were available to address questions and to guide the nursing staff.

A variety of data were collected as outlined below:

### 5.5.1 Demographic Data

Resident's age, gender, diagnosis, marital status, educational qualification, length of stay in current facility, sensory deficits, mobility and physical or chemical restraint history, were collected at baseline (see Appendix II). With the assistance of the RACF staff this data was collected from each resident's documentation and caregiver reports.

### 5.5.2 Instruments for the Agitation and Aggression

Agitated behavioural changes in people with dementia can be measured by several instruments such as the Behavioral Pathology in Alzheimer's Disease Rating Scale

(BEHAVE-AD) (Reisberg, et al., 1987), Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield, 1996; Cohen-Mansfield, et al., 1989), Dementia Behaviour Disturbance Scale (DBDS) (Baumgarten, Becker, & Gauthier, 1990), Nursing Home Behavior Problem Scale (NHBPS) (Ray, Taylor, Lichtenstein, & Meador, 1992), Neuropsychiatric Inventory (NPI) (Cummings, Mega, Gray, Rosemberg-Thompson, & Gornbein, 1994), Neurobehavioural Rating Scale (NRS) (Levin, et al., 1987), Pittsburgh Agitation Scale (PAS) (Rosen, et al., 1994), Rating Scale for Aggressive Behaviour in the Elderly (RAGE) (Patel & Hope, 1992) and Revised Memory and Behaviour Problem Checklist (RMBPC) (Teri, et al., 1992).

**5.5.2.1 Behavioral Pathology in Alzheimer's Disease Rating Scale (BEHAVE-AD)**
The Behavioral Pathology in Alzheimer's Disease Rating Scale (BEHAVE-AD) was developed by clinical experts to measure change in disruptive behaiour in people with Alzheimer's (Reisberg, et al., 1987; Sansoni, et al., 2007). The scale consists of seven categories in total of 25 items and a global rating, paranoid and delusion ideation, hallucinations, activity disturbance, aggressiveness, diurnal rhythm disturbances, affective disturbances and anxieties and phobias (Reisberg, et al., 1987). Those items are scored by adding severity scales from 0 to 3. The survey obtains information from carergivers and takes approxmately 20 minutes to complete.

**5.5.2.2 Cohen-Mansfield Agitation Inventory (CMAI)**
The Cohen-Mansfield Agitation Inventory (CMAI) is an internationally validated instrument that measures behavioural disturbance in people with dementia for the previous two weeks. The original CMAI was 29 items and was developed for use in nursing homes (Cohen-Mansfield, 1996; Cohen-Mansfield, et al., 1989). The inter-rater agreement rates of three units of a nursing home were .92, .92 and .88 (Cohen-Mansfield, et al., 1989). The CMAI has been reported to have significant correlations with measurements of behavioural disturbance such as BEHAVE-AD, NHPBS, RAGE and RMBPC (Ray, et al., 1992; Sansoni, et al., 2007; Shan, Evans, & Parkash, 1998). A 14 short-item version was modified in 1994 (Werner, Cohen-Mansfield, Koroknay, & Braun, 1994) and covers the areas of agitation and aggression. The inter-rater reliability of the short version has been reported as .93 (Werner, et al., 1994). The items are scored on a five-point frequency scale 1 "Never" to 5 "A few times an hour or continuous for half an hour or more". The scores can be summed if items

relating to specific behaviour or the domains (Werner, et al., 1994). This survey is completed by caregivers and takes approximately 10 minutes to complete.

**5.5.2.3 Dementia Behaviour Disturbance Scale (DBDS)**

The Dementia Behaviour Disturbance Scale (DBDS) is a 28-item instrument, which has been used in outpatient settings, residential cares and the community (Baumgarten, et al., 1990; Neville & Byrne, 2007; Ott, Tate, Gordon, & Heindel, 1996). A five-point scale ranges from 0 "Never " to 4 "All the time" to measure behavioural changes over the previous week; moreover, it can be completed in 15 minutes by interviewing caregivers (Baumgarten, et al., 1990). Although the scale has a good internal consistency of > .80, there was a limited information of the instrument used as an outcome measure in clinical trials (Sansoni, et al., 2007).

**5.5.2.4 Nursing Home Behaviour Problem Scale (NHBPS)**

The Nursing Home Behaviour Problem Scale (NHBPS) was developed to measure specific behaviour problems over the previous three days such as hallucinations (Ray, et al., 1992). There are 29 items in NHBPS and it uses a 5-point scale to assess behavioural frequency of occurrence from 0 "Never" to 4 "Always". The scale can be completed by various care providers and only requires three to five minutes to complete.

**5.5.2.5 Neuropsychiatric Inventory (NPI)**

The Neuropsychiatric Inventory (NPI) is based on a 10-15 minute structured interview with caregivers. The NPI includes 10 behavioural domains, delusions, hallucinations, agitation/aggression, depression, anxiety, euphoria, apathy, disinhibition, irritability, aberrant behaviours and night-time behaviours; in addition, it also contains two types of neuro-vegetative change, appetite and eating disorders (Cummings, et al., 1994). The internal consistency was .75 to .89 for each item (Cummings, et al., 1994). A screening question is asked "Yes" or "No" first for each item then the caregivers are asked to rate behavioural frequency from 1 to 4 and the severity from 1 to 3 (Cummings, et al., 1994).

### 5.5.2.6 Neurobehavioural Rating Scale (NRS)

The Neurobehavioural Rating Scale (NRS) was originally designed to focus on psychiatric symptoms in people with traumatic brain injury and has been used in the aged care setting (Levin, et al., 1987). The NRS measures behaviour, mood and cognitive function. A total of 27 items range between "Not Present" and "Extremely Severe" in a seven-point severity scale (Levin, et al., 1987). NRS has been used in hospital settings, the test-retest reliability was > .70 in people with dementia (Pollock, et al., 2002). "Fluent aphasia" was added as an additional item when measuring behavioural disturbance in people with dementia (Sultzer, Berisford, & Gunay, 1995).

### 5.5.2.7 Pittsburgh Agitation Scale (PAS)

The Pittsburgh Agitation Scale (PAS) is also a tool to assess the level of agitation in the dementia field (Rosen, et al., 1994). The PAS measures agitation in four domains, aberrant vocalisations, motor agitation, aggressiveness and resisting care. The scores are from 0 " Not Present" to 4 "Most Disruptive or Unsafe Behaviour"(Rosen, et al., 1994). Staff members observe the patient's behaviour during a rating period of four to eight hours and take less than 1 minute to complete it.

### 5.5.2.8 Rating Scale for Aggressive Behaviour in the Elderly (RAGE)

The Rating Scale for Aggressive Behaviour in the Elderly (RAGE) was developed to measure the quantity and severity of aggressive behaviour in people with dementia within a 3-day period (Patel & Hope, 1992). The RAGE includes three categories such as verbal aggression, physical aggression and antisocial behaviour. There are 21 items and scores range between 0 "Never" to 3 "More than once everyday in the past 3 days". The scale is applicable to assess mild to severe stages of dementia with five minutes of administration (Patel & Hope, 1992).

### 5.5.2.9 Revised Memory and Behaviour Problems Checklist (RMBPC)

The survey is a 24-item checklist that assesses behavioural problems in people with dementia. The checklist provides one total score and three subscores for the following problems: memory loss, depression and disruptive behaviours. A five-point scale ranges from 0 "Never occurred" to 4 "Daily or more often" and rates the frequency of the behaviour over the previous week. It also assesses the level of the caregiver's reactions to each behaviour on a range from 0 "not at all" to 4 "extremely". Internal

consistency was found to be .75 for the frequency estimates and .87 for caregiver reactions (Teri, et al., 1992). The RMBPC was identified as a suitable measurement for use in the nursing home and community environment (Neville & Byrne, 2001). RMBPC is also an easy-to-use tool which requires less than 10 minutes to complete (Neville & Byrne, 2001).

In this study, the measurements were considered according to (i) an easy as well as short time for administration of the measure, as the care staff were being asked to complete the measure, (ii) applicability as a global measure in dementia assessment, (iii) length of observation period (iv) the need for an assessment of staff reaction to the disruptive behaviour, and (v) instruments considered as being suitable according to the Dementia Outcome Measures (Sansoni et al., 2007). Although BEHAVE-AD and NPI are international standard measurements, 15-20 minutes of administration time was considered to be too long for nursing staff to complete in one interview. The DBDS is not commonly used in Australian aged care settings and also takes 15 minutes to complete the survey (Sansoni, et al., 2007). The PSI, NHBPS and RAGE require a short period of observation time (4 hours to three days) to record behavioural changes. Although the PSI may be suitable for use on acute care geriatric psychiatry wards it was not considered to be of use in nursing homes (Rosen, et al., 1994). NRS was originally designed for patients with brain injury and therefore may not be suitable for people with dementia (Sansoni, et al., 2007).

The CMAI and RMBPC were chosen for this study because these instruments have been identified as valid and reliable instruments for the measurement of disruptive behaviour in older people with dementia in both nursing homes and the community (Cohen-Mansfield, et al., 1989; Neville & Byrne, 2001; Teri, et al., 1992; Werner, et al., 1994). CMAI and RMBPC were completed by nursing staff at five data collection times (see previous Table 4.1). The 14-item survey of CMAI was chosen over the 29-item survey as it was felt that the decreased staff completion time would minimize the risk of incomplete data and decrease the likelihood of the data recording being seen as an inconvenience (see Appendix III and IV). RMBPC comprises the assessment of staff reaction that assisted obtaining information about how nursing staff react to disruptive behaviour in nursing homes (see Appendix V). Nursing staff measured residents' behaviours during their shift or information was provided from handover.

The investigator was available to oversee the completion of the instruments by the nursing staff.

### 5.5.3   Instruments for the Assessment of Cognitive Status

In this study, participants' cognitive function can be measured by their mental status such as orientation to time and place, concentration and short memory test (Sansoni, et al., 2007). Several instruments were selected because they covered a range of settings including nursing homes. These are Alzheimer's Disease Assessment Scale-Cognition (ADAS-Cog), Mini Mental Status Examination (MMSE), and Test for Severe Impairment (TSI).

### 5.5.3.1 Alzheimer's Disease Assessment Scale-Cognition (ADAS-Cog)

The Alzheimer's Disease Assessment Scale (ADAS) was developed to assess cognitive, affective and behavioural problems (Rosen, Mohs, & Davis, 1984). ADAS takes 30 to 45 minutes to complete, a total of 21 items scale including 11 item cognitive subscales (ADAS-Cog). The ADAS-Cog consists of three categories, memory, language and praxis, the total socre can range from 0 to 70. A higher score means worse impairment. A test-retest reliability was .93 (Sansoni, et al., 2007; Weyer, Erzigkeit, Kanowski, Ihl, & Hadler, 1997). ADAS-Cog was found to have significant correlation with the MMSE.

### 5.5.3.2 Memory Status- Mini Mental Status Examination (MMSE)

The MMSE is the most widely used measure of cognitive functioning and has been shown to have an excellent test/retest reliability of .89 and internal consistency of .83 (Tombaugh & Mclntyre, 1992). The MMSE is also used in the early assessment of symptoms related to Alzheimer's disease and usually requires only five to ten minutes to administer (Folstein, et al., 1975; Galasko, et al., 1990). The MMSE has a maximum score of 30 points. Eleven questions with different domains are assessed: orientation to time and place, registration of three words, attention and calculation, recall of three words, language, and visual construction (Folstein, et al., 1975). A MMSE score between 24 to 19 points indicates older people may have mild cognitive function impairment, moderate is 18 to 10 and severe cognitive impairment is less than 10 (Galea & Woodward, 2005; Ward, Caro, Kelley, Eggleston, & Molloy, 2002).

### 5.5.3.3 Test for Severe Impairment (TSI)

A basic tool of cognitive assessment, such as the MMSE, focuses only on detecting symptoms of dementia; it is not able to be used as a diagnostic screening instrument (Yesavage & Brooks, 1991). Furthermore, the MMSE can prove difficult to use in people with severe dementia. Albert and Cohen (1992) designed a reliable and valid measurement, called the Test for Severe Impairment (TSI), to assess the later stages of severe cognitive impairment. The TSI is highly correlated with the MMSE ($r = 0.83$, $p \leq 0.0001$), the internal reliability of the TSI was .90 and test-retest reliability was significant ($r = .96$, $p < 0.0001$) (Albert & Cohen, 1992). The TSI consists of six subsections with 24 items: motor performance (four items), language comprehension (four items), language production (four items), immediate and delayed memory (four items), general knowledge (four items) and conceptualisation (four items). In addition, the TSI only requires 10 minutes to complete (Albert & Cohen, 1992).

In conclusion, although the ADAS-Cog and TSI have good psychometric properties, they require a high degree of skill in administration and training (Sansoni, et al., 2007). Moreover, the ADAS-Cog is often completed by neuropsychologists or psychologists (McDowell, 2006; Sansoni, et al., 2007). Also, it is a time-consuming, and if the length of tests is too long, the participants may not be able to complete all questions due to their mental status. MMSE is a standard tool for screening cognitive impairment and is easy to score with 5-10 minutes administration time (see Appendix VI and VII). Participants were sought with any stage of cognitive impairment as the main focus was on each participant having a history of agitated behaviour. Therefore, the MMSE was considered to be a suitable choice in this study. The investigator was trained and experienced in use of the MMSE and she completed the MMSE for all participants.

## 5.6 Statistical Analysis

The CMAI and RMBPC were collected five times: pre-test, every second week during the intervention and post-test. The MMSE was collected twice: baseline and after completion of the intervention. The investigator coded data and a coding manual was prepared to define the numerical codes. Responses were coded and entered into the Statistical Package for Social Sciences (SPSS) version 15.0 program (Coakes, Steed,

& Dzidic, 2008). Missing values were coded as number " 7 ". To avoid entry errors, data were checked for completeness and inconsistencies (Polit & Beck, 2008). The data file was compared visually with codes on the original source; data were screened for errors (less than 0.001%) by examining ranges, frequencies, normality, missing values, descriptives and outliers using SPSS. Raw data such as participants' age and cognitive impairment were modified and transformed to new codes before analysing.

Data analysis was guided by the intention-to-treat (ITT) principle. The principle of the ITT approach includes available completed outcome data for all randomized participants. It can minimise bias such as Type I error (false positive) and missing data (withdrawal bias) (Hollis & Campbell, 1999; Jadad & Enkin, 2008; Kruse, et al., 2002; Lachin, 2000). Data from all of the 61 participants were included in this current study (see Figure 5.1). Descriptive statistics were used to analyse the demographic data. Descriptive statistics were used as a first step to examine the integrity of the data to be analysed with inferential statistics used to compare frequencies, percentages, means and standard deviations on each demographic (Polit & Beck, 2008). Chi-square test was used for testing independence of variables and homogeneity in the three groups (Polit & Beck, 2008).

The sample size of 61 participants is insufficient for factor analysis (Coakes, et al., 2008, p. 121). Therefore, the analysis for this current study is based on descriptive examination of CMAI and RMBPC's sub-items on the outcomes of previous factor-analytic studies. Rabinowitz et al. (2005) identified four factors for the CMAI 29-item long form as being equal to the CMAI 14-item short form. These were physically nonaggressive behaviours I (4 items), aggressive behaviours II (5 items), verbally agitated behaviours III (3 items), and hiding and hoarding IV (1 item) (Rabinowitz, et al., 2005).

Factor I – Physically nonaggressive comprised four items: "Paces, aimless wandering, trying to get to a different place"; "General restlessness, performing repetitious mannerisms, tapping"; "Inappropriate dress or disrobing"; and, "Handling things inappropriately". Factor II – Aggressive behaviours included: "Hitting, kicking, pushing, biting, scratching"; "Grabbing onto people, throwing things, tearing things or destroying property"; "Cursing or verbal aggression"; "Screaming"; and, "Other

aggressive behaviours – hurt self or other". Factor III – Verbal agitation included: "Constant request for attention or help"; "Complaining, negativism, refuses to follow direction"; and, "Repetitive sentences, calls, questions, or words". Factor IV was "Hiding and Hoarding things". "Strange noise" such as weird laughter or crying did not load on any factor in previous studies, so the item was not considered in the current study.

Teri et al. (1992) reported that 24 items from the RMBPC loaded on three factors. Factor I – Memory loss included seven items: "Asking the same question over and over"; "Trouble remembering a recent event"; "Trouble remembering significant past events"; "Losing or misplacing things"; "Forgetting what day it is"; "Starting, but not finishing things"; and "Difficulty concentrating on a task". Factor II – Depression included nine items: "Appears anxious or worries"; "Threats to hurt oneself"; "Appears sad or depressed"; "Expressing feeling of hopelessness or sadness about the future"; "Crying and tearfulness"; "Comments about death of self or others"; "Talking about feeling lonely"; "Comments about feeling worthless or being a burden to others"; and, "Comments about feeling like a failure or about not having any worthwhile accomplishments in life". Factor III – Disruptive behaviours included eight items: "Destroying property"; "Doing things that embarrass you"; "Waking other residents up at night"; "Talking loudly and rapidly"; "Engaging in behaviour that is potentially dangerous to self or others"; "Threats to hurt others"; "Aggressive to others verbally"; and, "Arguing, irritability, and/or complaining". Linear regression and a nonparametric Kruskal-Wallis test were applied to the data from this current study.

### 5.6.1 Post Analysis-Case Study

During the conduct of the RCT the researcher noted the way in which the interventions were experienced by those involved. As Jansen, Foest and de Bont (2009) argued, qualitative findings can usefully contribute to RCTs, particularly in regard to providing context for trial results. Although not planned in the original design, an exploration of these reflective notes identified interesting behavioural changes in participants during the trial and, although not the central focus of the study, they provided some valuable insights into the interventions. Case studies were developed

from an analysis of reflective notes to present examples of clinically important aspects of the interventions. Due to different characteristics, participants responded to the interventions differently; their behaviour at times also changed when receiving the treatment, and as such any changes in participants' behaviour were recorded in reflective notes by the investigator. Reflective notes included the date/time, the event, participants' behavioural or stated feelings over time and the action taken by the investigator (see example of the reflective notes from one of the participants that was developed into a case study in Appendix VIII). The cases were developed following identification from the investigator's reflective notes of impressive behavioural changes. These behaviours were defined in the Cohen-Mansfield Agitation Inventory (CMAI) and discussed in Chapter 2 (Cohen-Mansfield, 2000, 2003). Information was also obtained from nursing staff, family members, research assistants and the investigator's observations. Although the cases presented do not follow a rigorous case study approach (Yin, 2009), as a variety of evidence was available to the researcher, case studies were deemed to be the most useful way to present these participants' responses to the intervention. In a comparison with baseline data, case study participants had a significant negative or positive verbal or physical behavioural change during the six weeks of the intervention period. Three participants demonstrated examples of the positive effects of the interventions while others represented a negative reaction and the challenges of participant retention in this study. The reflective notes, information from others and results of CAMI and RMBPC were synthesized in such a way that a descriptive case study that illustrated the clinically important meanings and interpretations of the issues for these individual five participants was written. These case studies are presented in Chapter 6 and although not central to the research study provide an interesting context to the main RCT results.

## 5.7    Ethical Considerations

The ethical considerations of this study were based on three principles: beneficence, respect for human dignity, and justice (Polit & Beck, 2008). Ethical approval to conduct the study was obtained from the Human Research Ethics Committee (HREC) of Griffith University (ref. NRS/25/05/HREC) and from the aged care facility management (see Appendix IX, X and XI).

### 5.7.1   Informed Consent

Participants were not deliberately chosen by gender, race, religion or financial status. Participant selection complied with ethical standards and procedures for protecting the interests of study participants, including equitable selection and recruitment of participants, informed consent and ethical merits of the study (National Research Council of the National Academies, 2004).

Informed consent is usually focused on an individual; however, it can involve various levels in RCT such as ethics committees, grant awarding bodies, community consent, professional consent, household consent and experimental subjects (Hutton, 2001). A letter giving details of the research was sent to the facility managers of the three facilities, dementia care specialists, aromatherapists and general practitioners (GPs) to inform and consult a range of professionals within each of the facilities. To accommodate the different daily schedules of each facility, the investigator met with the facility managers and staff  a total of 12 times in each of the three facilities, as well as family members, to explain the research and to address any questions. Each of the facility managers was asked to address envelopes and to mail out the invitation to an information session, as well as an information and consent package, to families and health attorneys (World Medical Association, 2008). The information and consent forms were written in simple comprehensible language to avoid literacy bias (Coyne, et al., 2003; Jadad & Enkin, 2008). The information package gave clear details of the research (see Appendix XII) and gave adequate time (1 month) to consider participation. According to the Declaration of Helsinki, for minors and individuals who cannot reasonably give informed consent, those with power of attorney are allowed to give consent on their behalf (World Medical Association, 2008). Because of significant cognitive impairment, residents were unable to provide informed

consent; thus, consent was sought from residents' health attorney or family (see Appendix XIII). Eighty-six consent forms were returned from a potential sample of 165 participants or next of kin; however, only 67 participants met the inclusion criteria and commenced the study.

The placebo-controlled trial is ethically justifiable when there is a sound methodological consideration and the placebo treatment, in this case, water mist does not expose participants to excessive risk or harm. According to the ethical principles concerning human subjects of research (National Health and Medical Research Council, et al., 2007), this research was based on research merit and integrity, justice, beneficence and respect to protect participants with a cognitive impairment. In addition, equipoise is an important consideration in RCT research (Jadad & Enkin, 2008). Although the RCT is a fair design that allocates participants so that they have an equal chance to receive the treatment, some participants may benefit from the treatment, while others may not. Therefore, every participant has a right to choose whether or not to participate in the study. Participants might not be allocated to the groups they would prefer, but implied consent/assent for the procedure was sought when participants were asked at each session, prior to the intervention being given and whether they would like to receive the treatment. Participants had the right to withdraw at any time if they found they did not like the treatment or no longer wanted to be involved in the study (National Health and Medical Research Council, et al., 2007; World Medical Association, 1964). The informed consent forms explained that participation or non-paticipation would not affect service provision or care.

Participants with severe dementia may lack the verbal capacity to make on autonomous decision and to express their thoughts. These participants inevitably were ubable to give consent during the intervention. Therefore, a study protocol in Chapter 4 recommended the investigator and assistants stop administering treatments if participants showed negative facial expressions or physical resistance to treatments prior to or during the procedures. The investigator abided by the National Health and Medical Research Council (NHMRC) principles governing the ethical conduct of research which at all times was to protect the interests, comfort and safety of residents and relatives. The supervisors for this study supervised the project and ensured that the ethical principles were adhered to.

### 5.7.2 Ethical Management of Allergy and Data Security

There were minimal risks to participants in this study and these have been managed. As already indicated in page 72 and 84, a check for allergy to lavender oil was undertaken with all potential participants. To ensure confidentiality of participants all data was reported as grouped data and no individual was identified (Polit & Beck, 2008). Data was collected in an identifiable form and then coded with the keycode kept separately from the data. Data was securely stored at all times during data collection, analysis and upon completion of the study. Data will be stored at Griffith University for the required time period of five years after completion of the study before being destroyed.

### 5.8 Summary

In summary, a single blind randomized controlled trial (RCT) design was used in the study. Sixty-seven participants were randomly allocated to groups; experimental group 1 (Combination of aromatherapy & hand massage), experimental group 2 (Aromatherapy) and Control group (placebo – water mist). Five participants or their relatives withdrew consent from participation during the study and one participant died. The intervention was given twice a day, seven days a week for six weeks. The Cohen-Mansfield Agitation Inventory (CMAI) and Revised Memory and Behaviour Problems Checklist (RMBPC) were utilised for the observation of participants' disruptive behaviours by nursing staff. The Mini Mental Status Examination (MMSE) was collected as evidence of participants' cognitive status. Descriptive statistics, Chi-square test, linear regression and goodness of fit, a nonparametric Kruskal-Wallis test and post analysis were applied to the data. Ethical considerations explained how the study obtained the informed consent from participants and relatives. The next chapter describes the results of this analysis.

# CHAPTER 6
# RESULTS

**Chapter Overview**

This chapter presents the results of the study through descriptive and inferential statistics. First, the characteristics of the 61-person sample are described. Second, a demographic profile of the residents for each of the aged care facilities is presented. Third, descriptive statistics are reported for the Cohen-Mansfield Agitation Inventory (CMAI) and the Revised Memory and Behaviour Problem Checklist (RMBPC), including sub-items in three categories. Fourth, inferential statistics are reported for the hypotheses of interest. Finally, a post analysis of case studies is presented to provide several examples of individual residents' experiences.

## 6.1    Characteristics of the Sample

Table 6.1 shows that of the 61 participants from three facilities, 25 (41%) were males. Facility 1 had 24 participants with an equal number of males and females. Facility 2 had more female participants than the other facilities, 3 (18.8%) men and 13 (81.2%) women. Facility 3 included 10 (47.6%) men and 11 (52.4%) women. Participants ranged in age from 61 to 93 years with a mean age of 84 years (SD = 6.36). Regardless of facility, the majority of participants ranged in age from 80 to 89 years (70.5%, n = 43).

Approximately half of the participants (n = 32, 52.5%) were widowed and 20 (32.8%) married. More than 40% (n = 26) of these participants had lived in the participating facilities from one to three years. Nineteen (31.2%) participants had lived in their facility for less than one year. Only one (1.6%) participant had lived in their facility for more than 10 years.

Close to 50% (n = 28) of participants lived in a high care nursing home setting and 31% (n = 19) of participants lived in special care units. Fourteen (23%) participants lived in hostels; however, four (6.5%) of these participants still required high care. Nearly 90% (n = 53) of participants required high care and relied on nursing staff assisting them with daily activities, such as hygiene and feeding (see Table 6.1).

**Table 6.1 Participant demographics**

| Item | Sample (*n = 61*) | Percent (%) |
|---|---|---|
| **Facility** | | |
| Facility 1 | 24 | 39.4 |
| Facility 2 | 16 | 26.2 |
| Facility 3 | 21 | 34.4 |
| | | |
| **Gender** | | |
| Male | 25 | 41.0 |
| Female | 36 | 59.0 |
| | | |
| **Age** | | |
| 60-69 | 1 | 1.6 |
| 70-79 | 10 | 16.4 |
| 80-89 | 43 | 70.5 |
| 90 & higher | 7 | 11.5 |
| | | |
| **Marital status** | | |
| Single | 5 | 8.2 |
| Married | 20 | 32.8 |
| Widowed | 32 | 52.5 |
| Divorced | 3 | 4.9 |
| Separated | 1 | 1.6 |
| | | |
| **Period living in facility** | | |
| 3 and12 months | 19 | 31.2 |
| 1-3 years | 26 | 42.6 |
| 4-6 years | 12 | 19.7 |
| 7-9 years | 3 | 4.9 |
| 10 years plus | 1 | 1.6 |
| | | |
| **Living setting** | | |
| Hostel (low care) | 14 | 23 |
| Nursing home (high care) | 28 | 46 |
| Special care unit (high care) | 19 | 31 |
| | | |
| **Care setting** | | |
| High care | 53 | 86.9 |
| Low care | 8 | 13.1 |

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The health of participants was also reviewed. Most participants had at least one or two sensory deficits: vision (83.6%, n = 51) was a major health problem, followed by hearing (41%, n = 25) then pain (31.1%, n = 19). More than one-third of participants (41%, n = 25) walked with an assistive appliance; in addition, 18 (29.5%) participants were chair-fast (see Table 4.2). Fifteen participants (51.7%), who were chair-fast because of a physical condition, also had a severe cognitive impairment.

**Table 6.2 Participants' sensory deficits and mobility**

| Item | Sample (n = 61) | Percent (%) |
|---|---|---|
| **Sensory deficits** (can chose more than 1) | | |
| Hearing | 25 | 41.0 |
| Vision | 51 | 83.6 |
| Pain | 19 | 31.1 |
| | | |
| **Mobility** | | |
| Mobile | 18 | 29.5 |
| Wheelchair | 3 | 4.9 |
| Walking stick | 2 | 3.3 |
| Mobile Walker | 20 | 32.8 |
| Chair-fast | 18 | 29.5 |

Table 6.3 presents the diagnosis and cognitive impairment of the participants; of the 61 participants, 34 females and 19 males had a diagnosis. Almost half (n = 29) of the participants had been diagnosed with "dementia" followed by "Alzheimer's disease" (AD) (26.2%, n = 16). Eight participants (2 females and 6 males) did not have a definitive diagnosis; however, they had a cognitive impairment and met the criteria for AD according to DSM-IV-TR, such as multiple cognitive deficits including memory impairment, one or more cognitive disturbances, with or without behavioural disturbance (American Psychiatric Association, 2000).

The largest proportion (47.5%, n = 29) of participants had a MMSE that placed them within the category of severe cognitive impairment. Fourteen participants (23%) scored 0 on the MMSE, indicating they were not able to respond to any of the MMSE questions. Those 14 participants with severe cognitive impairment were distributed between the combination (aromatherapy and hand massage) group (42.9%, n = 6), aromatherapy group (21.4%, n = 3) and control group (35.7%, n = 5).

**Table 6.3 Participants' diagnosis and cognitive impairment**

| Item | Sample (*n = 61*) | Percent (%) |
|---|:---:|:---:|
| **Diagnosis** | | |
| Cognitive impairment | 8 | 13.1 |
| Dementia | 29 | 47.5 |
| Alzheimer's disease | 16 | 26.2 |
| Vascular dementia | 3 | 4.9 |
| Multi-infarct dementia | 2 | 3.3 |
| Other (e.g. Toxic dementia) | 3 | 4.9 |
| **Baseline-Mini-mental status (score)** | | |
| Mild (19-24) | 9 | 14.8 |
| Moderate (10-18) | 23 | 37.7 |
| Severe (0-9) | 29 | 47.5 |

The majority of participants at baseline had verbal (n = 43, 70.5%) and physical (n = 53, 86.9%) agitation, such as a constant request for attention or help and wandering. Close to half of the participants also had verbal aggression (n = 25, 41%), and 18 (29.5%) participants had physical aggression such as hitting, kicking, throwing things and tearing things (see Table 6.4).

**Table 6.4 Participant's disruptive behaviours at baseline**

| Item | Sample (*n = 61*) | Percent |
|---|:---:|:---:|
| **Disruptive Behaviours** (can chose more than 1) | | |
| Verbal agitation | 43 | 70.5 |
| Physical agitation | 53 | 86.9 |
| Verbal aggression | 25 | 41.0 |
| Physical aggression | 18 | 29.5 |

More than half (50.8%, n = 31) of the participants were given a regular analgesic, such as Paracetamol or Aspirin. A major proportion (n = 50, 82%) of participants were subject to both physical and chemical restraint. The total of 19 participants who lived in special care units (SCU) over 50% (n = 11) of the participants were taking antipsychotic medication (see Table 6.5).

**Table 6.5 Restraint and sedative/pain use**

| Item | Sample (*n = 61*) | Percent |
|---|:---:|:---:|
| **Restraints** | | |
| No restraint used | 1 | 1.6 |
| Physical restraint | 1 | 1.6 |
| Chemical restraint | 9 | 14.8 |
| A combination of physical and chemical | 50 | 82 |
| | | |
| **Regular antipsychotic medicine** | | |
| (can chose more than 1) | | |
| Risperidone | 9 | 14.8 |
| Haloperidol | 5 | 8.2 |
| Other (e.g. Temazepam, Zolpidem) | 14 | 22.8 |

## 6.2    Participant Demographic Profile

Figure 6.1 (below), provides an Optimal Scaling (SPSS) representation of the demographic profile of the participants of all three facilities. In this demographic profile, symbols represent these variables, and their labeling indicates specific response categories for variables. The vertical axis demarcates that the older age group tends to be female. Moreover, the horizontal axis is aligned with females versus males (left to right), such that female participants with severe cognitive impairment from Facility 2, were clustered in the bottom left-hand quadrant. Facility 1 tends to have more male participants with mild-moderate cognitive impairment. Participants from Facility 1 and Facility 3 had more male participants than Facility 2; moreover, the aromatherapy and hand massage treatment group tends to include younger (60 to 84 years old) participants with moderate-severe cognitive impairment. In these terms, the control group included participants with the full range of demographic characteristics.

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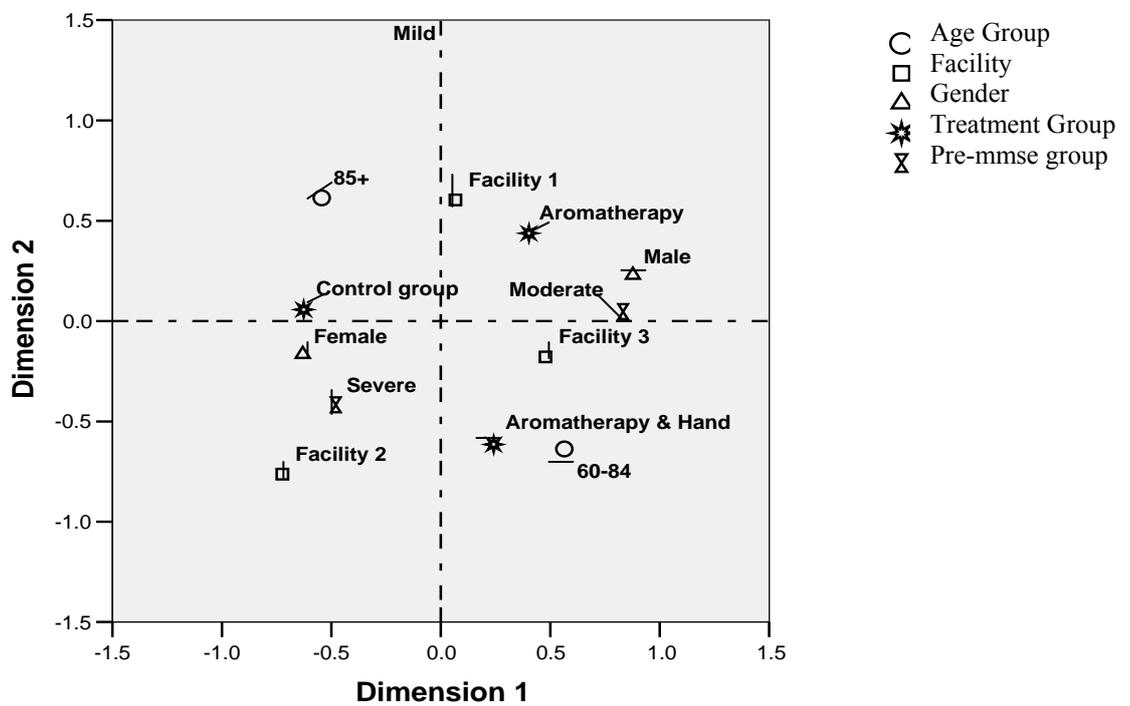
**Figure 6.1 Residential facility profile**

Although the differences between these clusters of response categories were statistically non-significant (Chi-Square statistic), they do reflect distinctive differences between the clientele of the facilities.

Figure 6.2 shows participants' level of cognitive impairment in the three research treatment groups. Most of the participants' cognitive impairments were moderate (n = 23, 37.7%) to severe (n = 29, 47.5%), with only nine (14.8%) participants having a MMSE score indicating mild cognitive impairment. Over 40% of the participants in each of the three treatment groups had severe cognitive impairment, and only 10-18% of the participants had MMSE scores of between 19 and 24.
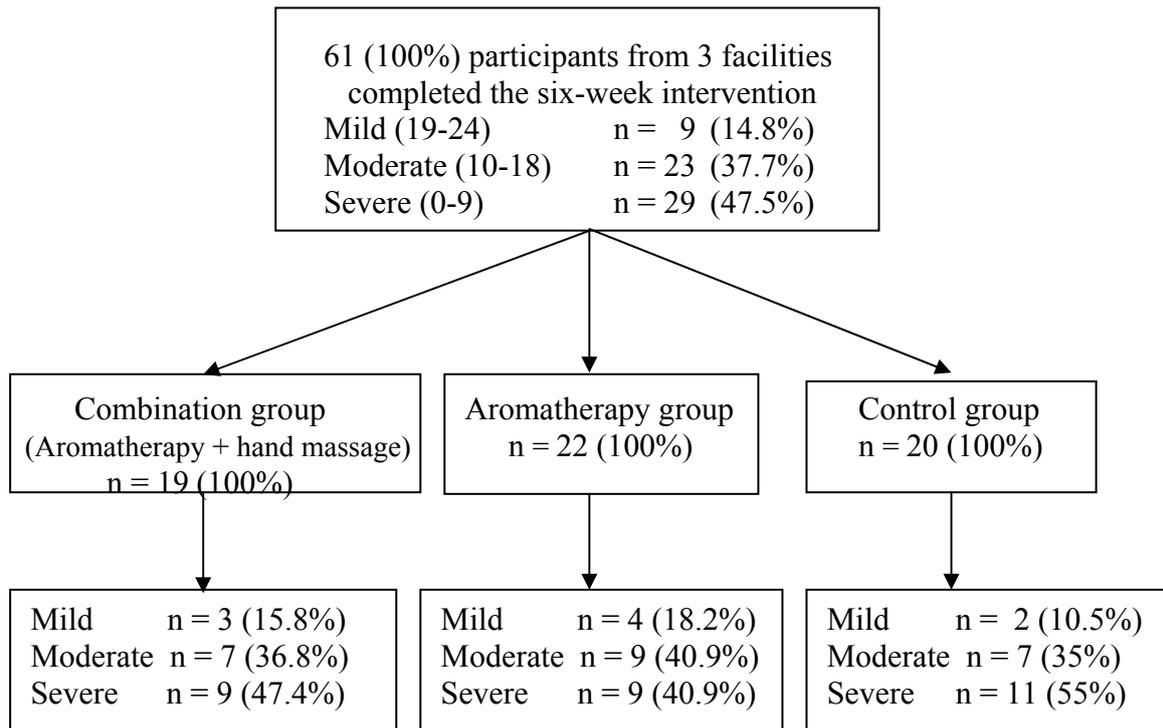
**Figure 6.2 Flow chart of participants' level of cognitive impairment in the three research treatment groups**

## 6.3    The Behavioural Measures of Descriptive Statistics

Sixty-seven participants initially commenced this study and data analysis was guided by the intention-to-treat (ITT) principle. The behavioural measurement data analysis involved 61 participants, because five participants refused to participate in the research treatment study and/or measurement. One participant died during the first week of treatment.

For the preliminary actions, participants' missing single items of baseline data were replaced by the stochastic regression imputation (SRI). SRI is used to substitute missing data with mean and random value. SRI has been found to fit most of the parameters to reduce the bias of missing completely at random (MCAR); moreover, SRI is equal to expectation maximization (EM) that handles missing values in likelihood scales (Polit & Beck, 2008; Zhou, 2001).

During four following data collections, five participants missed one measurement cycle of the CMAI and RMBPC, as MCAR. Four participants were hospitalized

during the two-week treatment period and one female participant died at the end of a post test data collection; these missing data points were replaced by the participants' last observations carried forward (LOCF). LOCF has commonly replaced dropout missing data in ITT analysis (Lane, 2008; Molnar, Man-Son-Hing, Hutton, & Fergusson, 2009). LOCF substitutes participants' missing data with the last measurement taken before dropping out. Recently, LOCF has been criticised in pharmaceutical studies because of the inappropriate use of LOCF analyses and false results (Lane, 2008; Mallinckrodt, et al., 2004; Molnar, et al., 2009; Overall, Tonidandel, & Starbuck, 2009). However, CAM modalities, such as lavender and massage, are not related to pharmaceutical medicine and lavender does not cause serious drug side effects (Blackwell, 1991; Buckle, 1993; Tisserand, 1990). It assumed that participants' response would remain constant from the moment of dropout onward or during unobserved periods to the end of the treatment (Verbeke & Molenberghs, 2001). The strength of LOCF is that it can avoid overestimating results by treating other single imputations and actually observing values of equal circumstance (Verbeke & Molenberghs, 2001).

RMBPC's choice "9", indicating "do not know/not applicable", was treated twice in the result. First, RMBPC's choice "9" was treated as an individual category, a descriptive statistic which was analysed in principal analyses. Due to a small sample size (n = 61) and over 10% of unanalysable RMBPC's choice "9" in SPSS system, RMBPC's choice "9" was replaced by the same method as the above (SRI and LOCF) procedure, for linear regression and Kruskal-Wallis test. CMAI and RMBPC mean scores were computed based on responses from the 61 participants.

### 6.3.1   Mean Scores for Cohen-Mansfield Agitation Inventory

The CMAI showed a high reliability for the five times it was used with a Cronbach's alpha estimate from .87 to .91 and the Guttman split-half reliability estimates from .78 to .89. Participants' challenging behaviours were measured at five points in time, using the Cohen-Mansfield Agitation Inventory.
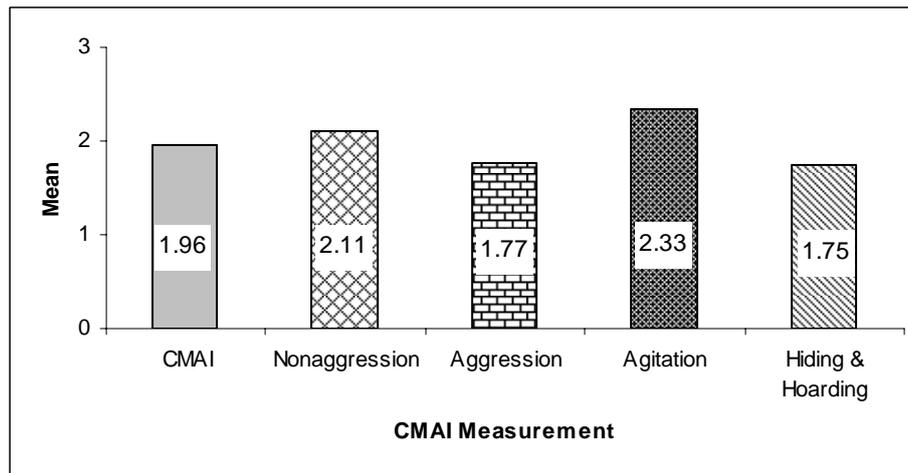
**Figure 6.3 Mean scores across five points in time for the CMAI total score and for the four CMAI subscales**

Figure 6.3 shows the average mean scores of the five time points data for the total CMAI item score, together with the four sub-scales, namely, physical nonaggression 2.11 (SD = .95), aggression 1.77 (SD = .68), verbal agitation 2.33 (SD = 1.09) and hiding and hoarding things 1.75 (SD = .96). These average scores together suggest that staff on average ranked participant behaviours between "2 = less than once a week" and "3 = once or several times a week" on these scales and subscales.

Comparing the two cognitive impairment groups, participants with severe cognitive impairment had higher CMAI baseline scores in nonaggressive 2.41 (SD = 1.35) and aggressive behaviours 2.16 (SD = .86), compared with participants with mild-moderate cognitive impairment. On the other hand, the mild-moderate group had a higher score on agitation 2.88 (SD = 1.08), compared with the severe cognitive impairment group.

Table 6.6 shows the mean scores for five time points of CMAI data in the 14 items. In nonaggression, "General restlessness, performing repetitious mannerisms, tapping, strange movements", the mean score decreased from 3.07 (SD = 1.47) to 2.28 (SD = 1.53). "Cursing or verbal aggression" had the highest baseline score of 2.61 (SD = 1.28) in the aggression subscale. "Repetitive sentences, calls, questions or words" (M = 2.82, SD = 1.53) and "Complaining, negativism, refusal to follow directions" (M = 2.75, SD = 1.36), were the most common agitated behaviours that occurred with participants.

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**Table 6.6 Data summary for five time points of the Cohen-Mansfield Agitation Inventory (CMAI)**

| CMAI subscales/ five time points (*n = 61*) | Baseline M (SD) | Week 2 M (SD) | Week 4 M (SD) | Week 6 M (SD) | Post-test M (SD) |
|---|---|---|---|---|---|
| **Nonaggression** | | | | | |
| 05. Pace, aimless wandering, trying to get to a different place | 2.48 (1.66) | 2.30 (1.50) | 2.38 (1.54) | 2.33 (1.51) | 2.18 (1.58) |
| 06. General restlessness, performing repetitious mannerisms, tapping, strange movements | 3.07 (1.47) | 2.61 (1.48) | 2.48 (1.50) | 2.41 (1.45) | 2.28 (1.53) |
| 07. Inappropriate dress or disrobing | 1.74 (1.05) | 1.79 (1.14) | 1.67 (0.96) | 1.77 (1.06) | 1.77 (1.16) |
| 08. Handling things inappropriately | 2.0  (1.33) | 1.80 (1.03) | 1.79 (1.14) | 1.75 (1.22) | 1.56 (0.98) |
| **Aggression** | | | | | |
| 01. Cursing or verbal aggression | 2.61 (1.28) | 2.36 (1.17) | 2.20 (1.21) | 2.13 (1.23) | 2.20 (1.15) |
| 02. Hitting, kicking, pushing, biting, scratching, aggressive spitting | 1.84 (1.07) | 1.77 (1.01) | 1.57 (0.97) | 1.62 (0.90) | 1.72 (1.02) |
| 03. Grabbing onto people, throwing things, tearing things or destroying property | 2.02 (1.23) | 1.90 (1.12) | 1.98 (1.27) | 1.82 (1.04) | 1.89 (1.07) |
| 04. Other aggressive behaviours or self abuse | 1.69 (1.04) | 1.59 (1.02) | 1.59 (1.02) | 1.54 (1.03) | 1.43 (0.87) |
| 14. Screaming | 1.36 (0.93) | 1.21 (0.76) | 1.31 (0.74) | 1.30 (0.72) | 1.28 (0.64) |
| **Agitation** | | | | | |
| 09. Constant request for attention or help | 2.38 (1.45) | 2.20 (1.45) | 2.21 (1.52) | 1.98 (1.32) | 2.0  (1.39) |
| 10. Repetitive sentences, calls, questions or words | 2.82 (1.53) | 2.56 (1.46) | 2.49 (1.50) | 2.34 (1.34) | 2.41 (1.42) |
| 11. Complaining, negativism, refusal to follow directions | 2.75 (1.36) | 2.38 (1.23) | 2.25 (1.35) | 2.03 (1.14) | 2.13 (1.38) |
| **Hiding & hold things** | | | | | |
| 13. Hiding things, hoarding things | 2.08 (1.44) | 1.74 (1.06) | 1.59 (1.01) | 1.67 (1.04) | 1.69 (1.15) |

Note: The scale ranged from 1 (Never) to 5 (A few times an hour or continuous for half an hour or more).
Question 12 Strange noise, did not fit into any sub-groups; therefore it was excluded from the study.

### 6.3.2 Mean Scores for Revised Memory and Behaviour Problem Checklist

The Cronbach's alpha value for the five time points of data of the RMBPC was .90 ~.93 and the Guttman split-half co-efficients indicated the value to be between .68 and .81. The Revised Memory and Behaviour Problem Checklist (RMBPC) was used to assess participants' challenging behaviours on five test occasions. Figure 6.4 shows the average mean scores of the five time points data for the total of RMBPC item score and three subscales of memory, depression and disruption. As shown in the graph, on average, participants obtained the highest scores for memory loss 2.31 (SD = 1.27) and the lowest mean scores for depression .92 (SD = .60) and disruption 1.01 (SD = .83). These suggest that nursing staff, on average, often ranked participants' behaviours on the RMBPC between "1 = Not in past week" and "2 = 1-2 times in past week".
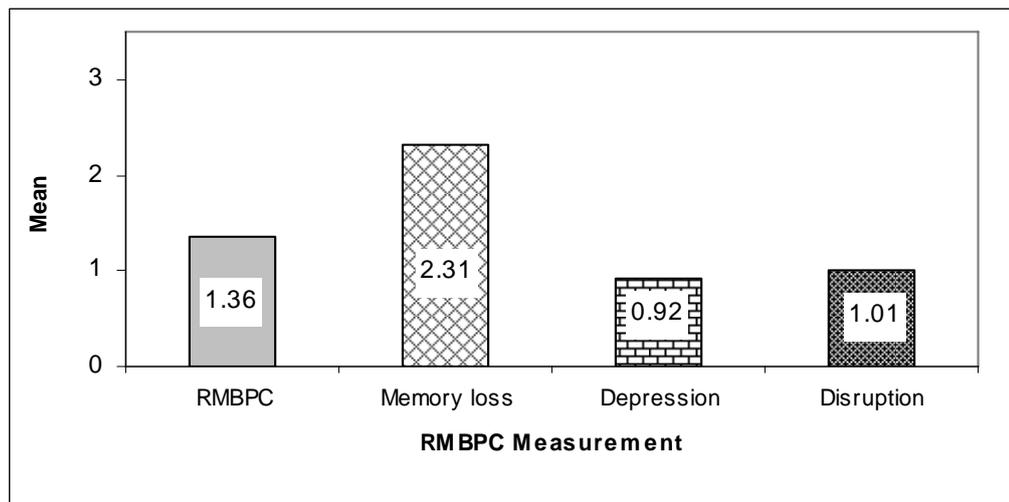


**Figure 6.4 Mean scores across five points in time for the RMBPC total score and for the three RMBPC subscales**

In addition, participants had higher baseline scores on memory loss 2.70 (SD = 1.30), depression 1.22 (SD = .87) and disruption 1.19 (SD = 1), with the four post-test scores lower than the baseline.

Table 6.7 presents the mean scores for five time points of data of the RMBPC's 24 items. "Forgetting what day it is" (M = 3.15, SD =1.38) was the most common behaviour of memory loss, followed by "Trouble remembering recent event" (M = 3.02, SD =1.48). In the depression subscale, "Appears anxious or worries" (M = 2.87,

SD = 1.48) was the highest baseline score compared to the other eight items. "Arguing, irritability, and/or complaining" was ranked as the most frequent behaviour in the disruption subscale.

**Table 6.7 Data Summary for five time points in the Revised Memory and Behaviour Problems Checklist (RMBPC) – Frequency Only**

| RMBPC subscales/ five times collection (*n = 61*) | Baseline M (SD) | Week 2 M (SD) | Week 4 M (SD) | Week 6 M (SD) | Post-test M (SD) |
|---|---|---|---|---|---|
| **Memory loss** | | | | | |
| 01. Asking the same question over and over | 2.05 (1.56) | 1.80 (1.68) | 1.66 (1.58) | 1.75 (1.65) | 1.87 (1.62) |
| 02. Trouble remembering recent event | 3.02 (1.48) | 2.69 (1.64) | 2.56 (1.61) | 2.54 (1.57) | 2.38 (1.68) |
| 03. Trouble remembering significant past events | 2.88 (1.52) | 2.54 (1.58) | 2.57 (1.60) | 2.52 (1.57) | 2.24 (1.68) |
| 04. Losing or misplacing things | 2.31 (1.74) | 1.96 (1.80) | 1.53 (1.71) | 1.68 (1.76) | 1.74 (1.72) |
| 05. Forgetting what day it is | 3.15 (1.38) | 2.84 (1.55) | 2.66 (1.60) | 2.56 (1.58) | 2.38 (1.66) |
| 06. Starting, but not finishing things | 2.60 (1.66) | 2.21 (1.75) | 1.88 (1.79) | 2.08 (1.78) | 1.93 (1.78) |
| 07. Difficulty concentrating on a task | 2.89 (1.54) | 2.51 (1.66) | 2.20 (1.72) | 2.34 (1.68) | 2.34 (1.58) |
| **Depression** | | | | | |
| 12. Appears anxious or worries | 2.87 (1.48) | 2.28 (1.45) | 2.31 (1.40) | 2.0  (1.43) | 2.25 (1.29) |
| 14. Threats to hurt oneself | 0.24 (0.67) | 0.21 (0.41) | 0.23 (0.60) | 0.34 (0.79) | 0.23 (0.46) |
| 17. Appears sad or depressed | 2.32 (1.37) | 1.98 (1.30) | 1.95 (1.33) | 1.46 (1.18) | 1.69 (1.19) |
| 18. Expressing feelings of hopelessness or sadness about the future | 1.41 (1.50) | 0.88 (1.13) | 0.54 (0.89) | 0.67 (1.04) | 0.75 (0.94) |
| 19. Crying and tearfulness | 0.88 (1.25) | 0.82 (1.16) | 0.79 (1.16) | 0.67 (1.04) | 0.77 (1.07) |
| 20. Commenting about death of self or others | 0.70 (1.17) | 0.39 (0.61) | 0.42 (0.80) | 0.34 (0.85) | 0.46 (0.85) |
| 21. Talking about feeling lonely | 1.12 (1.50) | 0.80 (1.17) | 0.64 (1.02) | 0.54 (0.99) | 0.61 (0.99) |
| 22. Comments about feeling worthless or being a burden to others | 1.05 (1.30) | 0.77 (1.10) | 0.51 (0.83) | 0.64 (1.08) | 0.59 (0.90) |
| 23. Comments about feeling like a failure or about not having any worthwhile accomplishments in life | 0.42 (0.86) | 0.22 (0.46) | 0.17 (0.43) | 0.27 (0.61) | 0.31 (0.74) |
| **Disruption** | | | | | |
| 08. Destroying property | 1.02 (1.54) | 0.90 (1.34) | 0.77 (1.18) | 0.93 (1.35) | 0.85 (1.18) |
| 09. Doing things that embarrass you | 0.69 (1.00) | 0.63 (0.99) | 0.57 (0.89) | 0.58 (0.90) | 0.33 (0.63) |
| 10. Waking you or other residents up at night | 0.67 (1.05) | 0.59 (0.94) | 0.48 (0.75) | 0.45 (0.72) | 0.57 (0.97) |
| 11. Talking loudly and rapidly | 1.13 (1.44) | 1.0  (1.39) | 0.81 (1.28) | 0.98 (1.36) | 0.98 (1.25) |
| 13. Engaging in behaviour that is potentially dangerous to self or others | 1.60 (1.63) | 1.61 (1.55) | 1.25 (1.50) | 0.98 (1.30) | 1.20 (1.53) |
| 15. Threats to hurt others | 0.70 (1.22) | 0.63 (1.02) | 0.50 (0.94) | 0.49 (0.94) | 0.64 (1.02) |
| 16. Aggressive to others verbally | 1.68 (1.46) | 1.42 (1.44) | 1.32 (1.53) | 1.28 (1.39) | 1.44 (1.48) |
| 24. Arguing, irritability, and/or complaining | 2.05 (1.54) | 1.67 (1.50) | 1.77 (1.56) | 1.67 (1.44) | 1.51 (1.51) |

Note: The scale ranged from 0 (Never occurred) to 4 (Daily or more often) and 9 (Do not know/not applicable).

## 6.4 Disruptive Behaviours and Staff Reaction in Revised Memory and Behaviour Problem Checklist (RMBPC)

Nursing staff ranked "do not know/not applicable (choice 9)", in relation to participants' frequency of behaviours and staff reaction during the five points in time data collection. Overall, the "do not know/not applicable" category in relation to the occurrence of participants' behaviours, did not match staff reaction.

Table 6.8 presents the memory loss subscales. More than 10% of participants were ranked "do not know/not applicable" in their memory behavioural measurement in the post-test. Staff seemed not to know about some participants' current cognitive status.

**Table 6.8 Data Summary for five points in time of the Memory loss Subscales of RMBPC – Behavioural Frequency and Staff reaction "Do not know/not applicable (9)"**

| RMBPC memory loss subscales/ five points in time collection (n = 61) | Baseline n (%) | Week 2 n (%) | Week 4 n (%) | Week 6 n (%) | Post-test n (%) |
|---|---|---|---|---|---|
| **Behavioural Frequency**<br>**Staff          Reaction** | | | | | |
| 01. Asking the same question over and over | 2 (3.3)<br>4 (6.6) | 1 (1.6)<br>4 (6.6) | 1 (1.6)<br>5 (8.2) | 3 (4.9)<br>1 (1.6) | 8 (13.1)<br>5 (8.2) |
| 02. Trouble remembering recent event | 2 (3.3)<br>2 (3.3) | 1 (1.6)<br>1 (1.6) | 1 (1.6)<br>1 (1.6) | 6 (9.8)<br>2 (3.3) | 11 (18.0)<br>6 (9.8) |
| 03. Trouble remembering significant past events | 1 (1.6)<br>1 (1.6) | 2 (3.3)<br>2 (3.3) | 1 (1.6)<br>1 (1.6) | 6 (9.8)<br>2 (3.3) | 12 (19.7)<br>8 (13.1) |
| 04. Losing or misplacing things | 3 (4.9)<br>5 (8.2) | 1 (1.6)<br>4 (6.6) | 2 (3.3)<br>5 (8.2) | 7 (11.5)<br>3 (4.9) | 11 (18.0)<br>6 (9.8) |
| 05. Forgetting what day it is | 1 (1.6)<br>1 (1.6) | 3 (4.9)<br>1 (1.6) | 1 (1.6)<br>1 (1.6) | 5 (8.2)<br>1 (1.6) | 9 (14.8)<br>6 (9.8) |
| 06. Starting, but not finishing things | 3 (4.9)<br>3 (4.9) | 1 (1.6)<br>4 (6.6) | 2 (3.3)<br>5 (8.2) | 7 (11.5)<br>3 (4.9) | 14 (23.0)<br>8 (13.1) |
| 07. Difficulty concentrating on a task | 0 (0)<br>1 (1.6) | 0 (0)<br>1 (1.6) | 0 (0)<br>3 (4.9) | 2 (3.3)<br>1 (1.6) | 9 (14.8)<br>5 (8.2) |

In the depression subscale, nursing staff ranked "do not know/not applicable", for depression behaviours of a few participants from the baseline to the sixth week collections. However, the number of times staff reaction was described as "do not know/not applicable (choice 9)", was twice the number (9) allocated to participants' behaviours (see Table 6.9). In the post-test, question 18, "Expressing feelings of hopelessness or sadness about the future", question 20, "Commenting about death of self or others", question 21, "Talking about feeling lonely", question 22, "Comments about feeling worthless or being a burden to others", question 23, "Comments about feeling like a failure or about not having any worthwhile accomplishments in life"

were the most difficult of the rank questions to answer in the RMBPC. More than 18% of the participants were ranked "do not know/not applicable (9)", by nursing staff. Interestingly, staff ranked choice (9) in question 12 "Appears anxious or worries", from the baseline to the sixth week data collection, where only one participant was ranked (9) in the post test.

**Table 6.9 Data Summary for five points in time of the Depression Subscales of RMBPC –**
**Behavioural Frequency and Staff reaction "Do not know/not applicable (9)"**

| RMBPC depression subscales/ five points in time collection (n = 61) | Baseline n (%) | Week 2 n (%) | Week 4 n (%) | Week 6 n (%) | Post-test n (%) |
|---|---|---|---|---|---|
| **Behavioural Frequency** **Staff Reaction** | | | | | |
| 12. Appears anxious or worries | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (1.6) |
| | 3 (4.9) | 2 (3.3) | 3 (4.9) | 0 (0) | 1 (1.6) |
| 14. Threats to hurt oneself | 3 (4.9) | 2 (3.3) | 2 (3.3) | 2 (3.3) | 9 (14.8) |
| | 11 (18.0) | 10 (16.4) | 7 (11.5) | 2 (3.3) | 6 (9.8) |
| 17. Appears sad or depressed | 1 (1.6) | 0 (0) | 2 (3.3) | 0 (0) | 5 (8.2) |
| | 4 (6.6) | 3 (4.9) | 4 (6.6) | 2 (3.3) | 5 (8.2) |
| 18. Expressing feelings of hopelessness or sadness about the future | 3 (4.9) | 1 (1.6) | 2 (3.3) | 3 (4.9) | 11 (18.0) |
| | 6 (9.8) | 8 (13.1) | 5 (8.2) | 2 (3.3) | 7 (11.5) |
| 19. Crying and tearfulness | 1 (1.6) | 3 (4.9) | 2 (3.3) | 2 (3.3) | 7 (11.5) |
| | 8 (13.1) | 9 (14.8) | 4 (6.6) | 1 (1.6) | 6 (9.8) |
| 20. Commenting about death of self or others | 3 (4.9) | 1 (1.6) | 3 (4.9) | 3 (4.9) | 12 (19.7) |
| | 10 (16.4) | 11 (18.0) | 6 (9.8) | 3 (4.9) | 7 (11.5) |
| 21. Talking about feeling lonely | 2 (3.3) | 1 (1.6) | 2 (3.3) | 3 (4.9) | 11 (18.0) |
| | 5 (8.2) | 5 (8.2) | 5 (8.2) | 1 (1.6) | 7 (11.5) |
| 22. Comments about feeling worthless or being a burden to others | 4 (6.6) | 1 (1.6) | 3 (4.9) | 4 (6.6) | 11 (18.0) |
| | 7 (11.5) | 6 (9.8) | 6 (9.8) | 3 (4.9) | 7 (11.5) |
| 23. Comments about feeling like a failure or about not having any worthwhile accomplishments in life | 4 (6.6) | 11 (1.6) | 3 (4.9) | 4 (6.6) | 11 (18.0) |
| | 9 (14.8) | 2 (19.7) | 6 (9.8) | 3 (4.9) | 7 (11.5) |

Table 6.10 presents the data summary, indicating questions where staff did not know participants might have disruptive behaviours, such as question 9, "Doing things that embarrass you" and question 10, "Waking you or other residents up at night". Up to 12 and 15 participants were ranked do not know/not applicable (9) in question 9 and question 10, at five points in time of the data collections.

**Table 6.10 Data Summary for five points in time of the Disruption Subscales of RMBPC – Behavioural Frequency and Staff reaction "Do not know/not applicable (9)"**

| RMBPC disruption subscales/ five points in time collection (n = 61) | Baseline n (%) | Week 2 n (%) | Week 4 n (%) | Week 6 n (%) | Post-test n (%) |
|---|---|---|---|---|---|
| **Behavioural Frequency** / **Staff Reaction** | | | | | |
| 08. Destroying property | 1 (1.6) | 1 (1.6) | 3 (4.9) | 4 (6.6) | 9 (14.8) |
| | 4 (6.6) | 4 (6.6) | 5 (8.2) | 5 (8.2) | 7 (11.5) |
| 09. Doing things that embarrass you | 10 (16.4) | 9 (14.8) | 10 (16.4) | 7 (11.5) | 12 (19.7) |
| | 9 (14.8) | 12 (19.7) | 11 (18.0) | 9 (14.8) | 10 (16.4) |
| 10. Waking you or other residents up at night | 15 (24.6) | 10 (16.4) | 10 (16.4) | 7 (11.5) | 14 (23.0) |
| | 12 (19.7) | 12 (19.7) | 12 (19.7) | 9 (14.8) | 10 (16.4) |
| 11. Talking loudly and rapidly | 1 (1.6) | 2 (3.3) | 2 (3.3) | 2 (3.3) | 10 (16.4) |
| | 2 (3.3) | 4 (6.6) | 5 (8.2) | 3 (4.9) | 7 (11.5) |
| 13. Engaging in behaviour that is potentially dangerous to self or others | 5 (8.2) | 3 (4.9) | 0 (0) | 0 (0) | 9 (14.8) |
| | 6 (9.8) | 5 (8.2) | 5 (8.2) | 0 (0) | 6 (9.8) |
| 15. Threats to hurt others | 1 (1.6) | 2 (3.3) | 2 (3.3) | 2 (3.3) | 9 (14.8) |
| | 5 (8.2) | 7 (11.5) | 6 (9.8) | 2 (3.3) | 6 (9.8) |
| 16. Aggressive to others verbally | 1 (1.6) | 1 (1.6) | 1 (1.6) | 2 (3.3) | 9 (14.8) |
| | 2 (3.3) | 3 (4.9) | 3 (4.9) | 2 (3.3) | 6 (9.8) |
| 24. Arguing, irritability, and/or complaining | 1 (1.6) | 1 (1.6) | 1 (1.6) | 2 (3.3) | 9 (14.8) |
| | 1 (1.6) | 5 (8.2) | 2 (3.3) | 2 (3.3) | 6 (9.8) |

Table 6.11 presents staff reactions to participants' behaviours on average (from 0 = Not at all to 4 = Extremely). Nearly all staff ranked their reaction to participants' behaviours as "0 = Not at all" to "1 = A little". The rank was low during the five data collection periods. Moreover, the mean scores of staff reaction gradually decreased from .67 (SD = .60) to .37 (SD = .33). The results showed the staff had no reaction to participants' disruptive behaviour.

**Table 6.11 Staff reaction to participants' behaviours (RMBPC)**

| RMBPC (n = 61) | Minimum | Maximum | Mean | Std. Deviation |
|---|---|---|---|---|
| RMBPC baseline | 0 | 2.17 | .67 | .60 |
| RMBPC week 2 | 0 | 1.75 | .52 | .43 |
| RMBPC week 4 | 0 | 1.67 | .43 | .35 |
| RMBPC week 6 | 0 | 2.08 | .35 | .36 |
| RMBPC post-test | 0 | 1.08 | .37 | .33 |

## 6.5 Linear Regression and Goodness of Fit: Investigating Cognition as a Modulating Variable of Interventional Changes

Two-dimensional linear regression was chosen to analyse the relationship between participants' disruptive behaviours and cognitive impairment in the treatment groups. The goal of regression analysis is to discover a set of independent variables that have high explanatory power, as measured through goodness of fit (Dunteman & Ho, 2006). To determine the goodness of fit, the residuals ($R^2$) of the model were examined; observations that have large residuals indicate a poor fit of the model to the independent variable for observations. On the other hand, observations with small residuals ($R^2$) close to 1, indicate a valuable fit in observations (Dunteman & Ho, 2006).

### 6.5.1 Linear Regression and Goodness of Fit for Cohen-Mansfield Agitation Inventory (CMAI)
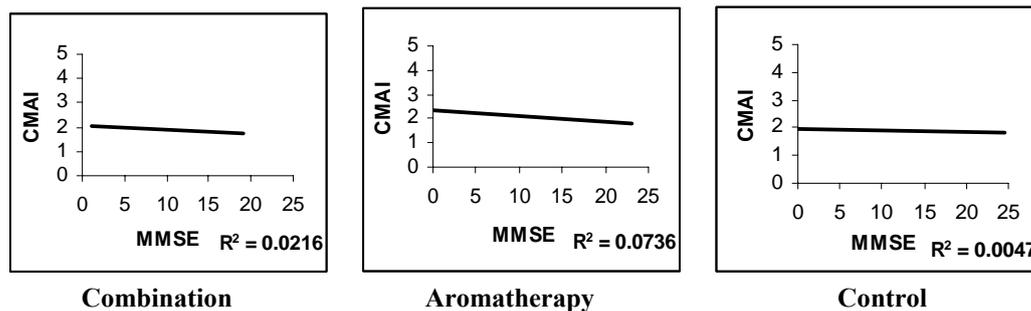


**Figure 6.5 Regression of CMAI mean scores across five points in time in three research treatment groups**

On average, it seemed that no treatments had a statistically significant effect on disruptive behaviours (see Figure 6.5).
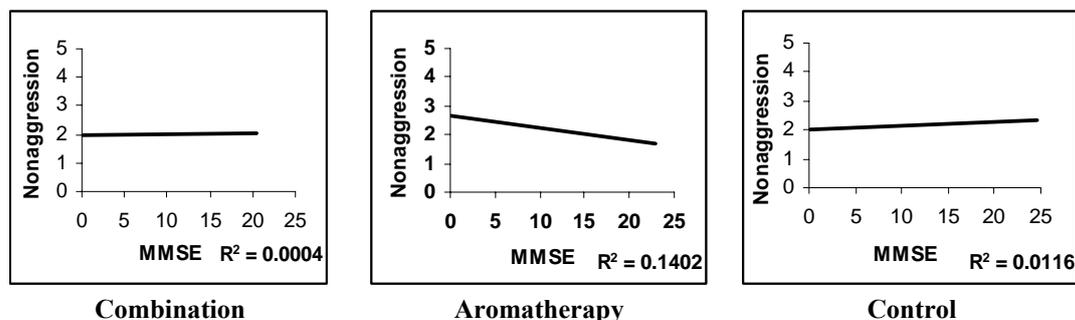


**Figure 6.6 Regression of CMAI physical nonaggression subscale mean scores across five points time in three research treatment groups**

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A trend line shows a relationship between the physical nonaggressive behaviours of the CMAI and the MMSE scores in the three treatment groups (see Figure 6.6). As shown in Figure 6.6, there was a relationship between participants' nonaggressive behaviours (CMAI) and their cognitive impairment (MMSE) ($R^2 = 0.1402$), and participants in the aromatherapy group who had higher MMSE scores, presented with less nonaggressive behaviour.
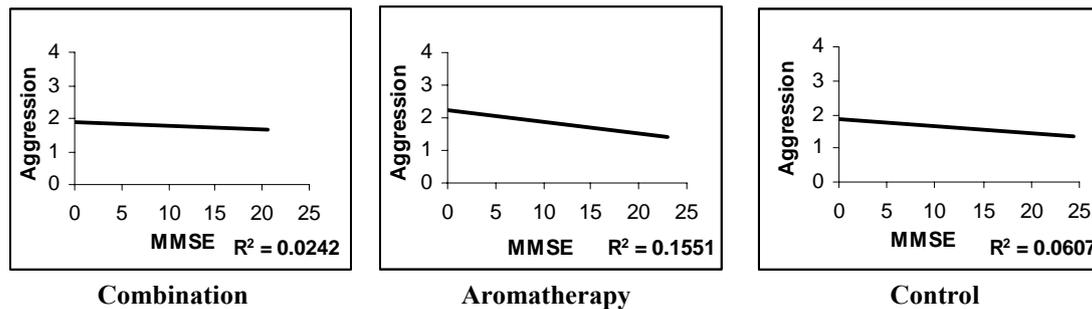


**Figure 6.7 Regression of CMAI aggression subscale mean scores across five points in time in three research treatment groups**

Comparing the three treatment groups, a relationship between aggressive behaviours (CMAI) and cognitive impairment (MMSE) ($R^2 > 0.15$) for the aromatherapy group appeared. Participants in the aromatherapy group, who had better cognition, showed less aggressive behaviour (see Figure 6.7).



**Figure 6.8 Regression of CMAI verbal agitation subscale mean scores across five points in time in three research treatment groups**

Figure 6.8 shows that in the aromatherapy and hand massage group, there was a strong relationship between agitated behaviours (CMAI) and cognitive impairment (MMSE) scores ($R^2 = 0.2671$). Participants in the combination (aromatherapy + hand massage) group who had higher cognitive scores, presented more agitated behaviours. On the other hand, there was no statistical relationship between agitation and

cognitive impairment in the control group ($R^2 = 3E\text{-}06$).
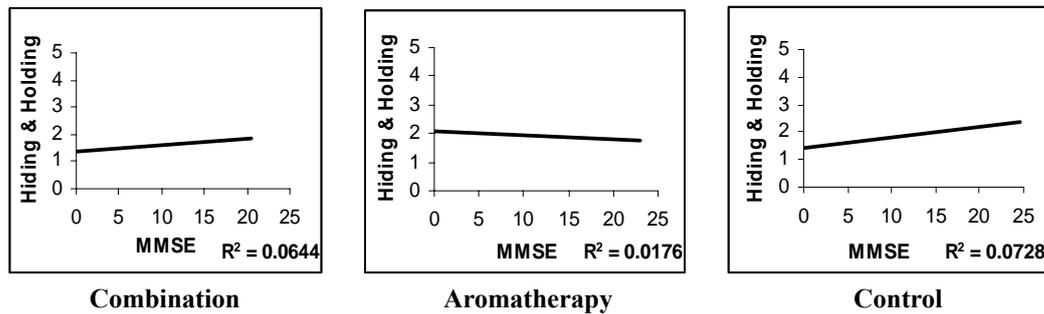


**Figure 6.9 Regression of CMAI hiding & hoarding things subscale mean scores across five points in time in three research treatment groups**

The three treatment groups did not present a regular pattern in decreasing the mean scores of agitated behaviours. It seemed that no treatment had a statistically different effect on agitated behaviours. However, participants in the aromatherapy and hand massage group ($R^2 = 0.0644$) and the control group ($R^2 = 0.0728$) with higher MMSE scores were more likely to present greater hiding and hoarding things behaviour, as shown in Figure 6.9.

## 6.5.2    Linear Regression and Goodness of Fit for Revised Memory and Behaviour Problem Checklist



**Figure 6.10 Regression of RMBPC memory subscale mean scores across five points in time in three research treatment groups**

Figure 6.10 shows a relationship between the disruptive behaviours measured by the RMBPC and the MMSE scores of participants in the three treatment groups. Participants in the combination (aromatherapy + hand massage) group ($R^2 = 0.1277$) and control group ($R^2 = 0.1022$) with higher cognitive scores, presented more disruptive behaviours.
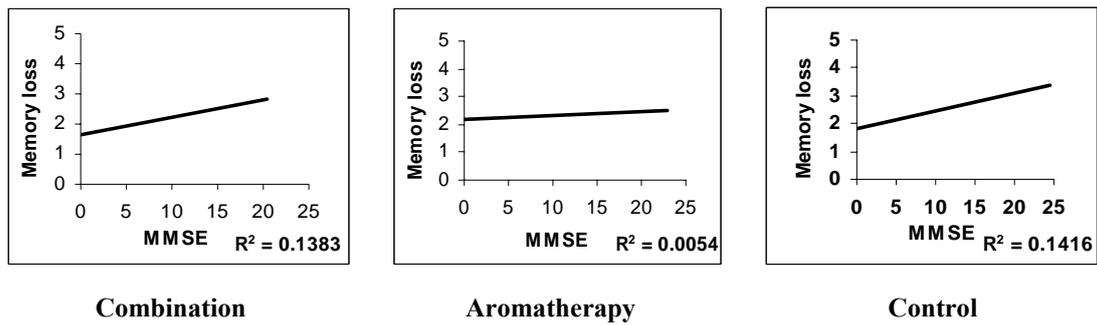
**Figure 6.11 Regression of RMBPC memory subscale mean scores across five points in time in three research treatment groups**

Figure 6.11 presents the relationship between memory loss (RMBPC) and cognitive impairment in two treatment groups. Participants who had a higher MMSE score, showed a higher trend line in memory loss in both the combination (aromatherapy + hand massage) ($R^2 = 0.1383$) and the control ($R^2 = 0.1416$) groups.
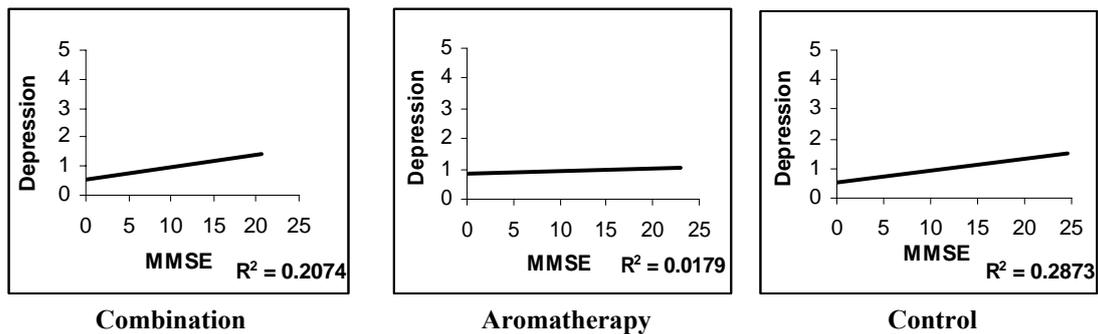


**Figure 6.12 Regression of RMBPC depression subscales across five points in time in three research treatment groups**

There was a strong relationship between depression (RMBPC) and cognitive impairment (MMSE) in the aromatherapy and hand massage and control groups. Figure 6.12 shows that participants with higher MMSE scores, tended to present more depressed symptoms in the combination ($R^2 = 0.2074$) and the control groups ($R^2 = 0.2873$).
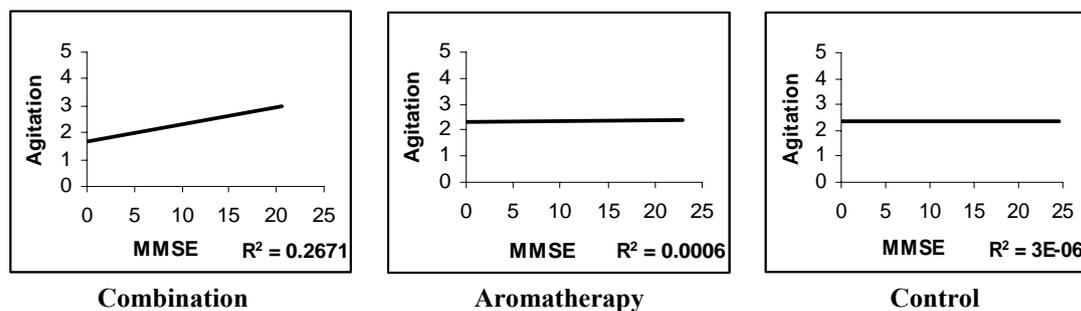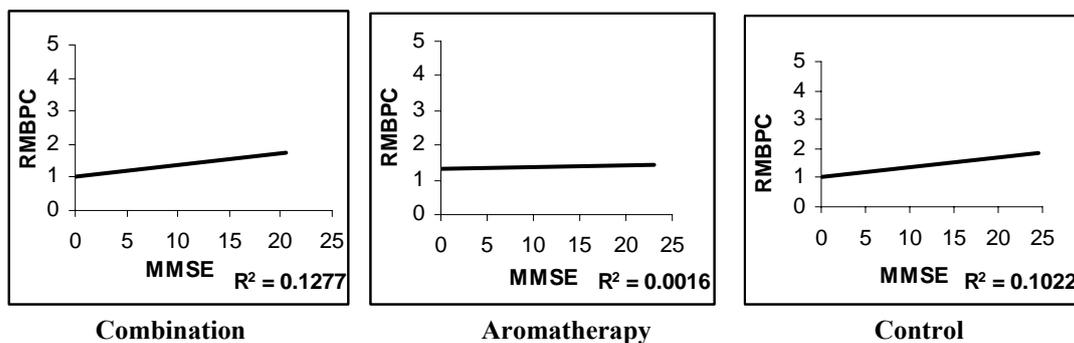
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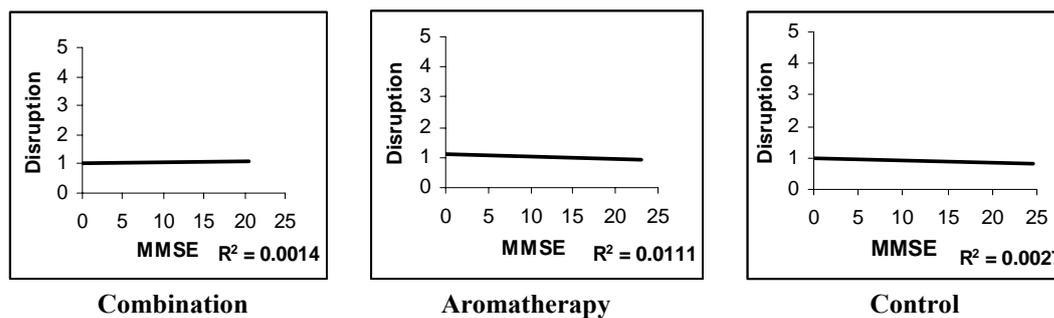
**Figure 6.13 Regression of RMBPC disruption subscales across five points in time in three research treatment groups**

Figure 6.13 shows that there was no relationship between disruption (RMBPC) and cognitive impairment (MMSE) in the three treatment groups ($R^2 < 0.10$). It seemed no treatment had an effect on participants' disruptive behaviours.

## 6.6 Kruskall-Wallis H test

Given the abnormal distribution of test scores and ordinal properties of scale items and scores, a nonparametric Kruskal-Wallis H test, the nonparametric equivalent of ANOVA, was used to identify statistically significant outcomes (Coakes & Steed, 2001). Additionally having noted that the participants' mean age was 84 years old (SD = 6.36), the interactive effect of the 60-84 age group and 85-plus age group was examined by splitting the dataset and conducting parallel analyses. Participants' level of cognition was also divided into severe and mild-moderate cognitive impairment groups for analysis. Eight male and 21 female participants had severe cognitive impairment. Despite the relatively small sample size (n = 61), this nonparametric measure was effective in identifying significant effects related to treatment conditions.

### 6.6.1 Cohen-Mansfield Agitation Inventory (CMAI)

Analysing the CMAI results for the three treatment groups, the aromatherapy and placebo treatment showed reduced disruptive behaviours at the end of the sixth week intervention over the observation periods (*p<.05*) (see Table 6.12).

**Table 6.12 CMAI rank scores on sixth week intervention test in three treatment groups**

| CMAI | Research Treatment Group | n (61) | Rank | Chi-square/ Significant (p<) |
|---|---|---|---|---|
| Week 6 | Combination group | 19 | 24.29 | 6.512 |
| | Aromatherapy | 22 | 29.86 | |
| | Control | 20 | 38.63 | *039 |

However, there were no statistically significant effects for participants in the severe and mild-moderate cognitive impairment groups ($p>.05$). Table 6.13 shows the control group (water mist) in the fourth and sixth weeks displayed reduced aggressive behaviour ($p<.05$). For those older than 84 years, there were non-significant effects, a result that could be interpreted as indicating that water is as effective as aromatherapy or aromatherapy and massage ($p>.05$).

**Table 6.13 CMAI rank scores on fourth week and sixth week intervention test in 60-84 age group**

| CMAI | Research Treatment Group | n (29) | Rank | Chi-square/ Significant (p<) |
|---|---|---|---|---|
| Week 4 | Combination group | 11 | 11.45 | 7.272 |
| | Aromatherapy | 10 | 13.50 | |
| | Control | 8 | 21.75 | *026 |
| Week 6 | Combination group | 11 | 9.27 | 8.874 |
| | Aromatherapy | 10 | 16.90 | |
| | Control | 8 | 20.50 | *012 |

The exploration of gender demonstrated there were no statistically significant effects for male participants. However, the female aromatherapy group participants had a significantly better treatment effect for lavender spray than for all other treatments after receiving the first two weeks of the intervention ($p<.01$). Interestingly, water mist treatment showed an effect on decreasing disruptive behaviour in the female control group participants at the end of the sixth week intervention ($p<.01$) (see Table 6.14).

**Table 6.14 CMAI rank scores on second week and sixth week intervention test in female group**

| CMAI | Research Treatment Group | n (36) | Rank | Chi-square/ Significant (p<) |
|------|--------------------------|--------|-------|------------------------------|
| Week 2 | Combination group | 11 | 10.82 | 9.821 |
| | Aromatherapy | 12 | 24.42 | |
| | Control | 13 | 19.54 | *007 |
| Week 6 | Combination group | 11 | 10.41 | 10.297 |
| | Aromatherapy | 12 | 19.96 | |
| | Control | 13 | 24.00 | *006 |

Figure 6.14 suggests that aromatherapy, combined with hand massage, had negative effects in the 60-84 age group, as those participants were more agitated compared with the 85-plus group participants.
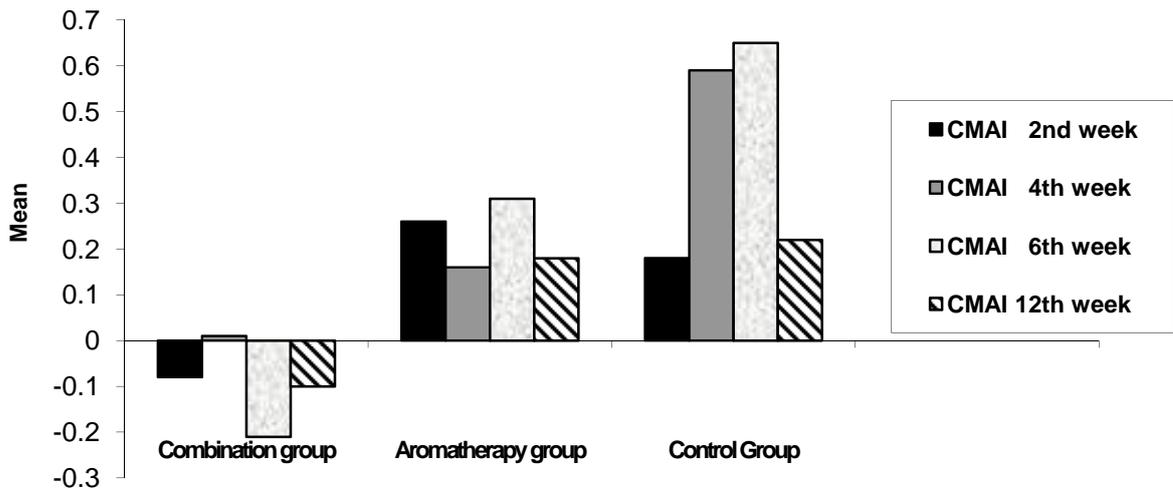


**Figure 6.14 CMAI four time periods of mean scores in 60-84 age group**
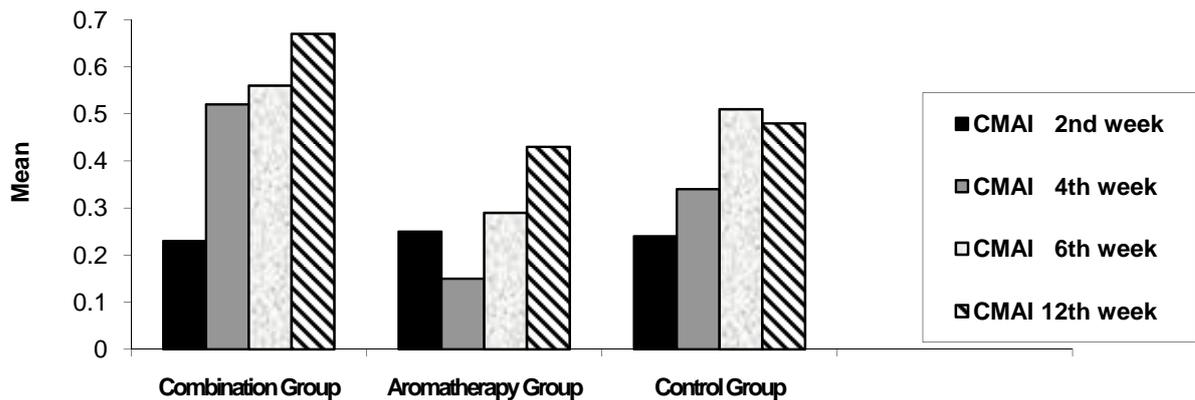
**Figure 6.15 CMAI four time periods of mean scores in 85+ age group**

In the 85-plus age group, all treatments were found to be beneficial and the effects seemed to be nonlinear (see Figure 6.15). There were no significant differences in participants' mean scores for the CMAI across all periods.

Table 6.15 shows the nonaggression factor of the CMAI at the fourth week and the sixth week. Water mist treatment had a more significant effect for the 60-84-year-old control group participants than for all other treatments after receiving six weeks of the intervention ($p < .05$).

**Table 6.15 CMAI rank scores of nonaggression on fourth week and sixth week intervention test in 60 - 84 age group**

| CMAI/ Nonaggression | Research Treatment Group | n (29) | Rank | Chi-square/ Significant (p<) |
|---|---|---|---|---|
| Week 4 | Combination group | 11 | 12.45 | 6.249 |
| | Aromatherapy | 10 | 12.75 | |
| | Control | 8 | 23.11 | *044 |
| Week 6 | Combination group | 11 | 9.23 | 9.679 |
| | Aromatherapy | 10 | 16.45 | |
| | Control | 8 | 21.31 | *008 |

Furthermore, the water mist treatment decreased the nonaggressive behaviours in the male control group at the fourth week ($p = .036$); the female control group also had a reduction in nonaggressive behaviours after receiving water mist treatment at the end of six weeks of the intervention ($p = .027$).

In the level of cognitive impairment groups, the water treatment had a significant effect on decreasing disruptive behaviours for the mild-moderate control group ($p<.05$) in the fourth week (see Table 6.16).

**Table 6.16 CMAI rank scores of nonaggression on fourth week intervention test in mild -moderate cognitive impairment group**

| CMAI/ Nonaggression | Research Treatment Group | n (32) | Rank | Chi-square/ Significant (p<) |
|---|---|---|---|---|
| Week 4 | Combination group | 10 | 15.55 | 6.959 |
| | Aromatherapy | 13 | 12.65 | |
| | Control | 9 | 23.11 | *031 |

In the aggression subscale of the CMAI, the control treatment (water mist) had a statistically significant effect on decreasing aggressive behaviours at the fourth week of the intervention ($p = .042$). Furthermore, the 60-84-year-old participants control group had less aggression at the end of the fourth week of the intervention ($p = .044$). Lavender spray and water mist achieved a significantly better treatment effect for the female aromatherapy group and control group participants at the second week ($p<.01$) and the sixth week of the intervention respectively ($p<.05$) (see Table 6.17).

**Table 6.17 CMAI rank scores of aggression on second week and sixth week intervention test in female group**

| CMAI Aggression | Research Treatment Group | n (36) | Rank | Chi-square/ Significant (p<) |
|---|---|---|---|---|
| Week 2 | Combination group | 11 | 12.77 | 10.784 |
| | Aromatherapy | 12 | 26.21 | |
| | Control | 13 | 16.23 | *005 |
| Week 6 | Combination group | 11 | 11.55 | 7.175 |
| | Aromatherapy | 12 | 20.83 | |
| | Control | 13 | 22.23 | *028 |

In the agitation subscale of the CMAI, aromatherapy and hand massage treatment had a statistically significant effect on decreasing agitated behaviours for those in the 85+ group at the post sixth week of the intervention ($p = .026$). With regards to the hiding and hoarding things subscale of the CMAI, only the females using aromatherapy

treatment had a statistically significant decrease in the behaviour at the second week of the intervention (*p = .022*).

### 6.6.2 Revised Memory and Behaviour Problem Checklist (RMBPC)

Analysis of the periods of the Revised Memory and Behaviour Problems Checklist (RMBPC) data, showed a non-significant effect for treatment (*p>.05*). There were also no statistically significant differences between the severe and mild-moderate cognitive impairment groups, age groups and gender groups in the participants' RMBPC behavioural analysis (*p>.05*).
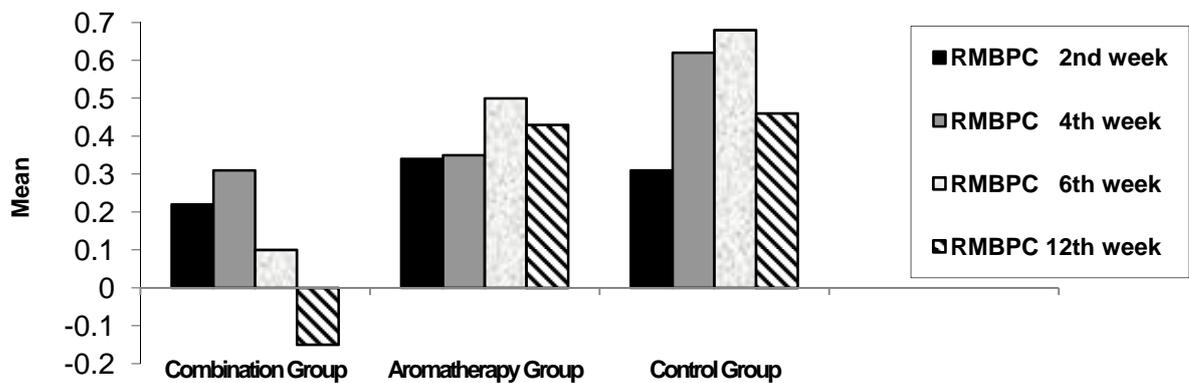


**Figure 6.16 RMBPC four time periods of mean scores in 60-84 age group**

In the 60-84 age group, the analysis of RMBPC observation data, did not demonstrate any significant differences in participants' mean scores. The treatments did not make any significant difference (see Figure 6.16).

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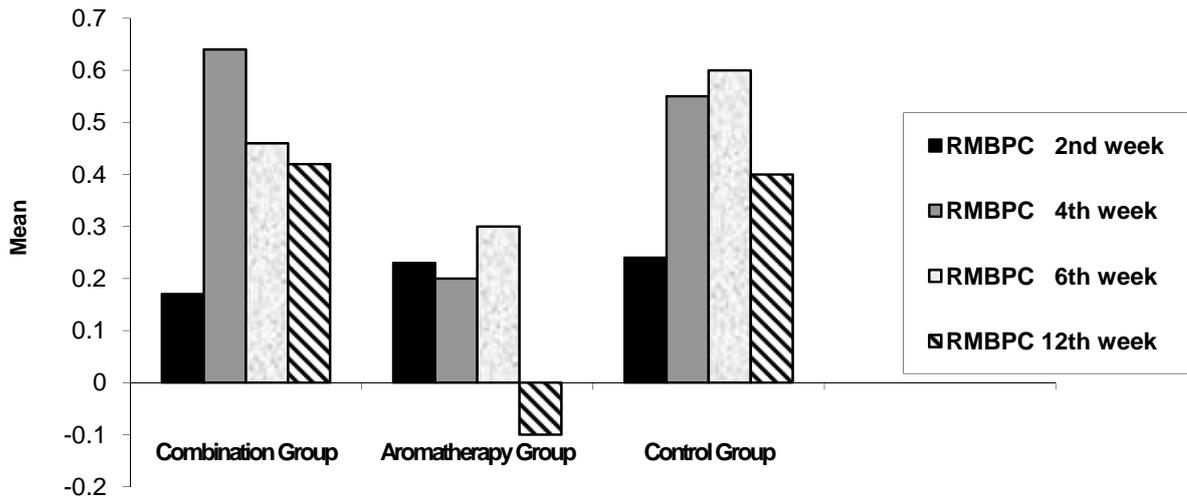
**Figure 6.17 RMBPC four time periods of mean scores in 85+ age group**

In the 85+ age group (see Figure 6.17), aromatherapy treatment seemed to have had negative effects. Aromatherapy treatment was found to have a similar effect to water mist (control) treatment, but had the least beneficial effect overall, whereas water mist treatment had a larger (overlapping) positive effect compared to the aromatherapy and hand massage.

Table 6.18 shows participants receiving water mist (control) treatment that had decreased memory loss after receiving six weeks of the intervention ($p < .05$)

**Table 6.18 RMBPC rank scores of memory loss on sixth week intervention test in the control group**

| RMBPC/ Memory loss | Research Treatment Group | n (29) | Rank | Chi-square/ Significant (p<) |
|---|---|---|---|---|
| Week 6 | Combination group | 19 | 24.76 | 7.009 |
| | Aromatherapy | 22 | 28.93 | |
| | Control | 20 | 39.20 | *030 |

Table 6.19 shows that only those in the 60-84 age group, who received water mist (control) treatment had a positive memory (RMBPC) effect at the sixth week of the intervention ($p < .05$).

**Table 6.19 RMBPC rank scores of memory loss on sixth week intervention test in 60-84 age group**

| RMBPC/ Memory loss | Research Treatment Group | n (29) | Rank | Chi-square/ Significant (p<) |
|---|---|---|---|---|
| Week 6 | Combination group | 11 | 9.91 | 7.588 |
| | Aromatherapy | 10 | 16.20 | |
| | Control | 8 | 20.50 | *023 |

There were no statistically significant effects for the subscale of depression. However, females receiving aromatherapy treatment had decreased disruptive behaviours after receiving six weeks of the intervention (*p< .05*) (see Table 6.20).

**Table 6.20 CMAI rank scores of aggression on sixth week intervention test in female group**

| RMBPC/ Disruption | Research Treatment Group | n (36) | Rank | Chi-square/ Significant (p<) |
|---|---|---|---|---|
| Week 6 | Combination group | 11 | 11.00 | 8.207 |
| | Aromatherapy | 12 | 22.42 | |
| | Control | 13 | 21.23 | *017 |

## 6.7    Overview of the Hypotheses

The results of the analysis indicate that the hypotheses H1, H2 and H3 were rejected. There was no significant difference in disruptive behaviours between participants who received the CAM modalities and participants who did not receive the CAM modalities. The results did not indicate a statistically significant effect on decreasing aggression and agitation in participants of any treatment groups. Aromatherapy and hand massage treatment had a negative effect compared to the other two treatment groups. Although aromatherapy treatment seemed to have a similar effect as water mist (control) treatment, the control group had decreased disruptive behaviours for treatment during the intervention periods.

The research sought to answer the previous posed in Chapter 2: What is the effect of aromatherapy with or without hand massage on disrupted behaviours in people with

dementia? The three hypotheses were addressed according to the results.

H1: those participants who received "aromatherapy (lavender oil spray) and "hand massage" treatment for six weeks did not display less agitation and aggression following the intervention than participants who received aromatherapy treatment only.

H2: those who received "aromatherapy (lavender oil spray) and "hand massage" treatment for six weeks, did not display less agitation and aggression following the intervention than participants who only received "water mist" treatment.

H3: those who received "aromatherapy" (lavender oil spray) treatment for six weeks did not display less agitation and aggression following the intervention than participants who received water mist treatment only.

## 6.8    Case Studies

The following section presents three participant case studies that aim to demonstrate the positive and negative effects of the treatments, which were not easily identified by the outcome measurements and may have been influenced by the challenges of retaining resident participation in the study. Cases 1, 2 and 3 demonstrate examples of positive effects of the interventions, even though they were not identified as having a statistically significant effect.

Cases 4 and 5 demonstrate the challenges of recruitment and retention of participants with dementia. The information used in these case studies was obtained by the investigator as she observed participants' behaviours, while administering the treatment and includes the experiences of participants as described by relatives and nursing staff during the six-week treatment. The backgrounds of participants are illustrated and participants' reactions to the treatment are described in this section. Pseudonyms are used to protect the identities of participants.

**Case 1**

Mrs. W was an 81-year-old married woman. She had a diagnosis of Alzheimer's disease and aphasia. Her MMSE score was recorded as 0 out of 30. Mrs. W was assessed as needing high care and she had been living in the current facility for two and a half years. Mrs. W needed assistance for daily living activities such as dressing and feeding. She was on regular antipsychotic medication (Risperdal 0.5 mg) twice a day. Mrs. W was a housekeeper before being admitted to the facility. According to her progress notes, she wandered and regularly intruded into other residents' rooms. She liked pulling at things such as curtains or table-cloths, moving furniture around and climbing onto tables and chairs. Furthermore, she made strange noises and sometimes called out. In addition, other residents complained that Mrs. W grabbed their hands. Mrs. W was randomized into the combination group (aromatherapy and hand massage). Because of her wandering behaviour, the investigator had to walk with her to administer treatment. On day one of week four, the investigator walked with her in the garden and administered the treatment. Mrs. W walked to a male resident's table; he was celebrating his birthday with family. Mrs. W sat on one of the chairs at the table and pulled the table-cloth while the investigator administered hand massage on her left hand. Mrs. W resisted the investigator's touch for several seconds; however, she soon relaxed, stopped pulling at the table and fell into a restful sleep while the hand massage was being administered. One female relative observed the situation and said to the investigator that she had never seen Mrs. W settled in a chair or asleep during the day. She thought that the hand massage treatment had calmed Mrs. W. Furthermore, Mrs. W's husband who visited his wife nearly every day and spent at least one to two hours with her, noticed a difference in her sleep pattern. Previously, Mrs. W used to go to sleep after 8:30pm or 9pm. After commencing aromatherapy and hand massage treatment, she fell asleep at 7:30pm. Moreover, the husband reported that she was more settled and appeared to be able to concentrate when he showed a family photograph album or talked to her. Although the CMAI and RMBPC did not show a significant decrease in her agitation scores, Mrs. W's husband was satisfied the treatment had a good effect on his wife.

**Case 2**

Mr. C was a 78-year-old divorced man. His diagnosis of dementia was reported as related to his prior alcohol abuse. He had lived in the facility for nearly nine years.

His MMSE score was 13 out of 30. Mr. C was categorised as needing low care. He wandered and was given regular Haloperidol (500mcg) twice a day and Zyprexa 5mg at night to sedate and reduce his disruptive behaviours. His disruptive behaviours included hiding paper tissues in his pockets and these remained in his soiled clothes for more than a week. These behaviours were a challenge for nursing staff especially when assisting Mr. C's daily dressing. Nursing staff reported Mr. C was sometimes verbally aggressive toward other residents and staff. Mr. C was randomized into the aromatherapy and hand massage group. On day one, Mr. C refused to participate in the treatment when the investigator tried to approach him twice in the morning. However, he was compliant with the investigator later in the afternoon. He appeared to enjoy the hand massage treatment and participated in the intervention until the end of the six-week intervention. Mr. C would call out, "I love it, love it", when the investigator administered this hand massage treatment to his hands. Furthermore, he would sit in the chair waiting for the investigator when the investigator was administering treatment to other participants. On one occasion, the investigator finished Mr. C's hand massage treatment and observed that he had a mass of dirty paper tissue in his pockets. The investigator gently asked him to hand over the paper tissue while explaining that the tissue was dirty as it had been used. Mr. C handed over the tissue without resistance; the investigator threw it in the rubbish bin and gave him a new tissue. The CMAI and RMBPC showed a slight decrease in his agitated behaviour over the five observations during the intervention.

**Case 3**

Mrs. S was an 83-year-old widow who had lived in the facility for five years and four months. Her dementia diagnosis was related to Korsakoff's syndrome. Mrs. S was categorised as needing high care and she was mobilised with a wheelie walker. Her disruptive behaviours included putting salt shakers or paper towel into her walker, abusing other residents, shouting, yelling, calling out for nurses and going in and out of the toilet many times a day. Her MMSE score was 12 out of 30. Mrs. S was not on any regular sedative medicine. She sat in the dining room every day, and occasions her mood was pleasant and she sometimes sang songs with other participants. Mrs. S was randomized into the control group, and was given water mist. During the six-week intervention, when the investigator sprayed the water mist on her chest, she would react nicely and say "I love the smell, it smells so good. I used to wear this

perfume. Thank you so much". Comparing her baseline assessment with the post six-week treatment test, her CMAI's mean score decreased from 3.64 to 2.71 and RMBPC score dropped from 2.79 to 1.79.

**Case 4**

Mr. D was an 84-year-old married man. He had a diagnosis of Frontotemporal dementia. His MMSE score was 18 out of 30. Mr. D was assessed as needing high care and he had been living in the current facility for 10 months. He was independently mobile and used to walk between each building every afternoon. Mr. D liked to spend most of the time in his room and just rested in bed covered with quilts and heavy blankets. His wife said Mr. D did not like the cold weather; in addition, every day, he wore long sleeves, jacket and hat, no matter the season. His disruptive behaviour included verbal aggression and he sometimes threw objects at people. Mr. D was not on any regular sedative medicine. During the recruitment of participants, Mr. D's wife was keen to let her husband participate in the study. She said to the investigator, her husband was a great man, but his personality had changed since he suffered from dementia. He did not have any patience and easily lost his temper. She believed aromatherapy treatment could have a good effect on him. She was not aware that Mr. D was randomized into the control group (water mist). After commencing the intervention, Mr. D agreed for the investigator to spray water mist on his chest. However, Mr. D started to refuse to participate in the intervention after the second week. If Mr. D refused the intervention, the investigator would ask him again at a later time during the intervention hours to participate. However, Mr. D became angrier with the investigator each time she asked. One day, Mr. D refused the intervention, swore and then threw a glass of water at the investigator. Mr. D said if the investigator kept bothering him he would call the police. He also told the RNs and his wife he did not like the intervention. On one afternoon in week four, when Mr. D again refused the intervention his wife was there. Mrs. D encouraged him to try one more time and Mr. D accepted. After the investigator left the room, Mrs. D followed the investigator and said she could not smell any fragrances even though the investigator sprayed the mist on Mr. D. She asked the investigator which group Mr. D was in. When she found out that her husband was in the control group, she said she would like her husband to withdraw from the study because Mr. D did not like it and

felt too cold when water was sprayed on him. Mr. D withdrew from the study from that day.

**Case 5**

Mrs. A was a 95-year-old widow with a hearing impairment. She had lived in the facility for two years and three months and was categorised as needing high care. Her diagnosis included depression and anxiety. Although she did not have a clear diagnosis of dementia, she met the criteria for dementia and her MMSE score was 15 out of 30. Nursing staff reported she was a negative person and became easily agitated. Mrs. A liked to spend most of the time in her room and disliked socializing with other people. Mrs. A often refused to participate in every activity and seldom talked with other residents. She described herself as useless and that she could not do anything good for other people. She told the investigator she could not see any benefit in her participating in the research. Although Mrs. A did not show any interest in participating in the study, her daughter asked for Mrs. A to participate in the study. Mrs. A was randomized into the aromatherapy and hand massage group; however, she only participated in the study for a few days. She refused to continue with the intervention because of fatigue. Mrs. A told the nurses and her daughter that she did not want the investigator to ask her any questions or come to see her again. The nursing staff were worried that Mrs. A would become depressed if she continued with the intervention; furthermore, Mrs. A's daughter asked the investigator to stop participation if her mother was getting upset. Mrs. A withdrew from the study at the end of the first week.

## 6.9    Summary

This chapter outlined the characteristics of the sample of 61 participants. The results showed most of the participants were 80 to 89 years old. More than 80% of the participants had moderate to severe cognitive impairment and they required high care. Participants had at least one or two sensory deficits. Both physical and chemical restraints were used in managing participants' disruptive behaviour on a daily basis. In addition, participants who lived in special care units (SCU) received more antipsychotic medication such as risperidone and haloperidol. The study analysed sub-items by using previous factor analysis studies: physically nonaggressive (four items),

verbally and physically aggressive (five items), and verbally agitated (three items) in the CMAI; and memory loss (seven items), depression (nine items), and disruption (eight items) in the RMBPC. The initial mean scores of the CMAI and RMBPC were low. Only nonaggressive and agitated behaviours of CMAI and memory of RMBPC showed changes in treatment groups. Linear regression and goodness of fit showed participants who had higher cognitive scores presented with more disruptive behaviours, memory loss and depressed symptoms. The results demonstrated that aromatherapy combined with hand massage treatment seemed to increase disruptive behaviours in the 60-84 age group. On the other hand, water mist treatment seemed to have better effects than the other two treatments in the 85+ age group. The ranking 9 (Do not know/not applicable) of RMBPC, was highly ranked at post-test; more than 10% of the participants had their behaviours ranked as "9", (Do not know/not applicable") in each question. Staff indicated that they had no reaction when they dealt with participants' disruptive behaviours. Case studies also presented three positive participants' behavioural reactions when they received the treatment. Two case studies demonstrated the challenges of recruitment and retention. The following chapter discusses these findings in relation to the research literature.

# CHAPTER 7
# DISCUSSION

## Chapter Overview

Based on the findings of the current study, the CAM modalities; aromatherapy and aromatherapy and hand massage did not show a statistically significant effect in decreasing participants' aggression and agitation. Therefore, the hypotheses identified in Chapter 4 were not supported. The findings indicated that aromatherapy and hand massage treatment had a negative effect on participants aged 60 to 84 years compared to the other two groups. The water mist used in the control group had a better effect in decreasing disruptive behaviours in participants aged over 85 years.

This study has methodological strengths that aimed to reduce the limitations of previous studies in the area. For instance, the research design, three treatment groups, including a control group, avoided a short period of washout and the lack of a comparative group, limitations identified in a number of previous studies (Holliday-Welsh, et al., 2009; Kim & Buschmann, 1999; MacMahon & Kermode, 1998). In addition, the six-week intervention provided an appropriate length of treatment for determining a dose-response (MacMahon & Kermode, 1998; Remington, 2002a; Woods, et al., 2005). This rigorously applied rrandomized control trial more readily allows the findings to be generalised. Using a single essential oil, and a clearly identified proportion of this essential oil (3% lavender angustifolia), avoided the lack of a standardised formula concentration which limited a number of previous studies (Beshara & Giddings, 2002; MacMahon & Kermode, 1998; Smallwood, et al., 2001). The collection of pre-intervention participant data provided baseline information and allowed for comparison with each post-test data set (Bowles, et al., 2002; Sansone & Schmitt, 2000).

The lack of significant treatment effects may result from low behavioural scores demonstrated over the five observation periods. Similarly, Remington's study (2002a) also found that none of the treatments (calming music and hand massage) significantly reduced physically aggressive behaviours as a result of the participants all having low baseline scores for disruptive behaviours. The low level of behavioural

symptoms at baseline increases the challenge of detecting a significant difference in observed behaviours.

However, the study findings are important and may reflect a number of clinical issues, which may account for the relatively low behavioural scores and low staff reaction to residents' behaviour across all data collection points. Examples of clinical issues are outlined in the following section and then described in more detail under section 7.1. First, the Commonwealth Government provides funding for residents with high care needs. This is determined through documented evidence in facility records. The need for clear documentation of high care needs may result in nursing staff focusing on recording resident's need for physical care – activities of daily living (ADL), such as personal hygiene, mobility and elimination – as these are more easily attended to rather than psychological needs, such as memory loss and depression and the behaviours that often accompany these. As a result it is likely that staff might not recognise the need to document disruptive behaviours contemporaneously or in addition they might not have the skills or knowledge to assess and document disruptive behaviours.

Secondly, the results may be related to the inclusion of study participants that may not have been capable of displaying all of the disruptive behaviours according to the Cohen-Mansfield Agitation Inventory (CMAI) criteria, or the Revised Memory and Behaviour Problem Checklist (RMBPC), as a result of participants' severe cognitive impairment and physical frailty. For example, such participants with severe cognitive impairment and physical frailty do not have the ability to perform agitated behaviour as documented in the CMAI such as wandering, starting but not finishing things, demonstrating they forget recent events or days and wearing inappropriate dress.

A final issue is related to nursing staff attitudes and knowledge. When nursing staff care for participants with advanced dementia, they may perceive participants' behaviours as being part of the dementia syndrome rather than being disruptive. Therefore, as a result they may have failed to continually update documentation and report changes in behaviour.  As a result, recruitment into this study may have been based on a history of documented disruptive behaviours rather than on behaviours currently displayed.

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This chapter discusses the results of the study and compares these findings to the research literature, and this is followed by the implications of the study.

## 7.1    Key Findings

The first purpose of the study was to investigate the effect of aromatherapy treatment with and without hand massage treatment on disruptive behaviours in people with dementia. Participants had low CMAI (M = 2.19, SD = .81) and low RMBPC (M = 1.65, SD = .84) baseline scores in the three research treatment groups. The analysis did not show any statistically significant effect in decreasing disruptive behaviours over the four different time periods in the three research treatment groups. This result is similar to the studies of both Gray et al. (2002) and Snow et al. (2004), which indicated that aromatherapy treatment had no statistically significant outcome in decreasing agitation in people with dementia. However, this result is contrary to two other previous lavender oil studies (Holmes, et al., 2002; Lin, et al., 2007). According to Holmes et al. (2002) 60% of participants had a decrease of agitated behaviour in the aromatherapy treatment group. Moreover, the total mean scores of the Chinese version of Cohen-Mansfield Agitation Inventory (CCMAI) showed a decrease from 24.68 to 17.77 ($p<.001$) in a study undertaken in Hong Kong (Lin, et al., 2007).

In addition, this study also found that aromatherapy combined with hand massage did not contribute an added benefit in decreasing disruptive behaviour in people with dementia. This finding is similar to the study of Remington (2002a), which showed no difference between a combination treatment (calming music and hand massage) and three other treatment groups. The findings are also supported by the work of Woods (2005), which  showed no significant difference between a therapeutic touch group and a placebo group. In the current study, hand massage seems not to have had a statistically significant effect on decreasing behavioural symptoms.

Secondly, in the current study 'verbal agitation' and 'memory loss' were the highest scored sub-scales of CMAI and RMBPC respectively. Although all sub-scales showed a slight decrease in disruptive behaviours at the second, third and fourth data collection points, the decrease in disruptive behaviours was not statistically significant. This finding once again does not support Lin et al.'s (2007) findings where verbal

agitation and physical aggression/nonaggression were found to be significantly reduced ($p<.001$) in the lavender treatment group.

Thirdly, although aromatherapy and hand massage did not show a statistically significant effect on decreasing behavioural problems, the 60-84 year-old participants in the current study who were in the aromatherapy and hand massage treatment group had increased disruptive behaviours. On the other hand, the 85+ year-old participants in the water mist treatment control group had reduced disruptive behaviours.

Lastly, case studies reported that some participants and relatives had positive feedback about aromatherapy and hand massage treatments. In the study of Woods (2005), the placebo group benefited from one-to-one social interaction, which had a positive effect on decreasing behavioural symptoms. The three treatments in the current study also provided the opportunity for positive social interaction as well as physical contact. An increase of social interaction between staff and participants may contribute a treatment effect (Ballard, et al., 2002). However, one-to-one social interaction did not suit all participants in this study and social interaction may be affected by participants' personality and level of cognitive impairment. Participants with a high level of cognitive impairment (MMSE = 0) were more likely to resist hand massage treatments. More details about each of these points are discussed in the next section.

### 7.1.1   Level of Cognitive Impairment

This study found that over 85% (n = 52) of the participants had moderate to severe cognitive impairment and only nine (14.8%) participants had mild cognitive impairment (MMSE = 19-24). This result is supported in the literature, which demonstrates that people in the mild stage of dementia usually lived in their home in the community while the majority of people in the moderate to severe stage of dementia are usually placed into an institution such as a nursing home (Australian Institute of Health and Welfare, 2007; Brodaty, et al., 2003a). Participants' level of cognitive impairment (moderate to severe) was similar to that of previous research on older people with dementia (Ballard, et al., 2002; Bowles, et al., 2002; Brooker, et al., 1997; Holmes, et al., 2002; Kilstoff & Chenoweth, 1998; Kim & Buschmann, 1999;

Lin, et al., 2007; Smallwood, et al., 2001; Snow, et al., 2004; Snyder, et al., 1995a, 1995b; Woods, et al., 2005).

Despite participants having low baseline RMBPC scores for memory 2.71 (SD = 1.30), depression 1.23 (SD = .88) and disruption 1.21 (SD = 1.01), nursing staff recorded lower post-test disruptive behaviours on the RMBPC in participants on all four occasions indicating that 'memory loss', 'depression' and 'disruption' mean scores improved over the duration of the study. However, post-intervention participants did not show any memory improvement on MMSE scores. Nursing staff stated that they rarely observed participants expressing feelings of 'hopelessness or sadness' as indicated in the depression subscale; this is in spite of depression being associated with cognitive impairment (Dash & Villemarette-Pittman, 2005; Desai & Grossberg, 2005; Ganzer, 2007; Leifer, 2003). The low scores for 'memory loss' and 'depression' suggest that nursing staff did not acknowledge that memory loss and depressed mood affected participants' daily lives and therefore these items were not identified as problems of concern especially in participants with severe cognitive impairment. This may also reflect a situation where nursing staff did not spend enough time to observe or converse with residents and therefore allow them the opportunity to make judgements about participants' feelings. Previous research indicates that staff working in RACF often focus on basic tasks of hygiene and nutrition and ignore the higher psychological and social needs of residents with cognitive impairment (Horn, Buerhaus, Bergstrom, & Smout, 2005; Richardson & Martin, 2004). This issue is discussed in section 7.2.3.

On the other hand, participants (n = 32, 52.5%) with mild-moderate cognitive impairment had higher CMAI scores in 'agitation', and RMBPC scores in 'memory' and 'depression', compared to participants with severe cognitive impairment. Although nursing staff might not easily identify behavioural problems in people with severe cognitive impairment, they seemed to be aware of behavioural changes in participants with mild-moderate cognitive impairment. Because of cognitive decline and poor performance in relation to ADL, participants with mild-moderate cognitive impairment may display regular anxiety and frustration. Their reported agitated behaviours, such as constant requests for attention or help and complaints may be an expression of low-self esteem and an inability to control their situation (Anderson &

Clarke, 1996; Cohen-Mansfield & Libin, 2005). Participants with mild-moderate cognitive impairment may therefore verbally express agitation and depression, for example, by being verbally aggressive to others and appearing anxious or worried, compared to participants with severe cognitive impairment. In the current study these behavioural changes were apparently more noticeable in participants with mild-moderate cognitive impairment compared to participants with severe cognitive impairment; therefore, nursing staff were more readily able to identify differences between both severe and mild to moderate participant groups during the intervention.

In addition to comprehension problems, 64% (n = 7) of the 60-84 years old participants in the aromatherapy and hand massage treatment group had severe cognitive impairment, compared to 25% (n = 2) of those in the 85+ age group of participants who had severe cognitive impairment from the combined treatment group. Participants with severe cognitive impairment may already have a decline in physical functioning ability and therefore may have been unable to perform ADL independently and therefore this may reduce their physical disruptive behaviours (William, et al., 2005). This may help to explain why the findings from the youngest group with severe dementia did not show significant behavioural improvements in behavioural scores, such as those for wandering and inappropriate dressing even after aromatherapy and hand massage treatment were applied.

In fact, applying aromatherapy and hand massage treatment had negative effects for the 60-84 age group and this may be because the majority of these participants in the combined treatment group had severe cognitive impairment (MMSE = 0-9). When the investigator or assistants explained the hand massage treatment to participants before applying the intervention; six participants did not appear to understand the process and were often more agitated when they received physical contact from the research assistants who were unfamiliar to them. An unfamiliar person could also be one of the reasons that precipitated disruptive behaviours in those participants with severe cognitive impairment; this is discussed in section 7.2.2.

Secondly, people with moderate stage of dementia often have difficulty understanding spoken language (Kempler, 2005). The severity of the memory impairment in people with dementia creates a problem with sentence comprehension, even with sentences

that are only of moderate length (Kempler, 2005). Loss of language and comprehension may have created problems with the participants' understanding of the intervention and this may have increased their agitation.

Lastly, the literature also reported that some people with severe dementia have a varying degree of olfactory dysfunction and therefore the lavender treatment may not benefit these participants (Brooker, et al., 1997; Holmes, et al., 2002; Lin, et al., 2007). Previous literature has also identified some negative response to aromatherapy. Bowles's (2002) results found essential oils can cause an increase in resistance to nursing care in people with severe cognitive impairment and argues this is as a result of an increase in alertness to staff interaction, Furthermore, Holmes (2002) found that one participant experienced a worsening of agitation during aromatherapy treatment compared with a placebo in his study.

Although the effect of aromatherapy and hand massage is limited in this study CAM treatment may have an effect on decreasing disruptive behaviours in people with dementia. These treatments need to consider an individual resident's needs and level of cognitive impairment. Person-Centered Care (PCC) may assist by focusing on people with dementia as the centre of the care process and meeting their physical, psychological and social needs (Boettcher, Kemeny, & Boerman, 2004; Kitwood, 1997). When people with dementia feel comfortable and trust staff from the therapy environment this decreases their behavioural problems and improves well-being.

### 7.1.2 Levels of Mobility Limitation

Participants (n = 14) who had a '0' MMSE score had lost the ability to communicate and as a result they displayed less agitated behaviours (M = 1.84, SD = 1.09) that were related to verbalisation, such as those investigated in the following CMAI questions: question 9 "constant request for attention or help", question 10 'repetitive sentences, calls, questions or words' and question 11 'complaining, negativism, refusal to follow directions'. However, these participants had higher CMAI baseline scores in nonaggressive (M = 2.47, SD = 1.35) and aggressive behaviours (M = 2.16, SD = .86) compared to people with mild-moderate cognitive impairment. Participants with severe cognitive impairment in this study had a high level of physical functioning impairment in the areas of mobility (chair-fast, n = 15, 51.7%) and had

lower scores of disruptive behaviours. In the current study, although some participants with severe cognitive impairment did display physical nonaggression and verbal agitation, such as wandering or repetitive sentences, eight participants who were mobility independent and with severe cognitive impairment, had the highest baseline scores on nonaggression (M = 4.06, SD = .61) and agitation (M = 3.63, SD = .77). This finding is similar to the Williams et al.'s study (2005) that found people with high levels of mobility impairment often exhibit less physical behavioural symptoms than those without mobility impairment. Moreover, a lack of appropriate activities may increase agitated behaviours in people with severe cognitive impairment (Cohen-Mansfield & Werner, 1995).

However, the Williams et al. (2005) study did not clearly distinguish between the types of disruptive behaviours in people with dementia from those with high levels of mobility limitation and those with low levels of mobility limitation. Those people with moderate to high levels of mobility limitation may still experience certain behavioural symptoms, greater than those with no or low levels of mobility limitation. Although participants with high levels of mobility limitation may have less physically disruptive behaviours, such as wandering; these participants may still display other verbally disruptive behaviours such as cursing or physical aggression, such as throwing and tearing things. This finding is supported by literature that suggests agitation is more likely to occur in the late stages of dementia (Dash & Villemarette-Pittman, 2005).

### 7.1.3   Physical Restraint Use

In this study, one participant lived in a hostel (low care) and did not receive any form of restraint measures. A larger proportion of participants had verbal (n = 43, 70.5%) and physical (n = 53, 86.9%) agitation, especially participants who were categorised as requiring high care. Given this, it is not unusual to find the application of both physical and chemical restraints in 82% (n = 50) of the participants. Furthermore, more than half of these participants were physically restrained by bed rails, and were either chair-fast or in a wheelchair.  Bed rails are indicated in the literature as the most common type of restraint used with older adults (Hamers, et al., 2004).

The main reason indicated for applying physical restraints was for the protection of residents against incidents such as injury from falls and wandering. However, given that the literature argues that restraint use does not improve the incidence of falls and the range of injuries, and may even increase disruptive behaviours (Doorn, et al., 2003; Flicker, 2005; Lee, et al., 2003; Weiner, et al., 2003), nursing staff knowledge and attitudes towards the use of physical restraint needs to be further investigated.

### 7.1.4   Impact of Antipsychotics Medication

Antipsychotics are usually given to reduce psychotic incidence and are given as a first choice medication treatment for behavioural and psychological symptoms in people with dementia (Greve & O'Connor, 2005). In the current study, more than 20% (n = 13) of the participants were given regular 'Risperidone' or 'Haloperidol' and 10% of the participants were prescribed these medications "as required". None of these participants had a documented psychiatric diagnosis. Other studies have also indicated a high use of antipsychotics in this population. For example Lin et al.'s study (2007), found more than half of the older residents (n = 36) were receiving antipsychotics. Snowdon et al. (2005) also found Olanzapine, Risperidone and Haloperidol were the most common antipsychotic drugs administered to people with dementia, even though 80% (n = 463) of the nursing home residents did not have a diagnosis of schizophrenia. In addition, Phillips et al. (2000) found residents in special care units were more likely to receive antipsychotic medication than those in traditional units. Findings from the current study also provide evidence for the high use of antipsychotic medicine, as over half of the participants (n = 11, 58%) who lived in the special care units (SCU) were given daily antipsychotic medication. Although there is an awareness of antipsychotic use in this population none of the previous aromatherapy treatment studies reviewed in Chapter 3, discuss or report on antipsychotic medication usage in participants and its potential to sedate and therefore to reduce agitation (Ballard, et al., 2002; Beshara & Giddings, 2002; Bowles, et al., 2002; Brooker, et al., 1997; Gray & Clair, 2002; Holmes, et al., 2002; Kilstoff & Chenoweth, 1998; MacMahon & Kermode, 1998; Smallwood, et al., 2001; Snow, et al., 2004). As antipsychotics have the potential to impact on disruptive behaviours, the use of such medication should be reported in behavioural intervention studies, such as those exploring the impact of aromatherapy treatment (Davison, Hudgson, McCabe, George, & Buchanan, 2007; Lin, et al., 2007).

### 7.1.5   Impact of Pain Relief Medication

The current study found approximately half (n = 31, 50.8%) of the participants were given regular medication, such as Aspirin or Paracetamol, for pain relief ranging from once per day to up to four times a day. Although less than one-third of participants had chronic pain recorded in their care records, this result may misrepresent participants with no record of chronic illness but experience discomfort such as from headaches or arthritis. The study confirms that acetaminophen and NSAIDs are commonly used in RACF; in addition, this result supports the literature that suggests over 25% of nursing home residents with daily pain receive no analgesic medicine (Allen, et al., 2003; Won, et al., 2004a).

In the current study, GPs and nursing staff may have noticed that pain is likely to trigger participants' agitation and aggression; therefore, a regular analgesic can be a part of the routine medication for participants. Or it may be that participants were routinely prescribed medication with limited assessment and evaluation of treatment. The regular use of analgesia and antipsychotics may have managed participants' behaviours effectively and therefore the effect of the CAM modalities was not apparent (Kunstler, et al., 2004). As it would be unethical to remove analgesia from participants given the likelihood that a number of participants may have regular pain from conditions such as arthritis it is unlikely that future research could address this issue.

### 7.1.6   Pain/Discomfort and Hand Massage

Massage and touch have been increasingly used in dementia care over the past decade. Such therapies aim to reduce psychological and behavioural manifestations of dementia (Cohen-Mansfield, 2001). The sensation of touch has an effect on decreasing the symptoms of discomfort, agitation and mood disorders and provides a calming, reassuring influence (Lund, et al., 2002). In reporting massage research in Chapter three, massage and touch seemed to be a relatively effective, low cost and safe intervention for use in the RACF.

In this study, participants with advanced dementia were usually unable to report their pain and discomfort because of their inability to communicate effectively; moreover, they were less likely to accept hand massage treatment. Those participants with severe

cognitive impairment appeared anxious, restless and physically resistive to research assistants or the investigator while receiving hand massage treatment. Besides the exposure to unfamiliar people, participants may see hand massage treatment as an intrusive action by outsiders, which disturbs their personal space or comfort zone. In Cohen-Mansfield et al.'s study (1992), the authors investigated twenty-four older nursing residents with high cognitive impairment about the relationship between agitation and attributes of the social environment. They found a combination of staff verbal behaviour and touch were most likely to trigger agitated behaviour in older residents (Cohen-Mansfield, et al., 1992). Moreover, Kovach et al. (2002) found that some people with dementia are highly sensitive to touch, and their stress threshold is exceeded even by touch. Furthermore, touch has been reported to trigger agitation in nursing home residents with dementia (Burgio, et al., 2000). Therefore, this background may help to explain why those participants with severe dementia refused hand massage treatment.

Despite the displeasure towards hand massage shown by those participants with severe cognitive impairment, the majority of participants indicated that they liked the hand massage treatment used in the study. In Chapter 6, case study 2 described in detail how Mr. C enjoyed this hand massage treatment and the data showed a slight decrease in his agitated behaviour over the five observations. This case study helps to strengthen the theoretical framework, body, spirit and mind that massage and touch treatment are still meaningful for people with dementia and are described as part of a general communicative situation to express encouragement and a sociable message (Bush, 2001; Kim & Buschmann, 1999). Hand massage treatment may provide comfort and enhance non-verbal communication between nursing staff and nursing home residents (Gleeson & Timmins, 2004). According to Maslow's (1970) hierarchy of needs, physiological and safety needs are paramount in human lives. Hand massage treatment may offer the opportunity to reduce pain and discomfort in participants and to strengthen participants' feeling of security. In addition, according to Kolcaba's (2003) theory of psychospiritual comfort, both the research assistant and the investigator's approach may also affect the outcome. Aromatherapy and hand massage provides a successful integration and balance with a physical mechanism and psychospiritual comfort. During the hand massage treatment, participants received extra attention from both the research assistants and the investigator. This may have

encouraged participants to feel they were more privileged than other residents who did not receive hand massage treatment; in addition, hand massage treatment may have helped participants to feel that this benefited their quality of life. Participants often responded with positive feedback; furthermore, some participants even told staff and families how good they felt after the treatment. Moreover, hand massage treatment provides an opportunity for nursing staff to engage in conversation with participants. Although this study did not find aromatherapy combined with hand massage treatment had an effect on agitated behaviours, hand massage treatment is a simple treatment that may provide comfort and could be incorporated into routine nursing care activities for older residents in RACF.

## 7.2    Challenges of Data Collection

In this study, three factors created a challenge to data collection: participants' diagnosis; organisational and environmental issues, and the attitudes and knowledge of nursing staff.

### 7.2.1   Participants' Diagnosis

Specifically, in relation to the current study, the majority of participants were female and in particular, in the high care facility (n = 33, 91.7%). Participants' gender and age characteristics are reflective of national data that indicates women are more likely to suffer from dementia than men due to a longer life expectancy (Australian Institute of Health and Welfare, 2007). In addition, the majority of participants ranged in age from 80 to 89 years old (n = 43, 70.5%). Similarly, Howe and Kung (2003) found that people with dementia in Australia are most likely to be aged between 80 and 89 years old. This result supports the conclusion that the prevalence of AD doubles every five years and that older people aged over 80 years constitute the greatest proportion (16–32%) of the population that develop dementia (Access Economics, 2003).

All participants in this current study met the DSM-IV-TR criteria for AD, although nearly half (n = 29, 47.5%) did not have a formal diagnosis of dementia recorded and eight (13%) participants had a diagnosis of 'cognitive impairment' or 'memory loss'. The result supports the suggestion that GPs may fail to diagnose participants' types of dementia and their level of dementia severity (Australian Institute of Health and

Welfare, 2002, 2004, 2007; Valcour, et al., 2000). The lack of a dementia diagnosis may have influenced staff perceptions about participants' potential for disruptive behaviours. This study's findings suggest that there is a real opportunity to improve screening for dementia. These issues and the lack of a formal diagnosis in this study also support the need to improve early screening and diagnosis in the community.

### 7.2.2 Organisational and Environmental Issues

A high percentage of participants (n = 53, 86.9%) in this study were categorized as requiring high care and this finding is also reflected in national data that reports the increasing proportion of older people categorised as requiring high care (Hogan, 2004). According to the Department of Health and Ageing (2008), the Australian Government spends more than $5 billion annually to support care for older people living in aged care facilities. There are over 90,000 older people with dementia living in RACF and more than 50,000 with dementia living in the community (Access Economics, 2009). The cost of residential aged care services for the care of people with dementia is a large proportion of the Australian Government's aged care service budget (Australian Institute of Health and Welfare, 2007). In 2003, $993 million was provided for the care of people with dementia and Alzheimer's disease living in residential aged care (Australian Institute of Health and Welfare, 2007). Such funds covered the full costs of all needs such as personal hygiene, assistance with nutrition and nursing procedures. High level residential aged care is generally allocated more than 90% of the overall aged care funding (Australian Institute of Health and Welfare, 2007). Older people with dementia who display disruptive behaviours usually have a greater need for more nursing care and resources and therefore require higher levels of funding to provide appropriate levels of care. Therefore, this style of funding limits the opportunity to focus on residents' capabilities for self care or to reduce the focus on agitated behaviours. For example there is the potential for facility managers to request nursing staff to record residents' disruptive behaviours at accreditation times to ensure appropriate government funding is sought. This has the potential to influence a resident's history of disruptive behaviours and for staff to record disruptive behaviours based on a prior history rather than a current assessment.

The CMAI and RMBPC measurements offer the opportunity for nursing staff to rate participants' behaviours according to their own interpretation. This is discussed

further in section 7.3. Individual interpretation may become problematic if a number of staff collect the CMAI and RMBPC data during the period of the intervention. For example, the facility managers at Facility 1 and Facility 2 allocated a small pool of nursing staff to collect the data. However, two staff went on annual leave at the end of each of the fourth week and sixth week data collection times. A number of the nursing staff were absent for a few days due to illness or they were not rostered on during the data collection period. Also, staff did not remain on the same wards, as they were rotated to different categories of care every month. Although the investigator tried to use regular staff who were familiar with the participants, because of the above challenges, the same nursing staff did not observe participants' behaviours over the five observation periods. Staff replacement created a challenge for data collection and had the potential to increase the risk of inconsistent results.

The study reported that aromatherapy and hand massage treatment impacted negatively on participants with severe cognitive impairment in the 60-84 age group. This may be related to the relationship between participants and care providers (McGilton, 2004). Researchers have found that people with dementia are emotionally attached to their personal belongings when they live in a home-like care setting such as special care units (SCU) (Cioffi, Fleming, Wilkes, Sinfield, & Miere, 2007; Zingmark, Sandman, & Norberg, 2002). Moreover, relatives and staff believe that the SCU provides a familiar, safe, pleasing, functional and comfortable atmosphere to enhance quality of care in people with dementia (Cioffi, et al., 2007; Zingmark, et al., 2002). In such environments, residents' sense of identity can be enhanced and maintained through social interaction with familiar staff (Loveday & Kitwood, 1998). People in the late stage of dementia are more sensitive to their caregivers' interactions and residents' levels of agitated behaviours are linked with caregivers' ineffective interactional behaviours (Magai, Cohen, & Gomberg, 2002). In the current study, nearly 35% (n = 19) of the participants lived in SCU, six participants with severe cognitive impairment displayed agitation when they received hand massage treatment from unfamiliar research assistants. An unfamiliar person may influence participants' negative mood states and behaviour. It is therefore important in addition to familiar staff that research assistants are well trained and given time to interact and to get to know participants and for participants to feel they are familiar before commencing research interventions. Although the research assistants were well trained the first

time they met residents was at the commencement of the intervention and therefore they were unfamiliar to residents.

Findings from the current study also revealed low scores for participants' disruptive behaviours. Such low scores may relate to the increasing numbers of unskilled/low skilled employees in RACF and their attitude and knowledge. Staff attitude and knowledge is one of the key factors in making positive changes to dementia care in facilities (Kovach & Krejci, 1998). However, RACF management tend to increase staffing based on the number of staff rather than the staff quality. This results in a concentration of low-level staff in the RACF staff mix (Kearney, 2008). For example, some RACF may reduce qualified staff and continue employing unskilled staff to fill the workload demand in order to minimise staffing costs. A Queensland study of 70 RACF (Hsu, et al., 2005) found that from a total of 107 surveys of RNs, over half had not completed more than a basic nursing qualification. Although the majority of staff reported they attended various educational programs or training sessions within the last 12 months, these courses were not degree programs and were only of short duration. Furthermore, nearly 20% of participants (n = 20) had not attended any training program in the previous 12 months (Hsu, et al., 2005). The large number of unskilled staff has the potential to affect the quality of care people with dementia as well as assessment and treatment. Furthermore, skilled staff may also positively influence the organisational culture and staff attitudes towards older people. Therefore, RACF managers should ensure that all staff have appropriate qualifications and competency skills for them to perform the role, and provide opportunities for further education and professional development in improving quality of care. The impact of nursing staff attitude and knowledge is discussed further in the next section.

### 7.2.3 Nursing Staff Attitudes and Knowledge
One possible explanation for the low scores for disruptive behaviours is the negative attitudes of some nursing staff. Nursing staff make decisions in reporting aggressive incidents that may be influenced by their attitudes. McCarthy (2003a, 2003b) identified three salient perspectives on health in aging: the decline perspective (DP), the vulnerable perspective (VP) and the healthful perspective (HP). Nurses with DP deemed that older people generally are unhealthy and cognitive impairment is inevitable. Therefore, these nurses expected older people to become confused and

viewed its occurrence as part of aging, nurses did not view such confusion negatively, unless it interfered with their work or threatened people's safety. Nurses with this perspective only act to control the effects of disruptive behaviours rather than attempt to assess older people for underlying causes of such behaviours. Such nurses might use chemical or physical restraints to alleviate problems and not investigate the reason for the behaviours.

Nurses with the second pattern of 'vulnerable perspective' (VP) believe that older people are at risk for the development of disease (McCarthy, 2003a, 2003b). These nurses tend to believe that older people are more likely to experience poor physical and cognitive conditions when compared to younger people. Although these nurses do not view cognitive impairment as a normal consequence of ageing, they accepted that cognitive impairment regularly occurs among older people. In addition, these nurses often relied on the support of other nurses or medical officers to reach clinical decisions to treat older people with cognitive impairment. Lastly, according to the 'healthy perspective' (HP), ageing is a natural part of adult development and not a disease (McCarthy, 2003a, 2003b). Therefore, nurses with this perspective regarded cognitive impairment as abnormal and thus older people with cognitive impairment require evaluation and treatment.

These perspectives can influence the way nursing staff provide care to older people with dementia. In this current study, if nursing staff had negative attitudes in caring for people with dementia, they might not see participants' behaviours as disruptive. Nursing staff who identified with DP might consider that such behaviours were acceptable. This may explain why the scores for disruptive behaviours were low, especially the RMBPC measurement. In the RMBPC, questions relating to memory such as "asking the same question over and over", 'losing or misplacing things' and so forth, often resulted in nursing staff recording 0 to indicate the behaviour never occurred. These nurses may have viewed disruptive behaviours as concomitant to dementia. Also, it may be that nursing staff who recorded 9 to indicate they do not know/not applicable, feel a lack of support or are uncertain about the symptoms of cognitive impairment in participants and this is consistent with the VP perspective.

The above literature supports the assumption that negative attitudes among nursing staff may have affected the results of participants' disruptive behaviours in this study. It is important to measure nursing staff attitudes before commencing data collection. Jansen et al. (2005) modified Fishbein and Ajzen's 32-item version of the Perception of Aggression Scale (POAS) into 18-item scales of the Attitude Towards Aggression Scale (ATAS). The ATAS used a five-point scale response from 1= 'strongly disagree' to 5= 'strongly agree' to measure staff attitudes toward patients' aggressive behaviours, including offensive (seven items), communicative (three items), destructive (three items), protective (two items) and intrusive (three items). The ATAS showed good reliability with a Cronbach's alpha ranging from .60 to .86 (Jansen, et al., 2005) and has been recommended to be used in the measurement of staff attitude (Nakahira, et al., 2009). Therefore in future research, the ATAS may assist researchers to identify nursing staff attitudes and reduce human bias in study results.

Another possible explanation for low participants' behavioural scores is a lack of knowledge and education in relation to nursing documentation. The purpose of nursing documentation generally includes communicating health information, facilitating quality assurance, assisting research, demonstrating nurses' accountability and facilitating funding (Martin, Hinds, & Felix, 1999). In Australia, nursing documentation demonstrates comprehensive written evidence of planning, delivery, assessment and evaluation of resident's care in RACF. Moreover, such documentation is also important to establish funding needs, meet accreditation requirements and demonstrate quality of care (Australian Government Department of Health and Ageing, 2003).

However, nursing staff in RACF often report less time for completing work, insufficient staff, high work stress and heavy workload, poor morale and dissatisfaction with levels of remuneration in this study and others (Hegney, Tuckett, Parker, & Eley, 2005). Other studies indicate that there is no doubt about RNs' complaints that they do not have sufficient time to complete nursing documentation (Daskein, Moyle, & Creedy, 2009; Martin, et al., 1999; Pelletier, Duffield, & Donoghue, 2005). Daskein et al. (2009) surveyed 360 RNs in 162 RACF in Queensland and found that RNs failed to document their concerns or residents'

activities or to read residents' reports during each shift due to frequent interruptions, time pressure and a noisy environment. Daskein et al. (2009) also reported that nursing staff often lacked knowledge and education regarding written documentation. Although these staff thought themselves knowledgeable about polices on documentation and writing discharge instructions, they were not familiar with the specifics of the documentation policy. This finding may also support a lack of reliable residents' documentation in the current study.

An American study in RACF reported that RNs only provided on average 16 minutes of direct nursing care time per resident per day; on the other hand, nursing assistants spent about 1.7 hours of care time per resident per day (Horn, et al., 2005). As nursing assistants spend eight times more time in direct nursing care than RNs, nursing assistants should be more aware of behavioural changes in participants with dementia (Horn, et al., 2005). However, Richardson and Martin (2004) conducted a survey of all Australian RACF and they found less than 20% of nursing staff feel they have enough time to look after each resident; moreover, only 40% of nurses spend less than one-third of their time providing direct care to residents. In this current study, one of the criteria for participants' recruitment was 'a 2 week documented behavioural history of agitation and aggression'. Participants might have had disruptive behaviours before recruitment but during data collection they no longer displayed the same behaviours that were previously documented. However, it may have been that nursing staff failed to observe participants' behavioural changes and kept using the original behavioural assessment, and did not update documentation such as progress notes and behavioural charts. Inaccurate participant documentation may have created a gap between the investigator's assumption of participants' level of disruptive behaviours and participants' actual disruptive behaviours. Furthermore, data was collected once a fortnight for eight weeks; these same staff could have consistently ranked participants' disruptive behaviours by memorising their previous records. All the above reasons could affect the accuracy of the participants' data.

The study also sought staff reaction to disruptive behaviours. The results found that nursing staff generally ranked their reaction to participants' behaviours as '0 = Not at all' to '1 = A little', during the five data collection periods. Although participants' low scores of disruptive behaviours might not cause a strong reaction from nursing staff,

another reason for this result could be social desirability bias (SDB). SDB is an issue generally in the fields of health care, social sciences and commercial market research, where the use of self-reporting is a common method of data collection (Brace, 2004; Fisher, 1993). SDB describes the tendency of individuals to reply in a favourable manner with regards to social norms (Brace, 2004; Jo, Nelson, & Kiecker, 1997). SDB usually occurs in responses that require an indication of the likelihood of an issue, such as 'strongly agree' or 'strong disagree' (Jo, et al., 1997). Social desirability may moderate the actual personal trait relationship, depending on the difference between the correction caused by social desirability and the actual personal trait correlation (Jo, et al., 1997). Common reasons for SDB are related to impression management, ego defence and self-deception, and instrumentation (Brace, 2004). People may answer certain questions honestly due to the need for approval, which is deemed to be impression management. Ego defence and self-deception mean that people convince themselves that their thoughts and behaviours are socially responsible even when they are not. Instrumentation means that respondents may give answers that in their own view bring about a socially desirable outcome (Brace, 2004).

In the current study, nursing staff may have tried to react in a way they perceived as desirable by society when they ranked their reaction to participants' behaviour. They may rank inaccurate answers both consciously for reasons of their own, and also without any conscious realisation that the information was inaccurate. Staff might be afraid to express a negative reaction to participants' behaviours as their belief may be that this reaction may not be acceptable. A negative reaction to participants' behaviours could damage their reputation or other people's expectations of them, such as facility managers or relatives, or they may have tried to impress the investigator or others. In addition, they may have believed themselves to be other than who they were, possibly a form of denial, which can be an ego defence or subconsciously self-deception (Brace, 2004). SDB might present an impression of over-claiming of environmentally friendly behaviours or attitudes that nursing staff would like to express. Therefore, they may rank a low score in relation to their behavioural reaction in order to fit in with societal desirability.

## 7.3    Measurement Challenges

CMAI and RMBPC, have been reported as suitable rating scales for nursing staff to measure disruptive behaviours in older people with dementia (Neville & Byrne, 2001). However, the investigator found there were some limitations in regards to these instruments, which have the potential to affect the study's findings.

It is possible for nursing staff to rate participants' behaviours subjectively and therefore this may result in an incorrect interpretation, even though the investigator provided education on how to use the two instruments to measure disruptive behaviours. For instance, participants with moderate to severe dementia might not have the physical capability to perform dressing or disrobing and therefore they would not exhibit this behaviour. In such cases, some nursing staff would leave a blank response to CMAI question 7., 'inappropriate dress or disrobing', or write 'staff dressed', instead of circling a score to indicate that this was not a problem. Similarly, for those participants with memory loss who did not converse or undertake some tasks regularly, nursing staff would rate the frequency of participants' behaviours as '0 = never occurred', while others would rate as '9 = do not know/not applicable' in the RMBPC.

Secondly, some nursing staff also used different interpretations when rating their reaction to participants' disruptive behaviours in the RMBPC. For example, in question 1 'asking the same question over and over', when nursing staff circled '0= never occurred' to indicate the behaviour, they were inconsistent in their rating of their reaction. For example, they circled '0 = not at all' or '9 = do not know/not applicable'. These two responses often appeared inconsistent with those recorded for the frequency of observed participant disruptive behaviours.

In addition, the MMSE as a tool of cognitive assessment, however, this tool is challenged in people with limited ability to verbalise, such as in individuals with severe cognitive impairment. The test for Severe Impairment (TSI) may overcome the limitations of the MMSE and assist in the identification of a score for severe cognitive impairment. Therefore in future research the TSI may be used to reveal impaired areas of function that can assist nursing staff to identify not only cognitive impairment but

also a decline in physical function in people with dementia. Furthermore, it may assist nursing staff in understanding that people with severe cognitive impairment may have physical limitations and present with different types of disruptive behaviours, compared to earlier stages of dementia.

## 7.4 Limitations of the Study

This section outlines several limitations of this study. Firstly, due to difficulty in participant recruitment, the sample size resulted in three treatment groups being smaller than planned. This sample size may limit the generalisability of this study. Furthermore, small sample size raises the possibility of a type II error in a hypothesis test (Califf & Topol, 2007; Freiman, Chalmers, Smith, & Kuebler, 1978). The investigator attempted to overcome sample size requirement challenges by extending the study timeline, extending the number of facilities involved, and providing explicit verbal and written information about the study. Even though the findings did not show a statistically significant effect, non-significant results may still have significant clinical meaningfulness (Munro, 2005). As indicated, the study offered a number of strengths and future studies could be further improved through a larger numerical sample.

Secondly, participants' level of olfactory function may be related to odour effectiveness (Luzzi, et al., 2007). There is evidence that people with dementia often have olfactory dysfunction and in particular, for those people with dementia with Lewy bodies (Gilbert, et al., 2004; Luzzi, et al., 2007; Olichney, et al., 2005; Royet, et al., 2001; Suzuki, Tamamoto, et al., 2004). If the participants in this study had olfactory impairment, the Lavender aroma might have had less effect on their disruptive behaviour. The investigator found it difficult to test the participant's olfactory functioning due to participants' various levels of cognitive impairment and disruptive behaviour. A reliable result was difficult to obtain from participants, in particular, if participants were not compliant or were unable to communicate with the investigator. Therefore, an olfactory function test was not undertaken. However, in any additional aromatherapy treatment studies, identification of olfactory functioning should be considered.

Thirdly, although the intervention was performed in the private areas of the care facility, it was difficult to ensure staff were completely blinded to the treatment. Some participants did not remain in their room and wandered around the unit. In addition, nursing staff continued implementing daily nursing care after participants finished their treatment. In this way, staff could have been aware of the resident's treatment group if a lavender odour was left in the environment or if they asked the participants. This may have led to nursing staff realising the nature of the treatment given to some participants, and therefore the recording of participants' disruptive behaviour may be affected by individual staff members' personal bias about particular treatment options. However, given that the majority of staff were well disposed to aromatherapy treatment and in light of the study findings, it is unlikely that staff were aware of all participants' treatment group.

Despite providing training in the use of the CMAI and RMBPC measurement in each facility, some staff continued to use subjective judgements about participants' behaviours. Nursing staff often stated that they viewed disruptive behaviours as a routine aspect of caring for people with dementia and something they had to deal with everyday. Staff reaction results on the RMBPC showed nursing staff had no reaction to participants' disruptive behaviour. Staff usually recorded '0 = not at all', in terms of their reaction to participant' behaviours. Such results suggest that some staff may have been afraid to show the investigator their personal beliefs about participants' behaviours.

Furthermore, aromatherapy treatment was used as an adjunct to existing pharmacological and non-pharmacological interventions in this study. The investigator could not control routine medication in participants' daily lives. Over 45% of the participants (n = 28) were given antipsychotic medication regularly; therefore, participants' behaviours might have been affected by ingestion of prescribed medication (Davison, et al., 2007; Lin, et al., 2007).

Finally, Brodaty et al. (2003b) found that staff members' five most pervasive perceptions of people with dementia were anxiety, little control of their behaviour, unpredictability, loneliness and fear. Therefore, as the treatment was intensive, in that it was given twice daily, seven days a week for six weeks, the participants received

extra attention from outsiders. Such regular contact may have been viewed positively or negatively by participants. An increase in social contact between the investigator/research assistants and participants might have therefore influenced the participants' behaviours.

## 7.5   Implications of the Study

There are four key implications in this study, which need to be considered. There are implications for general practitioners, nursing practice, nursing staff attitude and knowledge, and RACF.

### 7.5.1   Implications for General Practitioners

This study consisted of 61 participants from three RACF in Brisbane. The small sample size demonstrates the challenge of participant recruitment in people with dementia living in long-term aged care. Furthermore, a lack of formal diagnosis of participants with dementia (n = 29, 47.5%) and eight participants (13.1%) with an unclear diagnosis of cognitive impairment, made it impossible to identify if all types of dementia were represented in the study. These data also present concerns about Australian general practitioners' (GPs) abilities, knowledge and attitudes to screen older people for dementia. The research literature suggests that more than 40% of older people with dementia were unknown to their general practitioners and up to 91% of patients do not have their level of dementia severity identified (Chodosh, et al., 2004; Valcour, et al., 2000). This study and the findings of such studies indicate there is a need to improve early diagnosis in people with dementia so that sufferers can receive appropriate care and treatment, in particular in the early stages.  Furthermore, screening must continue within RACF so that new cases are identified and treatment and appropriate care provided. A detection of dementia is important, as it may affect resource allocation, choice of treatment and strategies used to care for and manage these people (Moyle, et al., 2010).

In a systematic literature search, Brodaty et al. (2006) found the General Practitioner Assessment of Cognition (GPCOG), Mini-Cog, and Memory Impairment Screen (MIS), were the most suitable instruments for regular dementia screening in general practice. Such instruments are similar to the MMSE, easy to administer and only

require administration spans of five minutes or less. It is recommended that GPs are encouraged to use the GPCOG, Mini-Cog or MIS to screen for early detection of dementia. Moreover, Bridges-Webb et al. (2006) suggested that dementia guidelines need to be widely used and promoted, and dementia assessment needs to be conducted regularly within the community. Furthermore, there is the opportunity for experienced gerontological nurse practitioners to assist GPs in dementia screening.

### 7.5.2   Implications for Nursing Practice

Nursing staff working in RACF, commonly treat disruptive behaviours in people with dementia with physical and chemical restraints. However, optimal treatment of disruptive behaviours should involve psychosocial approaches and use medications with demonstrated efficacy. Pharmacological treatment should target only those symptoms or behaviours that respond to medication. Nursing staff should consider how they might minimise unnecessary medication use and reduce adverse outcomes.

In the current study, although aromatherapy and hand massage treatment did not show a statistically significant effect on decreasing disruptive behaviours in people with dementia, water mist treatment surprisingly had a positive effect on those aged over 85. The findings of this study support a growing body of evidence that CAM modalities, non-pharmacological (psychosocial) interventions, and even water mist treatment, may be effective in decreasing behavioural symptoms of dementia. However, nursing staff should be encouraged to learn the meaning of the behaviours for people with dementia and treat the behaviour individually. For example, case study 3 in the current study showed an effect of the water spray on decreasing Mrs. S's disruptive behaviours; however, case study 4 outlined that Mr. D refused water mist treatment due to his disliking of the cold spray. The cold temperature of the water spray had the potential to increase noxious stimuli and therefore agitated behaviours in some residents (Cohen-Mansfield & Werner, 1995). Moreover, although hand massage treatment showed an increase in disruptive behaviours in people with severe dementia, the findings also demonstrate that some people such as case 1 Mrs. W and case 2 Mr. C benefit from hand massage. The key therefore is to understand individual needs and to address these needs and one means to do this is through a Person-Centred Care approach that contributes to a more personalized care environment (Buron, 2008). In addition appropriate physical touch as well as

spending time and providing individual attention may also make a difference to the comfort and quality of life of older people with dementia. Therefore, treatments may need to be individually planned for each resident with dementia in order to bring about significant change in behaviour.

### 7.5.3   Implications for Residential Aged Care Facilities

Regular educational programs on documentation and CAM may assist in decreasing disruptive behaviours, falls and other potential risks for older residents with dementia. In this study, there were two main areas identified to improve staff attitude and knowledge. First, facility managers need to employ appropriately skilled staff to care for people with dementia. A staff mix of both low numbers of qualified staff and high numbers of unskilled staff may not be readily able to perform efficient teamwork; furthermore, it may increase work stress and job dissatisfaction (The National Aged Care Alliance, 2004, 2005). Second, there is evidence that if nursing staff receive continuing education this can strengthen individualised care performance and result in increased job satisfaction and staff retention in RACF (Marquis, Freegard, & Hoogland, 2004). Regular attendance at educational programs or training sessions can improve staff knowledge and skills and may assist nursing staff with VP perceptions. Those staff may benefit from dementia-specific education that will help to enhance quality of care in people with dementia, and also staff confidence in professional development.

Furthermore, aggression and agitation increase the challenge of caring for people who have dementia and this has the potential to increase caregivers' stress (Mott & Kingsley, 2004; Shepherd, 2001). The consequences of the vicious cycle that may occur when staff feel frustrated with being unable to manage disruptive behaviours are staff burnout, decreased quality of care and problems with staff recruitment and retention (Ito, et al., 2001; Mayhew & Chappell, 2003; McMinn & Hinton, 2000). Therefore, effective management of disruptive behaviours is of primary concern in aged care settings.

People with dementia may have limited language skills to communicate their needs; therefore, they resort to verbal behaviour such as shouting when under stress (Dewing, 2003). Staff need to learn how to communicate with people with dementia effectively

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so as to prevent residents' behavioural problems. A behavioural training program based on the ABC model of disruptive behaviour management can be used as a framework for nursing staff (Crombie, Snell, & Boyd, 2008). The ABC model consists of A – antecedent and activating event, leading to B – behaviour and next C – consequence. A six-hour educational program proposed by (Crombie et al. 2008) includes five main training topics: understanding the dementia process; differentiating between dementia, delirium and depression; strategies to manage disruptive behaviours; pharmacological and non-pharmacological interventions; and disruptive behaviour management protocols. Research literature has shown a significant improvement (*p<.001*) in knowledge after staff received the ABC training program (Crombie, et al., 2008). The ABC model helps staff to use appropriate nursing strategies to deal with disruptive behaviours and may reduce the use of physical and chemical restraints in RACF.

## 7.6   Summary

The purpose of this study was to investigate the effect of two CAM modalities, aromatherapy and hand massage treatment and aromatherapy treatment only, on disruptive behaviours in people with dementia. This RCT design, with a sample of 61 participants consisted of three groups: (1) Combination (aromatherapy and hand massage), (2) Aromatherapy, and, (3) Control (placebo). The intervention was given twice a day, during two time periods, 9am to 11am and 2pm to 4pm, seven days a week. Agitated and aggressive resident behaviours were recorded on the CMAI and RMBPC. Data (resident behaviour) were collected five times throughout the study.

The research sought to test the hypotheses that participants with dementia who receive aromatherapy (lavender oil spray) and hand massage treatment, or aromatherapy (lavender oil spray) treatment would display less agitation and aggression following the intervention than participants who received water mist treatment only. The findings showed that there was no significant difference between the three treatment groups. Therefore the hypotheses were not supported. Aromatherapy and hand massage treatment did not decrease disruptive behaviours in participants aged 60 to 84 years, compared to the other two groups. Participants aged over 85 years in the water mist control treatment group however had an improved effect in decreasing

disruptive behaviours.

This chapter has focused on the findings in relation to the research literature. As revealed, the level of cognitive impairment in people with dementia may influence the effectiveness of aromatherapy and hand massage treatment in decreasing disruptive behaviours. Therefore, an accurate tool, such as the TSI for people with severe dementia may assist nursing staff in identifying and understanding care needs of people with severe cognitive impairment who present with different types of disruptive behaviours due to their physical inabilities. The 60-84-year-old participants with severe cognitive impairment and physical limitations were likely to be more agitated in the aromatherapy and hand massage treatment group. Conversely, hand massage treatment has the potential to enhance some participants' well-being and reduce pain/discomfort. In addition, hand massage treatment created an opportunity to increase interaction between staff and participants.

The chapter also discussed the challenge of unfamiliar research assistants, which has the potential to influence participants' mood states and disruptive behaviours. Furthermore, unqualified nursing staff, negative staff attitudes and insufficient knowledge in observing and recording of disruptive behaviours could affect the findings. The ATAS may assist researchers to identify nursing staff attitudes in future research. Social desirability bias (SDB) needs to be considered when collecting data so as to avoid unreliable data. Moreover, a lack of formal diagnoses in people with dementia presents a challenge for both the health system and for research. These findings in the current study also presented important implications for general practitioners, nursing practice and organisations. The final chapter draws on the major findings of this study to outline conclusions and recommendations for future research.

# CHAPTER 8

# CONCLUSIONS AND RECOMMENDATIONS

## 8.1    Conclusions

This study did not identify significant improvements in disruptive behaviours of people with dementia who participated in the aromatherapy or aromatherapy and hand massage treatment groups. Based on the findings outlined in earlier chapters, there are several major conclusions to be made. Three conclusions relate to the challenges identified in this study; these are (i) the impact of the participants' cognitive impairment on treatment outcomes, (ii) the potential impact of nursing staff negative attitudes and insufficient knowledge, and (iii) the influence of and need for positive relationships between caregivers and the person with dementia.

Firstly, none of the three treatments improved the participants' disruptive behaviours. This finding may indicate the influence of participants' levels of cognitive impairment on the outcome of the study treatments. Nearly half of the participants (n = 29, 47.5%) in the current study had severe cognitive impairment, and this is presented as a potential factor in influencing the findings. As a consequence of severe cognitive impairment, participants had a decline in physical functioning ability and therefore an inability to perform ADL independently. Participants' limited mobility reduced the likelihood that they would display agitation elements indicated in the CMAI, such as wandering. In future research it may be useful to place more emphasis on longer periods of observation to assist in the identification of agitation not easily identified by the CMAI, as well as identifying any subsequent reduction in agitation.

In addition, participants' severe cognitive impairment may have resulted in a reduction in olfactory function (Holmes, et al., 2002; Lin, Chan, Ng, & Lam, 2007) which therefore potentially limited the treatment effect. One of the limitations of this study was the lack of olfactory testing of participants and future research should address this limitation.

Participants with severe cognitive impairment appeared to have difficulty in understanding the treatment process that was communicated to them prior to each

treatment. Furthermore, they were often more agitated when they received the treatment from any of the research assistants, who were unfamiliar to them. These factors had the potential to influence participants' acceptance of complementary therapy treatments and therefore the study findings.

On the other hand, nursing staff were more aware of disruptive behaviour changes in people with mild and moderate dementia in relation to physical function and language ability than participants with severe stage dementia. Participants with mild-moderate cognitive impairment and the ability to mobilise were reported to be more agitated, such as appearing anxious, worried, sad and depressed, compared to participants with severe cognitive impairment and a high level of limited mobility. As a result of noticeable behavioural changes in participants with mild-moderate cognitive impairment, nursing staff seemed to be more aware of these participants' memory loss and depressed mood; as a result this may have helped with the documentation of behaviourial change in this group of participants.

Secondly, nursing staff ranked participants' behaviours using low scores, which may indicate that participants did not display disruptive behaviour, staff did not consider behaviours displayed by participants as problematic, or they may have considered memory loss and behavioural and psychological symptoms of dementia (BPSD) as a normal process of aging. Other potential views are that staff were ignoring behavioural disturbance; or the high frequency in the RMBPC where staff recorded "do not know/not applicable" may also indicate that the staff have limited knowledge about the symptoms of cognitive impairment. Furthermore, it could be that staff were not able to spend enough time with participants in order to assess behavioural disturbance. Recent research supports this view (Moyle et al. 2010).

In this study, nursing staff from each of the three facilities, including registered nurses (RNs), enrolled nurses (ENs), assistants in nursing (AINs) and activity therapists assisted in the data collection as the CMAI and RMBPC requires completion by people who have been able to observe the participant over the last two weeks. There is however the potential for nursing staff attitudes and knowledge to influence their interpretations of disruptive behaviours (Moyle et al. 2010). In addition, social desirability bias (SDB) may have influenced staff recording of behaviours. Therefore,

it may be useful in future research for data to be collected by a variety of methods, including non-staff recorded observations.

Furthermore findings from the current study may also have been influenced by no verification of baseline data to check that participants actually had a current history of disruptive behaviour. The researcher relied on documented evidence and staff reports rather than observation and recording of behaviours. Future research should consider baseline verification of disruptive behaviours.

Surprisingly, the water mist treatment (control group) showed more of an effect than either of the other two treatments on decreasing disruptive behaviours in the 85+ age group. This finding suggests that the extra attention given to the participants may have reduced participants' disruptive behaviours and supports the need for active engagement in the development of a positive care relationship between nursing staff and older people with dementia, one that offers time to be spent with individuals even if only a short period of time. It also indicates the need for the health system to focus on person centred care of people with dementia.

## 8.2    Recommendations

Caring for people with dementia is a responsibility and a challenge for aged care staff and providers. This study has contributed to the body of knowledge in relation to the investigation of CAM modalities and their use in reducing disruptive behaviours in people with dementia. Based on the findings of this study, several recommendations for further research, nursing practice, education and documentation are made. These are outlined below.

### 8.2.1    The Need for Further Research

The findings have important implications for nursing practice and research. The results of the study did not demonstrate a significant decrease in disruptive behaviours through the use of aromatherapy or aromatherapy and hand massage. Further research investigating non-pharmacological treatments such as CAM need to be evaluated using a RCT design in order to provide strong evidence-based research.  To date there have been a limited number of CAM trials in this area. The current study recruited 61

participants and it is assumed that not all sub-types of dementia were represented in this sample. To increase research rigour, further research needs to examine the effects of treatments in different dementia sub-types. For example, one study found that people with dementia with Lewy bodies, may experience negative effects after receiving lavender oils (Holmes, et al., 2002). In addition, people with frontotemporal dementia can have personality changes which cause emotional fluctuation and disruptive behaviours that are difficult to manage (Farmer & Grossman, 2005). Further research should expand this area by examining the various kinds of essential oils known for their relaxation properties in each sub-type of dementia.

In addition, only 24 participants had a formal diagnosis of dementia recorded and eight participants had a diagnosis of "cognitive impairment" or "memory loss". Lack of a dementia diagnosis may influence how nursing staff cares for people with dementia, and staff lack of understanding and knowledge of dementia may create issues in dealing with symptoms of dementia. If residents are assessed and conditions such as dementia diagnosed, then secondary prevention such as biomedical treatments could be used to slow the decline of cognition and prevent disease progression. Moreover, educated staff may be more aware of the way that staff can approach the person with dementia. Therefore, staff may adjust care plans to reflect the resident's physical abilities and needs. This in turn may reduce disruptive behaviours. Further research is needed to explore staff behaviours and how these influence disruptive behaviours.

Secondly, previous studies do not appear to have considered the effect of medications, such as antipsychotic and sedative medication during intervention periods. Although the ethics of removing sedative medicine needs to be explored further, future research should consider the impact of such medication on outcomes of intervention studies. Although the researcher documented regular medication use, consideration of medication use and the display of disruptive behaviours could not be explored further. Future research might also consider the relationships between treatments and physical and chemical restraints, as well as their influence on disruptive behaviours.

Lastly, chronic pain is a major health problem among older people (Kunstler, Greenblatt, & Moreno, 2004). More than 50% (n = 31) of the participants were given

a regular analgesic daily, such as Paracetamol or Aspirin. Further research is needed to investigate the relationship between pain and aromatherapy and massage treatment, and to investigate types of pain and discomfort and record duration, frequency and severity of pain, and the influence of pain on disruptive behaviour. Finally, due to the loss of verbal communication, it may also be important to observe and document nonverbal indications of people with advanced dementia, such as facial expression and body language.

### 8.2.2 Education of Nursing Staff to Improve Attitudes and Reset Stress Associated with Caring for People with Dementia

Further investigation of nursing staff attitudes and feelings of stress and the association with disruptive behaviours in people with dementia in RACF is also needed. In the past, studies have found RACF staff perceive older people in negative ways and experience high stress when providing care for residents who have dementia (Brodaty, Draper, & Low, 2003; Hsu, Moyle, Creedy, & Venturato, 2005; Jones, Matias, et al., 2007; McCarthy, 2003a, 2003b; Mott & Kingsley, 2004; Nakahira, Moyle, Creedy, & Hitomi, 2009; Shepherd, 2001). However, the findings of this study showed nursing staff tended to have a low level of reaction to participants' disruptive behaviours, and this needs further investigation. A group interview and staff behavioural observation may assist to understand the relationship between staff attitudes, stress, disruptive behaviour and staff dissatisfaction in aged care settings.

There is a need to increase dementia education support programs to encourage sufficient nursing staff with dementia knowledge and skills in aged care settings. An effective educational program offers nursing staff support that can improve care practices. Therefore, an increase in ongoing nursing training in dementia-specific and quality care can help quality person-centred care, and encourage nursing staff to have formalised dementia education and training so that they can understand the needs of people with dementia. The findings of the current study reveal that nursing staff require formal education to fulfil the special needs of people with dementia in several areas of dementia care, such as disruptive behavioural management, pain/discomfort programs, Person-Centred Care (PCC), and documentation.

### 8.2.2.1 Disruptive behavioural management

Disruptive behaviours are common occurrences in people with dementia living in RACF and such behaviours can create a safety risk. Therefore, an educational program to assist in the management of disruptive behaviours in people with dementia may help to reduce this risk. Disruptive behavioural management aims at increasing staff awareness of behavioural problems among people with dementia, and teaching appropriate strategies to reduce the incidence of disruptive behaviours.

### 8.2.2.2 Pain/discomfort program

A common misconception is that pain/discomfort is not able to be assessed in older people with dementia and therefore residents in RACF are less likely to receive pain relief medication (Delac, 2002; Jones, Vojir, Hutt, & Fink, 2007; Nygaard & Jarland, 2005). However, this is in spite of the knowledge that pain is a major cause of disruptive behaviours in people with dementia (Allen, Burgio, Fisher, Hardin, & Shuster, 2005; Kunik, et al., 2003; Kyomen & Whitfield, 2008; Won, et al., 2004). Therefore, an educational program about how to assess and treat pain/discomfort for people with dementia is an important educational need in RACF. Pain/discomfort educational programs involve both assessment and treatment. First, standard pain/discomfort assessments are used to detect facial expressions, body movement, changes in interpersonal interactions, changes in activity patterns and mental status changes in people who are unable to communicate verbally (Buffum, Hutt, Chang, Craine, & Snow, 2007). Secondly, an appropriate treatment includes pharmacological and non-pharmacological approaches in the relief of pain/discomfort in people with dementia. The educational program would aim to improve not only the pain/discomfort in people with dementia, but reduce their disruptive behaviours.

### 8.2.2.3 Person-Centred Care (PCC)

If nursing staff were likely to focus on basic nursing care and tended to omit individual needs, a limited understanding of Person-Centred Care may lead to staff having paternalistic attitudes and this may increase disruptive behaviours in people with dementia. It is important to improve staff knowledge of the individual resident in order to recognise the person at the centre of the disease (Kitwood, 1997). Person-Centred Care (PCC) represents the individual philosophy of the living environment and personal values, implying that nursing staff become familiar with residents' life

histories and incorporate these into individual care plans. Therefore, an educational PCC program for nursing staff may help to improve quality of care and well-being for people with dementia. This in term may help to reduce disruptive behaviours.

**8.2.2.4 Documentation**

The findings from the current study raise the important issue of nursing documentation. If staff do not feel they have sufficient time to complete documentation they may not place importance on updating residents' documentation and this has the potential to influence care provision and outcomes. An educational program for assisting understanding of documentation may assist in improving negative staff attitudes towards documentation. Furthermore, if nursing staff record residents' disruptive behaviours regularly this may assist by helping to make the nature and stage of that dementia more identifiable.

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